Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 210mg SC	4[redacted]	F	BLACK or AFRICAN AMERICAN	悪心	20[redacted]	3	2	N	Grade 1	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg SC	4[redacted]	F	BLACK or AFRICAN AMERICAN	四肢痛	20[redacted]	13	10	N	Grade 1	RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg SC	4[redacted]	F	BLACK or AFRICAN AMERICAN	片麻痺性片頭痛	20[redacted]	61	4	Y	Grade 3	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN HOSPITALIZED / PROLONGED HOSPITALIZATION
[redacted]	AMG 785 210mg SC	4[redacted]	F	BLACK or AFRICAN AMERICAN	高血圧	20[redacted]	61	4	N	Grade 2	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg SC	4[redacted]	F	BLACK or AFRICAN AMERICAN	高コレステロール血症	20[redacted]	63		N	Grade 1	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 210mg SC	4[redacted]	F	BLACK or AFRICAN AMERICAN	尿路感染	20[redacted]	64		N	Grade 1	NOT RELATED	NO ACTION TAKEN	OTHER

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 210 mg, SC	6[redacted]	F	WHITE	回帰性リウマチ	20[redacted]	10		Y	Grade 2	RELATED	DOSE NOT CHANGED	MEDICATION TAKEN
[redacted]	AMG 785 210 mg, SC	6[redacted]	F	WHITE	注射部位硬結	20[redacted]	1	4	N	Grade 1	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 210 mg, SC	6[redacted]	F	WHITE	注射部位疼痛	20[redacted]	1	4	N	Grade 1	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 210 mg, SC	6[redacted]	F	WHITE	上気道感染	20[redacted]	41	3	N	Grade 2	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN
[redacted]	AMG 785 210 mg, SC	6[redacted]	F	WHITE	上気道感染	20[redacted]	78	22	N	Grade 2	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 210 mg SC Prefilled Syringe	4[redacted]	F	WHITE	椎間板突出	20[redacted]	61		Y	Grade 3	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION
[redacted]	AMG 785 210 mg SC Prefilled Syringe	4[redacted]	F	WHITE	椎間板変性症	20[redacted]	31		N	Grade 2	NOT RELATED	DOSE NOT CHANGED	SURGICAL INTERVENTION
[redacted]	AMG 785 210 mg SC Prefilled Syringe	4[redacted]	F	WHITE	注射部位紅斑	20[redacted]	2	2	N	Grade 1	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 210 mg SC Prefilled Syringe	4[redacted]	F	WHITE	注射部位そう痒感	20[redacted]	2	2	N	Grade 1	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 210 mg SC Prefilled Syringe	4[redacted]	F	WHITE	靭帯捻挫	20[redacted]	31		N	Grade 2	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	注射部位紅斑	20[redacted]	1	9	N	Mild	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	悪心	20[redacted]	1	22	N	Mild	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	嘔吐	20[redacted]	1	22	N	Mild	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	肝炎	20[redacted]	2	25	Y	Severe	RELATED	DOSE NOT CHANGED	LIVER SONOGRAM,HEPATITIS PANEL, ENDOSCOPY
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	腋窩痛	20[redacted]	2	6	N	Mild	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	アフタ性口内炎	20[redacted]	2	6	N	Mild	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	Hispanic or Latino	頭痛	20[redacted]	5	2	N	Mild	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN, COLD COMPRESS
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	浮動性めまい	20[redacted]	12	11	N	Mild	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	尿路感染	20[redacted]	12	15	N	Moderate	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	尿路感染	20[redacted]	36	27	N	Moderate	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN
[redacted]	AMG 785 10 MG/KG SC	5[redacted]	F	HISPANIC or LATINO	腹痛	20[redacted]	73	Ongoing	N	Moderate	RELATED	DOSE NOT CHANGED	NO ACTION TAKEN

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	F	WHITE or CAUCASIAN	心雑音	20[redacted]	29	Ongoing	N	Mild	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	F	WHITE or CAUCASIAN	リンパ節症	20[redacted]	57	Ongoing	N	Mild	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	F	WHITE or CAUCASIAN	結腸ポリープ	20[redacted]	153	1	N	Mild	NOT RELATED	NO ACTION TAKEN	POLYPECTOMY
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	F	WHITE or CAUCASIAN	腸憩室	20[redacted]	160	Ongoing	N	Mild	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	F	WHITE or CAUCASIAN	血便排泄	20[redacted]	160	4	Y	Moderate	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	F	WHITE or CAUCASIAN	出血性貧血	20[redacted]	160	4	Y	Moderate	NOT RELATED	NO ACTION TAKEN	2 UNITS PACKED RED BLOOD CELLS GIVEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	F	WHITE or CAUCASIAN	貧血	20[redacted]	164	Ongoing	N	Moderate	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	季節性アレルギー	20[redacted]	2	48	N	Mild	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	咳嗽	20[redacted]	30	9	N	Mild	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	四肢痛	20[redacted]	59	21	N	Mild	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	関節痛	20[redacted]	87	8	N	Mild	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	胸痛	20[redacted]	115	1	N	Moderate	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	冠動脈疾患	20[redacted]	136	6	N	Moderate	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN CARDIAC CATHERIZATION

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	冠動脈疾患	20[redacted]	142	2	Y	Severe	NOT RELATED	NO ACTION TAKEN	HOSPITALIZED / PROLONGED HOSPITALIZATION CARDIAC STENT, CARDIAC ANGIOPLASTY; INTRAVASCULAR ULTRASOUND
[redacted]	AMG 785 3 mg/kg SC Q4W	6[redacted]	M	WHITE or CAUCASIAN	冠動脈疾患	20[redacted]	144	Ongoing	N	Moderate	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	嘔吐	20[redacted]	1	1	N	Grade 1	RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	副甲状腺機能亢進症	20[redacted]	29	22	N	Grade 1	RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	心拍数増加	20[redacted]	57	1	N	Grade 1	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	副甲状腺機能亢進症	20[redacted]	57	29	N	Grade 1	RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	貧血	20[redacted]	67	6	Y	Grade 3	NOT RELATED	NO ACTION TAKEN	HOSPITALIZED / PROLONGED HOSPITALIZATION
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	胃食道逆流性疾患	20[redacted]	68	5	N	Grade 1	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	喘鳴	20[redacted]	68		N	Grade 1	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	胃炎	20[redacted]	70		N	Grade 2	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	大腸ポリープ	20[redacted]	71	1	N	Grade 2	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	7[redacted]	F	BLACK or AFRICAN AMERICAN	痔核	20[redacted]	71		N	Grade 1	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	6[redacted]	M	BLACK or AFRICAN AMERICAN	低カルシウム血症	20[redacted]	8		N	Grade 2	RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 210mg	6[redacted]	M	BLACK or AFRICAN AMERICAN	僧帽弁疾患	20[redacted]	37	9	Y	Grade 4	NOT RELATED	NO ACTION TAKEN	HOSPITALIZED / PROLONGED HOSPITALIZATION SURGICAL INTERVENTION

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 210mg	6[redacted]	M	BLACK or AFRICAN AMERICAN	心房細動	20[redacted]	37		N	Grade 2	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 210mg	6[redacted]	M	BLACK or AFRICAN AMERICAN	高血糖	20[redacted]	44	2	N	Grade 2	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	下痢	20[redacted]	12	2	N	Mild	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	悪心	20[redacted]	12	5	N	Mild	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	不安	20[redacted]	64	4	Y	Severe	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN HOSPITALIZED / PROLONGED HOSPITALIZATION
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	脱水	20[redacted]	64	4	N	Moderate	NOT RELATED	DOSE NOT CHANGED	NO ACTION TAKEN
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	心電図異常	20[redacted]	64	1	N	Mild	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	胃排出不全	20[redacted]	64	4	Y	Severe	NOT RELATED	DOSE NOT CHANGED	MEDICATION TAKEN HOSPITALIZED / PROLONGED HOSPITALIZATION
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	白血球減少症	20[redacted]	64	4	Y	Severe	NOT RELATED	DOSE NOT CHANGED	HOSPITALIZED / PROLONGED HOSPITALIZATION
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	非心臓性胸痛	20[redacted]	64	4	N	Severe	NOT RELATED	DOSE NOT CHANGED	CT DONE TO R/O, PE AND STRESS ECHO
[redacted]	ALENDRONATE	7[redacted]	F	WHITE or CAUCASIAN	末梢性浮腫	20[redacted]	89	Ongoing	N	Mild	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	高血圧	20[redacted]	1	57	N	Severe	RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	変形性関節症	20[redacted]	77	Ongoing	N	Moderate	RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	感染性関節炎	20[redacted]	149	Ongoing	Y	Severe	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN HOSPITALIZED / PROLONGED HOSPITALIZATION
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	胸痛	20[redacted]	154	9	N	Mild	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	呼吸困難	20[redacted]	154	5	N	Mild	NOT RELATED	NO ACTION TAKEN	NO ACTION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	処置による悪心	20[redacted]	154	1	N	Mild	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	低カリウム血症	20[redacted]	154	18	N	Mild	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	発熱	20[redacted]	155	1	N	Mild	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	術後貧血	20[redacted]	155	7	N	Mild	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	AMG 785 3 mg/kg Q4W SC	6[redacted]	F	WHITE or CAUCASIAN	出血性胃腸潰瘍	20[redacted]	161	4	Y	Severe	NOT RELATED	NO ACTION TAKEN	HOSPITALIZED / PROLONGED HOSPITALIZATION
[redacted]	PLACEBO	6[redacted]	F	WHITE or CAUCASIAN	小腸炎	20[redacted]	8	2	N	Moderate	RELATED	NO ACTION TAKEN	MEDICATION TAKEN
[redacted]	PLACEBO	6[redacted]	F	WHITE or CAUCASIAN	筋骨格痛	20[redacted]	98	23	N	Mild	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN

Subject Identifier for the Study	Actual Treatment	Age	Sex	Race	Dictionary-Derived Term	Start Date of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Action Taken with Study Treatment	Other Action Taken
[redacted]	PLACEBO	6[redacted]	F	WHITE or CAUCASIAN	馬尾症候群	20[redacted]	141	Ongoing	Y	Severe	NOT RELATED	NO ACTION TAKEN	HOSPITALIZED / PROLONGED HOSPITALIZATION SURGICAL INTERVENTION WEARS A BRACE
[redacted]	PLACEBO	6[redacted]	F	WHITE or CAUCASIAN	尿路感染	20[redacted]	151	10	N	Moderate	NOT RELATED	NO ACTION TAKEN	MEDICATION TAKEN

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腕骨骨折	20[redacted]	134	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨折痛	20[redacted]	142	82	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨折痛	20[redacted]	224	364	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咽頭炎	20[redacted]	115	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋拘縮	20[redacted]	166	3	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	結晶性関節障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	673	.	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	673	.	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	骨痛	20[redacted]	7	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	死亡	20[redacted]	231	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	60	62	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	122	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺嚢腫	20[redacted]	132	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	175	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血腫	20[redacted]	175	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	175	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咽頭炎	20[redacted]	457	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肝嚢胞	20[redacted]	71	463	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心室性期外収縮	20[redacted]	287	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乳癌	20[redacted]	418	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	僧帽弁逸脱	20[redacted]	60	89	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉内出血	20[redacted]	61	15	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]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	61	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	295	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	334	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	医療機器位置異常	20[redacted]	472	101	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	472	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	583	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	四肢痛	20[redacted]	53	106	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	敗血症	20[redacted]	62	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	発熱	20[redacted]	99	2	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	107	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	肺炎	20[redacted]	107	52	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	細菌性関節炎	20[redacted]	122	37	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	ARGENTINA	PLACEBO		6[redacted]	F	WHITE	胸水	20[redacted]	143	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	33	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	55	45	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支痙攣	20[redacted]	119	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	124	191	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	そう痒症	20[redacted]	189	136	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支痙攣	20[redacted]	260	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	意識消失	20[redacted]	315	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	315	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	315	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	315	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	315	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	406	59	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	442	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎機能障害	20[redacted]	464	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	性器出血	20[redacted]	472	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	直腸出血	20[redacted]	472	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	.	.	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不整脈	20[redacted]	679	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭部損傷	20[redacted]	679	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	750	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	750	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	215	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	医療機器破損	20[redacted]	233	132	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	260	46	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	311	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	325	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋拘縮	20[redacted]	351	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱炎	20[redacted]	449	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	第７脳神経麻痺	20[redacted]	685	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	創壊死	20[redacted]	698	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	698	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	錯感覚	20[redacted]	726	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	顔面非対称	20[redacted]	726	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胸痛	20[redacted]	21	3	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胸痛	20[redacted]	122	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	150	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	155	126	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯の障害	20[redacted]	198	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯の障害	20[redacted]	218	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	.	84	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	281	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不安	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋拘縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	四肢痛	20[redacted]	13	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	心停止	20[redacted]	87	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	47	61	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	177	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	179	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	損傷	20[redacted]	191	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	191	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節炎	20[redacted]	318	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺腫	20[redacted]	372	3	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	396	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白血球増加症	20[redacted]	454	94	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	492	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	533	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	57	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嘔吐	20[redacted]	57	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	57	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿失禁	20[redacted]	211	230	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	びらん性胃炎	20[redacted]	265	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白血球尿	20[redacted]	540	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	CULTURE TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性冠動脈症候群	20[redacted]	.	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	64	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	73	190	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	89	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	基底細胞癌	20[redacted]	89	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	115	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	食中毒	20[redacted]	115	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	

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[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃炎	20[redacted]	166	67	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	197	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	207	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	261	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	263	424	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃炎	20[redacted]	275	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	297	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚創傷	20[redacted]	309	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	浮動性めまい	20[redacted]	398	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	398	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	444	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	骨粗鬆症	20[redacted]	467	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	527	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	湿性咳嗽	20[redacted]	527	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	529	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	529	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	529	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	621	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭部損傷	20[redacted]	621	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢性浮腫	20[redacted]	708	24	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	708	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胸椎骨折	20[redacted]	721	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	筋肉痛	20[redacted]	7	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	老年認知症	20[redacted]	7	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	貧血	20[redacted]	35	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	転倒	20[redacted]	56	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	関節痛	20[redacted]	56	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	健忘	20[redacted]	91	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	貧血	20[redacted]	91	.	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	食欲減退	20[redacted]	91	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	転倒	20[redacted]	102	1	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	転倒	20[redacted]	113	1	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO		7[redacted]	F	WHITE	全身健康状態低下	20[redacted]	120	66	Y	Grade 2	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	11	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	11	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乳房腫瘤	20[redacted]	23	147	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	意識消失	20[redacted]	153	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	153	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	153	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭部損傷	20[redacted]	153	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乳癌	20[redacted]	169	.	Y	Grade 3	NOT RELATED	UNKNOWN	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低血圧	20[redacted]	306	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	306	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃腸炎	20[redacted]	306	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹部膨満	20[redacted]	330	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	平衡障害	20[redacted]	345	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	425	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	500	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低血圧	20[redacted]	505	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	562	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	側腹部痛	20[redacted]	710	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	1	125	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性副鼻腔炎	20[redacted]	90	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	洞性不整脈	20[redacted]	97	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不安	20[redacted]	129	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	192	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	320	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	321	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	冠動脈疾患	20[redacted]	373	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	383	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	393	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉痛	20[redacted]	393	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	処置による疼痛	20[redacted]	395	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	398	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後貧血	20[redacted]	422	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯痛	20[redacted]	451	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	475	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乳房腫瘤	20[redacted]	477	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	537	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咽頭炎	20[redacted]	689	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	103	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	.	201	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋拘縮	20[redacted]	263	101	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頚部痛	20[redacted]	370	187	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚病変	20[redacted]	420	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節損傷	20[redacted]	420	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	455	102	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	457	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	536	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低カリウム血症	20[redacted]	546	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ARGENTINA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	556	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	2	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯の脱落	20[redacted]	35	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足骨折	20[redacted]	73	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	73	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位そう痒感	20[redacted]	97	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位そう痒感	20[redacted]	97	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	119	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	119	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	153	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	209	1	N	Grade 1	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	209	1	N	Grade 1	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位そう痒感	20[redacted]	209	1	N	Grade 1	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	295	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮脱	20[redacted]	338	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後イレウス	20[redacted]	338	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	そう痒症	20[redacted]	22	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	37	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嘔吐	20[redacted]	64	3	N	Grade 3	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼振	20[redacted]	64	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	172	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻漏	20[redacted]	172	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	204	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]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	187	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	706	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯牙破折	20[redacted]	15	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	滑液包炎	20[redacted]	30	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨梗塞	20[redacted]	57	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	96	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	96	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	145	566	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	蜂巣炎	20[redacted]	207	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	軟部組織損傷	20[redacted]	354	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	354	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脛骨骨折	20[redacted]	373	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腓骨骨折	20[redacted]	373	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRALIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後創感染	20[redacted]	406	154	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	細菌性上気道感染	20[redacted]	163	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	小腸閉塞	20[redacted]	573	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	過敏症	20[redacted]	3	5	Y	Grade 4	RELATED	RESOLVED	DRUG WITHDRAWN	MEDICATION TAKEN	N
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	喘息	20[redacted]	28	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	AUSTRALIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	第３脳神経不全麻痺	20[redacted]	664	31	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尺骨骨折	20[redacted]	34	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	34	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	34	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	85	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節周囲炎	20[redacted]	126	102	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	126	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	152	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	319	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	434	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	543	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	呼吸困難	20[redacted]	690	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	骨痛	20[redacted]	29	56	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	頭痛	20[redacted]	30	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	閉経期症状	20[redacted]	74	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	一過性脳虚血発作	20[redacted]	85	1	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	骨痛	20[redacted]	85	14	N	Grade 2	RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚神経内分泌癌	20[redacted]	6	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	REMOVED FROM STUDY	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	臍ヘルニア	20[redacted]	.	366	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	.	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	卵巣癌	20[redacted]	.	45	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	上腹部痛	20[redacted]	333	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	嘔吐	20[redacted]	341	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	腹痛	20[redacted]	341	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	血性下痢	20[redacted]	341	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	57	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	味覚異常	20[redacted]	220	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	220	25	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低酸素症	20[redacted]	244	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	675	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	677	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	12	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	96	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	124	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	153	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	153	57	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	153	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼出血	20[redacted]	237	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	237	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	268	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	268	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	311	117	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	413	255	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アレルギー性鼻炎	20[redacted]	129	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	そう痒症	20[redacted]	321	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	そう痒症	20[redacted]	425	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼出血	20[redacted]	545	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腕骨骨折	20[redacted]	641	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	67	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腸管ポリープ	20[redacted]	204	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	302	54	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱瘤	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	小脳虚血	20[redacted]	639	32	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	192	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	236	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	259	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	過角化	20[redacted]	356	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	BELGIUM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	709	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	172	167	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不全片麻痺	20[redacted]	254	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	硬膜下血腫	20[redacted]	254	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	300	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NON-IV ANTIMICROBIAL TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	541	247	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大動脈血栓症	20[redacted]	594	194	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性虚血	20[redacted]	594	46	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾性壊疽	20[redacted]	631	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大うつ病	20[redacted]	151	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	憩室	20[redacted]	192	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	206	209	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	静脈瘤性潰瘍	20[redacted]	286	200	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎仙痛	20[redacted]	373	113	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	弾発指	20[redacted]	586	98	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	BRAZIL	PLACEBO		6[redacted]	F	WHITE	死亡	20[redacted]	228	1	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	NO ACTION TAKEN	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	224	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疼痛	20[redacted]	273	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	迷路炎	20[redacted]	273	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	水頭症	20[redacted]	348	191	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BRAZIL	PLACEBO		6[redacted]	F	WHITE	湿性咳嗽	20[redacted]	28	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		6[redacted]	F	WHITE	肺結核	20[redacted]	61	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		6[redacted]	F	WHITE	出血性胃炎	20[redacted]	148	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO		6[redacted]	F	WHITE	胃癌	20[redacted]	180	89	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	132	8	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y

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[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	筋骨格痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	背部痛	20[redacted]	127	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	便秘	20[redacted]	144	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	うつ病	20[redacted]	174	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	膵癌	20[redacted]	260	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	REMOVED FROM STUDY	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	80	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	516	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	678	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	678	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	頭蓋脳損傷	20[redacted]	62	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	インフルエンザ	20[redacted]	166	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	胸骨損傷	20[redacted]	297	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	尺骨骨折	20[redacted]	561	.	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	転倒	20[redacted]	561	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	処置による疼痛	20[redacted]	565	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	四肢痛	20[redacted]	689	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	足骨折	20[redacted]	689	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	転倒	20[redacted]	689	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腱炎	20[redacted]	142	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	581	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	657	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アルツハイマー型認知症	20[redacted]	212	211	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	267	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭部損傷	20[redacted]	267	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アルツハイマー型認知症	20[redacted]	423	9	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	95	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳血管発作	20[redacted]	144	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	267	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢性浮腫	20[redacted]	470	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	高コレステロール血症	20[redacted]	184	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	胃炎	20[redacted]	329	66	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	そう痒症	20[redacted]	395	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	鼻炎	20[redacted]	505	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	血管中心性リンパ腫	20[redacted]	642	.	Y	Grade 3	RELATED	NOT RESOLVED	DRUG WITHDRAWN	OTHER	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	26	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	94	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮ポリープ	20[redacted]	626	196	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	徐脈	20[redacted]	159	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	背部痛	20[redacted]	438	312	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	高血圧	20[redacted]	491	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	脛骨骨折	20[redacted]	522	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	卵巣嚢胞	20[redacted]	634	108	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	便秘	20[redacted]	675	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎機能障害	20[redacted]	91	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	91	630	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腹部痛	20[redacted]	130	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	良性新生物	20[redacted]	239	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚擦過傷	20[redacted]	302	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	302	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	顔面痛	20[redacted]	302	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化性潰瘍	20[redacted]	420	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	434	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低血圧	20[redacted]	482	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	47	223	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚炎	20[redacted]	79	83	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	血圧低下	20[redacted]	90	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	尿路感染	20[redacted]	92	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	咳嗽	20[redacted]	161	167	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肺炎	20[redacted]	190	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	270	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	295	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	皮膚炎	20[redacted]	329	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	過敏症	20[redacted]	425	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	急性胆嚢炎	20[redacted]	536	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	36	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	錯感覚	20[redacted]	36	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	記憶障害	20[redacted]	38	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃腸炎	20[redacted]	162	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	うつ病	20[redacted]	266	60	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	268	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	うつ病	20[redacted]	377	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	副鼻腔炎	20[redacted]	534	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下腹部痛	20[redacted]	623	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	膵嚢胞	20[redacted]	647	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大腸ポリープ	20[redacted]	738	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	50	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	137	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食欲減退	20[redacted]	137	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	248	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	281	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血糖	20[redacted]	353	.	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]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	363	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	507	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	719	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	びらん性胃炎	20[redacted]	24	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	びらん性食道炎	20[redacted]	24	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	食欲減退	20[redacted]	25	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	尿路感染	20[redacted]	41	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	無力症	20[redacted]	49	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	50	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	喘息	20[redacted]	100	21	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	100	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	丹毒	20[redacted]	159	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	単径部膿瘍	20[redacted]	197	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	下痢	20[redacted]	212	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	244	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	尿路感染	20[redacted]	267	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	鉄欠乏性貧血	20[redacted]	267	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	314	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	胸水	20[redacted]	357	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	喘息	20[redacted]	392	153	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	脂質異常症	20[redacted]	436	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	524	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	喘息	20[redacted]	557	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	喘息	20[redacted]	595	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	621	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	高血圧	20[redacted]	621	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	OTHER	肺炎	20[redacted]	630	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嘔吐	20[redacted]	83	62	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	悪心	20[redacted]	83	62	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	疼痛	20[redacted]	221	85	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	皮膚炎	20[redacted]	231	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	580	192	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	胃腺癌	20[redacted]	675	97	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	691	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ストレス	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ	20[redacted]	85	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	水腎症	20[redacted]	519	114	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	93	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	挫傷	20[redacted]	154	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尺骨骨折	20[redacted]	198	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	363	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上腹部痛	20[redacted]	384	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	37	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	抑うつ気分	20[redacted]	90	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	嘔吐	20[redacted]	151	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	嘔吐	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脊椎痛	20[redacted]	349	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上腕骨骨折	20[redacted]	512	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	115	76	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	副鼻腔炎	20[redacted]	190	37	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	296	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	543	173	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	548	128	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	631	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	インフルエンザ	20[redacted]	17	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	第７脳神経麻痺	20[redacted]	22	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	間欠性跛行	20[redacted]	54	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	非ホジキンリンパ腫	20[redacted]	177	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	倦怠感	20[redacted]	179	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	10	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨痛	20[redacted]	22	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	低血糖	20[redacted]	174	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	子宮脱	20[redacted]	225	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	悪心	20[redacted]	654	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	345	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	345	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	345	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	丹毒	20[redacted]	440	15	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	下痢	20[redacted]	29	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嘔吐	20[redacted]	29	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	食欲減退	20[redacted]	438	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	急性膵炎	20[redacted]	706	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	排尿困難	20[redacted]	15	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	好中球減少症	20[redacted]	88	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	白血球減少症	20[redacted]	88	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	四肢損傷	20[redacted]	105	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	転倒	20[redacted]	105	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	丹毒	20[redacted]	113	36	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	丹毒	20[redacted]	195	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肩回旋筋腱板症候群	20[redacted]	266	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	下痢	20[redacted]	302	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	インフルエンザ	20[redacted]	306	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	食欲減退	20[redacted]	307	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	関節痛	20[redacted]	207	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	眼痛	20[redacted]	275	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	ラクナ梗塞	20[redacted]	542	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	意識消失	20[redacted]	542	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	貧血	20[redacted]	542	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	高血圧	20[redacted]	542	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	虚血性脳卒中	20[redacted]	592	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	尿路感染	20[redacted]	602	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	自己否定気分	20[redacted]	607	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	便秘	20[redacted]	13	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	背部痛	20[redacted]	112	319	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	235	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	浮動性めまい	20[redacted]	522	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	出血性卒中	20[redacted]	667	72	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺炎	20[redacted]	717	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	14	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	40	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆石症	20[redacted]	144	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肝酵素異常	20[redacted]	179	194	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動悸	20[redacted]	210	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢性浮腫	20[redacted]	230	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧性心疾患	20[redacted]	235	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋肉痛	20[redacted]	246	.	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]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	糖尿病	20[redacted]	269	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	丹毒	20[redacted]	287	117	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	薬物過敏症	20[redacted]	287	189	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動悸	20[redacted]	372	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	四肢痛	20[redacted]	8	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	尿路感染	20[redacted]	61	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	ウイルス性胃腸炎	20[redacted]	107	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	静脈炎	20[redacted]	108	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	失神	20[redacted]	136	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	錯乱状態	20[redacted]	136	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	154	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	転倒	20[redacted]	293	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	嵌頓臍径ヘルニア	20[redacted]	564	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	乳房不同	20[redacted]	590	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	145	185	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	迷路炎	20[redacted]	374	325	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	僧帽弁疾患	20[redacted]	545	154	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	545	154	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	698	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	変形性脊椎症	20[redacted]	139	168	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性閉塞性肺疾患	20[redacted]	206	482	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	不安	20[redacted]	271	417	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	咽頭炎	20[redacted]	272	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	湿性咳嗽	20[redacted]	296	38	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	上腹部痛	20[redacted]	337	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	抑うつ症状	20[redacted]	436	252	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	副鼻腔炎	20[redacted]	537	151	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	急性呼吸不全	20[redacted]	679	9	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	多臓器不全	20[redacted]	687	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	失神	20[redacted]	15	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	胆石症	20[redacted]	16	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	尿路感染	20[redacted]	25	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	インフルエンザ	20[redacted]	113	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	筋力低下	20[redacted]	127	195	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	甲状腺機能低下症	20[redacted]	134	188	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	糖尿病	20[redacted]	134	188	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	関節損傷	20[redacted]	145	177	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	蜂巣炎	20[redacted]	176	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	尿路感染	20[redacted]	215	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	痙攣発作	20[redacted]	215	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	耳痛	20[redacted]	257	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	不整脈	20[redacted]	319	3	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	房室ブロック	20[redacted]	319	3	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	多臓器不全	20[redacted]	320	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	OTHER	心原性ショック	20[redacted]	320	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	消化不良	20[redacted]	430	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	BLACK OR AFRICAN AMERICAN	胃癌	20[redacted]	430	.	Y	Grade 4	RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	尿路感染	20[redacted]	7	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	失神	20[redacted]	9	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	腰椎骨折	20[redacted]	9	8	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肺炎	20[redacted]	68	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	消化不良	20[redacted]	41	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	247	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	266	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	アスパラギン酸アミノトランスフェラーゼ増加	20[redacted]	274	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	アラニンアミノトランスフェラーゼ増加	20[redacted]	274	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	274	15	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	食道炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	22	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下部消化管出血	20[redacted]	38	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血小板減少症	20[redacted]	268	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	526	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食道炎	20[redacted]	526	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	125	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	127	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低血圧	20[redacted]	149	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	193	93	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腱障害	20[redacted]	216	429	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿失禁	20[redacted]	226	67	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	滑液包炎	20[redacted]	226	94	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	286	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	286	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	336	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病性ニューロパチー	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	136	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	182	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	208	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	217	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白血球数減少	20[redacted]	274	29	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白血球数減少	20[redacted]	274	29	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	297	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膵癌	20[redacted]	365	.	Y	Grade 4	RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	382	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腹部痛	20[redacted]	123	149	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	280	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化不良	20[redacted]	403	180	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腹部痛	20[redacted]	573	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	582	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食道炎	20[redacted]	582	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	腎不全	20[redacted]	1	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	脳神経障害	20[redacted]	80	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	静脈瘤	20[redacted]	128	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	動物咬傷	20[redacted]	233	73	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	胃ポリープ	20[redacted]	267	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	丹毒	20[redacted]	283	58	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	静脈瘤性潰瘍	20[redacted]	308	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	511	123	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	51	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上室性期外収縮	20[redacted]	155	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	235	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	98	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節損傷	20[redacted]	98	29	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耐糖能障害	20[redacted]	273	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	332	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯牙破折	20[redacted]	337	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	419	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	10	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	迷路炎	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	甲状腺機能亢進症	20[redacted]	534	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	95	682	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱癌	20[redacted]	682	74	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	46	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位そう痒感	20[redacted]	64	2	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	120	515	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	120	19	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	173	23	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	188	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	丹毒	20[redacted]	280	45	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不整脈	20[redacted]	302	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うっ血性心不全	20[redacted]	347	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	347	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	基底細胞癌	20[redacted]	418	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	丹毒	20[redacted]	526	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚病変	20[redacted]	536	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	丹毒	20[redacted]	658	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚真菌感染	20[redacted]	681	60	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腹部痛	20[redacted]	15	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	24	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腸出血	20[redacted]	66	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性胃腸炎	20[redacted]	100	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	207	1	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	207	116	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	382	520	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	デング熱	20[redacted]	708	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	88	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	469	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	9	263	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	143	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	手根管症候群	20[redacted]	252	427	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	443	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁狭窄症	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頚動脈硬化症	20[redacted]	444	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	664	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	146	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	291	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎機能障害	20[redacted]	362	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	468	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	468	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	糖尿病性ニューロパチー	20[redacted]	559	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	２型糖尿病	20[redacted]	13	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	脂肪肝	20[redacted]	33	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	悪心	20[redacted]	34	18	Y	Grade 4	NOT RELATED	RESOLVED	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	腹痛	20[redacted]	34	18	Y	Grade 4	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	膵癌	20[redacted]	51	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	WHITE	損傷	20[redacted]	148	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	WHITE	転倒	20[redacted]	148	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	WHITE	膀胱癌	20[redacted]	330	3	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	170	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	不安定狭心症	20[redacted]	213	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	254	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	272	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎結石症	20[redacted]	289	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	痔核	20[redacted]	517	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	BLACK OR AFRICAN AMERICAN	上腹部痛	20[redacted]	38	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	BLACK OR AFRICAN AMERICAN	上腹部痛	20[redacted]	69	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	BLACK OR AFRICAN AMERICAN	胆石症	20[redacted]	207	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	BLACK OR AFRICAN AMERICAN	胸痛	20[redacted]	207	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO		8[redacted]	F	BLACK OR AFRICAN AMERICAN	肺新生物	20[redacted]	274	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	橈骨骨折	20[redacted]	73	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	転倒	20[redacted]	73	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	腱障害	20[redacted]	180	314	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	50	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安定狭心症	20[redacted]	368	158	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈不全	20[redacted]	368	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	368	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	左室機能不全	20[redacted]	387	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮脱	20[redacted]	388	300	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	消化不良	20[redacted]	125	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	ウイルス性発疹	20[redacted]	216	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	咳嗽	20[redacted]	269	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	上部消化管出血	20[redacted]	307	39	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	深部静脈血栓症	20[redacted]	307	39	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	子宮脱	20[redacted]	.	709	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	UNKNOWN	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	インフルエンザ	20[redacted]	435	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	湿性咳嗽	20[redacted]	702	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頚部痛	20[redacted]	32	149	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	発声障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	食道炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	139	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	筋骨格痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腱障害	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	肺腫瘤	20[redacted]	613	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	8	18	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性肺炎	20[redacted]	74	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	146	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性肺炎	20[redacted]	224	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性肺炎	20[redacted]	241	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	356	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	3	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	74	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	111	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	115	54	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	312	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ	20[redacted]	343	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嘔吐	20[redacted]	82	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	83	18	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	83	187	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸菌性尿路感染	20[redacted]	165	597	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧クリーゼ	20[redacted]	202	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	.	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胸痛	20[redacted]	.	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	76	84	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アスパラギン酸アミノトランスフェラーゼ増加	20[redacted]	93	91	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アラニンアミノトランスフェラーゼ増加	20[redacted]	93	91	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎機能障害	20[redacted]	93	91	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腱鞘炎	20[redacted]	406	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	椎間板突出	20[redacted]	433	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腕骨骨折	20[redacted]	556	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	269	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	突然死	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL			Y

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[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	インフルエンザ	20[redacted]	.	59	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	体重減少	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	下痢	20[redacted]	166	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	腹痛	20[redacted]	166	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	湿性咳嗽	20[redacted]	173	71	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	腹痛	20[redacted]	253	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	BLACK OR AFRICAN AMERICAN	高血圧	20[redacted]	.	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	湿性咳嗽	20[redacted]	215	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	細菌性肺炎	20[redacted]	231	15	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	食欲減退	20[redacted]	342	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	BLACK OR AFRICAN AMERICAN	肺炎	20[redacted]	688	4	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢膿瘍	20[redacted]	163	53	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疼痛	20[redacted]	189	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発熱	20[redacted]	189	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼痛	20[redacted]	189	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食欲減退	20[redacted]	189	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃腸出血	20[redacted]	514	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	688	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	充血	20[redacted]	1	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	1	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	流涎過多	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆嚢炎	20[redacted]	709	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	709	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	.	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	208	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	271	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺扁平上皮癌	20[redacted]	499	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	BRAZIL	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	535	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	319	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腕骨骨折	20[redacted]	385	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	385	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	392	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	BRAZIL	PLACEBO		7[redacted]	F	WHITE	僧帽弁狭窄症	20[redacted]	34	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	爪甲脱落症	20[redacted]	8	76	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口呼吸	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	105	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	デュプイトラン拘縮	20[redacted]	253	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋萎縮	20[redacted]	253	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	虚血性大腸炎	20[redacted]	266	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外陰腟真菌感染	20[redacted]	276	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肉離れ	20[redacted]	297	29	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]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	427	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	427	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	427	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	429	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うつ病	20[redacted]	538	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	663	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	691	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発疹	20[redacted]	692	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	31	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	34	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	78	77	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重増加	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	感染による気管支拡張症の増悪	20[redacted]	187	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支肺アスペルギルス症	20[redacted]	187	316	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	口内乾燥	20[redacted]	253	161	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	眼乾燥	20[redacted]	253	161	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	287	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	366	28	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]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	368	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	過敏性腸症候群	20[redacted]	608	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃食道逆流性疾患	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	膝蓋大腿関節痛症候群	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	60	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	60	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	医療機器破損	20[redacted]	107	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アレルギー性鼻炎	20[redacted]	123	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	肺腺癌	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高コレステロール血症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	187	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	眼出血	20[redacted]	228	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋肉痛	20[redacted]	293	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	293	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻漏	20[redacted]	429	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	526	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	眼刺激	20[redacted]	717	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	そう痒症	20[redacted]	109	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	インフルエンザ様疾患	20[redacted]	252	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	そう痒症	20[redacted]	326	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	錯感覚	20[redacted]	368	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	上腕骨骨折	20[redacted]	524	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肋骨骨折	20[redacted]	524	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	55	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	マイコバクテリウム・アビウムコンプレックス感染	20[redacted]	175	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	副鼻腔炎	20[redacted]	249	122	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位内出血	20[redacted]	279	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位紅斑	20[redacted]	279	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	296	159	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	299	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	372	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	375	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢膿瘍	20[redacted]	442	49	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血管穿刺部位内出血	20[redacted]	455	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	470	21	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性肺炎	20[redacted]	725	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	746	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	創傷	20[redacted]	768	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	768	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	768	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	768	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	食欲減退	20[redacted]	14	5	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	便秘	20[redacted]	19	5	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	眼のアレルギー	20[redacted]	27	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	発声障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性胆嚢炎	20[redacted]	75	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	接触性皮膚炎	20[redacted]	75	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	イレウス	20[redacted]	78	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脂質異常症	20[redacted]	103	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胸痛	20[redacted]	112	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹部膨満	20[redacted]	156	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	視力障害	20[redacted]	159	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	健忘	20[redacted]	172	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	201	123	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脱毛症	20[redacted]	203	105	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不安障害	20[redacted]	476	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	疲労	20[redacted]	476	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CANADA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	521	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	721	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脱水	20[redacted]	721	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾癬	20[redacted]	.	185	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	錯感覚	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾癬	20[redacted]	190	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾癬	20[redacted]	342	359	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	365	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾癬	20[redacted]	701	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	ライム病	20[redacted]	1	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	ライム病	20[redacted]	35	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	過量投与	20[redacted]	59	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺腺腫	20[redacted]	174	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	288	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乳房障害	20[redacted]	316	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	328	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	節足動物咬傷	20[redacted]	408	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	442	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	虫垂炎	20[redacted]	497	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	524	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	528	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂漏性角化症	20[redacted]	629	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節障害	20[redacted]	637	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	肝機能検査異常	20[redacted]	93	79	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	MEDICATION TAKEN	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯肉痛	20[redacted]	15	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	253	71	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節炎	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	335	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腟ポリープ	20[redacted]	450	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食欲減退	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	憩室	20[redacted]	652	362	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹膜炎	20[redacted]	652	28	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	静脈瘤	20[redacted]	64	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス感染	20[redacted]	141	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	243	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	632	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	.	218	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	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]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	261	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	336	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	リウマチ性多発筋痛	20[redacted]	416	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸菌性尿路感染	20[redacted]	416	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	帯状疱疹	20[redacted]	476	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	498	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸菌性尿路感染	20[redacted]	545	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]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎結石症	20[redacted]	575	230	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	346	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻炎	20[redacted]	524	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	669	15	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	672	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	.	69	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	248	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	446	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	57	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	60	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	内頚動脈屈曲	20[redacted]	64	28	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃腸障害	20[redacted]	320	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	痔核	20[redacted]	360	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	455	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋緊張低下	20[redacted]	519	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	歯牙損傷	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	結膜炎	20[redacted]	54	127	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	179	69	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	61	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳鳴	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	扁桃炎	20[redacted]	174	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	197	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	線維性組織球腫	20[redacted]	223	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	267	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	497	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	504	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	60	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	79	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位疼痛	20[redacted]	122	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位腫脹	20[redacted]	122	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	140	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心的外傷後ストレス障害	20[redacted]	159	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス感染	20[redacted]	160	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	164	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	振戦	20[redacted]	311	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肝転移	20[redacted]	389	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	白血球増加症	20[redacted]	182	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	329	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	穿孔性胃潰瘍	20[redacted]	329	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N

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[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	処置後合併症	20[redacted]	332	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	麻痺性イレウス	20[redacted]	332	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	凝血異常	20[redacted]	335	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	心房細動	20[redacted]	336	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	身体疾患による人格変化	20[redacted]	344	19	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血管石灰化	20[redacted]	23	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	帯状疱疹	20[redacted]	680	24	Y	Grade 2	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外骨腫	20[redacted]	38	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	149	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	足変形	20[redacted]	149	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺腫	20[redacted]	317	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	423	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	427	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	427	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	副鼻腔炎	20[redacted]	443	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性膀胱炎	20[redacted]	105	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	111	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	119	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位そう痒感	20[redacted]	133	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位紅斑	20[redacted]	133	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿失禁	20[redacted]	200	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	559	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	小腸炎	20[redacted]	576	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	723	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	391	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚病変	20[redacted]	710	208	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	28	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	203	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性気管支炎	20[redacted]	225	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	副鼻腔炎	20[redacted]	252	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	252	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺臓炎	20[redacted]	252	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	414	30	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	507	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	508	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	57	5	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	81	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス感染	20[redacted]	83	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	423	20	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	521	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高トランスアミナーゼ血症	20[redacted]	545	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	15	4	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	58	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	交感神経性後頚部症候群	20[redacted]	77	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	86	3	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃腸炎	20[redacted]	86	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	90	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	122	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	122	15	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	148	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	171	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	176	2	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	178	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	207	2	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	219	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	239	8	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨挫傷	20[redacted]	257	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	267	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節拘縮	20[redacted]	.	71	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管気管支炎	20[redacted]	418	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	薬物過敏症	20[redacted]	420	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	消化不良	20[redacted]	437	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	憩室炎	20[redacted]	618	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	外傷性潰瘍	20[redacted]	31	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	白内障	20[redacted]	77	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	脳血管発作	20[redacted]	156	9	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	脳血管発作	20[redacted]	172	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		8[redacted]	F	WHITE	血管性脳症	20[redacted]	187	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	医療機器不具合	20[redacted]	358	8	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	医療機器不具合	20[redacted]	365	1	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	UNKNOWN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻炎	20[redacted]	447	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	帯状疱疹	20[redacted]	469	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮離開	20[redacted]	524	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副腎腺腫	20[redacted]	98	119	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副腎腺腫	20[redacted]	98	119	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	原発性アルドステロン症	20[redacted]	98	119	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	原発性アルドステロン症	20[redacted]	98	119	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	274	296	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副腎腺腫	20[redacted]	568	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	9	84	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	45	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性前庭症候群	20[redacted]	67	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	.	215	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	152	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低クロール血症	20[redacted]	187	13	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	187	13	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	284	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	346	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	377	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	443	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	526	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発熱	20[redacted]	526	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低クロール血症	20[redacted]	535	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	535	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	凝固低下状態	20[redacted]	535	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	546	184	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	洞結節機能不全	20[redacted]	630	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	164	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	233	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	274	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血中葉酸減少	20[redacted]	286	263	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足関節変形	20[redacted]	288	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆道仙痛	20[redacted]	357	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆嚢炎	20[redacted]	408	5	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ビタミンＢ１２欠乏	20[redacted]	510	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鉄欠乏	20[redacted]	510	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	滑膜炎	20[redacted]	513	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ラ音	20[redacted]	730	169	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高ナトリウム血症	20[redacted]	29	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	99	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス感染	20[redacted]	258	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス感染	20[redacted]	301	10	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	本態性高血圧症	20[redacted]	346	105	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	359	85	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	455	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	552	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨接合	20[redacted]	567	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃炎	20[redacted]	8	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	感染性下痢	20[redacted]	68	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	71	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	苦悶感	20[redacted]	149	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	右脚ブロック	20[redacted]	156	85	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	消化不良	20[redacted]	219	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	疲労	20[redacted]	219	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻炎	20[redacted]	250	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	442	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	洞結節機能不全	20[redacted]	710	97	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	131	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	147	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化不良	20[redacted]	181	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	265	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮ポリープ	20[redacted]	348	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮留膿症	20[redacted]	468	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	痔核	20[redacted]	518	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ヘリコバクター検査陽性	20[redacted]	531	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚有棘細胞癌	20[redacted]	534	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	547	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	66	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口腔ヘルペス	20[redacted]	66	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃腸障害	20[redacted]	183	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	385	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	385	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	385	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	547	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	547	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	17	5	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]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	17	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脳振盪	20[redacted]	17	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	17	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発疹	20[redacted]	37	138	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	4	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	238	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	呼吸困難	20[redacted]	238	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺高血圧症	20[redacted]	238	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	238	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	301	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頚部痛	20[redacted]	545	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎盂膀胱炎	20[redacted]	109	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	膀胱炎	20[redacted]	183	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	270	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	272	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	302	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	水腫性胆嚢炎	20[redacted]	48	295	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	62	3	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]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の脱落	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎分離	20[redacted]-[redacted]-[redacted]	130	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	馬尾症候群	20[redacted]-[redacted]-[redacted]	130	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性胆嚢炎	20[redacted]-[redacted]-[redacted]	211	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]-[redacted]-[redacted]	211	497	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂肪肝	20[redacted]-[redacted]-[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血管筋脂肪腫	20[redacted]-[redacted]-[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆道仙痛	20[redacted]-[redacted]-[redacted]	276	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咽頭炎	20[redacted]-[redacted]-[redacted]	280	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性胆嚢炎	20[redacted]-[redacted]-[redacted]	342	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性腎臓病	20[redacted]-[redacted]-[redacted]	232	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高尿酸血症	20[redacted]-[redacted]-[redacted]	232	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脂肪肝	20[redacted]-[redacted]-[redacted]	250	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	メニエール病	20[redacted]-[redacted]-[redacted]	253	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	網脈絡膜症	20[redacted]-[redacted]-[redacted]	279	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性膀胱炎	20[redacted]-[redacted]-[redacted]	357	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	多発ニューロパチー	20[redacted]-[redacted]-[redacted]	398	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	手根管症候群	20[redacted]-[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	メニエール病	20[redacted]-[redacted]-[redacted]	429	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	多発ニューロパチー	20[redacted]-[redacted]-[redacted]	468	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]-[redacted]-[redacted]	468	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	網脈絡膜症	20[redacted]	512	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	薬物過敏症	20[redacted]	549	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	網脈絡膜症	20[redacted]	589	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	多発ニューロパチー	20[redacted]	616	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	メニエール病	20[redacted]	645	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	網脈絡膜症	20[redacted]	694	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	網脈絡膜症	20[redacted]	695	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高尿酸血症	20[redacted]	842	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	842	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	挫傷	20[redacted]	51	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	転倒	20[redacted]	51	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	失神	20[redacted]	54	53	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	低血圧	20[redacted]	101	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	失神	20[redacted]	101	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	心房拡張	20[redacted]	101	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	心房細動	20[redacted]	101	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	肥大型心筋症	20[redacted]	101	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	挫傷	20[redacted]	272	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	転倒	20[redacted]	272	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	下痢	20[redacted]	335	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	消化不良	20[redacted]	335	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	60	.	Y	Grade 3	NOT RELATED	NOT 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]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ	20[redacted]	148	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発疹	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発熱	20[redacted]	687	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	687	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発疹	20[redacted]	688	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	呼吸困難	20[redacted]	689	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	クラミジア感染	20[redacted]	694	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	270	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節損傷	20[redacted]	270	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	282	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	.	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	568	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カルシウム血症	20[redacted]	568	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低マグネシウム血症	20[redacted]	568	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	568	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脱水	20[redacted]	568	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	臍ヘルニア	20[redacted]	86	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	帯状疱疹	20[redacted]	112	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	臍ヘルニア	20[redacted]	132	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	133	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	290	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	点状出血	20[redacted]	255	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	9	63	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	35	504	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	呼吸困難	20[redacted]	326	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	326	213	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	336	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	357	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	.	133	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	71	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	視力低下	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚病変	20[redacted]	272	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	351	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	351	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	単径ヘルニア	20[redacted]	.	75	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	単径ヘルニア	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化不良	20[redacted]	719	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	運動不能	20[redacted]	12	36	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	便秘	20[redacted]	112	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	運動不能	20[redacted]	112	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	乾癬	20[redacted]	64	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	歯痛	20[redacted]	341	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	頚部痛	20[redacted]	.	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	白内障	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	高血圧	20[redacted]	714	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	小脳梗塞	20[redacted]	716	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	肺気腫	20[redacted]	716	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	719	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ	20[redacted]	193	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	265	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	289	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節炎	20[redacted]	425	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ	20[redacted]	674	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	680	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	304	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咽頭炎	20[redacted]	153	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	465	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	465	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	交通事故	20[redacted]	557	1	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]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脳振盪	20[redacted]	557	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂傷	20[redacted]	557	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢腫脹	20[redacted]	34	98	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋力低下	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	体重減少	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	多発ニューロパチー	20[redacted]	455	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	488	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	栄養障害	20[redacted]	490	145	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	491	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低蛋白血症	20[redacted]	491	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低血圧	20[redacted]	491	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性心不全	20[redacted]	491	43	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脱水	20[redacted]	491	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	492	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	卵巣嚢胞	20[redacted]	497	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	497	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹水	20[redacted]	497	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆石症	20[redacted]	518	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	541	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	542	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	体内異物	20[redacted]	9	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	179	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	537	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腰椎骨折	20[redacted]	551	122	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	睡眠障害	20[redacted]	552	121	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低クロール血症	20[redacted]	553	120	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	553	120	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	556	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胸痛	20[redacted]	560	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	560	113	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	眼乾燥	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	認知症	20[redacted]	664	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	664	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	扁桃炎	20[redacted]	670	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	口腔腫脹	20[redacted]	671	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	呼吸不全	20[redacted]	671	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咽頭炎	20[redacted]	671	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心不全	20[redacted]	672	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回帰性リウマチ	20[redacted]	76	53	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	133	24	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	222	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	303	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	308	24	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	睡眠障害	20[redacted]	321	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気道感染	20[redacted]	336	24	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	344	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回帰性リウマチ	20[redacted]	367	54	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	547	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	睡眠障害	20[redacted]	547	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	580	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	694	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス血症	20[redacted]	305	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	434	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	サルモネラ症	20[redacted]	465	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	654	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ダニ媒介ウイルス脳炎	20[redacted]	74	21	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	118	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ダニ媒介ウイルス脳炎	20[redacted]	254	110	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ダニ媒介ウイルス脳炎	20[redacted]	254	110	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	728	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	124	26	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	480	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳垢栓塞	20[redacted]	9	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	103	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿道症候群	20[redacted]	118	49	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳痛	20[redacted]	164	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	164	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	203	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	術後創感染	20[redacted]	209	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧変動	20[redacted]	286	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧変動	20[redacted]	324	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化管感染	20[redacted]	521	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ライム病	20[redacted]	607	78	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	小腸炎	20[redacted]	659	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	678	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳鳴	20[redacted]	2	361	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	聴力低下	20[redacted]	2	361	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	49	314	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化不良	20[redacted]	95	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	錯感覚	20[redacted]	100	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	副鼻腔炎	20[redacted]	176	37	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外耳炎	20[redacted]	214	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	化膿性肉芽腫	20[redacted]	222	87	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	308	55	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	452	10	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]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	難聴	20[redacted]	483	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻炎	20[redacted]	533	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	701	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	膀胱炎	20[redacted]	5	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	膀胱炎	20[redacted]	64	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	咳嗽	20[redacted]	77	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	尿路感染	20[redacted]	200	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	大腸穿孔	20[redacted]	231	11	Y	Grade 4	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	120	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	148	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢損傷	20[redacted]	172	28	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脛骨骨折	20[redacted]	172	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脛骨骨折	20[redacted]	445	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腓骨骨折	20[redacted]	445	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	1	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	便秘	20[redacted]	85	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	95	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	視力障害	20[redacted]	125	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	回転性めまい	20[redacted]	244	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	振戦	20[redacted]	244	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]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	246	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	246	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	歯痛	20[redacted]	384	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	460	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	異常感覚	20[redacted]	554	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	554	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	坐骨神経痛	20[redacted]	623	98	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	624	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性気管支炎	20[redacted]	646	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	680	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上気道感染	20[redacted]	681	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	消化不良	20[redacted]	692	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高カルシウム血症	20[redacted]	723	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	273	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	卵巣腺腫	20[redacted]	649	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈血栓症	20[redacted]	47	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発疹	20[redacted]	47	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	83	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	158	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨盤腔内腫瘤	20[redacted]	187	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	靭帯捻挫	20[redacted]	231	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	靭帯捻挫	20[redacted]	231	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨盤血腫	20[redacted]	245	76	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尺骨骨折	20[redacted]	40	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚擦過傷	20[redacted]	40	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻炎	20[redacted]	64	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	65	57	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	硬膜下血腫	20[redacted]	78	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂傷	20[redacted]	78	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	硬膜下血腫	20[redacted]	81	3	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	82	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	83	904	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮障害	20[redacted]	91	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	平滑筋腫	20[redacted]	149	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	扁桃炎	20[redacted]	164	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アルコール乱用	20[redacted]	.	627	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	片頭痛	20[redacted]	302	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯髄炎	20[redacted]	303	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾癬	20[redacted]	426	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	458	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脛骨骨折	20[redacted]	731	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腓骨骨折	20[redacted]	731	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	25	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	70	55	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	117	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	硝子体障害	20[redacted]	139	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	165	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯痛	20[redacted]	210	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	237	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嚢胞様黄斑浮腫	20[redacted]	284	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	緑内障	20[redacted]	291	126	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	黄斑変性	20[redacted]	546	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	590	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	715	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	78	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	108	70	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	146	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	呼吸困難	20[redacted]	191	29	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	271	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	疲労	20[redacted]	289	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	子宮内膜増殖症	20[redacted]	432	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嘔吐	20[redacted]	14	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	15	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢静脈疾患	20[redacted]	49	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血腫	20[redacted]	88	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性鼻炎	20[redacted]	174	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不眠症	20[redacted]	196	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	218	29	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	246	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病	20[redacted]	275	356	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	352	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	451	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	コントロール不良の糖尿病	20[redacted]	631	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血管性脳症	20[redacted]	631	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	医療機器不具合	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	２型糖尿病	20[redacted]	334	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	680	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低浸透圧状態	20[redacted]	680	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	215	32	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	クリプトコッカス性肺炎	20[redacted]	222	32	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	クリプトコッカス性肺炎	20[redacted]	236	97	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	外骨腫	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腱付着部症	20[redacted]	444	55	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	歯髄炎	20[redacted]	24	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	47	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	筋痙縮	20[redacted]	54	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	咳嗽	20[redacted]	88	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	脊椎痛	20[redacted]	88	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	下痢	20[redacted]	117	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	上気道感染	20[redacted]	121	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	126	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	耳痛	20[redacted]	126	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	腹痛	20[redacted]	138	105	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	歯髄炎	20[redacted]	150	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	歯髄炎	20[redacted]	157	55	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	歯髄炎	20[redacted]	157	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	ライム病	20[redacted]	207	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	咽頭炎	20[redacted]	225	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	腹痛	20[redacted]	243	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	放屁	20[redacted]	246	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	消化不良	20[redacted]	249	65	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	288	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	放屁	20[redacted]	288	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	偽性根症候群	20[redacted]	320	259	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	リウマチ性多発筋痛	20[redacted]	336	.	N	Grade 2	RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	上気道感染	20[redacted]	336	36	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	リウマチ性多発筋痛	20[redacted]	539	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		6[redacted]	F	WHITE	背部痛	20[redacted]	648	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	72	125	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	神経根痛	20[redacted]	102	73	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	136	335	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	169	.	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]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮平滑筋腫	20[redacted]	169	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口腔ヘルペス	20[redacted]	174	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	444	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	623	100	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安定狭心症	20[redacted]	723	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	725	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	727	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動悸	20[redacted]	744	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	750	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	771	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	粘膜乾燥	20[redacted]	2	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	上気道感染	20[redacted]	6	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	体重減少	20[redacted]	13	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肺炎	20[redacted]	13	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	気管支炎	20[redacted]	56	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肺炎	20[redacted]	96	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	蓄膿	20[redacted]	96	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	29	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮頚部上皮異形成	20[redacted]	47	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	憩室炎	20[redacted]	88	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	127	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	140	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸ポリープ	20[redacted]	169	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腸憩室	20[redacted]	169	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	191	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	呼吸困難	20[redacted]	221	334	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	憩室炎	20[redacted]	348	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮平滑筋腫	20[redacted]	587	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮頚部上皮異形成	20[redacted]	587	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹膜癒着	20[redacted]	587	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	機械的イレウス	20[redacted]	592	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿失禁	20[redacted]	598	263	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆管拡張	20[redacted]	16	131	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆管拡張	20[redacted]	147	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	２型糖尿病	20[redacted]	280	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	424	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血管穿刺部位血腫	20[redacted]	724	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	88	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮頚部上皮異形成	20[redacted]	218	87	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	243	502	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	246	88	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮頚部上皮異形成	20[redacted]	304	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮平滑筋腫	20[redacted]	320	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮脱	20[redacted]	135	160	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	162	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	緊張性膀胱	20[redacted]	162	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮脱	20[redacted]	295	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	68	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	68	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	側腹部痛	20[redacted]	78	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咽頭炎	20[redacted]	119	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咽頭炎	20[redacted]	197	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	212	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	212	145	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢腫脹	20[redacted]	212	145	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	212	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血腫	20[redacted]	212	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	212	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腸ポリープ	20[redacted]	274	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	痔核	20[redacted]	274	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	398	403	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肩回旋筋腱板症候群	20[redacted]	584	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	618	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	705	62	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	22	801	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆汁うっ滞性黄疸	20[redacted]	722	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ節症	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ節症	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺気腫	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺腫瘤	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	727	96	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膵腺癌	20[redacted]	727	96	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺うっ血	20[redacted]	762	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	上気道の炎症	20[redacted]	237	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	再発乳癌	20[redacted]	274	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	脊椎痛	20[redacted]	336	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	47	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	49	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	61	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	64	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	92	18	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	108	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	108	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	151	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	扁桃炎	20[redacted]	154	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	狭心症	20[redacted]	185	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	208	37	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	狭心症	20[redacted]	228	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃障害	20[redacted]	261	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	痔核	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	304	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化不良	20[redacted]	503	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻炎	20[redacted]	62	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	放屁	20[redacted]	244	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	244	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	疲労	20[redacted]	249	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血腫	20[redacted]	367	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	交感神経性後頚部症候群	20[redacted]	506	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脱水	20[redacted]	506	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	髄膜腫	20[redacted]	506	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	椎骨脳底動脈不全	20[redacted]	511	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	511	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脱水	20[redacted]	511	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	膀胱炎	20[redacted]	511	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ビタミンD欠乏	20[redacted]	88	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	続発性副甲状腺機能亢進症	20[redacted]	88	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	151	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	365	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	366	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	閉経後出血	20[redacted]	607	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮ポリープ	20[redacted]	648	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乳房の良性新生物	20[redacted]	56	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乳癌	20[redacted]	566	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	核性白内障	20[redacted]	120	352	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮脱	20[redacted]	423	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿失禁	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	67	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	カタル	20[redacted]	74	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	139	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	249	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	出血性膀胱炎	20[redacted]	261	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃十二指腸炎	20[redacted]	497	163	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	497	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻炎	20[redacted]	85	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	244	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	274	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性膵炎	20[redacted]	274	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮質異形成	20[redacted]	274	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	274	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	274	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	275	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎萎縮	20[redacted]	275	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	341	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	狭心症	20[redacted]	94	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	閉塞性気道障害	20[redacted]	95	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	24	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腸腺腫	20[redacted]	.	37	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腸菌性尿路感染	20[redacted]	125	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	痔核	20[redacted]	125	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	126	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	181	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	394	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺腫	20[redacted]	394	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻炎	20[redacted]	147	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心不全	20[redacted]	229	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高尿酸血症	20[redacted]	229	492	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	突然死	20[redacted]	720	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	269	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	糖尿病性代謝代償不全	20[redacted]	272	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	術後貧血	20[redacted]	273	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	洞性頻脈	20[redacted]	274	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	膀胱炎	20[redacted]	274	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	褥瘡性潰瘍	20[redacted]	283	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	糖尿病性代謝代償不全	20[redacted]	290	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	115	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	149	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂肪肝	20[redacted]	150	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	325	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	イレウス	20[redacted]	122	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	122	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	IV ANTIBIOTICS TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	胆石症	20[redacted]	122	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	動脈硬化症	20[redacted]	126	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	PLACEBO		7[redacted]	F	WHITE	便秘	20[redacted]	174	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	184	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	CZECH REPUBLIC	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腰部脊柱管狭窄症	20[redacted]	387	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	5	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	嘔吐	20[redacted]	126	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発疹	20[redacted]	241	138	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膝蓋骨骨折	20[redacted]	703	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	181	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乳癌	20[redacted]	448	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	過敏症	20[redacted]	8	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	16	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	結腸直腸癌	20[redacted]	93	261	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	DENMARK	PLACEBO		6[redacted]	F	WHITE	腎機能障害	20[redacted]	93	261	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆管嚢胞	20[redacted]	148	119	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	213	53	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]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	266	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	267	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性肺炎	20[redacted]	559	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性肺炎	20[redacted]	671	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	33	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	215	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	221	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	225	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	敗血症	20[redacted]	225	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	悪心	20[redacted]	229	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	314	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	336	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性膀胱炎	20[redacted]	403	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性膀胱炎	20[redacted]	408	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性膀胱炎	20[redacted]	417	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	33	645	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	152	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	176	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎機能障害	20[redacted]	184	494	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	203	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	.	395	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	283	395	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋攣縮	20[redacted]	366	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	錯感覚	20[redacted]	379	119	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動悸	20[redacted]	497	181	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	死亡	20[redacted]	677	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	324	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乳癌	20[redacted]	365	50	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢腫脹	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症候群	20[redacted]	485	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	528	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	仙骨骨折	20[redacted]	538	.	Y		NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	538	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	581	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	581	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	便秘	20[redacted]	9	180	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	筋肉疲労	20[redacted]	14	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	22	283	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	アスパラギン酸アミノトランスフェラーゼ増加	20[redacted]	36	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	ビタミンＢ群欠乏	20[redacted]	245	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	変形性関節症	20[redacted]	287	79	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	失神	20[redacted]	295	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	形質細胞性骨髄腫	20[redacted]	349	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	アミロイドーシス	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	全身性浮腫	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	胸水	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	胸痛	20[redacted]	484	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	27	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	377	129	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	506	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	615	270	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	処置による疼痛	20[redacted]	332	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	332	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	処置による疼痛	20[redacted]	415	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	415	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	水疱	20[redacted]	34	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	39	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足指手術	20[redacted]	156	79	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	単径部痛	20[redacted]	156	94	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	171	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	171	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	171	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	消化不良	20[redacted]	191	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	263	.	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]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	500	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉痛	20[redacted]	701	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼のアレルギー	20[redacted]	32	94	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	159	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高カリウム血症	20[redacted]	194	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心雑音	20[redacted]	195	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高カリウム血症	20[redacted]	217	448	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	329	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎機能障害	20[redacted]	733	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	78	617	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	225	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	植物アレルギー	20[redacted]	474	221	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	死亡	20[redacted]	694	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳垢栓塞	20[redacted]	13	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	51	69	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	落ち着きのなさ	20[redacted]	64	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	結腸癌	20[redacted]	460	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	460	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	460	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	交通事故	20[redacted]	146	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肋骨の変形	20[redacted]	146	66	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	結膜炎	20[redacted]	276	16	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]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	507	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	507	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	中足骨痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	36	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	234	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	249	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	299	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気胸	20[redacted]	317	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	126	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	126	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	242	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	食道癌	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	記憶障害	20[redacted]	166	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	高血圧	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	限局性感染	20[redacted]	19	131	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	乳頭パジェット病	20[redacted]	49	101	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うつ病	20[redacted]	27	43	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うつ病	20[redacted]	395	21	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]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うつ病	20[redacted]	416	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の障害	20[redacted]	.	45	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	571	251	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心雑音	20[redacted]	734	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	.	353	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	263	207	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	263	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	くも膜下出血	20[redacted]	489	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	608	81	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	626	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	61	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	61	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯周炎	20[redacted]	134	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	286	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	526	230	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	689	53	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	171	183	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	354	391	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ヘモグロビン減少	20[redacted]	519	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿疹	20[redacted]	190	26	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	343	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	408	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	7	89	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉痛	20[redacted]	327	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	593	168	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	蜂巣炎	20[redacted]	714	43	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	丹毒	20[redacted]	513	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈瘤	20[redacted]	558	174	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	704	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胸水	20[redacted]	704	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	745	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯感染	20[redacted]	56	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	十二指腸炎	20[redacted]	101	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯周炎	20[redacted]	306	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈狭窄	20[redacted]	480	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	痔核	20[redacted]	481	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	足変形	20[redacted]	177	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	246	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	246	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鎖骨骨折	20[redacted]	246	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	健忘	20[redacted]	148	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	神経過敏	20[redacted]	148	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	214	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	239	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	357	1	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]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	317	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	348	137	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯牙破折	20[redacted]	116	112	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肉離れ	20[redacted]	253	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	271	420	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	汎血球減少症	20[redacted]	661	36	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿疹	20[redacted]	704	277	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	脳血管発作	20[redacted]	95	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	124	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	再生不良性貧血	20[redacted]	360	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳感染	20[redacted]	112	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	454	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼瞼下垂	20[redacted]	455	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	466	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	手首関節骨折	20[redacted]	466	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	466	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	466	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	15	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	113	16	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]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚良性新生物	20[redacted]	168	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膿瘍	20[redacted]	237	38	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	処置による疼痛	20[redacted]	238	55	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	345	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺障害	20[redacted]	512	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺感染	20[redacted]	719	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	3	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	直腸癌	20[redacted]	57	19	Y	Grade 1	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	DENMARK	PLACEBO		7[redacted]	F	WHITE	処置による疼痛	20[redacted]	78	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ビタミンＢ群欠乏	20[redacted]	194	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化管ストーマ合併症	20[redacted]	332	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	333	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脱水	20[redacted]	334	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	233	42	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	363	47	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房粗動	20[redacted]	482	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	29	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	外陰腟真菌感染	20[redacted]	120	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	128	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	外陰腟真菌感染	20[redacted]	192	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	235	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	401	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乳癌	20[redacted]	467	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後創感染	20[redacted]	508	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	外陰腟真菌感染	20[redacted]	533	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	200	263	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	209	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	292	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃潰瘍	20[redacted]	300	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	356	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	681	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	47	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	84	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	172	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	新生血管加齢黄斑変性	20[redacted]	175	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発疹	20[redacted]	207	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	消化不良	20[redacted]	228	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	眼感染	20[redacted]	482	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	眼感染	20[redacted]	489	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯痛	20[redacted]	617	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	創傷	20[redacted]	605	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	恥骨骨折	20[redacted]	605	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	創傷	20[redacted]	610	51	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	2	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	34	329	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	落ち着きのなさ	20[redacted]	34	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	34	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	92	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	局所腫脹	20[redacted]	154	5	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	165	82	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	爪破損	20[redacted]	178	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	188	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	244	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ヘルペスウイルス感染	20[redacted]	280	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	直腸炎	20[redacted]	308	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	355	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板突出	20[redacted]	362	229	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	錯感覚	20[redacted]	573	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	70	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿疹	20[redacted]	70	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	抜歯	20[redacted]	117	127	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯周炎	20[redacted]	117	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	197	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿疹	20[redacted]	513	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯内療法	20[redacted]	534	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯感染	20[redacted]	534	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足骨折	20[redacted]	593	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	645	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈瘤	20[redacted]	83	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	220	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節腫脹	20[redacted]	220	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肉離れ	20[redacted]	266	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	338	199	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	483	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	483	54	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	インフルエンザ様疾患	20[redacted]	1	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	関節痛	20[redacted]	31	174	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	REMOVED FROM STUDY	
[redacted]	DENMARK	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	背部痛	20[redacted]	50	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	リンパ節症	20[redacted]	90	55	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	上腹部痛	20[redacted]	116	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	DENMARK	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	女性乳癌	20[redacted]	144	4	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	16	423	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	118	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	510	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺塞栓症	20[redacted]	533	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	560	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	38	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	.	168	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯感染	20[redacted]	109	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	198	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	216	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性膀胱炎	20[redacted]	249	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	メラノサイト性母斑	20[redacted]	254	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮平滑筋腫	20[redacted]	264	116	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性膀胱炎	20[redacted]	270	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	273	8	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿管炎	20[redacted]	379	92	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性胃腸炎	20[redacted]	444	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎仙痛	20[redacted]	693	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	DENMARK	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頻尿	20[redacted]	693	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	疲労	20[redacted]	71	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	疲労	20[redacted]	99	36	N	Grade 1	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	186	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	284	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆石症	20[redacted]	332	258	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	100	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足底筋膜炎	20[redacted]	223	154	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱瘤	20[redacted]	254	121	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	急性胆嚢炎	20[redacted]	375	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	6	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱炎	20[redacted]	72	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	137	154	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	229	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	320	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	349	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	356	70	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹痛	20[redacted]	365	79	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	441	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	遠隔転移を伴う肺腺癌	20[redacted]	151	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾癬性関節症	20[redacted]	66	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脂質異常症	20[redacted]	66	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	66	59	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	361	94	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	396	180	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	睡眠障害	20[redacted]	700	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	錯感覚	20[redacted]	1	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	頻尿	20[redacted]	2	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	錯感覚	20[redacted]	31	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	頻尿	20[redacted]	32	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	35	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	頻尿	20[redacted]	60	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	140	14	Y	Grade 2	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胃炎	20[redacted]	247	240	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	甲状腺腫	20[redacted]	428	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	480	55	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	535	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	膀胱炎	20[redacted]	580	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	ウイルス性消化管感染	20[redacted]	714	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	倦怠感	20[redacted]	14	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨痛	20[redacted]	77	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨痛	20[redacted]	96	3	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎結石症	20[redacted]	106	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢腫脹	20[redacted]	161	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	そう痒症	20[redacted]	171	69	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	186	44	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	軟部組織の良性新生物	20[redacted]	241	318	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	倦怠感	20[redacted]	306	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨痛	20[redacted]	306	21	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	倦怠感	20[redacted]	340	8	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋力低下	20[redacted]	473	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安障害	20[redacted]	576	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	604	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	6	400	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚潰瘍	20[redacted]	50	345	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気道感染	20[redacted]	185	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	191	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	振戦	20[redacted]	340	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	394	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うっ血性心不全	20[redacted]	405	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	406	224	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	611	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	回転性めまい	20[redacted]	156	134	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	157	182	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	330	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	371	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性気管支炎	20[redacted]	2	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	9	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	黄斑変性	20[redacted]	159	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	174	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	297	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	454	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	544	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	125	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	130	559	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	318	49	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]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	318	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膝蓋骨骨折	20[redacted]	308	.	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	308	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	17	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	節足動物刺傷アレルギー	20[redacted]	18	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	23	85	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後癒着	20[redacted]	58	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	74	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	74	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後癒着	20[redacted]	128	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃腸炎	20[redacted]	161	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	イレウス	20[redacted]	252	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発熱	20[redacted]	348	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	394	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	539	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	98	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹部癒着	20[redacted]	98	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格痛	20[redacted]	127	204	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	創傷	20[redacted]	212	212	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	212	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	イレウス	20[redacted]	261	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	憩室	20[redacted]	319	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹痛	20[redacted]	362	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上気道感染	20[redacted]	441	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹痛	20[redacted]	533	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	出血性貧血	20[redacted]	66	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	66	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	びらん性胃炎	20[redacted]	75	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋虚血	20[redacted]	97	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外傷性気胸	20[redacted]	557	26	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	557	.	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	557	.	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋骨骨折	20[redacted]	557	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋骨骨折	20[redacted]	557	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鎖骨骨折	20[redacted]	557	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	顔面骨骨折	20[redacted]	557	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の脱落	20[redacted]	631	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	151	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性膵炎	20[redacted]	465	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	532	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	211	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	出血性胃腸管血管異形成	20[redacted]	273	80	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	273	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	315	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃腸管血管異形成	20[redacted]	330	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	TRANSFUSION PERFORMED	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	混合性大動脈弁疾患	20[redacted]	566	109	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	混合性大動脈弁疾患	20[redacted]	566	109	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	混合性大動脈弁疾患	20[redacted]	566	109	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃潰瘍	20[redacted]	93	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃腺癌	20[redacted]	93	153	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ESTONIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大腿骨骨折	20[redacted]	695	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	15	24	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	16	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	173	55	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歩行障害	20[redacted]	173	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	.	99	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膝蓋骨骨折	20[redacted]	310	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	深部静脈血栓症	20[redacted]	471	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	挫傷	20[redacted]	44	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	44	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚潰瘍	20[redacted]	261	474	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	MULTIPLE	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤性潰瘍	20[redacted]	381	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	感染性皮膚潰瘍	20[redacted]	431	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO		6[redacted]	F	WHITE	女性乳癌	20[redacted]	86	.	Y	Grade 4	RELATED	NOT RESOLVED	DRUG WITHDRAWN	NO ACTION TAKEN	N

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[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	瘢痕切除	20[redacted]	16	1	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	17	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	放屁	20[redacted]	232	74	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脱毛症	20[redacted]	314	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発疹	20[redacted]	379	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発疹	20[redacted]	379	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靱帯捻挫	20[redacted]	545	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	726	119	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ほてり	20[redacted]	29	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ほてり	20[redacted]	56	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮摘出	20[redacted]	111	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	靱帯捻挫	20[redacted]	127	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体重増加	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肛門脱	20[redacted]	.	220	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	GERMANY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	直腸瘤	20[redacted]	399	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸炎	20[redacted]	288	67	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	憩室炎	20[redacted]	464	14	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈弁狭窄	20[redacted]	477	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性気管支炎	20[redacted]	477	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚擦過傷	20[redacted]	714	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	医療機器機能不良	20[redacted]	386	9	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]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	595	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	595	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	出血性十二指腸潰瘍	20[redacted]	601	143	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	55	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	306	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	点状出血	20[redacted]	373	225	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	多臓器不全	20[redacted]	590	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	GERMANY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	後腹膜血腫	20[redacted]	595	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	56	83	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	口腔咽頭痛	20[redacted]	59	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	喀血	20[redacted]	68	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上顎炎	20[redacted]	113	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	148	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	195	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	295	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腱炎	20[redacted]	332	179	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	喀血	20[redacted]	358	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	皮膚擦過傷	20[redacted]	369	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血圧	20[redacted]	509	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	680	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	699	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	7	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	82	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	168	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	206	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	238	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	253	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	355	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	462	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	462	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	628	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	628	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	645	91	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	咳嗽	20[redacted]	682	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	肺炎	20[redacted]	682	161	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	体重減少	20[redacted]	713	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	食欲減退	20[redacted]	713	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	筋骨格系胸痛	20[redacted]	46	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	冠動脈疾患	20[redacted]	62	15	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高血圧	20[redacted]	70	599	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高脂血症	20[redacted]	76	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	139	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	154	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	気管支炎	20[redacted]	176	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	287	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	338	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	足骨折	20[redacted]	348	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	転倒	20[redacted]	348	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	創傷	20[redacted]	376	49	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	448	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	517	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	浮動性めまい	20[redacted]	662	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	頭痛	20[redacted]	662	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	意識消失	20[redacted]	667	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高血圧	20[redacted]	669	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	1	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	骨痛	20[redacted]	28	71	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	帯状疱疹	20[redacted]	45	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頚部痛	20[redacted]	59	640	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	ヘルペス後神経痛	20[redacted]	61	403	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	発疹	20[redacted]	112	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	190	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	221	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腹部膨満	20[redacted]	246	141	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	大腸ポリープ	20[redacted]	255	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	大腸ポリープ	20[redacted]	255	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	324	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	変形性脊椎症	20[redacted]	334	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腸憩室	20[redacted]	356	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	体重減少	20[redacted]	367	347	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	血尿	20[redacted]	385	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃食道逆流性疾患	20[redacted]	586	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	2	3	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	4	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	4	6	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	8	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	85	112	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	96	11	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	足底筋膜炎	20[redacted]	115	508	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	147	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頚髄症	20[redacted]	176	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯膿瘍	20[redacted]	177	520	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	207	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯肉炎	20[redacted]	272	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	気管支反応性亢進	20[redacted]	336	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃腸炎	20[redacted]	457	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	橈骨骨折	20[redacted]	488	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	488	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	488	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	615	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	扁桃炎	20[redacted]	711	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	咳嗽	20[redacted]	54	8	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]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	子宮頚部上皮異形成	20[redacted]	82	414	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭痛	20[redacted]	447	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	卵巣嚢胞	20[redacted]	495	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	歯痛	20[redacted]	659	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	足底筋膜炎	20[redacted]	721	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	記憶障害	20[redacted]	266	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	浮動性めまい	20[redacted]	363	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	浮動性めまい	20[redacted]	373	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	浮動性めまい	20[redacted]	373	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	虚血	20[redacted]	374	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	頭痛	20[redacted]	374	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	霧視	20[redacted]	376	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	浮動性めまい	20[redacted]	378	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	41	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	骨痛	20[redacted]	71	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻漏	20[redacted]	79	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	98	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	116	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	159	125	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	197	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	血腫	20[redacted]	241	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	241	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頭部損傷	20[redacted]	241	10	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	くも膜下出血	20[redacted]	242	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脳血管障害	20[redacted]	242	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脳血腫	20[redacted]	242	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	低カリウム血症	20[redacted]	243	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	下気道感染	20[redacted]	244	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高脂血症	20[redacted]	305	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	321	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	508	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋痙縮	20[redacted]	587	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	便秘	20[redacted]	19	474	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	35	113	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	150	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	189	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	糖尿病	20[redacted]	260	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	349	190	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腰部脊柱管狭窄症	20[redacted]	552	137	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	変形性脊椎症	20[redacted]	687	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脊椎すべり症	20[redacted]	687	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	体重減少	20[redacted]	688	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋力低下	20[redacted]	688	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	便秘	20[redacted]	689	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿閉	20[redacted]	690	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胆石症	20[redacted]	703	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アミラーゼ増加	20[redacted]	705	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血圧	20[redacted]	739	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	18	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	メニエール病	20[redacted]	103	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	口腔咽頭痛	20[redacted]	241	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	弾発指	20[redacted]	285	119	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	挫傷	20[redacted]	350	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	350	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	484	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	664	60	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	729	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	注射部位内出血	20[redacted]	1	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	35	152	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上腹部痛	20[redacted]	83	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	97	182	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	蕁麻疹	20[redacted]	192	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	蕁麻疹	20[redacted]	226	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	靭帯捻挫	20[redacted]	286	68	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	337	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アレルギー性皮膚炎	20[redacted]	400	107	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尺骨骨折	20[redacted]	649	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	橈骨骨折	20[redacted]	649	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	649	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	670	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	125	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	浮動性めまい	20[redacted]	128	101	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	148	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	323	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	350	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	373	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節周囲炎	20[redacted]	395	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	咳嗽	20[redacted]	449	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	インフルエンザ	20[redacted]	523	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	喘息	20[redacted]	523	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋痙縮	20[redacted]	546	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	歯牙破折	20[redacted]	614	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	橈骨骨折	20[redacted]	9	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	9	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	25	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	神経根障害	20[redacted]	158	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	328	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	384	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	431	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	656	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]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋骨格系胸痛	20[redacted]	661	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	682	35	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	682	35	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	うつ病	20[redacted]	686	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	急性ストレス反応	20[redacted]	686	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	四肢痛	20[redacted]	48	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	125	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	発疹	20[redacted]	608	33	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	低血圧	20[redacted]	609	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	609	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭部損傷	20[redacted]	609	5	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	34	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	下痢	20[redacted]	39	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	113	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	下痢	20[redacted]	216	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	239	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	252	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	肺炎	20[redacted]	264	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	327	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	創傷感染	20[redacted]	449	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	挫傷	20[redacted]	704	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	704	1	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]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	126	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	142	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	膀胱炎	20[redacted]	153	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	空腹時血中ブドウ糖不良	20[redacted]	170	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	174	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	下痢	20[redacted]	327	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	浮動性めまい	20[redacted]	617	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	21	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	91	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	体重減少	20[redacted]	195	268	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	敗血症	20[redacted]	195	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胆石症	20[redacted]	195	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	膵炎	20[redacted]	195	23	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	急性呼吸窮迫症候群	20[redacted]	197	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腎嚢胞	20[redacted]	295	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	膵嚢胞	20[redacted]	295	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	14	100	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	48	66	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	257	93	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯肉炎	20[redacted]	301	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アフタ性潰瘍	20[redacted]	324	138	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	蜂巣炎	20[redacted]	454	11	Y	Grade 2	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]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	154	309	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	155	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	消化不良	20[redacted]	174	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	202	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	呼吸困難	20[redacted]	327	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	左室肥大	20[redacted]	327	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	心拡大	20[redacted]	327	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	末梢性浮腫	20[redacted]	327	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	浮動性めまい	20[redacted]	327	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭痛	20[redacted]	327	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	327	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	327	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	327	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭部不快感	20[redacted]	333	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	463	146	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胸部不快感	20[redacted]	485	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	メニエール病	20[redacted]	698	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋肉痛	20[redacted]	115	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	148	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	口腔ヘルペス	20[redacted]	151	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	226	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	側腹部痛	20[redacted]	237	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	齲歯	20[redacted]	287	73	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	背部痛	20[redacted]	441	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	浮動性めまい	20[redacted]	473	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脳血管発作	20[redacted]	532	16	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋骨格痛	20[redacted]	622	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	622	92	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	体重減少	20[redacted]	714	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	食欲減退	20[redacted]	714	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	3	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腱炎	20[redacted]	33	37	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	うっ血性心不全	20[redacted]	34	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	心拡大	20[redacted]	41	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃潰瘍	20[redacted]	41	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	Ｂ型肝炎	20[redacted]	41	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	114	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	手根管症候群	20[redacted]	173	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	205	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	205	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	動悸	20[redacted]	239	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性脊椎症	20[redacted]	309	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	心筋虚血	20[redacted]	309	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上室性頻脈	20[redacted]	328	286	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	アレルギー性皮膚炎	20[redacted]	369	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上室性期外収縮	20[redacted]	376	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	消化不良	20[redacted]	376	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	493	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	613	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尺骨骨折	20[redacted]	26	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	橈骨骨折	20[redacted]	26	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	26	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頭痛	20[redacted]	35	3	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	92	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頭痛	20[redacted]	305	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	457	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	関節痛	20[redacted]	4	268	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	上気道感染	20[redacted]	87	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	上気道感染	20[redacted]	203	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	齲歯	20[redacted]	269	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	出血性関節症	20[redacted]	374	89	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	上気道感染	20[redacted]	50	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	上気道感染	20[redacted]	63	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	上気道感染	20[redacted]	84	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	振戦	20[redacted]	100	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	心拡大	20[redacted]	210	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	大脳萎縮	20[redacted]	212	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	27	15	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]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	27	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	変形性関節症	20[redacted]	62	45	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腹痛	20[redacted]	129	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腹部膨満	20[redacted]	129	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	256	100	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	323	68	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	336	55	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腹痛	20[redacted]	336	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上腹部痛	20[redacted]	380	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	びらん性胃炎	20[redacted]	404	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	大腸ポリープ	20[redacted]	404	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胆石症	20[redacted]	404	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脂肪肝	20[redacted]	404	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	664	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	冠動脈疾患	20[redacted]	22	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	52	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	硬便	20[redacted]	53	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭痛	20[redacted]	53	163	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頚部痛	20[redacted]	98	182	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	耳鳴	20[redacted]	174	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭痛	20[redacted]	249	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	歯牙破折	20[redacted]	292	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	296	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	296	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	310	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	悪心	20[redacted]	329	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	358	92	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胸痛	20[redacted]	398	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上腹部痛	20[redacted]	405	59	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胸部Ｘ線異常	20[redacted]	426	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	442	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	442	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頚部痛	20[redacted]	449	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋骨格痛	20[redacted]	453	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	453	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	尿管拡張	20[redacted]	503	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胸痛	20[redacted]	532	144	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋骨格系胸痛	20[redacted]	659	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	659	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	背部痛	20[redacted]	70	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	胃腸炎	20[redacted]	72	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	脊椎すべり症	20[redacted]	72	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	117	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	注射部位疼痛	20[redacted]	122	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	関節損傷	20[redacted]	267	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	298	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	453	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	末梢性浮腫	20[redacted]	11	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	筋肉痛	20[redacted]	23	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	口内乾燥	20[redacted]	24	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	眼乾燥	20[redacted]	24	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	眼乾燥	20[redacted]	67	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	上気道感染	20[redacted]	89	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	心筋虚血	20[redacted]	174	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO		7[redacted]	F	ASIAN	末梢性浮腫	20[redacted]	174	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	末梢性浮腫	20[redacted]	254	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	261	47	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	貧血	20[redacted]	278	71	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腱炎	20[redacted]	346	161	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	650	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	喀血	20[redacted]	14	96	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	気管支拡張症	20[redacted]	14	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	マイコバクテリア感染	20[redacted]	15	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頭痛	20[redacted]	141	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	無気肺	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	肝嚢胞	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胸膜障害	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	閉塞性気道障害	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	276	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	靭帯捻挫	20[redacted]	704	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咽頭炎	20[redacted]	726	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	39	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節損傷	20[redacted]	39	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	動悸	20[redacted]	163	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	不整脈	20[redacted]	181	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	骨痛	20[redacted]	227	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	湿疹	20[redacted]	355	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	394	58	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	464	47	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節周囲炎	20[redacted]	689	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	糖尿病	20[redacted]	50	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	鉄欠乏性貧血	20[redacted]	93	137	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	左脚ブロック	20[redacted]	98	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	胃十二指腸潰瘍	20[redacted]	100	56	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	23	255	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	上気道感染	20[redacted]	85	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	上気道感染	20[redacted]	147	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	帯状疱疹	20[redacted]	203	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	ヘルペス後神経痛	20[redacted]	216	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO		6[redacted]	F	ASIAN	心筋梗塞	20[redacted]	277	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	下痢	20[redacted]	12	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	帯状疱疹	20[redacted]	15	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	咳嗽	20[redacted]	53	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	齲歯	20[redacted]	97	22	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	142	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	靭帯捻挫	20[redacted]	202	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	209	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	224	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋力低下	20[redacted]	259	358	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	285	182	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	歯肉炎	20[redacted]	323	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	346	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腹部膨満	20[redacted]	517	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	注射部位疼痛	20[redacted]	34	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	62	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	霧視	20[redacted]	175	154	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	回転性めまい	20[redacted]	324	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	背部痛	20[redacted]	25	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	関節痛	20[redacted]	70	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	ウイルス性胃腸炎	20[redacted]	124	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	便秘	20[redacted]	130	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	変形性関節症	20[redacted]	156	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	四肢痛	20[redacted]	223	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	筋力低下	20[redacted]	223	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	四肢痛	20[redacted]	358	351	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上腹部痛	20[redacted]	360	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	470	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	転倒	20[redacted]	636	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	関節腫脹	20[redacted]	636	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	鉄欠乏性貧血	20[redacted]	731	168	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	尿失禁	20[redacted]	28	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	結膜炎	20[redacted]	88	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	344	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	495	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	肺炎	20[redacted]	603	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	譫妄	20[redacted]	604	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	変形性関節症	20[redacted]	32	137	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	ウイルス性気道感染	20[redacted]	72	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	ウイルス性気道感染	20[redacted]	117	52	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	挫傷	20[redacted]	144	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	転倒	20[redacted]	144	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	好酸球数増加	20[redacted]	190	532	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	歯肉炎	20[redacted]	199	60	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	ウイルス性気道感染	20[redacted]	484	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	敗血症	20[redacted]	491	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	細菌性尿路感染	20[redacted]	491	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	尿路感染	20[redacted]	509	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	血中尿素増加	20[redacted]	551	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	653	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	足骨折	20[redacted]	694	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯肉炎	20[redacted]	43	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋骨格痛	20[redacted]	105	183	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	メニエール病	20[redacted]	163	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	便秘	20[redacted]	183	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	204	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	痔核	20[redacted]	212	76	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	267	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	低ナトリウム血症	20[redacted]	277	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	317	129	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢損傷	20[redacted]	417	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	446	73	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HONG KONG	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿閉	20[redacted]	459	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	くも膜下出血	20[redacted]	120	27	Y	Grade 1	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	くも膜下出血	20[redacted]	320	42	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	33	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	68	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ボーエン病	20[redacted]	318	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	297	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	痔出血	20[redacted]	427	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尺骨骨折	20[redacted]	622	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	622	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃潰瘍	20[redacted]	385	4	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	703	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	25	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	25	.	N	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	糖尿病	20[redacted]	111	15	Y	Grade 4	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	354	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	狭心症	20[redacted]	323	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺機能亢進症	20[redacted]	332	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨盤静脈血栓症	20[redacted]	562	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	環状肉芽腫	20[redacted]	.	80	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性骨髄炎	20[redacted]	38	98	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脛骨骨折	20[redacted]	69	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安	20[redacted]	132	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性骨髄炎	20[redacted]	132	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性副鼻腔炎	20[redacted]	502	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	585	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	47	64	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	32	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	32	416	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	183	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	創傷	20[redacted]	477	9	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膝関節形成	20[redacted]	561	22	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	130	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頚動脈狭窄	20[redacted]	357	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱移行上皮癌	20[redacted]	427	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	SURGICAL INTERVENTION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	8	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	36	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	527	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	脂肪腫	20[redacted]	120	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	腎腺腫	20[redacted]	186	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胸膜炎	20[redacted]	198	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	偶発的過量投与	20[redacted]	456	1	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	HUNGARY	PLACEBO		7[redacted]	F	WHITE	脳血管発作	20[redacted]	172	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	PLACEBO		7[redacted]	F	WHITE	高血圧	20[redacted]	172	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	浸潤性乳管癌	20[redacted]	47	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃出血	20[redacted]	730	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	びらん性胃炎	20[redacted]	733	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	733	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	733	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	側弯症	20[redacted]	734	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆嚢コレステリン沈着症	20[redacted]	734	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	214	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リハビリテーション療法	20[redacted]	236	22	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	373	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	524	270	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リハビリテーション療法	20[redacted]	571	20	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	635	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	684	145	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	729	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈弁疾患	20[redacted]	167	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	声帯障害	20[redacted]	286	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安	20[redacted]	293	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	293	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	293	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺腫	20[redacted]	293	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	293	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アレルギー性結膜炎	20[redacted]	269	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	270	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	冠動脈狭窄	20[redacted]	301	35	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乳癌	20[redacted]	511	58	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心筋虚血	20[redacted]	564	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	糖尿病	20[redacted]	564	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋骨骨折	20[redacted]	670	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳振盪後症候群	20[redacted]	678	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	43	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	48	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	51	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	107	71	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	107	71	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	178	35	N	Grade 3	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	側弯症	20[redacted]	186	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	186	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	186	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脊椎すべり症	20[redacted]	186	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脊椎骨折	20[redacted]	186	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脳虚血	20[redacted]	223	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	痔核	20[redacted]	261	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腸憩室	20[redacted]	261	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	蜂巣炎	20[redacted]	329	88	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不安	20[redacted]	338	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	343	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	びらん性胃炎	20[redacted]	700	169	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	700	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食道炎	20[redacted]	700	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	パーキンソン病	20[redacted]	711	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃酸過多	20[redacted]	16	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節周囲炎	20[redacted]	476	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板変性症	20[redacted]	587	36	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節損傷	20[redacted]	666	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	708	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	427	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	イレウス	20[redacted]	428	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	226	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	単径ヘルニア	20[redacted]	260	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	単径ヘルニア	20[redacted]	365	90	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上室性期外収縮	20[redacted]	721	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	721	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	721	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	720	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻出血	20[redacted]	201	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性胆嚢炎	20[redacted]	482	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	555	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱炎	20[redacted]	76	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肉離れ	20[redacted]	156	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血栓性静脈炎	20[redacted]	283	27	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯牙破折	20[redacted]	348	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	結膜炎	20[redacted]	364	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	表在性血栓性静脈炎	20[redacted]	408	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺塞栓症	20[redacted]	411	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	HUNGARY	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	511	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	92	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	創傷	20[redacted]	171	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	204	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	創傷	20[redacted]	235	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	灼熱感	20[redacted]	236	140	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	301	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	発熱	20[redacted]	302	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	灼熱感	20[redacted]	442	151	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	442	151	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脱水	20[redacted]	572	11	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	死亡	20[redacted]	592	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	下痢	20[redacted]	88	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	下痢	20[redacted]	97	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	咳嗽	20[redacted]	120	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	糖尿病性ケトアシドーシス	20[redacted]	248	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	心肺停止	20[redacted]	249	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	咳嗽	20[redacted]	119	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	うっ血性心不全	20[redacted]	152	8	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	INDIA	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	心停止	20[redacted]	15	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	咳嗽	20[redacted]	239	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	発熱	20[redacted]	239	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血糖	20[redacted]	370	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	急性心筋梗塞	20[redacted]	464	6	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	流涙増加	20[redacted]	94	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血圧	20[redacted]	97	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	ウイルス性上気道感染	20[redacted]	302	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	コントロール不良の糖尿病	20[redacted]	554	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	577	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿路感染	20[redacted]	720	20	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	発熱	20[redacted]	748	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	コントロール不良の糖尿病	20[redacted]	271	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	コントロール不良の糖尿病	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	蜂巣炎	20[redacted]	407	49	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	31	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	免疫性血小板減少性紫斑病	20[redacted]	33	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	葉酸欠乏性貧血	20[redacted]	190	88	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腸閉塞	20[redacted]	630	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	低カリウム血症	20[redacted]	632	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高ビリルビン血症	20[redacted]	632	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	食欲減退	20[redacted]	650	246	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	排尿困難	20[redacted]	668	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	便秘	20[redacted]	57	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	細菌性尿路感染	20[redacted]	165	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	浮動性めまい	20[redacted]	327	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	大腸菌性尿路感染	20[redacted]	542	7	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿路感染	20[redacted]	602	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	119	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	リンパ節炎	20[redacted]	183	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	発熱	20[redacted]	184	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	貧血	20[redacted]	188	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	神経痛	20[redacted]	236	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	線維筋痛	20[redacted]	266	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	難聴	20[redacted]	266	83	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	上気道感染	20[redacted]	494	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	蕁麻疹	20[redacted]	619	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	蕁麻疹	20[redacted]	665	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	本態性高血圧症	20[redacted]	64	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血圧	20[redacted]	127	58	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	疼痛	20[redacted]	153	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	足部白癬	20[redacted]	326	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	末梢性浮腫	20[redacted]	349	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	白内障	20[redacted]	543	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	落屑緑内障	20[redacted]	543	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	658	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	697	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	糖尿病	20[redacted]	100	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃腸炎	20[redacted]	180	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	細菌性尿路感染	20[redacted]	246	74	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	糖尿病	20[redacted]	370	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	眼痛	20[redacted]	508	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	173	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃炎	20[redacted]	174	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	313	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃炎	20[redacted]	367	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	心房細動	20[redacted]	528	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	気管支炎	20[redacted]	584	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃炎	20[redacted]	616	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃炎	20[redacted]	637	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	全身性そう痒症	20[redacted]	83	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頭部損傷	20[redacted]	83	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頭痛	20[redacted]	89	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃腸炎	20[redacted]	241	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血糖	20[redacted]	298	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	下痢	20[redacted]	374	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯周炎	20[redacted]	435	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	直腸出血	20[redacted]	622	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯の脱落	20[redacted]	725	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	基底細胞癌	20[redacted]	9	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	脂質異常症	20[redacted]	128	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	失神	20[redacted]	190	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	蜂巣炎	20[redacted]	317	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	583	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	口腔内潰瘍形成	20[redacted]	29	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋肉痛	20[redacted]	60	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	貧血	20[redacted]	156	.	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]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯周炎	20[redacted]	319	24	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	330	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋肉痛	20[redacted]	350	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	397	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢膿瘍	20[redacted]	446	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アフタ性潰瘍	20[redacted]	538	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	骨粗鬆症	20[redacted]	590	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯痛	20[redacted]	621	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	腫脹	20[redacted]	653	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胃炎	20[redacted]	679	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	INDIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脂質異常症	20[redacted]	726	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	下痢	20[redacted]	15	110	N	Grade 3	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高尿酸血症	20[redacted]	64	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	発熱	20[redacted]	119	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	意識レベルの低下	20[redacted]	263	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿路感染	20[redacted]	422	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NON-IV ANTIMICROBIAL TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿路感染	20[redacted]	442	19	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	619	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	肺炎	20[redacted]	694	39	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	湿疹	20[redacted]	703	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	緑内障	20[redacted]	717	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脂質異常症	20[redacted]	717	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	インフルエンザ	20[redacted]	26	39	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	282	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	364	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	肛門癌	20[redacted]	139	86	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	放射線皮膚損傷	20[redacted]	174	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	31	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高血圧	20[redacted]	91	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	アレルギー性皮膚炎	20[redacted]	336	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	虚血性大腸炎	20[redacted]	456	29	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	湿疹	20[redacted]	486	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高血圧	20[redacted]	547	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	動悸	20[redacted]	1	74	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	味覚異常	20[redacted]	10	61	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	脳梗塞	20[redacted]	85	49	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MEDICATION TAKEN	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	54	25	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	処置による疼痛	20[redacted]	78	110	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	不眠症	20[redacted]	81	107	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	全身性そう痒症	20[redacted]	138	333	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	体重増加	20[redacted]	184	364	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	218	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	418	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	418	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭痛	20[redacted]	506	56	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	不眠症	20[redacted]	519	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	耳痛	20[redacted]	569	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	582	345	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	湿疹	20[redacted]	645	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頚部痛	20[redacted]	699	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	細菌性上気道感染	20[redacted]	711	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	肉離れ	20[redacted]	27	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	手骨折	20[redacted]	70	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胆嚢ポリープ	20[redacted]	179	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	391	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	緑内障	20[redacted]	391	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	400	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	705	57	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	8	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腓骨骨折	20[redacted]	286	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節周囲炎	20[redacted]	450	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮膚細菌感染	20[redacted]	117	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	129	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	細菌性上気道感染	20[redacted]	229	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	低色素性貧血	20[redacted]	274	453	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	結腸癌	20[redacted]	436	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	結腸癌	20[redacted]	436	124	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	アレルギー性鼻炎	20[redacted]	542	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	インフルエンザ	20[redacted]	592	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	597	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	617	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	706	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	膀胱癌	20[redacted]	541	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	肝嚢胞	20[redacted]	576	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	造影剤アレルギー	20[redacted]	590	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	顔面浮腫	20[redacted]	128	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	急性膵炎	20[redacted]	412	346	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	胆石症	20[redacted]	412	61	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	薬疹	20[redacted]	467	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	卵巣良性腫瘍	20[redacted]	573	119	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	瘢痕ヘルニア	20[redacted]	573	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	172	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	うっ血性心筋症	20[redacted]	297	22	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	胃炎	20[redacted]	311	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	17	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		8[redacted]	F	ASIAN	歯周炎	20[redacted]	62	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO		8[redacted]	F	ASIAN	坐骨神経痛	20[redacted]	77	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		8[redacted]	F	ASIAN	胃腸炎	20[redacted]	111	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		8[redacted]	F	ASIAN	ピロリン酸カルシウム結晶性軟骨石灰化症	20[redacted]	122	60	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO		8[redacted]	F	ASIAN	便秘	20[redacted]	150	.	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]	JAPAN	PLACEBO		8[redacted]	F	ASIAN	肺の悪性新生物	20[redacted]	160	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	REMOVED FROM STUDY	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	湿疹	20[redacted]	117	124	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	脊柱管狭窄症	20[redacted]	610	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	666	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	喀血	20[redacted]	707	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	喀血	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	結膜炎	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	255	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血圧	20[redacted]	261	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	神経症	20[redacted]	273	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	四肢痛	20[redacted]	373	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	373	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	不随意性筋収縮	20[redacted]	633	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	運動機能障害	20[redacted]	704	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯周病	20[redacted]	81	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	気管支炎	20[redacted]	489	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	膀胱炎	20[redacted]	515	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	直腸ポリープ	20[redacted]	636	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	変形性関節症	20[redacted]	677	212	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	白内障	20[redacted]	7	148	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	便秘	20[redacted]	67	99	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脂肪肝	20[redacted]	87	285	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脂肪肝	20[redacted]	280	92	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	便秘	20[redacted]	326	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	539	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	突発性難聴	20[redacted]	664	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	耳鳴	20[redacted]	664	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	変形性脊椎症	20[redacted]	80	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	胆嚢癌	20[redacted]	90	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	肝転移	20[redacted]	97	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	熱傷	20[redacted]	63	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腎結石症	20[redacted]	77	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮脂欠乏性湿疹	20[redacted]	245	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	262	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	307	482	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	314	80	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	深部静脈血栓症	20[redacted]	321	114	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	口内炎	20[redacted]	351	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮脂欠乏性湿疹	20[redacted]	351	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	肥満	20[redacted]	357	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	湿疹	20[redacted]	367	324	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	慢性色素性紫斑	20[redacted]	462	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮脂欠乏性湿疹	20[redacted]	565	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋骨格硬直	20[redacted]	567	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	肋骨骨折	20[redacted]	578	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃潰瘍	20[redacted]	594	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮脂欠乏性湿疹	20[redacted]	663	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋筋膜炎	20[redacted]	676	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋痙縮	20[redacted]	34	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	心房細動	20[redacted]	294	189	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	冠動脈狭窄	20[redacted]	402	211	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	末梢性浮腫	20[redacted]	446	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋痙縮	20[redacted]	498	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	プリンツメタル狭心症	20[redacted]	581	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	静脈瘤	20[redacted]	.	247	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	蜂巣炎	20[redacted]	681	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腱鞘炎	20[redacted]	130	111	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性脊椎症	20[redacted]	182	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	262	29	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節周囲炎	20[redacted]	356	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	傾眠	20[redacted]	359	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	嵌入爪	20[redacted]	567	45	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	710	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	嘔吐	20[redacted]	233	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	不眠症	20[redacted]	248	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	慢性胃炎	20[redacted]	248	700	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	248	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	嘔吐	20[redacted]	515	50	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	不眠症	20[redacted]	556	167	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	ヘリコバクター感染	20[redacted]	558	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	558	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	うつ病	20[redacted]	573	85	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	体重減少	20[redacted]	722	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	靭帯捻挫	20[redacted]	15	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	処置による疼痛	20[redacted]	71	78	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	処置後腫脹	20[redacted]	71	85	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	頭痛	20[redacted]	71	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	便秘	20[redacted]	73	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	直腸炎	20[redacted]	73	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	接触性皮膚炎	20[redacted]	106	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	処置による疼痛	20[redacted]	120	134	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	交通事故	20[redacted]	161	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	擦過傷	20[redacted]	161	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	浮動性めまい	20[redacted]	161	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	顎痛	20[redacted]	161	68	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	骨痛	20[redacted]	161	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	交通事故	20[redacted]	185	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	出血	20[redacted]	185	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	呼吸時疼痛	20[redacted]	185	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	185	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	挫傷	20[redacted]	185	87	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	背部痛	20[redacted]	185	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	胸痛	20[redacted]	185	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	胸骨骨折	20[redacted]	185	.	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	靭帯捻挫	20[redacted]	185	104	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	頭痛	20[redacted]	186	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	腹部不快感	20[redacted]	187	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	食欲減退	20[redacted]	187	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	頭痛	20[redacted]	188	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	不眠症	20[redacted]	189	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	骨痛	20[redacted]	189	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		6[redacted]	F	ASIAN	筋骨格痛	20[redacted]	190	79	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	膿痂疹性湿疹	20[redacted]	45	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	帯状疱疹	20[redacted]	54	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	ヘルペス後神経痛	20[redacted]	62	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮膚擦過傷	20[redacted]	395	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	湿疹	20[redacted]	446	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	虫垂炎	20[redacted]	595	12	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	虫垂新生物	20[redacted]	611	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	浮動性めまい	20[redacted]	10	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アルコール性肝疾患	20[redacted]	15	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アルコール症	20[redacted]	57	2	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アルコール離脱症候群	20[redacted]	58	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	食中毒	20[redacted]	149	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	179	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋骨格痛	20[redacted]	185	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	食中毒	20[redacted]	189	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	242	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節痛	20[redacted]	244	100	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	慢性気管支炎	20[redacted]	276	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	悪心	20[redacted]	284	44	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	そう痒症	20[redacted]	295	104	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	そう痒症	20[redacted]	295	104	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋痙縮	20[redacted]	354	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	節足動物刺傷	20[redacted]	360	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋骨格痛	20[redacted]	399	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	719	89	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	719	201	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	網膜出血	20[redacted]	719	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		6[redacted]	F	ASIAN	浮動性めまい	20[redacted]	1	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		6[redacted]	F	ASIAN	不眠症	20[redacted]	4	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		6[redacted]	F	ASIAN	うつ病	20[redacted]	39	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	JAPAN	PLACEBO		6[redacted]	F	ASIAN	非心臓性胸痛	20[redacted]	41	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		6[redacted]	F	ASIAN	変形性脊椎症	20[redacted]	73	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	JAPAN	PLACEBO		6[redacted]	F	ASIAN	肝嚢胞	20[redacted]	90	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		6[redacted]	F	ASIAN	腎嚢胞	20[redacted]	90	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	過角化	20[redacted]	65	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	歯周炎	20[redacted]	148	59	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	体重減少	20[redacted]	172	105	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	191	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	207	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	ウイルス性上気道感染	20[redacted]	231	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	口腔ヘルペス	20[redacted]	242	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮膚創傷	20[redacted]	276	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	不眠症	20[redacted]	374	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	変形性関節症	20[redacted]	448	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮下出血	20[redacted]	495	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	518	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	651	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	651	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	719	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	胃炎	20[redacted]	6	169	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	腰部脊柱管狭窄症	20[redacted]	7	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	慢性胃炎	20[redacted]	175	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	238	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高血圧	20[redacted]	327	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	回転性めまい	20[redacted]	394	192	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	緊張性頭痛	20[redacted]	455	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	栄養障害	20[redacted]	456	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	白内障	20[redacted]	503	288	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	筋痙縮	20[redacted]	45	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	嵌入爪	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	耳下腺炎	20[redacted]	265	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	変形性関節症	20[redacted]	418	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	腰部脊柱管狭窄症	20[redacted]	681	117	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	変形性関節症	20[redacted]	692	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	口内炎	20[redacted]	27	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃食道逆流性疾患	20[redacted]	27	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	81	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	91	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	黄斑線維症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	掌蹠角皮症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	齲歯	20[redacted]	.	200	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋痙縮	20[redacted]	342	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	401	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	滑液嚢腫	20[redacted]	425	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	下痢	20[redacted]	432	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	眼乾燥	20[redacted]	497	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	大脳動脈狭窄	20[redacted]	523	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	関節周囲炎	20[redacted]	40	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	副鼻腔炎	20[redacted]	105	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	歯周炎	20[redacted]	393	22	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	顎骨壊死	20[redacted]	435	.	Y	Grade 2	RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	脂質異常症	20[redacted]	63	70	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	63	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	112	53	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	112	67	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道感染	20[redacted]	302	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	308	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	浮動性めまい	20[redacted]	346	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高脂血症	20[redacted]	351	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	脱水	20[redacted]	121	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	腰部脊柱管狭窄症	20[redacted]	210	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	甲状腺腫	20[redacted]	341	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高血圧	20[redacted]	449	91	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	膀胱炎	20[redacted]	513	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	糖尿病	20[redacted]	29	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	85	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	口唇損傷	20[redacted]	106	169	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	感染性皮膚嚢腫	20[redacted]	253	78	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	炎症	20[redacted]	384	94	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃腸炎	20[redacted]	384	38	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃腸炎	20[redacted]	384	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	認知障害	20[redacted]	387	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	REMOVED FROM STUDY	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	四肢痛	20[redacted]	389	5	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]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	391	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	褥瘡性潰瘍	20[redacted]	394	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	394	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	爪の皮膚糸状菌症	20[redacted]	401	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	肛門脱	20[redacted]	437	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		8[redacted]	F	ASIAN	脱水	20[redacted]	57	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	145	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		8[redacted]	F	ASIAN	口内炎	20[redacted]	150	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		8[redacted]	F	ASIAN	急性腹症	20[redacted]	151	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	179	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	注射部位そう痒感	20[redacted]	1	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	25	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	医療機器による疼痛	20[redacted]	31	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE EXPLANTATION	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	175	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	発疹	20[redacted]	280	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	頭痛	20[redacted]	280	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	嚢胞	20[redacted]	317	350	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	不眠症	20[redacted]	348	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	348	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	肺炎	20[redacted]	351	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	大腸ポリープ	20[redacted]	675	175	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脊椎すべり症	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	慢性胃炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	335	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	眼充血	20[redacted]	359	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	ヘリコバクター感染	20[redacted]	429	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	狭心症	20[redacted]	430	26	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	頭痛	20[redacted]	431	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	便秘	20[redacted]	435	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	回転性めまい	20[redacted]	436	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	筋骨格痛	20[redacted]	455	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻炎	20[redacted]	508	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	嗜眠	20[redacted]	147	99	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上腹部痛	20[redacted]	189	30	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	519	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	浮動性めまい	20[redacted]	1	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	消化不良	20[redacted]	92	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	217	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	歯周炎	20[redacted]	365	133	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	橈骨骨折	20[redacted]	646	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	646	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋断裂	20[redacted]	662	101	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	便秘	20[redacted]	223	196	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	水頭症	20[redacted]	390	29	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	脳出血	20[redacted]	390	29	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	多臓器不全	20[redacted]	396	23	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	肺炎	20[redacted]	396	23	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	204	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	アレルギー性鼻炎	20[redacted]	48	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	不安障害	20[redacted]	48	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	挫傷	20[redacted]	49	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	脛骨骨折	20[redacted]	49	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	靭帯捻挫	20[redacted]	49	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	靭帯捻挫	20[redacted]	49	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	高血圧	20[redacted]	62	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	真菌感染	20[redacted]	69	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	湿疹	20[redacted]	85	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	113	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	上気道感染	20[redacted]	145	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	106	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	処置後感染	20[redacted]	139	137	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	交通事故	20[redacted]	329	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	挫傷	20[redacted]	329	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	食物アレルギー	20[redacted]	438	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	転倒	20[redacted]	517	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	顔面骨骨折	20[redacted]	517	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	交通事故	20[redacted]	150	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	150	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腓骨骨折	20[redacted]	150	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腓骨骨折	20[redacted]	150	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	152	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	そう痒症	20[redacted]	154	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋力低下	20[redacted]	157	195	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	下痢	20[redacted]	168	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	不眠症	20[redacted]	168	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	169	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	感覚鈍麻	20[redacted]	175	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	246	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節拘縮	20[redacted]	248	104	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節拘縮	20[redacted]	248	104	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	高血圧	20[redacted]	284	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	585	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	612	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	皮膚擦過傷	20[redacted]	635	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃腸炎	20[redacted]	656	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	緊張性膀胱	20[redacted]	693	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	パーキンソン病	20[redacted]	710	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	食欲減退	20[redacted]	725	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腎盂腎炎	20[redacted]	415	14	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	背部痛	20[redacted]	585	152	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]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	585	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	側腹部痛	20[redacted]	266	89	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	膵嚢胞	20[redacted]	302	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	508	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	558	67	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	白内障	20[redacted]	568	57	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	関節痛	20[redacted]	613	260	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	大腿骨頚部骨折	20[redacted]	183	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	転倒	20[redacted]	183	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	弛緩歯	20[redacted]	.	76	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	インフルエンザ	20[redacted]	332	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	関節周囲炎	20[redacted]	92	264	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	膀胱炎	20[redacted]	104	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	194	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	結膜炎	20[redacted]	397	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	442	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	ラクナ梗塞	20[redacted]	629	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	629	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	糖尿病	20[redacted]	719	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		8[redacted]	F	ASIAN	外耳炎	20[redacted]	137	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		8[redacted]	F	ASIAN	急性心筋梗塞	20[redacted]	161	30	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	湿疹	20[redacted]	150	303	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	アレルギー性胞隔炎	20[redacted]	267	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	気管支炎	20[redacted]	267	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	便秘	20[redacted]	169	53	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	結膜炎	20[redacted]	169	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	胃食道逆流性疾患	20[redacted]	169	53	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	胃腸炎	20[redacted]	197	25	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	高血圧	20[redacted]	254	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	胃食道逆流性疾患	20[redacted]	320	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	ASIAN	半月板損傷	20[redacted]	421	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	132	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	202	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	浮動性めまい	20[redacted]	395	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿管結石	20[redacted]	483	33	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	532	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	617	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	細気管支炎	20[redacted]	669	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	肺炎	20[redacted]	675	32	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	扁桃炎	20[redacted]	121	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	皮膚嚢腫	20[redacted]	143	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	大腸腺腫	20[redacted]	150	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	過敏性腸症候群	20[redacted]	157	.	N	Grade 1	NOT RELATED		DRUG WITHDRAWN	MULTIPLE	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	回転性めまい	20[redacted]	175	45	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	高血圧	20[redacted]	175	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	高血圧	20[redacted]	248	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	筋骨格硬直	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	373	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	下痢	20[redacted]	413	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	膀胱炎	20[redacted]	562	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	口内炎	20[redacted]	566	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	皮膚炎	20[redacted]	566	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	膀胱炎	20[redacted]	575	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM		7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	656	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	注射部位疼痛	20[redacted]	56	3	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	318	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	結節性変形性関節症	20[redacted]	330	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	鼻炎	20[redacted]	440	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	尿管結石	20[redacted]	479	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	四肢痛	20[redacted]	32	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	注射部位疼痛	20[redacted]	267	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	注射部位紅斑	20[redacted]	267	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	290	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃腸炎	20[redacted]	453	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃腸炎	20[redacted]	523	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腎盂腎炎	20[redacted]	523	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	咳嗽	20[redacted]	582	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	扁桃炎	20[redacted]	660	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	インフルエンザ	20[redacted]	681	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	気管支炎	20[redacted]	688	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	胃腸炎	20[redacted]	688	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腎盂腎炎	20[redacted]	688	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	693	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	白内障	20[redacted]	395	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	変形性関節症	20[redacted]	518	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	ASIAN	足部白癬	20[redacted]	587	47	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	アレルギー性皮膚炎	20[redacted]	88	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	口内炎	20[redacted]	150	70	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鉄欠乏性貧血	20[redacted]	183	105	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	筋骨格硬直	20[redacted]	251	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	悪性貧血	20[redacted]	454	.	Y	Grade 2	RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	480	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	下腹部痛	20[redacted]	483	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	交通事故	20[redacted]	554	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	挫傷	20[redacted]	554	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	腱鞘炎	20[redacted]	3	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	食欲減退	20[redacted]	37	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	便秘	20[redacted]	51	92	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	背部痛	20[redacted]	256	.	N	Grade 2	RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	弾発指	20[redacted]	310	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	末梢腫脹	20[redacted]	354	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	肝機能異常	20[redacted]	359	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	大腿骨骨折	20[redacted]	376	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	転倒	20[redacted]	376	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	不安定狭心症	20[redacted]	378	59	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	便秘	20[redacted]	378	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	譫妄	20[redacted]	379	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	発疹	20[redacted]	405	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	処置による疼痛	20[redacted]	437	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	不眠症	20[redacted]	593	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	PLACEBO		7[redacted]	F	ASIAN	転倒	20[redacted]	614	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	嘔吐	20[redacted]	196	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	無力症	20[redacted]	196	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	湿疹	20[redacted]	210	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	221	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	便秘	20[redacted]	329	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	鼻咽頭炎	20[redacted]	329	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腱鞘炎	20[redacted]	350	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	上気道の炎症	20[redacted]	399	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	体位性めまい	20[redacted]	450	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	腹部不快感	20[redacted]	546	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	ヘリコバクター感染	20[redacted]	581	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	JAPAN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	ASIAN	直腸Ｓ状結腸癌	20[redacted]	604	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N

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[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	321	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	横隔膜ヘルニア	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肝嚢胞	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膵仮性嚢胞	20[redacted]	331	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
3[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乳癌第３期	20[redacted]	576	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	98	6	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	.	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	162	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	260	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋間神経痛	20[redacted]	381	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	灼熱感	20[redacted]	29	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	29	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	.	44	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	108	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	無力症	20[redacted]	157	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	157	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	自己免疫性甲状腺炎	20[redacted]	195	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	273	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	391	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	56	37	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧性心疾患	20[redacted]	56	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎結石症	20[redacted]	83	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	91	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	イレウス	20[redacted]	135	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大腸ポリープ	20[redacted]	135	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性胃炎	20[redacted]	135	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腸憩室	20[redacted]	135	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	虚血性大腸炎	20[redacted]	135	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	丹毒	20[redacted]	260	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大脳萎縮	20[redacted]	289	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳動脈硬化症	20[redacted]	289	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	齲歯	20[redacted]	331	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上室性期外収縮	20[redacted]	358	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	歯の脱落	20[redacted]	362	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	407	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性心不全	20[redacted]	407	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	722	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	徐脈	20[redacted]	726	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	153	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歩行障害	20[redacted]	255	55	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	髄膜腫	20[redacted]	306	9	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歩行障害	20[redacted]	344	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	傾眠	20[redacted]	348	112	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	LATVIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	518	39	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸ポリープ	20[redacted]	113	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	113	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ロタウイルス感染	20[redacted]	358	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	428	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	429	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎結石症	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	卵巣嚢胞	20[redacted]	544	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮内膜増殖症	20[redacted]	544	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋肉痛	20[redacted]	693	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	44	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	慢性心不全	20[redacted]	44	111	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	44	111	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	90	65	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	高カリウム血症	20[redacted]	90	65	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LATVIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	脳挫傷	20[redacted]	154	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	洞結節機能不全	20[redacted]	.	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脂質異常症	20[redacted]	281	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	滑液包炎	20[redacted]	311	239	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]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	洞結節機能不全	20[redacted]	342	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆嚢ポリープ	20[redacted]	508	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	508	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血管筋脂肪腫	20[redacted]	508	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO		7[redacted]	F	WHITE	卵巣嚢胞	20[redacted]	91	29	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	37	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	57	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	神経症	20[redacted]	57	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	57	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節腫脹	20[redacted]	98	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	363	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	17	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肩回旋筋腱板症候群	20[redacted]	65	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	239	66	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿失禁	20[redacted]	315	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	316	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	428	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	516	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮ポリープ	20[redacted]	604	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	先天性嚢胞性腎疾患	20[redacted]	610	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LATVIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	722	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	460	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	統合失調症様障害	20[redacted]	591	19	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	統合失調症様障害	20[redacted]	716	31	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	統合失調症様障害	20[redacted]	747	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	407	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	椎骨動脈形成不全	20[redacted]	410	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	水頭症	20[redacted]	410	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血管性脳症	20[redacted]	410	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮脱	20[redacted]	163	86	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿失禁	20[redacted]	163	86	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	会陰損傷	20[redacted]	244	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮平滑筋腫	20[redacted]	244	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	直腸瘤	20[redacted]	244	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腟脱	20[redacted]	244	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱瘤	20[redacted]	244	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯周炎	20[redacted]	576	363	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	便秘	20[redacted]	6	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	末梢腫脹	20[redacted]	6	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	咽頭炎	20[redacted]	166	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	そう痒症	20[redacted]	220	107	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	斑状丘疹状皮疹	20[redacted]	264	63	N	Grade 2	RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	細菌性胃腸炎	20[redacted]	526	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	神経根障害	20[redacted]	70	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	神経根障害	20[redacted]	132	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	紅斑	20[redacted]	212	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	285	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上室性期外収縮	20[redacted]	295	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心室性期外収縮	20[redacted]	295	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	295	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳血腫	20[redacted]	295	61	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うつ病	20[redacted]	506	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性前庭症候群	20[redacted]	647	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	647	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頚髄神経根障害	20[redacted]	647	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	神経根障害	20[redacted]	657	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	動脈狭窄	20[redacted]	19	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	19	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	19	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	末梢性虚血	20[redacted]	19	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	65	12	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	76	44	N	Grade 3	RELATED		DRUG WITHDRAWN	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	全身性そう痒症	20[redacted]	142	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	アレルギー性鼻炎	20[redacted]	267	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	アレルギー性鼻炎	20[redacted]	340	128	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	白内障	20[redacted]	400	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	緑内障	20[redacted]	400	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	509	24	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	アレルギー性鼻炎	20[redacted]	509	24	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂質異常症	20[redacted]	124	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	230	46	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発疹	20[redacted]	386	62	N	Grade 2	RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	前庭性運動失調	20[redacted]	679	38	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	679	38	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	680	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	虚血性脳梗塞	20[redacted]	680	37	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高カルシウム血症	20[redacted]	730	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	15	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	50	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	160	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性前庭症候群	20[redacted]	418	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	甲状腺腫	20[redacted]	418	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	418	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	422	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	422	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不眠症	20[redacted]	604	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	669	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	帯状疱疹	20[redacted]	670	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	670	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	31	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	骨端症	20[redacted]	81	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	125	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	Ｂ型インフルエンザウイルス検査陽性	20[redacted]	125	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	261	231	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤	20[redacted]	366	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	齲歯	20[redacted]	535	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	548	200	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	210	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	210	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	214	24	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	前庭性運動失調	20[redacted]	228	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	228	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	228	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外骨腫	20[redacted]	228	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	狭心症	20[redacted]	228	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	228	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨端症	20[redacted]	228	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	266	53	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	266	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	305	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	緑内障	20[redacted]	400	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	びらん性胃炎	20[redacted]	81	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	284	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱炎	20[redacted]	302	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	失神	20[redacted]	478	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	482	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	492	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	514	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	歯膿瘍	20[redacted]	3	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	全身性そう痒症	20[redacted]	36	77	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	筋肉痛	20[redacted]	36	77	N	Grade 2	RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	関節痛	20[redacted]	36	77	N	Grade 2	RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	心室性期外収縮	20[redacted]	87	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	94	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	慢性膵炎	20[redacted]	172	28	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	不眠症	20[redacted]	193	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	弛緩歯	20[redacted]	207	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	神経根障害	20[redacted]	240	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	頚髄神経根障害	20[redacted]	240	42	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	前庭性運動失調	20[redacted]	270	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	270	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	変形性関節症	20[redacted]	270	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	脊椎すべり症	20[redacted]	270	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	頚部脊柱管狭窄症	20[redacted]	270	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	冠動脈疾患	20[redacted]	381	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	完全房室ブロック	20[redacted]	381	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	第二度房室ブロック	20[redacted]	381	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	高血圧性心筋症	20[redacted]	382	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	心室性頻脈	20[redacted]	388	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	歯牙破折	20[redacted]	604	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	679	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	679	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	腰髄神経根障害	20[redacted]	683	13	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO		6[redacted]	F	WHITE	膀胱機能障害	20[redacted]	683	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	空腹時血中ブドウ糖不良	20[redacted]	32	61	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	229	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	前庭性運動失調	20[redacted]	536	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	声帯嚢胞	20[redacted]	155	38	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	喉頭炎	20[redacted]	190	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	275	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口内炎	20[redacted]	70	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	99	240	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口内炎	20[redacted]	128	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	219	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	びらん性胃炎	20[redacted]	225	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安定狭心症	20[redacted]	225	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧性心疾患	20[redacted]	225	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外耳炎	20[redacted]	226	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳垢分泌過多	20[redacted]	226	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	四肢痛	20[redacted]	3	9	N	Grade 2	RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	骨痛	20[redacted]	3	9	N	Grade 2	RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	幻覚	20[redacted]	79	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大腿骨骨折	20[redacted]	285	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	緑内障	20[redacted]	421	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	熱傷	20[redacted]	438	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳虚血	20[redacted]	644	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯膿瘍	20[redacted]	145	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性気道感染	20[redacted]	526	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	680	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	帯状疱疹	20[redacted]	48	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	180	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	244	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱癌	20[redacted]	425	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	614	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	前庭性運動失調	20[redacted]	55	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	55	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	椎間板突出	20[redacted]	55	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	55	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎障害	20[redacted]	55	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頚髄神経根障害	20[redacted]	55	476	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	120	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	131	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血尿	20[redacted]	154	434	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮ポリープ	20[redacted]	191	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安定狭心症	20[redacted]	430	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	430	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	430	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	430	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧性心筋症	20[redacted]	430	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	びらん性十二指腸炎	20[redacted]	435	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃潰瘍	20[redacted]	435	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	狭心症	20[redacted]	436	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	浮動性めまい	20[redacted]	122	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大腿骨骨折	20[redacted]	392	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	出血性貧血	20[redacted]	394	348	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	接触性皮膚炎	20[redacted]	394	106	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳虚血	20[redacted]	394	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	聴神経炎	20[redacted]	3	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	244	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	前庭性運動失調	20[redacted]	320	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	320	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	320	412	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	多発ニューロパチー	20[redacted]	665	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	665	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病	20[redacted]	665	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肥満	20[redacted]	665	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂質異常症	20[redacted]	665	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	665	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	開放隅角緑内障	20[redacted]	665	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脂質異常症	20[redacted]	64	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	ウイルス性気道感染	20[redacted]	157	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性心不全	20[redacted]	160	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	160	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳虚血	20[redacted]	160	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧性心筋症	20[redacted]	160	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	骨端症	20[redacted]	638	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋間神経痛	20[redacted]	7	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気道感染	20[redacted]	46	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性前庭症候群	20[redacted]	76	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	身体疾患による不安障害	20[redacted]	76	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	124	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	132	218	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	足変形	20[redacted]	132	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	152	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	178	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	256	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腰髄神経根障害	20[redacted]	431	82	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	450	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	473	66	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不眠症	20[redacted]	503	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹部不快感	20[redacted]	517	147	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	日光角化症	20[redacted]	685	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腹部痛	20[redacted]	724	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	脂漏性皮膚炎	20[redacted]	70	76	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	鼻炎	20[redacted]	105	11	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	関節痛	20[redacted]	106	10	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	耳痛	20[redacted]	107	9	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	関節痛	20[redacted]	157	10	N	Grade 1	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	鼻炎	20[redacted]	157	10	N	Grade 1	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	184	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	胃酸過多	20[redacted]	230	113	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	胃酸過多	20[redacted]	252	91	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	関節痛	20[redacted]	291	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	上腹部痛	20[redacted]	372	73	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	胆石症	20[redacted]	394	45	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	高血圧クリーゼ	20[redacted]	430	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	四肢不快感	20[redacted]	702	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	119	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性胃炎	20[redacted]	120	771	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	121	770	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	121	770	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	過長結腸	20[redacted]	122	769	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺腫	20[redacted]	127	764	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺腫	20[redacted]	127	764	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	127	764	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	身体疾患による人格変化	20[redacted]	127	764	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	くも膜嚢胞	20[redacted]	128	763	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧性心疾患	20[redacted]	128	763	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能亢進症	20[redacted]	296	595	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨端症	20[redacted]	360	531	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉痛	20[redacted]	4	84	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	4	84	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	19	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	55	150	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	62	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	143	67	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	143	19	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胸膜炎	20[redacted]	148	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	呼吸困難	20[redacted]	156	128	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肝嚢胞	20[redacted]	157	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆石症	20[redacted]	157	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	182	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	195	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ワクチン接種部位硬結	20[redacted]	228	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	創傷	20[redacted]	228	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	冠動脈疾患	20[redacted]	287	437	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻出血	20[redacted]	309	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	312	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板変性症	20[redacted]	359	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	521	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	扁平苔癬	20[redacted]	609	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胸痛	20[redacted]	690	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	不安定狭心症	20[redacted]	85	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	嚢胞	20[redacted]	87	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	肝嚢胞	20[redacted]	87	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	腎嚢胞	20[redacted]	87	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	気管支閉塞	20[redacted]	88	.	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]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	挫傷	20[redacted]	144	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	転倒	20[redacted]	144	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	頭痛	20[redacted]	159	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	脳虚血	20[redacted]	264	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	高血圧	20[redacted]	264	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	肋間神経痛	20[redacted]	273	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO		7[redacted]	F	WHITE	乳癌	20[redacted]	314	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	扁平上皮癌	20[redacted]	24	217	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	胃炎	20[redacted]	153	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	胃炎	20[redacted]	182	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	処置後出血	20[redacted]	285	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	関節痛	20[redacted]	297	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	疲労	20[redacted]	301	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	背部痛	20[redacted]	347	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	脳虚血	20[redacted]	455	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	462	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	パーキンソン病	20[redacted]	616	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	薬物不耐性	20[redacted]	616	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	腎不全	20[redacted]	717	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	高血圧性腎症	20[redacted]	717	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	198	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳血管障害	20[redacted]	198	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	250	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	342	85	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	てんかん	20[redacted]	346	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	346	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腰髄神経根障害	20[redacted]	431	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	472	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢腫脹	20[redacted]	626	212	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	20	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腰髄神経根障害	20[redacted]	84	230	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	160	129	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳鳴	20[redacted]	247	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃炎	20[redacted]	334	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腰髄神経根障害	20[redacted]	339	147	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃炎	20[redacted]	349	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨壊死	20[redacted]	421	97	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後貧血	20[redacted]	512	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頚髄神経根障害	20[redacted]	587	443	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	髄膜腫	20[redacted]	631	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	帯状疱疹	20[redacted]	186	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大腿骨骨折	20[redacted]	366	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性腎不全	20[redacted]	372	3	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	直腸出血	20[redacted]	372	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	37	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不眠症	20[redacted]	42	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	399	37	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不眠症	20[redacted]	411	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	411	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	60	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	60	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	325	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	損傷	20[redacted]	325	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	325	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	LITHUANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	325	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頚髄神経根障害	20[redacted]	78	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	滑液包炎	20[redacted]	103	49	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢性ニューロパチー	20[redacted]	248	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	線維腫症	20[redacted]	248	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節周囲炎	20[redacted]	248	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	311	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	抜歯	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	423	98	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	挫傷	20[redacted]	729	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	不安定狭心症	20[redacted]	150	12	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	慢性心不全	20[redacted]	150	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	本態性高血圧症	20[redacted]	150	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	糖尿病性腎症	20[redacted]	191	.	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]	LITHUANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	不安定狭心症	20[redacted]	251	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腸憩室	20[redacted]	162	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	薬物不耐性	20[redacted]	332	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	51	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	430	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	617	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃内ｐＨ低下	20[redacted]	502	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	728	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性骨髄性白血病	20[redacted]	729	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	乳癌	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	耳感染	20[redacted]	2	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	関節痛	20[redacted]	33	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	傾眠	20[redacted]	38	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	疲労	20[redacted]	38	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	慢性副鼻腔炎	20[redacted]	87	241	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	健忘	20[redacted]	154	174	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	頭痛	20[redacted]	252	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	過眠症	20[redacted]	308	37	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	大腿骨頚部骨折	20[redacted]	633	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	MEXICO	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	OTHER	腱鞘炎	20[redacted]	709	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	蕁麻疹	20[redacted]	1	9	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	3	9	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]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	12	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	12	125	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	転倒	20[redacted]	15	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	消化不良	20[redacted]	29	261	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	免疫性血小板減少性紫斑病	20[redacted]	35	424	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	脂肪肝	20[redacted]	46	246	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	齲歯	20[redacted]	68	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	関節痛	20[redacted]	150	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	血中ブドウ糖増加	20[redacted]	366	93	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	ヘリコバクター性胃炎	20[redacted]	406	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	食道静脈瘤	20[redacted]	553	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	肝障害	20[redacted]	554	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	貧血	20[redacted]	554	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	門脈圧亢進症	20[redacted]	554	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	MEXICO	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	OTHER	血小板減少症	20[redacted]	731	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	挫傷	20[redacted]	7	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	転倒	20[redacted]	7	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	鼻咽頭炎	20[redacted]	47	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	脂質異常症	20[redacted]	88	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	抑うつ気分	20[redacted]	98	180	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	四肢痛	20[redacted]	163	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	消化不良	20[redacted]	163	120	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	背部痛	20[redacted]	163	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	

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[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	髄膜腫	20[redacted]	213	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	四肢痛	20[redacted]	26	.	N	Grade 3	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	関節痛	20[redacted]	134	4	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	無力症	20[redacted]	153	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	無力症	20[redacted]	153	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	うつ病	20[redacted]	216	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	線維筋痛	20[redacted]	226	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	MEXICO	AMG 785 210 MG SC QM		6[redacted]	F	OTHER	脊椎すべり症	20[redacted]	398	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	NEW ZEALAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	179	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	NEW ZEALAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	238	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	NEW ZEALAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	238	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	NEW ZEALAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ストレス心筋症	20[redacted]	304	158	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	NEW ZEALAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	304	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	NEW ZEALAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	623	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	NEW ZEALAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肉離れ	20[redacted]	633	65	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	爪線状隆起	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	211	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	穿孔性虫垂炎	20[redacted]	718	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	NEW ZEALAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	721	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心停止	20[redacted]	682	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	会陰膿瘍	20[redacted]	145	12	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯の脱落	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腕骨骨折	20[redacted]	705	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	交通事故	20[redacted]	705	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	内臓損傷	20[redacted]	705	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	恥骨骨折	20[redacted]	705	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	705	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心肺不全	20[redacted]	503	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	OTHER	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性胃炎	20[redacted]	370	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	370	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	370	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不全片麻痺	20[redacted]	493	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	493	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	493	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	493	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性肺炎	20[redacted]	493	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	493	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	493	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	14	34	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ヘリコバクター感染	20[redacted]	50	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	びらん性胃炎	20[redacted]	70	886	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食中毒	20[redacted]	98	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胸椎骨折	20[redacted]	155	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嵌頓臍ヘルニア	20[redacted]	200	15	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	286	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	322	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	380	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	473	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	652	92	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	椎間板障害	20[redacted]	675	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	臍ヘルニア	20[redacted]	107	311	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	116	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	166	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	244	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆管炎	20[redacted]	259	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	２型糖尿病	20[redacted]	303	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	節足動物咬傷	20[redacted]	511	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性扁桃炎	20[redacted]	729	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	.	163	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	242	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	262	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	抜歯	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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	342	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	342	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	僧帽弁狭窄症	20[redacted]	370	29	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アレルギー性鼻炎	20[redacted]	464	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位発疹	20[redacted]	66	7	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板障害	20[redacted]	177	13	N	Grade 1	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	逆流性胃炎	20[redacted]	281	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動脈硬化症	20[redacted]	294	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性腎臓病	20[redacted]	294	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	294	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢損傷	20[redacted]	54	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	54	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脛骨骨折	20[redacted]	82	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腓骨骨折	20[redacted]	82	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	表在性静脈炎	20[redacted]	268	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	317	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	596	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	634	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胸部Ｘ線異常	20[redacted]	702	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性副鼻腔炎	20[redacted]	107	80	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	副鼻腔炎	20[redacted]	186	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	回転性めまい	20[redacted]	229	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	233	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動脈硬化症	20[redacted]	236	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高コレステロール血症	20[redacted]	236	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	.	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤	20[redacted]	730	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢循環不全	20[redacted]	.	98	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	160	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	.	291	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嵌頓腹部ヘルニア	20[redacted]	473	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋虚血	20[redacted]	473	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	473	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心肺不全	20[redacted]	477	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	86	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	168	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	175	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下部消化管出血	20[redacted]	189	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	250	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節脱臼	20[redacted]	250	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	295	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	353	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心室性頻脈	20[redacted]	725	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢損傷	20[redacted]	763	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脊柱変形	20[redacted]	104	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	255	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢壊死	20[redacted]	.	28	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動脈硬化症	20[redacted]	533	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	蜂巣炎	20[redacted]	533	6	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	.	145	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	.	114	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤	20[redacted]	660	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	699	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	扁桃炎	20[redacted]	306	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎細胞癌	20[redacted]	412	91	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	714	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	161	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	機能性胃腸障害	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	冠動脈疾患	20[redacted]	264	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動脈硬化症	20[redacted]	264	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	266	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	266	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	436	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アレルギー性鼻炎	20[redacted]	48	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	109	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎結石症	20[redacted]	190	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高尿酸血症	20[redacted]	259	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性胆嚢炎	20[redacted]	354	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	443	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	62	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	126	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	354	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	側弯症	20[redacted]	504	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	504	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	505	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	505	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	716	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血小板増加症	20[redacted]	360	379	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	371	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	371	368	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	724	15	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	死亡	20[redacted]	605	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	45	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	64	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	64	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	334	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路性敗血症	20[redacted]	.	25	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	445	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	451	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	顔面骨骨折	20[redacted]	456	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	157	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	344	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	403	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	407	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	407	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	407	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺気腫	20[redacted]	407	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	僧帽弁狭窄症	20[redacted]	.	40	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性心不全	20[redacted]	462	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心膜切開後症候群	20[redacted]	469	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	.	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心不全	20[redacted]	218	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	耐糖能障害	20[redacted]	218	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤	20[redacted]	218	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	218	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	107	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	426	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	537	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	147	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	164	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	洞結節機能不全	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT 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]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	260	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	262	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	口内乾燥	20[redacted]	99	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	211	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腰椎骨折	20[redacted]	211	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	抜歯	20[redacted]	248	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	248	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	350	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	403	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	帯状疱疹	20[redacted]	472	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	526	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	抑うつ気分	20[redacted]	688	110	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	110	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	178	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	229	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	322	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	無力症	20[redacted]	354	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	400	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	414	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	536	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	水腎症	20[redacted]	540	67	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎結石症	20[redacted]	540	67	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	処置合併症	20[redacted]	558	43	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	35	98	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	247	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	261	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	353	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	450	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	左室機能不全	20[redacted]	535	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋梗塞	20[redacted]	535	12	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	535	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性咽頭炎	20[redacted]	11	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	手骨折	20[redacted]	37	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脊椎痛	20[redacted]	41	62	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	115	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	140	61	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	180	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	無力症	20[redacted]	205	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	237	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹痛	20[redacted]	261	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支炎	20[redacted]	308	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	冠動脈疾患	20[redacted]	331	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	331	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	347	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	360	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	正色素性正球性貧血	20[redacted]	373	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	524	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	記憶障害	20[redacted]	588	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	回転性めまい	20[redacted]	16	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	神経痛	20[redacted]	69	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	陰部ヘルペス	20[redacted]	86	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	無力症	20[redacted]	115	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	137	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	冠動脈疾患	20[redacted]	160	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	192	99	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	325	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	344	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	345	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	好中球減少症	20[redacted]	364	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白血球減少症	20[redacted]	364	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	回転性めまい	20[redacted]	368	24	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	461	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	461	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	477	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	495	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	正色素性正球性貧血	20[redacted]	495	53	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	洞結節機能不全	20[redacted]	495	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	埋込み部位血腫	20[redacted]	500	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	薬物過敏症	20[redacted]	521	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	好中球減少症	20[redacted]	730	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白血球減少症	20[redacted]	730	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿疹	20[redacted]	10	53	N	Grade 3	RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚炎	20[redacted]	166	152	Y	Grade 3	RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿失禁	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	74	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	84	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	聴覚障害	20[redacted]	84	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	霧視	20[redacted]	84	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺腫	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	115	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アスパラギン酸アミノトランスフェラーゼ増加	20[redacted]	182	93	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アラニンアミノトランスフェラーゼ増加	20[redacted]	182	93	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	γ－グルタミルトランスフェラーゼ増加	20[redacted]	247	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	313	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	313	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	344	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	344	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯痛	20[redacted]	538	15	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]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	582	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	589	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	589	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	589	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙破折	20[redacted]	.	217	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	445	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	網膜症	20[redacted]	445	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳血管発作	20[redacted]	.	.	Y	Grade 3	NOT RELATED	UNKNOWN	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外傷性緑内障	20[redacted]	4	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼外傷	20[redacted]	4	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	221	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ヘリコバクター感染	20[redacted]	441	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	441	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	中枢神経系病変	20[redacted]	441	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	441	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大脳萎縮	20[redacted]	441	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	小脳萎縮	20[redacted]	441	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性胃炎	20[redacted]	441	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耐糖能障害	20[redacted]	441	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	認知障害	20[redacted]	441	.	Y	Grade 1	RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	441	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鉄欠乏	20[redacted]	441	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	546	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	546	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	573	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	2	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高脂血症	20[redacted]	182	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	531	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	215	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	266	43	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹痛	20[redacted]	266	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	317	13	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	２型糖尿病	20[redacted]	1	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性咽頭炎	20[redacted]	127	40	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	144	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	側弯症	20[redacted]	167	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	167	20	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	186	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋虚血	20[redacted]	271	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎結石症	20[redacted]	275	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	316	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	317	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	317	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	317	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	２型糖尿病	20[redacted]	75	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乾癬	20[redacted]	155	42	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乾癬	20[redacted]	197	78	Y	Grade 3	RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	266	12	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	293	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	322	8	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	441	6	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	533	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	712	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部損傷	20[redacted]	712	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	712	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	乾癬	20[redacted]	721	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	193	86	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	193	86	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食欲減退	20[redacted]	193	86	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	294	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	246	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安定狭心症	20[redacted]	589	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	589	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	意識消失	20[redacted]	589	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	直腸癌第２期	20[redacted]	78	.	Y	Grade 3	RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	多発性関節炎	20[redacted]	6	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	6	10	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副腎障害	20[redacted]	64	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱の良性新生物	20[redacted]	64	489	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	160	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	293	5	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	512	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱乳頭腫	20[redacted]	553	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乳頭様甲状腺癌	20[redacted]	597	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高カルシウム血症	20[redacted]	609	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	認知症	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	REMOVED FROM STUDY	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢神経手術	20[redacted]	128	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食欲減退	20[redacted]	157	124	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体重減少	20[redacted]	177	172	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歩行障害	20[redacted]	460	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	粘膜乾燥	20[redacted]	537	5	Y	Grade 2	RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	小脳症候群	20[redacted]	700	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	700	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	700	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	79	12	N	Grade 2	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]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃腸炎	20[redacted]	125	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	灼熱感	20[redacted]	206	40	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	251	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	チック	20[redacted]	256	6	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	276	52	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食中毒	20[redacted]	331	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便潜血陽性	20[redacted]	554	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不安定狭心症	20[redacted]	653	5	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	食道静脈瘤	20[redacted]	655	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	161	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節腫脹	20[redacted]	328	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	429	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	441	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	566	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	直腸周囲膿瘍	20[redacted]	622	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腸憩室	20[redacted]	622	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	門脈血栓症	20[redacted]	622	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	664	21	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	13	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	14	1	N	Grade 3	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	15	16	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	36	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血管穿刺部位内出血	20[redacted]	37	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	39	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	49	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	119	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	122	1	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	149	1	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	157	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	161	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	166	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不安定狭心症	20[redacted]	259	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	259	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	264	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	そう痒性皮疹	20[redacted]	160	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	頭痛	20[redacted]	160	.	N	Grade 1	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	四肢痛	20[redacted]	226	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	脳幹部虚血	20[redacted]	274	10	Y	Grade 4	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮内膜増殖症	20[redacted]	504	55	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮頚部癌	20[redacted]	559	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乾癬	20[redacted]	617	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	小腸閉塞	20[redacted]	617	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	洞結節機能不全	20[redacted]	688	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	虚血性脳梗塞	20[redacted]	688	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	25	8	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	35	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	79	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	79	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動悸	20[redacted]	83	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	96	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	131	8	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	急性心筋梗塞	20[redacted]	151	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	189	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	196	15	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食欲減退	20[redacted]	196	15	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胸骨骨折	20[redacted]	229	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	229	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃腸炎	20[redacted]	277	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	455	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	461	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	461	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮腟脱	20[redacted]	629	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢損傷	20[redacted]	689	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	689	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	689	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	35	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	無力症	20[redacted]	35	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	骨痛	20[redacted]	35	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	坐骨神経痛	20[redacted]	147	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	坐骨神経痛	20[redacted]	220	21	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脊椎痛	20[redacted]	297	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	.	222	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	141	15	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	215	506	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	251	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	429	292	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	突然死	20[redacted]	720	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED		Y
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	耳鳴	20[redacted]	.	44	N	Grade 1	RELATED		DRUG WITHDRAWN	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	形質細胞性骨髄腫	20[redacted]	305	.	Y	Grade 3	RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	189	35	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	205	19	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	突然死	20[redacted]	223	1	Y	Grade 5	RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	心的外傷後ストレス障害	20[redacted]	90	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	眼球内黒色腫	20[redacted]	266	.	Y	Grade 3	RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	眼の母斑	20[redacted]	295	.	N	Grade 1	RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎梗塞	20[redacted]	108	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	消化不良	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃障害	20[redacted]	651	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	651	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肝硬変	20[redacted]	715	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肝不全	20[redacted]	100	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肝不全	20[redacted]	193	62	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎臓痛	20[redacted]	67	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎臓痛	20[redacted]	88	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	痔核	20[redacted]	324	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	359	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	形質細胞性骨髄腫	20[redacted]	.	.	Y	Grade 3	RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心臓瘤	20[redacted]	17	635	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低血圧	20[redacted]	46	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血液量減少症	20[redacted]	.	104	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心筋梗塞	20[redacted]	651	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	170	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	316	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	666	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	緑内障	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	非感染性膀胱炎	20[redacted]	721	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	100	11	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	100	11	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	152	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	半月板変性	20[redacted]	280	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嚢胞	20[redacted]	525	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	525	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腱炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	背部痛	20[redacted]	47	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	喉頭扁平上皮癌	20[redacted]	233	.	Y	Grade 3	RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	リンパ節症	20[redacted]	667	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	甲状腺の良性新生物	20[redacted]	667	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	抜歯	20[redacted]	716	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	61	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血圧変動	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	乳房石灰化	20[redacted]	670	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿管狭窄	20[redacted]	137	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血糖	20[redacted]	183	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性腎臓病	20[redacted]	187	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路性敗血症	20[redacted]	.	37	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膿腎症	20[redacted]	.	37	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳血管発作	20[redacted]	492	61	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血中アルカリホスファターゼ増加	20[redacted]	580	.	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	39	71	N	Grade 1	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	118	28	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈弁狭窄	20[redacted]	499	4	Y	Grade 3	RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	糖尿病	20[redacted]	188	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	糖尿病	20[redacted]	.	107	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	702	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚炎	20[redacted]	702	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脂肪織炎	20[redacted]	702	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	702	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肝臓血管腫	20[redacted]	707	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	707	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	敗血症	20[redacted]	708	8	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺炎球菌性敗血症	20[redacted]	365	45	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺炎球菌性髄膜炎	20[redacted]	365	45	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	神経系障害	20[redacted]	393	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	頻脈	20[redacted]	409	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	側弯症	20[redacted]	180	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脊椎痛	20[redacted]	185	55	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	側弯症	20[redacted]	355	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	筋肉痛	20[redacted]	2	50	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	頻脈	20[redacted]	56	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	皮膚病変	20[redacted]	99	21	N	Grade 1	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	クロストリジウム・ディフィシレ大腸炎	20[redacted]	165	11	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N

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[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	下痢	20[redacted]	548	5	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	下痢	20[redacted]	643	2	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	下痢	20[redacted]	676	3	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	下痢	20[redacted]	711	3	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼓膜穿孔	20[redacted]	1	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気道感染	20[redacted]	143	85	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	静脈瘤	20[redacted]	638	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	変形性関節症	20[redacted]	17	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	発熱	20[redacted]	71	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	咳嗽	20[redacted]	165	39	N	Grade 2	RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	気管支拡張症	20[redacted]	165	.	Y	Grade 3	RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	発熱	20[redacted]	165	30	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	間質性肺疾患	20[redacted]	223	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	339	18	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	下気道感染	20[redacted]	530	20	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	247	102	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	247	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	十二指腸胃逆流	20[redacted]	261	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	261	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	261	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	感覚鈍麻	20[redacted]	44	19	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	神経痛	20[redacted]	44	19	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	251	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	286	453	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	紅斑	20[redacted]	542	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	575	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	20	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	282	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	312	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢動脈狭窄	20[redacted]	368	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	142	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆石症	20[redacted]	165	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性膵炎	20[redacted]	166	38	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃炎	20[redacted]	167	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆石症	20[redacted]	167	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆石症	20[redacted]	172	93	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢損傷	20[redacted]	306	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	46	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	120	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性気管支炎	20[redacted]	131	7	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ヘリコバクター性胃炎	20[redacted]	240	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	齲歯	20[redacted]	.	153	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	貧血	20[redacted]	426	36	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	死亡	20[redacted]	461	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	56	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	181	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	203	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	203	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	359	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	522	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	投与部位疼痛	20[redacted]	1	8	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	冠動脈疾患	20[redacted]	11	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	25	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	25	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧上昇	20[redacted]	308	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	308	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	311	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧上昇	20[redacted]	311	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	650	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	650	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚炎	20[redacted]	654	99	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	薬物過敏症	20[redacted]	680	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	162	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	260	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不眠症	20[redacted]	327	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺腫	20[redacted]	450	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	582	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	口腔咽頭痛	20[redacted]	71	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	71	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋肉痛	20[redacted]	94	15	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	240	67	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	浮動性めまい	20[redacted]	280	27	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	前庭障害	20[redacted]	302	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	過敏性腸症候群	20[redacted]	313	17	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	耳痛	20[redacted]	368	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	393	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	ビタミンD欠乏	20[redacted]	778	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	11	131	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節可動域低下	20[redacted]	11	131	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	153	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	283	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨格損傷	20[redacted]	283	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	325	104	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	意識消失	20[redacted]	698	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脳血腫	20[redacted]	698	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	698	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	720	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心臓弁閉鎖不全	20[redacted]	720	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	空腹時血中ブドウ糖不良	20[redacted]	2	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	胃新生物	20[redacted]	4	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肋間神経痛	20[redacted]	23	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	無力症	20[redacted]	40	36	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発作性頻脈	20[redacted]	60	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	83	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	96	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹部膨満	20[redacted]	112	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	227	41	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	227	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腸管ポリープ	20[redacted]	.	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	憩室	20[redacted]	286	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	334	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	448	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	450	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	450	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	514	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不眠症	20[redacted]	87	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	95	50	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胸痛	20[redacted]	167	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	64	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	２型糖尿病	20[redacted]	223	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏	20[redacted]	297	141	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋肉痛	20[redacted]	339	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	19	259	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	19	259	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	19	259	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧上昇	20[redacted]	270	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	277	204	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	314	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	596	373	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	直腸癌	20[redacted]	596	422	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下腹部痛	20[redacted]	708	261	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	聴覚不全	20[redacted]	24	.	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	336	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	甲状腺腫	20[redacted]	364	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	血小板減少症	20[redacted]	365	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	尿路性敗血症	20[redacted]	711	36	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	骨腫	20[redacted]	715	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肝臓血管腫	20[redacted]	718	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胆石症	20[redacted]	718	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	下痢	20[redacted]	52	7	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	痔核	20[redacted]	53	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	過敏性腸症候群	20[redacted]	53	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	腎不全	20[redacted]	91	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	高血圧	20[redacted]	107	49	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]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	貧血	20[redacted]	149	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低血圧	20[redacted]	9	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	78	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋虚血	20[redacted]	137	4	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	弛緩歯	20[redacted]	.	82	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	出血性卒中	20[redacted]	73	11	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	出血性卒中	20[redacted]	74	686	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	110	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性胃腸炎	20[redacted]	207	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	207	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	726	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節腫脹	20[redacted]	726	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板障害	20[redacted]	327	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	.	82	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脊椎痛	20[redacted]	298	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節腫脹	20[redacted]	332	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	441	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	453	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	乳癌	20[redacted]	546	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	256	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	冠動脈疾患	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋虚血	20[redacted]	7	70	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心臓瘤	20[redacted]	76	728	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性上気道感染	20[redacted]	188	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	552	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	せつ	20[redacted]	163	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	409	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	119	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	210	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	橈骨骨折	20[redacted]	220	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大動脈瘤	20[redacted]	.	99	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺腺癌	20[redacted]	653	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	神経線維腫	20[redacted]	92	155	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	300	24	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	76	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	175	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	209	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭部損傷	20[redacted]	247	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳血管障害	20[redacted]	254	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺障害	20[redacted]	275	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚感染	20[redacted]	477	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	丹毒	20[redacted]	655	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	レンサ球菌性敗血症	20[redacted]	685	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	丹毒	20[redacted]	685	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	喘息	20[redacted]	200	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	398	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	弛緩歯	20[redacted]	473	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	640	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	喘息	20[redacted]	640	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	26	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	26	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	26	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚灼熱感	20[redacted]	65	158	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚灼熱感	20[redacted]	65	217	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	基底細胞癌	20[redacted]	93	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	ウイルス性下痢	20[redacted]	101	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	140	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	175	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節損傷	20[redacted]	175	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	175	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	口腔真菌感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	乳房痛	20[redacted]	282	92	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胸部Ｘ線異常	20[redacted]	292	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	ウイルス性下痢	20[redacted]	300	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	創傷	20[redacted]	376	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	376	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	靭帯捻挫	20[redacted]	376	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢損傷	20[redacted]	417	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	417	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節損傷	20[redacted]	417	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭部損傷	20[redacted]	417	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	基底細胞癌	20[redacted]	527	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	535	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	気管支拡張症	20[redacted]	536	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	マイコバクテリウム・アビウムコンプレックス感染	20[redacted]	540	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	インフルエンザ	20[redacted]	76	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性上気道感染	20[redacted]	252	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	459	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腸ポリープ	20[redacted]	30	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	結腸腺癌	20[redacted]	30	44	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	74	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	110	234	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	硝子体出血	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	105	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	２型糖尿病	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT 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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	146	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	直腸しぶり	20[redacted]	188	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気分変調性障害	20[redacted]	278	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腸憩室	20[redacted]	306	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	浮動性めまい	20[redacted]	154	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	乳癌	20[redacted]	169	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	冠動脈疾患	20[redacted]	87	15	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	失神	20[redacted]	87	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	うっ血性心不全	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	冠動脈疾患	20[redacted]	102	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	149	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	540	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎不全	20[redacted]	547	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不安	20[redacted]	62	275	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	ウイルス性下痢	20[redacted]	92	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不整脈	20[redacted]	127	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	150	191	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	195	78	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心室性期外収縮	20[redacted]	195	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	195	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	658	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節炎	20[redacted]	21	98	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	36	83	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	感染による慢性閉塞性気道疾患の増悪	20[redacted]	115	5	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支拡張症	20[redacted]	118	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	157	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	157	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血中ブドウ糖異常	20[redacted]	157	32	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	２型糖尿病	20[redacted]	191	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺機能低下症	20[redacted]	725	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	187	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	192	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	236	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	413	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	489	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	495	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	左室肥大	20[redacted]	503	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	てんかん	20[redacted]	651	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	652	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上室性期外収縮	20[redacted]	656	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	110	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	46	Y	Grade 2	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]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	31	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性上気道感染	20[redacted]	39	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	104	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	過敏性腸症候群	20[redacted]	104	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	202	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	202	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	205	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	293	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢損傷	20[redacted]	336	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	外骨腫	20[redacted]	366	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	422	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	閉塞隅角緑内障	20[redacted]	586	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	緑内障	20[redacted]	595	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	646	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	肺炎	20[redacted]	90	18	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	91	17	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	気管支炎	20[redacted]	151	15	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	212	4	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	57	78	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	.	230	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	424	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	黄斑線維症	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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎不全	20[redacted]	736	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	てんかん	20[redacted]	139	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	初期不眠症	20[redacted]	479	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	幻覚	20[redacted]	632	84	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血管性認知症	20[redacted]	691	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	喘息	20[redacted]	27	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	喘息	20[redacted]	65	51	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	65	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性肺炎	20[redacted]	93	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浸潤性乳管癌	20[redacted]	213	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	OTHER	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	アレルギー性結膜炎	20[redacted]	144	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心不全	20[redacted]	239	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	239	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	凝固時間延長	20[redacted]	318	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	変形性関節症	20[redacted]	96	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	細菌性上気道感染	20[redacted]	132	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	不整脈	20[redacted]	152	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	上腹部痛	20[redacted]	189	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	失神	20[redacted]	211	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢動脈血栓症	20[redacted]	82	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢動脈血栓症	20[redacted]	97	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	四肢痛	20[redacted]	102	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	処置後出血	20[redacted]	142	3	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	127	20	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	716	15	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	処置合併症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	関節障害	20[redacted]	.	191	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	関節痛	20[redacted]	228	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	手骨折	20[redacted]	456	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	無力症	20[redacted]	1	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不整脈	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	31	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	51	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	63	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	73	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	90	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	108	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯の脱落	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	444	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足骨折	20[redacted]	444	.	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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アスパラギン酸アミノトランスフェラーゼ増加	20[redacted]	560	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アラニンアミノトランスフェラーゼ増加	20[redacted]	560	51	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	94	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	102	12	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳血管障害	20[redacted]	102	12	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳虚血	20[redacted]	108	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	108	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳血管障害	20[redacted]	114	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	154	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	316	637	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	痛風	20[redacted]	372	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	53	106	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管炎	20[redacted]	55	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	67	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	258	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	483	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	注射部位腫脹	20[redacted]	1	4	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	喘息	20[redacted]	68	85	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	86	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	失神	20[redacted]	135	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	

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[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	喘息	20[redacted]	191	16	N	Grade 2	RELATED		DRUG WITHDRAWN	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	副鼻腔ポリープ	20[redacted]	563	14	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	歯牙破折	20[redacted]	683	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	嘔吐	20[redacted]	64	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	142	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	195	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	215	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	急性冠動脈症候群	20[redacted]	336	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	347	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	140	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脊椎痛	20[redacted]	170	214	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	191	327	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	34	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	147	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心房細動	20[redacted]	174	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性気管支炎	20[redacted]	199	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	線維性組織球腫	20[redacted]	204	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹痛	20[redacted]	204	827	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	246	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	444	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	712	37	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮脱	20[redacted]	298	193	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	457	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	525	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋梗塞	20[redacted]	525	6	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	720	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	42	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	111	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	192	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	284	438	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	702	20	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血管性紫斑病	20[redacted]	58	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腰部脊柱管狭窄症	20[redacted]	81	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	98	62	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口内乾燥	20[redacted]	98	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	98	448	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	206	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板突出	20[redacted]	124	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	過敏症	20[redacted]	153	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	373	9	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	529	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咽頭炎	20[redacted]	569	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	686	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	311	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	.	137	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	62	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	238	313	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	497	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節炎	20[redacted]	505	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性消化管感染	20[redacted]	62	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	93	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	93	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	.	288	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	151	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢腫脹	20[redacted]	232	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	運動耐性低下	20[redacted]	232	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	コントロール不良の糖尿病	20[redacted]	281	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	281	11	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病網膜症	20[redacted]	288	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂肪肝	20[redacted]	288	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	コントロール不良の糖尿病	20[redacted]	398	25	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	398	25	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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	422	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血糖	20[redacted]	548	84	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹部膨満	20[redacted]	621	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	39	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	39	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	126	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	126	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心拍数増加	20[redacted]	150	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	189	86	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	252	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	.	225	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板突出	20[redacted]	.	225	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳下腺炎	20[redacted]	741	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	100	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	241	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	335	38	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	406	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	407	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	618	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	623	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	623	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上腕骨骨折	20[redacted]	665	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	665	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	665	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	665	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節損傷	20[redacted]	665	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脛骨骨折	20[redacted]	279	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腓骨骨折	20[redacted]	279	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	靭帯捻挫	20[redacted]	279	94	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	トランスアミナーゼ上昇	20[redacted]	565	357	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血中ブドウ糖増加	20[redacted]	5	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	57	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	限局性感染	20[redacted]	128	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	169	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	321	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	子宮頚部癌	20[redacted]	494	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	16	25	Y	Grade 3	RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肝障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	難聴	20[redacted]	.	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	29	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発声障害	20[redacted]	110	18	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	214	15	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	中耳の炎症	20[redacted]	251	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	321	5	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	379	7	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	388	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	無力症	20[redacted]	388	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高カルシウム血症	20[redacted]	727	141	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	1	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	非感染性膀胱炎	20[redacted]	204	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃腸の炎症	20[redacted]	217	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	243	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋緊張	20[redacted]	243	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	278	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	298	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路の炎症	20[redacted]	322	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胆石症	20[redacted]	322	120	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	多発性硬化症再発	20[redacted]	627	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	65	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨盤痛	20[redacted]	96	8	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿性咳嗽	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	231	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	684	1	Y	Grade 4	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱炎	20[redacted]	686	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	708	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	期外収縮	20[redacted]	27	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	消化不良	20[redacted]	57	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	無力症	20[redacted]	71	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	無力症	20[redacted]	78	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	身体表現性心血管系障害	20[redacted]	98	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障手術	20[redacted]	116	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	靭帯捻挫	20[redacted]	164	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	344	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺腫	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺腫	20[redacted]	400	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血小板減少症	20[redacted]	550	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	119	28	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	185	34	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	373	45	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高脂血症	20[redacted]	402	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	600	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	600	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢静脈疾患	20[redacted]	631	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	リンパ節症	20[redacted]	690	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	硬化性苔癬	20[redacted]	30	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	141	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	炎症	20[redacted]	233	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	節足動物咬傷	20[redacted]	308	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	425	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	425	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈硬化症	20[redacted]	518	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	518	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心筋梗塞	20[redacted]	518	24	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気道感染	20[redacted]	553	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大動脈硬化症	20[redacted]	10	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	10	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脂質代謝障害	20[redacted]	29	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	カタル	20[redacted]	242	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	427	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血尿	20[redacted]	518	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	医療機器アレルギー	20[redacted]	534	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	過敏症	20[redacted]	534	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	副鼻腔炎	20[redacted]	661	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性脊椎症	20[redacted]	661	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大動脈拡張	20[redacted]	661	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢静脈疾患	20[redacted]	661	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳血管障害	20[redacted]	661	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	視力障害	20[redacted]	661	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	記憶障害	20[redacted]	661	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節硬直	20[redacted]	661	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻炎	20[redacted]	661	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	椎間板障害	20[redacted]	662	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腰髄神経根障害	20[redacted]	662	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	びらん性十二指腸炎	20[redacted]	672	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	びらん性胃炎	20[redacted]	672	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	十二指腸潰瘍	20[redacted]	672	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	672	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心筋虚血	20[redacted]	736	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性腎不全	20[redacted]	27	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋緊張低下	20[redacted]	27	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	98	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	233	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	240	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	240	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	365	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	カタル	20[redacted]	.	132	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	咳嗽	20[redacted]	.	132	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	不眠症	20[redacted]	55	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	尿失禁	20[redacted]	55	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	無力症	20[redacted]	55	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	疲労	20[redacted]	55	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	上気道感染	20[redacted]	110	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	大腸潰瘍	20[redacted]	135	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	結腸腺癌	20[redacted]	139	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	睡眠障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	121	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	277	562	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	338	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔炎	20[redacted]	406	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	扁桃周囲膿瘍	20[redacted]	431	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	蓄膿	20[redacted]	484	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性扁桃炎	20[redacted]	546	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭蓋内動脈瘤	20[redacted]	74	.	Y	Grade 1	NOT RELATED	UNKNOWN	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	抜歯	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	筋骨格痛	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	舌炎	20[redacted]	49	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	注射部位疼痛	20[redacted]	92	8	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	103	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	膀胱新生物	20[redacted]	115	80	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	気管支炎	20[redacted]	178	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	膀胱新生物	20[redacted]	195	5	Y	Grade 2	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	89	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	気管支炎	20[redacted]	427	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	動脈硬化症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	喘息	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	空腹時血中ブドウ糖不良	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	胆石症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	喘息	20[redacted]	440	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	四肢痛	20[redacted]	588	93	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位疼痛	20[redacted]	29	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位腫脹	20[redacted]	29	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	29	5	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	注射部位疼痛	20[redacted]	57	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	113	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	135	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	感覚鈍麻	20[redacted]	135	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢静脈疾患	20[redacted]	135	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	144	194	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢静脈疾患	20[redacted]	208	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	241	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	250	25	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	251	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	251	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	251	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	254	40	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	357	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳閉	20[redacted]	.	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	448	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	542	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	喘息	20[redacted]	1	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心筋虚血	20[redacted]	3	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	呼吸困難	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	喘息	20[redacted]	28	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	静脈瘤	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	喘息	20[redacted]	91	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肺炎	20[redacted]	91	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	動脈硬化症	20[redacted]	106	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	慢性腎臓病	20[redacted]	106	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢静脈疾患	20[redacted]	8	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	滑液嚢腫	20[redacted]	8	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	振戦	20[redacted]	44	141	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	睡眠の質低下	20[redacted]	44	130	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	55	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	816	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	906	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	カタル	20[redacted]	89	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頻尿	20[redacted]	96	226	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	152	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	184	124	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	子宮脱	20[redacted]	245	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱機能障害	20[redacted]	245	66	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	321	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	337	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	460	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	注射部位疼痛	20[redacted]	1	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	弛緩歯	20[redacted]	30	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	創傷感染	20[redacted]	.	46	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	173	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	173	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	限局性浮腫	20[redacted]	173	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	234	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足変形	20[redacted]	234	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨壊死	20[redacted]	234	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	263	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	263	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節可動域低下	20[redacted]	301	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節腫脹	20[redacted]	301	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿失禁	20[redacted]	483	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	血圧上昇	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	脊髄新生物	20[redacted]	211	114	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	色素沈着障害	20[redacted]	67	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻出血	20[redacted]	91	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	多汗症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	呼吸困難	20[redacted]	.	118	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈硬化症	20[redacted]	367	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心拡大	20[redacted]	367	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺塞栓症	20[redacted]	.	33	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低カリウム血症	20[redacted]	457	63	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心中隔肥大	20[redacted]	471	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	472	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	507	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嘔吐	20[redacted]	507	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	507	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	519	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	519	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血腫	20[redacted]	529	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	静脈炎	20[redacted]	529	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血行不全	20[redacted]	541	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ビタミンＢ１２欠乏	20[redacted]	551	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	葉酸欠乏	20[redacted]	551	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胸椎骨折	20[redacted]	610	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腰椎骨折	20[redacted]	610	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	620	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	679	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性腎不全	20[redacted]	679	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	679	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脱水	20[redacted]	679	.	Y	Grade 3	NOT RELATED	UNKNOWN	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	身体疾患による気分障害	20[redacted]	679	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	身体疾患による精神病性障害	20[redacted]	679	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	医療機器不具合	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	97	39	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	悪心	20[redacted]	97	37	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃炎	20[redacted]	128	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	足変形	20[redacted]	175	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	213	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃炎	20[redacted]	269	36	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	おくび	20[redacted]	305	189	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	放屁	20[redacted]	305	381	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	口腔咽頭痛	20[redacted]	364	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	粘膜乾燥	20[redacted]	364	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯肉痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	変形性関節症	20[redacted]	62	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	上気道感染	20[redacted]	90	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	筋骨格痛	20[redacted]	103	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	高血圧	20[redacted]	114	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	心中隔肥大	20[redacted]	121	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺高血圧症	20[redacted]	121	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	パンコースト腫瘍	20[redacted]	253	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胸水	20[redacted]	262	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	骨溶解	20[redacted]	264	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	視力障害	20[redacted]	288	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	.	135	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	89	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	89	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血管破裂	20[redacted]	134	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤破裂	20[redacted]	134	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	184	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤	20[redacted]	184	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	熱傷	20[redacted]	308	.	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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頚部痛	20[redacted]	336	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	336	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	体重減少	20[redacted]	366	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	視力障害	20[redacted]	366	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	366	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	傾眠	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	無力症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	徐脈	20[redacted]	457	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	節足動物咬傷	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脊椎痛	20[redacted]	644	6	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上気道感染	20[redacted]	645	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心不全	20[redacted]	647	308	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	53	62	N	Grade 2	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格痛	20[redacted]	53	62	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	53	62	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	傾眠	20[redacted]	84	31	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	出血性貧血	20[redacted]	93	364	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変色便	20[redacted]	93	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変色便	20[redacted]	103	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	117	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	振戦	20[redacted]	238	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	記憶障害	20[redacted]	238	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	238	90	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	回転性めまい	20[redacted]	245	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	歩行障害	20[redacted]	245	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	331	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿失禁	20[redacted]	□□□	.	N	Grade 3	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	睡眠障害	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血小板増加症	20[redacted]	457	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	457	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心臓弁閉鎖不全	20[redacted]	554	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	根症候群	20[redacted]	554	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	浮動性めまい	20[redacted]	555	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	根症候群	20[redacted]	556	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃炎	20[redacted]	557	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	557	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳動脈硬化症	20[redacted]	557	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	557	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腸憩室	20[redacted]	562	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	卵巣嚢胞	20[redacted]	563	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	リンパ節症	20[redacted]	570	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎機能障害	20[redacted]	728	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	錯感覚	20[redacted]	.	51	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	71	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	126	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疼痛	20[redacted]	127	5	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	161	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アレルギー性皮膚炎	20[redacted]	213	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	家塵アレルギー	20[redacted]	238	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	放屁	20[redacted]	322	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	感覚鈍麻	20[redacted]	.	289	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚障害	20[redacted]	357	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	359	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	第７脳神経麻痺	20[redacted]	366	263	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢損傷	20[redacted]	393	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	393	52	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	橈骨骨折	20[redacted]	393	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	393	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭部損傷	20[redacted]	393	65	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心臓弁閉鎖不全	20[redacted]	447	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	非感染性歯肉炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頻尿	20[redacted]	29	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	106	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	爪床障害	20[redacted]	172	529	N	Grade 1	DOS		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	367	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	81	190	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	292	340	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	325	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	硝子体剥離	20[redacted]	360	272	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	436	196	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	小脳腫瘍	20[redacted]	519	113	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	.	185	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	180	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上気道感染	20[redacted]	200	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	200	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	パーキンソン病	20[redacted]	255	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	255	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	255	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	255	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	303	129	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高脂血症	20[redacted]	332	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	450	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻粘膜肥厚	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	喘息	20[redacted]	549	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	562	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	679	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	701	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	リンパ節症	20[redacted]	717	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	211	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	484	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	543	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	Ｃ－反応性蛋白増加	20[redacted]	543	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体重減少	20[redacted]	559	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	.	42	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	637	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	扁桃周囲膿瘍	20[redacted]	637	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃ポリープ	20[redacted]	637	81	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	消化性潰瘍	20[redacted]	646	70	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	.	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	狭心症	20[redacted]	.	113	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭位性回転性めまい	20[redacted]	6	103	N	Grade 1	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	118	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	118	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭位性回転性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	抑うつ気分	20[redacted]	.	366	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	525	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	弛緩歯	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	671	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨痛	20[redacted]	1	436	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副鼻腔ポリープ	20[redacted]	.	538	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	喘息	20[redacted]	439	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	591	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体液貯留	20[redacted]	56	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹部ヘルニア	20[redacted]	56	5	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	術後創感染	20[redacted]	87	148	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病	20[redacted]	93	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹部ヘルニア	20[redacted]	211	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	.	65	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	顎痛	20[redacted]	.	56	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	234	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	427	29	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	427	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	604	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	604	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性胃炎	20[redacted]	604	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胆石症	20[redacted]	604	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	虚血性脳卒中	20[redacted]	604	10	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心筋虚血	20[redacted]	43	6	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	183	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肝臓血管腫	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体位性めまい	20[redacted]	213	647	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋肉痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	294	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	364	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動悸	20[redacted]	.	288	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板障害	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	343	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	440	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	540	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	636	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心筋虚血	20[redacted]	636	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	歯の脱落	20[redacted]	2	365	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格痛	20[redacted]	147	275	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	163	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節滲出液	20[redacted]	163	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	218	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心室性期外収縮	20[redacted]	366	184	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	.	74	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	30	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳痛	20[redacted]	30	532	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	うつ病	20[redacted]	687	72	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	鼻炎	20[redacted]	.	255	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	心不全	20[redacted]	39	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	甲状腺腫	20[redacted]	40	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	自己免疫性甲状腺炎	20[redacted]	40	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	150	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	流涙増加	20[redacted]	151	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	挫傷	20[redacted]	.	41	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		8[redacted]	F	WHITE	くしゃみ	20[redacted]	368	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	9	115	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	71	328	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腸憩室	20[redacted]	71	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	123	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	302	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	420	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	420	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	454	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	身長減少	20[redacted]	548	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	弾発指	20[redacted]	154	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ムンプス	20[redacted]	307	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿疹	20[redacted]	44	70	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大動脈石灰化	20[redacted]	61	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	123	120	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	123	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障手術合併症	20[redacted]	123	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	146	77	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	弛緩歯	20[redacted]	162	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯膿瘍	20[redacted]	162	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	223	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	睡眠障害	20[redacted]	247	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	.	215	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻出血	20[redacted]	433	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	化生	20[redacted]	454	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性胃炎	20[redacted]	454	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯痛	20[redacted]	546	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	体重減少	20[redacted]	1	236	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	呼吸困難	20[redacted]	.	79	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	無力症	20[redacted]	.	79	N	Grade 3	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心拍数増加	20[redacted]	184	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	死亡	20[redacted]	236	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	52	7	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]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢非対称	20[redacted]	59	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	66	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	147	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	204	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	消化不良	20[redacted]	271	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	感情障害	20[redacted]	.	142	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	364	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下肢静止不能症候群	20[redacted]	422	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	448	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	495	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	714	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	フィブリンDダイマー増加	20[redacted]	30	137	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	結膜炎	20[redacted]	87	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	フィブリンDダイマー増加	20[redacted]	167	730	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	軟骨溶解	20[redacted]	267	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹痛	20[redacted]	.	38	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動脈硬化症	20[redacted]	504	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	左脚ブロック	20[redacted]	504	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃腸障害	20[redacted]	504	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆管炎	20[redacted]	504	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	504	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腸重積症	20[redacted]	504	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胃炎	20[redacted]	511	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	オッディ括約筋機能不全	20[redacted]	526	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	憩室炎	20[redacted]	526	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性脊椎症	20[redacted]	.	232	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	88	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	216	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	358	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節損傷	20[redacted]	358	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動脈硬化症	20[redacted]	648	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	648	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺腫	20[redacted]	648	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肋骨骨折	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	聴覚障害	20[redacted]	12	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	55	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性心不全	20[redacted]	134	.	Y	Grade 3	NOT RELATED	UNKNOWN	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	141	133	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	副腎腺腫	20[redacted]	141	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動脈硬化症	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心筋虚血	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性腎臓病	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚血管腫	20[redacted]	141	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脊柱変形	20[redacted]	141	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎嚢胞	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	静脈瘤	20[redacted]	141	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高マグネシウム血症	20[redacted]	182	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	甲状腺腫	20[redacted]	230	598	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	過角化	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	305	104	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	内出血発生の増加傾向	20[redacted]	335	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心不全	20[redacted]	678	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺線維症	20[redacted]	679	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	間質性肺疾患	20[redacted]	679	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不安	20[redacted]	685	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	123	10	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	145	40	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	185	6	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	齲歯	20[redacted]	.	30	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節腫脹	20[redacted]	276	95	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咽頭炎	20[redacted]	451	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	493	14	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	495	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	嘔吐	20[redacted]	27	1	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	回転性めまい	20[redacted]	27	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板障害	20[redacted]	131	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	198	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	242	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	運動耐性低下	20[redacted]	250	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	てんかん	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	湿性咳嗽	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食道静脈瘤	20[redacted]	256	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動脈硬化症	20[redacted]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耐糖能障害	20[redacted]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	門脈圧亢進性胃障害	20[redacted]	321	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	398	213	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	悪心	20[redacted]	398	84	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	好中球減少症	20[redacted]	420	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	好中球減少症	20[redacted]	446	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	好中球減少症	20[redacted]	480	59	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	549	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	718	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	53	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT 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]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	89	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂肪肝	20[redacted]	173	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	表在性血栓性静脈炎	20[redacted]	173	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧上昇	20[redacted]	195	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	238	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尺骨骨折	20[redacted]	238	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	238	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	238	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	238	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	298	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	348	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	348	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	アラニンアミノトランスフェラーゼ増加	20[redacted]	363	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	放屁	20[redacted]	375	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	表在性血栓性静脈炎	20[redacted]	491	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	545	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	545	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	546	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	658	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	左房拡張	20[redacted]	658	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心室壁運動低下	20[redacted]	658	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	711	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	呼吸困難	20[redacted]	427	41	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	427	9	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障手術	20[redacted]	427	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	432	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	椎骨脳底動脈不全	20[redacted]	432	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	15	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	101	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	272	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性虚血	20[redacted]	321	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚潰瘍	20[redacted]	338	72	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	410	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿動脈閉塞	20[redacted]	488	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	睡眠障害	20[redacted]	531	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚潰瘍	20[redacted]	636	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	659	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動脈硬化症	20[redacted]	662	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性腎臓病	20[redacted]	662	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎不全	20[redacted]	662	56	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	704	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎不全	20[redacted]	718	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血圧変動	20[redacted]	60	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	153	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	181	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	305	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	体重減少	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	360	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血中クレアチニン増加	20[redacted]	370	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血中尿素増加	20[redacted]	370	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	骨折痛	20[redacted]	373	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上皮成長因子受容体減少	20[redacted]	385	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	385	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	411	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	532	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尺骨骨折	20[redacted]	576	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	橈骨骨折	20[redacted]	576	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大動脈硬化症	20[redacted]	600	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	挫傷	20[redacted]	607	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢腫脹	20[redacted]	607	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	699	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	筋肉痛	20[redacted]	.	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	齲歯	20[redacted]	.	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	流涎過多	20[redacted]	43	149	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	そう痒症	20[redacted]	71	121	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	皮膚乾燥	20[redacted]	94	98	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肺の悪性新生物	20[redacted]	.	63	Y	Grade 5	NOT RELATED	FATAL	DRUG WITHDRAWN	MULTIPLE	Y
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	脳血管発作	20[redacted]	.	32	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	UNKNOWN	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	50	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	変形性関節症	20[redacted]	54	311	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚潰瘍	20[redacted]	.	81	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚乾燥	20[redacted]	152	122	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	疼痛	20[redacted]	177	188	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心不全	20[redacted]	195	170	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心房細動	20[redacted]	195	170	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	甲状腺新生物	20[redacted]	195	170	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胸水	20[redacted]	195	170	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胸膜線維症	20[redacted]	195	170	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	195	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	動脈硬化症	20[redacted]	209	156	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	右室機能不全	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	左室機能不全	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心室拡張	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	心房拡張	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	駆出率減少	20[redacted]	209	156	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	266	99	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚炎	20[redacted]	315	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	死亡	20[redacted]	364	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	爪破損	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨痛	20[redacted]	26	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧上昇	20[redacted]	.	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	106	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	149	35	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咽頭炎	20[redacted]	186	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咽頭炎	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	456	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	左脚ブロック	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白血球増加症	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	第一度房室ブロック	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎盂腎杯拡張症	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血圧低下	20[redacted]	456	8	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頚動脈硬化症	20[redacted]	456	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	上室性不整脈	20[redacted]	461	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病	20[redacted]	463	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咽頭炎	20[redacted]	466	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	灼熱感	20[redacted]	533	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯膿瘍	20[redacted]	610	16	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	102	237	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	記憶障害	20[redacted]	185	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	甲状腺新生物	20[redacted]	244	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糸球体濾過率減少	20[redacted]	273	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ヘルペスウイルス感染	20[redacted]	275	278	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	355	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	370	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	420	295	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	420	295	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	524	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	525	12	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	724	3	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	733	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	変形性脊椎症	20[redacted]	308	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	5[redacted]	F	WHITE	子宮脱	20[redacted]	528	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	薬物不耐性	20[redacted]	25	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性消化管感染	20[redacted]	70	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼圧上昇	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	黄斑変性	20[redacted]	85	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	フィブリンDダイマー増加	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	383	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	副鼻腔炎	20[redacted]	385	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	687	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	56	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	121	830	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	会話障害	20[redacted]	157	1	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	霧視	20[redacted]	157	1	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	157	210	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨膜炎	20[redacted]	163	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	187	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	672	279	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	骨痛	20[redacted]	672	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	洞性徐脈	20[redacted]	13	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED		
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	びらん性胃炎	20[redacted]	68	78	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節滲出液	20[redacted]	129	107	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節痛	20[redacted]	129	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節滲出液	20[redacted]	236	198	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	253	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	うつ病	20[redacted]	464	138	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	体重減少	20[redacted]	464	138	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	栄養障害	20[redacted]	573	29	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	97	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	肺炎	20[redacted]	145	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	156	47	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	骨痛	20[redacted]	234	45	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大腸ポリープ	20[redacted]	533	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大動脈拡張	20[redacted]	596	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	640	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	痔核	20[redacted]	645	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高コレステロール血症	20[redacted]	645	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧性血管障害	20[redacted]	645	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	黄斑変性	20[redacted]	645	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎動脈狭窄症	20[redacted]	651	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯牙破折	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	353	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	網膜剥離	20[redacted]	510	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	1	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	60	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯膿瘍	20[redacted]	93	27	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	141	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚局面	20[redacted]	154	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	168	18	N	Grade 1	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	176	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃炎	20[redacted]	180	150	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	183	579	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸ポリープ	20[redacted]	291	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	憩室	20[redacted]	291	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	結腸新生物	20[redacted]	291	80	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	そう痒症	20[redacted]	317	594	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	343	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	.	350	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	92	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	感染による慢性閉塞性気道疾患の増悪	20[redacted]	96	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嘔吐	20[redacted]	101	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	感染による慢性閉塞性気道疾患の増悪	20[redacted]	115	8	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	148	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	148	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	206	380	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	274	39	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脱毛症	20[redacted]	333	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	437	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	689	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	689	24	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	689	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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	689	23	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性心不全	20[redacted]	711	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	712	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	発疹	20[redacted]	.	335	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上室性期外収縮	20[redacted]	288	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	521	7	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	521	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	うつ病	20[redacted]	527	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ほてり	20[redacted]	7	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	多汗症	20[redacted]	7	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	回転性めまい	20[redacted]	51	.	N	Grade 2	RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	159	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疼痛	20[redacted]	424	538	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	意識消失	20[redacted]	492	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	500	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	第７脳神経麻痺	20[redacted]	712	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	四肢痛	20[redacted]	77	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	無力症	20[redacted]	150	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	頭痛	20[redacted]	167	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	節足動物咬傷	20[redacted]	169	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	鼻出血	20[redacted]	206	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	不眠症	20[redacted]	223	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	不整脈	20[redacted]	323	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	注射部位疼痛	20[redacted]	330	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	筋炎	20[redacted]	332	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	腰椎骨折	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	筋肉痛	20[redacted]	375	30	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	口腔ヘルペス	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	慢性リンパ性白血病	20[redacted]	405	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	PLACEBO		6[redacted]	F	WHITE	変形性関節症	20[redacted]	419	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	167	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ヘモグロビン減少	20[redacted]	552	233	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	55	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳鳴	20[redacted]	71	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	115	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ球増加症	20[redacted]	282	84	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	302	28	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	不整脈	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	空腹時血中ブドウ糖不良	20[redacted]	365	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脱毛症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	.	.	Y	Grade 2	NOT RELATED	UNKNOWN	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	576	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上室性不整脈	20[redacted]	576	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上室性頻脈	20[redacted]	576	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	576	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性心不全	20[redacted]	576	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	心雑音	20[redacted]	736	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	細菌性扁桃炎	20[redacted]	174	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	空腹時血中ブドウ糖不良	20[redacted]	183	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	発作性頻脈	20[redacted]	193	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動悸	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	倦怠感	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	245	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血尿	20[redacted]	245	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	278	275	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上気道感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	回転性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	動脈硬化症	20[redacted]	465	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	三尖弁閉鎖不全症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低カリウム血症	20[redacted]	553	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	553	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	553	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心室性不整脈	20[redacted]	554	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心房細動	20[redacted]	560	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	上腹部痛	20[redacted]	566	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋骨骨折	20[redacted]	41	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	48	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発疹	20[redacted]	58	32	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋骨骨折	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	258	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	258	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不眠症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	710	31	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心不全	20[redacted]	.	204	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	頭部損傷	20[redacted]	127	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	死亡	20[redacted]	211	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の脱落	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	記憶障害	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	不眠症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	259	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血糖	20[redacted]	529	.	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]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	.	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	.	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発熱	20[redacted]	.	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脱水	20[redacted]	.	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血糖	20[redacted]	.	25	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	.	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動脈硬化症	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	.	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心不全	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	.	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病性ケトアシドーシス	20[redacted]	.	56	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脱水	20[redacted]	.	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	逆流性胃炎	20[redacted]	.	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	唾液腺の良性新生物	20[redacted]	.	46	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	SURGICAL INTERVENTION	N
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	180	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肝損傷	20[redacted]	552	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	急性冠動脈症候群	20[redacted]	3	6	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性膵炎	20[redacted]	116	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢損傷	20[redacted]	117	.	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]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	損傷	20[redacted]	117	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	橈骨骨折	20[redacted]	117	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	117	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	117	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭部損傷	20[redacted]	117	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢痛	20[redacted]	118	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性膵炎	20[redacted]	243	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	272	12	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	299	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	洞性徐脈	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性膵炎	20[redacted]	399	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	白内障	20[redacted]	432	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	慢性膵炎	20[redacted]	606	1	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	膵嚢胞	20[redacted]	606	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	膵嚢胞破裂	20[redacted]	632	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯周炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性冠動脈症候群	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	236	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	350	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高マグネシウム血症	20[redacted]	371	89	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

Subject Identifier for the Study	Country	Actual Treatment for Period 01	Actual Treatment for Period 02	Age	Sex	Race	Dictionary-Derived Term	Start Date/Time of Adverse Event	Study Day of Start of Adverse Event	Duration in Days	Serious Event	Toxicity Grade	Causality	Outcome of Serious Adverse Event	Action Taken with Study Treatment	Other Action Taken	Results in Death
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	緑内障	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高マグネシウム血症	20[redacted]	566	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	冠動脈疾患	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	卵巣嚢胞	20[redacted]	683	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	胸痛	20[redacted]	80	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	死亡	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	MULTIPLE	Y
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	120	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO		7[redacted]	F	WHITE	上腹部痛	20[redacted]	.	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	21	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	161	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	245	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	301	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	血栓性静脈炎	20[redacted]	338	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚カンジダ	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	四肢不快感	20[redacted]	15	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	下痢	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	大腸菌性膀胱炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	無力症	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	139	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胃腸出血	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	大腸腺腫	20[redacted]	292	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	憩室	20[redacted]	292	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	痔核	20[redacted]	292	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	神経症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	上気道感染	20[redacted]	422	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	回転性めまい	20[redacted]	422	23	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	血圧上昇	20[redacted]	422	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	白内障	20[redacted]	.	17	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	末梢動脈閉塞性疾患	20[redacted]	55	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高血圧	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	低血圧	20[redacted]	203	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	238	16	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	血小板増加症	20[redacted]	265	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	尿路感染	20[redacted]	273	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	高マグネシウム血症	20[redacted]	277	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	副腎新生物	20[redacted]	300	.	N	Grade 3	NOT RELATED		DRUG WITHDRAWN	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肺新生物	20[redacted]	300	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	肺線維症	20[redacted]	300	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	OTHER	
[redacted]	POLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	貧血	20[redacted]	300	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳鳴	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	膀胱炎	20[redacted]	71	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	89	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ヘリコバクター感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎結石症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	副腎腺腫	20[redacted]	158	345	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺腫	20[redacted]	158	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	201	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	節足動物咬傷	20[redacted]	261	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低カリウム血症	20[redacted]	263	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	304	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	308	1	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	MULTIPLE	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上腹部痛	20[redacted]	313	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	筋骨格痛	20[redacted]	313	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	POLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	原発性アルドステロン症	20[redacted]	349	154	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ROMANIA	PLACEBO		8[redacted]	F	WHITE	乳房新生物	20[redacted]	50	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	二分脊椎	20[redacted]	385	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性気道感染	20[redacted]	.	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	内臓ヘルニア	20[redacted]	589	3	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	咳嗽	20[redacted]	.	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	ROMANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	ウイルス性気道感染	20[redacted]	85	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	胸膜の良性新生物	20[redacted]	127	8	Y	Grade 3	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	120	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大脳萎縮	20[redacted]	151	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	意識消失	20[redacted]	151	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚損傷	20[redacted]	151	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳出血	20[redacted]	151	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭蓋脳損傷	20[redacted]	151	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	249	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	334	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	肝細胞損傷	20[redacted]	31	38	Y	Grade 3	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	胆汁うっ滞	20[redacted]	52	129	Y	Grade 2	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	抗核抗体増加	20[redacted]	68	49	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	副腎新生物	20[redacted]	89	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	大動脈硬化症	20[redacted]	89	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	腎結石症	20[redacted]	89	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	アスパラギン酸アミノトランスフェラーゼ増加	20[redacted]	155	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	アラニンアミノトランスフェラーゼ増加	20[redacted]	155	26	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	高血圧	20[redacted]	283	59	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	歯の障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	

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[redacted]	ROMANIA	PLACEBO		7[redacted]	F	WHITE	本態性高血圧症	20[redacted]	341	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	.	25	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	死亡	20[redacted]	.	.	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	359	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ節症	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管新生物	20[redacted]	444	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	甲状腺新生物	20[redacted]	444	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺動脈血栓症	20[redacted]	444	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺転移	20[redacted]	444	.	N	Grade 2	NOT RELATED		DRUG WITHDRAWN	OTHER	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重減少	20[redacted]	476	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	気管支炎	20[redacted]	204	11	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	足骨折	20[redacted]	253	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	500	34	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	呼吸不全	20[redacted]	521	13	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	UNKNOWN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脂肪肝	20[redacted]	521	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性呼吸不全	20[redacted]	533	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	好中球増加症	20[redacted]	556	181	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯牙損傷	20[redacted]	605	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肝嚢胞	20[redacted]	651	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎嚢胞	20[redacted]	651	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	急性呼吸不全	20[redacted]	660	16	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	糖尿病性腎症	20[redacted]	667	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肥満	20[redacted]	736	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	糖尿病	20[redacted]	32	57	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動脈硬化性網膜症	20[redacted]	137	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	137	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体重増加	20[redacted]	365	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性気道感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	573	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	659	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脂質異常症	20[redacted]	147	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	147	128	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭痛	20[redacted]	147	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	147	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	高血圧	20[redacted]	147	4	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	僧帽弁閉鎖不全症	20[redacted]	148	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	大動脈弁閉鎖不全症	20[redacted]	148	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鼻漏	20[redacted]	376	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆石症	20[redacted]	387	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脂肪肝	20[redacted]	387	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎結石症	20[redacted]	387	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腎障害	20[redacted]	387	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	過敏症	20[redacted]	569	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	感音性難聴	20[redacted]	8	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体重増加	20[redacted]	183	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	齲歯	20[redacted]	577	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿生殖器脱	20[redacted]	632	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿生殖器脱	20[redacted]	636	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	ROMANIA	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯膿瘍	20[redacted]	721	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ビタミンD過剰症	20[redacted]	1	22	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の脱落	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の脱落	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	サルモネラ症	20[redacted]	442	22	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎不全	20[redacted]	452	35	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低カルシウム血症	20[redacted]	458	28	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	副甲状腺機能亢進症	20[redacted]	458	115	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鉄芽球性貧血	20[redacted]	463	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	594	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SPAIN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	85	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SPAIN	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	虫垂炎	20[redacted]	347	7	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	季節性アレルギー	20[redacted]	99	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腱断裂	20[redacted]	316	53	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	処置による疼痛	20[redacted]	367	91	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]	SPAIN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	正常圧水頭症	20[redacted]	151	5	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SPAIN	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口腔真菌感染	20[redacted]	162	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	2	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚嚢腫	20[redacted]	156	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	211	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	急性腎盂腎炎	20[redacted]	266	73	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	SPAIN	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯牙破折	20[redacted]	545	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	PLACEBO		6[redacted]	F	WHITE	頭痛	20[redacted]	150	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO		6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	162	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO		6[redacted]	F	WHITE	背部痛	20[redacted]	170	71	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO		6[redacted]	F	WHITE	腰椎骨折	20[redacted]	170	71	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SWITZERLAND	PLACEBO		6[redacted]	F	WHITE	卵巣癌	20[redacted]	211	.	Y	Grade 4	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	154	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	急性膵炎	20[redacted]	245	5	Y	Grade 3	RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	2	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	口内乾燥	20[redacted]	2	6	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	口渇	20[redacted]	2	6	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	嗅覚錯誤	20[redacted]	2	6	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	2	6	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	2	6	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食欲減退	20[redacted]	2	6	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	アフタ性潰瘍	20[redacted]	12	3	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]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	15	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	悪心	20[redacted]	15	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	15	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	34	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	手骨折	20[redacted]	40	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	根症候群	20[redacted]	42	136	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	203	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節障害	20[redacted]	721	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	医療機器不快感	20[redacted]	204	2	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	41	146	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	褐色細胞腫	20[redacted]	60	50	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	87	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失神	20[redacted]	88	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	88	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	マロリー・ワイス症候群	20[redacted]	89	70	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	吐血	20[redacted]	89	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嘔吐	20[redacted]	89	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	吐血	20[redacted]	90	3	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	誤嚥性肺炎	20[redacted]	101	9	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格硬直	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	老人性難聴	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腱鞘炎	20[redacted]	.	551	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	186	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体温変動感	20[redacted]	243	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	266	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	298	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	682	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭位性回転性めまい	20[redacted]	682	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	683	194	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳振盪	20[redacted]	683	4	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂傷	20[redacted]	683	27	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	683	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歩行障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肋骨骨折	20[redacted]	4	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	14	151	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	28	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胸部損傷	20[redacted]	35	24	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	浮動性めまい	20[redacted]	55	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹部膨満	20[redacted]	59	198	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	悪心	20[redacted]	60	1	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	73	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	124	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	130	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血腫	20[redacted]	177	39	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	節足動物咬傷	20[redacted]	200	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	節足動物咬傷	20[redacted]	200	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	節足動物咬傷アレルギー	20[redacted]	200	57	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	222	35	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	放屁	20[redacted]	257	90	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	293	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	情動障害	20[redacted]	348	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血腫	20[redacted]	353	26	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	353	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	疲労	20[redacted]	393	259	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性関節症	20[redacted]	449	190	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	嚢胞	20[redacted]	483	169	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	.	65	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	悪寒	20[redacted]	1	10	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	悪心	20[redacted]	1	8	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	1	2	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	斑状皮疹	20[redacted]	3	8	Y	Grade 2	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	発熱	20[redacted]	3	5	N	Grade 3	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	アフタ性潰瘍	20[redacted]	4	5	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	剥脱性皮膚炎	20[redacted]	28	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	発熱	20[redacted]	28	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	舌痛	20[redacted]	28	6	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	血管浮腫	20[redacted]	28	4	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N

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[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	表皮融解	20[redacted]	33	4	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	そう痒症	20[redacted]	38	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	皮膚びらん	20[redacted]	38	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	斑状皮疹	20[redacted]	134	15	Y	Grade 3	RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高カルシウム血症	20[redacted]	1	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	半月板損傷	20[redacted]	8	44	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	8	49	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	半月板損傷	20[redacted]	35	16	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	168	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	節足動物咬傷	20[redacted]	174	47	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	188	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	半月板損傷	20[redacted]	214	117	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	半月板損傷	20[redacted]	256	75	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	293	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	処置後炎症	20[redacted]	329	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	340	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	白内障	20[redacted]	.	97	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻乾燥	20[redacted]	5	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	7	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	28	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下痢	20[redacted]	49	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	53	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	.	237	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]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨骨折	20[redacted]	91	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	91	170	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	91	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ビタミンＢ１２欠乏	20[redacted]	96	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血管性脳症	20[redacted]	103	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	皮膚障害	20[redacted]	.	91	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	219	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尾骨痛	20[redacted]	220	20	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	220	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	うつ病	20[redacted]	230	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肩回旋筋腱板症候群	20[redacted]	314	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊柱管狭窄症	20[redacted]	314	34	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脊椎すべり症	20[redacted]	324	24	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	326	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	処置による疼痛	20[redacted]	336	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	336	112	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	術後貧血	20[redacted]	336	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	TRANSFUSION PERFORMED	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高血圧	20[redacted]	336	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋萎縮性側索硬化症	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	体重減少	20[redacted]	368	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	弛緩歯	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	427	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N

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[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋萎縮性側索硬化症	20[redacted]	511	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ストーマ部膿瘍	20[redacted]	529	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯の脱落	20[redacted]	594	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	好中球減少症	20[redacted]	1	98	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頭痛	20[redacted]	93	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	93	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	癌手術	20[redacted]	155	73	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発声障害	20[redacted]	162	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ球増加症	20[redacted]	185	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	好中球減少症	20[redacted]	185	383	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	185	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃腸炎	20[redacted]	222	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血腫	20[redacted]	294	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	294	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	動物咬傷	20[redacted]	422	135	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	515	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	515	22	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	そう痒症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	628	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	633	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	腱炎	20[redacted]	23	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	上腹部痛	20[redacted]	27	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	上腹部痛	20[redacted]	51	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	

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[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	歯牙破折	20[redacted]	109	137	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	ほてり	20[redacted]	141	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	ヘリコバクター性胃炎	20[redacted]	141	123	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	労作性呼吸困難	20[redacted]	141	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	頚部痛	20[redacted]	320	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	治癒不良	20[redacted]	363	73	Y	Grade 1	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	OTHER	N
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	肩回旋筋腱板症候群	20[redacted]	365	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	口腔真菌感染	20[redacted]	372	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	過敏性腸症候群	20[redacted]	519	126	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	SWITZERLAND	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胃炎	20[redacted]	525	104	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性気道感染	20[redacted]	.	42	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血小板数増加	20[redacted]	1	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	細菌性尿路感染	20[redacted]	87	36	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	178	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	葉酸欠乏性貧血	20[redacted]	194	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	血小板増加症	20[redacted]	194	14	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	268	36	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	カテーテル留置部位血腫	20[redacted]	294	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	.	45	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	373	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	胃食道逆流性疾患	20[redacted]	642	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	好中球減少症	20[redacted]	34	530	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	橈骨骨折	20[redacted]	149	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺炎	20[redacted]	177	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	変形性脊椎症	20[redacted]	212	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼そう痒症	20[redacted]	.	59	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	流涙増加	20[redacted]	356	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	創傷出血	20[redacted]	445	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	挫傷	20[redacted]	445	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	445	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼出血	20[redacted]	455	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	485	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	504	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	貧血	20[redacted]	549	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	1	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	109	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	165	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	便秘	20[redacted]	168	5	N	Grade 2	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	胃炎	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	卵巣癌	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	尿路感染	20[redacted]	35	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	四肢痛	20[redacted]	38	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	乳房痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	肺腫瘤	20[redacted]	230	172	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	OTHER	N
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	脂肪肝	20[redacted]	301	.	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]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	高カリウム血症	20[redacted]	301	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	皮膚乾燥	20[redacted]	.	30	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	尿路感染	20[redacted]	371	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	尿路感染	20[redacted]	393	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	474	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	痛風	20[redacted]	534	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	発疹	20[redacted]	566	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	尿路感染	20[redacted]	695	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	鉄欠乏性貧血	20[redacted]	224	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	末梢性浮腫	20[redacted]	343	119	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	紅斑	20[redacted]	343	119	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	副腎腫瘤	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	憩室	20[redacted]	356	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格硬直	20[redacted]	533	358	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	脳血管発作	20[redacted]	591	1	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	四肢損傷	20[redacted]	7	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚擦過傷	20[redacted]	7	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格痛	20[redacted]	7	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格系胸痛	20[redacted]	7	87	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	7	450	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	転倒	20[redacted]	7	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頭部損傷	20[redacted]	7	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	

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[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	帯状疱疹	20[redacted]	82	119	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	88	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	抑うつ気分	20[redacted]	108	349	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	皮膚感染	20[redacted]	156	11	Y	Grade 4	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	不眠症	20[redacted]	261	218	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋痙縮	20[redacted]	292	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	腹部圧痛	20[redacted]	334	107	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	咳嗽	20[redacted]	416	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	胆石症	20[redacted]	441	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	呼吸困難	20[redacted]	478	185	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋痙縮	20[redacted]	626	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	716	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	動悸	20[redacted]	28	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	非心臓性胸痛	20[redacted]	28	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	138	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	頭痛	20[redacted]	214	36	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	268	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	低ナトリウム血症	20[redacted]	276	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腿骨頚部骨折	20[redacted]	285	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	285	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	関節痛	20[redacted]	285	75	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢循環不良	20[redacted]	322	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢性浮腫	20[redacted]	322	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	水疱破裂	20[redacted]	351	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	呼吸困難	20[redacted]	353	67	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	水疱	20[redacted]	353	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格不快感	20[redacted]	353	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	水疱	20[redacted]	357	173	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	左室機能不全	20[redacted]	420	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高カリウム血症	20[redacted]	529	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発疹	20[redacted]	632	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	歯肉退縮	20[redacted]	656	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳感染	20[redacted]	149	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腟脱	20[redacted]	.	128	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節腫脹	20[redacted]	41	23	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低血糖	20[redacted]	108	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	[redacted]	147	101	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	頚部痛	20[redacted]	163	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低血糖	20[redacted]	213	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	8[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	356	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	糖尿病	20[redacted]	366	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	背部痛	20[redacted]	447	11	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	低血糖	20[redacted]	545	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	8[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	636	1	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎機能障害	20[redacted]	13	910	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	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	61	32	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	背部痛	20[redacted]	94	.	N	Grade 1	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	呼吸困難	20[redacted]	228	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	254	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	323	37	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	胃腸炎	20[redacted]	423	4	N	Grade 1	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	急性腎不全	20[redacted]	540	6	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	543	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	7[redacted]	F	WHITE	下気道感染	20[redacted]	715	205	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	715	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	64	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肉離れ	20[redacted]	104	14	N	Grade 1	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	歯肉退縮	20[redacted]	153	.	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	子宮腟脱	20[redacted]	622	87	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	腹部ヘルニア	20[redacted]	97	187	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	膀胱脱	20[redacted]	177	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	注射部位紅斑	20[redacted]	212	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	呼吸困難	20[redacted]	279	33	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	排尿困難	20[redacted]	309	152	N	Grade 1	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	関節痛	20[redacted]	194	.	N	Grade 1	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	筋肉痛	20[redacted]	201	.	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	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	236	4	N	Grade 1	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	四肢痛	20[redacted]	305	6	N	Grade 1	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	顎痛	20[redacted]	320	4	N	Grade 1	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	インフルエンザ様疾患	20[redacted]	328	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	7[redacted]	F	WHITE	関節痛	20[redacted]	346	4	N	Grade 1	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	四肢痛	20[redacted]	377	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	7[redacted]	F	WHITE	ボーエン病	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	基底細胞癌	20[redacted]	.	258	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	SURGICAL INTERVENTION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	白内障	20[redacted]	.	.	N	Grade 1	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	鼻咽頭炎	20[redacted]	535	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尾骨痛	20[redacted]	177	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下痢	20[redacted]	215	8	N	Grade 2	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	低カリウム血症	20[redacted]	215	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	小腸閉塞	20[redacted]	215	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹部ヘルニア	20[redacted]	306	.	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	腹部不快感	20[redacted]	309	.	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	上腕骨骨折	20[redacted]	644	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	黄斑変性	20[redacted]	2	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	33	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	四肢痛	20[redacted]	130	644	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	筋骨格痛	20[redacted]	215	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	口腔内潰瘍形成	20[redacted]	628	39	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	膀胱炎	20[redacted]	628	14	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	薬物過敏症	20[redacted]	661	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	6[redacted]	F	WHITE	薬物過敏症	20[redacted]	661	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	6[redacted]	F	WHITE	肺炎	20[redacted]	662	9	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	薬物過敏症	20[redacted]	662	2	N	Grade 2	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	慢性閉塞性肺疾患	20[redacted]	17	16	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	48	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	呼吸困難	20[redacted]	75	674	N	Grade 2	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	眼部手術合併症	20[redacted]	157	.	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	慢性閉塞性肺疾患	20[redacted]	174	83	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	消化不良	20[redacted]	228	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	318	32	N	Grade 2	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	高血圧	20[redacted]	341	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	350	21	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	呼吸困難	20[redacted]	384	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高コレステロール血症	20[redacted]	392	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	狭心症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	489	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	501	21	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	550	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	.	.	N	Grade 2	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	慢性閉塞性肺疾患	20[redacted]	643	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	女性乳癌	20[redacted]	38	111	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	転倒	20[redacted]	71	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	発声障害	20[redacted]	78	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	乳房嚢胞	20[redacted]	107	50	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	筋痙縮	20[redacted]	116	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	嗜眠	20[redacted]	157	29	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	関節痛	20[redacted]	177	15	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	爪破損	20[redacted]	199	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	関節痛	20[redacted]	255	490	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	嗜眠	20[redacted]	.	43	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	咳嗽	20[redacted]	472	396	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	異物感	20[redacted]	472	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	口腔咽頭痛	20[redacted]	654	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腹痛	20[redacted]	28	1	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	脳血管発作	20[redacted]	47	18	Y	Grade 2	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	49	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	高コレステロール血症	20[redacted]	64	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	心房細動	20[redacted]	118	.	N	Grade 2	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咽喉乾燥	20[redacted]	157	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	630	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	医療機器不具合	20[redacted]	21	11	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	外陰部腟カンジダ症	20[redacted]	35	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	薬物性肝障害	20[redacted]	36	29	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	48	2	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	動物アレルギー	20[redacted]	91	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	105	129	N	Grade 2	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	筋骨格痛	20[redacted]	105	129	N	Grade 2	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	うつ病	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	全身性そう痒症	20[redacted]	122	18	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	インフルエンザ様疾患	20[redacted]	145	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	600	39	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	60	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	200	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	外陰膣乾燥	20[redacted]	252	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	342	9	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	呼吸困難	20[redacted]	344	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	344	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	２型糖尿病	20[redacted]	369	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	452	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	深部静脈血栓症	20[redacted]	517	.	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺塞栓症	20[redacted]	518	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	547	3	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹部膨満	20[redacted]	15	132	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	上気道感染	20[redacted]	171	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	嚢胞	20[redacted]	244	12	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	神経圧迫	20[redacted]	390	2	Y	Grade 2	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]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	関節炎	20[redacted]	40	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	悪心	20[redacted]	64	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	64	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	下痢	20[redacted]	118	2	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	嘔吐	20[redacted]	118	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	うつ病	20[redacted]	380	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	尿路感染	20[redacted]	457	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	帯状疱疹	20[redacted]	532	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	失神	20[redacted]	604	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		8[redacted]	F	WHITE	心筋梗塞	20[redacted]	320	2	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	Y
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	2	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発疹	20[redacted]	66	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	537	56	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	537	56	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	592	225	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	呼吸困難	20[redacted]	.	.	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	皮膚真菌感染	20[redacted]	34	43	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	挫傷	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浮動性めまい	20[redacted]	.	.	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	高コレステロール血症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	２ａ型高脂血症	20[redacted]	.	.	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	一過性脳虚血発作	20[redacted]	316	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	一過性脳虚血発作	20[redacted]	322	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	錯感覚	20[redacted]	368	.	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	第７脳神経麻痺	20[redacted]	378	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳感染	20[redacted]	397	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	546	4	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	倦怠感	20[redacted]	1	2	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	末梢腫脹	20[redacted]	51	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ほてり	20[redacted]	.	.	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	無力症	20[redacted]	.	135	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	175	21	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	175	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	眼窩周囲血腫	20[redacted]	256	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	裂傷	20[redacted]	256	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	.	93	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	神経根圧迫	20[redacted]	432	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	20	8	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	151	18	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱炎	20[redacted]	305	8	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	直腸瘤	20[redacted]	.	482	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	膀胱瘤	20[redacted]	.	482	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	失禁	20[redacted]	400	79	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	帯状疱疹	20[redacted]	609	40	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	高血圧	20[redacted]	71	183	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	下痢	20[redacted]	197	57	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	尿管穿孔	20[redacted]	213	41	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	腸管穿孔	20[redacted]	213	41	Y	Grade 3	NOT RELATED	RESOLVED	DOSE ALTERED OR WITHHELD	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	多臓器不全	20[redacted]	253	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	NO ACTION TAKEN	Y
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	浸潤性乳管癌	20[redacted]	57	373	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脱毛症	20[redacted]	.	.	N	Grade 2	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	胃食道逆流性疾患	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	憩室炎	20[redacted]	.	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	219	22	N	Grade 2	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	疼痛	20[redacted]	219	22	N	Grade 2	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	ブドウ球菌感染	20[redacted]	226	7	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	疲労	20[redacted]	261	22	N	Grade 2	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	筋肉痛	20[redacted]	261	22	N	Grade 2	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	爪真菌症	20[redacted]	305	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	呼吸困難	20[redacted]	.	.	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	疲労	20[redacted]	.	.	N	Grade 2	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	筋骨格系胸痛	20[redacted]	.	.	N	Grade 2	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	記憶障害	20[redacted]	.	.	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	消化管感染	20[redacted]	.	46	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	坐骨神経痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋膿瘍	20[redacted]	.	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	背部痛	20[redacted]	100	48	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	筋骨格痛	20[redacted]	210	3	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	坐骨神経痛	20[redacted]	212	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胃腸炎	20[redacted]	309	34	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	ストーマ部虚血	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	敗血症	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	腹部創離開	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	腸閉塞	20[redacted]	342	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食道扁平上皮癌	20[redacted]	.	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腎嚢胞	20[redacted]	481	.	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	肛門直腸障害	20[redacted]	569	.	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	胆管拡張	20[redacted]	569	.	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	膵管拡張	20[redacted]	569	.	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	処置後合併症	20[redacted]	.	.	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	.	.	N	Grade 2	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	白血球数増加	20[redacted]	.	.	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	創部分泌	20[redacted]	717	.	N	Grade 2	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	直腸脱	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	術後貧血	20[redacted]	731	27	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	マロリー・ワイス症候群	20[redacted]	44	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	44	.	Y	Grade 1	NOT 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	憩室	20[redacted]	596	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	113	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹痛	20[redacted]	151	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	241	2	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	423	19	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	517	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	546	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	大腿骨頚部骨折	20[redacted]	623	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低カルシウム血症	20[redacted]	629	6	N	Grade 1	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	変形性骨炎	20[redacted]	23	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	倦怠感	20[redacted]	35	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	便秘	20[redacted]	.	92	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	上気道感染	20[redacted]	107	13	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	軟部組織損傷	20[redacted]	221	48	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]	UNITED KINGDOM	AMG 785 210 MG SC QM		7[redacted]	F	WHITE	転倒	20[redacted]	221	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ウイルス性気管支炎	20[redacted]	282	12	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	気管支炎	20[redacted]	306	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	肺炎	20[redacted]	571	22	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	681	17	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	椎間板突出	20[redacted]	109	39	N	Grade 2	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	脊柱管狭窄症	20[redacted]	109	39	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	歯肉炎	20[redacted]	357	5	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚乳頭腫	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE ALTERED OR WITHHELD	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	164	23	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	多汗症	20[redacted]	.	.	N	Grade 2	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	背部痛	20[redacted]	.	.	N	Grade 2	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	呼吸困難	20[redacted]	565	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	冠動脈狭窄	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	歯肉炎	20[redacted]	119	13	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	大腿骨骨折	20[redacted]	196	.	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	196	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	転倒	20[redacted]	196	1	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	術後貧血	20[redacted]	197	2	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	基底扁平上皮癌	20[redacted]	.	.	Y	Grade 1	NOT 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	ワクチン接種部位内出血	20[redacted]	34	14	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	下気道感染	20[redacted]	287	15	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	穿孔性虫垂炎	20[redacted]	472	17	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N

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[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	瘢痕	20[redacted]	520	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	698	.	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	浮動性めまい	20[redacted]	.	38	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	靭帯捻挫	20[redacted]	284	18	N	Grade 1	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	脳血管発作	20[redacted]	562	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	デュプイトラン拘縮	20[redacted]	.	.	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	起立性低血圧	20[redacted]	.	42	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	発疹	20[redacted]	604	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	側弯症	20[redacted]	639	.	N	Grade 1	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	椎間板突出	20[redacted]	639	.	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	椎間板腔狭窄	20[redacted]	639	.	N	Grade 1	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	脊椎すべり症	20[redacted]	639	.	N	Grade 1	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	関節痛	20[redacted]	639	.	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	頚動脈硬化症	20[redacted]	639	.	N	Grade 1	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	上腕骨骨折	20[redacted]	.	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	転倒	20[redacted]	202	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	感染性皮膚嚢腫	20[redacted]	321	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大動脈瘤	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	医療機器不具合	20[redacted]	31	27	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺塞栓症	20[redacted]	529	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	714	8	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	

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[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	そう痒症	20[redacted]	1	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	筋骨格痛	20[redacted]	10	48	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	貧血	20[redacted]	177	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	8[redacted]	F	WHITE	心不全	20[redacted]	676	1	Y	Grade 5	NOT RELATED	FATAL	DOSE NOT CHANGED	UNKNOWN	Y
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	耳垢分泌過多	20[redacted]	2	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	末梢性浮腫	20[redacted]	8	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	皮膚擦過傷	20[redacted]	52	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	52	1	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	121	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	163	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	転倒	20[redacted]	248	1	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	248	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	インフルエンザ	20[redacted]	330	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	333	7	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	427	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	感染による慢性閉塞性気道疾患の増悪	20[redacted]	509	10	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	583	7	N	Grade 3	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	712	7	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上気道感染	20[redacted]	19	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	軟部組織損傷	20[redacted]	90	.	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	軟部組織損傷	20[redacted]	90	.	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	転倒	20[redacted]	90	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	上気道感染	20[redacted]	.	106	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腹痛	20[redacted]	.	324	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	発声障害	20[redacted]	.	.	N	Grade 2	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	喘息	20[redacted]	270	8	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	食道運動障害	20[redacted]	434	.	N	Grade 2	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	手根管症候群	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	SURGICAL INTERVENTION	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	四肢痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	痔核	20[redacted]	183	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MULTIPLE	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	210	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	そう痒症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	咳嗽	20[redacted]	332	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	474	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	524	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	下気道感染	20[redacted]	531	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肺腺癌	20[redacted]	745	.	Y	Grade 3	NOT RELATED	NOT RESOLVED	DOSE ALTERED OR WITHHELD	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	変形性関節症	20[redacted]	.	55	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性迷路炎	20[redacted]	69	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	平衡障害	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋痙縮	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	視力低下	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]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	肉離れ	20[redacted]	237	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腱損傷	20[redacted]	258	19	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	筋骨格痛	20[redacted]	285	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	357	5	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	口腔咽頭痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	憩室	20[redacted]	445	.	Y	Grade 1	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	NO ACTION TAKEN	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	背部痛	20[redacted]	463	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	大腸ポリープ	20[redacted]	499	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	レイノー現象	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	尿路感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高血圧	20[redacted]	2	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	骨減少症	20[redacted]	5	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	Y	Grade 2	NOT RELATED	NOT RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	242	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	上室性頻脈	20[redacted]	269	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	中耳炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節脱臼	20[redacted]	498	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	低カリウム血症	20[redacted]	744	.	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	悪心	20[redacted]	1	22	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	上気道感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	リンパ節症	20[redacted]	.	29	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	DEVICE/PROCEDURE INTERVENTION	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]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	四肢痛	20[redacted]	.	.	N	Grade 2	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	外陰腟乾燥	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	回転性めまい	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節腫脹	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	腸閉塞	20[redacted]	17	2	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	憩室	20[redacted]	92	5	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	胃炎	20[redacted]	98	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM		6[redacted]	F	WHITE	下肢静止不能症候群	20[redacted]	.	.	N	Grade 2	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	下気道感染	20[redacted]	4	11	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	121	6	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	127	9	N	Grade 2	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	ビタミンＢ１２欠乏	20[redacted]	265	.	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	変形性関節症	20[redacted]	.	.	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	疲労	20[redacted]	.	.	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	下気道感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性気道感染	20[redacted]	35	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	背部痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	細菌性下気道感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	憩室炎	20[redacted]	.	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	.	74	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	

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[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	136	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	全身性そう痒症	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	便秘	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	電解質失調	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	ウイルス性上気道感染	20[redacted]	463	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	腎損傷	20[redacted]	470	13	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	HOSPITALIZED/PROLONGED HOSPITALIZATION	N
[redacted]	UNITED KINGDOM	PLACEBO		6[redacted]	F	WHITE	慢性閉塞性肺疾患	20[redacted]	40	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	関節痛	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	鼻咽頭炎	20[redacted]	85	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	体液貯留	20[redacted]	.	63	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	裂孔ヘルニア	20[redacted]	189	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	353	10	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脳出血	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	血管腫	20[redacted]	.	.	Y	Grade 2	NOT RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	てんかん	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	咳嗽	20[redacted]	.	52	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	1	276	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	頚部痛	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	外陰腟乾燥	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	ボーエン病	20[redacted]	.	373	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N

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[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿失禁	20[redacted]	.	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MEDICATION TAKEN	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	扁平上皮癌	20[redacted]	.	373	Y	Grade 1	NOT RELATED	RESOLVED	DOSE NOT CHANGED	OTHER	N
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	366	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	尿路感染	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	貧血	20[redacted]	545	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	高脂血症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	脛骨骨折	20[redacted]	29	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	腓骨骨折	20[redacted]	29	.	Y	Grade 2	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	AMG 785 210 MG SC QM	DENOSUMAB 60 MG Q6M	6[redacted]	F	WHITE	下気道感染	20[redacted]	678	17	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	憩室穿孔	20[redacted]	16	3	Y	Grade 4	RELATED	RESOLVED	DRUG WITHDRAWN	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	消化管運動低下	20[redacted]	90	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	腹部癒着	20[redacted]	90	2	Y	Grade 3	NOT RELATED	RESOLVED	DOSE NOT CHANGED	MULTIPLE	N
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	歯牙破折	20[redacted]	249	70	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	高血圧	20[redacted]	249	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	歯肉炎	20[redacted]	363	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	糸球体濾過率減少	20[redacted]	368	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	血中クレアチニン増加	20[redacted]	368	10	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	放屁	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	腎嚢胞	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	OTHER	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	変形性関節症	20[redacted]	.	.	N	Grade 1	NOT RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO		7[redacted]	F	WHITE	蜂巣炎	20[redacted]	.	.	N	Grade 2	NOT RELATED		DOSE NOT CHANGED	EMERGENCY ROOM VISIT	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	耳感染	20[redacted]	10	.	N	Grade 2	RELATED		DOSE NOT CHANGED	MEDICATION TAKEN	
[redacted]	UNITED KINGDOM	PLACEBO	DENOSUMAB 60 MG Q6M	7[redacted]	F	WHITE	足変形	20[redacted]	10	.	N	Grade 2	RELATED		DOSE NOT CHANGED	NO ACTION TAKEN	