TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: LIM, LYNDELL (39600) TRT: ADALIMUMAB								
1300107# AGE:30 SEX:MALE RACE:WHITE WEIGHT:97 KG								
	POST	275 TO	12	286 31	R:UPPER RESPIRATORY TRACT INFECTION S:INFECTIONS AND INFESTATIONS P:UPPER RESPIRATORY TRACT INFECTION L:UPPER RESPIRATORY TRACT INFECTION	E:289 L:4 DAYS	S:MODERATE R:PROBABLY RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION M:NO A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: NOELLE, BERNHARD (46156) TRT: ADALIMUMAB									
1060703	AGE:31 SEX:FEMALE RACE:OTHER: KOSOVO-ALBANER WEIGHT:78 KG								
	DB	1 TO 52	15	15	31	R:ACCIDENTAL PREDNISONE OVERDOSE S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:ACCIDENTAL OVERDOSE L:DRUG OVERDOSE ACCIDENTAL	E:31 L:17 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:OTHER SONOGRAPHY, CHEST X-RAY AND ECHOCARDIOGRAPHY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:OVERDOSE OF PREDNISON SUBJECT TOOK 60MG FROM STUDY MEDICATION AND 60MG OWN PREDNISOLON M:NO A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB								
1201602	AGE:40 SEX:FEMALE RACE:BLACK WEIGHT:112 KG							
	DB	1 TO 79	9	9 40	R:RIGHT EYE WORSENING OF ANGLE CLOSURE GLAUCOMA S:EYE DISORDERS P:ANGLE CLOSURE GLAUCOMA L:ANGLE CLOSURE GLAUCOMA	E:9 D:4 HOURS	S:MODERATE R:NOT RELATED P:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER REFERRED TO GLAUCOMA SPECIALIST	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:CONCURRENT ILLNES (HISTORY OF ANGLE CLOSURE GLAUCOMA) A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB								
1201613#	AGE:79 SEX:FEMALE RACE:WHITE WEIGHT:75 KG							
	DB	1 TO 34	2	2	79	R:VOLUME OVERLOAD S:METABOLISM AND NUTRITION DISORDERS P:FLUID OVERLOAD L:VOLUME OVERLOAD	E:18 L:17 DAYS	S:MODERATE R:NOT RELATED P:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CHRONIC KIDNEY DISEASE STAGE IV A:NOT RELATED
	POST	35 TO	3	37	80	R:END STAGE RENAL DISEASE S:RENAL AND URINARY DISORDERS P:RENAL FAILURE CHRONIC L:END STAGE RENAL DISEASE (ESRD)	E:37 D:UNKNOWN	S:SEVERE R:NOT RELATED P:NOT RELATED A:DISCONT. ADA/PLACEBO A:DISCONT. PREDNISONE	U:NO S:YES, DEATH OF SUBJECT O:CAUSE OF DEATH END STAGE RENAL DISEASE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: SUHLER, ERIC (36481) TRT: PLACEBO								
1202004# AGE:43 SEX:FEMALE RACE:WHITE WEIGHT:95 KG								
	DB	1 TO 36	12	12 43	R:ACUTE PYELONEPHRITIS S:INFECTIONS AND INFESTATIONS P:PYELONEPHRITIS ACUTE L:ACUTE PYELONEPHRITIS	E:23 L:12 DAYS	S:SEVERE R:PROBABLY RELATED P:PROBABLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:PROBABLY NOT RELATED
			16	16 43	R:SEPSIS S:INFECTIONS AND INFESTATIONS P:SEPSIS L:SEPSIS	E:21 L:6 DAYS	S:SEVERE R:PROBABLY RELATED P:PROBABLY RELATED	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	--------- EPOCH -------- NAME	INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: VAN CALSTER, JOACHIM (39603) TRT: PLACEBO								
1020203	AGE:51 SEX:FEMALE RACE:WHITE WEIGHT:44 KG							
	DB	1 TO 148	75	75	51	R:TRAUMATIC BROKEN LEFT WRIST S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:WRIST FRACTURE L:WRIST FRACTURE	E:76 L:2 DAYS	S:MODERATE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER SURGERY + PLASTER	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:PATIENT FALL DOWN THE STAIRS A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
1020210# AGE:57 SEX:MALE RACE:WHITE WEIGHT:80 KG								
	DB	1 TO 248	242	242 58	R:GLIOBLASTOMA MULTIFORME, GRADE IV S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:GLIOBLASTOMA MULTIFORME L:GLIOBLASTOMA MULTIFORME	O:351 L:>110 DAYS	S:MILD R:PROBABLY RELATED P:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER CLINICAL NEUROLOGICAL EXAMINATION-LUMBAR PUNCTURE-MRI BRAINS-EDX EXAM-CT THORAX/ ABDOMEN-TUMOR MARKERS.IT REMAINS UNCLEAR WHETHER IT CONCERNS AN INFLAMMATORY/ TUMORAL INJURY-RADIOTHERAPY	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: BELFORT MATTOS JUNIO, RUBENS (46066) TRT: PLACEBO								
2230154	AGE:30 SEX:FEMALE RACE:WHITE WEIGHT:78 KG							
	DB	1 TO 50	36	36	30	R:HYPERTENSIVE CRISIS. BLOOD PRESSURE: SYSTOLIC 213, DIASTOLIC 153. S:VASCULAR DISORDERS P:HYPERTENSIVE CRISIS L:HYPERTENSIVE CRISIS	E:37 D:12 HOURS	S:MODERATE R:POSSIBLY RELATED P:POSSIBLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:HYPERTENSION RELATED, SECONDARY TO MEDICATION THAT CAN BE RELATED TO CYCLOSPORINE, ORAL PREDNISONE AND/OR STUDY DRUG OR ASSOCIATION OF THESE THREE. M:NO A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: CIARDELLA, ANTONIO (46486) TRT: ADALIMUMAB								
2080752# AGE:73 SEX:MALE RACE:WHITE WEIGHT:70 KG								
	POST	51 TO	14	64	74	R:BRONCHITIS S:INFECTIONS AND INFESTATIONS P:BRONCHITIS L:BRONCHITIS	O:120 L:>57 DAYS	S:MODERATE R:PROBABLY NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:DISCONT. PREDNISONE A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:BACTERIAL INFECTION. A:POSSIBLY RELATED
			19	69	74	R:PLEURITIS S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:PLEURISY L:PLEURITIS	E:80 L:12 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION . IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: CIARDELLA, ANTONIO (46486) TRT: ADALIMUMAB								
2080752# AGE:73 SEX:MALE RACE:WHITE WEIGHT:70 KG								
(CONT)	POST	51 TO	23 73	74	R:LEGIONELLA PNEUMONIAE S:INFECTIONS AND INFESTATIONS P:PNEUMONIA LEGIONELLA L:PNEUMONIA LEGIONELLA	O:87 L:>15 DAYS	S:SEVERE R:PROBABLY RELATED P:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: CIMINO, LUCA (45414) TRT: PLACEBO									
2080555	AGE:46 SEX:MALE RACE:WHITE WEIGHT:80 KG								
	DB	1 TO 274	3	3	46	R:FRACTURE OF THE RIGHT HEAD HUMERUS S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:HUMERUS FRACTURE L:HUMERUS FRACTURE	E:8 L:6 DAYS	S:MODERATE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER SURGERY OF RIGHT HEAD HUMERUS	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:ACCIDENTAL FALLS FROM STAIRS A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: DE SCHRYVER, ISLE (53643) TRT: ADALIMUMAB									
2020155#	AGE:41 SEX:FEMALE RACE:WHITE WEIGHT:50 KG								
	DB	1 TO 414	403	403	42	R:STATUS MIGRAINOSUS S:NERVOUS SYSTEM DISORDERS P:STATUS MIGRAINOSUS L:STATUS MIGRAINOSUS	O:491 L:>89 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER CONSULTATION OF THE EMERGY DEPARTMENT. BLOOD TEST AND CT BRAIN: NORMAL FINDINGS. FOLLOW UP BY NEUROLOGY: BLOOD TEST, LUMBAL PUNCTURE, MRI BRAIN, NEUROLOGICAL EXAMS: NORMAL FINDINGS.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:HOSPITALIZATION ONLY FOR LUMBAL PUNCTURE A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: DICK, ANDREW (39613) TRT: PLACEBO									
2120154	AGE:35 SEX:FEMALE RACE:BLACK WEIGHT:116 KG								
	DB	1 TO 344	2	2	35	R:DEEP VEIN THROMBOSIS S:VASCULAR DISORDERS P:DEEP VEIN THROMBOSIS L:DEEP VEIN THROMBOSIS	O:638 L:>637 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O:INCREASED RISK FACTORS ASSOCIATED WITH HEALTH (BMI)

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: DICK, ANDREW (39613) TRT: ADALIMUMAB								
2120157	AGE:70 SEX:FEMALE RACE:WHITE WEIGHT:61 KG							
	DB	1 TO 554	228	228	71	E:231 L:4 DAYS	S:MODERATE R:PROBABLY NOT RELATED P:PROBABLY NOT RELATED A:OTHER RAPID RHINO	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IDIOPATHIC A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: HASHIDA, NORIYASU (52321) TRT: PLACEBO								
2400754	AGE:46 SEX:MALE RACE:ASIAN WEIGHT:73 KG							
	DB	1 TO 106	78	78	46 R:RIGHT AVASCULAR NECROSIS FEMORAL HEAD S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:OSTEONECROSIS L:AVASCULAR NECROSIS FEMORAL HEAD	E:190 L:113 DAYS	S:MODERATE R:PROBABLY NOT RELATED P:POSSIBLY RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:STEROID PULSE THERAPY. PREDONISOLONE. A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: KIM, ROSA (38927) TRT: ADALIMUMAB									
2201050	AGE:48 SEX:MALE RACE:WHITE WEIGHT:83 KG								
	DB	1 TO 554	234	234	49	R:TRANSIENT VISION LOSS, DYSPHAGIA, DYSARTHRIA S:EYE DISORDERS P:BLINDNESS TRANSIENT L:TRANSIENT VISUAL LOSS	E:234 D:.5 HR	S:SEVERE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:THE CAUSE IS UNKNOWN. ALL WORKUP NORMAL, HOWEVER ASPIRIN QDAY RXD AS TIA COULD NOT BE RULED OUT A:PROBABLY NOT RELATED
				234	49	---------- S A M E A S A B O V E ---------- DISORDERS P:DYSPHAGIA L:DYSPHAGIA			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: KIM, ROSA (38927) TRT: ADALIMUMAB								
2201050	AGE:48 SEX:MALE RACE:WHITE WEIGHT:83 KG							
(CONT)	DB	1 TO 554	234	234	49 DISORDERS P:DYSARTHRIA L:DYSARTHRIA	---------- S A M E A S A B O V E ----------		

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: KUFFOVA, L (43780) TRT: ADALIMUMAB								
2120250#	AGE:55 SEX:FEMALE RACE:WHITE WEIGHT:68 KG							
	DB	1 TO 246	212	212 55	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:PNEUMONIA L:PNEUMONIA	E:246 L:35 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:INFECTION A:POSSIBLY RELATED
	POST	247 TO 6	252	56	R:NEUTROPENIA S:BLOOD AND LYMPHATIC SYSTEM DISORDERS P:NEUTROPENIA L:NEUTROPENIA	E:261 L:10 DAYS	S:MODERATE R:PROBABLY RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: LARSON, T (52561) TRT: PLACEBO									
2201953# AGE:46 SEX:FEMALE RACE:BLACK WEIGHT:65 KG									
	POST	219 TO	11	229	46	R:WORSENING OF ARTHRITIS (RIGHT KNEE) S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:ARTHRITIS L:ARTHRITIS AGGRAVATED	E:235 L:7 DAYS	S:MODERATE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER ELECTIVE KNEE SURGERY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PROGRESSION OF ARTHRITIS A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: MIYAZAKI, M (40586) TRT: ADALIMUMAB								
2400950#	AGE:42 SEX:FEMALE RACE:ASIAN WEIGHT:57 KG							
	POST	261 TO 14	274	43	R:LUNG CANCER STAGE IV ADENOCARCINOMA S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:LUNG ADENOCARCINOMA STAGE IV L:ADENOCARCINOMA LUNG STAGE IV	O:722 L:>449 DAYS	S:SEVERE R:PROBABLY RELATED P:PROBABLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: NESS, THOMAS (40289) TRT: PLACEBO								
2060351	AGE:23 SEX:FEMALE RACE:WHITE WEIGHT:63 KG							
	DB	1 TO 63	9	9 23	R:TONSILLITIS S:INFECTIONS AND INFESTATIONS P:TONSILLITIS L:TONSILLITIS	E:16 L:8 DAYS	S:MODERATE R:PROBABLY RELATED P:POSSIBLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:INFECTION COULD AS WELL BE SEVERED BY KORTICOSTEROIDS A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: SONODA, KOH-HEI (47594) TRT: ADALIMUMAB									
2401153	AGE:63 SEX:FEMALE RACE:ASIAN WEIGHT:50 KG								
	DB	1 TO 273	273	273	63	R:AGGRAVATION OF CATARACT(OU) S:EYE DISORDERS P:CATARACT L:CATARACT AGGRAVATED	E:86 L:100 DAYS	S:MILD R:NOT RELATED A:OTHER PEA(OU)	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:AGGRAVATION OF COMPLICATION,AGING A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: THORNE, JENNIFER (45831) TRT: PLACEBO								
2204051	AGE:39 SEX:FEMALE RACE:WHITE WEIGHT:86 KG							
	DB	1 TO 540	120	120	39	R:DRUG-INDUCED ASEPTIC MENINGITIS S:INFECTIONS AND INFESTATIONS P:MENINGITIS ASEPTIC L:ASEPTIC MENINGITIS	E:144 L:25 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER PREDNISONE WAS DISCOUNTINUED BY OTHER PHYSICIAN ON 7/1/13. WE DID NOT MAKE THIS CHANGE. SHE REMAINS ON CELLCEPT AT THIS TIME.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION . IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:ASEPTIC MENINGITIS SECONDARY TO BACTRIM A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (P1) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: THORNE, JENNIFER (45831) TRT: PLACEBO									
2204055#	AGE:67 SEX:FEMALE RACE:WHITE WEIGHT:70 KG								
	DB	1 TO 211	190	190	67	R:CHOROIDAL NEOVASCULARIZATION OU AND SUBRETINAL FLUID OD S:EYE DISORDERS P:CHOROIDAL NEOVASCULARISATION L:CHOROIDAL NEOVASCULARIZATION	O:255 L:>66 DAYS	S:MODERATE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER DIAGNOSIS CONFIRMED BY FA BY RETINAL SPECIALST. LUCENTIS OU GIVEN INTRAVITREALLY ON 10/1/14.F/U AT NEXT VISIT 10/30/14.	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:NEOVASCULARIZATION OU A:NOT RELATED
				190	67	---------- S A M E A S A B O V E ---------- P:SUBRETINAL FLUID L:SUBRETINAL FLUID			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: VAN CALSTER, JOACHIM (39603) TRT: PLACEBO									
2020251	AGE:26 SEX:FEMALE RACE:WHITE WEIGHT:75 KG								
	DB	1 TO 414	5	5	26	R:DEEP-VEIN THROMBOSIS S:VASCULAR DISORDERS P:DEEP VEIN THROMBOSIS L:DEEP VEIN THROMBOSIS	E:180 L:176 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER TREATMENT: LOW MOLECULAR WEIGHT HEPARIN + FENPROCOUMON. WEARING ELASTIC COMPRESSION.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:ORAL ANTICONCEPTION POSSIBLE COAGULATION DEFECT (UNDER INVESTIGATION) A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: VAN CALSTER, JOACHIM (39603) TRT: PLACEBO								
2020266	AGE:67 SEX:FEMALE RACE:WHITE WEIGHT:50 KG							
	POST	359 TO	5	363	68	R:PSEUDOPHAKIC RETINAL DETACHMENT OS S:EYE DISORDERS P:RETINAL DETACHMENT L:RETINAL DETACHMENT	E:101 L:117 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER VITRECTOMY OS	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IDIOPATHIC

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
2020259# AGE:62 SEX:MALE RACE:WHITE WEIGHT:73 KG								
	DB	1 TO 36	28	28	62 R:ACUTE AORTADISSECTION WITH CARDIAC TAMPONADE S:VASCULAR DISORDERS P:AORTIC DISSECTION L:AORTIC DISSECTION	E:54 L:27 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:DISCONT. PREDNISONE A:OTHER REFERRAL TO INTERNIST; CLINICAL EXAMINATION; LAB; ECG; RX THORAX; KIDNEY AND BLADDER ULTRASOUND; CT SCAN PULMONARY EMBOLISM.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , DEATH OF SUBJECT O:ANEURYSMA AORTAE ABDOMINALIS; CARDIAC A:PROBABLY NOT RELATED
			28	62	---------- S A M E A S A B O V E ---------- P:CARDIAC TAMPONADE L:CARDIAC TAMPONADE			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.3

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(PLACEBO CONTROLLED SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
2020268	AGE:39 SEX:MALE RACE:WHITE WEIGHT:91 KG							
	DB	1 TO 358	68	68	39	R:LEFT WEBER C FIBULA FRACTURE S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:FIBULA FRACTURE L:FIBULA FRACTURE	E:77 L:10 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER PLASTER CAST; PLATE OSTEOSUNTHESIS; CRUTCHES FOR 6 WEEKS; PHYSIOTHERAPY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:TRAUMA A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: DESCHENES, JEAN (39605) TRT: ADALIMUMAB								
1210202# AGE:56 SEX:FEMALE RACE:WHITE WEIGHT:61 KG								
	POST	95 TO 10	104	56	R:DRUG-INDUCED ACUTE LUPUS ERYTHEMATOSUS S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:LUPUS-LIKE SYNDROME L:DRUG-INDUCED LUPUS ERYTHEMATOSUS	E:120 L:17 DAYS	S:SEVERE R:PROBABLY RELATED P:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER HOSPITALIZATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:UNKNOWN A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (P1) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: DICK, ANDREW (39613) TRT: ADALIMUMAB									
1120102	AGE:30 SEX:FEMALE RACE:WHITE WEIGHT:80 KG								
	DB	1 TO 50	32	32	30	R:DEMYELINATING DISEASE S:NERVOUS SYSTEM DISORDERS P:DEMYELINATION L:DEMYELINATING DISEASE OF CENTRAL NERVOUS SYSTEM, UNSPECIFIED	O:134 L:>103 DAYS	S:SEVERE R:PROBABLY RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:OTHER BRAIN MRI SCAN	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: DICK, ANDREW (39613) TRT: ADALIMUMAB									
1120106#	AGE:39 SEX:FEMALE RACE:ASIAN WEIGHT:53 KG								
	DB	1 TO 176	164	164	39	R:TUBERCULOSIS S:INFECTIONS AND INFESTATIONS P:TUBERCULOSIS L:TUBERCULOSIS	O:259 L:>96 DAYS	S:SEVERE R:POSSIBLY RELATED P:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER LABORATORY TESTS COMPLETED	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UNKNOWNING EXPOSURE TO TB A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: LIM, LYNDELL (39600) TRT: ADALIMUMAB								
1300107# AGE:30 SEX:MALE RACE:WHITE WEIGHT:97 KG								
	POST	275 TO	12 286	31	R:UPPER RESPIRATORY TRACT INFECTION S:INFECTIONS AND INFESTATIONS P:UPPER RESPIRATORY TRACT INFECTION L:UPPER RESPIRATORY TRACT INFECTION	E:289 L:4 DAYS	S:MODERATE R:PROBABLY RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION M:NO A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB								
1201613# AGE:79 SEX:FEMALE RACE:WHITE WEIGHT:75 KG								
	DB	1 TO 34	2 2	79	R:VOLUME OVERLOAD S:METABOLISM AND NUTRITION DISORDERS P:FLUID OVERLOAD L:VOLUME OVERLOAD	E:18 L:17 DAYS	S:MODERATE R:NOT RELATED P:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CHRONIC KIDNEY DISEASE STAGE IV A:NOT RELATED
	POST	35 TO	3 37	80	R:END STAGE RENAL DISEASE S:RENAL AND URINARY DISORDERS P:RENAL FAILURE CHRONIC L:END STAGE RENAL DISEASE (ESRD)	E:37 D:UNKNOWN	S:SEVERE R:NOT RELATED P:NOT RELATED A:DISCONT. ADA/PLACEBO A:DISCONT. PREDNISONE	U:NO S:YES, DEATH OF SUBJECT O:CAUSE OF DEATH END STAGE RENAL DISEASE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
1020210# AGE:57 SEX:MALE RACE:WHITE WEIGHT:80 KG								
	DB	1 TO 248	242	242 58	R:GLIOBLASTOMA MULTIFORME, GRADE IV S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:GLIOBLASTOMA MULTIFORME L:GLIOBLASTOMA MULTIFORME	O:351 L:>110 DAYS	S:MILD R:PROBABLY RELATED P:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER CLINICAL NEUROLOGICAL EXAMINATION-LUMBAR PUNCTURE-MRI BRAINS-EDX EXAM-CT THORAX/ ABDOMEN-TUMOR MARKERS.IT REMAINS UNCLEAR WHETHER IT CONCERNS AN INFLAMMATORY/ TUMORAL INJURY-RADIOTHERAPY	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: CIARDELLA, ANTONIO (46486) TRT: ADALIMUMAB								
2080752# AGE:73 SEX:MALE RACE:WHITE WEIGHT:70 KG								
	POST	51 TO	14	64 74	R:BRONCHITIS S:INFECTIONS AND INFESTATIONS P:BRONCHITIS L:BRONCHITIS	O:120 L:>57 DAYS	S:MODERATE R:PROBABLY NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:DISCONT. PREDNISONE A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:BACTERIAL INFECTION. A:POSSIBLY RELATED
			19	69 74	R:PLEURITIS S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:PLEURISY L:PLEURITIS	E:80 L:12 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: CIARDELLA, ANTONIO (46486) TRT: ADALIMUMAB									
2080752# AGE:73 SEX:MALE RACE:WHITE WEIGHT:70 KG									
(CONT)	POST	51 TO	23	73	74	R:LEGIONELLA PNEUMONIAE S:INFECTIONS AND INFESTATIONS P:PNEUMONIA LEGIONELLA L:PNEUMONIA LEGIONELLA	O:87 L:>15 DAYS	S:SEVERE R:PROBABLY RELATED P:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: DE SCHRYVER, ISLE (53643) TRT: ADALIMUMAB									
2020155# AGE:41 SEX:FEMALE RACE:WHITE WEIGHT:50 KG									
	DB	1 TO 414	403	403	42	R:STATUS MIGRAINOSUS S:NERVOUS SYSTEM DISORDERS P:STATUS MIGRAINOSUS L:STATUS MIGRAINOSUS	O:491 L:>89 DAYS	S:SEVERE R:PROBABLY NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER CONSULTATION OF THE EMERGY DEPARTMENT. BLOOD TEST AND CT BRAIN: NORMAL FINDINGS. FOLLOW UP BY NEUROLOGY: BLOOD TEST, LUMBAL PUNCTURE, MRI BRAIN, NEUROLOGICAL EXAMS: NORMAL FINDINGS.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:HOSPITALIZATION ONLY FOR LUMBAL PUNCTURE A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: KIM, ROSA (38927) TRT: ADALIMUMAB									
2201050	AGE:48 SEX:MALE RACE:WHITE WEIGHT:83 KG								
	DB	1 TO 554	234	234	49	R:TRANSIENT VISION LOSS, DYSPHAGIA, DYSARTHRIA S:EYE DISORDERS P:BLINDNESS TRANSIENT L:TRANSIENT VISUAL LOSS	E:234 D:.5 HR	S:SEVERE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:THE CAUSE IS UNKNOWN. ALL WORKUP NORMAL, HOWEVER ASPIRIN QDAY RXD AS TIA COULD NOT BE RULED OUT A:PROBABLY NOT RELATED
				234	49	---------- S A M E A S A B O V E ---------- DISORDERS P:DYSPHAGIA L:DYSPHAGIA			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: KIM, ROSA (38927) TRT: ADALIMUMAB									
2201050	AGE:48 SEX:MALE RACE:WHITE WEIGHT:83 KG								
(CONT)	DB	1 TO 554	234	234	49	---------- S A M E A S A B O V E ---------- DISORDERS P:DYSARTHRIA L:DYSARTHRIA			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: KUFFOVA, L (43780) TRT: ADALIMUMAB								
2120250# AGE:55 SEX:FEMALE RACE:WHITE WEIGHT:68 KG								
	DB	1 TO 246	212	212 55	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:PNEUMONIA L:PNEUMONIA	E:246 L:35 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:INFECTION A:POSSIBLY RELATED
	POST	247 TO 6	252	56	R:NEUTROPENIA S:BLOOD AND LYMPHATIC SYSTEM DISORDERS P:NEUTROPENIA L:NEUTROPENIA	E:261 L:10 DAYS	S:MODERATE R:PROBABLY RELATED P:NOT RELATED A:DISCONT. ADA/PLACEBO	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: MIYAZAKI, M (40586) TRT: ADALIMUMAB								
2400950# AGE:42 SEX:FEMALE RACE:ASIAN WEIGHT:57 KG								
	POST	261 TO 14	274	43	R:LUNG CANCER STAGE IV ADENOCARCINOMA S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:LUNG ADENOCARCINOMA STAGE IV L:ADENOCARCINOMA LUNG STAGE IV	O:722 L:>449 DAYS	S:SEVERE R:PROBABLY RELATED P:PROBABLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB									
2020259# AGE:62 SEX:MALE RACE:WHITE WEIGHT:73 KG									
	DB	1 TO 36	28	28	62	R:ACUTE AORTADISSECTION WITH CARDIAC TAMPONADE S:VASCULAR DISORDERS P:AORTIC DISSECTION L:AORTIC DISSECTION	E:54 L:27 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:DISCONT. PREDNISONE A:OTHER REFERRAL TO INTERNIST; CLINICAL EXAMINATION; LAB; ECG; RX THORAX; KIDNEY AND BLADDER ULTRASOUND; CT SCAN PULMONARY EMBOLISM.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , DEATH OF SUBJECT O:ANEURYSMA AORTAE ABDOMINALIS; CARDIAC A:PROBABLY NOT RELATED
				28	62	---------- S A M E A S A B O V E ---------- P:CARDIAC TAMPONADE L:CARDIAC TAMPONADE			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ABE, TOSHIAKI (39663) TRT: ADALIMUMAB								
1400101	AGE:52 SEX:FEMALE RACE:ASIAN WEIGHT:51 KG							
	OL	80 TO	15	94	52	R:AGGRAVATION OF UVEITIS (OU) S:EYE DISORDERS P:UVEITIS L:UVEITIS	E:44 L:30 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UVEITIS A:NOT RELATED
			111	190	53	R:LUMBAR COMPRESSION FRACTURE S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:SPINAL COMPRESSION FRACTURE L:SPINAL COMPRESSION FRACTURE	E:483 L:373 DAYS	S:SEVERE R:NOT RELATED A:OTHER TRUNK FIXATION, HARD CORSET	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IT IS TRAUMATIC, AND ACCIDENTAL EVENT BY THE TRAFFIC ACCIDENT. A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ADAN, ALFREDO (39653) TRT: PLACEBO								
1110102# AGE:48 SEX:FEMALE RACE:WHITE WEIGHT:83 KG								
	OL	57 TO 99	36	92 48	R:NEURO-BEHCET S:VASCULAR DISORDERS P:BEHCET'S SYNDROME L:NEURO-BEHCET DISEASE	O:176 L:>85 DAYS	S:MODERATE R:NOT RELATED A:DISCONT. ADA/ PLACEBO	U:NO S:YES, PERSISTENT OR SIGNIFICANT DISABILITY O:IDIOPATHIC PERIPHERAL SENSORY POLYNEUROPATHY A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ADAN, ALFREDO (39653) TRT: PLACEBO								
1110102#	AGE:48 SEX:FEMALE RACE:WHITE WEIGHT:83 KG							
(CONT)	POST	100 TO	60	159	48	R:URINARY INFECTION S:INFECTIONS AND INFESTATIONS P:URINARY TRACT INFECTION L:URINARY INFECTION	E:116 L:14 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:URINARY INFECTION. URINARY CULTURE DISCLOSED E.COLI A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ADAN, ALFREDO (39653) TRT: ADALIMUMAB								
1110103# AGE:45 SEX:FEMALE RACE:WHITE WEIGHT:72 KG								
	OL	94 TO 164	54	147	R:DEMYELINATION S:NERVOUS SYSTEM DISORDERS P:DEMYELINATION L:DEMYELINATION	O:247 L:>101 DAYS	S:MODERATE R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO A:OTHER LUMBAR PUNCTURE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PERIVENTRICULAR DEMYELINATING BRAIN LESSIONS IN MRI A:POSSIBLY RELATED
	45							

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ANDROUDI, SOFIA (45761) TRT: PLACEBO								
1130101	AGE:37 SEX:MALE RACE:WHITE WEIGHT:80 KG							
	OL	51 TO 87	137	37	R:RESORPTION/ OSTEOLYSIS OF 2 LUMBAR VERTEBRAE S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:OSTEOLYSIS L:OSTEOLYSIS	E:189 L:103 DAYS	S:SEVERE R:NOT RELATED A:OTHER ON 6TH SEPTEMBER, UNDER LOCAL ANESTHESIA, "CEMENT" WAS USED TO REINFORCE THE VERTEBRAE	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:PROLONGED PREDNISONE USE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: CAMPOCHIARO, PETER (49981) TRT: ADALIMUMAB									
1201302# AGE:47 SEX:MALE RACE:WHITE WEIGHT:85 KG									
	DB	1 TO 78	75	75	47	R:ANAPHYLAXIS, HIVES S:IMMUNE SYSTEM DISORDERS P:ANAPHYLACTIC REACTION L:ANAPHYLAXIS	E:75 D:12 HOURS	S:SEVERE R:PROBABLY NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O:BEE STING A:PROBABLY NOT RELATED
				75	47	---------- S A M E A S A B O V E ----------			
						SUBCUTANEOUS TISSUE DISORDERS P:URTICARIA L:HIVES			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: CAMPOCHIARO, PETER (49981) TRT: ADALIMUMAB									
1201302# AGE:47 SEX:MALE RACE:WHITE WEIGHT:85 KG									
(CONT)	OL	92 TO 330	159	250	47	R:MULTIPLE SCLEROSIS S:NERVOUS SYSTEM DISORDERS P:MULTIPLE SCLEROSIS L:MULTIPLE SCLEROSIS	O:357 L:>108 DAYS	S:MILD R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER DIAGNOSTIC TESTS	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:INFLAMMATION OF THE NERVOUS SYSTEM A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (P1) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: CERVANTES CASTANEDA, RENE (45283) TRT: ADALIMUMAB									
1240106#	AGE:30 SEX:MALE RACE:WHITE WEIGHT:106 KG								
	POST	118 TO	19	136	30	R:QUANTIFERON TB GOLD POSITIVE S:INVESTIGATIONS P:MYCOBACTERIUM TUBERCULOSIS COMPLEX TEST POSITIVE L:TUBERCULOSIS TEST POSITIVE	O:140 L:>5 DAYS	S:MILD R:PROBABLY RELATED A:DISCONT. ADA/ PLACEBO A:OTHER SUBJECT WAS REFER TO INTERNAL MEDICINE FOR TREATMENT	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION M:NO A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: CHU, DAVID (38774) TRT: PLACEBO									
1203802	AGE:70	SEX:FEMALE	RACE:WHITE		WEIGHT:81 KG				
	OL	183 TO	3	185	70	R:PLEURAL EFFUSION S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:PLEURAL EFFUSION L:PLEURAL EFFUSION	E:15 L:13 DAYS	S:MILD R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER THORACENTESIS	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:ASSUMED SARCOIDOSIS A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: CHU, DAVID (38774) TRT: PLACEBO								
1203802	AGE:70	SEX:FEMALE	RACE:WHITE	WEIGHT:81 KG				
(CONT)	OL	183 TO 742	924	72	R:BACK PAIN RADIATING TO THE CHEST FROM COMPOUND FRACTURE S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:BACK PAIN L:BACK PAIN (WITH RADIATION)	E:743 D:48	S:SEVERE R:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:COMPOUND FRACTURES RELATED TO OSTEOPOROSIS. A:NOT RELATED
			924	72	---------- S A M E A S A B O V E ---------- AND PROCEDURAL COMPLICATIONS P:OPEN FRACTURE L:COMPOUND FRACTURE			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: CIARDELLA, ANTONIO (46486) TRT: PLACEBO								
1080701	AGE:20	SEX:FEMALE	RACE:WHITE	WEIGHT:70 KG				
	OL	85 TO	417 501	21	R:SEVERE GASTRITIS S:GASTROINTESTINAL DISORDERS P:CHRONIC GASTRITIS L:GASTRITIS CHRONIC	E:419 L:3 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:THE CAUSE OF THIS EVENT COULD BE CARDIOASPIRIN ADMINISTRATION. M:NO A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DAYANI, POUYA (41196) TRT: PLACEBO								
1203007	AGE:51 SEX:FEMALE RACE:WHITE WEIGHT:125 KG							
	OL	43 TO 603	645	53	R:WORSENING OF OBESITY S:METABOLISM AND NUTRITION DISORDERS P:OBESITY L:OBESITY	E:745 L:143 DAYS	S:MODERATE R:NOT RELATED A:OTHER SUBJECT UNDERWENT PLANNED GASTRIC BYPASS SURGERY 8/1/14.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:NOT RELATED; SUBJECT HAS HAD PREVIOUS MEDICAL HISTORY OF OBESITY A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DAYANI, POUYA (41196) TRT: PLACEBO									
1203007	AGE:51 SEX:FEMALE RACE:WHITE WEIGHT:125 KG								
(CONT)	OL	43 TO	793	835	53	R:LEFT KIDNEY STONES S:RENAL AND URINARY DISORDERS P:NEPHROLITHIASIS L:KIDNEY STONES	O:1135 L:>301 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER LITHOTRIPSY	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:ANY OF THE FOLLOWING COULD BE POSSIBLE CAUSES PER PI: TUBULOINTERSTITIAL NEPHRITIS, RECURRENT UTIS, OBESITY OR DIABETES A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DAYANI, POUYA (41196) TRT: PLACEBO								
1203007	AGE:51	SEX:FEMALE	RACE:WHITE	WEIGHT:125 KG				
(CONT)	OL	43 TO	1112	1154	54	R:WORSENING OF KIDNEY STONES S:RENAL AND URINARY DISORDERS P:NEPHROLITHIASIS L:KIDNEY STONES	O:1170 L:>17 DAYS	S:MODERATE R:NOT RELATED A:OTHER LEFT URETERAL STENT	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:SUBJECT HAS PREVIOUSLY REPORTED EVENT OF KIDNEY STONES A:PROBABLY NOT RELATED
			1132	1174	54	R:BLADDER INFECTION S:INFECTIONS AND INFESTATIONS P:CYSTITIS L:BLADDER INFECTION	O:1177 L:>4 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:AWAITING INFORMATION FROM PI ASSESSMENT A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (P1) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DAYANI, POUYA (41196) TRT: PLACEBO								
1203009# AGE:30 SEX:MALE RACE:BLACK WEIGHT:66 KG								
	OL	43 TO 701	15	57	R:VITREOUS HEMORRHAGE, OD, DECREASED VISUAL ACUITY. DROP FROM 87 LETTERS TO 2 LETTERS. S:EYE DISORDERS P:VISUAL ACUITY REDUCED L:VISUAL ACUITY DECREASED	O:813 L:>757 DAYS	S:SEVERE R:NOT RELATED A:OTHER B-SCAN (OD) WAS COMPLETED	U:YES S:YES, PERSISTENT OR SIGNIFICANT DISABILITY O:UNDERLYING CONCURRENT ILLNESS M:NO A:NOT RELATED
				57	30	---------- S A M E A S A B O V E ----------		
					P:VITREOUS HAEMORRHAGE L:VITREOUS HEMORRHAGE			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DAYANI, POUYA (41196) TRT: PLACEBO								
1203009# AGE:30 SEX:MALE RACE:BLACK WEIGHT:66 KG								
(CONT)	OL	43 TO 701	645	687	32	R:COMMUNITY ACQUIRED PNEUMONIA S:INFECTIONS AND INFESTATIONS P:PNEUMONIA L:COMMUNITY ACQUIRED PNEUMONIA	E:677 L:33 DAYS	S:SEVERE R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER HOSPITALIZED	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:INFECTIOUS A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DAYANI, POUYA (41196) TRT: PLACEBO									
1203011# AGE:26 SEX:MALE RACE:WHITE WEIGHT:88 KG									
	POST	338 TO	13	350	27	R:ANTI-NMDA RECEPTOR ENCEPHALITIS S:NERVOUS SYSTEM DISORDERS P:ENCEPHALITIS AUTOIMMUNE L:ANTI-NMDA RECEPTOR ENCEPHALITIS	E:338 L:31 DAYS	S:SEVERE R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER SUBJECT HOSPITALIZED FROM 4/23/14 TO 5/23/14; SEE SAE SUPPLEMENTARY DOCUMENTATION FOR ADDITIONAL INFORMATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:PER PI: INFLAMMATION OR INFECTION FROM FAMILY HISTORY OR SUBJECT'S PAST MEDICAL HISTORY M:NO A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DESCHENES, JEAN (39605) TRT: PLACEBO								
1210201# AGE:76 SEX:FEMALE RACE:WHITE WEIGHT:65 KG								
	POST	330 TO	19	348 77	R:ATAXIA S:NERVOUS SYSTEM DISORDERS P:ATAXIA L:ATAXIA	O:398 L:>51 DAYS	S:MODERATE R:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:PROBABLY SECONDARY TO SARCOIDOSIS TO HAVE TO BE CONFIRM WITHMORE EXAMS A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DICK, ANDREW (39613) TRT: PLACEBO								
1120104	AGE:58 SEX:FEMALE RACE:WHITE WEIGHT:70 KG							
	OL	124 TO 826	949	61	R:STRESS FRACTURES IN BOTH HIPS S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:STRESS FRACTURE L:STRESS FRACTURE	E:948 L:123 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:OTHER OPERATION TO PREVENT HIP DYSPLASIA	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UNKNOWN, NOT EXPECTED IN THIS PATIENT GROUP BUT POSSIBLY RELATED TO URGODEOXYXHOLIC ACID FOR LIVER DISEASE A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DICK, ANDREW (39613) TRT: PLACEBO								
1120113# AGE:40 SEX:FEMALE RACE:WHITE WEIGHT:97 KG								
	OL	98 TO 142	15	112	40	R:WORSENING VISUAL ACUITY, BILATERAL S:EYE DISORDERS P:VISUAL ACUITY REDUCED L:VISUAL ACUITY REDUCED	E:20 L:6 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER TO DISCUSS TREATMENT PLAN ON 6/12/13 FOLLOWING ELECTRODIAGNOSTIC TESTS	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:UNKNOWN A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: DICK, ANDREW (39613) TRT: ADALIMUMAB								
1120114	AGE:21 SEX:MALE RACE:WHITE WEIGHT:88 KG							
	POST	106 TO 120	10	115	22	R:ACTIVE NEOVASCULARISATION IN RIGHT EYE S:VASCULAR DISORDERS P:NEOVASCULARISATION L:NEOVASCULARISATION	O:115 L:>1 DAY	S:MODERATE R:PROBABLY NOT RELATED P:PROBABLY NOT RELATED A:OTHER PANRETINOPHOTOC-OAGULATION LASER	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:ACTIVE OCCLUSIVE VASCULITIS M:NO

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ERRERA, MARIE-HELENE (48975) TRT: PLACEBO								
1050502	AGE:68	SEX:FEMALE	RACE:WHITE	WEIGHT:88 KG				
	OL	114 TO 56	169	68	R:RETINAL VASCULITIS OU S:EYE DISORDERS P:RETINAL VASCULITIS L:RETINAL VASCULITIS	E:84 L:29 DAYS	S:MODERATE R:PROBABLY RELATED A:OTHER TO BE MONITORED AT THE NEXT SUBJECT'S VISIT.	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: FRANCO, PABLO (45421) TRT: ADALIMUMAB								
1220101	AGE:40 SEX:FEMALE RACE:WHITE WEIGHT:84 KG							
	OL	105 TO 580	684	42	R:NEPHROLITHIASIS S:RENAL AND URINARY DISORDERS P:NEPHROLITHIASIS L:NEPHROLITHIASIS		S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IDIOPATHIC A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: GARWEG, JUSTUS (45849) TRT: ADALIMUMAB								
1150201# AGE:40 SEX:MALE RACE:WHITE WEIGHT:114 KG								
	DB	1 TO 106	56	56	R:RUPTUR OF LIGAMENT OF QUADRICEPS RIGHT KNEE AND RUPTUR OF RETINACULUMS MEDIALIS RIGHT KNEE S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:LIGAMENT RUPTURE L:JOINT LIGAMENT RUPTURE	E:72 L:17 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER SURGERY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:DUE TO SLIPPING ON ICE A:NOT RELATED
			56	40	---------- S A M E A S A B O V E ---------- AND PROCEDURAL COMPLICATIONS P:TENDON RUPTURE L:QUADRICEPS TENDON RUPTURE			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: GARWEG, JUSTUS (45849) TRT: ADALIMUMAB									
1150201# AGE:40 SEX:MALE RACE:WHITE WEIGHT:114 KG									
(CONT)	OL	113 TO 211	40	152	41	R:MITOCHONDRIAL NEUROPATHY OF THE OPTIC NERVE OU S:EYE DISORDERS P:OPTIC NEUROPATHY L:OPTIC NEUROPATHY	O:309 L:>158 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO A:OTHER MRI BRAIN	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PATIENT HAS OPTIC NERVE NEURITIS LEFT SIDE IN HIS HISTORY, RELAPSE IS THEORETICALLY POSSIBLE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: GUEX-CROSIER, YAN (45850) TRT: PLACEBO								
1150107	AGE:45 SEX:FEMALE RACE:WHITE WEIGHT:73 KG							
	OL	22 TO 163	184	45	R:ACUTE GASTROENTERITIS S:INFECTIONS AND INFESTATIONS P:GASTROENTERITIS L:ACUTE GASTROENTERITIS	E:167 L:5 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:OTHER HOSPITALIZATION FROM 27NOV14 TO 01DEC14 AND LAB EXAM	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:FINAL MEDICAL DIAGNOSIS AT THE HOSPITAL WAS "ACUTE GASTROENTERITIS WITH UNKNOW GERM" A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HASHIDA, NORIYASU (52321) TRT: PLACEBO								
1400704# AGE:54 SEX:FEMALE RACE:ASIAN WEIGHT:78 KG								
	POST	247 TO 8	254	55	R:UVEITIS(OD) S:EYE DISORDERS P:UVEITIS L:UVEITIS	E:211 L:7 DAYS	S:MODERATE R:NOT RELATED A:OTHER CATARACT AND VITRECTOMY SURGERY(OD)	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UVEITIS A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HASHIDA, NORIYASU (52321) TRT: ADALIMUMAB									
1400703#	AGE:65	SEX:FEMALE	RACE:ASIAN	WEIGHT:58 KG					
	DB	1 TO 35	35	35	65	R:RIGHT URETERAL STONE S:RENAL AND URINARY DISORDERS P:CALCULUS URETERIC L:URETERAL CALCULUS	E:21 L:35 DAYS	S:MODERATE R:PROBABLY NOT RELATED P:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER CT	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:LACK OF PROPER HYDRATION A:NOT RELATED
	POST	91 TO	43	133	65	R:UVEITIS ASSOCIATED WITH SARCOIDOSIS OU S:IMMUNE SYSTEM DISORDERS P:SARCOIDOSIS L:SARCOIDOSIS	E:97 L:13 DAYS	S:MODERATE R:NOT RELATED A:OTHER CATARACT AND VITRECTOMY SURGERY(OU)	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UVEITIS A:NOT RELATED
				133	65	---------- S A M E A S A B O V E ---------- P:UVEITIS L:UVEITIS			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HEILIGENHAUS, ARND (40287) TRT: ADALIMUMAB								
1060104	AGE:22 SEX:FEMALE RACE:WHITE WEIGHT:130 KG							
	DB	1 TO 111	87	87 23	R:INFECTED PILONIDAL SINUS S:INFECTIONS AND INFESTATIONS P:PILONIDAL CYST L:PILONIDAL SINUS INFECTED	E:92 L:6 DAYS	S:MILD R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UNKNOWN M:NO A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HEILIGENHAUS, ARND (40287) TRT: ADALIMUMAB									
1060111# AGE:42 SEX:FEMALE RACE:WHITE WEIGHT:85 KG									
	DB	1 TO 343	239	239	43	R:NEUROENDOCRINE INTESTINAL TUMOR ON THE RECTUM , 6MM X3.6MM S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:CARCINOID TUMOUR OF THE GASTROINTESTINAL TRACT L:CARCINOID TUMOR OF THE GASTROINTESTINAL TRACT	E:251 L:13 DAYS	S:MODERATE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER ENDOSONOGRAPHY AND COLOSCOPY ON 19.03.14 THE REMOVAL OF THE TUMORS IS PLANNED	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:NOT RELATED TO STUDY DRUG AN D CAUSE OF EVENT IS UNKNOWN A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HOOPER, PHIL (39606) TRT: PLACEBO								
1210701	AGE:46	SEX:FEMALE	RACE:WHITE	WEIGHT:72 KG				
	OL	86 TO	92	177	46	R:PANSINUSITIS S:INFECTIONS AND INFESTATIONS P:SINUSITIS L:PANSINUSITIS	E:101 L:10 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:SINUS INFECTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HOOPER, PHIL (39606) TRT: PLACEBO								
1210701	AGE:46 SEX:FEMALE RACE:WHITE WEIGHT:72 KG							
(CONT)	OL	86 TO 470	555	47	R:MYOCARDIAL INFARCTION S:CARDIAC DISORDERS P:MYOCARDIAL INFARCTION L:MYOCARDIAL INFARCTION	E:470 D:6 HOURS	S:SEVERE R:PROBABLY NOT RELATED A:OTHER CORONARY ARTERY STENT SURGERY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, LIFE THREATENING O:POSSIBLE CORONARY ARTERY DISEASE SECONDARY TO SMOKING AND/OR INCREASED CHOLESTEROL AND TRIGLICERIDES A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HOOPER, PHIL (39606) TRT: PLACEBO								
1210701	AGE:46 SEX:FEMALE RACE:WHITE WEIGHT:72 KG							
(CONT)	OL	86 TO 489	574	47	R:VAGINAL BLEEDING S:REPRODUCTIVE SYSTEM AND BREAST DISORDERS P:VAGINAL HAEMORRHAGE L:VAGINAL BLEEDING	E:493 L:5 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:OTHER COUMADIN AND FRAGMIN DISCONTINUED, ENDOMETRIAL ABLATION DONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:USE OF WARFARIN A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: HOOPER, PHIL (39606) TRT: PLACEBO								
1210701	AGE:46 SEX:FEMALE RACE:WHITE WEIGHT:72 KG							
(CONT)	OL	86 TO 586	671	48	R:CHEST PAIN S:GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P:CHEST PAIN L:CHEST PAIN	E:588 L:3 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:OTHER EKG AND CHEST XRAY DONE (NORMAL)	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:LIKELY SECONDARY TO REFLUX ESOPHAGITIS A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KESTELYN, PHILIPPE (39602) / DE SCHRYVER, ISLE (53643) TRT: ADALIMUMAB								
1020102	AGE:50 SEX:FEMALE RACE:WHITE WEIGHT:93 KG							
	OL	41 TO 542	582	52	R:CYTOMEGALOVIRUS REACTIVATION (SYSTEMIC) S:INFECTIONS AND INFESTATIONS P:CYTOMEGALOVIRUS INFECTION L:CYTOMEGALOVIRUS INFECTION REACTIVATION	E:612 L:71 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER MONITORING THROUGH BLOOD TEST BY GP, CHEST X-RAY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:BECAUSE ADALIMUMAB SUPPRESSES TNF, WHICH IS PART OF THE IMMUNE SYSTEM, LATENT INFECTIONS CAN BE REACTIVATED (SEE SAE) A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KESTELYN, PHILIPPE (39602) / DE SCHRYVER, ISLE (53643) TRT: ADALIMUMAB								
1020102	AGE:50 SEX:FEMALE RACE:WHITE WEIGHT:93 KG							
(CONT)	OL	41 TO 603	643	52	R:POLYSYNOVITIS S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:SYNOVITIS L:SYNOVITIS	O:1429 L:>787 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER GASTROSCOPY, TOTAL BODY SCAN, X-RAY CHEST AND BOTH HANDS, BLOOD TEST	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CAUSE IS ON THIS MOMENT UNKNOWN AND UNDER INVESTIGATION A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KESTELYN, PHILIPPE (39602) / DE SCHRYVER, ISLE (53643) TRT: ADALIMUMAB									
1020111	AGE:71 SEX:FEMALE RACE:WHITE WEIGHT:75 KG								
	OL	42 TO	86	127	72	R:PROGRESSIVE CATARACT OD S:EYE DISORDERS P:CATARACT L:CATARACT AGGRAVATED	E:120 L:35 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER CATARACT SURGERY	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:AGE RELATED A:NOT RELATED
				127	72	R:PROGRESSIVE CATARACT OS S:EYE DISORDERS P:CATARACT L:CATARACT AGGRAVATED	E:316 L:231 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER CATARACT SURGERY ON 8 OCT 2014 AND YAG CAPSULOTOMY ON 19/01/2015	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:AGE RELATED A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KRAMER, MICHAL (39610) TRT: PLACEBO								
1070103	AGE:62 SEX:MALE RACE:WHITE WEIGHT:90 KG							
	OL	57 TO 928	984	64	R:BASAL CELL CARCINOMA ON LEFT SHOULDER S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:BASAL CELL CARCINOMA L:BASAL CELL CARCINOMA	O:1023 L:>40 DAYS	S:MODERATE R:POSSIBLY RELATED A:OTHER PUNCH BIOPSY AND SKIN LESION EXTRACTION	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:SUN EXPOSURE A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KRAMER, MICHAL (39610) TRT: ADALIMUMAB								
1070108# AGE:35 SEX:MALE RACE:WHITE WEIGHT:71 KG								
	DB	1 TO 158	127	127	35 R:URINARY TRACT INFECTION S:INFECTIONS AND INFESTATIONS P:URINARY TRACT INFECTION L:URINARY TRACT INFECTION	E:132 L:6 DAYS	S:MODERATE R:PROBABLY NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:INFECTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KUFFOVA, L (43780) TRT: PLACEBO									
1120201#	AGE:65 SEX:MALE RACE:WHITE WEIGHT:67 KG								
	POST	461 TO	13	473	66	R:LEFT HIP PAIN S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:ARTHRALGIA L:PAIN IN HIP	E:456 L:51 DAYS	S:SEVERE R:NOT RELATED A:OTHER PLANNED LEFT HIP REPLACMENT	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:GENERAL WEAR AND REAR - AGING A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KURUP, SHREE (43520) TRT: ADALIMUMAB								
1203302	AGE:66	SEX:FEMALE	RACE:WHITE	WEIGHT:99 KG				
	OL	120 TO 176	295	67	R:CORNEAL EDEMA RIGHT EYE SECONDARY TO UVEITIS S:EYE DISORDERS P:CORNEAL OEDEMA L:CORNEAL EDEMA	E:298 L:123 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER CORNEA TRANSPLANT DONE 01OCT2013	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:EVENT RELATED TO LONG TERM UVEITIS A:NOT RELATED
			295	67	---------- S A M E A S A B O V E ----------			
					P:UVEITIS L:UVEITIS			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KURUP, SHREE (43520) TRT: ADALIMUMAB									
1203308	AGE:42 SEX:MALE RACE:BLACK WEIGHT:174 KG								
	DB	1 TO 554	115	115	43	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:PNEUMONIA L:PNEUMONIA	E:121 L:7 DAYS	S:SEVERE R:POSSIBLY RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER CHEST XRAY WAS DONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UPPER RESPIRATORY INFECTION SECONDARY TO IMMUNOSUPPRESSION A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KURUP, SHREE (43520) TRT: ADALIMUMAB								
1203308	AGE:42	SEX:MALE	RACE:BLACK	WEIGHT:174 KG				
(CONT)	OL	558 TO	179	736 44	R:INFECTION OF NECK SECONDARY TO MULTIPLE TOOTH ABSCESSES S:INFECTIONS AND INFESTATIONS P:INFECTION L:INFECTION	E:194 L:16 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER HOSPITAL AND VANCOMYCIN	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:POSSSIBLY RELATED TO IMMUNOSUPPRESSION A:PROBABLY RELATED
				736 44	---------- S A M E A S A B O V E ----------			
					INFESTATIONS P:TOOTH ABSCESS L:TOOTH ABSCESS			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	--------- EPOCH --------- NAME	INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: KURUP, SHREE (43520) TRT: ADALIMUMAB								
1203308	AGE:42 SEX:MALE RACE:BLACK WEIGHT:174 KG							
(CONT)	OL	558 TO 183	740	44	R:ACUTE RESPIRATORY FAILURE S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:ACUTE RESPIRATORY FAILURE L:ACUTE RESPIRATORY FAILURE	E:186 L:4 DAYS	S:SEVERE R:NOT RELATED A:OTHER INTUBATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, LIFE THREATENING O:SUBJECT HAD SEVERE INFECTION IN NECK AREA DUE TO TOOTH ABSCESS A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: LARSON, T (52561) TRT: ADALIMUMAB								
1201903	AGE:26	SEX:FEMALE	RACE:BLACK	WEIGHT:64 KG				
	OL	281 TO 93	373	27	R:E. COLI URINARY TRACT INFECTION S:INFECTIONS AND INFESTATIONS P:ESCHERICHIA URINARY TRACT INFECTION L:ESCHERICHIA URINARY TRACT INFECTION	E:98 L:6 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PER PI, THE OCCURRENCE OF A URINARY TRACT INFECTION IS NOT RELATED TO STUDY DRUGS BUT RELATED TO FEMALE HYGIENE. A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: LARSON, T (52561) TRT: ADALIMUMAB								
1201903	AGE:26	SEX:FEMALE	RACE:BLACK	WEIGHT:64 KG				
(CONT)	OL	281 TO 301	581	28	R:ECTOPIC PREGNANCY S:PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS P:ECTOPIC PREGNANCY L:ECTOPIC PREGNANCY	E:302 L:2 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER SURGERY	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:SPONTANEOUS EVENT PER DR. STONE M:NO A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: MACKENSEN, FRIEDERIKE (40288) TRT: ADALIMUMAB								
1060202	AGE:60 SEX:MALE RACE:WHITE WEIGHT:100 KG							
	OL	85 TO	282	366 61	R:DIVERTICULITIS S:INFECTIONS AND INFESTATIONS P:DIVERTICULITIS L:DIVERTICULITIS	E:292 L:11 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER MYCOPHENOLIC ACID PAUSED	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PREEXISTING DIVERTICULITIS A:PROBABLY NOT RELATED
			309	393 61	R:DIVERTIKULITIS S:INFECTIONS AND INFESTATIONS P:DIVERTICULITIS L:DIVERTICULITIS	E:391 L:83 DAYS	S:MILD R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER RESECTION OF SIGMOID	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PREEXISTING DIVERTICULITIS A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: MIZUKI, NOBUHISA (39746) TRT: PLACEBO								
1400401# AGE:70 SEX:FEMALE RACE:ASIAN WEIGHT:83 KG								
	OL	42 TO 112	57 98	70	R:VITREOUS HEMORRAGE(OU) S:EYE DISORDERS P:VITREOUS HAEMORRHAGE L:VITREOUS HEMORRHAGE	E:109 L:53 DAYS	S:MODERATE R:NOT RELATED A:DISCONT. ADA/ PLACEBO A:OTHER VITREOS SURGERY	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:AGGRAVATION OF UVEITIS A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: NOELLE, BERNHARD (46156) TRT: ADALIMUMAB								
1060702#	AGE:71	SEX:FEMALE	RACE:WHITE	WEIGHT:67 KG				
	POST	72 TO	23 94	71	R:B-CELL-LYMPHOMA S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:B-CELL LYMPHOMA L:B-CELL LYMPHOMA	E:195 L:158 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER CEREBRAL BIOPSY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , DEATH OF SUBJECT O:UNKNOWN A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: NOELLE, BERNHARD (46156) TRT: ADALIMUMAB								
1060703	AGE:31 SEX:FEMALE RACE:OTHER: KOSOVO-ALBANER WEIGHT:78 KG							
	DB	1 TO 52	15	15 31	R:ACCIDENTAL PREDNISONE OVERDOSE S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:ACCIDENTAL OVERDOSE L:DRUG OVERDOSE ACCIDENTAL	E:31 L:17 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:OTHER SONOGRAPHY , CHEST X-RAY AND ECHOCARDIOGRAPHY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:OVERDOSE OF PREDNISON SUBJECT TOOK 60MG FROM STUDY MEDICATION AND 60MG OWN PREDNISOLON M:NO A:NOT RELATED
	OL	106 TO 256	361	32	R:TENSION HEADACHE S:NERVOUS SYSTEM DISORDERS P:TENSION HEADACHE L:TENSION HEADACHE	E:268 L:13 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER MRI, CT	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:HOSPITALIZATION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: PEREZ-ORTIZ, DON (39016) TRT: PLACEBO								
1202508	AGE:63 SEX:FEMALE RACE:WHITE WEIGHT:57 KG							
	OL	57 TO 307	363	64	R:BASAL CELL CARCINOMA S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:BASAL CELL CARCINOMA L:BASAL CELL CARCINOMA	E:443 L:137 DAYS	S:MILD R:NOT RELATED A:OTHER DERMATOLOGIST SURGERY, TUMOR REMOVED 4-16-13	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:ENVIRONMENTAL SUN EXPOSURE A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SCALES, DAVID (38787) TRT: PLACEBO									
1201614# AGE:29 SEX:MALE RACE:WHITE WEIGHT:130 KG									
	OL	173 TO 937	233	405	31	R:OPTIC DISK SWELLING OU S:EYE DISORDERS P:PAPILLOEDEMA L:OPTIC DISC ENGORGEMENT	E:468 L:236 DAYS	S:MILD R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UNKNOWN M:NO A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB									
1201601# AGE:40 SEX:FEMALE RACE:WHITE WEIGHT:72 KG									
	OL	569 TO 1044	416	984	43	R:RECTAL ADENOCARCINOMA S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:RECTAL ADENOCARCINOMA L:RECTAL ADENOCARCINOMA	E:484 L:69 DAYS	S:SEVERE R:NOT RELATED A:DISCONT. ADA/ PLACEBO A:OTHER POLYP RESECTION	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:PATIENT WITH HISTORY OF COLON POLYPS FOUND DURING COLONOSCOPY ON 19 APR 13; TWO POLYPS WERE BENING AND THIRD POLYP WAS SURGICAL REMOVED ON 10 JUN 13 AND CONFIMED MILIGNANT A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB								
1201602	AGE:40 SEX:FEMALE RACE:BLACK WEIGHT:112 KG							
	DB	1 TO 79	9 9	40	R:RIGHT EYE WORSENING OF ANGLE CLOSURE GLAUCOMA S:EYE DISORDERS P:ANGLE CLOSURE GLAUCOMA L:ANGLE CLOSURE GLAUCOMA	E:9 D:4 HOURS	S:MODERATE R:NOT RELATED P:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER REFERRED TO GLAUCOMA SPECIALIST	U:YES S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:CONCURRENT ILLNES (HISTORY OF ANGLE CLOSURE GLAUCOMA) A:NOT RELATED
	OL	85 TO	52 136	41	R:WORSENING OF HYPERTENSION S:VASCULAR DISORDERS P:HYPERTENSION L:HYPERTENSION WORSENED	E:55 L:4 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CONCURRENT ILLNESS A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB								
1201602	AGE:40	SEX:FEMALE	RACE:BLACK	WEIGHT:112 KG				
(CONT)	OL	85 TO 743	827	42	R:UTERINE LEIOMYOMAS S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:UTERINE LEIOMYOMA L:UTERINE LEIOMYOMA	E:787 L:45 DAYS	S:SEVERE R:NOT RELATED A:OTHER TOTAL ABDOMINAL HYSTERECTOMY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:UNKNOWN AT THIS TTME PATIENT HAD BENIGN LESION A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB									
1201608# AGE:72 SEX:FEMALE RACE:WHITE WEIGHT:98 KG									
	OL	568 TO 1380	91	658	74	R:WORSENING OF CYSTOCELE MIDLINE S:REPRODUCTIVE SYSTEM AND BREAST DISORDERS P:CYSTOCELE L:CYSTOCELE	E:183 L:93 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER CYSTOCELE REPAIR ON 23 APR 2013, BACTRIM 800MG BID PO POSTOPERATIVELY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:RELATED TO STRESS INCONTINENCE AND ANTERIOR VAGINAL PROLAPSE A:NOT RELATED
				658	74	R:RECTOCELE S:REPRODUCTIVE SYSTEM AND BREAST DISORDERS P:RECTOCELE L:RECTOCELE	E:183 L:93 DAYS	S:SEVERE R:NOT RELATED A:OTHER RECTOCELE REPAIR HOSPITAL STAY POSTOPERATIVELY UNTIL 24 APR 2013	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:STRESS INCONTINENCE WITH POSTERIOR PROLAPSE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SHEPPARD, JOHN (14296) TRT: PLACEBO								
1201703# AGE:51 SEX:MALE RACE:WHITE WEIGHT:113 KG								
	OL	106 TO 1184	436	541	R:CORNEAL LACERATION OD S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:CORNEAL ABRASION L:CORNEAL ABRASION	E:436 D:~10 HOURS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER RUPTURED GLOBE REPAIR	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:OCULAR TRAMA-SUBJECT WAS ACCIDENTLY HEADBUTTED A:NOT RELATED
	POST	1185 TO 7	1191	54	R:WORSENING OF GLAUCOMA OD S:EYE DISORDERS P:GLAUCOMA L:GLAUCOMA AGGRAVATED	E:1175 L:90 DAYS	S:MILD R:NOT RELATED A:DISCONT. ADA/PLACEBO A:OTHER SELECTIVE LASER TRABECULOPLASTY	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:WORSENING OF GLAUCOMA A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SHULMAN, SHIRI (39611) TRT: PLACEBO								
1070201	AGE:36 SEX:FEMALE RACE:WHITE WEIGHT:120 KG							
	OL	119 TO 884	1002	38	R:MORBID OBESITY S:METABOLISM AND NUTRITION DISORDERS P:OBESITY L:MORBID OBESITY	E:886 L:3 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER PATIENT WAS TREATED WITH : OMEPRADEX, CLEXAN, MULTI VITAMIN, TREBAMIN, CALCIUM + VITAMIN D. WAS REPORTED ON OM	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:NOT RELATED TO STUDY DRUG. THE SURGERY WAS DONE DUE TO MORBID OBESITY. A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SUHLER, ERIC (36481) TRT: PLACEBO									
1202001#	AGE:63 SEX:FEMALE RACE:WHITE WEIGHT:117 KG								
	POST	72 TO	13	84	63	R:ASPERGILLOSIS S:INFECTIONS AND INFESTATIONS P:ASPERGILLUS INFECTION L:ASPERGILLOSIS	E:57 L:44 DAYS	S:SEVERE R:PROBABLY RELATED A:DISCONT. ADA/ PLACEBO	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:POSSIBLY RELATED
				84	63	R:ACUTE RENAL FAILURE S:RENAL AND URINARY DISORDERS P:RENAL FAILURE ACUTE L:ACUTE RENAL FAILURE	O:141 L:>58 DAYS	S:SEVERE R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O:PREDNISONE, SEPTIC SHOCK A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SUHLER, ERIC (36481) TRT: PLACEBO								
1202001#	AGE:63 SEX:FEMALE RACE:WHITE WEIGHT:117 KG							
(CONT)	POST	72 TO	13	84 63	R:SEPTIC SHOCK S:INFECTIONS AND INFESTATIONS P:SEPTIC SHOCK L:SEPTIC SHOCK	E:28 L:15 DAYS	S:SEVERE R:PROBABLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SUHLER, ERIC (36481) TRT: PLACEBO								
1202001# AGE:63 SEX:FEMALE RACE:WHITE WEIGHT:117 KG								
(CONT)	POST	72 TO	13 84	63	R:ANASARCA S:GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P:GENERALISED OEDEMA L:ANASARCA	E:28 L:15 DAYS	S:SEVERE R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION . IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O:SECONDARY TO VOLUME RESUSCITATION A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SUHLER, ERIC (36481) TRT: PLACEBO									
1202001# AGE:63 SEX:FEMALE RACE:WHITE WEIGHT:117 KG									
(CONT)	POST	72 TO	13	84	63	R:URINARY TRACT INFECTION S:INFECTIONS AND INFESTATIONS P:URINARY TRACT INFECTION L:URINARY TRACT INFECTION	E:28 L:15 DAYS	S:SEVERE R:PROBABLY RELATED A:DISCONT. ADA/ PLACEBO	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SUHLER, ERIC (36481) TRT: PLACEBO									
1202001# AGE:63 SEX:FEMALE RACE:WHITE WEIGHT:117 KG									
(CONT)	POST	72 TO	18	89	63	R:PNEUMOTHORAX S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:PNEUMOTHORAX L:PNEUMOTHORAX	E:19 D:1	S:SEVERE R:NOT RELATED A:OTHER CHEST TUBE INSERTED	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O:MEDIASTINOSCOPY A:NOT RELATED
			30	101	63	R:ANTRAL GASTRIC ULCER S:GASTROINTESTINAL DISORDERS P:GASTRIC ULCER L:ANTRAL ULCER	E:32 L:2 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:COUMADIN A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: SUHLER, ERIC (36481) TRT: PLACEBO									
1202004#	AGE:43 SEX:FEMALE RACE:WHITE WEIGHT:95 KG								
	POST	44 TO 14	57		43	R:VISION LOSS S:EYE DISORDERS P:BLINDNESS L:VISION LOSS	O:119 L:>63 DAYS	S:MODERATE R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION	U:YES S:YES, PERSISTENT OR SIGNIFICANT DISABILITY O:NON-PHYSIOLOGIC VISION LOSS, BOTH EYES A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: VAN CALSTER, JOACHIM (39603) TRT: PLACEBO								
1020203	AGE:51	SEX:FEMALE	RACE:WHITE	WEIGHT:44 KG				
	OL	154 TO	50	203 51	R:RIGHT PATELLOFEMORAL PAIN S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:PATELLOFEMORAL PAIN SYNDROME L:PATELLOFEMORAL PAIN SYNDROME	E:125 L:76 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER RIGHT PATELLOFEMORAL PROTHESIS	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:HISTORY OF PAINFULL KNEE A:NOT RELATED
			447	600	R:PAIN LEFT KNEE S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:ARTHRALGIA L:PAIN IN KNEE	E:1176 L:730 DAYS	S:SEVERE R:NOT RELATED A:OTHER TOTAL LEFT KNEE PROTHESIS	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:HISTORY OF KNEE PROBLEMS M:NO

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: VAN CALSTER, JOACHIM (39603) TRT: PLACEBO								
1020203	AGE:51	SEX:FEMALE	RACE:WHITE	WEIGHT:44 KG				
(CONT)	OL	154 TO	628	781	53	R:WORSENING OF EPICONDYLITIS LATERALIS (RIGHT ARM) S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:EPICONDYLITIS L:LATERAL EPICONDYLITIS	E:688 L:61 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:OTHER SURGERY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:HISTORY OF EPICONDYLITIS LATERALIS A:PROBABLY NOT RELATED
			1052	1205	54	R:COMMINUTED OLECRANON FRACTURE (RIGHT) S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:COMMINUTED FRACTURE L:COMMINUTED FRACTURE	E:1115 L:64 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER OSTEOSYNTHESIS; PLASTER	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:TRAUMA AFTER FALL A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
1020204	AGE:70 SEX:MALE RACE:WHITE WEIGHT:75 KG							
	OL	190 TO	327	516 72	R:PYONEPHROSIS RIGHT S:INFECTIONS AND INFESTATIONS P:PYONEPHROSIS L:PYONEPHROSIS	E:410 L:84 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER NEPHROSTOMY IN SITU AND AFTERWARDS A NEFRECTOMY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:BLOCKAGE OF URETHRA A:PROBABLY RELATED
			334	523 72	R:PULMONARY EMBOLISM S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:PULMONARY EMBOLISM L:PULMONARY EMBOLISM	E:567 L:234 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER RX THORAX, CT SCAN THORAX, DUPLEX LE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:ACCIDENTAL DISCOVERY, NO CAUSE KNOWN A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ZAKO, M (47592) TRT: PLACEBO									
1401001	AGE:70	SEX:FEMALE	RACE:ASIAN	WEIGHT:67 KG					
	OL	85 TO	211	295	71	R:VITREOUS OPACITY(OU) S:EYE DISORDERS P:VITREOUS OPACITIES L:VITREOUS OPACITY	E:581 L:371 DAYS	S:MODERATE R:NOT RELATED A:OTHER PHACOEMULSIFICATION AND ASPIRATION + INTRAOCULAR LENS + VITRECTOMY	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:THE LEVELS OF VITREOUS OPACITY DID NOT CHANGE AFTER THE ADMINISTRATION OF THE ADALIMUMAB.THIS PATIENT JUST WANTED TO SEE CLEARLY BY THE VITRECTOMY. A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: ZAKO, M (47592) TRT: PLACEBO								
1401001	AGE:70 SEX:FEMALE RACE:ASIAN WEIGHT:67 KG							
(CONT)	OL	85 TO 600	684	72	R:RIGHT RHEGMATOGENONS RETINAL DETACHMENT S:EYE DISORDERS P:RETINAL DETACHMENT L:RHEGMATOGENOUS RETINAL DETACHMENT	E:613 L:14 DAYS	S:MODERATE R:NOT RELATED A:OTHER VITRECTOMY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IATRAGENIC RETINAL DETACHMENT AFTER VITRECTOMY A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: ARELLANES-GARCIA, LOURDES (45324) TRT: PLACEBO								
2240252# AGE:39 SEX:FEMALE RACE:OTHER: MESTIZO WEIGHT:88 KG								
	OL	92 TO 121	30 121	40	R:LATENT TB WITH POSITIVE QUANTIFERON S:INFECTIONS AND INFESTATIONS P:LATENT TUBERCULOSIS L:LATENT TUBERCULOSIS	E:142 L:113 DAYS	S:SEVERE R:PROBABLY RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER THE PATIENT IS UNDER INFECTOLOGY VALORATION AND TB TREATMENT	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: BARISANI-ASENBAUER, TALIN (39651) TRT: PLACEBO								
2010153 AGE:21 SEX:MALE RACE:WHITE WEIGHT:69 KG								
	OL	27 TO 1201	1227	25	R:ABSCESS LEFT AXILLA S:INFECTIONS AND INFESTATIONS P:SUBCUTANEOUS ABSCESS L:AXILLARY ABSCESS	E:1202 L:2 DAYS	S:MILD R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER ABSCESS EXCISION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:NO OTHER CAUSE HAS BEEN REPORTED M:NO A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: BEARE, NICHOLAS (48651) TRT: ADALIMUMAB								
2120452# AGE:25 SEX:FEMALE RACE:WHITE WEIGHT:87 KG								
	POST	607 TO	24 630	27	R:HYPEREMESIS OF PREGNANCY S:PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS P:HYPEREMESIS GRAVIDARUM L:HYPEREMESIS GRAVIDARUM	O:690 L:>61 DAYS	S:SEVERE R:NOT RELATED A:OTHER HOSPITAL FOR REHYDRATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PREGNANCY M:NO A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: CIMINO, LUCA (45414) TRT: PLACEBO								
2080554	AGE:57 SEX:MALE RACE:WHITE WEIGHT:117 KG							
	OL	85 TO	212 296	58	R:GALLSTONES S:HEPATOBILIARY DISORDERS P:CHOLELITHIASIS L:GALLSTONES	E:268 L:57 DAYS	S:SEVERE R:NOT RELATED A:OTHER RESECTION OF THE GALLBLADDER	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:GALLSTONES A:PROBABLY NOT RELATED
			267 351	58	R:WORSENING OF OBESITY S:METABOLISM AND NUTRITION DISORDERS P:OBESITY L:OBESITY	E:268 L:2 DAYS	S:MODERATE R:NOT RELATED A:OTHER SLEEVE GASTRECTOMY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:BINGE EATER A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: DE SCHRYVER, ISLE (53643) TRT: ADALIMUMAB								
2020150	AGE:47 SEX:FEMALE RACE:WHITE WEIGHT:88 KG							
	OL	561 TO	260	820	49	R:RETINAL DETACHMENT OD S:EYE DISORDERS P:RETINAL DETACHMENT L:RETINAL DETACHMENT	E:261 L:2 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER SURGERY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CAUSE IS UNKNOWN A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: DE SCHRYVER, ISLE (53643) TRT: ADALIMUMAB								
2020152# AGE:30 SEX:MALE RACE:WHITE WEIGHT:69 KG								
	POST	86 TO	7 92	30	R:POSITIVE PPD S:INVESTIGATIONS P:TUBERCULIN TEST POSITIVE L:PPD SKIN TEST POSITIVE	E:8 D:UNKNOWN	S:MILD R:NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER CHEST X-RAY, QUANTIFERON TB GOLD, CT MEDIASTINUM, PPD	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:UNKNOWN - QUANTIFERON TB GOLD WAS NEGATIVE A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: DICK, ANDREW (39613) TRT: PLACEBO									
2120163# AGE:49 SEX:FEMALE RACE:WHITE WEIGHT:94 KG									
	OL	127 TO 449	169	295	50	R:LOBULAR IN-SITU LEFT BREAST CARCINOMA S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:LOBULAR BREAST CARCINOMA IN SITU L:LOBULAR BREAST CARCINOMA IN SITU	E:239 L:71 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO A:OTHER LEFT WIRE GUIDED EXCISION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UNKNOWN A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: DICK, ANDREW (39613) TRT: ADALIMUMAB									
2120152# AGE:45 SEX:FEMALE RACE:WHITE WEIGHT:102 KG									
	POST	1134 TO	14	1147	48	R:FIBROTIC CHANGES IN LUNGS S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:PULMONARY FIBROSIS L:LUNG FIBROSIS	O:1246 L:>100 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER CHEST X-RAY CT SCAN	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:DIFFERENTIAL DIAGNOSIS OF SARCOID, HYPERSENSITIVITY PNEUMNOITIS OR ATYPICAL INFECTION BUT ACTUAL DIAGNIOSIS AND CAUSE UNKNOWN A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: DICK, ANDREW (39613) TRT: ADALIMUMAB									
2120157	AGE:70 SEX:FEMALE RACE:WHITE WEIGHT:61 KG								
	DB	1 TO 554	228	228	71	R:EPISTAXIS S:RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P:EPISTAXIS L:EPISTAXIS	E:231 L:4 DAYS	S:MODERATE R:PROBABLY NOT RELATED P:PROBABLY NOT RELATED A:OTHER RAPID RHINO	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IDIOPATHIC A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (P1) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: FRANCO, PABLO (45421) TRT: ADALIMUMAB									
2220155	AGE:47 SEX:MALE RACE:WHITE WEIGHT:93 KG								
	OL	121 TO	367	487	49	R:RIGHT TOE SOFT TISSUE INFECTION SECONDARY TO ONYCHOCRYPTOSIS S:SKIN AND SUBCUTANEOUS TISSUE DISORDERS P:INGROWING NAIL L:ONYCHOCRYPTOSIS	E:419 L:53 DAYS	S:MODERATE R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER TOILETTE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:AT WEEK 54 VISIT PATIENT REFERRED PAIN AT RIGHT TOE. THE CAUSE IS UNK A:POSSIBLY RELATED
				487	49	---------- S A M E A S A B O V E ---------- INFESTATIONS P:SOFT TISSUE INFECTION L:SOFT TISSUE INFECTION			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: GOTO, HIROSHI (40101) TRT: PLACEBO									
2400250# AGE:55 SEX:FEMALE RACE:ASIAN WEIGHT:99 KG									
	POST	716 TO	10	725	57	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:PNEUMONIA L:PNEUMONIA	E:743 L:61 DAYS	S:SEVERE R:POSSIBLY RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER THORACIC DRAINAGE THORACENTESIS BLOOD TEST CHESR X-RAY CHEST COMPUTED TOMOGRAPHY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:WORSENING OF ORDINARY FLU A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: GUEX-CROSIER, YAN (45850) TRT: ADALIMUMAB								
2150152	AGE:46 SEX:MALE RACE:WHITE WEIGHT:59 KG							
	OL	568 TO 255	822	48	R:TRANSIENT ISCHEMIC ATTACK S:NERVOUS SYSTEM DISORDERS P:TRANSIENT ISCHAEMIC ATTACK L:TRANSIENT ISCHEMIC ATTACKS	E:259 L:5 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:DUE TO CONGENITAL HEART DISEASE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: HASHIDA, NORIYASU (52321) TRT: ADALIMUMAB								
2400755# AGE:45 SEX:FEMALE RACE:ASIAN WEIGHT:58 KG								
	OL	42 TO 827	513	554 46	R:CATARACT(OD) S:EYE DISORDERS P:CATARACT L:CATARACT (RIGHT)	E:547 L:35 DAYS	S:MODERATE R:NOT RELATED A:OTHER CATARACT SURGERY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PREDONISOLONE A:PROBABLY NOT RELATED
			576	617 46	R:CATARACT(OS) S:EYE DISORDERS P:CATARACT L:CATARACT (LEFT)	E:638 L:63 DAYS	S:MODERATE R:NOT RELATED A:OTHER CATARAACT SURGERY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PREDONISOLONE A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: HASHIDA, NORIYASU (52321) TRT: ADALIMUMAB								
2400755# AGE:45 SEX:FEMALE RACE:ASIAN WEIGHT:58 KG								
(CONT)	OL	42 TO 827	745	786	47	R:COLORECTAL CANCER S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:COLORECTAL CANCER L:COLORECTAL CANCER	E:781 L:37 DAYS	S:MILD R:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: KABURAKI, TOSHIKATSU (39788) TRT: ADALIMUMAB									
2400351	AGE:52 SEX:FEMALE RACE:ASIAN WEIGHT:59 KG								
	OL	89 TO	246	334	53	R:INCREASED INTRAOCULAR PRESSURE (OS) S:INVESTIGATIONS P:INTRAOCULAR PRESSURE INCREASED L:INCREASED INTRAOCULAR PRESSURE	E:318 L:73 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER TRABECULOTOMY(O-S)	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UVEITIS,ANGLE CLOSURE SECONDARY GLAUCOMA A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: KEDHAR, SANJAY (38777) TRT: PLACEBO								
2202851	AGE:45 SEX:MALE RACE:WHITE WEIGHT:95 KG							
	OL	135 TO 602	736	47	R:RUPTURED APPENDIX S:INFECTIONS AND INFESTATIONS P:APPENDICITIS PERFORATED L:RUPTURED APPENDIX	E:605 L:4 DAYS	S:SEVERE R:PROBABLY NOT RELATED	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION . IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:ACUTE APPENDICITIS A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	--------- EPOCH --------- NAME	INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: KRAMER, MICHAL (39610) TRT: ADALIMUMAB								
2070151	AGE:23 SEX:FEMALE RACE:WHITE WEIGHT:57 KG							
	OL	568 TO	19	586 25	R:BILIARY COLIC S:HEPATOBILIARY DISORDERS P:BILIARY COLIC L:BILIARY COLIC	E:53 L:35 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:CHOLELITHIASIS A:NOT RELATED
			54	621 25	R:RIGHT SHOULDER PAIN S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:MUSCULOSKELETAL PAIN L:SHOULDER PAIN	E:55 L:2 DAYS	S:MODERATE R:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:S/P LAPAROSCOPIC CHOLECYSTECTOMY A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: LARSON, T (52561) TRT: ADALIMUMAB								
2201951	AGE:43 SEX:MALE RACE:BLACK WEIGHT:98 KG							
	OL	567 TO 618	1184	46	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:PNEUMONIA L:PNEUMONIA	E:623 L:6 DAYS	S:MODERATE R:PROBABLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: MACKENSEN, FRIEDERIKE (40288) TRT: PLACEBO								
2060250# AGE:48 SEX:FEMALE RACE:WHITE WEIGHT:62 KG								
	OL	36 TO 64	15	50 48	R:ADENO CA COLON ASCENDENS S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:ADENOCARCINOMA OF COLON L:ADENOCARCINOMA OF COLON	O:162 L:>113 DAYS	S:SEVERE R:NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION A:OTHER FURTHER EXAMINATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:UNKNOWN A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: MERRILL, PAULINE (38782) TRT: ADALIMUMAB								
2201252# AGE:42 SEX:FEMALE RACE:WHITE WEIGHT:72 KG								
	OL	568 TO 1387	590	1157	45 R:HERPES ZOSTER OPHTHALMITIS LEFT SIDE/OS S:INFECTIONS AND INFESTATIONS P:OPHTHALMIC HERPES ZOSTER L:OPHTHALMIC HERPES ZOSTER	E:617 L:28 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:SHINGLES A:PROBABLY NOT RELATED
			751	1318	45 R:PANCREATITIS S:GASTROINTESTINAL DISORDERS P:PANCREATITIS L:PANCREATITIS	E:786 L:36 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:GI PAIN AND ER VISIT A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: MERRILL, PAULINE (38782) TRT: ADALIMUMAB								
2201252# AGE:42 SEX:FEMALE RACE:WHITE WEIGHT:72 KG								
(CONT)	OL	568 TO 1387	786	1353	46	R:COLITIS S:GASTROINTESTINAL DISORDERS P:COLITIS L:COLITIS	E:815 L:30 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER ER VISIT, CT SCAN,	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:COLITIS A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: MERRILL, PAULINE (38782) TRT: ADALIMUMAB								
2201252# AGE:42 SEX:FEMALE RACE:WHITE WEIGHT:72 KG								
(CONT)	OL	568 TO 1387	795	1362	46	R:COLON POLYP S:GASTROINTESTINAL DISORDERS P:LARGE INTESTINE POLYP L:COLONIC POLYP	E:795 D:5-6 HOURS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER COLONOSCOPY AND ENDOSCOPY AND POLYP REMOVAL	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:GI PROBLEMS(COLITIS) A:PROBABLY NOT RELATED
			815	1382	46	R:CROHNS DISEASE FLARE S:GASTROINTESTINAL DISORDERS P:CROHN'S DISEASE L:CROHNS DISEASE AGGRAVATED	E:872 L:58 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:INFLAMMATORY BOWEL DISEASE A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: MISIUK-HOJLO, MARTA (45771) TRT: ADALIMUMAB									
2140150	AGE:56 SEX:FEMALE RACE:WHITE WEIGHT:68 KG								
	OL	359 TO	82	440	57	R:HYDROCELE FALLOPIAN TUBE S:REPRODUCTIVE SYSTEM AND BREAST DISORDERS P:HYDROCELE FEMALE L:HYDROCELE FEMALE	E:96 L:15 DAYS	S:MILD R:NOT RELATED A:NONE	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:MOST LIKELY CAUSE WAS AFTER INFLAMATION EFFECT . IMFLAMATION WAS RESULT OF SURGERY (C SECTION) A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: NAMBA, KENICHI (39745) TRT: PLACEBO								
2400653# AGE:62 SEX:FEMALE RACE:ASIAN WEIGHT:63 KG								
	OL	29 TO 351	211	239	62	R:LEFT EPIRETINAL MEMBRANE S:EYE DISORDERS P:MACULAR FIBROSIS L:EPIRETINAL MEMBRANE	E:224 L:14 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER LEFT EPIRETINAL MEMBRANE SURGERY WAS PARFORMED.	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CAUSED BY UVEITIS A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: NESS, THOMAS (40289) TRT: PLACEBO								
2060352	AGE:23 SEX:MALE RACE:WHITE WEIGHT:67 KG							
	OL	300 TO 784	1083	26	R:PERITONSILLAR ABSZESS S:INFECTIONS AND INFESTATIONS P:PERITONSILLAR ABSCESS L:PERITONSILLAR ABSCESS	E:804 L:21 DAYS	S:MODERATE R:POSSIBLY RELATED A:TREATED WITH MEDICATION A:OTHER INITIALLY THE PATIENT GOT ERYTHROMYCINE OVER 5 DAYS WITHOUT EFFECT, ON SATURDAY MEDICATION WAS CHANGED TO LEVOFLOXACIN AND TONSILLECTOMY WAS PERFORMED.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:IT IS AN INFECTION, THEREFORE IT MIGHT BE RELATED TO ADALIMUMAB M:NO A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: NESS, THOMAS (40289) TRT: PLACEBO									
2060352 AGE:23 SEX:MALE RACE:WHITE WEIGHT:67 KG									
(CONT)	OL	300 TO	801	1100	26	R:SLIGHT POSTOPERATIVE HEMORRHAGE AFTER TONSILLECTOMY S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:POST PROCEDURAL HAEMORRHAGE L:POSTOPERATIVE HEMORRHAGE	E:804 L:4 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:OTHER IN PATIENT MONITORING IN THE ENT DEPARTMENT	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PROBABLY NOT RELATED, IT IS RELATED TO THE SURGERY ON 17 MAY 2014 M:NO A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: PATEL, SARJU (50184) TRT: ADALIMUMAB								
2205251	AGE:75 SEX:MALE RACE:OTHER: LATINO WEIGHT:71 KG							
	OL	141 TO 120	260	76	R:HYPOGLYCEMIA S:METABOLISM AND NUTRITION DISORDERS P:HYPOGLYCAEMIA L:HYPOGLYCEMIA	E:120 D:UNKNOWN	S:MILD R:NOT RELATED A:OTHER STOPPED GLIMEPERIDE	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:GLIMEPERIDE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: PAVESIO, CARLOS (39615) TRT: PLACEBO								
2120350# AGE:56 SEX:MALE RACE:ASIAN WEIGHT:58 KG								
	OL	586 TO 673	88	673 57	R:ELEVATED ABNORMAL LIVER ENZYMES S:INVESTIGATIONS P:HEPATIC ENZYME INCREASED L:ELEVATED LIVER ENZYME LEVELS	E:267 L:180 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:DISCONT. ADA/ PLACEBO A:OTHER REFER TO GENERAL A&E	U:NO S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:ACUTE PANCREATITIS, MONONUCLEOSIS, EXCSEEIVE ALCOHOL CONSUMPTION, HEART ATTACK, USE OF MYCPHENOLATE MOFETIL A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: PAVESIO, CARLOS (39615) TRT: PLACEBO									
2120350# AGE:56 SEX:MALE RACE:ASIAN WEIGHT:58 KG									
(CONT)	POST	674 TO	1	674	57	R:TUBERCULOSIS S:INFECTIONS AND INFESTATIONS P:TUBERCULOSIS L:TUBERCULOSIS	O:852 L:>179 DAYS	S:SEVERE R:NOT RELATED A:DISCONT. ADA/ PLACEBO A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:THE CAUSE OF EVENT WAS PROBABLE TUBERCULOSIS A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB								
2201654	AGE:50 SEX:FEMALE RACE:BLACK WEIGHT:80 KG							
	OL	568 TO	306 873	52	R:RIGHT NASAL CELLULITIS S:INFECTIONS AND INFESTATIONS P:CELLULITIS L:CELLULITIS	E:311 L:6 DAYS	S:SEVERE R:POSSIBLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:UNDERLYING CHRONIC SINUS DISEASE A:PROBABLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: SONODA, KOH-HEI (47594) TRT: PLACEBO								
2401150	AGE:29 SEX:MALE RACE:ASIAN WEIGHT:98 KG							
	OL	30 TO	14 43	29	R:AGGRAVATION OF UVEITIS(OU) S:EYE DISORDERS P:UVEITIS L:UVEITIS	O:323 L:>281 DAYS	S:SEVERE R:NOT RELATED A:TREATED WITH MEDICATION	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:PREDONINE REDUCTION M:NO A:NOT RELATED
			322 351	30	R:AGGRAVATION OF OCULAR HYPERTENSION(OU) S:EYE DISORDERS P:OCULAR HYPERTENSION L:OCULAR HYPERTENSION	E:450 L:129 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER TLO(OU)	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:1,AGGRAVATION OF COMPLICATION 2,STEROID RESPONDER M:NO A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	--------- EPOCH --------- NAME	INTERVAL	DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: SONODA, KOH-HEI (47594) TRT: PLACEBO									
2401150	AGE:29 SEX:MALE RACE:ASIAN WEIGHT:98 KG								
(CONT)	OL	30 TO	506	535	31	R:CATARACT(OS) S:EYE DISORDERS P:CATARACT L:CATARACT (LEFT)	E:590 L:85 DAYS	S:MODERATE R:POSSIBLY RELATED A:OTHER SURGERY	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:STEROID RESPONDER, INFLAMATION INDUCED BY THE GLAUCOMA SURJERY M:NO A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: SONODA, KOH-HEI (47594) TRT: ADALIMUMAB									
2401153	AGE:63 SEX:FEMALE RACE:ASIAN WEIGHT:50 KG								
	DB	1 TO 273	273	273	63	R:AGGRAVATION OF CATARACT(OU) S:EYE DISORDERS P:CATARACT L:CATARACT AGGRAVATED	E:86 L:100 DAYS	S:MILD R:NOT RELATED A:OTHER PEA(OU)	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:AGGRAVATION OF COMPLICATION,AGING A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	EPOCH DAY	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: VAN CALSTER, JOACHIM (39603) TRT: PLACEBO									
2020252# AGE:52 SEX:MALE RACE:WHITE WEIGHT:80 KG									
	OL	36 TO 1380	425	460	53	R:MYOPATHY S:MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P:MYOPATHY L:MYOPATHY	O:1416 L:>957 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER EMG; MRI; MR; LABS; CLINICAL EXAM; BIOPSY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:SARCOID MYOPATHIE A:PROBABLY NOT RELATED
2020266 AGE:67 SEX:FEMALE RACE:WHITE WEIGHT:50 KG									
	OL	379 TO	105	483	68	R:PSEUDOPHAKIC RETINAL DETACHMENT OS S:EYE DISORDERS P:RETINAL DETACHMENT L:RETINAL DETACHMENT	E:141 L:37 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER VITRECTOMY OS	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IDIOPATHIC A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
2020250	AGE:53 SEX:MALE RACE:WHITE WEIGHT:82 KG							
	OL	57 TO	434	490 54	R:PERSISTENT PARS PLANITIS OS S:EYE DISORDERS P:UVEITIS L:PARS PLANITIS	E:497 L:64 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER SURGERY: VITRECTOMY + PHACO-EMULSIFICATION	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:UVEITIS A:NOT RELATED
			516	572 54	R:PERSISTENT LOW GRADE INFLAMMATION (RIGHT EYE) S:EYE DISORDERS P:EYE INFLAMMATION L:EYE INFLAMMATION	E:572 L:57 DAYS	S:MODERATE R:NOT RELATED A:TREATED WITH MEDICATION A:OTHER SURGERY VITRECTOMY, PHACO-EMULSIFICATION AND SYNECHIOLYSIS.	U:YES S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UVEITIS A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
2020250	AGE:53 SEX:MALE RACE:WHITE WEIGHT:82 KG							
(CONT)	OL	57 TO 1453	1509	57	R:RENAL COLIC RIGHT S:RENAL AND URINARY DISORDERS P:RENAL COLIC L:RENAL COLIC	E:1475 L:23 DAYS	S:MODERATE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER CT, ECHO	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:POSSIBLY DISTAL RIGHT URETEROLITHIASIS WITH LIGHT SIGNS OF CONGESTION A:PROBABLY NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
2020268	AGE:39 SEX:MALE RACE:WHITE WEIGHT:91 KG							
	DB	1 TO 358	68	68	39 R:LEFT WEBER C FIBULA FRACTURE S:INJURY, POISONING AND PROCEDURAL COMPLICATIONS P:FIBULA FRACTURE L:FIBULA FRACTURE	E:77 L:10 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:TREATED WITH MEDICATION A:OTHER PLASTER CAST; PLATE OSTEOSUNTHESIS; CRUTCHES FOR 6 WEEKS; PHYSIOTHERAPY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:TRAUMA A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.4.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
SERIOUS ADVERSE EVENTS
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880/M11-327 INV: ZAKO, M (47592) TRT: PLACEBO								
2401054	AGE:58	SEX:FEMALE	RACE:ASIAN	WEIGHT:88 KG				
	OL	253 TO	86 338	59	R:LEFT PYELONEPHRITIS S:INFECTIONS AND INFESTATIONS P:PYELONEPHRITIS L:PYELONEPHRITIS	E:102 L:17 DAYS	S:MODERATE R:POSSIBLY RELATED A:TREATED WITH MEDICATION	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:MEDICAL HISTORY OF URINARY TRACT INFECTION,AGING A:POSSIBLY RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD

Program Source Code: [redacted]

TABLE 2.4__2.7.6.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
ADVERSE EVENTS LEADING TO DEATH
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET DAY	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877 INV: SCALES, DAVID (38787) TRT: ADALIMUMAB								
1201613# AGE:79 SEX:FEMALE RACE:WHITE WEIGHT:75 KG								
	POST	35 TO	3	37 80	R:END STAGE RENAL DISEASE S:RENAL AND URINARY DISORDERS P:RENAL FAILURE CHRONIC L:END STAGE RENAL DISEASE (ESRD)	E:37 D:UNKNOWN	S:SEVERE R:NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:DISCONT. PREDNISONE	U:NO S:YES, DEATH OF SUBJECT O:CAUSE OF DEATH END STAGE RENAL DISEASE A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.6.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
ADVERSE EVENTS LEADING TO DEATH
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-880 INV: VAN CALSTER, JOACHIM (39603) TRT: ADALIMUMAB								
2020259# AGE:62 SEX:MALE RACE:WHITE WEIGHT:73 KG								
	DB	1 TO 36 28	28	62	R:ACUTE AORTADISSECTION WITH CARDIAC TAMPONADE S:VASCULAR DISORDERS P:AORTIC DISSECTION L:AORTIC DISSECTION	E:54 L:27 DAYS	S:SEVERE R:NOT RELATED P:NOT RELATED A:DISCONT. ADA/ PLACEBO A:DISCONT. PREDNISONE A:OTHER REFERRAL TO INTERNIST; CLINICAL EXAMINATION; LAB; ECG; RX THORAX; KIDNEY AND BLADDER ULTRASOUND; CT SCAN PULMONARY EMBOLISM.	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , DEATH OF SUBJECT O:ANEURYSMA AORTAE ABDOMINALIS; CARDIAC A:PROBABLY NOT RELATED
			28	62	---------- S A M E A S A B O V E ---------- P:CARDIAC TAMPONADE L:CARDIAC TAMPONADE			

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

TABLE 2.4__2.7.6.4

LISTING OF SUBJECTS WITH TREATMENT-EMERGENT
ADVERSE EVENTS LEADING TO DEATH
(ALL ADALIMUMAB SET)

SUBJECT NUMBER	EPOCH NAME	EPOCH INTERVAL	RX DAY OF ONSET	AGE AT ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 17.1 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AS OF RX DAY D:DURATION L:LENGTH I:INTERMITTENT	S:SEVERITY R:RELATIONSHIP TO ADA/PLO P:RELATIONSHIP TO PRESNISONE A:ACTIONS TAKEN	U:UVEITIS RELATED (PI) S:SERIOUS AE? O:OTHER CAUSE OF EVENT M:MALIGNANCY A:ABBVIE OPINION CAUSALITY (ADA/PLO)
STUDY:M10-877/M11-327 INV: NOELLE, BERNHARD (46156) TRT: ADALIMUMAB								
1060702# AGE:71 SEX:FEMALE RACE:WHITE WEIGHT:67 KG								
	POST	72 TO	23	94	71	R:B-CELL-LYMPHOMA S:NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P:B-CELL LYMPHOMA L:B-CELL LYMPHOMA	E:195 L:158 DAYS	S:SEVERE R:PROBABLY NOT RELATED A:TREATED WITH MEDICATION A:OTHER CEREBRAL BIOPSY	U:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION , DEATH OF SUBJECT O:UNKNOWN A:NOT RELATED

DB - DOUBLE BLIND PERIOD, OL - OPEN LABEL PERIOD
SUBJECT PREMATURELY DISCONTINUED.

Program Source Code: [redacted]

2.7.5 参考文献

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2.7.6 個々の試験のまとめ

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M10-877 試験（薬物動態）

治験の標題： A Multicenter Study of the Efficacy and Safety of the Human Anti-TNF Monoclonal Antibody Adalimumab as Maintenance Therapy in Subjects Requiring High Dose Corticosteroids for Active Non-infectious Intermediate-, Posterior-, or Pan-uveitis - VISUAL I	
施設数 / 実施国名： 74 施設（日本 7 施設を含む）	
治験期間： 最初の被験者の最初の来院日：2010 年 8 月 10 日 最後の被験者の最後の来院日：2014 年 8 月 29 日	開発のフェーズ： 第 III 相
目的： 本薬物動態報告書の目的は，高用量の副腎皮質ステロイドを必要とする活動性かつ非感染性の中間部，後部，又は汎ぶどう膜炎患者に，投与 0 週にアダリムマブを 80 mg 負荷投与（皮下）し，引き続き投与 1 週から 40 mg 隔週投与した時の薬物動態及び免疫原性を評価することである。	
治験方法： 本治験は，活動性かつ非感染性の中間部，後部，又は汎ぶどう膜炎の成人患者のうち，プレドニゾン経口剤換算 10 mg/日以上，60 mg/日以下の副腎皮質ステロイド（以下「ステロイド」）経口剤を 2 週間以上投与しているにもかかわらず，両眼又は片眼に活動性が認められる患者を対象とした，多施設共同無作為化プラセボ対照二重盲検比較試験である。本治験では日本の施設でのみ被験者を組入れる日本人サブ試験も実施した。 被験者は，治験薬投与開始前の免疫抑制剤使用の有無により層別し（日本人サブ試験は除く），二重盲検下，投与群 1 又は投与群 2 のどちらかに 1：1 の比率で割付けた。 血清中アダリムマブ濃度及び血清中抗アダリムマブ抗体（以下「AAA」）濃度の測定のために，次の時点の血液サンプルを採取した。 • 血清中アダリムマブ濃度：治験薬の投与開始時，投与 1，8，12，27，36，52 週及び治験終了 / 中止時（投与 52 週までに中止した場合）に採取した。予定外の来院時にも，投与 52 週までであった場合には，血清中アダリムマブ濃度測定用の血液サンプルを採取した。治験薬の投与開始時，投与 1 週及び 27 週の血清中アダリムマブ濃度測定用の血液は，治験薬（アダリムマブ又はプラセボ）を投与する前に採取した。 • 血清中 AAA 濃度：治験薬の投与開始時，投与 12，27，36，52 週及び治験終了 / 中止時（投与 52 週までに中止した場合）に採取した。予定外の来院時にも，投与 52 週までであった場合には，血清中 AAA 濃度測定用の血液サンプルを採取した。治験薬（アダリムマブ又はプラセボ）の投与開始時，及び投与 27 週の血清中 AAA 濃度測定用の血液は，治験薬を投与する前に採取した。	
被験者数（計画時と解析時）： 計画時：メイン試験（日本人以外）234 名，日本人サブ試験 32 名 組入れ数：239 名（メイン試験：223 名，日本人サブ試験：16 名） 薬物動態解析被験者数：233 名（メイン試験：217 名，日本人サブ試験：16 名）	

診断と主要な組み入れ基準：

主な選択基準：

- 18 歳以上の患者。
- 非感染性の中間部，後部，又は汎ぶどう膜炎と診断された患者。
- ベースライン評価来院時に，プレドニゾン経口剤換算 10 mg/日以上，60 mg/日以下のステロイド経口剤による維持療法を 2 週間以上実施しているにもかかわらず，片眼又は両眼が次のいずれかの疾患活動性を示す患者：
  - 活動性かつ炎症性の脈絡網膜病変又は網膜血管病変が認められる。
  - 前房内細胞が，国際ぶどう膜炎研究会 ぶどう膜炎の標準化委員会（以下「SUN」）基準のグレード 2 + 以上である。
  - 硝子体混濁が，米国国立眼病研究所（以下「NEI」）/SUN 基準のグレード 2 + 以上である。

被験薬，用量，投与方法及びバッチ番号：

全ての治験薬及びプラセボは皮下投与した。

アダリムマブ製造ロット番号： A* , B* , C* , D* , E*

プラセボ製造ロット番号： F* , G*

治療期間：二重盲検下の治験薬投与期間は，最長で，投与 80 週まで又は再燃した被験者が 138 名（日本人患者を除く）集積された時点までとした。日本人サブ試験の終了時期は，当初，メイン試験（日本人患者を除く）で再燃した被験者が 138 名集積された時点，又は日本人サブ試験で再燃した被験者が 19 名集積された時点としたが，日本人被験者の組入れが困難で，目標被験者数の達成がメイン試験の終了よりも大幅に遅くなると考えられたため，独立行政法人医薬品医療機器総合機構（PMDA）と相談し，日本人サブ試験の終了時期についてはメイン試験終了時とすることで合意を得た。

評価基準：

薬物動態：

血清中アダリムマブ濃度については各時点で記述統計量を算出した。また，再燃と判定された被験者と判定されなかった被験者の血清中アダリムマブ濃度を比較した。

免疫原性：

AAA 陽性被験者数及びその割合を算出した。また，AAA が血清中アダリムマブ濃度，有効性及び安全性に与える影響を評価した。

結果と結論：

投与 0 週にアダリムマブを 80 mg 負荷投与し，引き続き投与 1 週から 40 mg 隔週投与したとき，平均血清中アダリムマブ濃度は投与 1 週までに定常状態に達し（8–10 μg/mL），以降，投与 52 週までその濃度が維持された。再燃と判定されなかった被験者の血清中アダリムマブ濃度の平均値は，再燃と判定された被験者よりわずかに高い値を示した。

アダリムマブ 40 mg 隔週投与後に AAA 陽性と判定された被験者の割合は 3.4%（4/118 名）であった。AAA 陽性被験者における血清中アダリムマブ濃度は概して低かった。本試験で新たな安全性リスクは同定されなかった。免疫原性が有効性及び安全性への影響については，AAA 陽性被験者が少なかったため，明確な結論を得ることはできなかった。

M10-880 試験（薬物動態）

治験の標題： A Multicenter Study of the Efficacy and Safety of the Human Anti-TNF Monoclonal Antibody Adalimumab in Subjects with Inactive Non-infectious Intermediate, Posterior, or Pan-uveitis – VISUAL II	
施設数 / 実施国名： 72 施設（日本 10 施設を含む）	
治験期間： 最初の被験者の最初の来院日：2010 年 8 月 10 日 最後の被験者の最後の来院日：2015 年 5 月 14 日（電話での 70 日間の追跡調査）	開発のフェーズ： 第 III 相
目的： 本薬物動態報告書の目的は，高用量の副腎皮質ステロイドを必要とする非活動性かつ非感染性の中間部，後部，又は汎ぶどう膜炎患者に，投与 0 週にアダリムマブを 80 mg 負荷投与（皮下）し，引き続き投与 1 週から 40 mg 隔週投与した時の薬物動態及び免疫原性を評価することである。	
治験方法： 本治験は，治験薬投与開始の 28 日前から非活動性かつ非感染性の中間部，後部，又は汎ぶどう膜炎の成人患者のうち，非活動性を維持するため，プレドニゾン経口剤換算 10 mg/日以上の副腎皮質ステロイド（以下「ステロイド」）経口剤の長期投与が必要な患者を対象に，アダリムマブの有効性及び安全性を評価することを目的に計画された，多施設共同無作為化プラセボ対照二重盲検比較試験である。本治験では日本の施設でのみ被験者を組入れる日本人サブ試験も実施した。 被験者は，治験薬投与開始前の免疫抑制剤使用の有無により層別し（日本人サブ試験は除く），二重盲検下，投与群 1 又は投与群 2 のどちらかに 1：1 の比率で割付けた。投与群 1 では，投与 0 週にアダリムマブを 80 mg 負荷投与（皮下）し，引き続き投与 1 週から 40 mg 隔週投与した。投与群 2 では，投与群 1 と同じ用法でプラセボを投与した。 血清中アダリムマブ濃度及び血清中抗アダリムマブ抗体（以下「AAA」）濃度の測定のために，次の時点の血液サンプルを採取した。 • 血清中アダリムマブ濃度：治験薬の投与開始時，投与 2，8，12，27，36，52 週及び治験終了 / 中止時（投与 52 週までに中止した場合）に採取した。予定外の来院時にも，投与 52 週までであった場合には，血清中アダリムマブ濃度測定用の血液サンプルを採取した。治験薬の投与開始時，及び投与 27 週の血清中アダリムマブ濃度測定用の血液は，治験薬（アダリムマブ又はプラセボ）を投与する前に採取した。 • 血清中 AAA 濃度：治験薬の投与開始時，投与 12，27，36，52 週及び治験終了 / 中止時（投与 52 週までに中止した場合）に採取した。予定外の来院時にも，投与 52 週までであった場合には，血清中 AAA 濃度測定用の血液サンプルを採取した。治験薬の投与開始時，及び投与 27 週の血清中 AAA 濃度測定用の血液は，治験薬（アダリムマブ又はプラセボ）を投与する前に採取した。	

被験者数（計画時と解析時）：
計画時：メイン試験（日本人以外）220名，日本人サブ試験30名
組入れ数：261名（メイン試験：229名，日本人サブ試験：32名）
薬物動態解析被験者数：258名（メイン試験：226名，日本人サブ試験：32名）

診断と主要な組み入れ基準：
主な選択基準：

- 18歳以上の患者。
- 非感染性の中間部，後部，又は汎ぶどう膜炎と診断された患者。
- ベースライン評価来院の 28 日前から非活動性で，それを維持するためプレドニゾン経口剤換算10 mg/日以上のステロイド経口剤を投与され，かつスクリーニング時及び治験薬投与開始時に両眼が臨床的に以下の3項目を満たすと治験責任（分担）医師が判断した患者。
  - 活動性かつ炎症性の脈絡網膜病変又は網膜血管病変が認められない。
  - 前房内細胞が，国際ぶどう膜炎研究会 ぶどう膜炎の標準化委員会（以下「SUN」）基準のグレード0.5＋ 以下である。
  - 硝子体混濁が，米国国立眼病研究所（以下「NEI」）/SUN基準のグレード0.5＋ 以下である。
- 治験薬投与開始前にプレドニゾン経口剤換算 10–35 mg/日のステロイド経口剤を投与し，治験薬投与開始前28日以内に増量及び14日以内に減量をしていない患者。

被験薬，用量，投与方法及びバッチ番号：
全ての治験薬及びプラセボは皮下投与した。
アダリムマブ製造ロット番号： A* , B* , C* , D* , E*
プラセボ製造ロット番号： F* , G* , H*

治療期間：
個々の被験者の治験参加期間は最長で投与80週までとする。本治験は，再燃した被験者が約96名（84–107名，日本人患者を除く）集積されるまで継続する。日本人サブ試験の終了時期は，メイン試験で再燃した被験者が約96名（84–107名）集積された時点，又は日本人サブ試験で再燃した被験者が17名集積された時点のどちらか遅い方とした。

評価基準：
薬物動態：
血清中アダリムマブ濃度については各時点で記述統計量を算出した。また，再燃と判定された被験者と判定されなかった被験者の血清中アダリムマブ濃度を比較した。
免疫原性：
AAA陽性被験者数及びその割合を算出した。また，AAAが血清中アダリムマブ濃度，有効性及び安全性に与える影響を評価した。

結果と結論：

投与 0 週にアダリムマブを 80 mg 負荷投与し，引き続き投与 1 週から 40 mg 隔週投与したとき，平均血清中アダリムマブ濃度は投与 2 週までに定常状態に達し（8–10 μg/mL），以降，投与 52 週までその濃度が維持された。再燃と判定されなかった被験者の血清中アダリムマブ濃度の平均値は，8 週以降，再燃と判定された被験者よりわずかに高い値を示した。

アダリムマブ 40 mg 隔週投与後に AAA 陽性と判定された被験者の割合は 6.1%（8/131 名）であった。AAA 陽性被験者における血清中アダリムマブ濃度は概して低かった。本試験で新たな安全性リスクは同定されなかった。免疫原性が有効性及び安全性への影響については，AAA 陽性被験者が少なかったため，明確な結論を得ることはできなかった。

M10-877 試験

治験の標題： A Multicenter Study of the Efficacy and Safety of the Human Anti-TNF Monoclonal Antibody Adalimumab as Maintenance Therapy in Subjects Requiring High Dose Corticosteroids for Active Non-infectious Intermediate Uveitis, Posterior Uveitis, or Panuveitis	
治験調整医師： [redacted], [redacted], [redacted] USA	
施設数 / 実施国名：アルゼンチン，オーストラリア，オーストリア，ベルギー，カナダ，チェコ共和国，デンマーク，フランス，ドイツ，ギリシャ，イスラエル，イタリア，メキシコ，ポーランド，スペイン，スイス，英国及び米国の 67 施設（メイン試験）並びに日本の 7 施設（日本人サブ試験）	
公表文献（参考資料）：1 報	
治験期間： 最初の被験者の最初の来院日：2010 年 8 月 10 日 最後の被験者の最後の来院日：2014 年 8 月 29 日	開発のフェーズ：第 III 相
目的： 本試験の目的は，高用量の副腎皮質ステロイド（以下「ステロイド」）を必要とする活動性かつ非感染性の中間部，後部，又は汎ぶどう膜炎患者に，投与 0 週時にアダリムマブを 80 mg 負荷投与（皮下）し，引き続き投与 1 週時から 40 mg 隔週投与した時の有効性及び安全性をプラセボと比較検討することであった。	
治験方法： 本試験は，第 III 相多施設共同ランダム化二重盲検プラセボ対照比較試験であった。ベースラインの免疫抑制剤使用の有無を層別因子として，被験者をアダリムマブ群又はプラセボ群のいずれかに 1：1 の比率で無作為に割付けた。日本人サブ試験に組入れられた被験者は，メイン試験とは別に無作為に割付けた。日本人サブ試験の被験者数は少なかったため，ベースラインの免疫抑制剤使用の有無による層別は行わなかった。アダリムマブ群には，ベースラインでアダリムマブ 80 mg を負荷投与（皮下）し，引き続き投与 1 週時から 40 mg を隔週投与した。一方，プラセボ群には同じ用法でプラセボを投与した。治験薬の投与開始とともに，両群の被験者にプレドニゾンの投与を初期用量 60 mg/日から開始し，本治験実施計画書で規定した減量スケジュールに従って漸減し，投与 15 週時に投与を終了した。 本試験では，スクリーニング期間，投与期間及び追跡期間を設定した。二重盲検下の治験薬投与期間は最長で投与 80 週時まで（投与期間）又は治療不成功（以下「再燃」）例が 138 例（日本人被験者を除く）集積された時点までとした。被験者は，ベースライン，投与 1 週時，4 週時，6 週時，8 週時及びその後は投与 28 週時の代わりに投与 27 週時に来院した以外は，4 週間ごとに来院した。投与 6 週時及びそれ以降の来院時に，再燃の有無を評価した。 再燃と判定された被験者は，本試験を中止した。投与 6 週以降に再燃と判定された被験者は，非盲検継続投与試験（M11-327 試験）の組入れ基準を満たし，当該医療機関が M11-327 試験に参加していた場合には，M11-327 試験に移行できることとした。同様に，本試験（M10-877 試験）終了時まで再燃と判定されなかった被験者も，M11-327 試験の組入れ基準を満たし，当該医療機関が M11-327 試験に参加していた場合には，M11-327 試験に移行できることとした。 本試験終了以前に中止した被験者は，中止時の評価項目を実施した。新たに発現した有害事象又は持続中の有害事象の追跡情報を収集するため，電話又は来院により最終投与後 70 日間の追跡調査を行った。ただし，非盲検継続投与試験（M11-327 試験）で継続してアダリムマブの投与を受けた場合は，電話又は来院での 70 日間の追跡調査を不要とした。 日本人サブ試験：メイン試験で再燃例が 138 例集積された時点又は日本人サブ試験で再燃例が 19 例集積された時点（いずれか遅い方）で，国内実施医療機関での本試験の実施を終了した。	

被験者数（計画時と解析時）：

計画時：

メイン試験（日本人以外）：234 例，日本人サブ試験：32 例

解析時：

メイン試験：合計 223 例をメイン試験に組入れ，無作為に割付けた（日本人サブ試験を除く）。実施医療機関での有効性の原データが不完全であり，医薬品の臨床試験の実施の基準（GCP）の遵守に関して問題があった 2 施設の 6 例を intent-to-treat（ITT）解析から除外した。したがって，メイン試験の ITT 集団は 217 例であった。

日本人サブ試験：国内の実施医療機関で合計 16 例を日本人サブ試験に組入れ，無作為に割付けた。

併合解析集団：併合解析集団は，メイン試験及び日本人サブ試験のデータで構成される。74 施設で合計 239 例を本試験に組入れ，無作為に割付けた。上記に記載したとおり，2 施設の 6 例を有効性の解析から除外した。したがって，併合解析集団の ITT 集団は 233 例であった。

診断と主要な組入れ基準：

- 18 歳以上の男女の患者。
- 非感染性の中間部，後部，又は汎ぶどう膜炎と診断された患者（前部ぶどう膜炎のみと診断された患者は本試験から除外した）。
- ベースライン時に，プレドニゾン経口剤換算 10 mg/日以上，60 mg/日以下のステロイド経口剤による維持療法を 2 週間以上実施しているにもかかわらず，片眼又は両眼が次のいずれかの疾患活動性を示す患者：
    - 活動性かつ炎症性の脈絡網膜病変又は網膜血管病変が認められる患者。
    - 前房内細胞が，国際ぶどう膜炎研究会ぶどう膜炎の標準化委員会（以下「SUN」）基準のグレード 2＋以上である。
    - 硝子体混濁が，米国国立眼病研究所（以下「NEI」）/SUN 基準のグレード 2＋以上である。
- 本試験のスクリーニング前にプレドニゾン経口剤換算 10 mg/日以上，60 mg/日以下のステロイド経口剤を 2 週間以上投与し，スクリーニング時から治験薬投与開始前まで，用量を変更していない患者。
- 過去に活動性又は潜在性結核に罹患していない患者。
  本試験への参加には，1 種類だけの結核検査の実施が要求された。ツベルクリン反応検査で陰性（硬結が 5 mm 未満），又はクォンティフェロン®TB ゴールド検査（又はインターフェロンγ遊離測定法［以下「IGRA」］と同等の検査）で陰性であった患者とした。なお，クォンティフェロン®TB ゴールド検査（又は IGRA と同等の検査）で繰り返し判定保留の結果となった患者は，本試験に参加できないこととした。
- 日本人サブ試験：上記に加え，日本人サブ試験では以下の基準のいずれかに該当した患者は本試験から除外した：スクリーニング時の C 型肝炎検査が陽性であった患者又は β-D-グルカン検査で陽性又は判定保留であった患者。

被験薬，用量，投与方法及びバッチ番号：

アダリムマブ：40 mg/0.8 mL，皮下投与（プレフィルドシリンジ）

バルクロット番号：　A*　，　B*　，　C*　，　D*　，　E*

プレドニゾン：1 mg 錠，5 mg 錠及び 20 mg 錠

バルクロット番号：　I*　，　J*　，　K*　，　L*　，　M*　，　N*　，　O*　，
P*　，　Q*　，　R*　，　S*　，　T*　，　U*　，　V*　，　W*　，　X*　，
Y*　，　Z*　，　AA*　，　AB*　，　AC*　，　AD*　，　AE*　，　AF*　，　AG*　，
AH*　，　AI*　，　AJ*　，　AK*　，　AL*　，　AM*　，　AN*　，　AO*　，　AP*　，
AQ*

*新薬承認情報提供時に置き換え

治療期間：

メイン試験：本試験の二重盲検投与期間は，最長で 80 週間（投与期間）又は再燃例が 138 例（日本人被験者を除く）集積された時点までとした。

日本人サブ試験：再燃と判定されるか，本試験が終了するまで投与を継続することとした。日本人サブ試験の終了時期は，メイン試験で再燃例が 138 例集積された時点，又は日本人サブ試験で再燃例が 19 例集積された時点（いずれか遅い方）とした。活動性かつ非感染性の中間部，後部，又は汎ぶどう膜炎患者合計 16 例を，国内の 7 施設で組入れ，無作為に割付けた（日本人サブ試験データ）。メイン試験で再燃例が目標数に達した時点で，日本人サブ試験に組入れられた被験者数は 16 例（目標数：32 例）であり，日本人サブ試験は目標数より少ない被験者数で終了した。

対照薬，用量，投与方法及びバッチ番号：

プラセボ溶液 0.8 mL，皮下投与（プレフィルドシリンジ）

バルクロット番号： F* , G*

評価基準：

有効性：

本試験の有効性主要評価項目は，再燃（疾患活動性をコントロール又は維持できない）までの期間であり，本主要評価項目は 4 項目（炎症性の脈絡網膜病変及び / 又は網膜血管病変，前房内細胞のグレード，硝子体混濁のグレード及び視力）で構成された。

本試験では，以下に示すように，順位付けされた副次評価項目 9 項目を設定した。

- 第 1 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の前房内細胞のグレードの変化量
- 第 2 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の硝子体混濁のグレードの変化量
- 第 3 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の最高矯正視力の最小視角の対数（以下「logMAR」）の変化量
- 第 4 順位：光干渉断層計（以下「OCT」）で片眼又は両眼に黄斑浮腫が認められるまでの投与 6 週時以降の期間
- 第 5 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の網膜中心厚（以下「CRT」）の変化率
- 第 6 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の NEI の視力についてのアンケート（以下「VFQ-25」）の複合スコアの変化量
- 第 7 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の VFQ-25 のサブ項目である遠見視力による行動のスコアの変化量
- 第 8 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の VFQ-25 のサブ項目である近見視力による行動のスコアの変化量
- 第 9 順位：投与 6 週時以前の最善値と比較した治験終了 / 中止時の VFQ-25 のサブ項目である目の痛みのスコアの変化量

その他の有効性評価項目：

- 炎症：
    - 炎症の評価：前房内細胞のグレード及び硝子体混濁のグレード
    - 炎症のコントロール：ステロイド休薬後の寛解及び炎症が認められない状態
- 視力：logMAR 最高矯正視力
- 黄斑浮腫：黄斑浮腫及び CRT の変化が認められるまでの期間
- 患者報告アウトカム（PRO）
    - VFQ-25
    - EuroQol-5D 健康アンケート™（EQ-5D）

*新薬承認情報提供時に置き換え

評価基準：（続き）

有効性：（続き）

- 病院における不安と抑うつに関する質問票（HADS）
- 仕事の生産性及び活動障害に関する質問票（WPAI-SHP）
- SF-36®健康調査（SF-36）
- 医療機関の利用状況の調査（HRU）

薬物動態：

薬物動態測定用サンプルを，ベースライン，投与 1 週時，8 週時，12 週時，27 週時，36 週時，52 週時，予定外の来院時［可能な場合］，及び治験終了 / 中止時［投与 52 週時までに中止した場合］に採取し，血清中アダリムマブ濃度を測定した。また，アダリムマブの見かけのクリアランス及び見かけの分布容積（V/F）の推定を目的としてポピュレーション薬物動態モデルに基づく解析を実施した。解析結果は，別途報告書に示す。

安全性：

本試験期間中の有害事象，身体的所見，バイタルサイン及び臨床検査データを評価した。

統計手法：

人口統計学的特性及びベースラインの疾患特性は，投与群間で比較し，両側 *P* 値を算出した。

有効性：

メイン試験（日本人サブ試験の被験者を除く）：

ITT 集団を対象に，有効性の主要解析を実施した。ITT 集団には，海外で組入れられ，無作為に割付けられた被験者のうち，有効性の原データが不完全であり，GCP の遵守に関して問題があった 2 施設の 6 例を除く全例を含めた。

主要評価項目及び順位付け副次評価項目について，統計学的検定を実施した。有意水準は両側 0.05 とした。その他の評価項目についても，統計学的検定を実施した。有意水準は両側 0.05 とした。

主要評価項目は再燃までの期間であった。有効性の主要解析は，ITT 集団を対象として再燃までの期間を評価した。主要評価項目は，投与群ごとにカプラン・マイヤー法により推定値を算出するとともに，カプラン・マイヤー曲線を描いて評価した。投与 3 ヵ月，6 ヵ月，9 ヵ月，12 ヵ月及び 18 ヵ月の再燃率及びその 95%信頼区間（以下「CI」）を投与群ごとに算出した。再燃をイベントとして計数した。再燃以外の理由で脱落した被験者は，脱落時点で観察打ち切りとした。再燃までの期間は，投与群のみを因子とし，比例ハザードモデルを用いて評価した。ログランク検定によるハザード比を，95%CI 及び *P* 値とともに示した。

順位付け副次評価項目の検定は，主要評価項目で投与群間に統計学的有意差が認められた場合にのみ実施した。順位付け副次評価項目は，前述の階層的順序に従って統計学的検定を実施し，有意水準は両側 0.05 とした。階層上位項目で有意差が認められた場合に，下位項目の統計学的検定を実施し，有意水準は両側 0.05 とした。順位付け副次評価項目は，以下のとおりに解析した。

- 投与 6 週時以前の最善値と比較した治験終了 / 中止時の前房内細胞のグレードの変化量，硝子体混濁のグレードの変化量，logMAR 最高矯正視力の変化量，及び投与 6 週時以前の最善値と比較した治験終了 / 中止時の CRT の変化率については，集積した観測値（それぞれの眼の観測値）で補正し，投与群を因子とした分散分析（以下「ANOVA」）を用いて投与群間で比較した。CRT の変化率は，更に OCT 機器の種類で調整した。VFQ-25 の変化量については，投与群を因子とした ANOVA を用いて投与群間で比較した。投与 6 週時までに脱落した被験者は，前房内細胞のグレード，硝子体混濁のグレード，logMAR 最高矯正視力，CRT 及び VFQ-25 の評価対象から除外した。欠測値は，直前のデータで補完する手法（以下「LOCF」）で補完した。OCT で片眼又は両眼に黄斑浮腫が認められるまでの投与 6 週時以降の期間は，投与群を因子とした比例ハザードモデルを用いて投与群間で比較した。投与 6 週時以降の OCT での黄斑浮腫をイベントとして計数した。OCT での黄斑浮腫以外の理由で脱落した被験者は，その時点で観察打ち切りとした。

統計手法：（続き）

有効性：（続き）

メイン試験（日本人サブ試験の被験者を除く）：（続き）

その他の有効性評価項目は，定量的な評価項目であれば，投与群を因子とした ANOVA により解析し，Observed case（以下「OC」）又は LOCF を用いた。イベント発生までの期間は，投与群ごとにカプラン・マイヤー法により推定値を算出するとともに，カプラン・マイヤー曲線を描いて評価した。イベント発生までの期間は，投与群のみを因子とした比例ハザードモデルを用いて投与群間で比較した。分類変数の評価項目は，χ^2 検定を用いて割合を投与群間で比較し，欠測値は非反応例として取り扱った。

HRU の累積データは，各投与群の全被験者について総利用回数（全被験者）及び観察下での総利用時間（全被験者）の比を算出した。HRU については Observed Case のみとし，欠測値の補完は行わなかった。

事後解析は，黄斑円孔又は裂孔原性網膜剥離患者を除外した上で，CRT に基づく黄斑浮腫の定義を用いて実施した。黄斑浮腫は，以下の 3 種の OCT 機器（Stratus OCT，Cirrus OCT，又は Spectralis OCT）により測定した CRT が，それぞれ 260 μm 以上，320 μm 以上又は 340 μm 以上の場合と定義した。ただし，黄斑円孔及び / 又は網膜剥離患者は除外した。

日本人サブ試験：

日本人サブ試験では，試験対象集団が小さく，推測統計を実施しなかった場合を除き，メイン試験と同様の方法で解析を実施した。

併合解析集団（メイン試験 + 日本人サブ試験）：

併合解析集団では，メイン試験と同様の方法で解析を実施した。

薬物動態：

解析結果は，別途報告書に示す。

安全性：

メイン試験（日本人サブ試験の被験者を除く）：

安全性解析対象集団を対象として，安全性の解析を実施した。安全性解析対象集団には，海外で組入れられ，治験薬（プラセボ / アダリムマブ）を 1 回以上投与されたすべての被験者を含めた。投与群別にデータを解析した。有害事象は発現例数及び発現率で示した。また，臨床検査値及びバイタルサインの変化量を記述統計量を用いて要約した。

日本人サブ試験：

日本人サブ試験では，試験対象集団が小さく，推測統計を実施しなかった場合を除き，メイン試験と同様の方法で解析を実施した。

併合解析集団（メイン試験 + 日本人サブ試験）：

併合解析集団では，メイン試験と同様の方法で解析を実施した。

要約 / 結論

有効性：

メイン試験：

ITT 集団 217 例のうち，大部分は女性で白人であり，年齢は平均 42.7 歳であった。人口統計学的特性ではプラセボ群とアダリムマブ群との間に統計学的有意差は認められなかった。すべての被験者が非感染性の中間部，後部，又は汎ぶどう膜炎と診断され，多く（90.8%）の被験者が両眼とも罹患していると診断された。投与群間の統計学的比較を行ったベースラインの疾患特性では，ベースラインの平均値がプラセボ群と比べてアダリムマブ群の方が高かった SF-36 の体の痛み（$P = 0.041$）及び EQ VAS（$P = 0.047$）を除き，ベースラインの疾患活動性で投与群間に統計学的有意差は認められなかった。統計学的比較を行わなかったベースラインの疾患特性については，投与群間で数値的に同様であった。ベースラインでは，多く（60%超）の被験者で，いずれの眼にも黄斑浮腫は認められなかった。

要約 / 結論（続き）

有効性：（続き）

メイン試験：（続き）

本試験の主要評価項目である再燃までの期間について，アダリムマブ群とプラセボ群との比較を行った。試験期間を通して，再燃のリスクがプラセボ群と比べてアダリムマブ群で50%低下し，統計学的有意性が認められた（ハザード比：0.5，95%CI：0.36–0.70，ログランク検定：$P < 0.001$）。プラセボと比べてアダリムマブの効果は速やかに発現し，試験期間中，持続が認められた。また，再燃までの期間（中央値，ITT集団）は，プラセボ群（3ヵ月）と比べてアダリムマブ群（5.6ヵ月）の方が長かった。事前に規定した再燃の基準に該当した数は，アダリムマブ群と比べてプラセボ群の方が多かった。

事前に規定した再燃の基準の4項目で，最も群間差が大きかった項目は，硝子体混濁のグレード（アダリムマブ群：14.5%，プラセボ群：36.4%）であった。

主要評価項目を構成する個々の項目（活動性の炎症性病変，前房内細胞のグレード，硝子体混濁のグレード及びlogMAR最高矯正視力）で判定した再燃までの期間を個別に解析した結果，試験期間を通して，プラセボ群と比べてアダリムマブ群で再燃のリスクが統計学的に有意に減少し，減少率は活動性の炎症性病変では62%（$P = 0.001$），前房内細胞のグレードでは49%（$P = 0.010$），硝子体混濁のグレードでは68%（$P < 0.001$）及びlogMAR最高矯正視力では44%（$P = 0.040$）であった（各項目は個別に解析し，logMAR最高矯正視力は事後解析を行った）。

順位付け副次評価項目9項目について，アダリムマブ群とプラセボ群の統計学的有意性を階層的順序に従って検定した。その結果，有効性の順位付け副次評価項目のうち以下の第3順位までの項目で，投与6週時以前の最善値と比較した治験終了時の平均変化量でプラセボ群と比べてアダリムマブ群が優れており，統計学的に有意かつ臨床的に重要な差が認められた（ITT集団）。

- 第1順位：投与6週時以前の最善値と比較した治験終了 / 中止時の前房内細胞のグレードの変化量（$P = 0.011$）
- 第2順位：投与6週時以前の最善値と比較した治験終了 / 中止時の硝子体混濁のグレードの変化量（$P < 0.001$）
- 第3順位：投与6週時以前の最善値と比較した治験終了 / 中止時のlogMAR最高矯正視力の変化量（$P = 0.003$）

これより，階層下位の副次評価項目の4項目では，多重検定により，名義的有意水準で有意差が認められた。

- 第5順位：投与6週時以前の最善値と比較した治験終了 / 中止時のCRTの変化率（$P = 0.020$）
- 第6順位：投与6週時以前の最善値と比較した治験終了 / 中止時のVFQ-25複合スコアの変化量（$P = 0.010$）
- 第8順位：投与6週時以前の最善値と比較した治験終了 / 中止時のVFQ-25のサブ項目である近見視力による行動のスコアの変化量（$P = 0.036$）
- 第9順位：投与6週時以前の最善値と比較した治験終了 / 中止時のVFQ-25のサブ項目である目の痛みの変化量（$P < 0.001$）

順位付け副次評価項目のうち，第4順位（OCTで片眼又は両眼に黄斑浮腫［嚢胞形成］が認められるまでの投与6週時以降の期間）及び第7順位（投与6週時以前の最善値と比較した治験終了 / 中止時のVFQ-25サブ項目である遠見視力による行動のスコアの変化量）で統計学的有意差は認められなかったが，数値的にはプラセボ群と比べてアダリムマブ群で改善が認められ，臨床的に意義のある結果であった（ITT集団）。順位付け副次評価項目の第4順位及び第5順位（事後解析）について，黄斑円孔又は裂孔原性網膜剥離が認められない被験者のみを対象とし，黄斑浮腫の定義を嚢胞形成ではなく，CRT（OCT機器3種［Stratus OCT，Cirrus OCT又はSpectralis OCT］により測定したCRTが，それぞれ260 μm以上，320 μm以上，又は340 μm以上の場合）に基づき解析した。その結果，投与群間で統計学的有意差が認められ，アダリムマブ群の方が優れた結果を示した（OCTで片眼又は両眼に黄斑浮腫が認められるまでの投与6週時以降の期間：$P = 0.023$，最善値と比較した治験終了時のCRTの変化率について$P = 0.014$）。

メイン試験の有効性の解析結果より，以下の結果が示唆された。

要約 / 結論（続き）
有効性（続き）：
メイン試験（続き）：

- 有効性の早期発現及び持続性：再燃のリスクは，プラセボ群と比べてアダリムマブ群で 50%低下した（ハザード比：0.5，95%CI：0.36–0.70，ログランク検定：$P < 0.001$）。再燃までの期間を経時的に示したカプラン・マイヤー曲線では，最初の評価時期（投与 6 週時）からアダリムマブ群とプラセボ群で乖離が認められ，その後も本試験期間中を通じて乖離した状態が続いた。再燃までの期間の中央値は，アダリムマブ群で 5.6 ヵ月，プラセボ群で 3 ヵ月とアダリムマブ群の方が長かった。
- ぶどう膜炎の症状・徴候（炎症，視力及び CRT）に対する有効性：炎症関連の個々の項目別の再燃までの期間の解析では，活動性の炎症性病変，前房内細胞のグレード及び硝子体混濁のグレードで判定した再燃のリスクは，プラセボ群と比べてアダリムマブ群でそれぞれ 62%（$P = 0.001$），49%（$P = 0.010$）及び 68%（$P < 0.001$）低下した。前房内細胞のグレード及び硝子体混濁のグレードでは，最善値と比較した治験終了 / 中止時の平均変化量（［投与群間差］前房内細胞：–0.29［$P = 0.011$］，硝子体混濁：–0.027［$P < 0.001$］），及び再燃までの期間を X 軸，前房内細胞のグレード又は硝子体混濁のグレードを Y 軸にプロットした場合の時間曲線下面積（以下「AUC」）の平均値（［投与群間差］前房内細胞：34.28［$P = 0.008$］，硝子体混濁：35.42［$P = 0.004$］）で投与群間に統計学的有意差が認められ，それぞれアダリムマブ群の方が優れた結果を示した。logMAR 最高矯正視力では，最善値と比較した治験終了 / 中止時のグレードの平均変化量（投与群間差：–0.07［$P = 0.003$］）及び AUC の平均値（投与群間差：26.17［$P = 0.008$］）で投与群間に統計学的有意差が認められ，それぞれアダリムマブ群の方が優れた結果を示した。アダリムマブは，OCT で片眼又は両眼に黄斑浮腫（嚢胞形成）が認められるまでの投与 6 週時以降の期間を延長させると考えられた（ハザード比：0.7，95%CI：0.39–1.26，ログランク検定：$P = 0.231$）。黄斑円孔又は網膜剥離が認められない被験者のみを対象とし，黄斑浮腫の定義を嚢胞形成ではなく，臨床的に重大な網膜肥厚が認められる場合として事後解析を行った結果，黄斑浮腫のリスクはプラセボ群と比べてアダリムマブ群で 67%低下した（ハザード比：0.33，95%CI：0.12–0.90，$P = 0.023$）。最善値と比較した治験終了時の CRT の変化率では，投与群間に統計学的有意差が認められ，アダリムマブ群の方が優れた結果を示した（投与群間差：–11.4%，$P = 0.020$）。黄斑円孔又は網膜剥離が認められない被験者のみを対象とした解析（事後解析）では，投与群間の差が更に認められた（投与群間差：-12.0%，$P = 0.014$）。
- ステロイド節約効果：寛解を達成した被験者（活動性の炎症性病変がなく，前房内細胞のグレードが 0.5 以下かつ硝子体混濁のグレードが 0.5 以下），ステロイド休薬後に寛解を達成した被験者，炎症が認められなかった被験者（活動性の炎症性病変がなく，前房内細胞のグレードが 0 かつ硝子体混濁のグレードが 0），及びステロイド休薬後に炎症が認められなかった被験者の割合は，プラセボ群と比べてアダリムマブ群の方が高かった。
- 視力関連機能に対する効果：投与 6 週時以前の最善値と比較した治験終了 / 中止時の VFQ-25 スコアの平均変化量の減少は，色覚を除き，プラセボ群と比べてアダリムマブ群の方が小さかった。複合スコア，全体的見え方，近見視力による行動，目の痛み及び見え方による心の健康スコアの平均変化量の減少では，投与群間で統計学的有意差が認められ，アダリムマブ群の方が優れた結果を示した。しかし，遠見視力による行動では，投与群間で統計学的有意差は認められなかった。VFQ-25 複合スコアの AUC の平均値は，プラセボ群と比べてアダリムマブ群の方が高く，投与群間で統計学的有意差が認められた（平均値の差：726.94，95%CI：162.99–1290.90，$P = 0.012$）。

要約 / 結論（続き）

有効性（続き）：

メイン試験（続き）：

- 健康関連 QOL 及び仕事の生産性に対する効果：その他の PRO（勤務時間の喪失，勤務中の障害及び活動性の障害等）では，投与群間で統計学的有意差は認められなかったが，投与 6 週時以前の最善値と比較した治験終了 / 中止時の勤務時間の喪失の変化量では，プラセボ群と比べてアダリムマブ群で統計学的に有意な減少が認められた（投与群間差：−10.61，95%CI：−18.75 − −2.47，$P = 0.011$）。治験終了 / 中止時の EQ-5D 予測値及び EQ VAS は，プラセボ群と比べてアダリムマブ群の方が高かった。EQ-5D 予測値の投与 6 週時以前の最善値と比較した治験終了 / 中止時の変化量では，投与群間で統計学的有意差が認められ，プラセボ群と比べてアダリムマブ群の方が優れていたことから，アダリムマブ群では健康関連の生活の質が経時的に改善されることが示された。投与 6 週時以前の最善値と比較した HADS スコアの減少は，アダリムマブ群とプラセボ群で同程度であり，投与群間で統計学的有意差は認められなかった。

日本人サブ試験：

- 被験者の大部分（11/16 例）は女性であり，全被験者が日本人であった。年齢は平均 50.88 歳であった。人口統計学的特性，病歴，ぶどう膜炎の病歴又はベースラインの疾患特性で投与群間に臨床的に意義のある差は認められなかった。すべての被験者が，非感染性の中間部，後部，又は汎ぶどう膜炎と診断され，多く（87.5%）の被験者が両眼とも罹患していると診断された。
- 有効性の主要評価項目である再燃までの期間（炎症性の脈絡網膜病変及び / 又は網膜血管病変，前房内細胞のグレード，硝子体混濁のグレード及び視力の 4 項目で評価）の解析では，アダリムマブ群とプラセボ群の間に統計学的有意差は認められなかった（ハザード比：1.20，95%CI：0.41–3.54）。
- メイン試験が終了した時点で日本人サブ試験も終了したため，組入れ及び無作為に割付けられた被験者は合計 16 例のみであった。このため，日本人サブ試験の被験者数が少なかったことから，2 つの投与群間の有効性データの比較は限定的であり，結果の解釈は慎重を要すると考えられた。

併合解析集団（メイン試験 + 日本人サブ試験）：

併合解析集団 233 例（ITT 集団）の人口統計学的特性及びぶどう膜炎を含む病歴は，メイン試験の結果と同様であった。同様に，併合解析集団のベースラインの疾患特性は，1 つの例外を除き，メイン試験の解析結果と同様であった。投与群間の統計学的比較を行ったベースラインの疾患特性のうち，ベースラインの疾患活動性では，投与群間で統計学的有意差は認められなかった。

メイン試験及び日本人サブ試験のデータを併合解析した結果，主要評価項目，順位付け副次評価項目及びその他の有効性の評価項目では，メイン試験と同様の傾向が認められた。また，有効性の様々な解析結果でも同様の傾向が認められた。メイン試験の結果と同様に，主要評価項目で統計学的有意差が認められ，プラセボ群と比べてアダリムマブ群で再燃のリスクが 44%低下した（ハザード比：0.56，95%CI：0.40–0.76，ログランク検定：$P < 0.001$）。

また，順位付け副次評価項目のうち，第 3 順位までの項目（最善値と比較した治験終了時の前房内細胞のグレード，硝子体混濁のグレード及び logMAR 最高矯正視力の変化量）でも統計学的有意差が認められ，アダリムマブ群の方が優れた結果を示した（それぞれ $P = 0.019$，$P < 0.001$ 及び $P = 0.008$）。併合解析集団での有効性の結果は，メイン試験と同様の傾向を示したが，メイン試験と同様に，併合解析集団の結果で投与群間に統計学的有意差が認められなかった項目があった。詳細を以下に示す。

要約 / 結論（続き）

有効性（続き）：

併合解析集団（メイン試験＋日本人サブ試験）（続き）：

- 順位付け副次評価項目：
  - 順位付け副次評価項目のうち，第 4 順位（OCT で黄斑浮腫が認められるまでの期間），第 5 順位（CRT の変化率），第 7 順位（投与 6 週時以前の最善値と比較した治験終了時の VFQ-25 サブ項目である遠見視力による行動のスコアの変化量）及び第 8 順位（投与 6 週時以前の最善値と比較した治験終了時の VFQ-25 サブ項目である近見視力による行動のスコアの変化量）で統計学的有意差は認められなかったが，数値的にはプラセボ群と比べてアダリムマブ群で改善が認められ，臨床的に意義のある結果であった（ITT 集団）。
  - 順位付け副次評価項目の第 5 順位：CRT の投与 6 週時以前の最善値と比較した治験終了時の平均変化率について，治験実施計画書で規定した解析及び事後解析（黄斑円孔又は網膜剥離が認められる被験者を除外した解析）を行った結果，アダリムマブ群とプラセボ群の間に統計学的有意差は認められなかった（全被験者：$P = 0.428$，黄斑円孔又は網膜剥離が認められる被験者を除外した解析：$P = 0.409$）。しかし，いずれの解析でも，CRT の投与 6 週時以前の最善値と比較した治験終了時の平均変化率は，プラセボ群と比べてアダリムマブ群で数値的に改善が認められたことから，アダリムマブ群で CRT の増加が抑制されることが示唆された。

- 視力関連機能：
  - メイン試験と同様に，投与 6 週時以前の最善値と比較した治験終了時の VFQ-25 スコアの平均変化量は，色覚及び周辺視覚を除き，アダリムマブ群と比べてプラセボ群の方が減少した。しかし，プラセボ群と比べてアダリムマブ群で統計学的に有意に優れていたサブ項目は，メイン試験とは異なっていた。プラセボ群と比べてアダリムマブ群が統計学的に有意に優れていた項目は，複合スコア，全般的健康感，全体的見え方，目の痛み及び見え方による心の健康であったが，遠見視力及び近見視力による行動のスコアの変化量では，投与群間で統計学的有意差は認められなかった。

薬物動態：

解析結果は，別途報告書に示す。

安全性：

メイン試験：

有害事象，治験薬（プラセボ / アダリムマブ）との因果関係「多分関連あり」以上と判断された有害事象及び重症度別に集計した有害事象の発現頻度について，投与群間に統計学的に有意な差は認められなかった。

アダリムマブ群の 1 例に死亡が認められた（慢性腎不全，アダリムマブとの因果関係は「関連なし」）。重篤な有害事象が認められた被験者の割合は，アダリムマブ群（15 例［13.5%］）でプラセボ群（5 例［4.5%］）と比較して，統計学的に有意に高かった（$P = 0.020$）。重篤な有害事象の発現率は，アダリムマブ群で 100 人年あたり 28.83 件/100 人年，プラセボ群で 13.56 件/100 人年であった。基本語の有害事象はすべて単独の発現であり，2 例以上の報告はなかった。治験責任医師により治験薬（プラセボ / アダリムマブ）との因果関係「多分関連あり」又は「関連あり」と判断された有害事象及び治験薬（プラセボ / アダリムマブ）の投与中止に至った有害事象の発現率は，投与群間に統計学的に有意な差はみられなかった。

治験責任医師により治験薬（プラセボ / アダリムマブ）との因果関係が「多分関連あり」又は「関連あり」と判断された重篤な有害事象，治験薬（プラセボ / アダリムマブ）の投与中止に至った有害事象及びぶどう膜炎関連の有害事象（治験責任医師の判断及びその後の医学的レビューに基づく）の発現率は，投与群間に統計学的に有意な差はみられなかった。

特に注目すべき有害事象のうち，感染症（口腔カンジダ症及び結核を除く），アレルギー反応及び注射部位反応を除き，発現例数はいずれも 3 例未満であった。

要約 / 結論（続き）

安全性（続き）：

メイン試験（続き）：

- 感染症が認められた被験者の割合は，アダリムマブ群（44.1%）でプラセボ群（28.6%）と比較して，統計学的に有意に高かった（$P = 0.018$）。感染症の発現率は，アダリムマブ群で 156.98 件/100 人年，プラセボ群で 124.29 件/100 人年であった。最も多く認められた感染症は，いずれの投与群でも鼻咽頭炎であった。鼻咽頭炎及び尿路感染は，プラセボ群と比較してアダリムマブ群で多く認められ，統計学的に有意な差が認められた（$P \leq 0.010$）。プラセボ群の 2 例（1.8%）及びアダリムマブ群の 5 例（4.5%）に 1 件以上の重篤な感染症が認められたが，投与群間に統計学的に有意な差は認められず，基本語の有害事象は 2 例以上の報告はなかった。重篤な感染症の発現率は，アダリムマブ群（8.01 件/100 人年）とプラセボ群（6.78 件/100 人年）で同程度であった。
- アダリムマブ群の 2 例（1.8%）に，結核に関連した有害事象が認められた。1 例が活動性結核のため入院した。活動性結核（重篤な有害事象）は，治験責任医師により治験薬との因果関係が「多分関連あり」と判断された。1 例に非重篤の有害事象として結核菌群検査陽性が認められた。非活動性結核である本事象は，治験責任医師により治験薬との因果関係「関連あり」と判断された。
- アダリムマブ群の 2 例（1.8%）に，悪性腫瘍が認められた。1 例（0.9%）が消化管のカルチノイド腫瘍のために入院した。消化管のカルチノイド腫瘍（重篤な有害事象）は，治験責任医師により治験薬との因果関係「関連なし」と判断された。1 例（0.9%）に重篤な有害事象として多形性神経膠芽細胞腫が認められた。多形性神経膠芽細胞腫は，治験責任医師により治験薬との因果関係「関連あり」と判断された。
- 合計 14 例（プラセボ群 4 例［3.6%］，アダリムマブ群 10 例［9.0%］）にアレルギー反応が認められた。器官別大分類の皮膚および皮下組織障害として報告された有害事象のうち，プラセボ群（0.9%）と比較してアダリムマブ群（7.2%）の発現率が高かったのはアレルギー反応のみであった（$P = 0.019$）。治験責任医師により治験薬との因果関係「多分関連あり」以上と判断されたアレルギー反応は，アダリムマブ群で 4 件（4 例），プラセボ群で 1 件（1 例）であった。アダリムマブ群の 1 例に，重篤な有害事象としてアナフィラキシー反応及び蕁麻疹が認められた。アナフィラキシー反応及び蕁麻疹（重篤な有害事象）は，治験責任医師により治験薬との因果関係「多分関連なし」と判断された。いずれの投与群でも，3 例以上に認められた有害事象はなかった。
- 注射部位反応は，14 例（プラセボ群 7 例［6.3%］，アダリムマブ群 7 例［6.3%］）に発現し，投与群間に統計学的に有意な差は認められなかった。注射部位反応の多くは，治験責任医師により治験薬（プラセボ / アダリムマブ）との因果関係「関連あり」と判断された。重篤な有害事象，高度の有害事象，又は治験薬（プラセボ / アダリムマブ）の投与中止に至った注射部位反応はみられなかった。
- その他の特に注目すべき有害事象には，アダリムマブ群で報告された口腔カンジダ症，ループス様症候群，皮膚サルコイドーシス，脱髄，好中球減少症及び小球性貧血（各 1 例）などがあった。更に，プラセボ群の有害事象は，皮膚以外の血管炎及び急性肝炎（各 1 例）が含まれた。
- レジオネラ感染，憩室炎，日和見感染（口腔カンジダ症及び結核を除く），寄生虫感染，B 型肝炎の再活性化，進行性多巣性白質脳症，リンパ腫，肝脾 T 細胞リンパ腫，皮膚癌（黒色腫を除く），黒色腫，白血病，皮膚血管炎，自己免疫性肝炎，心筋梗塞，脳血管発作，うっ血性心不全，肺塞栓症，間質性肺疾患，腸管穿孔，膵炎，スティーブンス・ジョンソン症候群，多形紅斑，乾癬の悪化及び新規発現，筋萎縮性側索硬化症，可逆性後白質脳症症候群又はアダリムマブ投与に関連する投薬過誤などのその他の注目すべき有害事象は認められなかった。

血液学的検査，生化学検査及び尿検査のベースライン時からの最終来院時を比較した測定値の平均変化量に，有意性及び臨床的意味は認められなかった。血液学検査，生化学検査及び尿検査において，ベースライン時の正常値から最低値又は最高値への変化はおおむね少なかった。本治験期間中の臨床検査値の変動は，多くの被験者で一過性であり，最終来院時までに回復した。臨床検査値及びバイタルサインの解析では，アダリムマブの重大な安全性の懸念を示唆する特定の傾向は認められなかった。

要約 / 結論（続き）

安全性（続き）：

日本人サブ試験：

- メイン試験終了時にサブ試験も終了したため，組入れられ，無作為割付けされた被験者は合計 16 例のみであった。この日本人サブ試験の被験者数が少ないことから，2 つの投与群間の安全性データの比較には限界があり，結果の解釈には慎重を要する。
- 日本人サブ試験の期間中，死亡例は報告されなかった。アダリムマブ群の 1 例に重篤な有害事象（尿管結石）が認められた。尿管結石は，治験責任医師により治験薬投与（アダリムマブ）との因果関係が「多分関連なし」と判断された。治験薬（プラセボ / アダリムマブ）の中止に至った有害事象は，認められなかった。日本人サブ試験で認められた特に注目すべき有害事象は，感染症のみであり，感染症のうち最も多かったのは鼻咽頭炎であった。
- 少数の被験者で実施された日本人サブ試験では，アダリムマブはおおむね安全性に問題なく，良好な忍容性を示した。原疾患と関連する事象を除いて，アダリムマブの有害事象プロファイルは，既に承認されている他の適応症で確立された安全性プロファイルと同様であった。新たな安全性のシグナルは認められなかった。

併合解析集団（メイン試験＋日本人サブ試験）：

日本人サブ試験では，組入れた被験者数が少なく，重大な安全性所見は報告されなかったことから，併合解析集団データから得られた全体としての安全性の結果は，上述のメイン試験のデータから得られた結果と同様であった。

結論：

高用量の副腎皮質ステロイドを必要とする非感染性の中間部，後部又は汎ぶどう膜炎患者を対象とした本試験で，アダリムマブは，炎症及び視力喪失を抑制することにより，疾患活動性のコントロールの達成及び維持に有効であることが示された。また，アダリムマブはおおむね安全であり，良好な忍容性を示した。原疾患と関連する事象を除き，アダリムマブの有害事象プロファイルは，既に承認されている他の適応症で確立された安全性プロファイルと同様であった。また，新たな安全性シグナルは検出されなかった。日本人サブ試験の被験者数が少なかったため，明確な結論は得られなかったが，メイン試験と日本人サブ試験を併合した結果は，有効性及び安全性の結論に影響を及ぼすものではなかった。

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
ANY ADVERSE EVENT	88 (78.6)	94 (84.7)	182 (81.6)	
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
INCREASED TENDENCY TO BRUISE	1 (0.9)	0	1 (0.4)	
IRON DEFICIENCY ANAEMIA	0	2 (1.8)	2 (0.9)	
LYMPH NODE PAIN	1 (0.9)	0	1 (0.4)	
LYMPHADENOPATHY	1 (0.9)	0	1 (0.4)	
MICROCYTIC ANAEMIA	0	1 (0.9)	1 (0.4)	
NEUTROPENIA	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.8)	4 (3.6)	6 (2.7)	
CARDIAC DISORDERS				
ATRIAL FIBRILLATION	0	1 (0.9)	1 (0.4)	
PALPITATIONS	1 (0.9)	3 (2.7)	4 (1.8)	
PRINZMETAL ANGINA	0	1 (0.9)	1 (0.4)	
TACHYCARDIA	1 (0.9)	1 (0.9)	2 (0.9)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.8)	6 (5.4)	8 (3.6)	
CONGENITAL, FAMILIAL AND GENETIC DISORDERS				
ICHTHYOSIS	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	0	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
EAR AND LABYRINTH DISORDERS				
EAR PAIN	1 (0.9)	0	1 (0.4)	
EAR PRURITUS	1 (0.9)	0	1 (0.4)	
TINNITUS	3 (2.7)	1 (0.9)	4 (1.8)	
VERTIGO	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	5 (4.5)	2 (1.8)	7 (3.1)	
ENDOCRINE DISORDERS				
CUSHINGOID	1 (0.9)	2 (1.8)	3 (1.3)	
HYPERPARATHYROIDISM PRIMARY	1 (0.9)	0	1 (0.4)	
HYPOTHYROIDISM	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.8)	3 (2.7)	5 (2.2)	
EYE DISORDERS				
ABNORMAL SENSATION IN EYE	1 (0.9)	0	1 (0.4)	
ANGLE CLOSURE GLAUCOMA	0	1 (0.9)	1 (0.4)	
ANTERIOR CHAMBER INFLAMMATION	1 (0.9)	0	1 (0.4)	
ASTHENOPIA	0	1 (0.9)	1 (0.4)	
BLEPHARITIS	3 (2.7)	0	3 (1.3)	
BLINDNESS	0	1 (0.9)	1 (0.4)	
CATARACT	1 (0.9)	2 (1.8)	3 (1.3)	
CATARACT SUBCAPSULAR	1 (0.9)	2 (1.8)	3 (1.3)	
CHALAZION	1 (0.9)	1 (0.9)	2 (0.9)	
CHORIORETINAL DISORDER	1 (0.9)	0	1 (0.4)	
CHOROIDAL NEOVASCULARISATION	0	3 (2.7)	3 (1.3)	
CHOROIDITIS	1 (0.9)	0	1 (0.4)	
COLOUR BLINDNESS ACQUIRED	0	1 (0.9)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
EYE DISORDERS (CONT.)				
CONJUNCTIVAL HAEMORRHAGE	1 (0.9)	0	1 (0.4)	
CONJUNCTIVITIS ALLERGIC	1 (0.9)	3 (2.7)	4 (1.8)	
CORNEAL DEPOSITS	0	1 (0.9)	1 (0.4)	
CORNEAL EROSION	0	1 (0.9)	1 (0.4)	
CORNEAL OEDEMA	0	1 (0.9)	1 (0.4)	
CYSTOID MACULAR OEDEMA	6 (5.4)	3 (2.7)	9 (4.0)	
DEPOSIT EYE	1 (0.9)	0	1 (0.4)	
DIPLOPIA	0	1 (0.9)	1 (0.4)	
DRY EYE	4 (3.6)	3 (2.7)	7 (3.1)	
EYE DISCHARGE	0	1 (0.9)	1 (0.4)	
EYE HAEMORRHAGE	0	1 (0.9)	1 (0.4)	
EYE INFLAMMATION	1 (0.9)	0	1 (0.4)	
EYE IRRITATION	0	1 (0.9)	1 (0.4)	
EYE PAIN	2 (1.8)	9 (8.1)	11 (4.9)	0.034
EYE PRURITUS	1 (0.9)	0	1 (0.4)	
EYE SWELLING	1 (0.9)	0	1 (0.4)	
EYELID OEDEMA	1 (0.9)	1 (0.9)	2 (0.9)	
EYELIDS PRURITUS	1 (0.9)	0	1 (0.4)	
FOREIGN BODY SENSATION IN EYES	2 (1.8)	0	2 (0.9)	
IRIDOCYCLITIS	0	1 (0.9)	1 (0.4)	
IRIS ADHESIONS	1 (0.9)	0	1 (0.4)	
IRITIS	0	1 (0.9)	1 (0.4)	
LACRIMATION INCREASED	3 (2.7)	0	3 (1.3)	
MACULAR FIBROSIS	1 (0.9)	0	1 (0.4)	
MACULAR OEDEMA	2 (1.8)	0	2 (0.9)	
OCULAR HYPERAEMIA	2 (1.8)	1 (0.9)	3 (1.3)	
OCULAR HYPERTENSION	1 (0.9)	3 (2.7)	4 (1.8)	
PAPILLOEDEMA	1 (0.9)	0	1 (0.4)	
PERIORBITAL OEDEMA	1 (0.9)	1 (0.9)	2 (0.9)	
PHOTOPHOBIA	3 (2.7)	0	3 (1.3)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
EYE DISORDERS (CONT.)				
POSTERIOR CAPSULE OPACIFICATION	0	2 (1.8)	2 (0.9)	
RETINAL DETACHMENT	1 (0.9)	1 (0.9)	2 (0.9)	
RETINAL HAEMORRHAGE	2 (1.8)	1 (0.9)	3 (1.3)	
RETINAL TEAR	1 (0.9)	1 (0.9)	2 (0.9)	
RETINAL VASCULAR DISORDER	1 (0.9)	0	1 (0.4)	
RETINOPATHY	1 (0.9)	0	1 (0.4)	
SUBRETINAL FLUID	0	1 (0.9)	1 (0.4)	
UVEITIS	8 (7.1)	11 (9.9)	19 (8.5)	
VISION BLURRED	2 (1.8)	8 (7.2)	10 (4.5)	0.059
VISUAL ACUITY REDUCED	3 (2.7)	4 (3.6)	7 (3.1)	
VISUAL IMPAIRMENT	0	1 (0.9)	1 (0.4)	
VITREOUS DETACHMENT	1 (0.9)	0	1 (0.4)	
VITREOUS DISORDER	1 (0.9)	0	1 (0.4)	
VITREOUS FLOATERS	4 (3.6)	5 (4.5)	9 (4.0)	
VITREOUS OPACITIES	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	40 (35.7)	53 (47.7)	93 (41.7)	0.078
GASTROINTESTINAL DISORDERS				
ABDOMINAL DISCOMFORT	2 (1.8)	0	2 (0.9)	
ABDOMINAL DISTENSION	1 (0.9)	1 (0.9)	2 (0.9)	
ABDOMINAL PAIN	3 (2.7)	3 (2.7)	6 (2.7)	
ABDOMINAL PAIN LOWER	0	1 (0.9)	1 (0.4)	
ABDOMINAL PAIN UPPER	2 (1.8)	3 (2.7)	5 (2.2)	
APHTHOUS STOMATITIS	1 (0.9)	0	1 (0.4)	
CHEILITIS	0	1 (0.9)	1 (0.4)	
COLITIS	2 (1.8)	0	2 (0.9)	
DENTAL CARIES	0	2 (1.8)	2 (0.9)	
DIARRHOEA	3 (2.7)	1 (0.9)	4 (1.8)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)		ADALIMUMAB (N=111) n (%)		TOTAL (N=223) n (%)		P-VALUE@
GASTROINTESTINAL DISORDERS (CONT.)							
DRY MOUTH	1	(0.9)	5	(4.5)	6	(2.7)	
DYSPEPSIA	5	(4.5)	3	(2.7)	8	(3.6)	
FREQUENT BOWEL MOVEMENTS	0		1	(0.9)	1	(0.4)	
GASTRITIS	1	(0.9)	2	(1.8)	3	(1.3)	
GASTROOESOPHAGEAL REFLUX DISEASE	2	(1.8)	2	(1.8)	4	(1.8)	
GINGIVAL ATROPHY	0		1	(0.9)	1	(0.4)	
GLOSSODYNIA	0		1	(0.9)	1	(0.4)	
HAEMATOCHEZIA	1	(0.9)	0		1	(0.4)	
HAEMORRHOIDS	1	(0.9)	1	(0.9)	2	(0.9)	
HIATUS HERNIA	1	(0.9)	0		1	(0.4)	
IRRITABLE BOWEL SYNDROME	1	(0.9)	0		1	(0.4)	
LIP SWELLING	0		1	(0.9)	1	(0.4)	
NAUSEA	7	(6.3)	6	(5.4)	13	(5.8)	
PROCTALGIA	0		1	(0.9)	1	(0.4)	
SENSITIVITY OF TEETH	1	(0.9)	1	(0.9)	2	(0.9)	
TONGUE COATED	1	(0.9)	0		1	(0.4)	
TONGUE DISCOLOURATION	0		1	(0.9)	1	(0.4)	
TONGUE ULCERATION	0		1	(0.9)	1	(0.4)	
TOOTH DISORDER	1	(0.9)	0		1	(0.4)	
TOOTHACHE	1	(0.9)	0		1	(0.4)	
VOMITING	4	(3.6)	2	(1.8)	6	(2.7)	
SUBJECTS WITH ONE OR MORE EVENTS	26	(23.2)	24	(21.6)	50	(22.4)	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS							
ADVERSE DRUG REACTION	0		1	(0.9)	1	(0.4)	
ASTHENIA	1	(0.9)	2	(1.8)	3	(1.3)	
CHEST DISCOMFORT	0		1	(0.9)	1	(0.4)	
CHEST PAIN	0		1	(0.9)	1	(0.4)	

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@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS (CONT.)				
CHILLS	0	1 (0.9)	1 (0.4)	
DRUG INTOLERANCE	1 (0.9)	0	1 (0.4)	
FACE OEDEMA	1 (0.9)	1 (0.9)	2 (0.9)	
FATIGUE	7 (6.3)	12 (10.8)	19 (8.5)	
FEELING COLD	0	1 (0.9)	1 (0.4)	
FEELING HOT	0	1 (0.9)	1 (0.4)	
INFLAMMATION	0	1 (0.9)	1 (0.4)	
INFLUENZA LIKE ILLNESS	2 (1.8)	1 (0.9)	3 (1.3)	
INJECTION SITE BRUISING	2 (1.8)	1 (0.9)	3 (1.3)	
INJECTION SITE ERYTHEMA	0	2 (1.8)	2 (0.9)	
INJECTION SITE HYPERSENSITIVITY	1 (0.9)	0	1 (0.4)	
INJECTION SITE PAIN	4 (3.6)	2 (1.8)	6 (2.7)	
INJECTION SITE PRURITUS	0	1 (0.9)	1 (0.4)	
INJECTION SITE RASH	0	1 (0.9)	1 (0.4)	
INJECTION SITE REACTION	0	1 (0.9)	1 (0.4)	
INJECTION SITE SWELLING	0	2 (1.8)	2 (0.9)	
LOCAL SWELLING	0	2 (1.8)	2 (0.9)	
MALAISE	1 (0.9)	1 (0.9)	2 (0.9)	
NON-CARDIAC CHEST PAIN	0	1 (0.9)	1 (0.4)	
OEDEMA	0	1 (0.9)	1 (0.4)	
OEDEMA PERIPHERAL	2 (1.8)	5 (4.5)	7 (3.1)	
PAIN	0	2 (1.8)	2 (0.9)	
PYREXIA	0	4 (3.6)	4 (1.8)	0.060
SUPRAPUBIC PAIN	0	1 (0.9)	1 (0.4)	
TENDERNESS	0	1 (0.9)	1 (0.4)	
THIRST	0	1 (0.9)	1 (0.4)	
XEROSIS	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	19 (17.0)	28 (25.2)	47 (21.1)	

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@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
HEPATOBILIARY DISORDERS				
CHOLELITHIASIS	0	1 (0.9)	1 (0.4)	
HEPATITIS ACUTE	1 (0.9)	0	1 (0.4)	
HYPERBILIRUBINAEMIA	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	2 (1.8)	3 (1.3)	
IMMUNE SYSTEM DISORDERS				
ANAPHYLACTIC REACTION	0	1 (0.9)	1 (0.4)	
DRUG HYPERSENSITIVITY	1 (0.9)	2 (1.8)	3 (1.3)	
HOUSE DUST ALLERGY	0	1 (0.9)	1 (0.4)	
HYPERSENSITIVITY	1 (0.9)	1 (0.9)	2 (0.9)	
SEASONAL ALLERGY	3 (2.7)	1 (0.9)	4 (1.8)	
SUBJECTS WITH ONE OR MORE EVENTS	4 (3.6)	6 (5.4)	10 (4.5)	
INFECTIONS AND INFESTATIONS				
ABDOMINAL INFECTION	1 (0.9)	0	1 (0.4)	
ARTHRITIS BACTERIAL	1 (0.9)	0	1 (0.4)	
BACTERIURIA	0	1 (0.9)	1 (0.4)	
BORRELIA INFECTION	0	1 (0.9)	1 (0.4)	
BRONCHITIS	4 (3.6)	7 (6.3)	11 (4.9)	
BRONCHITIS BACTERIAL	0	1 (0.9)	1 (0.4)	
CONJUNCTIVITIS	2 (1.8)	2 (1.8)	4 (1.8)	
CYSTITIS	1 (0.9)	2 (1.8)	3 (1.3)	
CYTOMEGALOVIRUS INFECTION	1 (0.9)	0	1 (0.4)	
EAR INFECTION	1 (0.9)	0	1 (0.4)	
ERYTHEMA MIGRANS	0	1 (0.9)	1 (0.4)	
ESCHERICHIA URINARY TRACT INFECTION	0	1 (0.9)	1 (0.4)	

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
INFECTIONS AND INFESTATIONS (CONT.)				
FUNGAL INFECTION	0	1 (0.9)	1 (0.4)	
FUNGAL SKIN INFECTION	0	1 (0.9)	1 (0.4)	
FURUNCLE	0	1 (0.9)	1 (0.4)	
GASTROENTERITIS	0	2 (1.8)	2 (0.9)	
GASTROENTERITIS VIRAL	1 (0.9)	0	1 (0.4)	
GASTROINTESTINAL INFECTION	1 (0.9)	0	1 (0.4)	
HELICOBACTER INFECTION	0	2 (1.8)	2 (0.9)	
HERPES SIMPLEX	0	1 (0.9)	1 (0.4)	
HERPES ZOSTER	0	1 (0.9)	1 (0.4)	
HORDEOLUM	2 (1.8)	2 (1.8)	4 (1.8)	
INFECTION	0	1 (0.9)	1 (0.4)	
INFLUENZA	5 (4.5)	1 (0.9)	6 (2.7)	
LARYNGITIS	1 (0.9)	0	1 (0.4)	
LOWER RESPIRATORY TRACT INFECTION	2 (1.8)	0	2 (0.9)	
NASOPHARYNGITIS	8 (7.1)	21 (18.9)	29 (13.0)	0.010
ONYCHOMYCOSIS	1 (0.9)	0	1 (0.4)	
OPHTHALMIC HERPES SIMPLEX	0	1 (0.9)	1 (0.4)	
ORAL FUNGAL INFECTION	0	1 (0.9)	1 (0.4)	
ORAL HERPES	1 (0.9)	2 (1.8)	3 (1.3)	
OTITIS MEDIA	1 (0.9)	1 (0.9)	2 (0.9)	
PHARYNGITIS	1 (0.9)	3 (2.7)	4 (1.8)	
PHARYNGITIS STREPTOCOCCAL	2 (1.8)	0	2 (0.9)	
PILONIDAL CYST	0	1 (0.9)	1 (0.4)	
PNEUMONIA	0	1 (0.9)	1 (0.4)	
PULPITIS DENTAL	1 (0.9)	0	1 (0.4)	
PYELONEPHRITIS ACUTE	1 (0.9)	0	1 (0.4)	
RESPIRATORY TRACT INFECTION	1 (0.9)	0	1 (0.4)	
RHINITIS	0	1 (0.9)	1 (0.4)	
SEPSIS	1 (0.9)	0	1 (0.4)	
SINUSITIS	1 (0.9)	4 (3.6)	5 (2.2)	

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
INFECTIONS AND INFESTATIONS (CONT.)				
SKIN CANDIDA	0	1 (0.9)	1 (0.4)	
STAPHYLOCOCCAL INFECTION	1 (0.9)	0	1 (0.4)	
TINEA CRURIS	0	1 (0.9)	1 (0.4)	
TINEA INFECTION	2 (1.8)	0	2 (0.9)	
TOOTH INFECTION	2 (1.8)	0	2 (0.9)	
TRACHEITIS	0	1 (0.9)	1 (0.4)	
TUBERCULOSIS	0	1 (0.9)	1 (0.4)	
UPPER RESPIRATORY TRACT INFECTION	4 (3.6)	5 (4.5)	9 (4.0)	
URINARY TRACT INFECTION	0	7 (6.3)	7 (3.1)	0.007
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (0.9)	0	1 (0.4)	
VULVOVAGINAL CANDIDIASIS	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	35 (31.3)	49 (44.1)	84 (37.7)	0.054

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
INJURY, POISONING AND PROCEDURAL COMPLICATIONS				
ACCIDENTAL OVERDOSE	0	1 (0.9)	1 (0.4)	
ARTHROPOD BITE	0	1 (0.9)	1 (0.4)	
CONTUSION	3 (2.7)	2 (1.8)	5 (2.2)	
EPICONDYLITIS	0	2 (1.8)	2 (0.9)	
EXCORIATION	1 (0.9)	1 (0.9)	2 (0.9)	
EYE INJURY	1 (0.9)	1 (0.9)	2 (0.9)	
FALL	1 (0.9)	0	1 (0.4)	
FOOT FRACTURE	1 (0.9)	0	1 (0.4)	
HUMERUS FRACTURE	0	1 (0.9)	1 (0.4)	
LACERATION	1 (0.9)	0	1 (0.4)	
LIGAMENT RUPTURE	0	1 (0.9)	1 (0.4)	
LIGAMENT SPRAIN	0	2 (1.8)	2 (0.9)	
MENISCUS INJURY	1 (0.9)	0	1 (0.4)	
RESPIRATORY FUME INHALATION DISORDER	0	1 (0.9)	1 (0.4)	
RIB FRACTURE	1 (0.9)	0	1 (0.4)	
SCAR	0	1 (0.9)	1 (0.4)	
SCRATCH	1 (0.9)	0	1 (0.4)	
SPINAL FRACTURE	1 (0.9)	0	1 (0.4)	
SUTURE RELATED COMPLICATION	0	1 (0.9)	1 (0.4)	
TENDON INJURY	0	1 (0.9)	1 (0.4)	
TENDON RUPTURE	0	1 (0.9)	1 (0.4)	
TOOTH FRACTURE	1 (0.9)	0	1 (0.4)	
TOXICITY TO VARIOUS AGENTS	1 (0.9)	0	1 (0.4)	
TRAUMATIC HAEMATOMA	0	1 (0.9)	1 (0.4)	
WRIST FRACTURE	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	12 (10.7)	15 (13.5)	27 (12.1)	

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
INVESTIGATIONS				
ALANINE AMINOTRANSFERASE INCREASED	2 (1.8)	1 (0.9)	3 (1.3)	
ASPARTATE AMINOTRANSFERASE INCREASED	1 (0.9)	1 (0.9)	2 (0.9)	
BASOPHIL COUNT INCREASED	0	1 (0.9)	1 (0.4)	
BLOOD ALKALINE PHOSPHATASE DECREASED	0	1 (0.9)	1 (0.4)	
BLOOD CREATININE INCREASED	2 (1.8)	4 (3.6)	6 (2.7)	
BLOOD GLUCOSE INCREASED	1 (0.9)	1 (0.9)	2 (0.9)	
BLOOD PHOSPHORUS DECREASED	1 (0.9)	0	1 (0.4)	
BLOOD POTASSIUM DECREASED	1 (0.9)	0	1 (0.4)	
BLOOD PRESSURE INCREASED	1 (0.9)	3 (2.7)	4 (1.8)	
BLOOD TRIGLYCERIDES INCREASED	1 (0.9)	0	1 (0.4)	
BLOOD URIC ACID INCREASED	0	1 (0.9)	1 (0.4)	
BREATH SOUNDS ABNORMAL	0	1 (0.9)	1 (0.4)	
CRYSTAL URINE PRESENT	1 (0.9)	0	1 (0.4)	
HEART RATE INCREASED	1 (0.9)	1 (0.9)	2 (0.9)	
HEPATIC ENZYME INCREASED	0	1 (0.9)	1 (0.4)	
INTRAOCULAR PRESSURE INCREASED	2 (1.8)	3 (2.7)	5 (2.2)	
LIGHT CHAIN ANALYSIS INCREASED	0	1 (0.9)	1 (0.4)	
LIVER FUNCTION TEST ABNORMAL	0	2 (1.8)	2 (0.9)	
LYMPHOCYTE COUNT DECREASED	1 (0.9)	3 (2.7)	4 (1.8)	
MONOCYTE COUNT DECREASED	1 (0.9)	0	1 (0.4)	
MONOCYTE COUNT INCREASED	0	1 (0.9)	1 (0.4)	
MYCOBACTERIUM TUBERCULOSIS COMPLEX TEST POSITIVE	0	1 (0.9)	1 (0.4)	
NEUTROPHIL COUNT INCREASED	1 (0.9)	3 (2.7)	4 (1.8)	
PLATELET COUNT DECREASED	1 (0.9)	0	1 (0.4)	
PLATELET COUNT INCREASED	1 (0.9)	0	1 (0.4)	
PREGNANCY TEST POSITIVE	1 (0.9)	0	1 (0.4)	
WEIGHT INCREASED	2 (1.8)	3 (2.7)	5 (2.2)	
WHITE BLOOD CELL COUNT DECREASED	1 (0.9)	0	1 (0.4)	

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
INVESTIGATIONS (CONT.)				
WHITE BLOOD CELL COUNT INCREASED	2 (1.8)	3 (2.7)	5 (2.2)	
SUBJECTS WITH ONE OR MORE EVENTS	17 (15.2)	23 (20.7)	40 (17.9)	
METABOLISM AND NUTRITION DISORDERS				
DECREASED APPETITE	2 (1.8)	0	2 (0.9)	
DIABETES MELLITUS	0	2 (1.8)	2 (0.9)	
FLUID OVERLOAD	1 (0.9)	1 (0.9)	2 (0.9)	
HYPERCHOLESTEROLAEMIA	0	1 (0.9)	1 (0.4)	
HYPERGLYCAEMIA	1 (0.9)	1 (0.9)	2 (0.9)	
HYPERTRIGLYCERIDAEMIA	0	1 (0.9)	1 (0.4)	
HYPOKALAEMIA	2 (1.8)	0	2 (0.9)	
HYPOVITAMINOSIS	0	1 (0.9)	1 (0.4)	
INCREASED APPETITE	0	2 (1.8)	2 (0.9)	
TYPE 2 DIABETES MELLITUS	2 (1.8)	1 (0.9)	3 (1.3)	
VITAMIN D DEFICIENCY	1 (0.9)	1 (0.9)	2 (0.9)	
SUBJECTS WITH ONE OR MORE EVENTS	9 (8.0)	11 (9.9)	20 (9.0)	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
ARTHRALGIA	11 (9.8)	10 (9.0)	21 (9.4)	
ARTHRITIS	0	2 (1.8)	2 (0.9)	
ARTHROPATHY	0	1 (0.9)	1 (0.4)	
BACK PAIN	2 (1.8)	9 (8.1)	11 (4.9)	0.034
COCCYDYNIA	1 (0.9)	0	1 (0.4)	
COSTOCHONDRITIS	0	1 (0.9)	1 (0.4)	
EXOSTOSIS	1 (0.9)	0	1 (0.4)	
FLANK PAIN	1 (0.9)	0	1 (0.4)	

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS (CONT.)				
JOINT SWELLING	1 (0.9)	1 (0.9)	2 (0.9)	
LIGAMENT LAXITY	2 (1.8)	0	2 (0.9)	
LOWER EXTREMITY MASS	0	1 (0.9)	1 (0.4)	
LUPUS-LIKE SYNDROME	0	1 (0.9)	1 (0.4)	
MUSCLE SPASMS	4 (3.6)	7 (6.3)	11 (4.9)	
MUSCULAR WEAKNESS	0	3 (2.7)	3 (1.3)	
MUSCULOSKELETAL CHEST PAIN	1 (0.9)	1 (0.9)	2 (0.9)	
MUSCULOSKELETAL STIFFNESS	1 (0.9)	2 (1.8)	3 (1.3)	
MYALGIA	2 (1.8)	5 (4.5)	7 (3.1)	
MYOKYMIA	0	1 (0.9)	1 (0.4)	
NECK PAIN	1 (0.9)	0	1 (0.4)	
OSTEOARTHRITIS	0	1 (0.9)	1 (0.4)	
OSTEOPOROSIS	1 (0.9)	1 (0.9)	2 (0.9)	
PAIN IN EXTREMITY	2 (1.8)	3 (2.7)	5 (2.2)	
PLANTAR FASCIITIS	0	1 (0.9)	1 (0.4)	
RHEUMATOID ARTHRITIS	0	1 (0.9)	1 (0.4)	
SPINAL OSTEOARTHRITIS	0	1 (0.9)	1 (0.4)	
SYNOVIAL CYST	0	1 (0.9)	1 (0.4)	
TENDON DISORDER	0	1 (0.9)	1 (0.4)	
TENDON PAIN	1 (0.9)	0	1 (0.4)	
TENDONITIS	1 (0.9)	1 (0.9)	2 (0.9)	
TENOSYNOVITIS	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	28 (25.0)	30 (27.0)	58 (26.0)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)				
ANOGENITAL WARTS	1 (0.9)	1 (0.9)	2 (0.9)	
CARCINOID TUMOUR OF THE GASTROINTESTINAL TRACT	0	1 (0.9)	1 (0.4)	
GLIOBLASTOMA MULTIFORME	0	1 (0.9)	1 (0.4)	
LIPOMA	0	1 (0.9)	1 (0.4)	
SEBORRHOEIC KERATOSIS	1 (0.9)	0	1 (0.4)	
SKIN PAPILLOMA	0	2 (1.8)	2 (0.9)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.8)	6 (5.4)	8 (3.6)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
NERVOUS SYSTEM DISORDERS				
AGEUSIA	0	2 (1.8)	2 (0.9)	
ANOSMIA	0	1 (0.9)	1 (0.4)	
CARPAL TUNNEL SYNDROME	2 (1.8)	1 (0.9)	3 (1.3)	
CLUSTER HEADACHE	0	1 (0.9)	1 (0.4)	
DEMYELINATION	0	1 (0.9)	1 (0.4)	
DIZZINESS	2 (1.8)	3 (2.7)	5 (2.2)	
DIZZINESS POSTURAL	0	1 (0.9)	1 (0.4)	
DYSGEUSIA	0	1 (0.9)	1 (0.4)	
HEADACHE	15 (13.4)	12 (10.8)	27 (12.1)	
HYPERAESTHESIA	0	1 (0.9)	1 (0.4)	
HYPOAESTHESIA	0	1 (0.9)	1 (0.4)	
LETHARGY	0	1 (0.9)	1 (0.4)	
LOSS OF CONSCIOUSNESS	0	1 (0.9)	1 (0.4)	
MIGRAINE	2 (1.8)	2 (1.8)	4 (1.8)	
MIGRAINE WITH AURA	0	1 (0.9)	1 (0.4)	
MIGRAINE WITHOUT AURA	0	1 (0.9)	1 (0.4)	
NEURALGIA	0	1 (0.9)	1 (0.4)	
NEUROPATHY PERIPHERAL	0	1 (0.9)	1 (0.4)	
PARAESTHESIA	0	6 (5.4)	6 (2.7)	0.014
SCIATICA	1 (0.9)	0	1 (0.4)	
SOMNOLENCE	1 (0.9)	0	1 (0.4)	
TENSION HEADACHE	0	1 (0.9)	1 (0.4)	
TREMOR	1 (0.9)	4 (3.6)	5 (2.2)	
SUBJECTS WITH ONE OR MORE EVENTS	22 (19.6)	29 (26.1)	51 (22.9)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
PSYCHIATRIC DISORDERS				
ANXIETY	0	5 (4.5)	5 (2.2)	0.029
BINGE EATING	0	1 (0.9)	1 (0.4)	
DEPRESSED MOOD	1 (0.9)	2 (1.8)	3 (1.3)	
DEPRESSION	1 (0.9)	1 (0.9)	2 (0.9)	
INSOMNIA	8 (7.1)	5 (4.5)	13 (5.8)	
IRRITABILITY	0	2 (1.8)	2 (0.9)	
LIBIDO DECREASED	0	1 (0.9)	1 (0.4)	
NERVOUSNESS	1 (0.9)	0	1 (0.4)	
RESTLESSNESS	2 (1.8)	1 (0.9)	3 (1.3)	
STRESS	1 (0.9)	0	1 (0.4)	
SUICIDAL IDEATION	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	11 (9.8)	14 (12.6)	25 (11.2)	
RENAL AND URINARY DISORDERS				
ENURESIS	0	1 (0.9)	1 (0.4)	
NEPHROLITHIASIS	0	1 (0.9)	1 (0.4)	
POLLAKIURIA	1 (0.9)	2 (1.8)	3 (1.3)	
POLYURIA	0	1 (0.9)	1 (0.4)	
RENAL FAILURE CHRONIC	0	1 (0.9)	1 (0.4)	
RENAL PAIN	0	1 (0.9)	1 (0.4)	
URINE ABNORMALITY	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	7 (6.3)	8 (3.6)	0.035

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
REPRODUCTIVE SYSTEM AND BREAST DISORDERS				
AMENORRHOEA	0	1 (0.9)	1 (0.4)	
MENSTRUATION IRREGULAR	0	1 (0.9)	1 (0.4)	
OVARIAN CYST	1 (0.9)	0	1 (0.4)	
OVARIAN CYST RUPTURED	0	1 (0.9)	1 (0.4)	
PREMENSTRUAL SYNDROME	0	1 (0.9)	1 (0.4)	
PROSTATITIS	1 (0.9)	0	1 (0.4)	
VAGINAL HAEMORRHAGE	1 (0.9)	0	1 (0.4)	
VULVOVAGINAL DRYNESS	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	3 (2.7)	4 (3.6)	7 (3.1)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS				
ASTHMA	1 (0.9)	0	1 (0.4)	
COUGH	4 (3.6)	7 (6.3)	11 (4.9)	
DRY THROAT	0	1 (0.9)	1 (0.4)	
DYSPNOEA	4 (3.6)	4 (3.6)	8 (3.6)	
DYSPNOEA EXERTIONAL	1 (0.9)	1 (0.9)	2 (0.9)	
EPISTAXIS	1 (0.9)	3 (2.7)	4 (1.8)	
LARYNGEAL INFLAMMATION	1 (0.9)	0	1 (0.4)	
LUNG DISORDER	1 (0.9)	0	1 (0.4)	
NASAL CONGESTION	2 (1.8)	0	2 (0.9)	
OROPHARYNGEAL PAIN	5 (4.5)	5 (4.5)	10 (4.5)	
PHARYNGEAL INFLAMMATION	0	1 (0.9)	1 (0.4)	
PRODUCTIVE COUGH	0	1 (0.9)	1 (0.4)	
RALES	0	1 (0.9)	1 (0.4)	
RHINITIS ALLERGIC	0	1 (0.9)	1 (0.4)	
RHINORRHOEA	1 (0.9)	1 (0.9)	2 (0.9)	
RHONCHI	0	1 (0.9)	1 (0.4)	
SINUS CONGESTION	1 (0.9)	0	1 (0.4)	
SLEEP APNOEA SYNDROME	0	1 (0.9)	1 (0.4)	
SNORING	1 (0.9)	0	1 (0.4)	
THROAT IRRITATION	1 (0.9)	0	1 (0.4)	
TONSILLAR HYPERTROPHY	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	17 (15.2)	22 (19.8)	39 (17.5)	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
ACNE	5 (4.5)	5 (4.5)	10 (4.5)	
ALOPECIA	3 (2.7)	1 (0.9)	4 (1.8)	
BLISTER	1 (0.9)	1 (0.9)	2 (0.9)	
CUTANEOUS SARCOIDOSIS	0	1 (0.9)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
SKIN AND SUBCUTANEOUS TISSUE DISORDERS (CONT.)				
DERMAL CYST	0	1 (0.9)	1 (0.4)	
DERMATITIS	0	1 (0.9)	1 (0.4)	
DERMATITIS ALLERGIC	1 (0.9)	0	1 (0.4)	
DERMATITIS CONTACT	0	1 (0.9)	1 (0.4)	
DIABETIC FOOT	1 (0.9)	0	1 (0.4)	
ECCHYMOSIS	1 (0.9)	1 (0.9)	2 (0.9)	
ECZEMA	1 (0.9)	0	1 (0.4)	
ERYTHEMA	3 (2.7)	2 (1.8)	5 (2.2)	
HYPERHIDROSIS	3 (2.7)	7 (6.3)	10 (4.5)	
NEURODERMATITIS	1 (0.9)	1 (0.9)	2 (0.9)	
PETECHIAE	1 (0.9)	0	1 (0.4)	
PHOTOSENSITIVITY REACTION	1 (0.9)	1 (0.9)	2 (0.9)	
PRURIGO	1 (0.9)	0	1 (0.4)	
PRURITUS	3 (2.7)	5 (4.5)	8 (3.6)	
PRURITUS ALLERGIC	1 (0.9)	2 (1.8)	3 (1.3)	
PRURITUS GENERALISED	0	2 (1.8)	2 (0.9)	
PURPURA	1 (0.9)	0	1 (0.4)	
RASH	2 (1.8)	4 (3.6)	6 (2.7)	
RASH GENERALISED	0	2 (1.8)	2 (0.9)	
RASH PAPULAR	0	1 (0.9)	1 (0.4)	
SEBORRHOEIC DERMATITIS	1 (0.9)	1 (0.9)	2 (0.9)	
SKIN DISCOLOURATION	0	1 (0.9)	1 (0.4)	
SKIN EXFOLIATION	0	1 (0.9)	1 (0.4)	
SKIN HAEMORRHAGE	0	1 (0.9)	1 (0.4)	
SKIN LESION	1 (0.9)	1 (0.9)	2 (0.9)	
SKIN MASS	0	1 (0.9)	1 (0.4)	
SKIN OEDEMA	1 (0.9)	0	1 (0.4)	
SKIN STRIAE	1 (0.9)	0	1 (0.4)	
SKIN ULCER	0	1 (0.9)	1 (0.4)	
SOLAR DERMATITIS	1 (0.9)	0	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
SKIN AND SUBCUTANEOUS TISSUE DISORDERS (CONT.)				
SWELLING FACE	1 (0.9)	1 (0.9)	2 (0.9)	
URTICARIA	0	3 (2.7)	3 (1.3)	
SUBJECTS WITH ONE OR MORE EVENTS	24 (21.4)	34 (30.6)	58 (26.0)	
SURGICAL AND MEDICAL PROCEDURES				
ABORTION INDUCED	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	0	1 (0.4)	
VASCULAR DISORDERS				
BEHCET'S SYNDROME	1 (0.9)	0	1 (0.4)	
FLUSHING	0	2 (1.8)	2 (0.9)	
HOT FLUSH	2 (1.8)	3 (2.7)	5 (2.2)	
HYPERTENSION	1 (0.9)	4 (3.6)	5 (2.2)	
HYPOTENSION	1 (0.9)	0	1 (0.4)	
NEOVASCULARISATION	0	1 (0.9)	1 (0.4)	
ORTHOSTATIC HYPOTENSION	0	1 (0.9)	1 (0.4)	
PERIPHERAL COLDNESS	0	1 (0.9)	1 (0.4)	
THROMBOPHLEBITIS	0	1 (0.9)	1 (0.4)	
VENOUS INSUFFICIENCY	2 (1.8)	0	2 (0.9)	
VENOUS THROMBOSIS LIMB	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	7 (6.3)	12 (10.8)	19 (8.5)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.J

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
COUNTRY=JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=8) n (%)	ADALIMUMAB (N=8) n (%)	TOTAL (N=16) n (%)
ANY ADVERSE EVENT	7 (87.5)	7 (87.5)	14 (87.5)
CARDIAC DISORDERS			
PALPITATIONS	0	1 (12.5)	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (12.5)	1 (6.3)
ENDOCRINE DISORDERS			
CUSHINGOID	2 (25.0)	1 (12.5)	3 (18.8)
SUBJECTS WITH ONE OR MORE EVENTS	2 (25.0)	1 (12.5)	3 (18.8)
EYE DISORDERS			
CATARACT	1 (12.5)	0	1 (6.3)
CONJUNCTIVAL HAEMORRHAGE	2 (25.0)	0	2 (12.5)
CONJUNCTIVITIS ALLERGIC	1 (12.5)	0	1 (6.3)
DACRYOSTENOSIS ACQUIRED	0	1 (12.5)	1 (6.3)
DRY EYE	0	1 (12.5)	1 (6.3)
UVEITIS	0	1 (12.5)	1 (6.3)
VITREOUS HAEMORRHAGE	1 (12.5)	0	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	4 (50.0)	3 (37.5)	7 (43.8)

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.J

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
COUNTRY=JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=8) n (%)	ADALIMUMAB (N=8) n (%)	TOTAL (N=16) n (%)
GASTROINTESTINAL DISORDERS			
ABDOMINAL DISCOMFORT	0	3 (37.5)	3 (18.8)
CONSTIPATION	0	1 (12.5)	1 (6.3)
DRY MOUTH	0	1 (12.5)	1 (6.3)
ENTERITIS	0	1 (12.5)	1 (6.3)
GLOSSODYNIA	0	1 (12.5)	1 (6.3)
TOOTHACHE	1 (12.5)	0	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	1 (12.5)	4 (50.0)	5 (31.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
MALAISE	1 (12.5)	0	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	1 (12.5)	0	1 (6.3)
INFECTIONS AND INFESTATIONS			
HORDEOLUM	0	1 (12.5)	1 (6.3)
INFLUENZA	1 (12.5)	0	1 (6.3)
KERION	0	1 (12.5)	1 (6.3)
NASOPHARYNGITIS	3 (37.5)	0	3 (18.8)
PARONYCHIA	0	1 (12.5)	1 (6.3)
PHARYNGITIS	1 (12.5)	0	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	4 (50.0)	3 (37.5)	7 (43.8)

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.J

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
COUNTRY=JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=8) n (%)	ADALIMUMAB (N=8) n (%)	TOTAL (N=16) n (%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			
CONTUSION	0	1 (12.5)	1 (6.3)
LIGAMENT SPRAIN	0	1 (12.5)	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (12.5)	1 (6.3)
METABOLISM AND NUTRITION DISORDERS			
DIABETES MELLITUS	0	1 (12.5)	1 (6.3)
GOUT	1 (12.5)	0	1 (6.3)
INCREASED APPETITE	1 (12.5)	0	1 (6.3)
LIPID METABOLISM DISORDER	1 (12.5)	0	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	2 (25.0)	1 (12.5)	3 (18.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
ARTHRALGIA	1 (12.5)	0	1 (6.3)
BACK PAIN	1 (12.5)	0	1 (6.3)
JOINT EFFUSION	0	1 (12.5)	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	2 (25.0)	1 (12.5)	3 (18.8)
NERVOUS SYSTEM DISORDERS			
HEADACHE	1 (12.5)	1 (12.5)	2 (12.5)
SUBJECTS WITH ONE OR MORE EVENTS	1 (12.5)	1 (12.5)	2 (12.5)

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.J

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
COUNTRY=JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=8) n (%)	ADALIMUMAB (N=8) n (%)	TOTAL (N=16) n (%)
PSYCHIATRIC DISORDERS			
ANXIETY	0	1 (12.5)	1 (6.3)
INSOMNIA	0	4 (50.0)	4 (25.0)
SUBJECTS WITH ONE OR MORE EVENTS	0	4 (50.0)	4 (25.0)
RENAL AND URINARY DISORDERS			
CALCULUS URETERIC	0	1 (12.5)	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (12.5)	1 (6.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
ECZEMA ASTEATOTIC	0	1 (12.5)	1 (6.3)
ERYTHEMA	1 (12.5)	0	1 (6.3)
RASH	2 (25.0)	0	2 (12.5)
SUBJECTS WITH ONE OR MORE EVENTS	2 (25.0)	1 (12.5)	3 (18.8)

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
ANY ADVERSE EVENT	95 (79.2)	101 (84.9)	196 (82.0)	
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
INCREASED TENDENCY TO BRUISE	1 (0.8)	0	1 (0.4)	
IRON DEFICIENCY ANAEMIA	0	2 (1.7)	2 (0.8)	
LYMPH NODE PAIN	1 (0.8)	0	1 (0.4)	
LYMPHADENOPATHY	1 (0.8)	0	1 (0.4)	
MICROCYTIC ANAEMIA	0	1 (0.8)	1 (0.4)	
NEUTROPENIA	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.7)	4 (3.4)	6 (2.5)	
CARDIAC DISORDERS				
ATRIAL FIBRILLATION	0	1 (0.8)	1 (0.4)	
PALPITATIONS	1 (0.8)	4 (3.4)	5 (2.1)	
PRINZMETAL ANGINA	0	1 (0.8)	1 (0.4)	
TACHYCARDIA	1 (0.8)	1 (0.8)	2 (0.8)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.7)	7 (5.9)	9 (3.8)	
CONGENITAL, FAMILIAL AND GENETIC DISORDERS				
ICHTHYOSIS	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	0	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
EAR AND LABYRINTH DISORDERS				
EAR PAIN	1 (0.8)	0	1 (0.4)	
EAR PRURITUS	1 (0.8)	0	1 (0.4)	
TINNITUS	3 (2.5)	1 (0.8)	4 (1.7)	
VERTIGO	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	5 (4.2)	2 (1.7)	7 (2.9)	
ENDOCRINE DISORDERS				
CUSHINGOID	3 (2.5)	3 (2.5)	6 (2.5)	
HYPERPARATHYROIDISM PRIMARY	1 (0.8)	0	1 (0.4)	
HYPOTHYROIDISM	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	4 (3.3)	4 (3.4)	8 (3.3)	
EYE DISORDERS				
ABNORMAL SENSATION IN EYE	1 (0.8)	0	1 (0.4)	
ANGLE CLOSURE GLAUCOMA	0	1 (0.8)	1 (0.4)	
ANTERIOR CHAMBER INFLAMMATION	1 (0.8)	0	1 (0.4)	
ASTHENOPIA	0	1 (0.8)	1 (0.4)	
BLEPHARITIS	3 (2.5)	0	3 (1.3)	
BLINDNESS	0	1 (0.8)	1 (0.4)	
CATARACT	2 (1.7)	2 (1.7)	4 (1.7)	
CATARACT SUBCAPSULAR	1 (0.8)	2 (1.7)	3 (1.3)	
CHALAZION	1 (0.8)	1 (0.8)	2 (0.8)	
CHORIORETINAL DISORDER	1 (0.8)	0	1 (0.4)	
CHOROIDAL NEOVASCULARISATION	0	3 (2.5)	3 (1.3)	
CHOROIDITIS	1 (0.8)	0	1 (0.4)	
COLOUR BLINDNESS ACQUIRED	0	1 (0.8)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
EYE DISORDERS (CONT.)				
CONJUNCTIVAL HAEMORRHAGE	3 (2.5)	0	3 (1.3)	
CONJUNCTIVITIS ALLERGIC	2 (1.7)	3 (2.5)	5 (2.1)	
CORNEAL DEPOSITS	0	1 (0.8)	1 (0.4)	
CORNEAL EROSION	0	1 (0.8)	1 (0.4)	
CORNEAL OEDEMA	0	1 (0.8)	1 (0.4)	
CYSTOID MACULAR OEDEMA	6 (5.0)	3 (2.5)	9 (3.8)	
DACRYOSTENOSIS ACQUIRED	0	1 (0.8)	1 (0.4)	
DEPOSIT EYE	1 (0.8)	0	1 (0.4)	
DIPLOPIA	0	1 (0.8)	1 (0.4)	
DRY EYE	4 (3.3)	4 (3.4)	8 (3.3)	
EYE DISCHARGE	0	1 (0.8)	1 (0.4)	
EYE HAEMORRHAGE	0	1 (0.8)	1 (0.4)	
EYE INFLAMMATION	1 (0.8)	0	1 (0.4)	
EYE IRRITATION	0	1 (0.8)	1 (0.4)	
EYE PAIN	2 (1.7)	9 (7.6)	11 (4.6)	0.034
EYE PRURITUS	1 (0.8)	0	1 (0.4)	
EYE SWELLING	1 (0.8)	0	1 (0.4)	
EYELID OEDEMA	1 (0.8)	1 (0.8)	2 (0.8)	
EYELIDS PRURITUS	1 (0.8)	0	1 (0.4)	
FOREIGN BODY SENSATION IN EYES	2 (1.7)	0	2 (0.8)	
IRIDOCYCLITIS	0	1 (0.8)	1 (0.4)	
IRIS ADHESIONS	1 (0.8)	0	1 (0.4)	
IRITIS	0	1 (0.8)	1 (0.4)	
LACRIMATION INCREASED	3 (2.5)	0	3 (1.3)	
MACULAR FIBROSIS	1 (0.8)	0	1 (0.4)	
MACULAR OEDEMA	2 (1.7)	0	2 (0.8)	
OCULAR HYPERAEMIA	2 (1.7)	1 (0.8)	3 (1.3)	
OCULAR HYPERTENSION	1 (0.8)	3 (2.5)	4 (1.7)	
PAPILLOEDEMA	1 (0.8)	0	1 (0.4)	
PERIORBITAL OEDEMA	1 (0.8)	1 (0.8)	2 (0.8)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
EYE DISORDERS (CONT.)				
PHOTOPHOBIA	3 (2.5)	0	3 (1.3)	
POSTERIOR CAPSULE OPACIFICATION	0	2 (1.7)	2 (0.8)	
RETINAL DETACHMENT	1 (0.8)	1 (0.8)	2 (0.8)	
RETINAL HAEMORRHAGE	2 (1.7)	1 (0.8)	3 (1.3)	
RETINAL TEAR	1 (0.8)	1 (0.8)	2 (0.8)	
RETINAL VASCULAR DISORDER	1 (0.8)	0	1 (0.4)	
RETINOPATHY	1 (0.8)	0	1 (0.4)	
SUBRETINAL FLUID	0	1 (0.8)	1 (0.4)	
UVEITIS	8 (6.7)	12 (10.1)	20 (8.4)	
VISION BLURRED	2 (1.7)	8 (6.7)	10 (4.2)	0.059
VISUAL ACUITY REDUCED	3 (2.5)	4 (3.4)	7 (2.9)	
VISUAL IMPAIRMENT	0	1 (0.8)	1 (0.4)	
VITREOUS DETACHMENT	1 (0.8)	0	1 (0.4)	
VITREOUS DISORDER	1 (0.8)	0	1 (0.4)	
VITREOUS FLOATERS	4 (3.3)	5 (4.2)	9 (3.8)	
VITREOUS HAEMORRHAGE	1 (0.8)	0	1 (0.4)	
VITREOUS OPACITIES	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	44 (36.7)	56 (47.1)	100 (41.8)	
GASTROINTESTINAL DISORDERS				
ABDOMINAL DISCOMFORT	2 (1.7)	3 (2.5)	5 (2.1)	
ABDOMINAL DISTENSION	1 (0.8)	1 (0.8)	2 (0.8)	
ABDOMINAL PAIN	3 (2.5)	3 (2.5)	6 (2.5)	
ABDOMINAL PAIN LOWER	0	1 (0.8)	1 (0.4)	
ABDOMINAL PAIN UPPER	2 (1.7)	3 (2.5)	5 (2.1)	
APHTHOUS STOMATITIS	1 (0.8)	0	1 (0.4)	
CHEILITIS	0	1 (0.8)	1 (0.4)	
COLITIS	2 (1.7)	0	2 (0.8)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)		ADALIMUMAB (N=119) n (%)		TOTAL (N=239) n (%)		P-VALUE@
GASTROINTESTINAL DISORDERS (CONT.)							
CONSTIPATION	0		1	(0.8)	1	(0.4)	
DENTAL CARIES	0		2	(1.7)	2	(0.8)	
DIARRHOEA	3	(2.5)	1	(0.8)	4	(1.7)	
DRY MOUTH	1	(0.8)	6	(5.0)	7	(2.9)	0.066
DYSPEPSIA	5	(4.2)	3	(2.5)	8	(3.3)	
ENTERITIS	0		1	(0.8)	1	(0.4)	
FREQUENT BOWEL MOVEMENTS	0		1	(0.8)	1	(0.4)	
GASTRITIS	1	(0.8)	2	(1.7)	3	(1.3)	
GASTROOESOPHAGEAL REFLUX DISEASE	2	(1.7)	2	(1.7)	4	(1.7)	
GINGIVAL ATROPHY	0		1	(0.8)	1	(0.4)	
GLOSSODYNIA	0		2	(1.7)	2	(0.8)	
HAEMATOCHEZIA	1	(0.8)	0		1	(0.4)	
HAEMORRHOIDS	1	(0.8)	1	(0.8)	2	(0.8)	
HIATUS HERNIA	1	(0.8)	0		1	(0.4)	
IRRITABLE BOWEL SYNDROME	1	(0.8)	0		1	(0.4)	
LIP SWELLING	0		1	(0.8)	1	(0.4)	
NAUSEA	7	(5.8)	6	(5.0)	13	(5.4)	
PROCTALGIA	0		1	(0.8)	1	(0.4)	
SENSITIVITY OF TEETH	1	(0.8)	1	(0.8)	2	(0.8)	
TONGUE COATED	1	(0.8)	0		1	(0.4)	
TONGUE DISCOLOURATION	0		1	(0.8)	1	(0.4)	
TONGUE ULCERATION	0		1	(0.8)	1	(0.4)	
TOOTH DISORDER	1	(0.8)	0		1	(0.4)	
TOOTHACHE	2	(1.7)	0		2	(0.8)	
VOMITING	4	(3.3)	2	(1.7)	6	(2.5)	
SUBJECTS WITH ONE OR MORE EVENTS	27	(22.5)	28	(23.5)	55	(23.0)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
ADVERSE DRUG REACTION	0	1 (0.8)	1 (0.4)	
ASTHENIA	1 (0.8)	2 (1.7)	3 (1.3)	
CHEST DISCOMFORT	0	1 (0.8)	1 (0.4)	
CHEST PAIN	0	1 (0.8)	1 (0.4)	
CHILLS	0	1 (0.8)	1 (0.4)	
DRUG INTOLERANCE	1 (0.8)	0	1 (0.4)	
FACE OEDEMA	1 (0.8)	1 (0.8)	2 (0.8)	
FATIGUE	7 (5.8)	12 (10.1)	19 (7.9)	
FEELING COLD	0	1 (0.8)	1 (0.4)	
FEELING HOT	0	1 (0.8)	1 (0.4)	
INFLAMMATION	0	1 (0.8)	1 (0.4)	
INFLUENZA LIKE ILLNESS	2 (1.7)	1 (0.8)	3 (1.3)	
INJECTION SITE BRUISING	2 (1.7)	1 (0.8)	3 (1.3)	
INJECTION SITE ERYTHEMA	0	2 (1.7)	2 (0.8)	
INJECTION SITE HYPERSENSITIVITY	1 (0.8)	0	1 (0.4)	
INJECTION SITE PAIN	4 (3.3)	2 (1.7)	6 (2.5)	
INJECTION SITE PRURITUS	0	1 (0.8)	1 (0.4)	
INJECTION SITE RASH	0	1 (0.8)	1 (0.4)	
INJECTION SITE REACTION	0	1 (0.8)	1 (0.4)	
INJECTION SITE SWELLING	0	2 (1.7)	2 (0.8)	
LOCAL SWELLING	0	2 (1.7)	2 (0.8)	
MALAISE	2 (1.7)	1 (0.8)	3 (1.3)	
NON-CARDIAC CHEST PAIN	0	1 (0.8)	1 (0.4)	
OEDEMA	0	1 (0.8)	1 (0.4)	
OEDEMA PERIPHERAL	2 (1.7)	5 (4.2)	7 (2.9)	
PAIN	0	2 (1.7)	2 (0.8)	
PYREXIA	0	4 (3.4)	4 (1.7)	0.060
SUPRAPUBIC PAIN	0	1 (0.8)	1 (0.4)	
TENDERNESS	0	1 (0.8)	1 (0.4)	
THIRST	0	1 (0.8)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS (CONT.)				
XEROSIS	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	20 (16.7)	28 (23.5)	48 (20.1)	
HEPATOBILIARY DISORDERS				
CHOLELITHIASIS	0	1 (0.8)	1 (0.4)	
HEPATITIS ACUTE	1 (0.8)	0	1 (0.4)	
HYPERBILIRUBINAEMIA	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	2 (1.7)	3 (1.3)	
IMMUNE SYSTEM DISORDERS				
ANAPHYLACTIC REACTION	0	1 (0.8)	1 (0.4)	
DRUG HYPERSENSITIVITY	1 (0.8)	2 (1.7)	3 (1.3)	
HOUSE DUST ALLERGY	0	1 (0.8)	1 (0.4)	
HYPERSENSITIVITY	1 (0.8)	1 (0.8)	2 (0.8)	
SEASONAL ALLERGY	3 (2.5)	1 (0.8)	4 (1.7)	
SUBJECTS WITH ONE OR MORE EVENTS	4 (3.3)	6 (5.0)	10 (4.2)	
INFECTIONS AND INFESTATIONS				
ABDOMINAL INFECTION	1 (0.8)	0	1 (0.4)	
ARTHRITIS BACTERIAL	1 (0.8)	0	1 (0.4)	
BACTERIURIA	0	1 (0.8)	1 (0.4)	
BORRELIA INFECTION	0	1 (0.8)	1 (0.4)	
BRONCHITIS	4 (3.3)	7 (5.9)	11 (4.6)	
BRONCHITIS BACTERIAL	0	1 (0.8)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
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Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
INFECTIONS AND INFESTATIONS (CONT.)				
CONJUNCTIVITIS	2 (1.7)	2 (1.7)	4 (1.7)	
CYSTITIS	1 (0.8)	2 (1.7)	3 (1.3)	
CYTOMEGALOVIRUS INFECTION	1 (0.8)	0	1 (0.4)	
EAR INFECTION	1 (0.8)	0	1 (0.4)	
ERYTHEMA MIGRANS	0	1 (0.8)	1 (0.4)	
ESCHERICHIA URINARY TRACT INFECTION	0	1 (0.8)	1 (0.4)	
FUNGAL INFECTION	0	1 (0.8)	1 (0.4)	
FUNGAL SKIN INFECTION	0	1 (0.8)	1 (0.4)	
FURUNCLE	0	1 (0.8)	1 (0.4)	
GASTROENTERITIS	0	2 (1.7)	2 (0.8)	
GASTROENTERITIS VIRAL	1 (0.8)	0	1 (0.4)	
GASTROINTESTINAL INFECTION	1 (0.8)	0	1 (0.4)	
HELICOBACTER INFECTION	0	2 (1.7)	2 (0.8)	
HERPES SIMPLEX	0	1 (0.8)	1 (0.4)	
HERPES ZOSTER	0	1 (0.8)	1 (0.4)	
HORDEOLUM	2 (1.7)	3 (2.5)	5 (2.1)	
INFECTION	0	1 (0.8)	1 (0.4)	
INFLUENZA	6 (5.0)	1 (0.8)	7 (2.9)	
KERION	0	1 (0.8)	1 (0.4)	
LARYNGITIS	1 (0.8)	0	1 (0.4)	
LOWER RESPIRATORY TRACT INFECTION	2 (1.7)	0	2 (0.8)	
NASOPHARYNGITIS	11 (9.2)	21 (17.6)	32 (13.4)	0.060
ONYCHOMYCOSIS	1 (0.8)	0	1 (0.4)	
OPHTHALMIC HERPES SIMPLEX	0	1 (0.8)	1 (0.4)	
ORAL FUNGAL INFECTION	0	1 (0.8)	1 (0.4)	
ORAL HERPES	1 (0.8)	2 (1.7)	3 (1.3)	
OTITIS MEDIA	1 (0.8)	1 (0.8)	2 (0.8)	
PARONYCHIA	0	1 (0.8)	1 (0.4)	
PHARYNGITIS	2 (1.7)	3 (2.5)	5 (2.1)	
PHARYNGITIS STREPTOCOCCAL	2 (1.7)	0	2 (0.8)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
INFECTIONS AND INFESTATIONS (CONT.)				
PILONIDAL CYST	0	1 (0.8)	1 (0.4)	
PNEUMONIA	0	1 (0.8)	1 (0.4)	
PULPITIS DENTAL	1 (0.8)	0	1 (0.4)	
PYELONEPHRITIS ACUTE	1 (0.8)	0	1 (0.4)	
RESPIRATORY TRACT INFECTION	1 (0.8)	0	1 (0.4)	
RHINITIS	0	1 (0.8)	1 (0.4)	
SEPSIS	1 (0.8)	0	1 (0.4)	
SINUSITIS	1 (0.8)	4 (3.4)	5 (2.1)	
SKIN CANDIDA	0	1 (0.8)	1 (0.4)	
STAPHYLOCOCCAL INFECTION	1 (0.8)	0	1 (0.4)	
TINEA CRURIS	0	1 (0.8)	1 (0.4)	
TINEA INFECTION	2 (1.7)	0	2 (0.8)	
TOOTH INFECTION	2 (1.7)	0	2 (0.8)	
TRACHEITIS	0	1 (0.8)	1 (0.4)	
TUBERCULOSIS	0	1 (0.8)	1 (0.4)	
UPPER RESPIRATORY TRACT INFECTION	4 (3.3)	5 (4.2)	9 (3.8)	
URINARY TRACT INFECTION	0	7 (5.9)	7 (2.9)	0.007
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (0.8)	0	1 (0.4)	
VULVOVAGINAL CANDIDIASIS	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	39 (32.5)	52 (43.7)	91 (38.1)	0.084

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
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Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
INJURY, POISONING AND PROCEDURAL COMPLICATIONS				
ACCIDENTAL OVERDOSE	0	1 (0.8)	1 (0.4)	
ARTHROPOD BITE	0	1 (0.8)	1 (0.4)	
CONTUSION	3 (2.5)	3 (2.5)	6 (2.5)	
EPICONDYLITIS	0	2 (1.7)	2 (0.8)	
EXCORIATION	1 (0.8)	1 (0.8)	2 (0.8)	
EYE INJURY	1 (0.8)	1 (0.8)	2 (0.8)	
FALL	1 (0.8)	0	1 (0.4)	
FOOT FRACTURE	1 (0.8)	0	1 (0.4)	
HUMERUS FRACTURE	0	1 (0.8)	1 (0.4)	
LACERATION	1 (0.8)	0	1 (0.4)	
LIGAMENT RUPTURE	0	1 (0.8)	1 (0.4)	
LIGAMENT SPRAIN	0	3 (2.5)	3 (1.3)	
MENISCUS INJURY	1 (0.8)	0	1 (0.4)	
RESPIRATORY FUME INHALATION DISORDER	0	1 (0.8)	1 (0.4)	
RIB FRACTURE	1 (0.8)	0	1 (0.4)	
SCAR	0	1 (0.8)	1 (0.4)	
SCRATCH	1 (0.8)	0	1 (0.4)	
SPINAL FRACTURE	1 (0.8)	0	1 (0.4)	
SUTURE RELATED COMPLICATION	0	1 (0.8)	1 (0.4)	
TENDON INJURY	0	1 (0.8)	1 (0.4)	
TENDON RUPTURE	0	1 (0.8)	1 (0.4)	
TOOTH FRACTURE	1 (0.8)	0	1 (0.4)	
TOXICITY TO VARIOUS AGENTS	1 (0.8)	0	1 (0.4)	
TRAUMATIC HAEMATOMA	0	1 (0.8)	1 (0.4)	
WRIST FRACTURE	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	12 (10.0)	16 (13.4)	28 (11.7)	

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)		ADALIMUMAB (N=119) n (%)		TOTAL (N=239) n (%)		P-VALUE@
INVESTIGATIONS							
ALANINE AMINOTRANSFERASE INCREASED	2	(1.7)	1	(0.8)	3	(1.3)	
ASPARTATE AMINOTRANSFERASE INCREASED	1	(0.8)	1	(0.8)	2	(0.8)	
BASOPHIL COUNT INCREASED	0		1	(0.8)	1	(0.4)	
BLOOD ALKALINE PHOSPHATASE DECREASED	0		1	(0.8)	1	(0.4)	
BLOOD CREATININE INCREASED	2	(1.7)	4	(3.4)	6	(2.5)	
BLOOD GLUCOSE INCREASED	1	(0.8)	1	(0.8)	2	(0.8)	
BLOOD PHOSPHORUS DECREASED	1	(0.8)	0		1	(0.4)	
BLOOD POTASSIUM DECREASED	1	(0.8)	0		1	(0.4)	
BLOOD PRESSURE INCREASED	1	(0.8)	3	(2.5)	4	(1.7)	
BLOOD TRIGLYCERIDES INCREASED	1	(0.8)	0		1	(0.4)	
BLOOD URIC ACID INCREASED	0		1	(0.8)	1	(0.4)	
BREATH SOUNDS ABNORMAL	0		1	(0.8)	1	(0.4)	
CRYSTAL URINE PRESENT	1	(0.8)	0		1	(0.4)	
HEART RATE INCREASED	1	(0.8)	1	(0.8)	2	(0.8)	
HEPATIC ENZYME INCREASED	0		1	(0.8)	1	(0.4)	
INTRAOCULAR PRESSURE INCREASED	2	(1.7)	3	(2.5)	5	(2.1)	
LIGHT CHAIN ANALYSIS INCREASED	0		1	(0.8)	1	(0.4)	
LIVER FUNCTION TEST ABNORMAL	0		2	(1.7)	2	(0.8)	
LYMPHOCYTE COUNT DECREASED	1	(0.8)	3	(2.5)	4	(1.7)	
MONOCYTE COUNT DECREASED	1	(0.8)	0		1	(0.4)	
MONOCYTE COUNT INCREASED	0		1	(0.8)	1	(0.4)	
MYCOBACTERIUM TUBERCULOSIS COMPLEX TEST POSITIVE	0		1	(0.8)	1	(0.4)	
NEUTROPHIL COUNT INCREASED	1	(0.8)	3	(2.5)	4	(1.7)	
PLATELET COUNT DECREASED	1	(0.8)	0		1	(0.4)	
PLATELET COUNT INCREASED	1	(0.8)	0		1	(0.4)	
PREGNANCY TEST POSITIVE	1	(0.8)	0		1	(0.4)	
WEIGHT INCREASED	2	(1.7)	3	(2.5)	5	(2.1)	
WHITE BLOOD CELL COUNT DECREASED	1	(0.8)	0		1	(0.4)	

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Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
INVESTIGATIONS (CONT.)				
WHITE BLOOD CELL COUNT INCREASED	2 (1.7)	3 (2.5)	5 (2.1)	
SUBJECTS WITH ONE OR MORE EVENTS	17 (14.2)	23 (19.3)	40 (16.7)	
METABOLISM AND NUTRITION DISORDERS				
DECREASED APPETITE	2 (1.7)	0	2 (0.8)	
DIABETES MELLITUS	0	3 (2.5)	3 (1.3)	
FLUID OVERLOAD	1 (0.8)	1 (0.8)	2 (0.8)	
GOUT	1 (0.8)	0	1 (0.4)	
HYPERCHOLESTEROLAEMIA	0	1 (0.8)	1 (0.4)	
HYPERGLYCAEMIA	1 (0.8)	1 (0.8)	2 (0.8)	
HYPERTRIGLYCERIDAEMIA	0	1 (0.8)	1 (0.4)	
HYPOKALAEMIA	2 (1.7)	0	2 (0.8)	
HYPOVITAMINOSIS	0	1 (0.8)	1 (0.4)	
INCREASED APPETITE	1 (0.8)	2 (1.7)	3 (1.3)	
LIPID METABOLISM DISORDER	1 (0.8)	0	1 (0.4)	
TYPE 2 DIABETES MELLITUS	2 (1.7)	1 (0.8)	3 (1.3)	
VITAMIN D DEFICIENCY	1 (0.8)	1 (0.8)	2 (0.8)	
SUBJECTS WITH ONE OR MORE EVENTS	11 (9.2)	12 (10.1)	23 (9.6)	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
ARTHRALGIA	12 (10.0)	10 (8.4)	22 (9.2)	
ARTHRITIS	0	2 (1.7)	2 (0.8)	
ARTHROPATHY	0	1 (0.8)	1 (0.4)	
BACK PAIN	3 (2.5)	9 (7.6)	12 (5.0)	0.084
COCCYDYNIA	1 (0.8)	0	1 (0.4)	
COSTOCHONDRITIS	0	1 (0.8)	1 (0.4)	

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@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS (CONT.)				
EXOSTOSIS	1 (0.8)	0	1 (0.4)	
FLANK PAIN	1 (0.8)	0	1 (0.4)	
JOINT EFFUSION	0	1 (0.8)	1 (0.4)	
JOINT SWELLING	1 (0.8)	1 (0.8)	2 (0.8)	
LIGAMENT LAXITY	2 (1.7)	0	2 (0.8)	
LOWER EXTREMITY MASS	0	1 (0.8)	1 (0.4)	
LUPUS-LIKE SYNDROME	0	1 (0.8)	1 (0.4)	
MUSCLE SPASMS	4 (3.3)	7 (5.9)	11 (4.6)	
MUSCULAR WEAKNESS	0	3 (2.5)	3 (1.3)	
MUSCULOSKELETAL CHEST PAIN	1 (0.8)	1 (0.8)	2 (0.8)	
MUSCULOSKELETAL STIFFNESS	1 (0.8)	2 (1.7)	3 (1.3)	
MYALGIA	2 (1.7)	5 (4.2)	7 (2.9)	
MYOKYMIA	0	1 (0.8)	1 (0.4)	
NECK PAIN	1 (0.8)	0	1 (0.4)	
OSTEOARTHRITIS	0	1 (0.8)	1 (0.4)	
OSTEOPOROSIS	1 (0.8)	1 (0.8)	2 (0.8)	
PAIN IN EXTREMITY	2 (1.7)	3 (2.5)	5 (2.1)	
PLANTAR FASCIITIS	0	1 (0.8)	1 (0.4)	
RHEUMATOID ARTHRITIS	0	1 (0.8)	1 (0.4)	
SPINAL OSTEOARTHRITIS	0	1 (0.8)	1 (0.4)	
SYNOVIAL CYST	0	1 (0.8)	1 (0.4)	
TENDON DISORDER	0	1 (0.8)	1 (0.4)	
TENDON PAIN	1 (0.8)	0	1 (0.4)	
TENDONITIS	1 (0.8)	1 (0.8)	2 (0.8)	
TENOSYNOVITIS	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	30 (25.0)	31 (26.1)	61 (25.5)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
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Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)				
ANOGENITAL WARTS	1 (0.8)	1 (0.8)	2 (0.8)	
CARCINOID TUMOUR OF THE GASTROINTESTINAL TRACT	0	1 (0.8)	1 (0.4)	
GLIOBLASTOMA MULTIFORME	0	1 (0.8)	1 (0.4)	
LIPOMA	0	1 (0.8)	1 (0.4)	
SEBORRHOEIC KERATOSIS	1 (0.8)	0	1 (0.4)	
SKIN PAPILLOMA	0	2 (1.7)	2 (0.8)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.7)	6 (5.0)	8 (3.3)	

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TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
NERVOUS SYSTEM DISORDERS				
AGEUSIA	0	2 (1.7)	2 (0.8)	
ANOSMIA	0	1 (0.8)	1 (0.4)	
CARPAL TUNNEL SYNDROME	2 (1.7)	1 (0.8)	3 (1.3)	
CLUSTER HEADACHE	0	1 (0.8)	1 (0.4)	
DEMYELINATION	0	1 (0.8)	1 (0.4)	
DIZZINESS	2 (1.7)	3 (2.5)	5 (2.1)	
DIZZINESS POSTURAL	0	1 (0.8)	1 (0.4)	
DYSGEUSIA	0	1 (0.8)	1 (0.4)	
HEADACHE	16 (13.3)	13 (10.9)	29 (12.1)	
HYPERAESTHESIA	0	1 (0.8)	1 (0.4)	
HYPOAESTHESIA	0	1 (0.8)	1 (0.4)	
LETHARGY	0	1 (0.8)	1 (0.4)	
LOSS OF CONSCIOUSNESS	0	1 (0.8)	1 (0.4)	
MIGRAINE	2 (1.7)	2 (1.7)	4 (1.7)	
MIGRAINE WITH AURA	0	1 (0.8)	1 (0.4)	
MIGRAINE WITHOUT AURA	0	1 (0.8)	1 (0.4)	
NEURALGIA	0	1 (0.8)	1 (0.4)	
NEUROPATHY PERIPHERAL	0	1 (0.8)	1 (0.4)	
PARAESTHESIA	0	6 (5.0)	6 (2.5)	0.014
SCIATICA	1 (0.8)	0	1 (0.4)	
SOMNOLENCE	1 (0.8)	0	1 (0.4)	
TENSION HEADACHE	0	1 (0.8)	1 (0.4)	
TREMOR	1 (0.8)	4 (3.4)	5 (2.1)	
SUBJECTS WITH ONE OR MORE EVENTS	23 (19.2)	30 (25.2)	53 (22.2)	

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TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
PSYCHIATRIC DISORDERS				
ANXIETY	0	6 (5.0)	6 (2.5)	0.014
BINGE EATING	0	1 (0.8)	1 (0.4)	
DEPRESSED MOOD	1 (0.8)	2 (1.7)	3 (1.3)	
DEPRESSION	1 (0.8)	1 (0.8)	2 (0.8)	
INSOMNIA	8 (6.7)	9 (7.6)	17 (7.1)	
IRRITABILITY	0	2 (1.7)	2 (0.8)	
LIBIDO DECREASED	0	1 (0.8)	1 (0.4)	
NERVOUSNESS	1 (0.8)	0	1 (0.4)	
RESTLESSNESS	2 (1.7)	1 (0.8)	3 (1.3)	
STRESS	1 (0.8)	0	1 (0.4)	
SUICIDAL IDEATION	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	11 (9.2)	18 (15.1)	29 (12.1)	
RENAL AND URINARY DISORDERS				
CALCULUS URETERIC	0	1 (0.8)	1 (0.4)	
ENURESIS	0	1 (0.8)	1 (0.4)	
NEPHROLITHIASIS	0	1 (0.8)	1 (0.4)	
POLLAKIURIA	1 (0.8)	2 (1.7)	3 (1.3)	
POLYURIA	0	1 (0.8)	1 (0.4)	
RENAL FAILURE CHRONIC	0	1 (0.8)	1 (0.4)	
RENAL PAIN	0	1 (0.8)	1 (0.4)	
URINE ABNORMALITY	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	8 (6.7)	9 (3.8)	0.019

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
REPRODUCTIVE SYSTEM AND BREAST DISORDERS				
AMENORRHOEA	0	1 (0.8)	1 (0.4)	
MENSTRUATION IRREGULAR	0	1 (0.8)	1 (0.4)	
OVARIAN CYST	1 (0.8)	0	1 (0.4)	
OVARIAN CYST RUPTURED	0	1 (0.8)	1 (0.4)	
PREMENSTRUAL SYNDROME	0	1 (0.8)	1 (0.4)	
PROSTATITIS	1 (0.8)	0	1 (0.4)	
VAGINAL HAEMORRHAGE	1 (0.8)	0	1 (0.4)	
VULVOVAGINAL DRYNESS	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	3 (2.5)	4 (3.4)	7 (2.9)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS				
ASTHMA	1 (0.8)	0	1 (0.4)	
COUGH	4 (3.3)	7 (5.9)	11 (4.6)	
DRY THROAT	0	1 (0.8)	1 (0.4)	
DYSPNOEA	4 (3.3)	4 (3.4)	8 (3.3)	
DYSPNOEA EXERTIONAL	1 (0.8)	1 (0.8)	2 (0.8)	
EPISTAXIS	1 (0.8)	3 (2.5)	4 (1.7)	
LARYNGEAL INFLAMMATION	1 (0.8)	0	1 (0.4)	
LUNG DISORDER	1 (0.8)	0	1 (0.4)	
NASAL CONGESTION	2 (1.7)	0	2 (0.8)	
OROPHARYNGEAL PAIN	5 (4.2)	5 (4.2)	10 (4.2)	
PHARYNGEAL INFLAMMATION	0	1 (0.8)	1 (0.4)	
PRODUCTIVE COUGH	0	1 (0.8)	1 (0.4)	
RALES	0	1 (0.8)	1 (0.4)	
RHINITIS ALLERGIC	0	1 (0.8)	1 (0.4)	
RHINORRHOEA	1 (0.8)	1 (0.8)	2 (0.8)	
RHONCHI	0	1 (0.8)	1 (0.4)	
SINUS CONGESTION	1 (0.8)	0	1 (0.4)	
SLEEP APNOEA SYNDROME	0	1 (0.8)	1 (0.4)	
SNORING	1 (0.8)	0	1 (0.4)	
THROAT IRRITATION	1 (0.8)	0	1 (0.4)	
TONSILLAR HYPERTROPHY	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	17 (14.2)	22 (18.5)	39 (16.3)	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
ACNE	5 (4.2)	5 (4.2)	10 (4.2)	
ALOPECIA	3 (2.5)	1 (0.8)	4 (1.7)	
BLISTER	1 (0.8)	1 (0.8)	2 (0.8)	
CUTANEOUS SARCOIDOSIS	0	1 (0.8)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
SKIN AND SUBCUTANEOUS TISSUE DISORDERS (CONT.)				
DERMAL CYST	0	1 (0.8)	1 (0.4)	
DERMATITIS	0	1 (0.8)	1 (0.4)	
DERMATITIS ALLERGIC	1 (0.8)	0	1 (0.4)	
DERMATITIS CONTACT	0	1 (0.8)	1 (0.4)	
DIABETIC FOOT	1 (0.8)	0	1 (0.4)	
ECCHYMOSIS	1 (0.8)	1 (0.8)	2 (0.8)	
ECZEMA	1 (0.8)	0	1 (0.4)	
ECZEMA ASTEATOTIC	0	1 (0.8)	1 (0.4)	
ERYTHEMA	4 (3.3)	2 (1.7)	6 (2.5)	
HYPERHIDROSIS	3 (2.5)	7 (5.9)	10 (4.2)	
NEURODERMATITIS	1 (0.8)	1 (0.8)	2 (0.8)	
PETECHIAE	1 (0.8)	0	1 (0.4)	
PHOTOSENSITIVITY REACTION	1 (0.8)	1 (0.8)	2 (0.8)	
PRURIGO	1 (0.8)	0	1 (0.4)	
PRURITUS	3 (2.5)	5 (4.2)	8 (3.3)	
PRURITUS ALLERGIC	1 (0.8)	2 (1.7)	3 (1.3)	
PRURITUS GENERALISED	0	2 (1.7)	2 (0.8)	
PURPURA	1 (0.8)	0	1 (0.4)	
RASH	4 (3.3)	4 (3.4)	8 (3.3)	
RASH GENERALISED	0	2 (1.7)	2 (0.8)	
RASH PAPULAR	0	1 (0.8)	1 (0.4)	
SEBORRHOEIC DERMATITIS	1 (0.8)	1 (0.8)	2 (0.8)	
SKIN DISCOLOURATION	0	1 (0.8)	1 (0.4)	
SKIN EXFOLIATION	0	1 (0.8)	1 (0.4)	
SKIN HAEMORRHAGE	0	1 (0.8)	1 (0.4)	
SKIN LESION	1 (0.8)	1 (0.8)	2 (0.8)	
SKIN MASS	0	1 (0.8)	1 (0.4)	
SKIN OEDEMA	1 (0.8)	0	1 (0.4)	
SKIN STRIAE	1 (0.8)	0	1 (0.4)	
SKIN ULCER	0	1 (0.8)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__1.3.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS
BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
SKIN AND SUBCUTANEOUS TISSUE DISORDERS (CONT.)				
SOLAR DERMATITIS	1 (0.8)	0	1 (0.4)	
SWELLING FACE	1 (0.8)	1 (0.8)	2 (0.8)	
URTICARIA	0	3 (2.5)	3 (1.3)	
SUBJECTS WITH ONE OR MORE EVENTS	26 (21.7)	35 (29.4)	61 (25.5)	
SURGICAL AND MEDICAL PROCEDURES				
ABORTION INDUCED	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	0	1 (0.4)	
VASCULAR DISORDERS				
BEHCET'S SYNDROME	1 (0.8)	0	1 (0.4)	
FLUSHING	0	2 (1.7)	2 (0.8)	
HOT FLUSH	2 (1.7)	3 (2.5)	5 (2.1)	
HYPERTENSION	1 (0.8)	4 (3.4)	5 (2.1)	
HYPOTENSION	1 (0.8)	0	1 (0.4)	
NEOVASCULARISATION	0	1 (0.8)	1 (0.4)	
ORTHOSTATIC HYPOTENSION	0	1 (0.8)	1 (0.4)	
PERIPHERAL COLDNESS	0	1 (0.8)	1 (0.4)	
THROMBOPHLEBITIS	0	1 (0.8)	1 (0.4)	
VENOUS INSUFFICIENCY	2 (1.7)	0	2 (0.8)	
VENOUS THROMBOSIS LIMB	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	7 (5.8)	12 (10.1)	19 (7.9)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
ANY ADVERSE EVENT	35 (31.3)	45 (40.5)	80 (35.9)	
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
MICROCYTIC ANAEMIA	0	1 (0.9)	1 (0.4)	
NEUTROPENIA	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (1.8)	2 (0.9)	
ENDOCRINE DISORDERS				
HYPOTHYROIDISM	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.9)	1 (0.4)	
EYE DISORDERS				
ANTERIOR CHAMBER INFLAMMATION	1 (0.9)	0	1 (0.4)	
CYSTOID MACULAR OEDEMA	0	1 (0.9)	1 (0.4)	
MACULAR OEDEMA	1 (0.9)	0	1 (0.4)	
UVEITIS	3 (2.7)	1 (0.9)	4 (1.8)	
VISION BLURRED	0	1 (0.9)	1 (0.4)	
VISUAL ACUITY REDUCED	1 (0.9)	1 (0.9)	2 (0.9)	
VITREOUS FLOATERS	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	4 (3.6)	3 (2.7)	7 (3.1)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
GASTROINTESTINAL DISORDERS				
ABDOMINAL PAIN UPPER	0	1 (0.9)	1 (0.4)	
DRY MOUTH	0	1 (0.9)	1 (0.4)	
DYSPEPSIA	0	1 (0.9)	1 (0.4)	
FREQUENT BOWEL MOVEMENTS	0	1 (0.9)	1 (0.4)	
GINGIVAL ATROPHY	0	1 (0.9)	1 (0.4)	
GLOSSODYNIA	0	1 (0.9)	1 (0.4)	
LIP SWELLING	0	1 (0.9)	1 (0.4)	
NAUSEA	0	2 (1.8)	2 (0.9)	
TONGUE DISCOLOURATION	0	1 (0.9)	1 (0.4)	
TONGUE ULCERATION	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	6 (5.4)	6 (2.7)	0.014

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
ASTHENIA	0	1 (0.9)	1 (0.4)	
FATIGUE	2 (1.8)	5 (4.5)	7 (3.1)	
INFLUENZA LIKE ILLNESS	1 (0.9)	0	1 (0.4)	
INJECTION SITE BRUISING	1 (0.9)	0	1 (0.4)	
INJECTION SITE ERYTHEMA	0	2 (1.8)	2 (0.9)	
INJECTION SITE HYPERSENSITIVITY	1 (0.9)	0	1 (0.4)	
INJECTION SITE PAIN	3 (2.7)	2 (1.8)	5 (2.2)	
INJECTION SITE PRURITUS	0	1 (0.9)	1 (0.4)	
INJECTION SITE RASH	0	1 (0.9)	1 (0.4)	
INJECTION SITE REACTION	0	1 (0.9)	1 (0.4)	
INJECTION SITE SWELLING	0	2 (1.8)	2 (0.9)	
MALAISE	1 (0.9)	1 (0.9)	2 (0.9)	
OEDEMA	0	1 (0.9)	1 (0.4)	
OEDEMA PERIPHERAL	0	2 (1.8)	2 (0.9)	
PYREXIA	0	2 (1.8)	2 (0.9)	
TENDERNESS	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	9 (8.0)	12 (10.8)	21 (9.4)	
HEPATOBILIARY DISORDERS				
HEPATITIS ACUTE	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	0	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
IMMUNE SYSTEM DISORDERS				
HYPERSENSITIVITY	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.9)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
INFECTIONS AND INFESTATIONS				
BACTERIURIA	0	1 (0.9)	1 (0.4)	
BRONCHITIS	0	4 (3.6)	4 (1.8)	0.060
BRONCHITIS BACTERIAL	0	1 (0.9)	1 (0.4)	
CONJUNCTIVITIS	1 (0.9)	0	1 (0.4)	
HERPES ZOSTER	0	1 (0.9)	1 (0.4)	
INFECTION	0	1 (0.9)	1 (0.4)	
NASOPHARYNGITIS	1 (0.9)	8 (7.2)	9 (4.0)	0.019
OPHTHALMIC HERPES SIMPLEX	0	1 (0.9)	1 (0.4)	
ORAL FUNGAL INFECTION	0	1 (0.9)	1 (0.4)	
ORAL HERPES	0	1 (0.9)	1 (0.4)	
OTITIS MEDIA	1 (0.9)	0	1 (0.4)	
PNEUMONIA	0	1 (0.9)	1 (0.4)	
PYELONEPHRITIS ACUTE	1 (0.9)	0	1 (0.4)	
SEPSIS	1 (0.9)	0	1 (0.4)	
SINUSITIS	1 (0.9)	0	1 (0.4)	
TOOTH INFECTION	1 (0.9)	0	1 (0.4)	
TRACHEITIS	0	1 (0.9)	1 (0.4)	
TUBERCULOSIS	0	1 (0.9)	1 (0.4)	
UPPER RESPIRATORY TRACT INFECTION	1 (0.9)	3 (2.7)	4 (1.8)	
URINARY TRACT INFECTION	0	2 (1.8)	2 (0.9)	
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	6 (5.4)	19 (17.1)	25 (11.2)	0.006

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
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Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
INJURY, POISONING AND PROCEDURAL COMPLICATIONS				
CONTUSION	1 (0.9)	0	1 (0.4)	
SCAR	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	1 (0.9)	2 (0.9)	
INVESTIGATIONS				
ALANINE AMINOTRANSFERASE INCREASED	1 (0.9)	1 (0.9)	2 (0.9)	
ASPARTATE AMINOTRANSFERASE INCREASED	0	1 (0.9)	1 (0.4)	
BLOOD ALKALINE PHOSPHATASE DECREASED	0	1 (0.9)	1 (0.4)	
BLOOD CREATININE INCREASED	0	1 (0.9)	1 (0.4)	
BLOOD POTASSIUM DECREASED	1 (0.9)	0	1 (0.4)	
BLOOD PRESSURE INCREASED	0	1 (0.9)	1 (0.4)	
BREATH SOUNDS ABNORMAL	0	1 (0.9)	1 (0.4)	
HEART RATE INCREASED	1 (0.9)	0	1 (0.4)	
HEPATIC ENZYME INCREASED	0	1 (0.9)	1 (0.4)	
LIVER FUNCTION TEST ABNORMAL	0	1 (0.9)	1 (0.4)	
LYMPHOCYTE COUNT DECREASED	1 (0.9)	2 (1.8)	3 (1.3)	
MONOCYTE COUNT DECREASED	1 (0.9)	0	1 (0.4)	
MONOCYTE COUNT INCREASED	0	1 (0.9)	1 (0.4)	
MYCOBACTERIUM TUBERCULOSIS COMPLEX TEST POSITIVE	0	1 (0.9)	1 (0.4)	
NEUTROPHIL COUNT INCREASED	1 (0.9)	2 (1.8)	3 (1.3)	
PLATELET COUNT INCREASED	1 (0.9)	0	1 (0.4)	
WHITE BLOOD CELL COUNT INCREASED	0	2 (1.8)	2 (0.9)	
SUBJECTS WITH ONE OR MORE EVENTS	5 (4.5)	8 (7.2)	13 (5.8)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
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Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
ARTHRALGIA	4 (3.6)	3 (2.7)	7 (3.1)	
ARTHROPATHY	0	1 (0.9)	1 (0.4)	
BACK PAIN	0	1 (0.9)	1 (0.4)	
FLANK PAIN	1 (0.9)	0	1 (0.4)	
JOINT SWELLING	0	1 (0.9)	1 (0.4)	
LUPUS-LIKE SYNDROME	0	1 (0.9)	1 (0.4)	
MUSCLE SPASMS	1 (0.9)	1 (0.9)	2 (0.9)	
PAIN IN EXTREMITY	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	6 (5.4)	6 (5.4)	12 (5.4)	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)				
ANOGENITAL WARTS	1 (0.9)	1 (0.9)	2 (0.9)	
GLIOBLASTOMA MULTIFORME	0	1 (0.9)	1 (0.4)	
SKIN PAPILLOMA	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	3 (2.7)	4 (1.8)	
NERVOUS SYSTEM DISORDERS				
DEMYELINATION	0	1 (0.9)	1 (0.4)	
HEADACHE	1 (0.9)	4 (3.6)	5 (2.2)	
MIGRAINE WITHOUT AURA	0	1 (0.9)	1 (0.4)	
PARAESTHESIA	0	2 (1.8)	2 (0.9)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	6 (5.4)	7 (3.1)	0.065

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
PSYCHIATRIC DISORDERS				
DEPRESSION	0	1 (0.9)	1 (0.4)	
NERVOUSNESS	1 (0.9)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.9)	1 (0.9)	2 (0.9)	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS				
COUGH	1 (0.9)	2 (1.8)	3 (1.3)	
DYSPNOEA	0	1 (0.9)	1 (0.4)	
DYSPNOEA EXERTIONAL	0	1 (0.9)	1 (0.4)	
LARYNGEAL INFLAMMATION	1 (0.9)	0	1 (0.4)	
OROPHARYNGEAL PAIN	0	1 (0.9)	1 (0.4)	
RALES	0	1 (0.9)	1 (0.4)	
SLEEP APNOEA SYNDROME	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.8)	6 (5.4)	8 (3.6)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.M

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS EXCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=112) n (%)	ADALIMUMAB (N=111) n (%)	TOTAL (N=223) n (%)	P-VALUE@
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
ACNE	1 (0.9)	0	1 (0.4)	
ALOPECIA	2 (1.8)	0	2 (0.9)	
DERMATITIS	0	1 (0.9)	1 (0.4)	
DERMATITIS ALLERGIC	1 (0.9)	0	1 (0.4)	
ERYTHEMA	0	1 (0.9)	1 (0.4)	
HYPERHIDROSIS	0	1 (0.9)	1 (0.4)	
PETECHIAE	1 (0.9)	0	1 (0.4)	
PRURITUS	1 (0.9)	3 (2.7)	4 (1.8)	
PRURITUS ALLERGIC	1 (0.9)	1 (0.9)	2 (0.9)	
RASH	1 (0.9)	2 (1.8)	3 (1.3)	
RASH GENERALISED	0	2 (1.8)	2 (0.9)	
RASH PAPULAR	0	1 (0.9)	1 (0.4)	
SKIN DISCOLOURATION	0	1 (0.9)	1 (0.4)	
SKIN OEDEMA	1 (0.9)	0	1 (0.4)	
SKIN ULCER	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	8 (7.1)	11 (9.9)	19 (8.5)	
VASCULAR DISORDERS				
FLUSHING	0	1 (0.9)	1 (0.4)	
PERIPHERAL COLDNESS	0	1 (0.9)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (1.8)	2 (0.9)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.J

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
COUNTRY=JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=8) n (%)	ADALIMUMAB (N=8) n (%)	TOTAL (N=16) n (%)
ANY ADVERSE EVENT	0	1 (12.5)	1 (6.3)
INFECTIONS AND INFESTATIONS			
PARONYCHIA	0	1 (12.5)	1 (6.3)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (12.5)	1 (6.3)

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
ANY ADVERSE EVENT	35 (29.2)	46 (38.7)	81 (33.9)	
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
MICROCYTIC ANAEMIA	0	1 (0.8)	1 (0.4)	
NEUTROPENIA	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (1.7)	2 (0.8)	
ENDOCRINE DISORDERS				
HYPOTHYROIDISM	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.8)	1 (0.4)	
EYE DISORDERS				
ANTERIOR CHAMBER INFLAMMATION	1 (0.8)	0	1 (0.4)	
CYSTOID MACULAR OEDEMA	0	1 (0.8)	1 (0.4)	
MACULAR OEDEMA	1 (0.8)	0	1 (0.4)	
UVEITIS	3 (2.5)	1 (0.8)	4 (1.7)	
VISION BLURRED	0	1 (0.8)	1 (0.4)	
VISUAL ACUITY REDUCED	1 (0.8)	1 (0.8)	2 (0.8)	
VITREOUS FLOATERS	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	4 (3.3)	3 (2.5)	7 (2.9)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
GASTROINTESTINAL DISORDERS				
ABDOMINAL PAIN UPPER	0	1 (0.8)	1 (0.4)	
DRY MOUTH	0	1 (0.8)	1 (0.4)	
DYSPEPSIA	0	1 (0.8)	1 (0.4)	
FREQUENT BOWEL MOVEMENTS	0	1 (0.8)	1 (0.4)	
GINGIVAL ATROPHY	0	1 (0.8)	1 (0.4)	
GLOSSODYNIA	0	1 (0.8)	1 (0.4)	
LIP SWELLING	0	1 (0.8)	1 (0.4)	
NAUSEA	0	2 (1.7)	2 (0.8)	
TONGUE DISCOLOURATION	0	1 (0.8)	1 (0.4)	
TONGUE ULCERATION	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	6 (5.0)	6 (2.5)	0.014

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
ASTHENIA	0	1 (0.8)	1 (0.4)	
FATIGUE	2 (1.7)	5 (4.2)	7 (2.9)	
INFLUENZA LIKE ILLNESS	1 (0.8)	0	1 (0.4)	
INJECTION SITE BRUISING	1 (0.8)	0	1 (0.4)	
INJECTION SITE ERYTHEMA	0	2 (1.7)	2 (0.8)	
INJECTION SITE HYPERSENSITIVITY	1 (0.8)	0	1 (0.4)	
INJECTION SITE PAIN	3 (2.5)	2 (1.7)	5 (2.1)	
INJECTION SITE PRURITUS	0	1 (0.8)	1 (0.4)	
INJECTION SITE RASH	0	1 (0.8)	1 (0.4)	
INJECTION SITE REACTION	0	1 (0.8)	1 (0.4)	
INJECTION SITE SWELLING	0	2 (1.7)	2 (0.8)	
MALAISE	1 (0.8)	1 (0.8)	2 (0.8)	
OEDEMA	0	1 (0.8)	1 (0.4)	
OEDEMA PERIPHERAL	0	2 (1.7)	2 (0.8)	
PYREXIA	0	2 (1.7)	2 (0.8)	
TENDERNESS	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	9 (7.5)	12 (10.1)	21 (8.8)	
HEPATOBILIARY DISORDERS				
HEPATITIS ACUTE	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	0	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
IMMUNE SYSTEM DISORDERS				
HYPERSENSITIVITY	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.8)	1 (0.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
INFECTIONS AND INFESTATIONS				
BACTERIURIA	0	1 (0.8)	1 (0.4)	
BRONCHITIS	0	4 (3.4)	4 (1.7)	0.060
BRONCHITIS BACTERIAL	0	1 (0.8)	1 (0.4)	
CONJUNCTIVITIS	1 (0.8)	0	1 (0.4)	
HERPES ZOSTER	0	1 (0.8)	1 (0.4)	
INFECTION	0	1 (0.8)	1 (0.4)	
NASOPHARYNGITIS	1 (0.8)	8 (6.7)	9 (3.8)	0.019
OPHTHALMIC HERPES SIMPLEX	0	1 (0.8)	1 (0.4)	
ORAL FUNGAL INFECTION	0	1 (0.8)	1 (0.4)	
ORAL HERPES	0	1 (0.8)	1 (0.4)	
OTITIS MEDIA	1 (0.8)	0	1 (0.4)	
PARONYCHIA	0	1 (0.8)	1 (0.4)	
PNEUMONIA	0	1 (0.8)	1 (0.4)	
PYELONEPHRITIS ACUTE	1 (0.8)	0	1 (0.4)	
SEPSIS	1 (0.8)	0	1 (0.4)	
SINUSITIS	1 (0.8)	0	1 (0.4)	
TOOTH INFECTION	1 (0.8)	0	1 (0.4)	
TRACHEITIS	0	1 (0.8)	1 (0.4)	
TUBERCULOSIS	0	1 (0.8)	1 (0.4)	
UPPER RESPIRATORY TRACT INFECTION	1 (0.8)	3 (2.5)	4 (1.7)	
URINARY TRACT INFECTION	0	2 (1.7)	2 (0.8)	
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	6 (5.0)	20 (16.8)	26 (10.9)	0.004

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)		ADALIMUMAB (N=119) n (%)		TOTAL (N=239) n (%)		P-VALUE@
INJURY, POISONING AND PROCEDURAL COMPLICATIONS							
CONTUSION	1	(0.8)	0		1	(0.4)	
SCAR	0		1	(0.8)	1	(0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1	(0.8)	1	(0.8)	2	(0.8)	
INVESTIGATIONS							
ALANINE AMINOTRANSFERASE INCREASED	1	(0.8)	1	(0.8)	2	(0.8)	
ASPARTATE AMINOTRANSFERASE INCREASED	0		1	(0.8)	1	(0.4)	
BLOOD ALKALINE PHOSPHATASE DECREASED	0		1	(0.8)	1	(0.4)	
BLOOD CREATININE INCREASED	0		1	(0.8)	1	(0.4)	
BLOOD POTASSIUM DECREASED	1	(0.8)	0		1	(0.4)	
BLOOD PRESSURE INCREASED	0		1	(0.8)	1	(0.4)	
BREATH SOUNDS ABNORMAL	0		1	(0.8)	1	(0.4)	
HEART RATE INCREASED	1	(0.8)	0		1	(0.4)	
HEPATIC ENZYME INCREASED	0		1	(0.8)	1	(0.4)	
LIVER FUNCTION TEST ABNORMAL	0		1	(0.8)	1	(0.4)	
LYMPHOCYTE COUNT DECREASED	1	(0.8)	2	(1.7)	3	(1.3)	
MONOCYTE COUNT DECREASED	1	(0.8)	0		1	(0.4)	
MONOCYTE COUNT INCREASED	0		1	(0.8)	1	(0.4)	
MYCOBACTERIUM TUBERCULOSIS COMPLEX TEST POSITIVE	0		1	(0.8)	1	(0.4)	
NEUTROPHIL COUNT INCREASED	1	(0.8)	2	(1.7)	3	(1.3)	
PLATELET COUNT INCREASED	1	(0.8)	0		1	(0.4)	
WHITE BLOOD CELL COUNT INCREASED	0		2	(1.7)	2	(0.8)	
SUBJECTS WITH ONE OR MORE EVENTS	5	(4.2)	8	(6.7)	13	(5.4)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
ARTHRALGIA	4 (3.3)	3 (2.5)	7 (2.9)	
ARTHROPATHY	0	1 (0.8)	1 (0.4)	
BACK PAIN	0	1 (0.8)	1 (0.4)	
FLANK PAIN	1 (0.8)	0	1 (0.4)	
JOINT SWELLING	0	1 (0.8)	1 (0.4)	
LUPUS-LIKE SYNDROME	0	1 (0.8)	1 (0.4)	
MUSCLE SPASMS	1 (0.8)	1 (0.8)	2 (0.8)	
PAIN IN EXTREMITY	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	6 (5.0)	6 (5.0)	12 (5.0)	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)				
ANOGENITAL WARTS	1 (0.8)	1 (0.8)	2 (0.8)	
GLIOBLASTOMA MULTIFORME	0	1 (0.8)	1 (0.4)	
SKIN PAPILLOMA	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	3 (2.5)	4 (1.7)	
NERVOUS SYSTEM DISORDERS				
DEMYELINATION	0	1 (0.8)	1 (0.4)	
HEADACHE	1 (0.8)	4 (3.4)	5 (2.1)	
MIGRAINE WITHOUT AURA	0	1 (0.8)	1 (0.4)	
PARAESTHESIA	0	2 (1.7)	2 (0.8)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	6 (5.0)	7 (2.9)	0.066

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
PSYCHIATRIC DISORDERS				
DEPRESSION	0	1 (0.8)	1 (0.4)	
NERVOUSNESS	1 (0.8)	0	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.8)	1 (0.8)	2 (0.8)	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS				
COUGH	1 (0.8)	2 (1.7)	3 (1.3)	
DYSPNOEA	0	1 (0.8)	1 (0.4)	
DYSPNOEA EXERTIONAL	0	1 (0.8)	1 (0.4)	
LARYNGEAL INFLAMMATION	1 (0.8)	0	1 (0.4)	
OROPHARYNGEAL PAIN	0	1 (0.8)	1 (0.4)	
RALES	0	1 (0.8)	1 (0.4)	
SLEEP APNOEA SYNDROME	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	2 (1.7)	6 (5.0)	8 (3.3)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

TABLE 14.3__2.5.1.I

NUMBER AND PERCENTAGE OF SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS RATED AT LEAST POSSIBLY RELATED TO ADALIMUMAB/PLACEBO BY THE INVESTIGATOR BY PRIMARY MEDDRA SYSTEM ORGAN CLASS AND PREFERRED TERM
ALL SUBJECTS INCLUDING JAPAN
(SAFETY ANALYSIS SET)

SYSTEM ORGAN CLASS MEDDRA 17.0 PREFERRED TERM	PLACEBO (N=120) n (%)	ADALIMUMAB (N=119) n (%)	TOTAL (N=239) n (%)	P-VALUE@
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
ACNE	1 (0.8)	0	1 (0.4)	
ALOPECIA	2 (1.7)	0	2 (0.8)	
DERMATITIS	0	1 (0.8)	1 (0.4)	
DERMATITIS ALLERGIC	1 (0.8)	0	1 (0.4)	
ERYTHEMA	0	1 (0.8)	1 (0.4)	
HYPERHIDROSIS	0	1 (0.8)	1 (0.4)	
PETECHIAE	1 (0.8)	0	1 (0.4)	
PRURITUS	1 (0.8)	3 (2.5)	4 (1.7)	
PRURITUS ALLERGIC	1 (0.8)	1 (0.8)	2 (0.8)	
RASH	1 (0.8)	2 (1.7)	3 (1.3)	
RASH GENERALISED	0	2 (1.7)	2 (0.8)	
RASH PAPULAR	0	1 (0.8)	1 (0.4)	
SKIN DISCOLOURATION	0	1 (0.8)	1 (0.4)	
SKIN OEDEMA	1 (0.8)	0	1 (0.4)	
SKIN ULCER	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	8 (6.7)	11 (9.2)	19 (7.9)	
VASCULAR DISORDERS				
FLUSHING	0	1 (0.8)	1 (0.4)	
PERIPHERAL COLDNESS	0	1 (0.8)	1 (0.4)	
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (1.7)	2 (0.8)	

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
@ P-VALUE FOR COMPARISONS BETWEEN PLACEBO AND ACTIVE USING FISHER'S EXACT TEST. ONLY P-VALUES <= 0.100 ARE PRESENTED.

Program Source Code: [redacted]

重篤な有害事象の個別症例の詳細

Subject 1020210 (39603)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
GLIOBLASTOMA MULTIFORME	X	X		

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
39603	1020210	ADALIMUMAB	57	MALE	WHITE

Medical / Surgical History *	Onset Date
SURGERY: VASECTOMY	19[redacted]
OTHER: BACKACHE	20[redacted]
SURGERY: HERNIA	20[redacted]
OTHER: ACHILLES TENDON RUPTURE, LEFT	20[redacted]
HYPERLIPIDEMIA: HYPERCHOLESTEROLEMIA	20[redacted]
OTHER: SINUSITUS	20[redacted]
OTHER: EPICONDYLITIS LATERALIS, RIGHT	20[redacted]
OTHER: HIGH CREATININ LEVEL	20[redacted]
OTHER: POSITIVE ANA-TEST	20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
POSTERIOR - BIRDSHOT CHOROIDOPATHY	[redacted]20[redacted]	103.1	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (45 YEARS, 1 PACKS/DAY)	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20[redacted] / 1	[redacted]20[redacted] / 248	248
PREDNISONE	60 MG	ORAL		[redacted]20[redacted] / 1	[redacted]20[redacted] / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20[redacted] / 15	[redacted]20[redacted] / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20[redacted] / 22	[redacted]20[redacted] / 28	7

PREDNISONE	30 MG	ORAL	[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL	[redacted]20 / 36	[redacted]20 / 42	7
PREDNISONE	15 MG	ORAL	[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL	[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL	[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL	[redacted]20 / 64	[redacted]20 / 70	7
PREDNISONE	5 MG	ORAL	[redacted]20 / 71	[redacted]20 / 77	7
PREDNISONE	4 MG	ORAL	[redacted]20 / 78	[redacted]20 / 84	7
PREDNISONE	3 MG	ORAL	[redacted]20 / 85	[redacted]20 / 91	7
PREDNISONE	2 MG	ORAL	[redacted]20 / 92	[redacted]20 / 98	7
PREDNISONE	1 MG	ORAL	[redacted]20 / 99	[redacted]20 / 105	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
INDOMETACIN	UVEITIS	1 DROP $	QID	Y: 20[redacted]	Y: 20[redacted]
BETAMETHASONE	UVEITIS	1 DOSE $	QD	Y: 20[redacted]	Y: 20[redacted]
HOMATROPINE	UVEITIS	1 DROP $	QD	Y: 20[redacted]	Y: 20[redacted]
PREDNISOLONE	UVEITIS	1 DROP $	OTHER: 8 TIMES	Y: 20[redacted]	Y: 20[redacted]
METHYLPREDNISOLONE	UVEITIS	64 MG $	QD	Y: 20[redacted]	Y: 20[redacted]
PHENYLEPHRINE	UVEITIS	1 DROP $	QD	Y: 20[redacted]	Y: 20[redacted]
TRIAMCINOLONE	UVEITIS	0.1 CC $	QD	Y: 20[redacted]	Y: 20[redacted]
CICLOSPORIN	UVEITIS	200 MG $	BID	Y: 20[redacted]	Y: 20[redacted]
METHYLPREDNISOLONE	UVEITIS	64 MG $	QD	Y: 20[redacted]	Y: 20[redacted]
CICLOSPORIN	UVEITIS	200 MG $	BID	Y: 20[redacted]	Y: 20[redacted]
FENOFIBRATE	HYPERCHOLESTEROLEMIA	267MG	QD	Y: 20[redacted]	313
CICLOSPORIN	UVEITIS	200 MG $	QD	Y: 20[redacted]	-55
METHYLPREDNISOLONE	UVEITIS	32 MG $	QD	Y: 20[redacted]	Y: 20[redacted]
METHYLPREDNISOLONE	UVEITIS	16MG	QD	-55	-1
CODEINE	COUGHING FITS	1DOSE	TID	19	30
ESOMEPRAZOLE	HELICOBACTER BACTERIA	20MG	BID	91	141
PROPRANOLOL	HEADACHE	160MG	QD	132	145
PARACETAMOL	HEADACHE	1G	PRN	141	145

VALPROIC ACID	MIGRAINE WITHOUT AURA	300MG	QD	159	192
VALPROIC ACID	MIGRAINE WITHOUT AURA	300MG	BID	163	ONGOING
ESOMEPRAZOLE	HP BACTERIA	20MG	BID	194	207

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug*

Event Description	GLIOBLASTOMA MULTIFORME, GRADE IV
Preferred term	GLIOBLASTOMA MULTIFORME
AE Onset Date / Rx Day	[redacted]20[redacted] / 242
Age at AE Onset	58
AE Stopped Rx Day	351 (ONGOING)
Duration of AE	ONGOING
Severity	MILD
Relation to Adalimumab or Placebo by Investigator	PROBABLY RELATED
Relation to Prednisone by Investigator	PROBABLY NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY RELATED
Other Cause of Event	
Discontinued Adalimumab or Placebo Due to the Event	YES
Discontinued Prednisone Due to the Event	
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，散弾状脈絡膜症を主体とする両眼性の後部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 57 歳白人男性であり，重篤な有害事象として多形性神経膠芽細胞腫（グレード IV）が認められた。関連する病歴は抗核抗体検査陽性であり，現喫煙者（45 年間，1 箱/日）で，有害事象として前兆を伴わない片頭痛が継続中であった。

事象 1 の臨床経過：

58 歳時（投与 242 日目）に，前兆を伴わない片頭痛（非重篤な有害事象）が持続し，活力喪失，もの忘れ及び集中力欠如の症状が認められたため，頭部の単純核磁気共鳴映像法（以下「MRI」）検査を実施した。その結果，頭頂葉白質に病変が確認され，多発性硬化症に伴う脱髄巣又はバロー同心円性硬化症が疑われた。

投与 294 日目（投与終了後 46 日目）に陽電子放出断層撮影を実施したところ，右後頭部に腫瘍細胞の糖代謝亢進がみられ，周囲に浮腫性病変も生じていた。その他に，原発性悪性腫瘍を示唆する病変は認められなかった。投与 299 日目（投与終了後 51 日目）に頭部の機能的 MRI を実施した結果，強い造影効果を示す明瞭な損傷部位が存在し，中心性の壊死性病変，限局性の病変周囲浮腫，相対的局所脳血流量の増加及び見かけの拡散係数の低下が認められた。神経膠芽細胞腫と孤立性転移の鑑別診断は困難であった。左半球の言語領域に異常は認められなかった。

被験者は投与 313 日目に入院し，投与 314 日目（投与終了後 66 日目）に右後頭部を占拠する損傷部位の切除を実施した。切除標本の病理診断は，多形性神経膠芽細胞腫（グレード IV）であった。投与 315 日目（投与終了後 67 日目）に実施した術後頭部コンピュータ断層撮影（以下「CT」）では，残存腫瘍や出血は認められなかった。現在，術後化学療法及び放射線療法を施行中である。処置として，paracetamol，プロプラノロール，バルプロ酸及びテモゾロミドを投与した。被験者は投与 319 日目に退院した。本事象により，アダリムマブ / プラセボの投与を中止した。アダリムマブ / プラセボの最終投与日は投与 248 日目であった。本事象は，投与 351 日目（投与終了後 103 日目）の時点で継続中と判断された。

多形性神経膠芽細胞腫は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連あり」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連あり」と判断した。

また，多形性神経膠芽細胞腫（グレード IV）は，治験責任医師によりプレドニゾンとの因果関係「多分関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，アダリムマブ / プラセボと関連する可能性が高いと報告した。

Subject 1060104 (40287)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
PILONIDAL CYST	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
40287	1060104	ADALIMUMAB	22	FEMALE	WHITE

Medical / Surgical History *	Onset Date
SURGERY: PALATAL VELUM	19[redacted]
OTHER: OBESITY	20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
PANUVEITIS - MULTIFOCAL CHOROIDITIS AND PANUVEITIS	[redacted]20[redacted]	2.3	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (7 YEARS, .5 PACKS/DAY)	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 111	111
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 34	6
PREDNISONE	20 MG	ORAL		[redacted]20 / 35	[redacted]20 / 41	7
PREDNISONE	15 MG	ORAL		[redacted]20 / 42	[redacted]20 / 48	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 49	[redacted]20 / 55	7
PREDNISONE	10 MG	ORAL		[redacted]20	[redacted]20	7

PREDNISONE	7.5 MG	ORAL	[redacted] / 56	[redacted] / 62	7
PREDNISONE	5 MG	ORAL	[redacted] / 63	[redacted] / 69	7
PREDNISONE	4 MG	ORAL	[redacted] / 70	[redacted] / 76	7
PREDNISONE	3 MG	ORAL	[redacted] / 77	[redacted] / 83	7
PREDNISONE	2 MG	ORAL	[redacted] / 84	[redacted] / 90	7
PREDNISONE	1 MG	ORAL	[redacted] / 91	[redacted] / 97	7
			[redacted] / 98	[redacted] / 104	

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISOLONE	UVEITIS	2.5MG $	QD	-304	-214
PREDNISOLONE	UVEITIS	40MG $	QD	-244	-214
PREDNISOLONE	UVEITIS	20MG	QD	-28	-1

Event #1: Serious Adverse Event*

Event Description	INFECTED PILONIDAL SINUS
Preferred term	PILONIDAL CYST
AE Onset Date / Rx Day	[redacted] / 87
Age at AE Onset	23
AE Stopped Rx Day	92
Duration of AE	6 DAYS
Severity	MILD
Relation to Adalimumab or Placebo by Investigator	NOT RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY NOT RELATED
Other Cause of Event	UNKNOWN
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.

(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，両眼性の多発性脈絡膜炎及び汎ぶどう膜炎（発症：20[redacted] 年 [redacted] 月 [redacted] 日）を有する 22 歳白人女性であり，重篤な有害事象として毛巣嚢胞が認められた。関連する病歴 / 危険因子は長期にわたる免疫抑制，肥満及び現喫煙者（7 年間，0.5 箱/日）であった。

事象 1 の臨床経過：

23 歳時（投与 87 日目）に，感染性の毛巣嚢胞が認められ入院した。感染した毛巣洞の創切除を施行した。処置として，metamizole を投与した。本事象により，アダリムマブ / プラセボの投与を一時中断し（最終投与日：投与 85 日目），投与 111 日目に投与を再開した。被験者は退院し，本事象は投与 92 日目に消失したと判断された。

毛巣嚢胞は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「多分関連なし」と判断し，長期にわたる免疫抑制が原因の可能性が高いと報告した。

また，毛巣嚢胞は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「多分関連なし」と判断し，長期にわたる免疫抑制が原因の可能性が高いと報告した。

Subject 1060111 (40287)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
CARCINOID TUMOUR OF THE GASTROINTESTINAL TRACT	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
40287	1060111	ADALIMUMAB	42	FEMALE	WHITE

Medical / Surgical History *	Onset Date
EYE DISEASE/DISORDER: CONJUNCTIVITS SICCA	[redacted]
SURGERY: STERILIZATION FOR BIRTH CONTROL	[redacted]
HYPOTHYROIDISM	[redacted]
SURGERY: KNOT FORMATION IN THE THYROID	[redacted]
OTHER: LIVER HEMANGIOMA.	[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
POSTERIOR - BIRDSHOT CHOROIDOPATHY	[redacted]	130.6	BOTH EYES

Tobacco Use*	Alcohol Use
NEVER USED	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted] / 1	[redacted] / 343	343
PREDNISONE	60 MG	ORAL		[redacted] / 1	[redacted] / 14	14
PREDNISONE	50 MG	ORAL		[redacted] / 15	[redacted] / 21	7
PREDNISONE	40 MG	ORAL		[redacted] / 22	[redacted] / 28	7
PREDNISONE	30 MG	ORAL		[redacted] / 29	[redacted] / 35	7
PREDNISONE	20 MG	ORAL		[redacted] / 36	[redacted] / 42	7
PREDNISONE	15 MG	ORAL		[redacted]	[redacted]	7

PREDNISONE	12.5 MG	ORAL	/ 43 20 / 50	/ 49 20 / 56	7
PREDNISONE	10 MG	ORAL	20 / 57	20 / 63	7
PREDNISONE	7.5 MG	ORAL	20 / 64	20 / 70	7
PREDNISONE	5 MG	ORAL	20 / 71	20 / 77	7
PREDNISONE	4 MG	ORAL	20 / 78	20 / 84	7
PREDNISONE	3 MG	ORAL	20 / 85	20 / 91	7
PREDNISONE	2 MG	ORAL	20 / 92	20 / 98	7
PREDNISONE	1 MG	ORAL	20 / 99	20 / 105	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
CICLOSPORIN	UVEITIS	125MG $	BID	Y: 20	Y: 20
PREDNISOLONE	UVEITIS	5 MG $	QD	Y: 20	-41
LEVOTHYROXINE	HYPOTHYROIDISM	125MICROGRAMM	QD	Y: 20	ONGOING
PREDNISOLONE	UVEITIS	10MG	QD	-41	-1
PREDNISOLONE	UVEITIS	1 DROP $	QD	-31	-25
HYALURONIC ACID	CONJUNCTIVITIS SICCA	1DROP	OTHER: 5X	16	76
PROGESTERONE	ABSENCE OF MENORRHOEA	200MG	QD	84	94
CLOTRIMAZOLE	VAGINAL THRUSH	1TABLETS	QD	128	128
IBEROGAST	NEUROENDOCRINE INTESTINAL TUMOR	20DROPS	TID	239	ONGOING

Event #1: Serious Adverse Event*

Event Description	NEUROENDOCRINE INTESTINAL TUMOR ON THE RECTUM , 6MM X3.6MM
Preferred term	CARCINOID TUMOUR OF THE GASTROINTESTINAL TRACT
AE Onset Date / Rx Day	20 / 239
Age at AE Onset	43
AE Stopped Rx Day	251
Duration of AE	13 DAYS
Severity	MODERATE
Relation to Adalimumab or Placebo by	NOT RELATED

Investigator	
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	POSSIBLY RELATED
Other Cause of Event	NOT RELATED TO STUDY DRUG AN D CAUSE OF EVENT IS UNKNOWN
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，散弾状脈絡膜症を主体とする両眼性の後部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 42 歳白人女性であり，重篤な有害事象として消化管のカルチノイド腫瘍が認められた。

事象 1 の臨床経過：

43 歳時（投与 239 日目）に，再発性の鼓腸，便秘及び腹痛が認められた。被験者は，投与 246 日目に腹痛及び血便のため入院した。CT 検査の結果，直腸腫瘤が確認された。内視鏡的切除術により，消化管に発現した 6 mm × 3.6 mm の固形の非悪性神経内分泌腫瘍を切除した。非悪性腫瘍であることは，超音波内視鏡検査で確認した。組織学的検査の結果，単形性の増殖を認め，TNM-クラス分類は ICD-OC20，PT1，NX，MX，G1，L0，V0，PN0，R0，ENETS-STADIUM PT1A であり，増殖活性の低い微小な高分化型神経内分泌腫瘍であった。処置として，Iberogast を投与した。被験者は投与 251 日目に退院した。本事象によるアダリムマブ / プラセボの投与一時中断はなかった。本事象は，投与 251 日目に消失したと判断された。

消化管のカルチノイド腫瘍は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「多分関連あり」と判断し，その理由として，神経内分泌腫瘍は緩徐に成長するため，ベースライン時には既に存在していた可能性を指摘した。

また，消化管のカルチノイド腫瘍は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，その理由として，アダリムマブ / プラセボと関連があるか，プレドニゾンの投与時期から考えて関連性は極めて低いことを挙げた。

Subject 1060703 (46156)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
ACCIDENTAL OVERDOSE	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
46156	1060703	ADALIMUMAB	31	FEMALE	OTHER: KOSOVO-ALBANER

Medical / Surgical History *	Onset Date
OTHER: VOGT KOYANAGI HARADA SYNDROM	20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
PANUVEITIS - VOGT KOYANAGI HARADA	[redacted]20[redacted]	8.6	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (13 YEARS, 1 PACKS/DAY)	DRINKER LIGHT

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 52	52
CORTICOSTEROID	1 DROPS/DAY	TOPICAL		[redacted]20 / 1	[redacted]20 / 36	36
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 36	[redacted]20 / 42	7
PREDNISONE	15 MG	ORAL		[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL		[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL		[redacted]20 / 64	[redacted]20 / 70	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISOLONE	UVEITIS	1 $	QD	Y: 20[redacted]	98
PREDNISOLONE	UVEITIS	20MG $	QD	-86	-56
PREDNISOLONE	UVEITIS	20MG $	QD	-36	-29
PREDNISONE	UVEITIS	10MG	QD	-28	-1
PREDNISOLONE	UVEITIS	60MG	QD	1	30

Event #1: Serious Adverse Event*	
Event Description	ACCIDENTAL PREDNISONE OVERDOSE
Preferred term	ACCIDENTAL OVERDOSE
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	31
AE Stopped Rx Day	31
Duration of AE	17 DAYS
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	NOT RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	NOT RELATED
Other Cause of Event	OVERDOSE OF PREDNISON SUBJECT TOOK 60MG FROM STUDY MEDICATION AND 60MG OWN PREDNISOLON
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，フォークト・小柳・原田病による両眼性の汎ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 31 歳コソボ・アルバニア人女性であり，重篤な有害事象として偶発的過量投与が認められた。被験者は，現喫煙者（13 年間，1 箱/日）であった。

事象 1 の臨床経過：

31 歳時（投与 15 日目）に頭痛，息切れ及び喉のつまりの症状が認められ，投与 29 日目に動悸及び発汗も認められたため入院した。被験者は投与 1 日目から投与 30 日目まで，治験実施計画書に規定したプレドニゾン投与（短期高用量投与後，漸減）に加え，市販のプレドニゾロン 60 mg を誤って自己投与したため，プレドニゾンの過量投与が生じた。頸部及び腹部の超音波画像，胸部 X 線画像，並びに経胸壁心エコー像では，異常所見は認められなかった。被験者は投与 31 日目に退院し，本事象は消失したと判断された。本事象によるアダリムマブ / プラセボの投与一時中断はなかった。

偶発的過量投与は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連なし」と判断し，その理由として，プレドニゾンの過量投与であることを指摘した。

また，偶発的過量投与は，治験責任医師によりプレドニゾンとの因果関係「関連あり」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，人為的な過誤による可能性が高いと報告した。

Subject 1070108 (39610)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
URINARY TRACT INFECTION	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
39610	1070108	ADALIMUMAB	35	MALE	WHITE

Medical / Surgical History *	Onset Date
OTHER: RECURRENT GENITAL APHHTHAE	20
OTHER: RECURRENT ORAL APHTHAE	20
OTHER: PAN UVEITIS	20
OTHER: BEHCETS	20
OTHER: INFLAMMATORY DEBRIS ON POSTERIOR LENS CAPSULE	20

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
PANUVEITIS - BEHCET'S	20	12.5	BOTH EYES

Tobacco Use*	Alcohol Use
NEVER USED	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	20 / 1	20 / 158	158
CORTICOSTEROID	1 DROPS/DAY	TOPICAL		20 / 1	20 / 7	7
PREDNISONE	60 MG	ORAL		20 / 1	20 / 14	14
PREDNISONE	50 MG	ORAL		20 / 15	20 / 21	7
PREDNISONE	40 MG	ORAL		20 / 22	20 / 28	7
PREDNISONE	30 MG	ORAL		20 / 29	20 / 35	7
PREDNISONE	20 MG	ORAL		20 / 36	20 / 42	7
PREDNISONE	15 MG	ORAL		20	20	7

PREDNISONE	12.5 MG	ORAL	/ 43 [redacted]20 / 50	/ 49 [redacted]20 / 56	7
PREDNISONE	10 MG	ORAL	[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL	[redacted]20 / 64	[redacted]20 / 70	7
PREDNISONE	5 MG	ORAL	[redacted]20 / 71	[redacted]20 / 77	7
PREDNISONE	4 MG	ORAL	[redacted]20 / 78	[redacted]20 / 84	7
PREDNISONE	3 MG	ORAL	[redacted]20 / 85	[redacted]20 / 91	7
PREDNISONE	2 MG	ORAL	[redacted]20 / 92	[redacted]20 / 98	7
PREDNISONE	1 MG	ORAL	[redacted]20 / 99	[redacted]20 / 105	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISOLONE	UVEITIS	6 GUTT $	OTHER: 6 GUTT PER DAY (OU)	Y: 20[redacted]	-33
PREDNISONE	UVEITIS	60MG $	QD	Y: 20[redacted]	-33
OMEPRAZOLE	PREVENTION OF GASTRIC DISORDER	20MG	QD	Y: 20[redacted]	ONGOING
METHOTREXATE	UVEITIS	20MG $	OTHER: 1 PER WEEK	-235	-39
FOLIC ACID	SUPPLEMENTAL TO MTX	5MG	QID	-235	ONGOING
PREDNISOLONE	UVEITIS	1DROP	QD	-32	-1
PREDNISONE	UVEITIS	20MG	QD	-32	-1
METHOTREXATE	UVEITIS	15MG	OTHER: WEEKLY	-32	ONGOING
ERGOCALCIFEROL	SUPPLEMENTARY TO PREDNISONE	400IU	BID	33	78
LODOXAMIDE	ALLERGIC CONJUCTIVITIS	1DROP	BID	109	125
PARACETAMOL	FEVER	500MG	PRN	127	130

Event #1: Serious Adverse Event*

Event Description	URINARY TRACT INFECTION
Preferred term	URINARY TRACT INFECTION
AE Onset Date / Rx Day	[redacted]20[redacted] / 127
Age at AE Onset	35
AE Stopped Rx Day	132

Duration of AE	6 DAYS
Severity	MODERATE
Relation to Adalimumab or Placebo by Investigator	PROBABLY NOT RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY RELATED
Other Cause of Event	INFECTION
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，ベーチェット病による両眼性の汎ぶどう膜炎（発症：20[redacted] 年 [redacted]月 [redacted] 日）を有する 35 歳白人男性であり，重篤な有害事象として尿路感染が認められた。関連する病歴は，再発性の口腔内及び陰部アフタを伴うベーチェット病，並びに有害事象として報告された発熱及び倦怠感であった。

事象 1 の臨床経過：

35 歳時（投与 127 日目）に，発熱及び悪寒のため入院した。尿培養で感染が確認された。処置として，セフロキシムを投与した。被験者は投与 132 日目に退院した。本事象により，アダリムマブ / プラセボの投与を一時中断し（最終投与日：投与 116 日目），投与 158 日目に投与を再開した。本事象は，投与 132 日目に消失したと判断された。

尿路感染は，治験責任医師によりアダリムマブ / プラセボとの因果関係「多分関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連あり」と判断した。

また，尿路感染は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，アダリムマブ / プラセボによる可能性が高いと報告した。

Subject 1120102 (39613)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
DEMYELINATION	X	X		

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
39613	1120102	ADALIMUMAB	30	FEMALE	WHITE

Medical / Surgical History *	Onset Date
OTHER: ACNE	[redacted]20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
INTERMEDIATE - IDIOPATHIC	[redacted]20[redacted]	33.4	RIGHT EYE

Tobacco Use*	Alcohol Use
	DRINKER LIGHT

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 50	50
CORTICOSTEROID	3 DROPS/DAY	TOPICAL		[redacted]20 / 1	[redacted]20 / 9	9
CORTICOSTEROID	2 DROPS/DAY	TOPICAL		[redacted]20 / 10	[redacted]20 / 29	20
CORTICOSTEROID	1 DROPS/DAY	TOPICAL		[redacted]20 / 30	[redacted]20 / 41	12
PREDNISONE	60 MG	ORAL		[redacted]20 / 2	[redacted]20 / 15	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 16	[redacted]20 / 22	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 23	[redacted]20 / 29	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 30	[redacted]20 / 36	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 37	[redacted]20 / 43	7
PREDNISONE	15 MG	ORAL		[redacted]20	[redacted]20	7

PREDNISONE	12.5 MG	ORAL	/ 44 [redacted]20 / 51	/ 50 [redacted]20 / 57	7
PREDNISONE	10 MG	ORAL	[redacted]20 / 58	[redacted]20 / 64	7
PREDNISONE	7.5 MG	ORAL	[redacted]20 / 65	[redacted]20 / 69	5

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
EUGYNON	CONTRACEPTION	1TABLET	OTHER: ONCE A DAY	Y: 19[redacted]	ONGOING
MULTIVITAMIN	PROPHYLAXIS	1UN	OTHER: ONCE A DAY	Y: 20[redacted]	ONGOING
PREDNISOLONE	UVEITIS	60 MG $	QD	Y: 20[redacted]	-45
MYCOPHENOLIC ACID	UVEITIS	1.5G	BID	-256	-1
DOXYCYCLINE	ACNE	50MG	OTHER: ONCE A DAY	-103	ONGOING
ERYTHROMYCIN	ACNE	12MG	PRN	-103	ONGOING
OMEPRAZOLE	STOMACH PROTECTION	20MG	OTHER: ONCE A DAY	-72	ONGOING
PREDNISOLONE	TO REDUCE INFLAMMATION	1PERCENT	OTHER: ONCE A DAY	-51	9
CYCLOPENTOLATE	DILATION OF PUPIL	0.5PERCENT	OTHER: STAT	-51	ONGOING
PREDNISONE	UVEITIS	40MGS	QD	-44	1
MYCOPHENOLIC ACID	UVEITIS	1G	BID	1	118

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug*

Event Description	DEMYELINATING DISEASE
Preferred term	DEMYELINATION
AE Onset Date / Rx Day	[redacted]20[redacted] / 32
Age at AE Onset	30
AE Stopped Rx Day	134 (ONGOING)
Duration of AE	ONGOING
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	PROBABLY RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY RELATED
Other Cause of Event	
Discontinued Adalimumab or Placebo Due to the Event	YES
Discontinued Prednisone Due to the Event	
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，20[redacted]年[redacted]月[redacted]日に M10-877 試験に組入れられ，アダリムマブに無作為割付けされた，右眼に特発性中間部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 30 歳白人女性であり，重篤な有害事象として脱髄が認められた。被験者は，元タバコ使用者（15 年間）で，軽度の飲酒者（1 日 2 杯未満）であり，投与 6 日目に自ら掻きむしって生じた挫傷が有害事象として継続していた。

事象 1 の臨床経過：

30 歳時（ベースライン後 32 日目）に，手足のピリピリ感及び冷感，紫斑ができやすい，並びに下肢後面の発疹が認められた。治験実施施設によると，被験者には，本試験開始前に脱髄を示唆する既往はなかった。その後，下肢が重く感じられ，歩行困難となり，バランスに影響した。また，左手の親指，人差し指及び中指のしびれ感，ピリピリ感，ふるえとともに，右手に振戦があった。投与 65 日目（投与終了後 15 日目）に頭部 MRI 検査を実施した結果，皮質と脊椎の両方に脱髄を示す像が報告された。徴候・症状は持続し，両下肢にピリピリ感及び冷感，右下肢及び両足にしびれ感，右手に微小振戦，両下肢に疼痛が認められた。処置として，ガバペンチンを投与した。アダリムマブ / プラセボの最終投与日は投与 50 日目であり，プレドニゾ

ンは投与 69 日目まで漸減を継続した。更に，投与 118 日目までミコフェノール酸を投与した。被験者は投与 50 日目に試験を中止したが，投与 57 日目及び投与 70 日目に合計 2 回，規定外に来院した。治験実施施設からのその後の情報では，新たな発現は認められていない。当初の症状が持続・悪化したことから，20[redacted] 年 [redacted]月に多発性硬化症と疑われ，20[redacted] 年 [redacted] 月に確定診断され，炎症性脳病変が判明した。本事象は，投与 6 日目に発現した非重篤な有害事象の挫傷とともに，投与 134 日目（投与終了後 84 日目）の時点で継続中と判断された。

脱髄は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連あり」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連あり」と判断した。

また，脱髄は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，その理由として，プレドニゾンの使用後に脱髄疾患は認められておらず，アダリムマブ / プラセボと多分関連することを挙げた。

Subject 1120106 (39613)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
TUBERCULOSIS	X	X		

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
39613	1120106	ADALIMUMAB	39	FEMALE	ASIAN

Medical / Surgical History *	Onset Date
No information.	

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
POSTERIOR - IDIOPATHIC	[redacted]20[redacted]	4.2	RIGHT EYE

Tobacco Use*	Alcohol Use
NEVER USED	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 176	176
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 36	8
PREDNISONE	20 MG	ORAL		[redacted]20 / 37	[redacted]20 / 42	6
PREDNISONE	15 MG	ORAL		[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL		[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL		[redacted]20	[redacted]20	7

PREDNISONE	5 MG	ORAL	/ 64 20 / 71	/ 70 20 / 77	7
PREDNISONE	4 MG	ORAL	20 / 78	20 / 84	7
PREDNISONE	3 MG	ORAL	20 / 85	20 / 91	7
PREDNISONE	2 MG	ORAL	20 / 92	20 / 98	7
PREDNISONE	1 MG	ORAL	20 / 99	20 / 105	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISONE	UVEITIS	30 MG $	QD	-127	-31
METHYLPREDNISOLONE	UVEITIS	1 GRAM $	OTHER: THREE DOSES	-127	-98
PREDNISONE	UVEITIS	30MG	QD	-30	-1
PARACETAMOL	PYREXIC	1GRAM	PRN	39	42
TRIMETHOPRIM	UTI	200MG	BID	133	135
PHOLCODINE	DRY COUGH	5MG	PRN	164	167

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug*

Event Description	TUBERCULOSIS
Preferred term	TUBERCULOSIS
AE Onset Date / Rx Day	[redacted]20[redacted] / 164
Age at AE Onset	39
AE Stopped Rx Day	259 (ONGOING)
Duration of AE	ONGOING
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	POSSIBLY RELATED
Relation to Prednisone by Investigator	POSSIBLY RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY RELATED
Other Cause of Event	UNKNOWNING EXPOSURE TO TB
Discontinued Adalimumab or Placebo Due to the Event	YES
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，右眼に特発性後部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 39 歳アジア人女性であり，重篤な有害事象として結核が認められた。関連する有害事象（消失又は継続中）として，発熱，疲労，関節痛及び冷感が認められた。

事象 1 の臨床経過：

39 歳時（投与 164 日目）に，乾性咳嗽，発熱及び呼吸困難の症状が認められ入院した。投与 185 日目の胸部 X 線検査で，融合影，小葉中心性粒状影（tree-in-bud pattern），石灰化結節を認め，結核の所見と一致したが，クォンティフェロン TB ゴールド検査は陰性であった。投与 198 日目の喀痰抗酸菌培養で，結核の確定診断を得た。投与 211 日目（投与終了後 29 日目）に再度，クォンティフェロン TB ゴールド検査を実施したところ，結核陽性の判定であった。入院時（当該実施施設での臨床検査結果），アラニンアミノトランスフェラーゼ（以下「ALT」）値は 55.0 IU/L と高く，血清アルブミン値は 26.0 g/L と低かった。

なお，スクリーニング時の精製ツベルクリン（PPD）検査は陰性で，胸部 X 線画像は正常であり，スクリーニング時点では，結核の高リスク患者ではないと考えられていた。

処置として，アモキシシリン，Laxido，paracetamol，クラリスロマイシン，ベンジルペニシリン，エノキサパリン，Ventolin，クラリスロマイシン，エタンブトール，Tazocin，Rifater 及びメトクロプラミドを投与した。本事象により，アダリムマブ / プラセボの投与を中止した。アダリムマブ / プラセボの最終投与日は投与 176 日目であった。被験者は投与 203 日目に退院した。本事象は，投与 259 日目（投与終了後 84 日目）の時点で継続中と判断された。

結核は，治験責任医師によりアダリムマブ / プラセボとの因果関係「多分関連あり」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連あり」と判断した。

また，結核は，治験責任医師によりプレドニゾンとの因果関係「多分関連あり」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連あり」と判断した。

Subject 1120114 (39613)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
NEOVASCULARISATION	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
39613	1120114	ADALIMUMAB	21	MALE	WHITE

Medical / Surgical History *	Onset Date
OTHER: SARCOIDOSIS	[redacted]20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
PANUVEITIS - SARCOID	[redacted]20[redacted]	4.9	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (8 YEARS, 1 PACKS/DAY)	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 105	105
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 36	[redacted]20 / 42	7
PREDNISONE	15 MG	ORAL		[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL		[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL		[redacted]20	[redacted]20	7

PREDNISONE	5 MG	ORAL	/ 64 [redacted]20 / 71	/ 70 [redacted]20 / 77	7
PREDNISONE	4 MG	ORAL	[redacted]20 / 78	[redacted]20 / 84	7
PREDNISONE	3 MG	ORAL	[redacted]20 / 85	[redacted]20 / 91	7
PREDNISONE	2 MG	ORAL	[redacted]20 / 92	[redacted]20 / 98	7
PREDNISONE	1 MG	ORAL	[redacted]20 / 99	[redacted]20 / 105	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISOLONE	UVEITIS	60 MG $	QD	-146	-37
PREDNISOLONE	UVEITIS	20MG	QD	-36	-1

Event #1: Serious Adverse Event*

Event Description	ACTIVE NEOVASCULARISATION IN RIGHT EYE
Preferred term	NEOVASCULARISATION
AE Onset Date / Rx Day	[redacted]20[redacted] / 115 (10 DAYS AFTER LAST TREATMENT)
Age at AE Onset	22
AE Stopped Rx Day	115 (ONGOING)
Duration of AE	ONGOING
Severity	MODERATE
Relation to Adalimumab or Placebo by Investigator	PROBABLY NOT RELATED
Relation to Prednisone by Investigator	PROBABLY NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY NOT RELATED
Other Cause of Event	UVEITIS
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，サルコイドーシスによる両眼性の汎ぶどう膜炎（発症：20[redacted] 年 [redacted] 月 [redacted] 日）を有する 21 歳白人男性であり，重篤な有害事象として右眼に血管新生が認められた。被験者は，現喫煙者（8 年間，1 箱/日）であった。

事象 1 の臨床経過：

22 歳時（投与 115 日目［投与終了後 10 日目］）に，右眼に血管新生が認められた。約 2 週間前から，症状として右眼に浮遊物があった。蛍光眼底血管造影（FFA）を実施した結果，閉塞性血管炎とともに，広範囲にわたる虚血，血管鞘及び出血が認められた。血管新生の発現時点で，右眼の網膜血管に新たな炎症性病変もあり，治療不成功の基準に該当していたことが判明した。投与 126 日目に，汎網膜光凝固術を実施した。治療不成功により，アダリムマブ / プラセボの投与は本事象の発現日以前に中止された。血管新生は，投与 115 日目（投与終了後 10 日目）の時点で継続中と判断された。追加情報は得られていない。

血管新生は，治験責任医師によりアダリムマブ / プラセボとの因果関係「多分関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「多分関連なし」と判断し，原疾患に伴う活動性の閉塞性血管炎による可能性が高いと報告した。

また，血管新生は，治験責任医師によりプレドニゾンとの因果関係「多分関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「多分関連なし」と判断し，原疾患に伴う活動性の閉塞性血管炎による可能性が高いと報告した。

Subject 1150201 (45849)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
LIGAMENT RUPTURE	X			
TENDON RUPTURE	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
45849	1150201	ADALIMUMAB	40	MALE	WHITE

Medical / Surgical History *	Onset Date
OBESITY: ADIPOSITAS	[redacted]19[redacted]
HYPERTENSION	[redacted]19[redacted]
OTHER: DERMATOLOGIC ERYTHEMA EXSUDATION	[redacted]19[redacted]
OTHER: QUADIRCEPS LIGAMENT RUPTUR, RIGHT KNEE	20
OTHER: COLON POLYPS	20
OTHER: HEMORRHOIDS	20
EYE DISEASE/DISORDER: LEFT EYE RETROBULBARENEURITIS	[redacted]20[redacted]
OTHER: RIGHT LEG COMPARTMENT SYNDROM	[redacted]20[redacted]
EYE DISEASE/DISORDER: CERATOCONJUNCITVITISSICCA	20
EYE DISEASE/DISORDER: PRESBYOPIE	20
EYE DISEASE/DISORDER: MYOPIA MEDIA	20
OTHER: PERIANALTHROMBOSIS	20
EYE DISEASE/DISORDER: DISCREET VENOUS HYPERAEMIA	[redacted]20[redacted]
OTHER: SLEEP DISORDER DUE TO CORTISON THERAPY	[redacted]20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
INTERMEDIATE - OTHER: PARS PLANITIS	[redacted]20[redacted]	35.1	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (4 YEARS, .2 PACKS/DAY)	DRINKER LIGHT

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 106	106
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 36	[redacted]20 / 40	5
PREDNISONE	20 MG	ORAL		[redacted]20 / 41	[redacted]20 / 42	2
PREDNISONE	15 MG	ORAL		[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 50	[redacted]20 / 55	6
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 56	[redacted]20 / 56	1
PREDNISONE	10 MG	ORAL		[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL		[redacted]20 / 64	[redacted]20 / 70	7
PREDNISONE	5 MG	ORAL		[redacted]20 / 71	[redacted]20 / 77	7
PREDNISONE	4 MG	ORAL		[redacted]20 / 78	[redacted]20 / 84	7
PREDNISONE	3 MG	ORAL		[redacted]20 / 85	[redacted]20 / 91	7
PREDNISONE	2 MG	ORAL		[redacted]20 / 92	[redacted]20 / 98	7
PREDNISONE	1 MG	ORAL		[redacted]20 / 99	[redacted]20 / 105	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
LERCANIDIPINE	HYPERTENSION	10MG	QD	Y: 20[redacted]	71
PREDNISOLONE	UVEITIS	3 DROPS $	QD	-257	-107
METHYLPREDNISOLONE	UVEITIS	1 GR $	QD	-136	-107
PREDNISONE	UVEITIS	75 $	QD	-136	-33
PREDNISONE	UVEITIS	20 MG $	QD	-75	-49
PREDNISONE	UVEITIS	10 MG $	QD	-48	-41
PREDNISONE	UVEITIS	10 MG $	OTHER: EVERY 2ND DAY	-40	-34
PREDNISONE	UVEITIS	10MG	QD	-26	-1
LEKOVIT CA	PROPHYLAXIS DUE TO STEROID THERAPY	1TAB	QD	-12	105
OMEPRAZOLE	PROPHYLAXIS DUE TO STEROID THERAPY	20MG	QD	1	29
ZOLPIDEM	SLEEP DISORDER DUE TO CORTISON THERAPY	10MG	PRN	1	64
OMEPRAZOLE	PROPHYLAXIS DUE TO PREDNISON	40MG	QD	30	64

Event #1: Serious Adverse Event*

Event Description	RUPTUR OF LIGAMENT OF QUADRICEPS RIGHT KNEE AND RUPTUR OF RETINACULUMS MEDIALIS RIGHT KNEE
Preferred term	LIGAMENT RUPTURE ; TENDON RUPTURE
AE Onset Date / Rx Day	[redacted]20[redacted] / 56
Age at AE Onset	40
AE Stopped Rx Day	72
Duration of AE	17 DAYS
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	NOT RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	NOT RELATED
Other Cause of Event	DUE TO SLIPPING ON ICE
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，毛様体扁平部炎を主体とする両眼性の中間部ぶどう膜炎（発症：20[redacted] 年 [redacted] 月 [redacted] 日）を有する 40 歳白人男性であり，重篤な有害事象として靭帯及び腱断裂が認められた。被験者は現喫煙者（4 年間，0.2 箱/日）であり，関連する病歴は，肥満及び右膝の四頭筋腱断裂であった。

事象 1 の臨床経過：

40 歳時（投与 56 日目）に，氷の上で転倒した際に生じた右膝の疼痛及び腫脹のため入院した。投与 57 日目に右膝の MRI 検査を実施した結果，大腿四頭筋腱の部分断裂及び内側支帯の断裂が認められた。投与 64 日目に，右膝の四頭筋腱の再建手術を施行した。処置として，セフロキシム，アセトアミノフェン，dipyrone，イブプロフェン，エソメプラゾール及びエノキサパリンを投与した。被験者は退院し，本事象は投与 72 日目に消失したと判断された。本事象により治験薬の投与を一時中断し（最終投与日：投与 50 日目），投与 78 日目に投与を再開した。その後，再発は認められなかった。

靭帯及び腱断裂は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連なし」と判断し，氷上での転倒が原因の可能性が高いと報告した。

また，靭帯及び腱断裂は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，氷上での転倒が原因の可能性が高いと報告した。

Subject 1201302 (49981)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
ANAPHYLACTIC REACTION	X			
URTICARIA	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
49981	1201302	ADALIMUMAB	47	MALE	WHITE

Medical / Surgical History *	Onset Date
SURGERY: TONSILLECTOMY	19[redacted]
GASTROESOPHAGEAL REFLUX DISEASE	19[redacted]
OTHER: ECZEMA RIGHT THUMB	19[redacted]
OTHER: HIATAL HERNIA	19[redacted]
SURGERY: CARPEL TUNNEL SURGERY	19[redacted]
HYPERTENSION	19[redacted]
OTHER: SEASONAL ALLERGIES	19[redacted]
OTHER: INCREASED SERUM TRIGLYCERIDES	[redacted]20[redacted]
EYE DISEASE/DISORDER: CATARACT EXTRACTION RIGHT EYE	[redacted]20[redacted]
EYE DISEASE/DISORDER: INCREASED INTRA OCULAR PRESSURE BOTH EYES	[redacted]20[redacted]
OTHER: FUNGAL RASH IN GROIN.	[redacted]20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
INTERMEDIATE - IDIOPATHIC	[redacted]20[redacted]	99.4	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (25 YEARS, 1 PACKS/DAY)	DRINKER MODERATE

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 78	78
CORTICOSTEROID	4 DROPS/DAY	TOPICAL		[redacted]20 / 1	[redacted]20 / 8	8
CORTICOSTEROID	3 DROPS/DAY	TOPICAL		[redacted]20 / 8	[redacted]20 / 23	16
CORTICOSTEROID	1 DROPS/DAY	TOPICAL		[redacted]20 / 23	[redacted]20 / 40	18
PREDNISONE	40 MG	ORAL		[redacted]20 / 1	[redacted]20 / 1	1
PREDNISONE	60 MG	ORAL		[redacted]20 / 2	[redacted]20 / 14	13
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 36	[redacted]20 / 42	7
PREDNISONE	15 MG	ORAL		[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL		[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL		[redacted]20 / 64	[redacted]20 / 70	7
PREDNISONE	5 MG	ORAL		[redacted]20 / 71	[redacted]20 / 77	7
PREDNISONE	4 MG	ORAL		[redacted]20 / 78	[redacted]20 / 84	7
PREDNISONE	3 MG	ORAL		[redacted]20 / 85	[redacted]20 / 90	6

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
AMLODIPINE	HYPERTENSION	10MG	QD	Y: 19[redacted]	ONGOING
OMEPRAZOLE	GERD	20MG	QD	Y: 19[redacted]	ONGOING
LORATADINE	SEASONAL ALLERGIES	10MG	QD	Y: 19[redacted]	ONGOING
LOVASTATIN	INCREASED TRIGLYCERIDES IN BLOOD	40MG	QD	Y: 20[redacted]	ONGOING
KETOROLAC	UVEITIS	1DROP	QID	Y: 20[redacted]	ONGOING
COSOPT	INCREASED IOP	1DROP	BID	Y: 20[redacted]	ONGOING
MYCOPHENOLIC ACID	UVEITIS	2000MG $	QD	Y: 20[redacted]	Y: 20[redacted]
MYCOPHENOLIC ACID	UVEITIS	2500MG $	QD	Y: 20[redacted]	Y: 20[redacted]
MYCOPHENOLIC ACID	UVEITIS	2500MG $	QD	Y: 20[redacted]	Y: 20[redacted]
PREDNISONE	UVEITIS	20MG	QD	Y: 20[redacted]	-1
MYCOPHENOLIC ACID	UVEITIS	3000MG $	QD	Y: 20[redacted]	Y: 20[redacted]
PREDNISONE	UVEITIS	12MG	QD	1	1
AMOXICILLIN	SINUSITIS	500MG	TID	16	20
GUAIFENESIN	SINUSITIS	600MG	BID	16	20
DIPHENHYDRAMINE	ANAPHYLACTIC REACTION TO BEE STING	50MG	OTHER: STAT	75	75
EPINEPHRINE	ANAPHYLAXIS	0.3ML	OTHER: STAT	75	75
FAMOTIDINE	PROPHYLACTICALLY FOR STOMACH ACIDITY	20MG	OTHER: STAT	75	75
METHYLPREDNISOLONE	ANAPHYLAXIS	125MG	OTHER: STAT	75	75

Event #1: Serious Adverse Event*	
Event Description	ANAPHYLAXIS, HIVES
Preferred term	ANAPHYLACTIC REACTION ; URTICARIA
AE Onset Date / Rx Day	[redacted]20[redacted] / 75
Age at AE Onset	47
AE Stopped Rx Day	75
Duration of AE	12 HOURS
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	PROBABLY NOT RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY NOT RELATED
Other Cause of Event	BEE STING
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，両眼性の特発性中間部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 47 歳白人男性であり，重篤な有害事象としてアナフィラキシー反応及び蕁麻疹が認められた。関連する病歴は，季節性アレルギー，右親指の湿疹であり，喫煙者（25 年間，1 箱/日）及び中程度の飲酒者であった。

事象 1 の臨床経過：

47 歳時（投与 75 日目）に，蜂に刺された際にアナフィラキシー反応及び蕁麻疹が認められた。救急室での処置として，メチルプレドニゾロン，ジフェンヒドラミン，エピネフリン及びファモチジンを投与した。これらの事象は，発現から 12 時間後（投与 75 日目）に消失したと判断された。治療不成功の基準に該当したため，投与 78 日目にアダリムマブ / プラセボの投与を中止した。追加情報は得られていない。

アナフィラキシー反応及び蕁麻疹は，治験責任医師によりアダリムマブ / プラセボとの因果関係「多分関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「多分関連なし」と判断し，これらの事象の発現前に発生した蜂刺されが原因の可能性が高いと報告した。

また，アナフィラキシー反応及び蕁麻疹は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，これらの事象の発現前に発生した蜂刺されが原因の可能性が高いと報告した。

Subject 1201602 (38787)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
ANGLE CLOSURE GLAUCOMA	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
38787	1201602	ADALIMUMAB	40	FEMALE	BLACK

Medical / Surgical History *	Onset Date
HYPERTENSION: HYPERTENSION	19[redacted]
OTHER: OBESITY	20[redacted]
SURGERY: C-SECTION	[redacted]20
HYPERTENSION: GESTATIONAL HYPERTENSION	[redacted]20
SURGERY: C-SECTION	[redacted]20
SURGERY: PARTIAL SALPINGECTOMY	[redacted]20
DEPRESSION: DEPRESSION	[redacted]20
OTHER: ANXIETY	[redacted]20
EYE DISEASE/DISORDER: CATARACT OU (BOTH EYES)	[redacted]20
EYE DISEASE/DISORDER: GLAUCOMA LEFT EYE	[redacted]20
OTHER: BAND KERATOPATHY	[redacted]20
OTHER: MACULAR EDEMA	[redacted]20
EYE DISEASE/DISORDER: ANGLE CLOSURE GLAUCOMA RIGHT EYE	[redacted]20
SURGERY: CATARACT SURGERY LEFT EYE	[redacted]20
SURGERY: CATARACT SURGERY RIGHT EYE	[redacted]20

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
INTERMEDIATE - IDIOPATHIC	[redacted]20[redacted]	9	BOTH EYES

Tobacco Use*	Alcohol Use
EX-USER OF CIGARETTES (5 YEARS, 1 PACKS/DAY)	DRINKER LIGHT

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 79	79
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 36	[redacted]20 / 42	7
PREDNISONE	15 MG	ORAL		[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL		[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL		[redacted]20 / 64	[redacted]20 / 70	7
PREDNISONE	5 MG	ORAL		[redacted]20 / 71	[redacted]20 / 77	7
PREDNISONE	4 MG	ORAL		[redacted]20 / 78	[redacted]20 / 84	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISOLONE	UVEITIS	EVERY 1 HOUR $	OTHER: Q HOUR	-207	-187
PREDNISONE	UVEITIS	60 MG $	QD	-196	-193
PREDNISONE	UVEITIS	5 MG $	QD	-176	-156
PREDNISONE	UVEITIS	10MG	QD	-49	-1
ACETAZOLAMIDE	INCREASED INTRA OCULAR PRESSURE	500MG	OTHER: ONCE	9	9

Event #1: Serious Adverse Event*	
Event Description	RIGHT EYE WORSENING OF ANGLE CLOSURE GLAUCOMA
Preferred term	ANGLE CLOSURE GLAUCOMA
AE Onset Date / Rx Day	[redacted]20[redacted] / 9
Age at AE Onset	40
AE Stopped Rx Day	9
Duration of AE	4 HOURS
Severity	MODERATE
Relation to Adalimumab or Placebo by Investigator	NOT RELATED
Relation to Prednisone by Investigator	POSSIBLY RELATED
Relation to Adalimumab or Placebo by AbbVie	NOT RELATED
Other Cause of Event	CONCURRENT ILLNES (HISTORY OF ANGLE CLOSURE GLAUCOMA)
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，両眼性の特発性中間部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 40 歳黒人女性であり，重篤な有害事象として右眼に閉塞隅角緑内障が認められた。関連する病歴は，高血圧，両眼の白内障手術，左眼の緑内障，右眼の閉塞隅角緑内障であり，元喫煙者（5 年間，1 箱/日）であった。

事象 1 の臨床経過：

40 歳時（投与 9 日目）に，閉塞隅角緑内障（眼圧：63 mmHg）が認められた。緑内障専門医を受診し，同日，YAG レーザー周辺虹彩切開術を施行したところ，眼圧は正常化し，本事象は消失したと判断された。本事象によるアダリムマブ / プラセボの投与一時中断はなかった。処置として，アセタゾラミドを投与した。

閉塞隅角緑内障は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連なし」と判断し，閉塞隅角緑内障の既往及びぶどう膜炎が原因の可能性が高いと報告した。

また，閉塞隅角緑内障は，治験責任医師によりプレドニゾンとの因果関係「多分関連あり」と判断された。治験依頼者では，プレドニゾンとの因果関係「多分関連なし」と判断し，閉塞隅角緑内障の既往及びぶどう膜炎が原因の可能性が高いと報告した。

Subject 1201613 (38787)

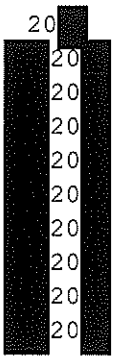
Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
FLUID OVERLOAD	X			
RENAL FAILURE CHRONIC	X	X	X	

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
38787	1201613	ADALIMUMAB	79	FEMALE	WHITE

Medical / Surgical History *	Onset Date
OTHER: OBESITY	19
OTHER: APPENDECTOMY	19
OTHER: APPENDICITIS	19
OSTEOARTHRITIS	19
OTHER: ARHROSCLEROTIC HEART DISEASE	19
HYPERTENSION	19
CHOLECYSTITIS	19
OTHER: CHOLECYSTECTOMY	19
OTHER: GOUT	19
OTHER: RIGHT KNEE REPLACEMENT	19
OTHER: LEFT KNEE REPLACEMENT	19
DIVERTICULITIS	20
OTHER: COLON RESECTION	20
OTHER: HERNIORRHAPHY ABDOMEN	20
OTHER: POSTOP COLON RESECTION INSCISIONAL HERNIA	20
OTHER: HYPERLIPIDEMIA	20
OTHER: RIGHT BUNDLE BRANCH BLOCK	20
CARDIAC ARRHYTHMIA: POST BYPASS	20
OTHER: CORONARY ARTERY BYPASS WITH FOUR GRAFTS	20
KIDNEY DISORDER: CHRONIC KIDNEY DISEASE	20
OTHER: ACIDOSIS	20
OTHER: BILATERAL INFLAMMATORY LYMPHEDEMA	20
OTHER: PHOSPHEROUS METABOLISM DISORDER	20
OTHER: CHRONIC ANEMIA	20
OTHER: BARRETTS ESOPHAGUS	20
OTHER: ARTERIAL VENOUS FISTULA PLACEMENT LEFT ARM	20
OTHER: CATARACT LEFT EYE	20
OTHER: CATARACT RIGHT EYE	20
OTHER: VITAMIN D DEFICIANCY	20
OTHER: LEFT VENTRICULAR HYPERTROPATHY	20
OTHER: PULMONARY HYPERTENSION	20
OTHER: LYMPHOCYTIC COLITIS	20

OTHER: SEASONAL ALLERGIES
OTHER: AGE RELATED MACULAR DEGENERATION OU
OTHER: CATARACT EXTRACTION LEFT EYE
OTHER: CATARACT EXTRACTION RIGHT EYE
OTHER: EPIRETINAL MEMBRANE OU
OTHER: VITREOUS DEGENERATION OU
OTHER: CORNEAL EDEMA LEFT EYE
OTHER: CELLULITIS
OTHER: RIGHT LOWER LEG WOUND
OTHER: POSITIVE CLOSTRIDIUM DIFFICILE



Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
PANUVEITIS - IDIOPATHIC	[redacted]	6.3	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (60 YEARS, .25 PACKS/DAY)	DRINKER MODERATE

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted] / 1	[redacted] / 34	34
PREDNISONE	60 MG	ORAL		[redacted] / 2	[redacted] / 15	14
PREDNISONE	50 MG	ORAL		[redacted] / 16	[redacted] / 22	7
PREDNISONE	40 MG	ORAL		[redacted] / 23	[redacted] / 29	7
PREDNISONE	30 MG	ORAL		[redacted] / 30	[redacted] / 36	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
ALLOPURINOL	GOUT	100MG	QD	Y: 20[redacted]	ONGOING
CALCIUM	SUPPLEMENT	600MG	QD	Y: 20[redacted]	ONGOING
METOPROLOL	HYPERTENSION	150MG	QD	Y: 20[redacted]	ONGOING
YUCCA SCHIDIGERA	OSTEOARTHRITIS SUPPLEMENT	450MG	QD	Y: 20[redacted]	ONGOING
ACETYLSALICYLIC ACID	ARTHERSCLEROTIC HEART DISEASE	81MG	QD	Y: 20[redacted]	ONGOING
MULTIVITAMINS	SUPPLEMENT	1TAB	QD	Y: 20[redacted]	ONGOING
OMEPRAZOLE	LYMPHCYTIC COLITIS	20MG	QD	Y: 20[redacted]	ONGOING
ROSUVASTATIN	HYPERLIPIDEMIA	5MG	QD	Y: 20[redacted]	ONGOING
OLMESARTAN	HYPERTENSION	40MG	QD	Y: 20[redacted]	ONGOING
FEXOFENADINE	SEASONAL ALLERGIES	180MG	PRN	-355	ONGOING
FUROSEMIDE	PREIPHERAL EDEMA	40MG	QD	-332	ONGOING
HYDRALAZINE	HYPERTENSION	25MG	TID	-309	ONGOING
SODIUM BICARBONATE	ACIDOSIS	650MG	BID	-262	ONGOING
BROMFENAC	UVEITIS	1 DROP $	QD	-234	11
DIFLUPREDNATE	UVEITIS	1GTT	OTHER: Q2H	-203	-112
DIFLUPREDNATE	UVEITIS	1 DROP $	OTHER: EVERY 2 HOURS	-203	-112
PREDNISONE	UVEITIS	60 MG $	QD	-203	-143
HOMATROPINE	UVEITIS	1 DROP $	BID	-173	-112
PREDNISONE	UVEITIS	60 MG $	QD	-142	-82
TRIAMCINOLONE	UVEITIS	1 ML $	OTHER: ONE TIME	-111	-82
PREDNISONE	UVEITIS	10MG	QD	-42	1
ERGOCALCIFEROL	VITAMIN D DEFICIANCY	5000UNITS	OTHER: EVERY 2 WEEKS	-42	ONGOING
METRONIDAZOLE	POSITIVE CLOSTRIDIUM DIFFICILE	500MG	TID	-34	-23
METRONIDAZOLE	POSITIVE CLOSTRIIUM DIFFICILE	500MG	TID	-20	37
WARFARIN	BLOOD THINNER	3MG	QD	12	ONGOING
AMIODARONE	ATRIAL FIRILLATION	400MG	BID	19	ONGOING
DILTIAZEM	ATRIAL FIBRILLATION	30MG	TID	19	ONGOING
PARACETAMOL	OSTEOARTHRITIS	650MG	PRN	19	ONGOING

VANCOMYCIN	POSITIVE CLOSTRIDIUM DIFFICILE	250MG	QID	19	ONGOING

Event #1: Serious Adverse Event*

Event Description	VOLUME OVERLOAD
Preferred term	FLUID OVERLOAD
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	79
AE Stopped Rx Day	18
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Adalimumab or Placebo by Investigator	NOT RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	NOT RELATED
Other Cause of Event	CHRONIC KIDNEY DISEASE STAGE IV
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, AE Leading to Discontinuation of Prednisone, Death*

Event Description	END STAGE RENAL DISEASE
Preferred term	RENAL FAILURE CHRONIC
AE Onset Date / Rx Day	[redacted]20[redacted] / 37 (3 DAYS AFTER LAST TREATMENT)
Age at AE Onset	80
AE Stopped Rx Day	37 (3 DAYS AFTER LAST TREATMENT)
Duration of AE	UNKNOWN
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	NOT RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	NOT RELATED
Other Cause of Event	CAUSE OF DEATH END STAGE RENAL DISEASE
Discontinued Adalimumab or Placebo Due to the Event	YES
Discontinued Prednisone Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，両眼性の特発性汎ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 79 歳白人女性であり，重篤な有害事象として水分過負荷及び慢性腎不全（転帰：死亡）が認められた。関連する病歴は，慢性腎臓病，リンパ球性大腸炎，憩室炎，結腸切除，肺高血圧症，心不整脈，左室肥大，右脚ブロック，冠動脈バイパス，アテローム性動脈硬化症，高脂血症，アシドーシス，クロストリジウム・ディフィシレ，リン代謝障害，痛風，両側性炎症性リンパ浮腫，蜂巣炎であり，現喫煙者（60 年間，0.25 箱/日）及び中程度の飲酒者（1 日 2–4 杯）であった。

事象 1 の臨床経過：

80 歳時に，水分過負荷が認められた（投与終了後 2 日目）。投与 2 日目に，体重増加及び下肢の湿潤性浮腫の悪化により入院した。発熱はなく，心拍数 120–130 で頻脈状態であり，右下肢上部の血腫及び組織損傷が認められた。被験者は自らの判断で，処方されたフロセミドなどの利尿薬の使用を中止していた。心電図所見は，頻拍性（RVR）心房細動（A-Fib）及び右脚ブロック（RBBB）であった。投与 4 日目に経胸壁心エコーを実施した結果，駆出率 45%–50%で軽度の左室収縮機能低下が認められた。内視鏡下で左上肢尺側皮静脈の移動術を完了した。投与 7 日目にカテーテル（Perma Cath）を留置し，正しく留置されているか確認した。左腕の動静

脈瘻の超音波画像により，動脈性静脈グラフトの開存性が確認され，高度な限局性狭窄の徴候はなく，問題となる限局性仮性動脈瘤も認められなかった。投与 11 日目に胸部 X 線検査を実施したところ，うっ血性心不全を示す心拡大及び中心静脈のうっ血及び少量の両側胸水が認められた。投与 12 日目の胸部 X 線所見の変化はなく，投与 17 日目の再検査では活動性疾患は認められなかった。関連する臨床検査値を以下に示す。

被験者は，治療継続のため別の施設に転院した。血液透析を開始する被験者は退院し，本事象は投与 18 日目に消失したと判断された。その他の処置として，ジルチアゼム，アミオダロン，フロセミド，ワルファリン及びメトロニダゾールを投与した。本事象によるアダリムマブ / プラセボの投与一時中断はなかった。

水分過負荷は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連なし」と判断し，基礎疾患の腎機能不全による可能性が高いと報告した。

また，水分過負荷は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，基礎疾患の腎機能不全による可能性が高いと報告した。

Laboratory Results

Treatment Day	Creatinine, Enzymatic Reference range: (0.51 – 0.95 mg/dL) *(0.6 – 1.3 mg/dL)	Urea, BUN Reference range: (9.0 – 24.0 mg/dL)	Sodium Reference range: (134.0 – 146.0 mmol/L)	Potassium Reference range: (3.6 – 5.2 mmol/L)
Treatment Day –22	2.92	119.0	141.0	3.8
Treatment Day –05	3.36	146.0	140.0	3.4
Treatment Day 1	3.24	138.0	142.0	3.8
Treatment Day 15	*3.6	Not Provided	Not Provided	Not Provided
Treatment Day 18	*2.3	Not Provided	Not Provided	Not Provided
Treatment Day 28	2.06	22.0	139.0	3.4

Treatment Day	Calcium Reference range: (8.4 – 10.2 mg/dL)	Phosphate Reference range: (2.4 – 4.9 mg/dL)	Uric Acid Reference range: (2.2 – 6.4 mg/dL)	Alkaline Phosphatase Reference range: (40.0 – 135.0 U/L)
Treatment Day –22	8.7	6.0	10.2	98.0
Treatment Day –05	8.5	6.4	11.6	128.0
Treatment Day 1	8.5	6.3	11.5	228.0
Treatment Day 28	8.8	2.0	4.1	153.0

Treatment Day	Hematocrit Reference range: (35.0% – 47.0%)	Hemoglobin Reference range: (11.5 – 15.5 g/dL)	WBC Reference range: ($3.5 – 11.1 \times 10^9$/L)	HCG, Quantitative Reference range: (≤ 15.90 mIU/mL)
Treatment Day –22	32.8	10.8	11.8	37.7
Treatment Day –05	32.1	10.3	7.62	39.8
Treatment Day 1	38.8	12.2	9.2	48.0
Treatment Day 23	*Not Provided	*11.2	*8.23	Not Provided
Treatment Day 28	33.6	10.9	13.37	Not Provided

* Hospital Laboratory Value.
Laboratory Samples for Treatment Day 1 were received frozen.
Subject was re-screened after gynecological clearance due to HCG Quantitative level.

事象 2 の臨床経過：

投与 37 日目（投与終了後 3 日目）に慢性腎不全が認められた（転帰：死亡）。被験者は自宅で痙攣発作を起こし，救急車の到着前に死亡した。死亡診断書によると，主たる死因は末期腎疾患であり，副次的な死因として高血圧が報告されている。

慢性腎不全は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「関連なし」と判断し，腎疾患の既往が原因である可能性が高いと報告した。

また，慢性腎不全は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断し，腎疾患の既往が原因である可能性が高いと報告した。

Subject 1203308 (43520)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
PNEUMONIA	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
43520	1203308	ADALIMUMAB	42	MALE	BLACK

Medical / Surgical History *	Onset Date
SURGERY: UMBILICAL HERNIA REPAIR	20[redacted]
OTHER: HILAR ADENPOATHY	[redacted]20[redacted]
HYPERTENSION	[redacted]20[redacted]
OBESITY	[redacted]20[redacted]
EYE DISEASE/DISORDER: VITRECTOMY LEFT EYE FOR HEMORRHAGE	[redacted]20[redacted]
DIVERTICULITIS	20[redacted]
OTHER: SARCOID CUTANEOUS SKIN LESIONS	20[redacted]
SURGERY: RUPTURED BOWEL REPAIR	20[redacted]
OTHER: SLEEP APNEA	[redacted]20[redacted]
CONGESTIVE HEART FAILURE: CLASS 1	[redacted]20[redacted]
HYPERLIPIDEMIA: HYPERCHOLESTEROL AND LIPIDS	[redacted]20[redacted]
OTHER: INTERMITTANT ELEVATED GLUCOSE	20[redacted]
EYE DISEASE/DISORDER: ACUTE ANGLE CLOSURE GLAUCOMA	[redacted]20[redacted]
EYE DISEASE/DISORDER: YAG LASER PERIPHERAL IRIDECTOMY RIGHT EYE	[redacted]20[redacted]

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
PANUVEITIS - SARCOID	[redacted]20[redacted]	147.4	BOTH EYES

Tobacco Use*	Alcohol Use
EX-USER OF CIGARETTES (6 YEARS, .5 PACKS/DAY)	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 554	554
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 7	7
PREDNISONE	60 MG	ORAL		[redacted]20 / 8	[redacted]20 / 14	7
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 36	[redacted]20 / 42	7
PREDNISONE	15 MG	ORAL		[redacted]20 / 43	[redacted]20 / 49	7
PREDNISONE	12.5 MG	ORAL		[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL		[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL		[redacted]20 / 64	[redacted]20 / 70	7
PREDNISONE	5 MG	ORAL		[redacted]20 / 71	[redacted]20 / 77	7
PREDNISONE	4 MG	ORAL		[redacted]20 / 78	[redacted]20 / 83	6
PREDNISONE	3 MG	ORAL		[redacted]20 / 85	[redacted]20 / 91	7
PREDNISONE	2 MG	ORAL		[redacted]20 / 92	[redacted]20 / 98	7
PREDNISONE	1 MG	ORAL		[redacted]20 / 99	[redacted]20 / 105	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISOLONE	UVEITIS	1 DROP $	OTHER: EVERY HOUR	Y: 20[redacted]	-257
TRIAMCINOLONE	UVEITIS	40 MG $	OTHER: X1	Y: 20[redacted]	-288
PREDNISONE	UVEITIS	100 MG $	QD	Y: 20[redacted]	Y: 20[redacted]
TRIAMCINOLONE	UVEITIS	40 MG $	OTHER: X1	Y: 20[redacted]	-288
METHOTREXATE	UVEITIS	30 MG $	OTHER: WEEKLY	Y: 20[redacted]	-296
CARVEDILOL	MILD CONGESTIVE HEART FAILURE	50MG	BID	Y: 20[redacted]	ONGOING
FUROSEMIDE	HYPERTENSION	20MG	QD	Y: 20[redacted]	ONGOING
LISINOPRIL	HYPERTENSION	20MG	QD	Y: 20[redacted]	ONGOING
SIMVASTATIN	HYPERCHOLESTEROL	40MG	QD	Y: 20[redacted]	ONGOING
ACETYLSALICYLIC ACID	HEALTH MAINTANENCE	325MG	QD	-256	ONGOING
PREDNISONE	UVEITIS	15MG	QD	-69	-1
AZATHIOPRINE	UVEITIS	150MG	QD	-66	ONGOING
TACROLIMUS	SARCOID SKIN LESION	1CM	PRN	58	536
DICLOFENAC	SPRAINED ACHILLES TENDON	1INCH	PRN	65	110

Event #1: Serious Adverse Event*	
Event Description	PNEUMONIA
Preferred term	PNEUMONIA
AE Onset Date / Rx Day	[redacted]20[redacted] / 115
Age at AE Onset	43
AE Stopped Rx Day	121
Duration of AE	7 DAYS
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	POSSIBLY RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	POSSIBLY RELATED
Other Cause of Event	UPPER RESPIRATORY INFECTION SECONDARY TO IMMUNOSUPPRESSION
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，サルコイドーシスによる両眼性の汎ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 42 歳黒人男性であり，重篤な有害事象として肺炎が認められた。関連する病歴は，軽度のうっ血性心不全，肺門リンパ節腫脹，高血圧，肥満，睡眠時無呼吸であり，元喫煙者（6 年間，0.5 箱/日）であった。

事象 1 の臨床経過：

43 歳時（投与 115 日目）に，咳嗽，胸部うっ血，鼻漏，喘鳴及び息切れを訴え救急科を受診後，入院した。入院時の胸部 X 線検査で軽度の肺炎が認められたが，投与 119 日目の喀痰培養は陰性であった。処置として，モキシフロキサシン及び Mucinex DM を投与した。本事象により，投与 106 日目からアダリムマブ / プラセボの投与を一時中断し，投与 134 日目に投与を再開した。投与再開後，本事象の再発はなかった。被験者は投与 121 日目に退院し，本事象は消失したと判断された。

肺炎は，治験責任医師によりアダリムマブ / プラセボとの因果関係「多分関連あり」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「多分関連あり」と判断し，長期にわたる免疫抑制も一因となった可能性があると報告した。

また，肺炎は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「関連なし」と判断した。

Subject 1210202 (39605)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
LUPUS-LIKE SYNDROME	X	X		

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
39605	1210202	ADALIMUMAB	56	FEMALE	WHITE

Medical / Surgical History *	Onset Date
SURGERY: REPAIR OF BLADDER PROLAPSE	20
EYE DISEASE/DISORDER: RIGHT EYE PAPILLOMA	20
OTHER: GASTRIC DISCOMFORT DUE TO INTOLERANCE TO IMURAN	20
DIABETES MELLITUS: DIABETES MELLITUS TYPE II	20
HYPERLIPIDEMIA: DYSLIPIDEMIA	20
OTHER: FACIAL ACNE	20
OTHER: SEBORRHEIC KERATOSIS LOCATED IN FACE AND UPPER BACK	20
OTHER: TENDINITIS LEFT ARM	20

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
POSTERIOR - BIRDSHOT CHOROIDOPATHY	20	46.1	BOTH EYES

Tobacco Use*	Alcohol Use
NEVER USED	DRINKER LIGHT

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	20 / 1	20 / 94	94
PREDNISONE	52.5 MG	ORAL		20 / 1	20 / 1	1
PREDNISONE	60 MG	ORAL		20 / 2	20 / 9	8
PREDNISONE	25 MG	ORAL		20 / 10	20 / 27	18
PREDNISONE	20 MG	ORAL		20 / 28	20 / 42	15
PREDNISONE	15 MG	ORAL		20 / 43	20 / 49	7

PREDNISONE	12.5 MG	ORAL	[redacted]20 / 50	[redacted]20 / 56	7
PREDNISONE	10 MG	ORAL	[redacted]20 / 57	[redacted]20 / 63	7
PREDNISONE	7.5 MG	ORAL	[redacted]20 / 64	[redacted]20 / 70	7
PREDNISONE	5 MG	ORAL	[redacted]20 / 71	[redacted]20 / 77	7
PREDNISONE	4 MG	ORAL	[redacted]20 / 78	[redacted]20 / 84	7
PREDNISONE	3 MG	ORAL	[redacted]20 / 85	[redacted]20 / 91	7
PREDNISONE	2 MG	ORAL	[redacted]20 / 92	[redacted]20 / 98	7
PREDNISONE	1 MG	ORAL	[redacted]20 / 99	[redacted]20 / 104	6

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
KETOROLAC	UVEITIS	4 GTT QD $	PRN	Y: 20[redacted]	-33
AZATHIOPRINE	UVEITIS	125 MG QD $	QD	Y: 20[redacted]	Y: 20[redacted]
MYCOPHENOLIC ACID	UVEITIS	2 GM QD $	BID	Y: 20[redacted]	Y: 20[redacted]
ACETYLSALICYLIC ACID	PROPHYLAXIS CARDIOVASCULAR EVENTS	80MG	QD	Y: 20[redacted]	ONGOING
RAMIPRIL	PROPHYLAXIS CARDIOVASCULAR EVENTS	2.5MG	QD	Y: 20[redacted]	ONGOING
ROSUVASTATIN	DYSLIPIDEMIA	20MG	QD	Y: 20[redacted]	ONGOING
OMEPRAZOLE	PROPHYLAXIS GASTRIC UPSET	20MG	QD	Y: 20[redacted]	108
PREDNISONE	UVEITIS	20 MG $	QD	Y: 20[redacted]	Y: 20[redacted]
CICLOSPORIN	UVEITIS	100 MG $	BID	Y: 20[redacted]	-47
PREDNISONE	UVEITIS	20 MG QD $	QD	Y: 20[redacted]	Y: 20[redacted]
TRIAMCINOLONE	UVEITIS	40 MG POSTERIOR SUBTENON INJ $	OTHER: ACCORDING TO TREATING OPHTHALMOLOGIST'S DECISION	Y: 20[redacted]	Y: 20[redacted]
METFORMIN	DIABETES TYPEII	250MG	BID	Y: 20[redacted]	11
MYCOPHENOLIC ACID	UVEITIS	2 GRAMS PER DAY $	BID	-221	-47
ISONIAZID	PROPHYLAXIS TB	300MG	QD	-5	104
METFORMIN	HYPERGLYCEMIA	500MG	BID	11	109

GLIBENCLAMIDE	HYPERGLYCEMIA	10MG	QD	11	27
GLIBENCLAMIDE	DMII	7.5MG	QD	28	43
PYRIDOXINE	PROPHYLAXIS OF SECONDARY EFFECTS OF ISONIAZID	300MG	QD	29	104
CENTRUM	VITAMIN SUPPLEMENTS	1TABLET	QD	29	ONGOING
BACTRIM	URINARY TRACT INFECTION	1TABLET	BID	32	42
GLIBENCLAMIDE	DMII	5MG	QD	44	109
HYDROCORTISONE	ANTI-NFLAMMATORY AND TO FOR PROTECTION OF BODY AGAINST STRESS	100MG	OTHER: CONTINUOUS X 24 HOURS	104	105
SODIUM CHLORIDE	FOR REHYDRATION	150CC	OTHER: CONTINOUS	104	105
PIP/TAZO	ANTIBIOTICS IN AN IMMUNOSUPPRESSED STATE	3GM	OTHER: Q 6 HOURS	104	109
NAPROXEN	ABDOMINAL PAIN	500MG	PRN	104	122

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug*

Event Description	DRUG-INDUCED ACUTE LUPUS ERYTHEMATOSUS
Preferred term	LUPUS-LIKE SYNDROME
AE Onset Date / Rx Day	[redacted]20[redacted] / 104 (10 DAYS AFTER LAST TREATMENT)
Age at AE Onset	56
AE Stopped Rx Day	120 (26 DAYS AFTER LAST TREATMENT)
Duration of AE	17 DAYS
Severity	SEVERE
Relation to Adalimumab or Placebo by Investigator	PROBABLY RELATED
Relation to Prednisone by Investigator	PROBABLY NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY RELATED
Other Cause of Event	UNKNOWN
Discontinued Adalimumab or Placebo Due to the Event	YES
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，散弾状脈絡膜症を主体とする両眼性の後部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 56 歳白人女性であり，重篤な有害事象としてループス様症候群が認められた。関連する病歴は，膀胱脱修復，イムラン不耐容による胃部不快感，2 型糖尿病，右眼の乳頭腫，顔面ざ瘡，上背部及び顔面の脂漏性角化症，並びに左腕の腱炎であった。

事象 1 の臨床経過：

56 歳時（投与 104 日目［投与終了後 10 日目］）にループス様症候群が認められ，集中治療室（ICU）に入院した。主訴は，悪心，腹痛及び末梢性浮腫であった。投与 105 日目に上腹部の超音波検査を実施したところ，内部均一の肝腫大，胆嚢壁肥厚及び中等度の腹水が認められた。胆嚢壁肥厚は，肝炎等でみられるような胆嚢周囲炎の徴候であると考えられる。心エコーの結果，各領域に欠損は認められず，左室駆出率は 70%，心嚢液貯留は 13 mm で，タンポナーデの徴候はなく，疣腫はなく，問題となる弁膜症も認められなかった。投与 108 日目の血管造影 CT 検査では，肺塞栓症，両側胸水は認められず，心嚢液貯留は 8 mm で，腹水は認められなかった。抗核抗体（ANA）検査陽性であり，抗ヒストン抗体は 24.0（基準範囲：15.0 U/mL 未満）であった。過去に抗核抗体検査を受けたことはなかった。その他の関連する臨床検査値（投与 105 日目）から，血小板数減少，白血球数増加，AST 上昇及び ALT 上昇が確認された（下表参照）。処置として，プレドニゾン，ヒドロコルチゾン，ピペラシリン・タゾバクタム（pip / tazo），ナプロキセン，生理食塩水及び pantoprazole を投与した。本事象により，アダリムマブ / プラセボの投与を中止した（最終投与日：投与 94 日目）。被験者は投与 109 日目に退院した。本事象は，投与 120 日目（投与終了後 26 日目）に消失したと判断された。

ループス様症候群は，治験責任医師及び治験依頼者により，アダリムマブ / プラセボとの因果関係「関連あり」と判断された。

また，ループス様症候群は，治験責任医師によりプレドニゾンとの因果関係「多分関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「多分関連なし」と判断し，その理由として，20[redacted]年[redacted]月[redacted]日から 20[redacted]年[redacted]月[redacted]日までプレドニゾンを漸減し，休薬したたことを挙げた。本事象発現時には，プレドニゾン 1.0 mg を投与中であった。

Laboratory Results

Treatment Day	Platelets Reference range: ($140.0 - 400.0 \times 10^9$/L)	Neutrophils ABS Reference range: ($1.8 - 7.5 \times 10^9$/L)	Monocytes ABS Reference range: ($0.05 - 1.3 \times 10^9$/L)	White Blood Cells Reference range: ($4.5 - 11.0 \times 10^9$/L)
Treatment Day 1	230.0 (150 – 400)	8.65 (1.8 – 7.0)	0.26 (0 – 0.8)	9.83 (3.5 – 11.1)
Treatment Day 104	36.0	7.56	2.15	15.2
Treatment Day 105	60.0	8.04	1.85	12.5
Treatment Day 106	105.0	9.38	Not Provided	14.4
Treatment Day 109	227.0	6.8	Not Provided	12.8

Treatment Day	Eosinophils ABS Reference range: (0.05 – 0.43)	AST Reference range: (14.0 – 36.0 U/L)	ALT Reference range: (9.0 – 52.0 U/L)	C-Reactive Protein Reference range: (0 – 5.0 mg/L)
Treatment Day 1	0.02 (0 – 0.5)	22.0 (0 – 37)	30.0 (0 – 47)	N/A
Treatment Day 104	3.12	91.0	21.0	Not Provided
Treatment Day 105	0.53	76.0	71.0	Not Provided
Treatment Day 106	Not Provided	55.0	69.0	Not Provided
Treatment Day 108	Not Provided	Not Provided	Not Provided	21.3
Treatment Day 109	0.46	Not Provided	Not Provided	8.1

Subject 1300107 (39600)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
UPPER RESPIRATORY TRACT INFECTION	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
39600	1300107	ADALIMUMAB	30	MALE	WHITE

Medical / Surgical History *	Onset Date
SURGERY: METAL PLATE IN LEFT ARM AFTER BROKEN ARM	20
OTHER: INTERMITTENT HEADACHE	20
OTHER: BEHCETS DISEASE	20
EYE DISEASE/DISORDER: INCREASED IOP	20
HYPERTENSION	20
OTHER: DEPRESSIVE MOOD	20
OTHER: FOLLICULITIS	20

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
POSTERIOR - BEHCET'S	20	7.1	BOTH EYES

Tobacco Use*	Alcohol Use
USER OF CIGARETTES (13 YEARS, .5 PACKS/DAY)	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	20 / 1	20 / 274	274
CORTICOSTEROID	4 DROPS/DAY	TOPICAL		20 / 1	20 / 15	15
CORTICOSTEROID	2 DROPS/DAY	TOPICAL		20 / 16	20 / 22	7
CORTICOSTEROID	1 DROPS/DAY	TOPICAL		20 / 23	20 / 29	7
PREDNISONE	60 MG	ORAL		20 / 1	20 / 15	15
PREDNISONE	50 MG	ORAL		20 / 16	20 / 21	6
PREDNISONE	40 MG	ORAL		20	20	7

PREDNISONE	30 MG	ORAL	/ 22 20 / 29	/ 28 20 / 35	7
PREDNISONE	20 MG	ORAL	20 / 36	20 / 43	8
PREDNISONE	15 MG	ORAL	20 / 44	20 / 50	7
PREDNISONE	12.5 MG	ORAL	20 / 51	20 / 57	7
PREDNISONE	10 MG	ORAL	20 / 58	20 / 64	7
PREDNISONE	7.5 MG	ORAL	20 / 65	20 / 70	6
PREDNISONE	5 MG	ORAL	20 / 71	20 / 77	7
PREDNISONE	2.5 MG	ORAL	20 / 78	20 / 84	7

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
PREDNISOLONE	UVEITIS	100 MG $	QD	-242	-15
PREDNISOLONE	UVEITIS	1DROP	QID	-211	-1
PREDNISOLONE	UVEITIS	1 DROP $	OTHER: 10-12 TIMES PER DAY	-211	-15
BACTRIM	INFECTION PROPHYLAXIS	800MG	OTHER: THREE TIMES PER WEEK	-211	84
CALCIUM	PROPHYLACTIC BONE THINNING WITH PREDNISOLONE	600MG	OTHER: FOUR TIMES PER WEEK	-211	84
ERGOCALCIFEROL	PROPHYLACTIC BONE THINNING	1000IU	QD	-211	84
OMEPRAZOLE	GASTRO INTESTINAL PROPHYLAXIS	20MG	BID	-211	84
METHYLPREDNISOLONE	UVEITIS	500 MG $	QD	-201	-198
AZATHIOPRINE	UVEITIS	75 MG $	QD	-180	-155
TRIAMCINOLONE	UVEITIS	40 MG $	OTHER: ONCE DOSE IN EACH EYE	-166	-152
CICLOSPORIN	UVEITIS	100MG	BID	-155	84
PERINDOPRIL	PROPHYLACTIC HYPERTENSION	2.5MG	QD	-121	-1

COMBIGAN	INCREASED INTRAOCULAR PRESSURE	1DROP	BID	-113	84
PREDNISOLONE	UVEITIS	15MG	QD	-14	1
PNEUMOCOCCAL VACCINE	VACCINATION	0.5ML	OTHER: ONCE	27	27
CICLOSPORIN	UVEITIS	100MG	BID	113	ONGOING

Event #1: Serious Adverse Event*

Event Description	UPPER RESPIRATORY TRACT INFECTION
Preferred term	UPPER RESPIRATORY TRACT INFECTION
AE Onset Date / Rx Day	[redacted]20[redacted] / 286 (12 DAYS AFTER LAST TREATMENT)
Age at AE Onset	31
AE Stopped Rx Day	289 (15 DAYS AFTER LAST TREATMENT)
Duration of AE	4 DAYS
Severity	MODERATE
Relation to Adalimumab or Placebo by Investigator	PROBABLY RELATED
Relation to Prednisone by Investigator	NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	POSSIBLY RELATED
Other Cause of Event	
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，ベーチェット病による両眼性の後部ぶどう膜炎（発症：20[redacted] 年 [redacted]月 [redacted] 日）を有する 30 歳白人男性であり，重篤な有害事象としてウイルス性上気道感染が認められた。関連する病歴はベーチェット病であり，現喫煙者（13 年間，0.5 箱/日）であった。

事象 1 の臨床経過：

31 歳時（投与 286 日目）に，39.1°C の発熱を訴え入院した。血液培養は陰性であった。処置として，ドキシサイクリン及びベンジルペニシリンを投与した。被験者は退院し，本事象は投与 289 日目（投与終了後 15 日目）に消失したと判断された。本事象により，アダリムマブ / プラセボの投与を中止した（最終投与日：投与 274 日目）。追加情報は得られていない。

ウイルス性上気道感染は，治験責任医師によりアダリムマブ / プラセボとの因果関係「関連あり」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「多分関連あり」と判断し，基礎疾患のベーチェット病又はプレドニゾンも一因となった可能性があると報告した。

また，ウイルス性上気道感染は，治験責任医師によりプレドニゾンとの因果関係「関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「多分関連あり」と判断し，基礎疾患のベーチェット病又はアダリムマブも一因となった可能性があると報告した。

Subject 1400703 (52321)

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study	Death	Event of Interest
CALCULUS URETERIC	X			

Investigator	Subject	Treatment Group	Age at Study Start	Sex	Race
52321	1400703	ADALIMUMAB	65	FEMALE	ASIAN

Medical / Surgical History *	Onset Date
SURGERY: ACUTE APPENDISITIS	19[redacted]
OTHER: HYSTEROMYOMA	19[redacted]
SURGERY: HYSTEROMYOMECTOMY	19[redacted]
OTHER: MIGRAINE	20[redacted]
HYPERTENSION	[redacted]20[redacted]
GASTROESOPHAGEAL REFLUX DISEASE	20[redacted]
HYPERLIPIDEMIA	[redacted]20
PEPTIC ULCER DISEASE	[redacted]20
OTHER: SARCOIDOSIS SYSTEMIC	[redacted]20
SURGERY: SARCOIDOSIS	[redacted]20
SURGERY: SEGMENTAL EXCISION OF LUNG (LEFT)DUE TO SARCOIDOSIS	[redacted]20
EYE DISEASE/DISORDER: CATARACT OD	[redacted]20
EYE DISEASE/DISORDER: CATARACT OS	[redacted]20
OTHER: COMMON COLD	[redacted]20

Uveitis Disease History

Type / Diagnosis of Uveitis	Diagnosis Date	Duration [Months]	Location
POSTERIOR - SARCOID	[redacted]20[redacted]	16.6	BOTH EYES

Tobacco Use*	Alcohol Use
NEVER USED	NON-DRINKER

Study Drug (Blinded Adalimumab or Placebo and Prednisone Burst and Taper) and Initial Topical Corticosteroid Taper

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ADALIMUMAB	(1)	SC	EOW	[redacted]20 / 1	[redacted]20 / 35	35
CORTICOSTEROID	2 DROPS/DAY	TOPICAL		[redacted]20 / 1	[redacted]20 / 7	7
CORTICOSTEROID	1 DROPS/DAY	TOPICAL		[redacted]20 / 8	[redacted]20 / 14	7
PREDNISONE	60 MG	ORAL		[redacted]20 / 1	[redacted]20 / 14	14
PREDNISONE	50 MG	ORAL		[redacted]20 / 15	[redacted]20 / 21	7
PREDNISONE	40 MG	ORAL		[redacted]20 / 22	[redacted]20 / 28	7
PREDNISONE	30 MG	ORAL		[redacted]20 / 29	[redacted]20 / 35	7
PREDNISONE	20 MG	ORAL		[redacted]20 / 36	[redacted]20 / 41	6

Prior Medication and Concomitant Medication until Onset of the Narrative Adverse Event

Medication Name (WHO Drug)	Indication	Dose/Units	Frequency	Start RX Day or Year	Stop RX Day
HYZAAR	HYPERETENSION	1TAB	QD	Y: 20[redacted]	ONGOING
EZETIMIBE	HYPERLIPIDEMIA	10MG	QD	Y: 20[redacted]	ONGOING
BETAMETHASONE	UVEITIS	3 DROP $	TID	Y: 20[redacted]	Y: 20[redacted]
BETAMETHASONE	UVEITIS	3 DROP $	TID	Y: 20[redacted]	Y: 20[redacted]
TRAVOPROST	UVEITIS	1DROP	QD	Y: 20[redacted]	ONGOING
TRAVOPROST	UVEITIS	1DROP	QD	Y: 20[redacted]	ONGOING
BETAMETHASONE	UVEITIS	2DROP	BID	Y: 20[redacted]	-1
BETAMETHASONE	UVEITIS	2DROP	BID	Y: 20[redacted]	-1
PREDNISOLONE	UVEITIS	20MG $	BID	Y: 20[redacted]	Y: 20[redacted]
LOSARTAN	HYPERTENSION	50MG	QD	Y: 20[redacted]	ONGOING
RABEPRAZOLE	PREVENTION OF GASTRITIS	20MG	QD	Y: 20[redacted]	ONGOING
MOSAPRIDE	PREVENTION OF GASTRITIS	5MG	TID	-345	ONGOING
PREDNISOLONE	UVEITIS	10MG $	QD	-246	-218
FAMOTIDINE	PREVENTION OF GASTRITIS	20MG	BID	-78	-23
PREDNISOLONE	UVEITIS	10MG	QD	-77	-23
ALENDRONIC ACID	PREVENTION OF OSTEOPOROSIS	35MG	OTHER: WEEKLY	-77	ONGOING
LOXOPROFEN	MIGRAINE	120MG	QD	-70	-43
REBAMIPIDE	PREVENTION OF	100MG	BID	-70	-43

	GASTRITIS				
BENIDIPINE	HYPERTENSION	4MG	QD	-69	ONGOING
MARZULENE S	GASTROESOPHAGEAL REFLUS DISEASE	0.5G	QD	-42	ONGOING
PA	COMMON COLD	1G	TID	-30	-24
PREDNISOLONE	UVEITIS	10MG	QD	-22	-1
RILMAZAFONE	INSOMNIA	1MG	PRN	3	27
CEFDITOREN	RIGHT URETERAL STONE	100MG	TID	35	44
CLOSTRIDIUM BUTYRICUM	ENTERITIS	1TAB	TID	35	44

Event #1: Serious Adverse Event*

Event Description	RIGHT URETERAL STONE
Preferred term	CALCULUS URETERIC
AE Onset Date / Rx Day	[redacted]20[redacted] / 35
Age at AE Onset	65
AE Stopped Rx Day	48 (ONGOING)
Duration of AE	ONGOING
Severity	MODERATE
Relation to Adalimumab or Placebo by Investigator	PROBABLY NOT RELATED
Relation to Prednisone by Investigator	PROBABLY NOT RELATED
Relation to Adalimumab or Placebo by AbbVie	PROBABLY NOT RELATED
Other Cause of Event	LACK OF PROPER HYDRATION
Discontinued Adalimumab or Placebo Due to the Event	
Discontinued Prednisone Due to the Event	
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

* Information presented verbatim as provided by the investigator.
$ Prior drugs from Uveitis medication history reporting the highest dose during the course.
(1) 80 MG at week 0, 40 MG at week 1, 40 MG EOW from week 3 onwards.

本症例は，サルコイドーシスによる両眼性の後部ぶどう膜炎（発症：20[redacted]年[redacted]月[redacted]日）を有する 65 歳アジア人女性であり，重篤な有害事象として右尿管結石が認められた。関連する病歴は全身性サルコイドーシスであった。

事象 1 の臨床経過：

65 歳時（投与 35 日目）に，尿管結石が認められた。悪心，腰痛，腹痛の症状があり，体温 36.8℃，血圧 130/96 mmHg で，投与 36 日目に入院した。入院時に実施した腎臓の CT 検査で，右尿管に結石が確認された。尿培養の結果，コリネバクテリウム属が検出された。血液培養は陰性であった。また，非重篤な有害事象として小腸炎を併発した。尿管結石に対する処置として，ソルデム 3A 及びセフジトレンを投与した。症状が改善したため，投与 39 日目に退院した。尿管結石は，投与 48 日目の時点で継続中と判断された。アダリムマブ / プラセボの投与は本事象の発現日以前に治療不成功により中止された。

尿管結石は，治験責任医師によりアダリムマブ / プラセボとの因果関係「多分関連なし」と判断された。治験依頼者では，アダリムマブ / プラセボとの因果関係「多分関連なし」と判断し，その理由として，腎結石は脱水から生じた可能性があると報告した。

また，尿管結石は，治験責任医師によりプレドニゾンとの因果関係「多分関連なし」と判断された。治験依頼者では，プレドニゾンとの因果関係「多分関連なし」と判断し，その理由として，腎結石は脱水から生じた可能性があると報告した。