TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	32	77.34	22.324	16.7	66.67	83.33	95.83	100.0			
	ADA	38	75.44	25.108	16.7	50.00	83.33	100.00	100.0			
	TOT	70	76.31	23.725	16.7	58.33	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	32	70.96	25.783	8.3	58.33	75.00	95.83	100.0			
	ADA	38	71.71	29.290	16.7	50.00	83.33	100.00	100.0			
	TOT	70	71.37	27.547	8.3	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	32	-6.38	13.175	-50.0	-12.50	0.00	0.00	8.3			
	ADA	38	-3.73	12.052	-33.3	-8.33	0.00	0.00	16.7			
	TOT	70	-4.94	12.556	-50.0	-8.33	0.00	0.00	16.7			
										2.65	(-3.37, 8.67)	0.383A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	32	87.11	21.647	25.0	75.00	100.00	100.00	100.0			
	ADA	38	88.16	19.484	25.0	75.00	100.00	100.00	100.0			
	TOT	70	87.68	20.356	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	32	80.08	28.726	12.5	75.00	93.75	100.00	100.0			
	ADA	38	83.72	22.770	12.5	75.00	100.00	100.00	100.0			
	TOT	70	82.05	25.536	12.5	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	32	-7.03	15.855	-62.5	-12.50	0.00	0.00	25.0			
	ADA	38	-4.44	11.340	-50.0	-12.50	0.00	0.00	12.5			
	TOT	70	-5.63	13.550	-62.5	-12.50	0.00	0.00	25.0			
										2.59	(-3.91, 9.10)	0.430A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	32	70.70	26.010	0.0	59.38	75.00	90.63	100.0			
	ADA	38	66.94	24.005	0.0	56.25	68.75	87.50	100.0			
	TOT	70	68.66	24.829	0.0	56.25	75.00	87.50	100.0			
FINAL/ET VALUE	PLO	32	66.60	30.971	0.0	53.13	75.00	93.75	100.0			
	ADA	38	66.78	27.382	0.0	56.25	75.00	87.50	100.0			
	TOT	70	66.70	28.862	0.0	56.25	75.00	93.75	100.0			
CHG FROM BEST*	PLO	32	-4.10	16.081	-56.3	-6.25	0.00	6.25	25.0			
	ADA	38	-0.16	20.212	-62.5	-6.25	0.00	12.50	43.8			
	TOT	70	-1.96	18.416	-62.5	-6.25	0.00	6.25	43.8			
										3.94	(-4.89, 12.77)	0.377A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	32	71.48	26.985	12.5	50.00	75.00	100.00	100.0			
	ADA	38	70.72	26.521	0.0	50.00	75.00	100.00	100.0			
	TOT	70	71.07	26.542	0.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	32	66.02	32.415	0.0	50.00	75.00	100.00	100.0			
	ADA	38	67.11	31.222	0.0	37.50	75.00	100.00	100.0			
	TOT	70	66.61	31.545	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	32	-5.47	16.170	-25.0	-18.75	0.00	0.00	50.0			
	ADA	38	-3.62	28.012	-87.5	-25.00	0.00	12.50	50.0			
	TOT	70	-4.46	23.219	-87.5	-25.00	0.00	0.00	50.0			
										1.85	(-9.34, 13.04)	0.742A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	32	83.33	27.353	0.0	79.17	100.00	100.00	100.0			
	ADA	38	83.77	25.183	0.0	75.00	100.00	100.00	100.0			
	TOT	70	83.57	26.005	0.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	32	77.73	31.602	0.0	70.83	91.67	100.00	100.0			
	ADA	38	79.61	29.996	0.0	58.33	100.00	100.00	100.0			
	TOT	70	78.75	30.529	0.0	66.67	100.00	100.00	100.0			
CHG FROM BEST*	PLO	32	-5.60	15.176	-66.7	-8.33	0.00	0.00	29.2			
	ADA	38	-4.17	18.149	-66.7	0.00	0.00	0.00	33.3			
	TOT	70	-4.82	16.752	-66.7	-8.33	0.00	0.00	33.3			
										1.43	(-6.64, 9.50)	0.724A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	27	69.91	32.323	0.0	50.00	83.33	91.67	100.0			
	ADA	37	65.65	32.741	0.0	41.67	75.00	91.67	100.0			
	TOT	64	67.45	32.376	0.0	45.83	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	27	60.19	32.876	0.0	33.33	66.67	83.33	100.0			
	ADA	37	60.81	35.293	0.0	33.33	75.00	91.67	100.0			
	TOT	64	60.55	34.029	0.0	33.33	70.83	87.50	100.0			
CHG FROM BEST*	PLO	27	-9.72	16.707	-58.3	-16.67	-8.33	0.00	16.7			
	ADA	37	-4.84	18.096	-50.0	-8.33	0.00	0.00	50.0			
	TOT	64	-6.90	17.556	-58.3	-14.58	0.00	0.00	50.0			
										4.88	(-3.99, 13.75)	0.276A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	32	95.31	11.773	50.0	100.00	100.00	100.00	100.0			
	ADA	38	91.45	15.679	25.0	75.00	100.00	100.00	100.0			
	TOT	70	93.21	14.066	25.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	32	94.53	12.271	50.0	100.00	100.00	100.00	100.0			
	ADA	38	85.53	20.658	25.0	75.00	100.00	100.00	100.0			
	TOT	70	89.64	17.802	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	32	-0.78	10.009	-25.0	0.00	0.00	0.00	25.0			
	ADA	38	-5.92	18.775	-75.0	-25.00	0.00	0.00	25.0			
	TOT	70	-3.57	15.514	-75.0	0.00	0.00	0.00	25.0			
										-5.14	(-12.52, 2.24)	0.169A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	32	79.69	23.277	25.0	75.00	75.00	100.00	100.0			
	ADA	38	77.63	26.502	25.0	50.00	87.50	100.00	100.0			
	TOT	70	78.57	24.922	25.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	32	74.22	27.301	25.0	50.00	75.00	100.00	100.0			
	ADA	38	75.00	29.062	25.0	50.00	75.00	100.00	100.0			
	TOT	70	74.64	28.070	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	32	-5.47	18.767	-75.0	0.00	0.00	0.00	50.0			
	ADA	38	-2.63	15.145	-50.0	0.00	0.00	0.00	25.0			
	TOT	70	-3.93	16.830	-75.0	0.00	0.00	0.00	50.0			
										2.84	(-5.25, 10.92)	0.486A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	32	77.55	19.244	25.7	70.05	83.16	93.91	98.7			
	ADA	38	75.16	19.841	14.7	61.70	81.74	90.04	99.4			
	TOT	70	76.25	19.466	14.7	62.77	82.56	91.36	99.4			
FINAL/ET VALUE	PLO	32	72.44	22.627	21.1	63.73	76.25	91.14	100.0			
	ADA	38	73.54	22.791	18.5	61.46	79.38	93.07	99.4			
	TOT	70	73.04	22.558	18.5	63.41	77.01	93.07	100.0			
CHG FROM BEST*	PLO	32	-5.11	10.911	-44.4	-9.26	-4.31	0.28	11.7			
	ADA	38	-1.62	12.867	-39.0	-4.85	0.09	4.17	25.8			
	TOT	70	-3.22	12.055	-44.4	-8.64	-0.85	3.52	25.8			
										3.48	(-2.27, 9.24)	0.231A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
GENERAL HEALTH									
BEST VALUE*	PLO	18	54.17	21.437	25.0	50.00	50.00	75.00	100.0
	ADA	19	57.89	18.732	25.0	50.00	50.00	75.00	100.0
	TOT	37	56.08	19.900	25.0	50.00	50.00	75.00	100.0
FINAL/ET VALUE	PLO	18	44.44	26.507	0.0	25.00	50.00	50.00	100.0
	ADA	19	48.68	22.782	0.0	25.00	50.00	50.00	100.0
	TOT	37	46.62	24.411	0.0	25.00	50.00	50.00	100.0
CHG FROM BEST*	PLO	18	-9.72	12.541	-25.0	-25.00	0.00	0.00	0.0
	ADA	19	-9.21	14.932	-25.0	-25.00	0.00	0.00	25.0
	TOT	37	-9.46	13.631	-25.0	-25.00	0.00	0.00	25.0

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
GENERAL VISION									
BEST VALUE*	PLO	18	66.67	15.339	40.0	60.00	60.00	80.00	100.0
	ADA	19	64.74	16.455	40.0	60.00	60.00	80.00	100.0
	TOT	37	65.68	15.730	40.0	60.00	60.00	80.00	100.0
FINAL/ET VALUE	PLO	18	57.78	19.268	20.0	40.00	60.00	60.00	100.0
	ADA	19	61.05	20.520	20.0	60.00	60.00	80.00	100.0
	TOT	37	59.46	19.713	20.0	40.00	60.00	80.00	100.0
CHG FROM BEST*	PLO	18	-8.89	14.096	-40.0	-20.00	0.00	0.00	0.0
	ADA	19	-3.68	13.000	-40.0	0.00	0.00	0.00	20.0
	TOT	37	-6.22	13.612	-40.0	-20.00	0.00	0.00	20.0

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Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
OCULAR PAIN									
BEST VALUE*	PLO	18	86.81	13.875	50.0	75.00	87.50	100.00	100.0
	ADA	19	83.55	16.694	50.0	62.50	87.50	100.00	100.0
	TOT	37	85.14	15.263	50.0	75.00	87.50	100.00	100.0
FINAL/ET VALUE	PLO	18	83.33	19.648	25.0	75.00	87.50	100.00	100.0
	ADA	19	78.29	20.345	50.0	62.50	75.00	100.00	100.0
	TOT	37	80.74	19.894	25.0	62.50	87.50	100.00	100.0
CHG FROM BEST*	PLO	18	-3.47	16.497	-50.0	-12.50	0.00	12.50	12.5
	ADA	19	-5.26	18.312	-37.5	-25.00	0.00	0.00	25.0
	TOT	37	-4.39	17.234	-50.0	-12.50	0.00	0.00	25.0

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Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
NEAR VISION									
BEST VALUE*	PLO	18	71.76	21.225	25.0	58.33	70.83	83.33	100.0
	ADA	19	62.94	22.944	29.2	41.67	66.67	75.00	100.0
	TOT	37	67.23	22.269	25.0	50.00	66.67	83.33	100.0
FINAL/ET VALUE	PLO	18	60.19	30.459	8.3	33.33	66.67	83.33	100.0
	ADA	19	63.16	23.127	33.3	41.67	58.33	83.33	100.0
	TOT	37	61.71	26.604	8.3	41.67	66.67	83.33	100.0
CHG FROM BEST*	PLO	18	-11.57	19.832	-58.3	-16.67	-8.33	0.00	25.0
	ADA	19	0.22	10.801	-25.0	0.00	0.00	0.00	20.8
	TOT	37	-5.52	16.726	-58.3	-8.33	0.00	0.00	25.0

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Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
DISTANCE VISION									
BEST VALUE*	PLO	18	71.53	25.735	25.0	50.00	75.00	100.00	100.0
	ADA	19	71.71	19.962	41.7	50.00	75.00	91.67	100.0
	TOT	37	71.62	22.627	25.0	50.00	75.00	91.67	100.0
FINAL/ET VALUE	PLO	18	67.13	32.649	16.7	33.33	83.33	91.67	100.0
	ADA	19	66.23	22.986	25.0	50.00	66.67	83.33	100.0
	TOT	37	66.67	27.708	16.7	50.00	75.00	91.67	100.0
CHG FROM BEST*	PLO	18	-4.40	18.104	-50.0	-8.33	0.00	8.33	25.0
	ADA	19	-5.48	10.398	-25.0	-16.67	0.00	0.00	16.7
	TOT	37	-4.95	14.462	-50.0	-8.33	0.00	0.00	25.0

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TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
SOCIAL FUNCTIONING									
BEST VALUE*	PLO	18	86.81	18.427	37.5	75.00	93.75	100.00	100.0
	ADA	19	86.18	20.368	37.5	75.00	100.00	100.00	100.0
	TOT	37	86.49	19.180	37.5	75.00	100.00	100.00	100.0
FINAL/ET VALUE	PLO	18	79.17	27.786	12.5	62.50	93.75	100.00	100.0
	ADA	19	80.92	20.142	37.5	75.00	75.00	100.00	100.0
	TOT	37	80.07	23.837	12.5	75.00	87.50	100.00	100.0
CHG FROM BEST*	PLO	18	-7.64	15.541	-50.0	-12.50	0.00	0.00	12.5
	ADA	19	-5.26	15.205	-37.5	-12.50	0.00	0.00	25.0
	TOT	37	-6.42	15.202	-50.0	-12.50	0.00	0.00	25.0

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Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
MENTAL HEALTH									
BEST VALUE*	PLO	18	64.93	22.498	18.8	43.75	71.88	81.25	93.8
	ADA	19	63.16	21.337	18.8	50.00	62.50	81.25	100.0
	TOT	37	64.02	21.621	18.8	50.00	68.75	81.25	100.0
FINAL/ET VALUE	PLO	18	60.65	28.769	12.5	31.25	62.50	81.25	100.0
	ADA	19	65.02	25.700	6.3	43.75	68.75	81.25	100.0
	TOT	37	62.89	26.944	6.3	43.75	68.75	81.25	100.0
CHG FROM BEST*	PLO	18	-4.28	24.614	-75.0	-6.25	0.00	6.25	25.0
	ADA	19	1.86	14.008	-18.8	-6.25	-2.08	12.50	31.3
	TOT	37	-1.13	19.847	-75.0	-6.25	0.00	12.50	31.3

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TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
ROLE DIFFICULTIES									
BEST VALUE*	PLO	18	69.44	29.463	25.0	50.00	75.00	100.00	100.0
	ADA	19	64.47	27.721	12.5	50.00	50.00	100.00	100.0
	TOT	37	66.89	28.293	12.5	50.00	62.50	100.00	100.0
FINAL/ET VALUE	PLO	18	56.25	35.160	0.0	25.00	62.50	87.50	100.0
	ADA	19	59.21	34.065	0.0	25.00	50.00	100.00	100.0
	TOT	37	57.77	34.150	0.0	25.00	50.00	100.00	100.0
CHG FROM BEST*	PLO	18	-13.19	21.639	-75.0	-25.00	0.00	0.00	12.5
	ADA	19	-5.26	21.375	-62.5	-12.50	0.00	12.50	25.0
	TOT	37	-9.12	21.580	-75.0	-25.00	0.00	0.00	25.0

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CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
DEPENDENCY									
BEST VALUE*	PLO	18	79.17	26.545	25.0	58.33	95.83	100.00	100.0
	ADA	19	79.39	22.286	25.0	66.67	83.33	100.00	100.0
	TOT	37	79.28	24.106	25.0	66.67	91.67	100.00	100.0
FINAL/ET VALUE	PLO	18	71.76	31.589	8.3	50.00	75.00	100.00	100.0
	ADA	19	74.56	26.567	16.7	58.33	83.33	100.00	100.0
	TOT	37	73.20	28.743	8.3	58.33	83.33	100.00	100.0
CHG FROM BEST*	PLO	18	-7.41	19.780	-75.0	-8.33	0.00	0.00	16.7
	ADA	19	-4.82	16.969	-41.7	-16.67	0.00	0.00	33.3
	TOT	37	-6.08	18.178	-75.0	-16.67	0.00	0.00	33.3

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TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
DRIVING									
BEST VALUE*	PLO	15	60.00	34.244	0.0	33.33	75.00	83.33	100.0
	ADA	18	59.95	28.766	0.0	50.00	62.50	83.33	100.0
	TOT	33	59.97	30.865	0.0	41.67	66.67	83.33	100.0
FINAL/ET VALUE	PLO	15	45.28	40.116	0.0	0.00	37.50	83.33	100.0
	ADA	18	56.02	33.187	0.0	41.67	58.33	83.33	100.0
	TOT	33	51.14	36.313	0.0	16.67	58.33	83.33	100.0
CHG FROM BEST*	PLO	15	-14.72	22.651	-75.0	-33.33	-8.33	0.00	8.3
	ADA	18	-3.94	15.021	-41.7	-8.33	0.00	8.33	16.7
	TOT	33	-8.84	19.341	-75.0	-16.67	0.00	0.00	16.7

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CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
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LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
COLOR VISION									
BEST VALUE*	PLO	18	91.67	14.852	50.0	75.00	100.00	100.00	100.0
	ADA	19	92.11	11.939	75.0	75.00	100.00	100.00	100.0
	TOT	37	91.89	13.247	50.0	75.00	100.00	100.00	100.0
FINAL/ET VALUE	PLO	18	84.72	24.463	25.0	75.00	100.00	100.00	100.0
	ADA	19	89.47	15.174	50.0	75.00	100.00	100.00	100.0
	TOT	37	87.16	20.088	25.0	75.00	100.00	100.00	100.0
CHG FROM BEST*	PLO	18	-6.94	11.522	-25.0	-25.00	0.00	0.00	0.0
	ADA	19	-2.63	16.446	-50.0	0.00	0.00	0.00	25.0
	TOT	37	-4.73	14.237	-50.0	0.00	0.00	0.00	25.0

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TABLE 14.2__1000.4.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
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LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
PERIPHERAL VISION									
BEST VALUE*	PLO	18	72.22	26.965	25.0	50.00	75.00	100.00	100.0
	ADA	19	78.95	20.855	25.0	75.00	75.00	100.00	100.0
	TOT	37	75.68	23.926	25.0	50.00	75.00	100.00	100.0
FINAL/ET VALUE	PLO	18	66.67	29.704	0.0	50.00	75.00	100.00	100.0
	ADA	19	68.42	21.798	25.0	50.00	75.00	75.00	100.0
	TOT	37	67.57	25.594	0.0	50.00	75.00	75.00	100.0
CHG FROM BEST*	PLO	18	-5.56	16.169	-50.0	0.00	0.00	0.00	25.0
	ADA	19	-10.53	19.213	-50.0	-25.00	0.00	0.00	25.0
	TOT	37	-8.11	17.731	-50.0	-25.00	0.00	0.00	25.0

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LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
TOTAL SCORE									
BEST VALUE*	PLO	18	72.74	18.736	39.1	58.94	74.23	88.42	98.3
	ADA	19	69.62	17.364	40.1	55.27	65.30	86.14	95.3
	TOT	37	71.14	17.861	39.1	56.89	70.61	86.52	98.3
FINAL/ET VALUE	PLO	18	67.07	23.547	27.6	50.42	71.55	83.67	98.0
	ADA	19	69.18	19.213	29.7	51.86	65.68	85.38	98.2
	TOT	37	68.15	21.155	27.6	50.91	70.61	83.67	98.2
CHG FROM BEST*	PLO	18	-5.67	14.404	-48.0	-8.37	-1.36	2.46	9.6
	ADA	19	-0.44	9.397	-22.9	-4.28	1.14	4.55	13.9
	TOT	37	-2.99	12.213	-48.0	-4.36	-0.57	3.48	13.9

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	27	63.89	21.183	25.0	50.00	75.00	75.00	100.0			
	ADA	20	68.75	19.660	50.0	50.00	75.00	75.00	100.0			
	TOT	47	65.96	20.474	25.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	27	44.44	26.251	0.0	25.00	50.00	50.00	100.0			
	ADA	20	48.75	29.774	0.0	25.00	50.00	62.50	100.0			
	TOT	47	46.28	27.573	0.0	25.00	50.00	50.00	100.0			
CHG FROM BEST*	PLO	27	-19.44	27.151	-100.0	-25.00	-25.00	0.00	25.0			
	ADA	20	-20.00	30.992	-100.0	-25.00	-25.00	0.00	25.0			
	TOT	47	-19.68	28.522	-100.0	-25.00	-25.00	0.00	25.0			
										-0.56	(-17.69, 16.58)	0.948A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	27	74.81	13.118	40.0	60.00	80.00	80.00	100.0			
	ADA	20	68.00	11.965	40.0	60.00	60.00	80.00	80.0			
	TOT	47	71.91	12.961	40.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	27	65.19	17.180	40.0	60.00	60.00	80.00	100.0			
	ADA	20	63.00	18.666	20.0	60.00	60.00	70.00	100.0			
	TOT	47	64.26	17.662	20.0	60.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	27	-9.63	17.863	-60.0	-20.00	0.00	0.00	20.0			
	ADA	20	-5.00	15.728	-40.0	-20.00	0.00	0.00	20.0			
	TOT	47	-7.66	16.967	-60.0	-20.00	0.00	0.00	20.0			
										4.63	(-5.47, 14.73)	0.361A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	27	86.57	17.990	37.5	75.00	100.00	100.00	100.0			
	ADA	20	80.63	17.897	50.0	62.50	75.00	100.00	100.0			
	TOT	47	84.04	18.002	37.5	62.50	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	27	70.37	29.651	12.5	50.00	75.00	100.00	100.0			
	ADA	20	73.75	20.237	50.0	50.00	75.00	100.00	100.0			
	TOT	47	71.81	25.864	12.5	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	27	-16.20	26.132	-87.5	-25.00	0.00	0.00	12.5			
	ADA	20	-6.88	11.806	-37.5	-12.50	0.00	0.00	12.5			
	TOT	47	-12.23	21.570	-87.5	-12.50	0.00	0.00	12.5			
										9.33	(-3.32, 21.98)	0.145A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	27	78.40	18.527	33.3	66.67	83.33	91.67	100.0			
	ADA	20	74.58	21.025	33.3	62.50	75.00	91.67	100.0			
	TOT	47	76.77	19.500	33.3	66.67	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	27	66.36	25.683	25.0	50.00	66.67	91.67	100.0			
	ADA	20	71.25	21.710	25.0	58.33	75.00	87.50	100.0			
	TOT	47	68.44	23.947	25.0	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	27	-12.04	15.215	-41.7	-25.00	-8.33	0.00	16.7			
	ADA	20	-3.33	11.278	-16.7	-12.50	-4.17	4.17	25.0			
	TOT	47	-8.33	14.223	-41.7	-16.67	-8.33	0.00	25.0			
										8.70	(0.57, 16.84)	0.037A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	27	79.32	18.253	41.7	66.67	83.33	91.67	100.0			
	ADA	20	73.13	20.612	12.5	66.67	79.17	83.33	100.0			
	TOT	47	76.68	19.323	12.5	66.67	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	27	68.83	27.381	16.7	41.67	75.00	91.67	100.0			
	ADA	20	71.25	19.771	25.0	62.50	75.00	83.33	100.0			
	TOT	47	69.86	24.221	16.7	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	27	-10.49	12.836	-37.5	-25.00	-8.33	0.00	8.3			
	ADA	20	-1.88	9.604	-25.0	-8.33	0.00	0.00	16.7			
	TOT	47	-6.83	12.238	-37.5	-16.67	0.00	0.00	16.7			
										8.62	(1.74, 15.50)	0.015A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	27	90.74	16.479	50.0	87.50	100.00	100.00	100.0			
	ADA	20	88.75	17.631	37.5	87.50	100.00	100.00	100.0			
	TOT	47	89.89	16.819	37.5	87.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	27	81.94	22.018	25.0	75.00	87.50	100.00	100.0			
	ADA	20	85.63	19.141	25.0	75.00	87.50	100.00	100.0			
	TOT	47	83.51	20.705	25.0	75.00	87.50	100.00	100.0			
CHG FROM BEST*	PLO	27	-8.80	12.886	-37.5	-12.50	0.00	0.00	12.5			
	ADA	20	-3.13	8.954	-25.0	-12.50	0.00	0.00	12.5			
	TOT	47	-6.38	11.619	-37.5	-12.50	0.00	0.00	12.5			
										5.67	(-1.10, 12.44)	0.098A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	27	74.31	22.888	25.0	62.50	81.25	93.75	100.0			
	ADA	20	66.67	22.499	12.5	53.13	71.88	82.29	93.8			
	TOT	47	71.05	22.798	12.5	56.25	81.25	87.50	100.0			
FINAL/ET VALUE	PLO	27	63.97	28.657	6.3	37.50	68.75	93.75	100.0			
	ADA	20	66.25	23.420	12.5	56.25	68.75	84.38	100.0			
	TOT	47	64.94	26.307	6.3	50.00	68.75	87.50	100.0			
CHG FROM BEST*	PLO	27	-10.34	15.850	-43.8	-18.75	-6.25	0.00	18.8			
	ADA	20	-0.42	10.891	-12.5	-10.42	0.00	6.25	25.0			
	TOT	47	-6.12	14.683	-43.8	-12.50	-6.25	2.08	25.0			
										9.92	(1.62, 18.23)	0.020A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	27	75.00	27.298	12.5	50.00	87.50	100.00	100.0			
	ADA	20	69.38	20.867	50.0	50.00	62.50	87.50	100.0			
	TOT	47	72.61	24.677	12.5	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	27	66.20	29.786	12.5	37.50	75.00	100.00	100.0			
	ADA	20	65.63	31.118	0.0	50.00	68.75	93.75	100.0			
	TOT	47	65.96	30.025	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	27	-8.80	20.160	-62.5	-25.00	0.00	0.00	25.0			
	ADA	20	-3.75	25.682	-75.0	-12.50	0.00	0.00	37.5			
	TOT	47	-6.65	22.550	-75.0	-12.50	0.00	0.00	37.5			
										5.05	(-8.42, 18.51)	0.454A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	27	86.11	21.183	33.3	83.33	91.67	100.00	100.0			
	ADA	20	85.00	20.697	41.7	70.83	95.83	100.00	100.0			
	TOT	47	85.64	20.757	33.3	75.00	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	27	75.93	26.887	16.7	50.00	83.33	100.00	100.0			
	ADA	20	81.67	24.273	25.0	62.50	91.67	100.00	100.0			
	TOT	47	78.37	25.694	16.7	58.33	91.67	100.00	100.0			
CHG FROM BEST*	PLO	27	-10.19	21.722	-50.0	-25.00	0.00	0.00	50.0			
	ADA	20	-3.33	17.605	-25.0	-12.50	0.00	0.00	58.3			
	TOT	47	-7.27	20.161	-50.0	-25.00	0.00	0.00	58.3			
										6.85	(-5.08, 18.79)	0.254A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	26	69.87	28.682	0.0	50.00	79.17	91.67	100.0			
	ADA	17	63.73	28.404	0.0	41.67	75.00	83.33	100.0			
	TOT	43	67.44	28.395	0.0	41.67	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	26	59.94	33.168	0.0	41.67	62.50	91.67	100.0			
	ADA	17	63.24	28.422	0.0	50.00	75.00	83.33	100.0			
	TOT	43	61.24	31.068	0.0	41.67	66.67	83.33	100.0			
CHG FROM BEST*	PLO	26	-9.94	17.162	-50.0	-25.00	-8.33	0.00	33.3			
	ADA	17	-0.49	11.957	-16.7	-8.33	0.00	0.00	33.3			
	TOT	43	-6.20	15.863	-50.0	-16.67	0.00	0.00	33.3			
										9.45	(-0.22, 19.11)	0.055A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	27	93.52	14.859	50.0	100.00	100.00	100.00	100.0			
	ADA	20	95.00	10.260	75.0	100.00	100.00	100.00	100.0			
	TOT	47	94.15	12.993	50.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	27	90.28	15.633	50.0	75.00	100.00	100.00	100.0			
	ADA	20	96.25	9.159	75.0	100.00	100.00	100.00	100.0			
	TOT	47	92.82	13.479	50.0	87.50	100.00	100.00	100.0			
CHG FROM BEST*	PLO	27	-3.24	14.541	-50.0	0.00	0.00	0.00	25.0			
	ADA	20	1.25	5.590	0.0	0.00	0.00	0.00	25.0			
	TOT	47	-1.33	11.724	-50.0	0.00	0.00	0.00	25.0			
										4.49	(-2.42, 11.40)	0.197A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	27	82.87	22.239	25.0	75.00	100.00	100.00	100.0			
	ADA	20	76.25	24.967	25.0	62.50	75.00	100.00	100.0			
	TOT	47	80.05	23.409	25.0	75.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	27	74.07	25.459	25.0	50.00	75.00	100.00	100.0			
	ADA	20	70.00	27.625	25.0	50.00	75.00	100.00	100.0			
	TOT	47	72.34	26.186	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	27	-8.80	14.633	-50.0	-25.00	0.00	0.00	12.5			
	ADA	20	-6.25	15.967	-50.0	-12.50	0.00	0.00	25.0			
	TOT	47	-7.71	15.098	-50.0	-25.00	0.00	0.00	25.0			
										2.55	(-6.49, 11.58)	0.573A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	27	78.83	16.708	43.9	68.79	85.30	90.98	97.4			
	ADA	20	74.10	15.287	44.7	66.72	76.31	86.48	97.0			
	TOT	47	76.82	16.121	43.9	68.79	79.54	89.66	97.4			
FINAL/ET VALUE	PLO	27	71.27	20.913	28.4	51.86	75.53	90.42	100.0			
	ADA	20	73.24	16.881	39.9	64.73	72.77	83.92	99.4			
	TOT	47	72.11	19.128	28.4	58.94	74.58	88.48	100.0			
CHG FROM BEST*	PLO	27	-7.56	11.001	-32.2	-15.08	-6.97	1.70	8.9			
	ADA	20	-0.86	6.351	-12.4	-4.60	-2.33	2.80	12.0			
	TOT	47	-4.71	9.812	-32.2	-8.26	-3.60	2.08	12.0			
										6.70	(1.16, 12.24)	0.019A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	52	60.10	24.882	0.0	50.00	50.00	75.00	100.0			
	ADA	51	62.25	19.604	25.0	50.00	50.00	75.00	100.0			
	TOT	103	61.17	22.341	0.0	50.00	50.00	75.00	100.0			
FINAL/ET VALUE	PLO	52	45.19	25.263	0.0	25.00	50.00	50.00	100.0			
	ADA	51	50.98	22.339	0.0	50.00	50.00	75.00	100.0			
	TOT	103	48.06	23.920	0.0	25.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	52	-14.90	19.339	-75.0	-25.00	-25.00	0.00	25.0			
	ADA	51	-11.27	24.142	-75.0	-25.00	0.00	0.00	50.0			
	TOT	103	-13.11	21.818	-75.0	-25.00	0.00	0.00	50.0			
										3.63	(-4.91, 12.17)	0.401A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	52	68.85	16.527	40.0	60.00	70.00	80.00	100.0			
	ADA	51	62.94	13.608	20.0	60.00	60.00	80.00	80.0			
	TOT	103	65.92	15.367	20.0	60.00	60.00	80.00	100.0			
FINAL/ET VALUE	PLO	52	60.00	19.803	20.0	40.00	60.00	80.00	100.0			
	ADA	51	59.02	17.465	20.0	40.00	60.00	80.00	100.0			
	TOT	103	59.51	18.597	20.0	40.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	52	-8.85	15.549	-40.0	-20.00	0.00	0.00	20.0			
	ADA	51	-3.92	17.097	-40.0	-20.00	0.00	0.00	40.0			
	TOT	103	-6.41	16.441	-40.0	-20.00	0.00	0.00	40.0			
										4.92	(-1.46, 11.31)	0.129A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	52	87.02	15.648	37.5	75.00	87.50	100.00	100.0			
	ADA	51	81.37	19.585	25.0	62.50	87.50	100.00	100.0			
	TOT	103	84.22	17.847	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	52	73.80	25.032	12.5	62.50	75.00	100.00	100.0			
	ADA	51	78.92	20.840	25.0	62.50	75.00	100.00	100.0			
	TOT	103	76.33	23.083	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	52	-13.22	20.771	-87.5	-25.00	-6.25	0.00	12.5			
	ADA	51	-2.45	16.397	-37.5	-12.50	0.00	0.00	37.5			
	TOT	103	-7.89	19.412	-87.5	-12.50	0.00	0.00	37.5			
										10.77	(3.45, 18.09)	0.004A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	52	72.52	23.298	16.7	58.33	75.00	91.67	100.0			
	ADA	51	63.15	22.428	16.7	50.00	66.67	75.00	100.0			
	TOT	103	67.88	23.240	16.7	50.00	66.67	87.50	100.0			
FINAL/ET VALUE	PLO	52	63.70	26.110	8.3	50.00	66.67	85.42	100.0			
	ADA	51	61.60	22.674	16.7	41.67	66.67	83.33	100.0			
	TOT	103	62.66	24.372	8.3	41.67	66.67	83.33	100.0			
CHG FROM BEST*	PLO	52	-8.81	15.756	-50.0	-16.67	-8.33	0.00	41.7			
	ADA	51	-1.55	15.745	-50.0	-8.33	0.00	8.33	50.0			
	TOT	103	-5.22	16.092	-50.0	-16.67	0.00	0.00	50.0			
										7.26	(1.10, 13.42)	0.021A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	52	73.48	22.792	16.7	58.33	83.33	91.67	100.0			
	ADA	51	64.46	22.022	12.5	50.00	66.67	83.33	100.0			
	TOT	103	69.01	22.760	12.5	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	52	65.71	28.697	8.3	39.58	75.00	91.67	100.0			
	ADA	51	60.01	25.468	16.7	33.33	58.33	83.33	100.0			
	TOT	103	62.88	27.165	8.3	33.33	66.67	83.33	100.0			
CHG FROM BEST*	PLO	52	-7.77	13.733	-50.0	-16.67	-4.17	0.00	25.0			
	ADA	51	-4.45	13.794	-50.0	-16.67	0.00	0.00	25.0			
	TOT	103	-6.13	13.797	-50.0	-16.67	0.00	0.00	25.0			
										3.32	(-2.06, 8.70)	0.224A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	52	88.70	18.401	25.0	81.25	100.00	100.00	100.0			
	ADA	51	80.15	21.239	25.0	62.50	87.50	100.00	100.0			
	TOT	103	84.47	20.221	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	52	79.57	26.200	12.5	68.75	87.50	100.00	100.0			
	ADA	51	75.37	24.380	12.5	50.00	75.00	100.00	100.0			
	TOT	103	77.49	25.279	12.5	62.50	87.50	100.00	100.0			
CHG FROM BEST*	PLO	52	-9.13	16.064	-50.0	-12.50	0.00	0.00	37.5			
	ADA	51	-4.78	14.555	-50.0	-12.50	0.00	0.00	37.5			
	TOT	103	-6.98	15.417	-50.0	-12.50	0.00	0.00	37.5			
										4.36	(-1.64, 10.35)	0.153A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	52	65.99	24.203	0.0	50.00	75.00	84.38	100.0			
	ADA	51	59.60	23.703	0.0	43.75	62.50	81.25	93.8			
	TOT	103	62.82	24.054	0.0	43.75	68.75	81.25	100.0			
FINAL/ET VALUE	PLO	52	60.18	28.340	0.0	37.50	62.50	87.50	100.0			
	ADA	51	60.78	26.724	0.0	37.50	68.75	81.25	100.0			
	TOT	103	60.48	27.418	0.0	37.50	62.50	81.25	100.0			
CHG FROM BEST*	PLO	52	-5.81	16.770	-58.3	-15.63	0.00	6.25	31.3			
	ADA	51	1.18	17.251	-43.8	-12.50	0.00	12.50	43.8			
	TOT	103	-2.35	17.287	-58.3	-12.50	0.00	6.25	43.8			
										6.99	(0.34, 13.64)	0.039A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	52	68.27	28.489	12.5	50.00	75.00	100.00	100.0			
	ADA	51	61.03	26.297	0.0	50.00	50.00	87.50	100.0			
	TOT	103	64.68	27.533	0.0	50.00	62.50	87.50	100.0			
FINAL/ET VALUE	PLO	52	58.89	31.246	0.0	25.00	56.25	87.50	100.0			
	ADA	51	58.58	31.074	0.0	37.50	62.50	87.50	100.0			
	TOT	103	58.74	31.008	0.0	37.50	62.50	87.50	100.0			
CHG FROM BEST*	PLO	52	-9.38	19.784	-75.0	-25.00	0.00	0.00	25.0			
	ADA	51	-2.45	25.863	-75.0	-12.50	0.00	12.50	50.0			
	TOT	103	-5.95	23.145	-75.0	-25.00	0.00	0.00	50.0			
										6.92	(-2.07, 15.91)	0.130A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	52	79.33	26.118	0.0	62.50	91.67	100.00	100.0			
	ADA	51	74.51	26.895	0.0	58.33	83.33	100.00	100.0			
	TOT	103	76.94	26.486	0.0	58.33	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	52	71.96	31.915	0.0	50.00	91.67	100.00	100.0			
	ADA	51	72.55	29.967	0.0	50.00	83.33	100.00	100.0			
	TOT	103	72.25	30.816	0.0	50.00	91.67	100.00	100.0			
CHG FROM BEST*	PLO	52	-7.37	20.456	-75.0	-12.50	0.00	0.00	50.0			
	ADA	51	-1.96	20.179	-66.7	-16.67	0.00	0.00	58.3			
	TOT	103	-4.69	20.401	-75.0	-16.67	0.00	0.00	58.3			
										5.41	(-2.53, 13.35)	0.180A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	47	66.84	31.589	0.0	41.67	75.00	91.67	100.0			
	ADA	43	51.55	32.185	0.0	33.33	50.00	83.33	100.0			
	TOT	90	59.54	32.613	0.0	33.33	62.50	83.33	100.0			
FINAL/ET VALUE	PLO	47	53.99	32.957	0.0	33.33	58.33	83.33	100.0			
	ADA	43	47.77	34.841	0.0	16.67	50.00	75.00	100.0			
	TOT	90	51.02	33.823	0.0	16.67	58.33	83.33	100.0			
CHG FROM BEST*	PLO	47	-12.85	18.488	-58.3	-25.00	-8.33	0.00	33.3			
	ADA	43	-3.78	17.079	-41.7	-8.33	0.00	0.00	50.0			
	TOT	90	-8.52	18.306	-58.3	-16.67	-4.17	0.00	50.0			
										9.08	(1.60, 16.55)	0.018A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	52	93.75	12.981	50.0	100.00	100.00	100.00	100.0			
	ADA	51	89.22	16.012	25.0	75.00	100.00	100.00	100.0			
	TOT	103	91.50	14.667	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	52	90.63	17.128	25.0	75.00	100.00	100.00	100.0			
	ADA	51	85.29	18.826	50.0	75.00	100.00	100.00	100.0			
	TOT	103	87.99	18.099	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	52	-3.13	10.754	-25.0	0.00	0.00	0.00	25.0			
	ADA	51	-3.92	16.862	-50.0	0.00	0.00	0.00	25.0			
	TOT	103	-3.52	14.048	-50.0	0.00	0.00	0.00	25.0			
										-0.80	(-6.31, 4.72)	0.775A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	52	80.05	22.451	25.0	68.75	75.00	100.00	100.0			
	ADA	50	71.00	23.883	25.0	50.00	75.00	100.00	100.0			
	TOT	102	75.61	23.493	25.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	52	72.12	26.034	25.0	50.00	75.00	100.00	100.0			
	ADA	50	66.00	26.611	25.0	50.00	75.00	100.00	100.0			
	TOT	102	69.12	26.368	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	52	-7.93	14.858	-50.0	-25.00	0.00	0.00	25.0			
	ADA	50	-5.00	19.562	-50.0	-25.00	0.00	0.00	25.0			
	TOT	102	-6.50	17.300	-50.0	-25.00	0.00	0.00	25.0			
										2.93	(-3.87, 9.74)	0.395A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	52	74.38	18.632	25.7	58.71	77.99	89.98	98.2			
	ADA	51	66.15	17.565	14.7	55.27	65.30	78.30	97.0			
	TOT	103	70.30	18.490	14.7	56.89	71.93	87.20	98.2			
FINAL/ET VALUE	PLO	52	68.39	22.170	21.1	50.51	75.25	87.72	96.5			
	ADA	51	65.92	20.035	18.5	50.91	65.49	83.98	97.6			
	TOT	103	67.17	21.073	18.5	50.61	70.61	87.16	97.6			
CHG FROM BEST*	PLO	52	-5.99	11.211	-48.0	-9.30	-4.44	-0.09	20.6			
	ADA	51	-0.23	10.824	-38.0	-6.82	-0.15	6.70	25.8			
	TOT	103	-3.14	11.342	-48.0	-8.26	-1.52	2.65	25.8			
										5.76	(1.45, 10.07)	0.009A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	35	64.29	22.101	25.0	50.00	50.00	75.00	100.0			
	ADA	38	60.53	18.952	25.0	50.00	50.00	75.00	100.0			
	TOT	73	62.33	20.465	25.0	50.00	50.00	75.00	100.0			
FINAL/ET VALUE	PLO	35	49.29	25.355	0.0	25.00	50.00	75.00	100.0			
	ADA	38	46.05	21.377	0.0	25.00	50.00	50.00	75.0			
	TOT	73	47.60	23.260	0.0	25.00	50.00	50.00	100.0			
CHG FROM BEST*	PLO	35	-15.00	18.391	-75.0	-25.00	0.00	0.00	0.0			
	ADA	38	-14.47	21.460	-75.0	-25.00	0.00	0.00	25.0			
	TOT	73	-14.73	19.911	-75.0	-25.00	0.00	0.00	25.0			
										0.53	(-8.84, 9.89)	0.911A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	35	69.71	16.357	40.0	60.00	80.00	80.00	100.0			
	ADA	37	62.43	14.416	20.0	60.00	60.00	80.00	80.0			
	TOT	72	65.97	15.714	20.0	60.00	60.00	80.00	100.0			
FINAL/ET VALUE	PLO	35	60.00	21.144	20.0	40.00	60.00	80.00	100.0			
	ADA	37	57.30	16.440	20.0	40.00	60.00	60.00	80.0			
	TOT	72	58.61	18.788	20.0	40.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	35	-9.71	15.622	-40.0	-20.00	0.00	0.00	20.0			
	ADA	37	-5.14	16.265	-40.0	-20.00	0.00	0.00	40.0			
	TOT	72	-7.36	16.010	-40.0	-20.00	0.00	0.00	40.0			
										4.58	(-2.92, 12.08)	0.228A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	35	86.79	14.835	50.0	75.00	87.50	100.00	100.0			
	ADA	38	83.22	19.982	25.0	75.00	87.50	100.00	100.0			
	TOT	73	84.93	17.673	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	35	72.50	25.867	12.5	50.00	75.00	100.00	100.0			
	ADA	38	78.62	20.736	25.0	62.50	75.00	100.00	100.0			
	TOT	73	75.68	23.375	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	35	-14.29	21.468	-87.5	-25.00	0.00	0.00	12.5			
	ADA	38	-4.61	17.296	-37.5	-12.50	0.00	0.00	37.5			
	TOT	73	-9.25	19.877	-87.5	-25.00	0.00	0.00	37.5			
										9.68	(0.61, 18.75)	0.037A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	35	67.62	22.119	25.0	58.33	66.67	83.33	100.0			
	ADA	38	63.49	23.836	16.7	50.00	66.67	75.00	100.0			
	TOT	73	65.47	22.964	16.7	50.00	66.67	83.33	100.0			
FINAL/ET VALUE	PLO	35	60.71	25.047	8.3	50.00	58.33	83.33	100.0			
	ADA	38	59.43	23.020	16.7	41.67	58.33	75.00	100.0			
	TOT	73	60.05	23.853	8.3	41.67	58.33	75.00	100.0			
CHG FROM BEST*	PLO	35	-6.90	16.726	-33.3	-16.67	-8.33	0.00	41.7			
	ADA	38	-4.06	16.680	-50.0	-16.67	0.00	0.00	50.0			
	TOT	73	-5.42	16.648	-50.0	-16.67	0.00	0.00	50.0			
										2.85	(-4.95, 10.65)	0.469A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	35	73.81	20.921	25.0	58.33	75.00	91.67	100.0			
	ADA	38	65.79	22.887	12.5	50.00	66.67	83.33	100.0			
	TOT	73	69.63	22.184	12.5	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	35	66.19	26.942	16.7	41.67	75.00	91.67	100.0			
	ADA	38	60.31	26.097	16.7	33.33	66.67	83.33	100.0			
	TOT	73	63.13	26.486	16.7	41.67	66.67	83.33	100.0			
CHG FROM BEST*	PLO	35	-7.62	14.451	-37.5	-16.67	-8.33	0.00	25.0			
	ADA	38	-5.48	14.631	-50.0	-16.67	0.00	0.00	16.7			
	TOT	73	-6.51	14.484	-50.0	-16.67	0.00	0.00	25.0			
										2.14	(-4.66, 8.93)	0.533A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	35	85.36	19.992	37.5	75.00	100.00	100.00	100.0			
	ADA	38	80.59	23.012	25.0	62.50	87.50	100.00	100.0			
	TOT	73	82.88	21.601	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	35	77.86	25.381	12.5	62.50	87.50	100.00	100.0			
	ADA	38	73.52	26.613	12.5	50.00	81.25	100.00	100.0			
	TOT	73	75.60	25.941	12.5	50.00	87.50	100.00	100.0			
CHG FROM BEST*	PLO	35	-7.50	17.468	-37.5	-25.00	0.00	0.00	37.5			
	ADA	38	-7.07	13.489	-50.0	-12.50	0.00	0.00	25.0			
	TOT	73	-7.28	15.416	-50.0	-12.50	0.00	0.00	37.5			
										0.43	(-6.82, 7.68)	0.907A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	35	62.50	22.019	6.3	50.00	68.75	81.25	93.8			
	ADA	38	60.75	25.338	0.0	43.75	62.50	83.33	93.8			
	TOT	73	61.59	23.657	0.0	43.75	62.50	81.25	93.8			
FINAL/ET VALUE	PLO	35	57.50	26.203	0.0	37.50	56.25	81.25	100.0			
	ADA	38	58.22	25.835	0.0	37.50	62.50	75.00	100.0			
	TOT	73	57.88	25.833	0.0	37.50	62.50	81.25	100.0			
CHG FROM BEST*	PLO	35	-5.00	17.336	-43.8	-18.75	-6.25	6.25	31.3			
	ADA	38	-2.52	15.704	-43.8	-12.50	0.00	6.25	31.3			
	TOT	73	-3.71	16.438	-43.8	-12.50	0.00	6.25	31.3			
										2.48	(-5.23, 10.19)	0.524A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	35	67.14	26.095	25.0	50.00	62.50	100.00	100.0			
	ADA	38	63.82	28.444	0.0	50.00	56.25	87.50	100.0			
	TOT	73	65.41	27.205	0.0	50.00	62.50	100.00	100.0			
FINAL/ET VALUE	PLO	35	56.79	30.065	12.5	25.00	50.00	75.00	100.0			
	ADA	38	57.24	33.595	0.0	37.50	50.00	87.50	100.0			
	TOT	73	57.02	31.731	0.0	25.00	50.00	87.50	100.0			
CHG FROM BEST*	PLO	35	-10.36	19.050	-62.5	-25.00	-12.50	0.00	25.0			
	ADA	38	-6.58	27.835	-75.0	-25.00	0.00	0.00	50.0			
	TOT	73	-8.39	23.941	-75.0	-25.00	0.00	0.00	50.0			
										3.78	(-7.45, 15.00)	0.504A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	35	76.19	27.723	0.0	50.00	91.67	100.00	100.0			
	ADA	38	76.10	29.394	0.0	58.33	87.50	100.00	100.0			
	TOT	73	76.14	28.407	0.0	58.33	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	35	70.00	29.787	0.0	41.67	75.00	100.00	100.0			
	ADA	38	72.15	31.793	0.0	41.67	83.33	100.00	100.0			
	TOT	73	71.12	30.653	0.0	41.67	83.33	100.00	100.0			
CHG FROM BEST*	PLO	35	-6.19	21.134	-50.0	-8.33	0.00	8.33	50.0			
	ADA	38	-3.95	22.068	-66.7	-16.67	0.00	0.00	58.3			
	TOT	73	-5.02	21.505	-66.7	-8.33	0.00	0.00	58.3			
										2.24	(-7.86, 12.35)	0.659A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	31	60.75	33.761	0.0	33.33	75.00	83.33	100.0			
	ADA	32	53.52	34.605	0.0	25.00	58.33	83.33	100.0			
	TOT	63	57.08	34.111	0.0	33.33	58.33	83.33	100.0			
FINAL/ET VALUE	PLO	31	50.54	34.355	0.0	8.33	58.33	75.00	100.0			
	ADA	32	46.09	35.291	0.0	12.50	50.00	79.17	100.0			
	TOT	63	48.28	34.624	0.0	8.33	50.00	75.00	100.0			
CHG FROM BEST*	PLO	31	-10.22	25.066	-58.3	-25.00	-8.33	0.00	50.0			
	ADA	32	-7.42	17.317	-41.7	-14.58	-4.17	0.00	50.0			
	TOT	63	-8.80	21.353	-58.3	-16.67	-8.33	0.00	50.0			
										2.79	(-8.03, 13.62)	0.608A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	35	92.86	14.312	50.0	100.00	100.00	100.00	100.0			
	ADA	38	89.47	17.077	25.0	75.00	100.00	100.00	100.0			
	TOT	73	91.10	15.795	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	35	88.93	17.355	25.0	75.00	100.00	100.00	100.0			
	ADA	38	84.87	18.870	50.0	75.00	100.00	100.00	100.0			
	TOT	73	86.82	18.149	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	35	-3.93	10.834	-25.0	0.00	0.00	0.00	25.0			
	ADA	38	-4.61	19.150	-50.0	-25.00	0.00	0.00	25.0			
	TOT	73	-4.28	15.621	-50.0	0.00	0.00	0.00	25.0			
										-0.68	(-8.02, 6.67)	0.855A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	35	79.64	21.880	25.0	62.50	75.00	100.00	100.0			
	ADA	37	72.97	23.108	25.0	50.00	75.00	100.00	100.0			
	TOT	72	76.22	22.611	25.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	35	72.86	24.533	25.0	50.00	75.00	100.00	100.0			
	ADA	37	66.89	27.672	25.0	50.00	75.00	100.00	100.0			
	TOT	72	69.79	26.182	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	35	-6.79	15.853	-50.0	-25.00	0.00	0.00	25.0			
	ADA	37	-6.08	18.071	-50.0	0.00	0.00	0.00	25.0			
	TOT	72	-6.42	16.913	-50.0	-25.00	0.00	0.00	25.0			
										0.70	(-7.30, 8.71)	0.861A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	35	72.32	17.048	43.6	55.45	72.50	88.71	97.3			
	ADA	38	67.53	19.606	14.7	50.53	71.17	85.49	95.3			
	TOT	73	69.83	18.455	14.7	54.39	71.93	86.14	97.3			
FINAL/ET VALUE	PLO	35	66.90	20.410	27.6	50.61	70.61	84.04	100.0			
	ADA	38	64.96	20.816	18.5	48.00	66.40	83.79	97.6			
	TOT	73	65.89	20.502	18.5	50.61	67.54	83.79	100.0			
CHG FROM BEST*	PLO	35	-5.42	11.494	-32.2	-12.21	-3.22	2.65	20.6			
	ADA	38	-2.57	11.761	-38.0	-7.42	-1.29	3.79	25.8			
	TOT	73	-3.94	11.642	-38.0	-9.47	-2.46	2.95	25.8			
										2.85	(-2.58, 8.29)	0.299A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	46	65.22	20.054	25.0	50.00	62.50	75.00	100.0			
	ADA	53	63.68	19.956	25.0	50.00	50.00	75.00	100.0			
	TOT	99	64.39	19.914	25.0	50.00	50.00	75.00	100.0			
FINAL/ET VALUE	PLO	46	52.17	27.802	0.0	25.00	50.00	75.00	100.0			
	ADA	53	56.60	23.591	0.0	50.00	50.00	75.00	100.0			
	TOT	99	54.55	25.596	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	46	-13.04	22.815	-100.0	-25.00	0.00	0.00	25.0			
	ADA	53	-7.08	24.207	-100.0	-25.00	0.00	0.00	25.0			
	TOT	99	-9.85	23.641	-100.0	-25.00	0.00	0.00	25.0			
										5.97	(-3.46, 15.40)	0.212A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	46	75.22	14.101	40.0	60.00	80.00	80.00	100.0			
	ADA	53	75.47	13.383	40.0	60.00	80.00	80.00	100.0			
	TOT	99	75.35	13.651	40.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	46	62.17	22.402	20.0	40.00	60.00	80.00	100.0			
	ADA	53	70.19	19.854	20.0	60.00	80.00	80.00	100.0			
	TOT	99	66.46	21.348	20.0	60.00	80.00	80.00	100.0			
CHG FROM BEST*	PLO	46	-13.04	21.589	-60.0	-20.00	0.00	0.00	20.0			
	ADA	53	-5.28	17.165	-60.0	-20.00	0.00	0.00	20.0			
	TOT	99	-8.89	19.634	-60.0	-20.00	0.00	0.00	20.0			
										7.76	(0.02, 15.50)	0.049A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	46	82.88	16.533	37.5	75.00	87.50	100.00	100.0			
	ADA	53	86.79	15.585	50.0	75.00	100.00	100.00	100.0			
	TOT	99	84.97	16.069	37.5	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	46	71.74	24.071	25.0	50.00	75.00	100.00	100.0			
	ADA	53	82.08	19.690	25.0	62.50	87.50	100.00	100.0			
	TOT	99	77.27	22.330	25.0	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	46	-11.14	21.926	-75.0	-25.00	0.00	0.00	25.0			
	ADA	53	-4.72	16.486	-75.0	-12.50	0.00	0.00	25.0			
	TOT	99	-7.70	19.374	-75.0	-12.50	0.00	0.00	25.0			
										6.42	(-1.26, 14.10)	0.100A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	46	78.99	18.404	33.3	66.67	75.00	100.00	100.0			
	ADA	53	86.16	17.824	33.3	75.00	91.67	100.00	100.0			
	TOT	99	82.83	18.359	33.3	75.00	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	46	71.01	24.829	8.3	50.00	75.00	91.67	100.0			
	ADA	53	80.58	21.819	25.0	66.67	91.67	100.00	100.0			
	TOT	99	76.14	23.636	8.3	58.33	83.33	100.00	100.0			
CHG FROM BEST*	PLO	46	-7.97	18.422	-66.7	-8.33	-4.17	0.00	25.0			
	ADA	53	-5.58	17.582	-66.7	-8.33	0.00	0.00	25.0			
	TOT	99	-6.69	17.925	-66.7	-8.33	0.00	0.00	25.0			
										2.39	(-4.80, 9.58)	0.511A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	46	77.54	19.866	25.0	66.67	75.00	100.00	100.0			
	ADA	53	85.61	16.638	41.7	75.00	91.67	100.00	100.0			
	TOT	99	81.86	18.561	25.0	75.00	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	46	74.18	23.531	16.7	58.33	75.00	100.00	100.0			
	ADA	53	81.45	21.223	25.0	66.67	91.67	100.00	100.0			
	TOT	99	78.07	22.506	16.7	66.67	83.33	100.00	100.0			
CHG FROM BEST*	PLO	46	-3.35	14.424	-33.3	-8.33	0.00	0.00	41.7			
	ADA	53	-4.17	14.572	-66.7	-8.33	0.00	0.00	16.7			
	TOT	99	-3.79	14.435	-66.7	-8.33	0.00	0.00	41.7			
										-0.82	(-6.62, 4.99)	0.781A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	46	86.41	18.224	37.5	75.00	100.00	100.00	100.0			
	ADA	53	96.46	11.066	50.0	100.00	100.00	100.00	100.0			
	TOT	99	91.79	15.584	37.5	87.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	46	83.42	21.898	12.5	75.00	87.50	100.00	100.0			
	ADA	53	91.51	15.067	50.0	87.50	100.00	100.00	100.0			
	TOT	99	87.75	18.897	12.5	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	46	-2.99	13.990	-37.5	-12.50	0.00	0.00	25.0			
	ADA	53	-4.95	11.587	-50.0	0.00	0.00	0.00	12.5			
	TOT	99	-4.04	12.731	-50.0	-12.50	0.00	0.00	25.0			
										-1.96	(-7.07, 3.14)	0.447A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	46	68.75	26.021	6.3	50.00	71.88	93.75	100.0			
	ADA	53	75.35	20.960	18.8	62.50	81.25	87.50	100.0			
	TOT	99	72.29	23.558	6.3	56.25	81.25	93.75	100.0			
FINAL/ET VALUE	PLO	46	64.58	30.477	0.0	50.00	71.88	87.50	100.0			
	ADA	53	74.14	23.811	12.5	62.50	81.25	93.75	100.0			
	TOT	99	69.70	27.391	0.0	56.25	75.00	93.75	100.0			
CHG FROM BEST*	PLO	46	-4.17	19.380	-75.0	-6.25	0.00	6.25	25.0			
	ADA	53	-1.22	15.984	-62.5	-6.25	0.00	6.25	31.3			
	TOT	99	-2.59	17.613	-75.0	-6.25	0.00	6.25	31.3			
										2.95	(-4.11, 10.00)	0.409A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	46	74.73	24.365	25.0	50.00	75.00	100.00	100.0			
	ADA	53	80.90	20.599	37.5	62.50	87.50	100.00	100.0			
	TOT	99	78.03	22.523	25.0	62.50	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	46	67.93	29.890	0.0	50.00	75.00	100.00	100.0			
	ADA	53	75.94	28.886	0.0	50.00	87.50	100.00	100.0			
	TOT	99	72.22	29.481	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	46	-6.79	17.620	-50.0	-25.00	0.00	0.00	37.5			
	ADA	53	-4.95	22.379	-87.5	0.00	0.00	0.00	37.5			
	TOT	99	-5.81	20.228	-87.5	-12.50	0.00	0.00	37.5			
										1.84	(-6.28, 9.96)	0.654A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	46	81.52	25.755	0.0	66.67	91.67	100.00	100.0			
	ADA	53	91.19	19.018	16.7	91.67	100.00	100.00	100.0			
	TOT	99	86.70	22.804	0.0	83.33	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	46	74.18	31.373	0.0	66.67	83.33	100.00	100.0			
	ADA	53	86.95	24.214	0.0	83.33	100.00	100.00	100.0			
	TOT	99	81.02	28.355	0.0	66.67	100.00	100.00	100.0			
CHG FROM BEST*	PLO	46	-7.34	17.769	-75.0	-16.67	0.00	0.00	29.2			
	ADA	53	-4.25	16.230	-75.0	0.00	0.00	0.00	50.0			
	TOT	99	-5.68	16.946	-75.0	-8.33	0.00	0.00	50.0			
										3.09	(-3.69, 9.88)	0.368A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	42	68.55	29.509	0.0	50.00	75.00	91.67	100.0			
	ADA	51	81.29	17.606	41.7	75.00	83.33	100.00	100.0			
	TOT	93	75.54	24.437	0.0	66.67	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	42	61.31	32.396	0.0	33.33	66.67	83.33	100.0			
	ADA	51	75.49	23.358	0.0	66.67	83.33	91.67	100.0			
	TOT	93	69.09	28.541	0.0	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	42	-7.24	21.406	-75.0	-16.67	0.00	0.00	50.0			
	ADA	51	-5.80	14.603	-66.7	-8.33	0.00	0.00	16.7			
	TOT	93	-6.45	17.906	-75.0	-8.33	0.00	0.00	50.0			
										1.44	(-6.00, 8.89)	0.701A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	46	94.57	11.682	50.0	100.00	100.00	100.00	100.0			
	ADA	53	97.64	7.377	75.0	100.00	100.00	100.00	100.0			
	TOT	99	96.21	9.691	50.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	46	92.39	14.785	50.0	100.00	100.00	100.00	100.0			
	ADA	53	93.87	15.431	25.0	100.00	100.00	100.00	100.0			
	TOT	99	93.18	15.076	25.0	100.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	46	-2.17	12.721	-50.0	0.00	0.00	0.00	25.0			
	ADA	53	-3.77	15.029	-75.0	0.00	0.00	0.00	25.0			
	TOT	99	-3.03	13.957	-75.0	0.00	0.00	0.00	25.0			
										-1.60	(-7.20, 4.00)	0.572A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#		P-VALUE@
PERIPHERAL VISION													
BEST VALUE*	PLO	46	78.80	22.954	25.0	75.00	75.00	100.00	100.0				
	ADA	53	90.09	17.223	25.0	75.00	100.00	100.00	100.0				
	TOT	99	84.85	20.769	25.0	75.00	100.00	100.00	100.0				
FINAL/ET VALUE	PLO	46	77.72	23.111	0.0	75.00	75.00	100.00	100.0				
	ADA	53	83.49	21.339	25.0	75.00	100.00	100.00	100.0				
	TOT	99	80.81	22.254	0.0	75.00	75.00	100.00	100.0				
CHG FROM BEST*	PLO	46	-1.09	15.773	-25.0	0.00	0.00	0.00	50.0				
	ADA	53	-6.60	17.091	-50.0	-25.00	0.00	0.00	25.0				
	TOT	99	-4.04	16.640	-50.0	0.00	0.00	0.00	50.0				
										-5.52	(-12.11,	1.08)	0.100A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	46	77.36	16.964	39.2	64.62	79.62	94.20	98.7			
	ADA	53	84.57	13.065	48.1	82.08	88.98	93.07	100.0			
	TOT	99	81.22	15.354	39.2	70.67	86.14	93.64	100.0			
FINAL/ET VALUE	PLO	46	72.99	19.895	30.5	63.67	75.11	90.23	100.0			
	ADA	53	81.45	17.575	31.2	66.63	90.04	94.39	99.4			
	TOT	99	77.52	19.069	30.5	65.11	83.56	93.07	100.0			
CHG FROM BEST*	PLO	46	-4.37	11.817	-37.7	-9.51	-1.42	2.92	19.7			
	ADA	53	-3.12	11.172	-39.0	-4.17	-0.95	2.39	12.3			
	TOT	99	-3.70	11.434	-39.0	-5.11	-1.14	2.54	19.7			
										1.26	(-3.33, 5.85)	0.588A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	72	64.58	24.012	0.0	50.00	75.00	75.00	100.0			
	ADA	67	63.81	20.544	25.0	50.00	50.00	75.00	100.0			
	TOT	139	64.21	22.330	0.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	72	50.69	27.824	0.0	25.00	50.00	75.00	100.0			
	ADA	67	58.58	22.843	0.0	50.00	50.00	75.00	100.0			
	TOT	139	54.50	25.759	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	72	-13.89	22.552	-100.0	-25.00	-25.00	0.00	25.0			
	ADA	67	-5.22	24.440	-100.0	-25.00	0.00	0.00	50.0			
	TOT	139	-9.71	23.795	-100.0	-25.00	0.00	0.00	50.0			
										8.67	(0.78, 16.55)	0.031A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	72	73.06	15.072	40.0	60.00	80.00	80.00	100.0			
	ADA	67	73.43	13.206	40.0	60.00	80.00	80.00	100.0			
	TOT	139	73.24	14.153	40.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	72	62.78	21.311	20.0	40.00	60.00	80.00	100.0			
	ADA	67	69.40	18.980	20.0	60.00	80.00	80.00	100.0			
	TOT	139	65.97	20.420	20.0	60.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	72	-10.28	19.857	-60.0	-20.00	0.00	0.00	20.0			
	ADA	67	-4.03	17.500	-60.0	-20.00	0.00	0.00	30.0			
	TOT	139	-7.27	18.951	-60.0	-20.00	0.00	0.00	30.0			
										6.25	(-0.05, 12.54)	0.052A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	72	84.03	16.943	37.5	75.00	87.50	100.00	100.0			
	ADA	67	83.96	16.968	50.0	62.50	87.50	100.00	100.0			
	TOT	139	83.99	16.894	37.5	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	72	72.74	23.950	25.0	62.50	75.00	100.00	100.0			
	ADA	67	81.53	19.867	25.0	62.50	87.50	100.00	100.0			
	TOT	139	76.98	22.434	25.0	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	72	-11.28	20.996	-75.0	-25.00	0.00	0.00	25.0			
	ADA	67	-2.43	15.269	-75.0	-12.50	0.00	0.00	25.0			
	TOT	139	-7.01	18.922	-75.0	-12.50	0.00	0.00	25.0			
										8.86	(2.66, 15.06)	0.005A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	72	79.57	19.243	16.7	66.67	83.33	100.00	100.0			
	ADA	67	80.47	21.347	33.3	66.67	91.67	100.00	100.0			
	TOT	139	80.01	20.215	16.7	66.67	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	72	71.93	25.570	8.3	54.17	75.00	91.67	100.0			
	ADA	67	77.55	22.496	25.0	58.33	83.33	100.00	100.0			
	TOT	139	74.64	24.215	8.3	58.33	83.33	100.00	100.0			
CHG FROM BEST*	PLO	72	-7.64	18.316	-66.7	-16.67	-4.17	0.00	33.3			
	ADA	67	-2.92	16.949	-66.7	-8.33	0.00	0.00	25.0			
	TOT	139	-5.37	17.765	-66.7	-8.33	0.00	0.00	33.3			
										4.72	(-1.22, 10.65)	0.118A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	72	76.91	21.245	16.7	66.67	83.33	95.83	100.0			
	ADA	67	80.60	19.578	33.3	66.67	83.33	100.00	100.0			
	TOT	139	78.69	20.468	16.7	66.67	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	72	72.92	26.203	8.3	58.33	75.00	95.83	100.0			
	ADA	67	76.65	23.714	25.0	66.67	83.33	100.00	100.0			
	TOT	139	74.72	25.014	8.3	58.33	83.33	100.00	100.0			
CHG FROM BEST*	PLO	72	-3.99	13.640	-50.0	-8.33	0.00	0.00	41.7			
	ADA	67	-3.95	13.734	-66.7	-8.33	0.00	0.00	25.0			
	TOT	139	-3.97	13.636	-66.7	-8.33	0.00	0.00	41.7			
										0.04	(-4.55, 4.64)	0.985A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	72	89.58	17.172	25.0	87.50	100.00	100.00	100.0			
	ADA	67	92.54	14.279	50.0	87.50	100.00	100.00	100.0			
	TOT	139	91.01	15.856	25.0	87.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	72	84.20	22.885	12.5	75.00	100.00	100.00	100.0			
	ADA	67	88.25	17.795	25.0	75.00	100.00	100.00	100.0			
	TOT	139	86.15	20.616	12.5	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	72	-5.38	13.568	-50.0	-12.50	0.00	0.00	25.0			
	ADA	67	-4.29	12.791	-50.0	-12.50	0.00	0.00	37.5			
	TOT	139	-4.86	13.163	-50.0	-12.50	0.00	0.00	37.5			
										1.09	(-3.34, 5.52)	0.627A

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PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	72	71.44	25.281	0.0	62.50	75.00	93.75	100.0			
	ADA	67	70.52	22.503	18.8	50.00	81.25	87.50	100.0			
	TOT	139	71.00	23.900	0.0	56.25	81.25	87.50	100.0			
FINAL/ET VALUE	PLO	72	66.67	29.899	0.0	56.25	75.00	93.75	100.0			
	ADA	67	71.64	25.914	12.5	56.25	81.25	93.75	100.0			
	TOT	139	69.06	28.060	0.0	56.25	75.00	93.75	100.0			
CHG FROM BEST*	PLO	72	-4.77	18.005	-75.0	-6.25	0.00	6.25	25.0			
	ADA	67	1.12	17.473	-62.5	-6.25	0.00	12.50	43.8			
	TOT	139	-1.93	17.931	-75.0	-6.25	0.00	6.25	43.8			
										5.89	(-0.06, 11.85)	0.052A

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PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	72	74.48	26.574	12.5	56.25	75.00	100.00	100.0			
	ADA	67	74.63	23.834	12.5	50.00	75.00	100.00	100.0			
	TOT	139	74.55	25.199	12.5	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	72	67.53	30.305	0.0	50.00	75.00	100.00	100.0			
	ADA	67	73.69	27.450	0.0	50.00	75.00	100.00	100.0			
	TOT	139	70.50	29.024	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	72	-6.94	20.001	-75.0	-25.00	0.00	0.00	50.0			
	ADA	67	-0.93	21.355	-87.5	0.00	0.00	12.50	37.5			
	TOT	139	-4.05	20.809	-87.5	-12.50	0.00	0.00	50.0			
										6.01	(-0.92, 12.95)	0.089A

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PRIOR TO WEEK 6) WERE EXCLUDED.
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PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	72	84.49	23.624	0.0	79.17	95.83	100.00	100.0			
	ADA	67	85.57	21.980	16.7	75.00	100.00	100.00	100.0			
	TOT	139	85.01	22.771	0.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	72	76.45	31.260	0.0	66.67	91.67	100.00	100.0			
	ADA	67	83.46	25.438	0.0	75.00	100.00	100.00	100.0			
	TOT	139	79.83	28.716	0.0	66.67	100.00	100.00	100.0			
CHG FROM BEST*	PLO	72	-8.04	17.474	-75.0	-16.67	0.00	0.00	29.2			
	ADA	67	-2.11	15.980	-75.0	-8.33	0.00	0.00	50.0			
	TOT	139	-5.19	16.972	-75.0	-8.33	0.00	0.00	50.0			
										5.93	(0.30, 11.56)	0.039A

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PRIOR TO WEEK 6) WERE EXCLUDED.
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PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	66	71.02	28.518	0.0	50.00	83.33	91.67	100.0			
	ADA	63	73.74	24.839	0.0	58.33	83.33	91.67	100.0			
	TOT	129	72.35	26.715	0.0	58.33	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	66	62.06	32.010	0.0	33.33	75.00	83.33	100.0			
	ADA	63	71.10	27.033	0.0	58.33	75.00	91.67	100.0			
	TOT	129	66.47	29.914	0.0	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	66	-8.96	18.378	-75.0	-16.67	-2.08	0.00	33.3			
	ADA	63	-2.65	15.047	-66.7	-8.33	0.00	4.17	33.3			
	TOT	129	-5.88	17.066	-75.0	-8.33	0.00	0.00	33.3			
										6.32	(0.45, 12.19)	0.035A

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TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	72	94.79	11.821	50.0	100.00	100.00	100.00	100.0			
	ADA	67	95.90	9.331	75.0	100.00	100.00	100.00	100.0			
	TOT	139	95.32	10.670	50.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	72	92.36	16.054	50.0	100.00	100.00	100.00	100.0			
	ADA	67	92.16	16.405	25.0	100.00	100.00	100.00	100.0			
	TOT	139	92.27	16.165	25.0	100.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	72	-2.43	12.699	-50.0	0.00	0.00	0.00	25.0			
	ADA	67	-3.73	13.239	-75.0	0.00	0.00	0.00	25.0			
	TOT	139	-3.06	12.931	-75.0	0.00	0.00	0.00	25.0			
										-1.30	(-5.65, 3.05)	0.555A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	72	80.21	23.338	25.0	75.00	75.00	100.00	100.0			
	ADA	67	84.33	22.961	25.0	75.00	100.00	100.00	100.0			
	TOT	139	82.19	23.165	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	72	76.39	24.784	0.0	75.00	75.00	100.00	100.0			
	ADA	67	78.73	24.330	25.0	75.00	75.00	100.00	100.0			
	TOT	139	77.52	24.505	0.0	75.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	72	-3.82	14.929	-50.0	0.00	0.00	0.00	50.0			
	ADA	67	-5.60	18.372	-50.0	-25.00	0.00	0.00	25.0			
	TOT	139	-4.68	16.640	-50.0	0.00	0.00	0.00	50.0			
										-1.78	(-7.38, 3.82)	0.531A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
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TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	72	78.25	17.734	25.7	69.72	82.95	93.07	98.7			
	ADA	67	79.51	15.983	35.6	63.22	85.04	92.42	100.0			
	TOT	139	78.86	16.864	25.7	68.79	84.25	92.42	100.0			
FINAL/ET VALUE	PLO	72	73.47	21.110	21.1	63.64	76.63	91.12	100.0			
	ADA	67	78.50	18.508	31.2	64.09	84.55	94.58	99.4			
	TOT	139	75.89	19.986	21.1	63.67	81.52	93.07	100.0			
CHG FROM BEST*	PLO	72	-4.79	11.480	-48.0	-8.83	-1.55	2.24	19.7			
	ADA	67	-1.02	10.735	-39.0	-3.41	0.00	3.52	17.9			
	TOT	139	-2.97	11.247	-48.0	-6.97	-0.95	2.84	19.7			
										3.77	(0.03, 7.50)	0.048A

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PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	34	58.09	24.402	0.0	50.00	50.00	75.00	100.0			
	ADA	31	58.06	20.804	25.0	50.00	50.00	75.00	100.0			
	TOT	65	58.08	22.581	0.0	50.00	50.00	75.00	100.0			
FINAL/ET VALUE	PLO	34	41.91	26.629	0.0	25.00	50.00	50.00	100.0			
	ADA	31	54.84	20.836	0.0	50.00	50.00	75.00	100.0			
	TOT	65	48.08	24.728	0.0	25.00	50.00	50.00	100.0			
CHG FROM BEST*	PLO	34	-16.18	22.931	-75.0	-25.00	-25.00	0.00	25.0			
	ADA	31	-3.23	23.929	-50.0	-25.00	0.00	0.00	50.0			
	TOT	65	-10.00	24.125	-75.0	-25.00	0.00	0.00	50.0			
										12.95	(1.33, 24.57)	0.029A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	34	69.41	15.752	40.0	60.00	80.00	80.00	100.0			
	ADA	31	66.45	13.051	40.0	60.00	60.00	80.00	100.0			
	TOT	65	68.00	14.491	40.0	60.00	60.00	80.00	100.0			
FINAL/ET VALUE	PLO	34	57.06	19.153	20.0	40.00	60.00	80.00	80.0			
	ADA	31	68.06	17.967	20.0	60.00	60.00	80.00	100.0			
	TOT	65	62.31	19.265	20.0	40.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	34	-12.35	17.067	-40.0	-20.00	0.00	0.00	20.0			
	ADA	31	1.61	16.752	-40.0	0.00	0.00	20.00	40.0			
	TOT	65	-5.69	18.198	-40.0	-20.00	0.00	0.00	40.0			
										13.97	(5.57, 22.36)	0.001A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	34	84.56	15.094	50.0	75.00	87.50	100.00	100.0			
	ADA	31	83.06	20.552	25.0	62.50	100.00	100.00	100.0			
	TOT	65	83.85	17.777	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	34	69.85	26.848	12.5	50.00	75.00	100.00	100.0			
	ADA	31	79.84	20.585	50.0	62.50	75.00	100.00	100.0			
	TOT	65	74.62	24.404	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	34	-14.71	24.900	-87.5	-25.00	0.00	0.00	12.5			
	ADA	31	-3.23	14.779	-37.5	-12.50	0.00	0.00	37.5			
	TOT	65	-9.23	21.341	-87.5	-12.50	0.00	0.00	37.5			
										11.48	(1.20, 21.76)	0.029A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	34	72.30	21.973	16.7	58.33	75.00	91.67	100.0			
	ADA	31	70.16	24.793	16.7	50.00	75.00	91.67	100.0			
	TOT	65	71.28	23.200	16.7	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	34	62.50	26.132	16.7	33.33	62.50	83.33	100.0			
	ADA	31	69.89	23.341	25.0	50.00	75.00	91.67	100.0			
	TOT	65	66.03	24.926	16.7	50.00	66.67	91.67	100.0			
CHG FROM BEST*	PLO	34	-9.80	17.099	-50.0	-25.00	-8.33	0.00	25.0			
	ADA	31	-0.27	15.288	-25.0	-8.33	0.00	0.00	50.0			
	TOT	65	-5.26	16.833	-50.0	-8.33	-8.33	0.00	50.0			
										9.54	(1.47, 17.61)	0.021A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	34	74.14	23.521	25.0	50.00	79.17	91.67	100.0			
	ADA	31	74.73	20.804	41.7	58.33	83.33	91.67	100.0			
	TOT	65	74.42	22.096	25.0	58.33	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	34	63.36	28.497	16.7	41.67	66.67	91.67	100.0			
	ADA	31	73.66	20.982	33.3	58.33	75.00	91.67	100.0			
	TOT	65	68.27	25.534	16.7	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	34	-10.78	14.975	-50.0	-16.67	-8.33	0.00	25.0			
	ADA	31	-1.08	11.127	-25.0	-8.33	0.00	0.00	25.0			
	TOT	65	-6.15	14.055	-50.0	-8.33	-8.33	0.00	25.0			
										9.71	(3.12, 16.30)	0.005A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	34	86.03	19.160	25.0	75.00	100.00	100.00	100.0			
	ADA	31	89.11	15.726	50.0	75.00	100.00	100.00	100.0			
	TOT	65	87.50	17.539	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	34	76.10	24.496	12.5	50.00	81.25	100.00	100.0			
	ADA	31	85.48	20.181	25.0	75.00	100.00	100.00	100.0			
	TOT	65	80.58	22.861	12.5	75.00	87.50	100.00	100.0			
CHG FROM BEST*	PLO	34	-9.93	19.163	-62.5	-25.00	0.00	0.00	25.0			
	ADA	31	-3.63	11.270	-25.0	-12.50	0.00	0.00	25.0			
	TOT	65	-6.92	16.092	-62.5	-12.50	0.00	0.00	25.0			
										6.30	(-1.59, 14.19)	0.116A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	34	63.79	25.828	0.0	50.00	65.63	81.25	100.0			
	ADA	31	66.33	21.021	25.0	50.00	68.75	87.50	93.8			
	TOT	65	65.00	23.510	0.0	50.00	68.75	87.50	100.0			
FINAL/ET VALUE	PLO	34	55.82	30.579	0.0	31.25	56.25	87.50	100.0			
	ADA	31	69.29	23.017	25.0	56.25	68.75	87.50	100.0			
	TOT	65	62.24	27.865	0.0	37.50	68.75	87.50	100.0			
CHG FROM BEST*	PLO	34	-7.97	20.924	-58.3	-12.50	-3.13	6.25	25.0			
	ADA	31	2.96	14.168	-25.0	-6.25	0.00	12.50	43.8			
	TOT	65	-2.76	18.711	-58.3	-12.50	0.00	6.25	43.8			
										10.92	(1.98, 19.87)	0.018A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	34	69.49	25.036	12.5	50.00	75.00	87.50	100.0			
	ADA	31	68.55	27.551	0.0	50.00	75.00	100.00	100.0			
	TOT	65	69.04	26.062	0.0	50.00	75.00	87.50	100.0			
FINAL/ET VALUE	PLO	34	58.09	29.975	0.0	37.50	50.00	87.50	100.0			
	ADA	31	63.71	30.848	0.0	50.00	62.50	100.00	100.0			
	TOT	65	60.77	30.288	0.0	37.50	50.00	87.50	100.0			
CHG FROM BEST*	PLO	34	-11.40	23.104	-75.0	-25.00	-12.50	0.00	50.0			
	ADA	31	-4.84	21.330	-62.5	-12.50	0.00	0.00	37.5			
	TOT	65	-8.27	22.347	-75.0	-25.00	0.00	0.00	50.0			
										6.56	(-4.50, 17.61)	0.240A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	34	78.92	27.921	0.0	66.67	91.67	100.00	100.0			
	ADA	31	82.53	25.672	0.0	66.67	100.00	100.00	100.0			
	TOT	65	80.64	26.725	0.0	66.67	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	34	66.79	35.243	0.0	33.33	75.00	100.00	100.0			
	ADA	31	83.60	23.122	16.7	66.67	100.00	100.00	100.0			
	TOT	65	74.81	31.027	0.0	50.00	91.67	100.00	100.0			
CHG FROM BEST*	PLO	34	-12.13	27.493	-75.0	-25.00	0.00	0.00	50.0			
	ADA	31	1.08	16.064	-25.0	0.00	0.00	8.33	58.3			
	TOT	65	-5.83	23.556	-75.0	-16.67	0.00	0.00	58.3			
										13.21	(1.90, 24.51)	0.023A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	29	59.48	35.755	0.0	33.33	75.00	91.67	100.0			
	ADA	28	70.83	25.509	16.7	50.00	83.33	91.67	100.0			
	TOT	57	65.06	31.396	0.0	41.67	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	29	43.25	37.374	0.0	0.00	50.00	75.00	100.0			
	ADA	28	63.24	26.861	0.0	41.67	64.58	83.33	100.0			
	TOT	57	53.07	33.882	0.0	25.00	58.33	83.33	100.0			
CHG FROM BEST*	PLO	29	-16.24	18.910	-58.3	-33.33	-8.33	0.00	0.0			
	ADA	28	-7.59	14.525	-41.7	-16.67	-8.33	0.00	25.0			
	TOT	57	-11.99	17.307	-58.3	-16.67	-8.33	0.00	25.0			
										8.65	(-0.33, 17.62)	0.059A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	34	92.65	13.098	50.0	75.00	100.00	100.00	100.0			
	ADA	31	91.94	13.520	50.0	75.00	100.00	100.00	100.0			
	TOT	65	92.31	13.201	50.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	34	89.34	17.444	50.0	75.00	100.00	100.00	100.0			
	ADA	31	91.94	11.880	75.0	75.00	100.00	100.00	100.0			
	TOT	65	90.58	14.992	50.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	34	-3.31	10.348	-25.0	0.00	0.00	0.00	25.0			
	ADA	31	0.00	12.910	-25.0	0.00	0.00	0.00	25.0			
	TOT	65	-1.73	11.667	-25.0	0.00	0.00	0.00	25.0			
										3.31	(-2.47, 9.08)	0.257A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	34	79.78	23.839	25.0	62.50	87.50	100.00	100.0			
	ADA	31	80.65	24.757	25.0	50.00	100.00	100.00	100.0			
	TOT	65	80.19	24.094	25.0	62.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	34	72.79	27.085	25.0	50.00	75.00	100.00	100.0			
	ADA	31	76.61	24.946	25.0	50.00	75.00	100.00	100.0			
	TOT	65	74.62	25.955	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	34	-6.99	19.265	-75.0	0.00	0.00	0.00	25.0			
	ADA	31	-4.03	18.368	-50.0	-25.00	0.00	0.00	25.0			
	TOT	65	-5.58	18.754	-75.0	0.00	0.00	0.00	25.0			
										2.95	(-6.40, 12.30)	0.530A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	34	73.53	19.423	25.7	58.94	74.54	89.85	98.7			
	ADA	31	74.40	17.870	31.5	60.19	80.19	88.41	99.4			
	TOT	65	73.94	18.558	25.7	60.19	74.58	89.17	99.4			
FINAL/ET VALUE	PLO	34	65.33	22.193	21.1	50.27	64.53	86.89	98.0			
	ADA	31	75.18	17.745	44.8	59.05	79.24	91.17	99.4			
	TOT	65	70.03	20.642	21.1	51.86	70.72	90.04	99.4			
CHG FROM BEST*	PLO	34	-8.19	14.233	-48.0	-17.16	-3.24	1.14	9.6			
	ADA	31	0.78	8.551	-22.9	-3.41	-0.45	8.79	17.9			
	TOT	65	-3.92	12.615	-48.0	-8.37	-1.33	2.39	17.9			
										8.97	(3.08, 14.86)	0.003A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	76	67.11	22.064	25.0	50.00	75.00	75.00	100.0			
	ADA	78	65.38	19.833	25.0	50.00	75.00	75.00	100.0			
	TOT	154	66.23	20.913	25.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	76	52.63	26.950	0.0	37.50	50.00	75.00	100.0			
	ADA	78	54.17	24.314	0.0	50.00	50.00	75.00	100.0			
	TOT	154	53.41	25.576	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	76	-14.47	20.922	-100.0	-25.00	-12.50	0.00	25.0			
	ADA	78	-11.22	23.371	-100.0	-25.00	0.00	0.00	25.0			
	TOT	154	-12.82	22.184	-100.0	-25.00	0.00	0.00	25.0			
										3.26	(-3.81, 10.32)	0.364A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	76	72.63	15.264	40.0	60.00	80.00	80.00	100.0			
	ADA	77	70.52	15.209	20.0	60.00	80.00	80.00	100.0			
	TOT	153	71.57	15.223	20.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	76	63.95	21.421	20.0	60.00	60.00	80.00	100.0			
	ADA	77	63.64	19.662	20.0	60.00	60.00	80.00	100.0			
	TOT	153	63.79	20.488	20.0	60.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	76	-8.68	18.857	-60.0	-20.00	0.00	0.00	20.0			
	ADA	77	-6.88	16.243	-60.0	-20.00	0.00	0.00	20.0			
	TOT	153	-7.78	17.555	-60.0	-20.00	0.00	0.00	20.0			
										1.80	(-3.82, 7.42)	0.528A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	76	85.03	16.835	37.5	75.00	87.50	100.00	100.0			
	ADA	78	84.46	16.757	25.0	75.00	87.50	100.00	100.0			
	TOT	154	84.74	16.743	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	76	73.68	23.146	12.5	62.50	75.00	100.00	100.0			
	ADA	78	80.77	20.013	25.0	62.50	87.50	100.00	100.0			
	TOT	154	77.27	21.836	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	76	-11.35	18.839	-62.5	-25.00	-6.25	0.00	25.0			
	ADA	78	-3.69	16.626	-75.0	-12.50	0.00	0.00	25.0			
	TOT	154	-7.47	18.107	-75.0	-12.50	0.00	0.00	25.0			
										7.66	(2.01, 13.32)	0.008A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	76	77.36	20.142	25.0	66.67	79.17	100.00	100.0			
	ADA	78	75.59	22.927	16.7	58.33	75.00	100.00	100.0			
	TOT	154	76.46	21.546	16.7	66.67	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	76	70.67	25.544	8.3	50.00	75.00	91.67	100.0			
	ADA	78	70.78	24.568	16.7	50.00	75.00	100.00	100.0			
	TOT	154	70.73	24.973	8.3	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	76	-6.69	18.144	-66.7	-16.67	-4.17	0.00	41.7			
	ADA	78	-4.81	16.869	-66.7	-8.33	0.00	0.00	25.0			
	TOT	154	-5.74	17.478	-66.7	-8.33	0.00	0.00	41.7			
										1.88	(-3.69, 7.46)	0.506A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	76	77.41	19.899	16.7	66.67	83.33	91.67	100.0			
	ADA	78	75.21	22.692	12.5	62.50	75.00	100.00	100.0			
	TOT	154	76.30	21.318	12.5	62.50	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	76	73.96	24.973	8.3	58.33	75.00	100.00	100.0			
	ADA	78	69.47	27.124	16.7	43.75	75.00	91.67	100.0			
	TOT	154	71.69	26.097	8.3	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	76	-3.45	13.834	-37.5	-8.33	0.00	2.08	41.7			
	ADA	78	-5.74	14.675	-66.7	-8.33	0.00	0.00	16.7			
	TOT	154	-4.61	14.266	-66.7	-8.33	0.00	0.00	41.7			
										-2.29	(-6.83, 2.25)	0.321A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	76	89.64	17.487	37.5	87.50	100.00	100.00	100.0			
	ADA	78	87.50	20.045	25.0	75.00	100.00	100.00	100.0			
	TOT	154	88.56	18.795	25.0	87.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	76	84.54	23.351	12.5	75.00	100.00	100.00	100.0			
	ADA	78	81.81	22.974	12.5	75.00	87.50	100.00	100.0			
	TOT	154	83.16	23.125	12.5	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	76	-5.10	13.720	-50.0	-12.50	0.00	0.00	37.5			
	ADA	78	-5.69	13.596	-50.0	-12.50	0.00	0.00	37.5			
	TOT	154	-5.40	13.616	-50.0	-12.50	0.00	0.00	37.5			
										-0.59	(-4.94, 3.76)	0.789A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	76	71.22	23.432	6.3	59.38	75.00	87.50	100.0			
	ADA	78	67.49	24.717	0.0	50.00	75.00	87.50	100.0			
	TOT	154	69.33	24.085	0.0	50.00	75.00	87.50	100.0			
FINAL/ET VALUE	PLO	76	67.13	27.805	0.0	56.25	75.00	90.63	100.0			
	ADA	78	65.87	27.488	0.0	43.75	71.88	93.75	100.0			
	TOT	154	66.49	27.561	0.0	50.00	75.00	93.75	100.0			
CHG FROM BEST*	PLO	76	-4.08	16.827	-75.0	-9.38	0.00	6.25	31.3			
	ADA	78	-1.63	17.381	-62.5	-6.25	0.00	6.25	31.3			
	TOT	154	-2.84	17.098	-75.0	-6.25	0.00	6.25	31.3			
										2.46	(-2.99, 7.90)	0.375A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	76	73.68	26.893	12.5	50.00	75.00	100.00	100.0			
	ADA	78	71.63	25.135	0.0	50.00	75.00	100.00	100.0			
	TOT	154	72.65	25.953	0.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	76	66.78	30.315	0.0	50.00	75.00	100.00	100.0			
	ADA	78	68.91	30.866	0.0	50.00	75.00	100.00	100.0			
	TOT	154	67.86	30.514	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	76	-6.91	17.724	-50.0	-25.00	0.00	0.00	37.5			
	ADA	78	-2.72	24.726	-87.5	0.00	0.00	12.50	50.0			
	TOT	154	-4.79	21.589	-87.5	-12.50	0.00	0.00	50.0			
										4.18	(-2.68, 11.05)	0.230A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	76	83.77	23.684	0.0	75.00	91.67	100.00	100.0			
	ADA	78	82.16	24.645	0.0	66.67	95.83	100.00	100.0			
	TOT	154	82.95	24.110	0.0	75.00	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	76	77.85	28.204	0.0	66.67	91.67	100.00	100.0			
	ADA	78	77.46	29.581	0.0	58.33	91.67	100.00	100.0			
	TOT	154	77.65	28.816	0.0	66.67	91.67	100.00	100.0			
CHG FROM BEST*	PLO	76	-5.92	13.998	-50.0	-8.33	0.00	0.00	16.7			
	ADA	78	-4.70	18.783	-75.0	-8.33	0.00	0.00	50.0			
	TOT	154	-5.30	16.552	-75.0	-8.33	0.00	0.00	50.0			
										1.22	(-4.06, 6.50)	0.649A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	70	70.65	28.626	0.0	58.33	79.17	91.67	100.0			
	ADA	71	65.14	31.278	0.0	41.67	75.00	91.67	100.0			
	TOT	141	67.88	30.011	0.0	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	70	64.40	29.893	0.0	41.67	75.00	83.33	100.0			
	ADA	71	61.62	34.112	0.0	41.67	75.00	83.33	100.0			
	TOT	141	63.00	32.003	0.0	41.67	75.00	83.33	100.0			
CHG FROM BEST*	PLO	70	-6.25	20.483	-75.0	-16.67	0.00	0.00	50.0			
	ADA	71	-3.52	16.147	-66.7	-8.33	0.00	0.00	50.0			
	TOT	141	-4.88	18.413	-75.0	-8.33	0.00	0.00	50.0			
										2.73	(-3.41, 8.87)	0.381A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	76	95.07	12.261	50.0	100.00	100.00	100.00	100.0			
	ADA	78	93.91	12.859	25.0	100.00	100.00	100.00	100.0			
	TOT	154	94.48	12.540	25.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	76	92.43	15.822	25.0	100.00	100.00	100.00	100.0			
	ADA	78	88.46	19.193	25.0	75.00	100.00	100.00	100.0			
	TOT	154	90.42	17.666	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	76	-2.63	12.635	-50.0	0.00	0.00	0.00	25.0			
	ADA	78	-5.45	16.439	-75.0	0.00	0.00	0.00	25.0			
	TOT	154	-4.06	14.706	-75.0	0.00	0.00	0.00	25.0			
										-2.82	(-7.49, 1.86)	0.236A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	76	80.59	22.211	25.0	75.00	75.00	100.00	100.0			
	ADA	77	79.87	23.311	25.0	75.00	75.00	100.00	100.0			
	TOT	153	80.23	22.699	25.0	75.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	76	75.66	24.143	0.0	75.00	75.00	100.00	100.0			
	ADA	77	73.38	26.388	25.0	50.00	75.00	100.00	100.0			
	TOT	153	74.51	25.241	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	76	-4.93	15.286	-25.0	-25.00	0.00	0.00	50.0			
	ADA	77	-6.49	17.864	-50.0	-25.00	0.00	0.00	25.0			
	TOT	153	-5.72	16.597	-50.0	-25.00	0.00	0.00	50.0			
										-1.56	(-6.87, 3.75)	0.563A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	76	77.88	16.580	39.2	65.34	82.52	92.97	98.3			
	ADA	78	75.38	18.401	14.7	60.79	79.30	91.74	100.0			
	TOT	154	76.61	17.514	14.7	62.77	81.46	91.82	100.0			
FINAL/ET VALUE	PLO	76	73.81	20.114	27.0	63.50	76.63	90.32	100.0			
	ADA	78	72.72	21.191	18.5	57.16	74.65	92.69	99.2			
	TOT	154	73.26	20.606	18.5	61.46	76.40	91.17	100.0			
CHG FROM BEST*	PLO	76	-4.07	10.549	-37.7	-8.86	-1.70	2.46	20.6			
	ADA	78	-2.66	11.640	-39.0	-6.82	-0.36	3.22	25.8			
	TOT	154	-3.35	11.102	-39.0	-7.69	-1.14	2.84	25.8			
										1.41	(-2.13, 4.95)	0.431A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	41	57.93	24.647	0.0	50.00	50.00	75.00	100.0			
	ADA	37	61.49	20.912	25.0	50.00	50.00	75.00	100.0			
	TOT	78	59.62	22.874	0.0	50.00	50.00	75.00	100.0			
FINAL/ET VALUE	PLO	41	42.07	27.635	0.0	25.00	50.00	50.00	100.0			
	ADA	37	51.35	22.781	0.0	50.00	50.00	75.00	100.0			
	TOT	78	46.47	25.712	0.0	25.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	41	-15.85	23.556	-75.0	-25.00	-25.00	0.00	25.0			
	ADA	37	-10.14	21.618	-50.0	-25.00	0.00	0.00	50.0			
	TOT	78	-13.14	22.694	-75.0	-25.00	0.00	0.00	50.0			
										5.72	(-4.51, 15.95)	0.269A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	41	69.27	15.555	40.0	60.00	80.00	80.00	100.0			
	ADA	36	66.67	15.119	40.0	60.00	80.00	80.00	100.0			
	TOT	77	68.05	15.307	40.0	60.00	60.00	80.00	100.0			
FINAL/ET VALUE	PLO	41	59.02	21.425	20.0	40.00	60.00	80.00	100.0			
	ADA	36	58.33	20.494	20.0	40.00	60.00	80.00	100.0			
	TOT	77	58.70	20.860	20.0	40.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	41	-10.24	18.505	-60.0	-20.00	0.00	0.00	20.0			
	ADA	36	-8.33	21.044	-60.0	-20.00	0.00	0.00	40.0			
	TOT	77	-9.35	19.624	-60.0	-20.00	0.00	0.00	40.0			
										1.91	(-7.07, 10.89)	0.673A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	41	82.62	18.303	37.5	62.50	87.50	100.00	100.0			
	ADA	37	86.82	17.664	25.0	75.00	100.00	100.00	100.0			
	TOT	78	84.62	18.010	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	41	68.60	24.705	12.5	50.00	75.00	87.50	100.0			
	ADA	37	80.07	18.741	25.0	75.00	75.00	100.00	100.0			
	TOT	78	74.04	22.682	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-14.02	19.605	-87.5	-25.00	-12.50	0.00	12.5			
	ADA	37	-6.76	21.163	-75.0	-25.00	0.00	0.00	37.5			
	TOT	78	-10.58	20.552	-87.5	-25.00	-6.25	0.00	37.5			
										7.27	(-1.93, 16.46)	0.120A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	41	72.76	22.128	16.7	58.33	75.00	91.67	100.0			
	ADA	37	72.52	24.601	16.7	50.00	75.00	91.67	100.0			
	TOT	78	72.65	23.180	16.7	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	41	63.62	28.732	8.3	33.33	66.67	91.67	100.0			
	ADA	37	68.13	22.357	25.0	50.00	66.67	83.33	100.0			
	TOT	78	65.76	25.840	8.3	50.00	66.67	91.67	100.0			
CHG FROM BEST*	PLO	41	-9.15	20.481	-66.7	-16.67	-8.33	0.00	25.0			
	ADA	37	-4.39	19.393	-58.3	-8.33	0.00	0.00	50.0			
	TOT	78	-6.89	19.986	-66.7	-8.33	-2.08	0.00	50.0			
										4.75	(-4.27, 13.77)	0.297A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	41	73.58	23.563	25.0	50.00	83.33	91.67	100.0			
	ADA	37	72.41	21.094	33.3	58.33	75.00	91.67	100.0			
	TOT	78	73.02	22.289	25.0	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	41	66.36	28.993	16.7	41.67	75.00	91.67	100.0			
	ADA	37	66.50	26.336	25.0	43.75	66.67	91.67	100.0			
	TOT	78	66.43	27.585	16.7	41.67	75.00	91.67	100.0			
CHG FROM BEST*	PLO	41	-7.22	13.406	-50.0	-8.33	-8.33	0.00	16.7			
	ADA	37	-5.91	15.368	-50.0	-16.67	0.00	0.00	25.0			
	TOT	78	-6.60	14.290	-50.0	-16.67	0.00	0.00	25.0			
										1.30	(-5.19, 7.79)	0.690A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	41	83.54	21.184	25.0	75.00	100.00	100.00	100.0			
	ADA	37	86.15	18.348	50.0	75.00	100.00	100.00	100.0			
	TOT	78	84.78	19.805	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	74.70	28.158	12.5	50.00	87.50	100.00	100.0			
	ADA	37	79.56	23.692	25.0	62.50	87.50	100.00	100.0			
	TOT	78	77.00	26.082	12.5	62.50	87.50	100.00	100.0			
CHG FROM BEST*	PLO	41	-8.84	17.058	-62.5	-12.50	0.00	0.00	25.0			
	ADA	37	-6.59	15.999	-50.0	-12.50	0.00	0.00	37.5			
	TOT	78	-7.77	16.496	-62.5	-12.50	0.00	0.00	37.5			
										2.25	(-5.23, 9.73)	0.550A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	41	63.26	28.682	0.0	43.75	68.75	87.50	100.0			
	ADA	37	65.54	24.189	18.8	50.00	68.75	87.50	100.0			
	TOT	78	64.34	26.499	0.0	43.75	68.75	87.50	100.0			
FINAL/ET VALUE	PLO	41	54.32	33.684	0.0	25.00	56.25	83.33	100.0			
	ADA	37	64.13	29.590	6.3	37.50	68.75	93.75	100.0			
	TOT	78	58.97	31.986	0.0	31.25	62.50	87.50	100.0			
CHG FROM BEST*	PLO	41	-8.94	19.891	-75.0	-12.50	-6.25	0.00	25.0			
	ADA	37	-1.41	20.259	-62.5	-12.50	0.00	6.25	43.8			
	TOT	78	-5.37	20.292	-75.0	-12.50	-1.04	6.25	43.8			
										7.54	(-1.53, 16.60)	0.102A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	41	67.99	27.393	12.5	50.00	75.00	100.00	100.0			
	ADA	37	69.26	27.258	0.0	50.00	75.00	100.00	100.0			
	TOT	78	68.59	27.159	0.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	58.23	32.066	0.0	37.50	50.00	87.50	100.0			
	ADA	37	67.91	32.078	0.0	50.00	75.00	100.00	100.0			
	TOT	78	62.82	32.231	0.0	37.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-9.76	21.743	-50.0	-25.00	0.00	0.00	50.0			
	ADA	37	-1.35	27.605	-87.5	-12.50	0.00	12.50	50.0			
	TOT	78	-5.77	24.894	-87.5	-25.00	0.00	0.00	50.0			
										8.40	(-2.75, 19.56)	0.137A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	41	74.39	31.917	0.0	50.00	91.67	100.00	100.0			
	ADA	37	78.60	26.024	0.0	66.67	91.67	100.00	100.0			
	TOT	78	76.39	29.160	0.0	58.33	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	41	68.19	37.031	0.0	33.33	91.67	100.00	100.0			
	ADA	37	74.10	31.043	0.0	58.33	91.67	100.00	100.0			
	TOT	78	70.99	34.231	0.0	41.67	91.67	100.00	100.0			
CHG FROM BEST*	PLO	41	-6.20	21.064	-66.7	-16.67	0.00	0.00	50.0			
	ADA	37	-4.50	20.656	-75.0	-16.67	0.00	0.00	33.3			
	TOT	78	-5.40	20.753	-75.0	-16.67	0.00	0.00	50.0			
										1.69	(-7.73, 11.12)	0.721A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	38	62.17	35.387	0.0	41.67	70.83	91.67	100.0			
	ADA	31	60.35	31.894	0.0	41.67	66.67	91.67	100.0			
	TOT	69	61.35	33.630	0.0	41.67	66.67	91.67	100.0			
FINAL/ET VALUE	PLO	38	55.48	39.244	0.0	0.00	58.33	91.67	100.0			
	ADA	31	59.27	32.733	0.0	33.33	66.67	83.33	100.0			
	TOT	69	57.19	36.253	0.0	33.33	66.67	83.33	100.0			
CHG FROM BEST*	PLO	38	-6.69	22.250	-75.0	-16.67	0.00	0.00	50.0			
	ADA	31	-1.08	17.611	-50.0	-8.33	0.00	8.33	50.0			
	TOT	69	-4.17	20.350	-75.0	-12.50	0.00	0.00	50.0			
										5.61	(-4.20, 15.42)	0.257A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	41	92.68	13.969	50.0	100.00	100.00	100.00	100.0			
	ADA	37	92.57	12.997	50.0	75.00	100.00	100.00	100.0			
	TOT	78	92.63	13.429	50.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	88.11	19.355	25.0	75.00	100.00	100.00	100.0			
	ADA	37	88.51	19.180	50.0	75.00	100.00	100.00	100.0			
	TOT	78	88.30	19.148	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-4.57	12.424	-50.0	0.00	0.00	0.00	25.0			
	ADA	37	-4.05	15.039	-50.0	0.00	0.00	0.00	25.0			
	TOT	78	-4.33	13.638	-50.0	0.00	0.00	0.00	25.0			
										0.52	(-5.68, 6.72)	0.868A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	41	78.35	23.556	25.0	50.00	75.00	100.00	100.0			
	ADA	37	77.70	22.657	25.0	75.00	75.00	100.00	100.0			
	TOT	78	78.04	22.986	25.0	75.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	71.95	27.497	25.0	50.00	75.00	100.00	100.0			
	ADA	37	71.62	26.459	25.0	50.00	75.00	100.00	100.0			
	TOT	78	71.79	26.835	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-6.40	16.086	-75.0	0.00	0.00	0.00	25.0			
	ADA	37	-6.08	19.900	-50.0	-25.00	0.00	0.00	25.0			
	TOT	78	-6.25	17.877	-75.0	-25.00	0.00	0.00	25.0			
										0.32	(-7.81, 8.45)	0.937A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	41	72.35	19.746	25.7	54.96	72.80	90.38	98.7			
	ADA	37	72.84	18.207	31.5	59.73	73.71	88.98	98.2			
	TOT	78	72.58	18.910	25.7	57.05	73.09	90.38	98.7			
FINAL/ET VALUE	PLO	41	66.09	23.729	21.1	43.79	70.04	87.65	100.0			
	ADA	37	70.47	21.046	29.7	49.77	71.55	91.17	98.2			
	TOT	78	68.17	22.459	21.1	48.03	71.21	90.23	100.0			
CHG FROM BEST*	PLO	41	-6.26	12.588	-44.4	-9.51	-1.52	2.54	11.7			
	ADA	37	-2.37	13.694	-39.0	-7.39	-2.65	4.36	25.8			
	TOT	78	-4.41	13.184	-44.4	-9.02	-1.86	2.92	25.8			
										3.89	(-2.04, 9.82)	0.195A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	69	68.12	21.388	25.0	50.00	75.00	75.00	100.0			
	ADA	72	64.24	20.047	25.0	50.00	50.00	75.00	100.0			
	TOT	141	66.13	20.731	25.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	69	53.62	26.176	0.0	50.00	50.00	75.00	100.0			
	ADA	72	55.90	23.547	0.0	50.00	50.00	75.00	100.0			
	TOT	141	54.79	24.805	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	69	-14.49	20.295	-100.0	-25.00	-25.00	0.00	25.0			
	ADA	72	-8.33	24.823	-100.0	-25.00	0.00	0.00	50.0			
	TOT	141	-11.35	22.850	-100.0	-25.00	0.00	0.00	50.0			
										6.16	(-1.41, 13.73)	0.110A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	69	73.04	15.272	40.0	60.00	80.00	80.00	100.0			
	ADA	72	70.69	14.372	20.0	60.00	80.00	80.00	100.0			
	TOT	141	71.84	14.813	20.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	69	63.48	20.567	20.0	40.00	60.00	80.00	100.0			
	ADA	72	68.19	17.788	20.0	60.00	70.00	80.00	100.0			
	TOT	141	65.89	19.275	20.0	60.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	69	-9.57	18.346	-60.0	-20.00	0.00	0.00	20.0			
	ADA	72	-2.50	13.916	-40.0	-10.00	0.00	0.00	30.0			
	TOT	141	-5.96	16.561	-60.0	-20.00	0.00	0.00	30.0			
										7.07	(1.66, 12.47)	0.011A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	69	86.23	14.875	37.5	75.00	87.50	100.00	100.0			
	ADA	72	82.64	17.870	25.0	62.50	87.50	100.00	100.0			
	TOT	141	84.40	16.513	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	69	74.82	23.919	12.5	62.50	75.00	100.00	100.0			
	ADA	72	80.73	20.868	25.0	62.50	87.50	100.00	100.0			
	TOT	141	77.84	22.528	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	69	-11.41	21.623	-75.0	-25.00	0.00	0.00	25.0			
	ADA	72	-1.91	12.528	-37.5	-12.50	0.00	0.00	25.0			
	TOT	141	-6.56	18.150	-75.0	-12.50	0.00	0.00	25.0			
										9.50	(3.65, 15.36)	0.002A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	69	77.60	19.843	25.0	66.67	75.00	100.00	100.0			
	ADA	72	74.83	23.029	16.7	54.17	75.00	100.00	100.0			
	TOT	141	76.18	21.497	16.7	66.67	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	69	70.83	23.850	16.7	50.00	75.00	91.67	100.0			
	ADA	72	71.76	25.041	16.7	50.00	75.00	100.00	100.0			
	TOT	141	71.31	24.383	16.7	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	69	-6.76	16.107	-50.0	-16.67	-8.33	0.00	41.7			
	ADA	72	-3.07	14.917	-66.7	-8.33	0.00	0.00	25.0			
	TOT	141	-4.88	15.566	-66.7	-8.33	0.00	0.00	41.7			
										3.70	(-1.47, 8.86)	0.159A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	69	78.08	19.355	16.7	66.67	83.33	91.67	100.0			
	ADA	72	76.45	22.587	12.5	60.42	83.33	100.00	100.0			
	TOT	141	77.25	21.008	12.5	66.67	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	69	73.25	24.665	8.3	58.33	83.33	91.67	100.0			
	ADA	72	72.80	24.980	16.7	58.33	75.00	91.67	100.0			
	TOT	141	73.02	24.739	8.3	58.33	75.00	91.67	100.0			
CHG FROM BEST*	PLO	69	-4.83	15.186	-50.0	-16.67	0.00	0.00	41.7			
	ADA	72	-3.65	13.082	-66.7	-8.33	0.00	0.00	16.7			
	TOT	141	-4.23	14.112	-66.7	-8.33	0.00	0.00	41.7			
										1.19	(-3.53, 5.90)	0.620A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	69	91.49	15.233	37.5	87.50	100.00	100.00	100.0			
	ADA	72	88.89	19.177	25.0	87.50	100.00	100.00	100.0			
	TOT	141	90.16	17.347	25.0	87.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	69	86.23	20.012	25.0	75.00	100.00	100.00	100.0			
	ADA	72	84.55	21.343	12.5	75.00	100.00	100.00	100.0			
	TOT	141	85.37	20.646	12.5	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	69	-5.25	14.760	-50.0	-12.50	0.00	0.00	37.5			
	ADA	72	-4.34	11.133	-50.0	-12.50	0.00	0.00	12.5			
	TOT	141	-4.79	12.995	-50.0	-12.50	0.00	0.00	37.5			
										0.91	(-3.43, 5.25)	0.678A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	69	72.28	20.825	18.8	62.50	75.00	87.50	100.0			
	ADA	72	68.00	23.472	0.0	50.00	75.00	87.50	100.0			
	TOT	141	70.09	22.241	0.0	56.25	75.00	87.50	100.0			
FINAL/ET VALUE	PLO	69	69.17	24.491	16.7	56.25	75.00	87.50	100.0			
	ADA	72	68.23	24.438	0.0	56.25	71.88	87.50	100.0			
	TOT	141	68.69	24.381	0.0	56.25	75.00	87.50	100.0			
CHG FROM BEST*	PLO	69	-3.11	16.863	-58.3	-6.25	0.00	6.25	31.3			
	ADA	72	0.23	14.491	-43.8	-6.25	0.00	6.25	31.3			
	TOT	141	-1.40	15.730	-58.3	-6.25	0.00	6.25	31.3			
										3.34	(-1.89, 8.57)	0.208A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	69	75.00	25.455	25.0	62.50	75.00	100.00	100.0			
	ADA	72	71.53	25.107	0.0	50.00	75.00	100.00	100.0			
	TOT	141	73.23	25.248	0.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	69	67.57	28.946	0.0	50.00	75.00	100.00	100.0			
	ADA	72	67.19	30.361	0.0	50.00	75.00	100.00	100.0			
	TOT	141	67.38	29.572	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	69	-7.43	18.230	-75.0	-12.50	0.00	0.00	37.5			
	ADA	72	-4.34	21.616	-75.0	-12.50	0.00	0.00	37.5			
	TOT	141	-5.85	20.020	-75.0	-12.50	0.00	0.00	37.5			
										3.09	(-3.59, 9.76)	0.362A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	69	86.96	18.605	25.0	83.33	91.67	100.00	100.0			
	ADA	72	84.14	24.151	0.0	70.83	100.00	100.00	100.0			
	TOT	141	85.52	21.585	0.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	69	78.14	26.044	8.3	66.67	83.33	100.00	100.0			
	ADA	72	81.83	26.028	0.0	70.83	100.00	100.00	100.0			
	TOT	141	80.02	26.009	0.0	66.67	91.67	100.00	100.0			
CHG FROM BEST*	PLO	69	-8.82	18.240	-75.0	-16.67	0.00	0.00	16.7			
	ADA	72	-2.31	16.855	-66.7	0.00	0.00	0.00	58.3			
	TOT	141	-5.50	17.785	-75.0	-8.33	0.00	0.00	58.3			
										6.50	(0.66, 12.35)	0.029A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	61	70.63	27.955	0.0	50.00	83.33	91.67	100.0			
	ADA	68	69.67	28.478	0.0	50.00	83.33	91.67	100.0			
	TOT	129	70.12	28.126	0.0	50.00	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	61	59.90	29.582	0.0	37.50	66.67	83.33	100.0			
	ADA	68	63.36	31.973	0.0	41.67	75.00	83.33	100.0			
	TOT	129	61.72	30.794	0.0	41.67	75.00	83.33	100.0			
CHG FROM BEST*	PLO	61	-10.72	19.282	-58.3	-16.67	-8.33	0.00	33.3			
	ADA	68	-6.31	14.656	-66.7	-8.33	0.00	0.00	33.3			
	TOT	129	-8.40	17.077	-66.7	-16.67	-8.33	0.00	33.3			
										4.41	(-1.52, 10.34)	0.143A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	69	95.29	11.565	50.0	100.00	100.00	100.00	100.0			
	ADA	72	93.75	13.102	25.0	100.00	100.00	100.00	100.0			
	TOT	141	94.50	12.353	25.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	69	93.48	13.993	50.0	100.00	100.00	100.00	100.0			
	ADA	72	89.93	16.604	25.0	75.00	100.00	100.00	100.0			
	TOT	141	91.67	15.430	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	69	-1.81	11.599	-50.0	0.00	0.00	0.00	25.0			
	ADA	72	-3.82	16.065	-75.0	0.00	0.00	0.00	25.0			
	TOT	141	-2.84	14.045	-75.0	0.00	0.00	0.00	25.0			
										-2.01	(-6.69, 2.68)	0.398A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	69	81.52	22.134	25.0	75.00	75.00	100.00	100.0			
	ADA	71	81.34	24.171	25.0	75.00	100.00	100.00	100.0			
	TOT	140	81.43	23.107	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	69	76.45	23.438	0.0	75.00	75.00	100.00	100.0			
	ADA	71	75.70	25.695	25.0	50.00	75.00	100.00	100.0			
	TOT	140	76.07	24.523	0.0	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	69	-5.07	16.923	-50.0	-25.00	0.00	0.00	50.0			
	ADA	71	-5.63	17.007	-50.0	-25.00	0.00	0.00	25.0			
	TOT	140	-5.36	16.907	-50.0	-25.00	0.00	0.00	50.0			
										-0.56	(-6.23, 5.11)	0.845A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	69	79.03	15.703	39.1	70.04	81.97	91.93	98.3			
	ADA	72	76.26	18.175	14.7	62.90	82.41	91.78	100.0			
	TOT	141	77.62	17.007	14.7	66.06	82.08	91.82	100.0			
FINAL/ET VALUE	PLO	69	74.22	18.811	27.0	64.05	75.64	90.04	100.0			
	ADA	72	74.94	19.761	18.5	60.80	81.78	92.41	99.4			
	TOT	141	74.59	19.236	18.5	63.41	77.92	91.17	100.0			
CHG FROM BEST*	PLO	69	-4.80	11.530	-48.0	-9.02	-2.46	1.88	20.6			
	ADA	72	-1.32	9.277	-38.7	-3.81	-0.06	3.03	13.9			
	TOT	141	-3.03	10.548	-48.0	-6.63	-1.14	2.39	20.6			
										3.48	(0.00, 6.96)	0.050A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
GENERAL HEALTH									
BEST VALUE*	PLO	5	35.00	28.504	0.0	25.00	25.00	50.00	75.0
	ADA	3	66.67	28.868	50.0	50.00	50.00	100.00	100.0
	TOT	8	46.88	31.161	0.0	25.00	50.00	62.50	100.0
FINAL/ET VALUE	PLO	5	20.00	20.917	0.0	0.00	25.00	25.00	50.0
	ADA	3	58.33	14.434	50.0	50.00	50.00	75.00	75.0
	TOT	8	34.38	26.517	0.0	12.50	37.50	50.00	75.0
CHG FROM BEST*	PLO	5	-15.00	22.361	-25.0	-25.00	-25.00	-25.00	25.0
	ADA	3	-8.33	14.434	-25.0	-25.00	0.00	0.00	0.0
	TOT	8	-12.50	18.898	-25.0	-25.00	-25.00	0.00	25.0

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
GENERAL VISION									
BEST VALUE*	PLO	5	76.00	16.733	60.0	60.00	80.00	80.00	100.0
	ADA	3	66.67	30.551	40.0	40.00	60.00	100.00	100.0
	TOT	8	72.50	21.213	40.0	60.00	70.00	90.00	100.0
FINAL/ET VALUE	PLO	5	48.00	10.954	40.0	40.00	40.00	60.00	60.0
	ADA	3	73.33	11.547	60.0	60.00	80.00	80.00	80.0
	TOT	8	57.50	16.690	40.0	40.00	60.00	70.00	80.0
CHG FROM BEST*	PLO	5	-28.00	10.954	-40.0	-40.00	-20.00	-20.00	-20.0
	ADA	3	6.67	30.551	-20.0	-20.00	0.00	40.00	40.0
	TOT	8	-15.00	25.635	-40.0	-30.00	-20.00	-10.00	40.0

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
OCULAR PAIN									
BEST VALUE*	PLO	5	87.50	0.000	87.5	87.50	87.50	87.50	87.5
	ADA	3	66.67	38.188	25.0	25.00	75.00	100.00	100.0
	TOT	8	79.69	23.085	25.0	81.25	87.50	87.50	100.0
FINAL/ET VALUE	PLO	5	60.00	22.361	25.0	50.00	75.00	75.00	75.0
	ADA	3	83.33	19.094	62.5	62.50	87.50	100.00	100.0
	TOT	8	68.75	23.146	25.0	56.25	75.00	81.25	100.0
CHG FROM BEST*	PLO	5	-27.50	22.361	-62.5	-37.50	-12.50	-12.50	-12.5
	ADA	3	16.67	19.094	0.0	0.00	12.50	37.50	37.5
	TOT	8	-10.94	30.206	-62.5	-25.00	-12.50	6.25	37.5

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
NEAR VISION									
BEST VALUE*	PLO	5	66.67	26.352	33.3	50.00	66.67	83.33	100.0
	ADA	3	66.67	43.301	16.7	16.67	91.67	91.67	91.7
	TOT	8	66.67	30.538	16.7	41.67	75.00	91.67	100.0
FINAL/ET VALUE	PLO	5	56.67	21.570	33.3	50.00	50.00	58.33	91.7
	ADA	3	75.00	8.333	66.7	66.67	75.00	83.33	83.3
	TOT	8	63.54	19.384	33.3	50.00	62.50	79.17	91.7
CHG FROM BEST*	PLO	5	-10.00	23.124	-33.3	-33.33	-8.33	8.33	16.7
	ADA	3	8.33	36.324	-16.7	-16.67	-8.33	50.00	50.0
	TOT	8	-3.13	27.795	-33.3	-25.00	-8.33	12.50	50.0

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
DISTANCE VISION									
BEST VALUE*	PLO	5	66.67	25.685	33.3	58.33	58.33	83.33	100.0
	ADA	3	77.78	17.347	58.3	58.33	83.33	91.67	91.7
	TOT	8	70.83	22.272	33.3	58.33	70.83	87.50	100.0
FINAL/ET VALUE	PLO	5	55.83	31.950	25.0	25.00	58.33	70.83	100.0
	ADA	3	83.33	14.434	66.7	66.67	91.67	91.67	91.7
	TOT	8	66.15	29.076	25.0	41.67	68.75	91.67	100.0
CHG FROM BEST*	PLO	5	-10.83	18.540	-33.3	-25.00	-8.33	0.00	12.5
	ADA	3	5.56	4.811	0.0	0.00	8.33	8.33	8.3
	TOT	8	-4.69	16.583	-33.3	-16.67	0.00	8.33	12.5

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
SOCIAL FUNCTIONING									
BEST VALUE*	PLO	5	85.00	22.361	50.0	75.00	100.00	100.00	100.0
	ADA	3	83.33	28.868	50.0	50.00	100.00	100.00	100.0
	TOT	8	84.38	22.903	50.0	62.50	100.00	100.00	100.0
FINAL/ET VALUE	PLO	5	65.00	28.504	25.0	50.00	75.00	75.00	100.0
	ADA	3	75.00	43.301	25.0	25.00	100.00	100.00	100.0
	TOT	8	68.75	32.043	25.0	37.50	75.00	100.00	100.0
CHG FROM BEST*	PLO	5	-20.00	11.180	-25.0	-25.00	-25.00	-25.00	0.0
	ADA	3	-8.33	14.434	-25.0	-25.00	0.00	0.00	0.0
	TOT	8	-15.63	12.939	-25.0	-25.00	-25.00	0.00	0.0

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
MENTAL HEALTH									
BEST VALUE*	PLO	5	48.75	30.746	12.5	25.00	50.00	68.75	87.5
	ADA	3	64.58	34.422	25.0	25.00	81.25	87.50	87.5
	TOT	8	54.69	30.755	12.5	25.00	59.38	84.38	87.5
FINAL/ET VALUE	PLO	5	35.00	24.447	0.0	18.75	50.00	50.00	56.3
	ADA	3	64.58	25.259	37.5	37.50	68.75	87.50	87.5
	TOT	8	46.09	27.536	0.0	28.13	50.00	62.50	87.5
CHG FROM BEST*	PLO	5	-13.75	14.252	-37.5	-12.50	-12.50	-6.25	0.0
	ADA	3	0.00	12.500	-12.5	-12.50	0.00	12.50	12.5
	TOT	8	-8.59	14.538	-37.5	-12.50	-9.38	0.00	12.5

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
ROLE DIFFICULTIES									
BEST VALUE*	PLO	5	62.50	29.315	37.5	37.50	50.00	87.50	100.0
	ADA	3	58.33	52.042	0.0	0.00	75.00	100.00	100.0
	TOT	8	60.94	35.630	0.0	37.50	62.50	93.75	100.0
FINAL/ET VALUE	PLO	5	45.00	25.921	12.5	25.00	50.00	62.50	75.0
	ADA	3	58.33	52.042	0.0	0.00	75.00	100.00	100.0
	TOT	8	50.00	34.718	0.0	18.75	56.25	75.00	100.0
CHG FROM BEST*	PLO	5	-17.50	31.375	-62.5	-25.00	-25.00	12.50	12.5
	ADA	3	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	8	-10.94	25.388	-62.5	-25.00	0.00	6.25	12.5

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
DEPENDENCY									
BEST VALUE*	PLO	5	71.67	31.513	25.0	58.33	75.00	100.00	100.0
	ADA	3	66.67	57.735	0.0	0.00	100.00	100.00	100.0
	TOT	8	69.79	39.071	0.0	41.67	87.50	100.00	100.0
FINAL/ET VALUE	PLO	5	60.00	40.995	8.3	25.00	75.00	91.67	100.0
	ADA	3	72.22	48.113	16.7	16.67	100.00	100.00	100.0
	TOT	8	64.58	40.764	8.3	20.83	83.33	100.00	100.0
CHG FROM BEST*	PLO	5	-11.67	20.069	-33.3	-25.00	-16.67	0.00	16.7
	ADA	3	5.56	9.623	0.0	0.00	0.00	16.67	16.7
	TOT	8	-5.21	18.332	-33.3	-20.83	0.00	8.33	16.7

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
DRIVING									
BEST VALUE*	PLO	5	66.67	31.180	33.3	50.00	50.00	100.00	100.0
	ADA	1	83.33		83.3	83.33	83.33	83.33	83.3
	TOT	6	69.44	28.707	33.3	50.00	66.67	100.00	100.0
FINAL/ET VALUE	PLO	5	55.00	33.124	8.3	50.00	50.00	66.67	100.0
	ADA	1	75.00		75.0	75.00	75.00	75.00	75.0
	TOT	6	58.33	30.732	8.3	50.00	58.33	75.00	100.0
CHG FROM BEST*	PLO	5	-11.67	26.087	-50.0	-25.00	0.00	0.00	16.7
	ADA	1	-8.33		-8.3	-8.33	-8.33	-8.33	-8.3
	TOT	6	-11.11	23.373	-50.0	-25.00	-4.17	0.00	16.7

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
COLOR VISION									
BEST VALUE*	PLO	5	100.00	0.000	100.0	100.00	100.00	100.00	100.0
	ADA	3	83.33	28.868	50.0	50.00	100.00	100.00	100.0
	TOT	8	93.75	17.678	50.0	100.00	100.00	100.00	100.0
FINAL/ET VALUE	PLO	5	95.00	11.180	75.0	100.00	100.00	100.00	100.0
	ADA	3	91.67	14.434	75.0	75.00	100.00	100.00	100.0
	TOT	8	93.75	11.573	75.0	87.50	100.00	100.00	100.0
CHG FROM BEST*	PLO	5	-5.00	11.180	-25.0	0.00	0.00	0.00	0.0
	ADA	3	8.33	14.434	0.0	0.00	0.00	25.00	25.0
	TOT	8	0.00	13.363	-25.0	0.00	0.00	0.00	25.0

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
PERIPHERAL VISION									
BEST VALUE*	PLO	5	80.00	27.386	50.0	50.00	100.00	100.00	100.0
	ADA	3	83.33	14.434	75.0	75.00	75.00	100.00	100.0
	TOT	8	81.25	22.160	50.0	62.50	87.50	100.00	100.0
FINAL/ET VALUE	PLO	5	55.00	32.596	25.0	25.00	50.00	75.00	100.0
	ADA	3	75.00	25.000	50.0	50.00	75.00	100.00	100.0
	TOT	8	62.50	29.881	25.0	37.50	62.50	87.50	100.0
CHG FROM BEST*	PLO	5	-25.00	17.678	-50.0	-25.00	-25.00	-25.00	0.0
	ADA	3	-8.33	14.434	-25.0	-25.00	0.00	0.00	0.0
	TOT	8	-18.75	17.678	-50.0	-25.00	-25.00	0.00	0.0

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
TOTAL SCORE									
BEST VALUE*	PLO	5	71.70	19.325	52.8	55.45	66.06	89.85	94.3
	ADA	3	69.39	32.977	31.5	31.50	85.04	91.63	91.6
	TOT	8	70.83	22.924	31.5	54.13	75.55	90.74	94.3
FINAL/ET VALUE	PLO	5	57.32	22.089	28.4	43.79	58.94	70.61	84.8
	ADA	3	74.87	23.601	48.0	48.00	84.36	92.25	92.3
	TOT	8	63.90	22.814	28.4	45.89	64.77	84.58	92.3
CHG FROM BEST*	PLO	5	-14.38	14.520	-30.9	-27.01	-9.51	-9.02	4.5
	ADA	3	5.48	9.565	-0.7	-0.68	0.63	16.50	16.5
	TOT	8	-6.93	15.883	-30.9	-18.26	-4.85	2.59	16.5

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	105	65.71	21.997	25.0	50.00	75.00	75.00	100.0			
	ADA	106	63.21	20.180	25.0	50.00	50.00	75.00	100.0			
	TOT	211	64.45	21.091	25.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	105	50.71	26.733	0.0	25.00	50.00	75.00	100.0			
	ADA	106	54.25	23.521	0.0	50.00	50.00	75.00	100.0			
	TOT	211	52.49	25.173	0.0	25.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	105	-15.00	21.539	-100.0	-25.00	-25.00	0.00	25.0			
	ADA	106	-8.96	23.952	-100.0	-25.00	0.00	0.00	50.0			
	TOT	211	-11.97	22.929	-100.0	-25.00	0.00	0.00	50.0			
										6.04	(-0.15, 12.22)	0.056A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	105	71.43	15.407	40.0	60.00	80.00	80.00	100.0			
	ADA	105	69.43	14.266	20.0	60.00	80.00	80.00	100.0			
	TOT	210	70.43	14.846	20.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	105	62.48	21.067	20.0	40.00	60.00	80.00	100.0			
	ADA	105	64.67	19.368	20.0	60.00	60.00	80.00	100.0			
	TOT	210	63.57	20.217	20.0	60.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	105	-8.95	18.183	-60.0	-20.00	0.00	0.00	20.0			
	ADA	105	-4.76	16.355	-60.0	-20.00	0.00	0.00	30.0			
	TOT	210	-6.86	17.379	-60.0	-20.00	0.00	0.00	30.0			
										4.19	(-0.51, 8.90)	0.081A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	105	84.76	16.625	37.5	75.00	87.50	100.00	100.0			
	ADA	106	84.55	17.039	25.0	75.00	87.50	100.00	100.0			
	TOT	211	84.66	16.794	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	105	73.10	24.316	12.5	62.50	75.00	100.00	100.0			
	ADA	106	80.42	20.194	25.0	62.50	87.50	100.00	100.0			
	TOT	211	76.78	22.588	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	105	-11.67	20.603	-87.5	-25.00	0.00	0.00	25.0			
	ADA	106	-4.13	15.691	-75.0	-12.50	0.00	0.00	25.0			
	TOT	211	-7.88	18.644	-87.5	-12.50	0.00	0.00	25.0			
										7.54	(2.57, 12.51)	0.003A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	105	76.23	20.510	16.7	66.67	75.00	91.67	100.0			
	ADA	106	74.25	23.022	16.7	50.00	75.00	100.00	100.0			
	TOT	211	75.24	21.779	16.7	58.33	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	105	68.69	26.034	8.3	50.00	75.00	91.67	100.0			
	ADA	106	70.40	24.424	16.7	50.00	75.00	91.67	100.0			
	TOT	211	69.55	25.193	8.3	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	105	-7.54	17.650	-66.7	-16.67	-8.33	0.00	41.7			
	ADA	106	-3.85	15.829	-66.7	-8.33	0.00	0.00	25.0			
	TOT	211	-5.69	16.822	-66.7	-8.33	0.00	0.00	41.7			
										3.69	(-0.86, 8.24)	0.112A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	105	76.87	20.817	16.7	66.67	83.33	91.67	100.0			
	ADA	106	75.00	22.257	12.5	58.33	75.00	91.67	100.0			
	TOT	211	75.93	21.521	12.5	58.33	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	105	71.39	26.124	8.3	50.00	75.00	91.67	100.0			
	ADA	106	70.30	25.696	16.7	50.00	75.00	91.67	100.0			
	TOT	211	70.84	25.854	8.3	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	105	-5.48	14.379	-50.0	-8.33	0.00	0.00	41.7			
	ADA	106	-4.70	13.947	-66.7	-8.33	0.00	0.00	25.0			
	TOT	211	-5.08	14.136	-66.7	-8.33	0.00	0.00	41.7			
										0.78	(-3.07, 4.62)	0.690A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	105	88.69	17.891	25.0	87.50	100.00	100.00	100.0			
	ADA	106	88.09	18.691	25.0	75.00	100.00	100.00	100.0			
	TOT	211	88.39	18.256	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	105	82.74	23.538	12.5	75.00	87.50	100.00	100.0			
	ADA	106	83.08	21.650	12.5	75.00	93.75	100.00	100.0			
	TOT	211	82.91	22.556	12.5	75.00	87.50	100.00	100.0			
CHG FROM BEST*	PLO	105	-5.95	15.610	-62.5	-12.50	0.00	0.00	37.5			
	ADA	106	-5.01	12.979	-50.0	-12.50	0.00	0.00	37.5			
	TOT	211	-5.48	14.322	-62.5	-12.50	0.00	0.00	37.5			
										0.94	(-2.95, 4.84)	0.635A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	105	69.88	23.733	0.0	56.25	75.00	87.50	100.0			
	ADA	106	67.24	23.490	0.0	50.00	68.75	87.50	100.0			
	TOT	211	68.55	23.592	0.0	50.00	75.00	87.50	100.0			
FINAL/ET VALUE	PLO	105	65.00	28.615	0.0	50.00	75.00	87.50	100.0			
	ADA	106	66.90	26.375	0.0	43.75	71.88	87.50	100.0			
	TOT	211	65.96	27.464	0.0	43.75	75.00	87.50	100.0			
CHG FROM BEST*	PLO	105	-4.88	18.306	-75.0	-12.50	0.00	6.25	31.3			
	ADA	106	-0.33	16.744	-62.5	-6.25	0.00	6.25	43.8			
	TOT	211	-2.60	17.644	-75.0	-6.25	0.00	6.25	43.8			
										4.55	(-0.21, 9.31)	0.061A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	105	72.86	26.201	12.5	50.00	75.00	100.00	100.0			
	ADA	106	71.11	25.022	0.0	50.00	75.00	100.00	100.0			
	TOT	211	71.98	25.569	0.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	105	65.00	30.343	0.0	50.00	75.00	100.00	100.0			
	ADA	106	67.69	30.368	0.0	50.00	75.00	100.00	100.0			
	TOT	211	66.35	30.313	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	105	-7.86	18.930	-75.0	-25.00	0.00	0.00	50.0			
	ADA	106	-3.42	24.062	-87.5	-12.50	0.00	12.50	50.0			
	TOT	211	-5.63	21.723	-87.5	-12.50	0.00	0.00	50.0			
										4.44	(-1.44, 10.32)	0.138A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	105	82.78	24.766	0.0	75.00	91.67	100.00	100.0			
	ADA	106	82.70	23.730	0.0	66.67	95.83	100.00	100.0			
	TOT	211	82.74	24.193	0.0	66.67	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	105	75.12	30.336	0.0	58.33	91.67	100.00	100.0			
	ADA	106	79.40	27.512	0.0	58.33	91.67	100.00	100.0			
	TOT	211	77.27	28.962	0.0	58.33	91.67	100.00	100.0			
CHG FROM BEST*	PLO	105	-7.66	19.330	-75.0	-16.67	0.00	0.00	50.0			
	ADA	106	-3.30	18.318	-75.0	-8.33	0.00	0.00	58.3			
	TOT	211	-5.47	18.910	-75.0	-8.33	0.00	0.00	58.3			
										4.36	(-0.75, 9.47)	0.094A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	94	67.42	31.282	0.0	50.00	75.00	91.67	100.0			
	ADA	98	66.58	29.849	0.0	41.67	75.00	91.67	100.0			
	TOT	192	66.99	30.482	0.0	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	94	58.38	33.682	0.0	33.33	66.67	83.33	100.0			
	ADA	98	61.95	32.240	0.0	41.67	75.00	83.33	100.0			
	TOT	192	60.20	32.916	0.0	33.33	70.83	83.33	100.0			
CHG FROM BEST*	PLO	94	-9.04	20.281	-75.0	-16.67	-2.08	0.00	50.0			
	ADA	98	-4.63	15.817	-66.7	-8.33	0.00	0.00	50.0			
	TOT	192	-6.79	18.226	-75.0	-16.67	0.00	0.00	50.0			
										4.41	(-0.76, 9.57)	0.094A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	105	94.05	12.749	50.0	100.00	100.00	100.00	100.0			
	ADA	106	93.63	12.470	25.0	100.00	100.00	100.00	100.0			
	TOT	211	93.84	12.581	25.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	105	91.31	16.547	25.0	87.50	100.00	100.00	100.0			
	ADA	106	89.39	17.576	25.0	75.00	100.00	100.00	100.0			
	TOT	211	90.34	17.058	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	105	-2.74	12.007	-50.0	0.00	0.00	0.00	25.0			
	ADA	106	-4.25	15.611	-75.0	0.00	0.00	0.00	25.0			
	TOT	211	-3.50	13.922	-75.0	0.00	0.00	0.00	25.0			
										-1.51	(-5.29, 2.28)	0.433A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	105	80.36	22.525	25.0	75.00	75.00	100.00	100.0			
	ADA	105	80.00	23.869	25.0	75.00	75.00	100.00	100.0			
	TOT	210	80.18	23.152	25.0	75.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	105	75.71	24.381	0.0	50.00	75.00	100.00	100.0			
	ADA	105	74.29	26.049	25.0	50.00	75.00	100.00	100.0			
	TOT	210	75.00	25.179	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	105	-4.64	16.006	-75.0	0.00	0.00	0.00	50.0			
	ADA	105	-5.71	18.100	-50.0	-25.00	0.00	0.00	25.0			
	TOT	210	-5.18	17.052	-75.0	0.00	0.00	0.00	50.0			
										-1.07	(-5.72, 3.58)	0.650A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	105	76.77	17.513	25.7	66.63	80.00	91.36	98.7			
	ADA	106	75.26	17.835	14.7	60.79	79.30	91.17	100.0			
	TOT	211	76.01	17.649	14.7	62.77	79.89	91.36	100.0			
FINAL/ET VALUE	PLO	105	71.85	20.876	21.1	57.54	75.53	90.23	100.0			
	ADA	106	73.38	20.245	18.5	59.05	76.34	92.12	99.4			
	TOT	211	72.62	20.527	18.5	57.54	75.64	91.17	100.0			
CHG FROM BEST*	PLO	105	-4.91	11.669	-48.0	-9.02	-1.70	2.29	20.6			
	ADA	106	-1.88	10.932	-39.0	-4.73	-0.51	3.52	25.8			
	TOT	211	-3.39	11.379	-48.0	-7.42	-1.14	2.84	25.8			
										3.03	(-0.04, 6.10)	0.053A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	49	65.82	25.867	0.0	50.00	75.00	75.00	100.0			
	ADA	37	72.97	18.983	25.0	50.00	75.00	75.00	100.0			
	TOT	86	68.90	23.306	0.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	49	53.57	31.458	0.0	25.00	50.00	75.00	100.0			
	ADA	37	58.78	22.986	0.0	50.00	50.00	75.00	100.0			
	TOT	86	55.81	28.095	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	49	-12.24	23.453	-75.0	-25.00	0.00	0.00	25.0			
	ADA	37	-14.19	22.470	-100.0	-25.00	0.00	0.00	25.0			
	TOT	86	-13.08	22.921	-100.0	-25.00	0.00	0.00	25.0			
										-1.94	(-11.92, 8.03)	0.699A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	49	70.61	15.331	40.0	60.00	80.00	80.00	100.0			
	ADA	37	72.97	14.311	20.0	60.00	80.00	80.00	100.0			
	TOT	86	71.63	14.861	20.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	49	59.59	24.661	20.0	40.00	60.00	80.00	100.0			
	ADA	37	65.41	18.042	20.0	60.00	60.00	80.00	100.0			
	TOT	86	62.09	22.129	20.0	40.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	49	-11.02	20.437	-60.0	-20.00	0.00	0.00	20.0			
	ADA	37	-7.57	16.567	-60.0	-20.00	0.00	0.00	20.0			
	TOT	86	-9.53	18.843	-60.0	-20.00	0.00	0.00	20.0			
										3.45	(-4.72, 11.63)	0.403A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	49	84.69	17.726	37.5	75.00	87.50	100.00	100.0			
	ADA	37	86.15	18.816	25.0	75.00	100.00	100.00	100.0			
	TOT	86	85.32	18.108	25.0	75.00	93.75	100.00	100.0			
FINAL/ET VALUE	PLO	49	68.37	24.354	12.5	50.00	75.00	87.50	100.0			
	ADA	37	81.76	20.957	25.0	62.50	87.50	100.00	100.0			
	TOT	86	74.13	23.778	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	49	-16.33	21.831	-87.5	-25.00	-12.50	0.00	25.0			
	ADA	37	-4.39	17.974	-75.0	-12.50	0.00	0.00	25.0			
	TOT	86	-11.19	21.007	-87.5	-25.00	-6.25	0.00	25.0			
										11.93	(3.16, 20.71)	0.008A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	49	74.32	21.773	16.7	58.33	75.00	91.67	100.0			
	ADA	37	73.87	23.088	16.7	58.33	75.00	91.67	100.0			
	TOT	86	74.13	22.215	16.7	58.33	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	49	65.73	28.353	8.3	41.67	66.67	91.67	100.0			
	ADA	37	68.81	25.489	25.0	50.00	75.00	91.67	100.0			
	TOT	86	67.05	27.046	8.3	41.67	75.00	91.67	100.0			
CHG FROM BEST*	PLO	49	-8.59	20.098	-66.7	-16.67	0.00	0.00	33.3			
	ADA	37	-5.07	19.768	-66.7	-8.33	0.00	8.33	25.0			
	TOT	86	-7.07	19.917	-66.7	-16.67	0.00	0.00	33.3			
										3.52	(-5.12, 12.16)	0.420A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	49	74.57	23.078	16.7	58.33	75.00	91.67	100.0			
	ADA	37	74.55	24.977	12.5	58.33	83.33	100.00	100.0			
	TOT	86	74.56	23.769	12.5	58.33	79.17	91.67	100.0			
FINAL/ET VALUE	PLO	49	67.86	29.105	8.3	41.67	75.00	91.67	100.0			
	ADA	37	70.27	28.160	16.7	41.67	75.00	100.00	100.0			
	TOT	86	68.90	28.559	8.3	41.67	75.00	91.67	100.0			
CHG FROM BEST*	PLO	49	-6.72	15.586	-50.0	-16.67	-8.33	0.00	25.0			
	ADA	37	-4.28	16.477	-66.7	-16.67	0.00	8.33	16.7			
	TOT	86	-5.67	15.926	-66.7	-16.67	0.00	4.17	25.0			
										2.44	(-4.48, 9.36)	0.485A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	49	87.24	19.514	25.0	75.00	100.00	100.00	100.0			
	ADA	37	86.82	21.839	25.0	75.00	100.00	100.00	100.0			
	TOT	86	87.06	20.423	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	49	77.30	27.323	12.5	50.00	87.50	100.00	100.0			
	ADA	37	79.05	25.525	12.5	75.00	87.50	100.00	100.0			
	TOT	86	78.05	26.425	12.5	62.50	87.50	100.00	100.0			
CHG FROM BEST*	PLO	49	-9.95	18.396	-62.5	-25.00	0.00	0.00	25.0			
	ADA	37	-7.77	13.291	-50.0	-12.50	0.00	0.00	12.5			
	TOT	86	-9.01	16.343	-62.5	-12.50	0.00	0.00	25.0			
										2.18	(-4.93, 9.28)	0.544A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	49	65.94	30.273	0.0	50.00	75.00	93.75	100.0			
	ADA	37	67.91	26.767	0.0	43.75	81.25	87.50	100.0			
	TOT	86	66.79	28.669	0.0	50.00	75.00	87.50	100.0			
FINAL/ET VALUE	PLO	49	59.01	35.476	0.0	18.75	62.50	93.75	100.0			
	ADA	37	65.03	28.354	0.0	43.75	68.75	87.50	100.0			
	TOT	86	61.60	32.561	0.0	31.25	68.75	93.75	100.0			
CHG FROM BEST*	PLO	49	-6.93	18.352	-58.3	-12.50	0.00	6.25	18.8			
	ADA	37	-2.87	19.409	-62.5	-12.50	0.00	6.25	31.3			
	TOT	86	-5.18	18.810	-62.5	-12.50	0.00	6.25	31.3			
										4.06	(-4.09, 12.21)	0.325A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	49	74.49	28.293	12.5	50.00	87.50	100.00	100.0			
	ADA	37	74.32	26.012	0.0	50.00	75.00	100.00	100.0			
	TOT	86	74.42	27.178	0.0	50.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	49	61.99	33.846	0.0	37.50	75.00	100.00	100.0			
	ADA	37	69.26	30.844	0.0	50.00	75.00	100.00	100.0			
	TOT	86	65.12	32.603	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	49	-12.50	21.041	-75.0	-25.00	-12.50	0.00	37.5			
	ADA	37	-5.07	24.555	-87.5	-12.50	0.00	0.00	37.5			
	TOT	86	-9.30	22.783	-87.5	-25.00	0.00	0.00	37.5			
										7.43	(-2.36, 17.23)	0.135A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	49	78.74	30.145	0.0	66.67	100.00	100.00	100.0			
	ADA	37	79.95	27.740	0.0	66.67	91.67	100.00	100.0			
	TOT	86	79.26	28.973	0.0	66.67	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	49	67.69	36.270	0.0	25.00	83.33	100.00	100.0			
	ADA	37	75.45	30.866	0.0	58.33	91.67	100.00	100.0			
	TOT	86	71.03	34.078	0.0	50.00	83.33	100.00	100.0			
CHG FROM BEST*	PLO	49	-11.05	19.938	-75.0	-16.67	0.00	0.00	16.7			
	ADA	37	-4.50	13.117	-33.3	-8.33	0.00	0.00	33.3			
	TOT	86	-8.24	17.550	-75.0	-16.67	0.00	0.00	33.3			
										6.55	(-0.96, 14.06)	0.087A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	47	69.68	29.408	0.0	50.00	83.33	91.67	100.0			
	ADA	35	70.00	31.519	0.0	50.00	83.33	91.67	100.0			
	TOT	82	69.82	30.136	0.0	50.00	83.33	91.67	100.0			
FINAL/ET VALUE	PLO	47	61.61	32.180	0.0	33.33	66.67	83.33	100.0			
	ADA	35	63.57	33.765	0.0	41.67	75.00	100.00	100.0			
	TOT	82	62.45	32.674	0.0	37.50	75.00	91.67	100.0			
CHG FROM BEST*	PLO	47	-8.07	22.428	-58.3	-16.67	0.00	0.00	50.0			
	ADA	35	-6.43	19.183	-66.7	-16.67	0.00	0.00	50.0			
	TOT	82	-7.37	20.995	-66.7	-16.67	0.00	0.00	50.0			
										1.64	(-7.74, 11.02)	0.729A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	49	95.41	11.032	50.0	100.00	100.00	100.00	100.0			
	ADA	37	91.89	15.650	25.0	75.00	100.00	100.00	100.0			
	TOT	86	93.90	13.249	25.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	49	91.58	17.190	50.0	100.00	100.00	100.00	100.0			
	ADA	37	86.49	18.252	50.0	75.00	100.00	100.00	100.0			
	TOT	86	89.39	17.731	50.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	49	-3.83	13.551	-50.0	0.00	0.00	0.00	25.0			
	ADA	37	-5.41	16.807	-50.0	-25.00	0.00	0.00	25.0			
	TOT	86	-4.51	14.965	-50.0	0.00	0.00	0.00	25.0			
										-1.58	(-8.09, 4.93)	0.631A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	49	79.85	22.938	25.0	62.50	75.00	100.00	100.0			
	ADA	36	79.17	25.000	25.0	75.00	75.00	100.00	100.0			
	TOT	85	79.56	23.689	25.0	75.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	49	71.94	27.306	0.0	50.00	75.00	100.00	100.0			
	ADA	36	76.39	25.315	25.0	62.50	75.00	100.00	100.0			
	TOT	85	73.82	26.420	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	49	-7.91	17.435	-75.0	-25.00	0.00	0.00	25.0			
	ADA	36	-2.78	16.667	-50.0	0.00	0.00	0.00	25.0			
	TOT	85	-5.74	17.203	-75.0	0.00	0.00	0.00	25.0			
										5.13	(-2.34, 12.60)	0.176A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	49	75.98	19.618	25.7	63.71	81.52	94.20	98.7			
	ADA	37	75.85	20.231	14.7	61.52	82.73	92.20	100.0			
	TOT	86	75.92	19.766	14.7	62.39	82.41	93.07	100.0			
FINAL/ET VALUE	PLO	49	68.36	24.416	21.1	43.79	72.50	90.72	100.0			
	ADA	37	72.59	22.101	18.5	53.07	76.21	93.07	98.5			
	TOT	86	70.18	23.408	18.5	51.10	73.11	92.88	100.0			
CHG FROM BEST*	PLO	49	-7.62	13.256	-48.0	-11.78	-4.47	1.82	10.7			
	ADA	37	-3.26	13.115	-39.0	-8.14	-1.70	3.79	25.8			
	TOT	86	-5.74	13.297	-48.0	-9.58	-3.03	2.54	25.8			
										4.36	(-1.35, 10.08)	0.133A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	41	62.20	18.643	25.0	50.00	50.00	75.00	100.0			
	ADA	49	57.14	16.925	25.0	50.00	50.00	75.00	100.0			
	TOT	90	59.44	17.807	25.0	50.00	50.00	75.00	100.0			
FINAL/ET VALUE	PLO	41	46.34	21.331	0.0	25.00	50.00	50.00	75.0			
	ADA	49	52.55	22.387	0.0	50.00	50.00	75.00	100.0			
	TOT	90	49.72	22.011	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	41	-15.85	18.334	-50.0	-25.00	-25.00	0.00	25.0			
	ADA	49	-4.59	26.356	-75.0	-25.00	0.00	0.00	50.0			
	TOT	90	-9.72	23.612	-75.0	-25.00	0.00	0.00	50.0			
										11.26	(1.56, 20.96)	0.023A

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NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	41	73.66	12.992	40.0	60.00	80.00	80.00	100.0			
	ADA	49	68.78	13.171	40.0	60.00	60.00	80.00	100.0			
	TOT	90	71.00	13.244	40.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	41	65.37	15.508	40.0	60.00	60.00	80.00	80.0			
	ADA	49	66.73	19.082	20.0	60.00	60.00	80.00	100.0			
	TOT	90	66.11	17.462	20.0	60.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	41	-8.29	15.476	-40.0	-20.00	0.00	0.00	20.0			
	ADA	49	-2.04	16.070	-60.0	0.00	0.00	0.00	30.0			
	TOT	90	-4.89	16.023	-60.0	-20.00	0.00	0.00	30.0			
										6.25	(-0.40, 12.90)	0.065A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	41	82.32	15.046	50.0	75.00	87.50	100.00	100.0			
	ADA	49	83.93	15.729	50.0	75.00	87.50	100.00	100.0			
	TOT	90	83.19	15.356	50.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	41	73.17	22.974	12.5	62.50	75.00	100.00	100.0			
	ADA	49	81.63	19.281	25.0	62.50	87.50	100.00	100.0			
	TOT	90	77.78	21.347	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-9.15	19.167	-62.5	-12.50	0.00	0.00	12.5			
	ADA	49	-2.30	14.131	-37.5	0.00	0.00	0.00	25.0			
	TOT	90	-5.42	16.870	-62.5	-12.50	0.00	0.00	25.0			
										6.85	(-0.14, 13.84)	0.055A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	41	78.86	16.884	33.3	66.67	75.00	91.67	100.0			
	ADA	49	77.98	22.341	29.2	66.67	83.33	100.00	100.0			
	TOT	90	78.38	19.938	29.2	66.67	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	41	72.15	21.377	16.7	58.33	75.00	91.67	100.0			
	ADA	49	74.15	24.782	16.7	50.00	75.00	100.00	100.0			
	TOT	90	73.24	23.186	16.7	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	41	-6.71	13.847	-33.3	-8.33	-8.33	0.00	16.7			
	ADA	49	-3.83	13.971	-58.3	-8.33	0.00	0.00	25.0			
	TOT	90	-5.14	13.911	-58.3	-8.33	0.00	0.00	25.0			
										2.88	(-2.97, 8.73)	0.331A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	41	79.67	17.083	41.7	66.67	83.33	91.67	100.0			
	ADA	49	77.30	21.230	33.3	62.50	83.33	100.00	100.0			
	TOT	90	78.38	19.382	33.3	66.67	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	41	75.30	22.407	25.0	58.33	83.33	91.67	100.0			
	ADA	49	72.83	24.993	16.7	58.33	75.00	91.67	100.0			
	TOT	90	73.96	23.750	16.7	58.33	75.00	91.67	100.0			
CHG FROM BEST*	PLO	41	-4.37	13.564	-33.3	-8.33	0.00	0.00	41.7			
	ADA	49	-4.46	12.442	-50.0	-8.33	0.00	0.00	25.0			
	TOT	90	-4.42	12.891	-50.0	-8.33	0.00	0.00	41.7			
										-0.09	(-5.55, 5.36)	0.973A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	41	90.24	16.657	37.5	87.50	100.00	100.00	100.0			
	ADA	49	90.56	17.027	37.5	87.50	100.00	100.00	100.0			
	TOT	90	90.42	16.765	37.5	87.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	87.20	19.463	25.0	75.00	100.00	100.00	100.0			
	ADA	49	88.90	16.793	43.8	75.00	100.00	100.00	100.0			
	TOT	90	88.13	17.974	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-3.05	11.450	-37.5	-12.50	0.00	0.00	25.0			
	ADA	49	-1.66	12.420	-50.0	-6.25	0.00	0.00	37.5			
	TOT	90	-2.29	11.942	-50.0	-12.50	0.00	0.00	37.5			
										1.39	(-3.65, 6.43)	0.585A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	41	72.41	17.058	25.0	62.50	75.00	87.50	93.8			
	ADA	49	70.71	20.525	12.5	62.50	75.00	87.50	100.0			
	TOT	90	71.48	18.939	12.5	62.50	75.00	87.50	100.0			
FINAL/ET VALUE	PLO	41	68.50	19.699	18.8	56.25	68.75	83.33	100.0			
	ADA	49	71.05	24.128	12.5	56.25	81.25	93.75	100.0			
	TOT	90	69.88	22.137	12.5	56.25	75.00	87.50	100.0			
CHG FROM BEST*	PLO	41	-3.91	15.118	-43.8	-12.50	0.00	6.25	18.8			
	ADA	49	0.34	14.138	-43.8	-6.25	0.00	6.25	25.0			
	TOT	90	-1.60	14.665	-43.8	-6.25	0.00	6.25	25.0			
										4.25	(-1.88, 10.39)	0.172A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	41	70.43	24.962	25.0	50.00	75.00	100.00	100.0			
	ADA	49	71.68	25.101	12.5	50.00	75.00	100.00	100.0			
	TOT	90	71.11	24.905	12.5	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	65.55	27.355	12.5	50.00	75.00	87.50	100.0			
	ADA	49	68.37	28.653	0.0	50.00	75.00	100.00	100.0			
	TOT	90	67.08	27.948	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-4.88	16.507	-62.5	-12.50	0.00	0.00	25.0			
	ADA	49	-3.32	22.646	-75.0	-12.50	0.00	12.50	37.5			
	TOT	90	-4.03	19.992	-75.0	-12.50	0.00	0.00	37.5			
										1.56	(-6.89, 10.01)	0.714A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	41	86.79	17.871	41.7	83.33	91.67	100.00	100.0			
	ADA	49	88.27	18.076	41.7	75.00	100.00	100.00	100.0			
	TOT	90	87.59	17.897	41.7	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	81.50	24.261	8.3	75.00	91.67	100.00	100.0			
	ADA	49	84.35	24.629	16.7	83.33	100.00	100.00	100.0			
	TOT	90	83.06	24.366	8.3	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-5.28	19.163	-75.0	-8.33	0.00	0.00	50.0			
	ADA	49	-3.91	21.791	-75.0	-8.33	0.00	0.00	58.3			
	TOT	90	-4.54	20.533	-75.0	-8.33	0.00	0.00	58.3			
										1.37	(-7.31, 10.05)	0.754A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	37	68.13	31.246	0.0	50.00	83.33	91.67	100.0			
	ADA	46	67.39	27.601	0.0	41.67	75.00	91.67	100.0			
	TOT	83	67.72	29.100	0.0	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	37	59.23	32.913	0.0	41.67	75.00	83.33	100.0			
	ADA	46	63.86	32.011	0.0	41.67	75.00	83.33	100.0			
	TOT	83	61.80	32.300	0.0	41.67	75.00	83.33	100.0			
CHG FROM BEST*	PLO	37	-8.90	16.142	-50.0	-16.67	-8.33	0.00	33.3			
	ADA	46	-3.53	14.217	-41.7	-8.33	0.00	0.00	33.3			
	TOT	83	-5.92	15.249	-50.0	-8.33	0.00	0.00	33.3			
										5.36	(-1.27, 12.00)	0.112A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	41	92.68	13.969	50.0	100.00	100.00	100.00	100.0			
	ADA	49	95.41	9.781	75.0	100.00	100.00	100.00	100.0			
	TOT	90	94.17	11.881	50.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	92.68	13.969	50.0	100.00	100.00	100.00	100.0			
	ADA	49	92.35	16.301	25.0	100.00	100.00	100.00	100.0			
	TOT	90	92.50	15.200	25.0	100.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	41	0.00	9.682	-25.0	0.00	0.00	0.00	25.0			
	ADA	49	-3.06	14.098	-75.0	0.00	0.00	0.00	25.0			
	TOT	90	-1.67	12.316	-75.0	0.00	0.00	0.00	25.0			
										-3.06	(-8.23, 2.11)	0.242A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	41	81.10	23.572	25.0	75.00	75.00	100.00	100.0			
	ADA	49	81.63	23.813	25.0	75.00	100.00	100.00	100.0			
	TOT	90	81.39	23.572	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	41	77.44	23.588	25.0	75.00	75.00	100.00	100.0			
	ADA	49	75.00	27.481	25.0	50.00	75.00	100.00	100.0			
	TOT	90	76.11	25.668	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	41	-3.66	18.167	-50.0	0.00	0.00	0.00	50.0			
	ADA	49	-6.63	16.751	-50.0	-25.00	0.00	0.00	25.0			
	TOT	90	-5.28	17.375	-50.0	-25.00	0.00	0.00	50.0			
										-2.97	(-10.30, 4.35)	0.422A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

TABLE 14.2__1000.4.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT
IN VISUAL FUNCTIONING QUESTIONNAIRE (VFQ-25)
LOCF
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

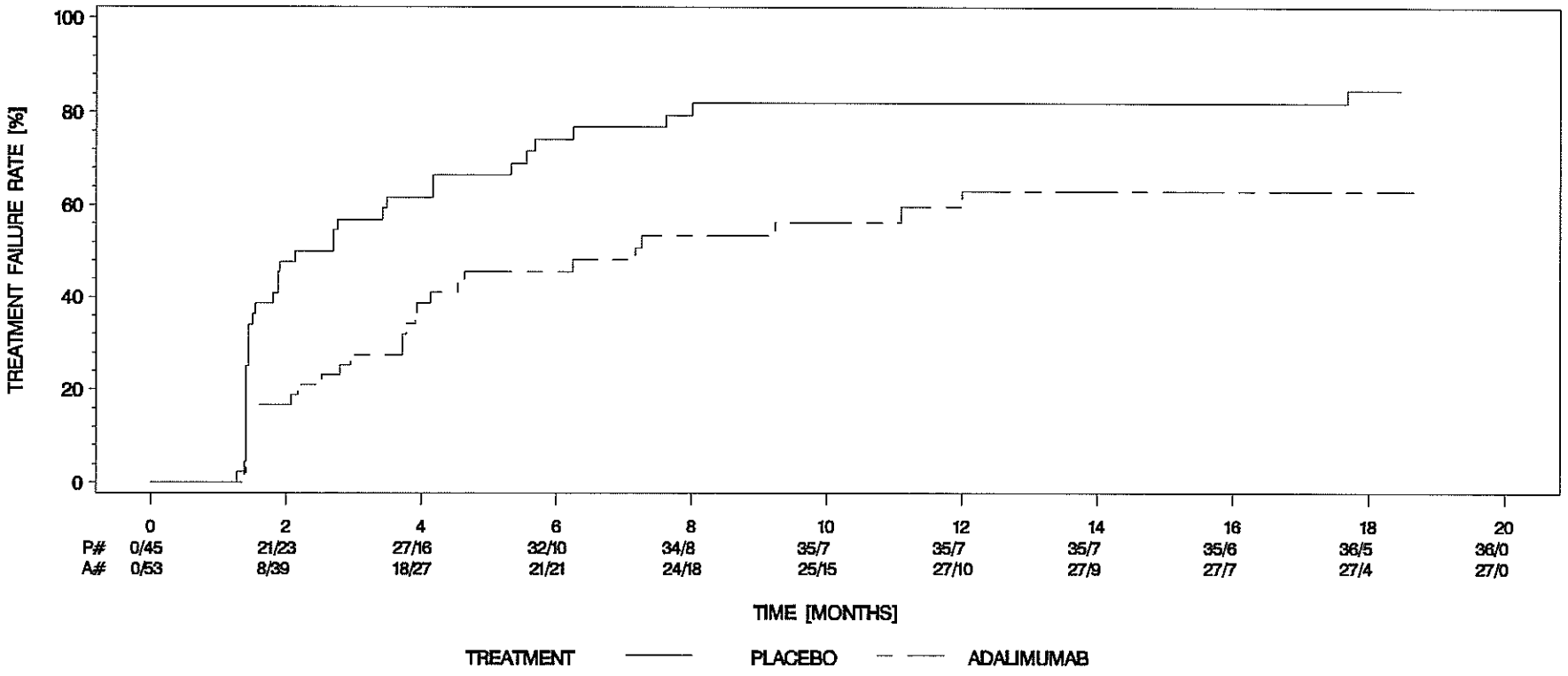
VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	41	77.78	14.832	47.0	69.02	78.94	90.11	97.9			
	ADA	49	77.29	16.072	42.6	65.30	83.86	91.36	99.4			
	TOT	90	77.51	15.435	42.6	66.63	79.62	91.36	99.4			
FINAL/ET VALUE	PLO	41	74.61	16.782	28.4	65.00	76.59	90.04	98.0			
	ADA	49	76.26	18.918	29.6	63.22	82.54	92.12	99.4			
	TOT	90	75.51	17.897	28.4	63.41	78.62	90.98	99.4			
CHG FROM BEST*	PLO	41	-3.17	9.628	-30.9	-8.52	-1.33	2.20	19.7			
	ADA	49	-1.03	9.973	-38.3	-2.95	0.00	2.84	17.9			
	TOT	90	-2.01	9.821	-38.3	-4.73	-0.61	2.84	19.7			
										2.14	(-1.99, 6.27)	0.306A

* BEST MEANS BEST STATE ACHIEVED PRIOR TO WEEK 6.
NOTE: ONLY SUBJECTS WITH BOTH BEST STATE ACHIEVED AND FINAL/ET VISIT VALUES ARE SHOWN.
SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION
PRIOR TO WEEK 6) WERE EXCLUDED.
TOTAL SCORE AND SUBSCORES WERE CALCULATED BASED ON ALL NON-MISSING SUBSCORES OR ITEMS.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
$ MEAN DIFFERENCE IN CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/ET VISIT WITH TREATMENT AS FACTOR.

Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

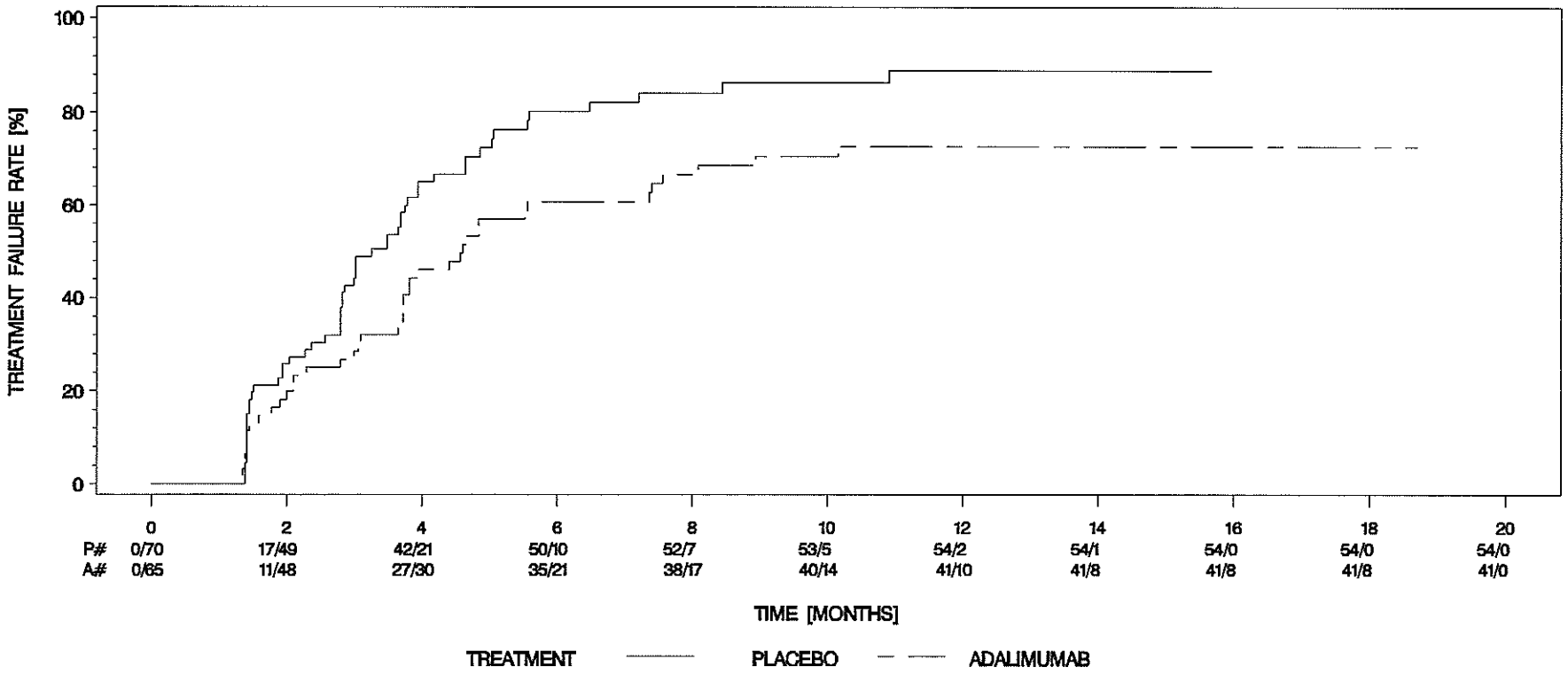
FIGURE 14.2__1000.1.1.4.1.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

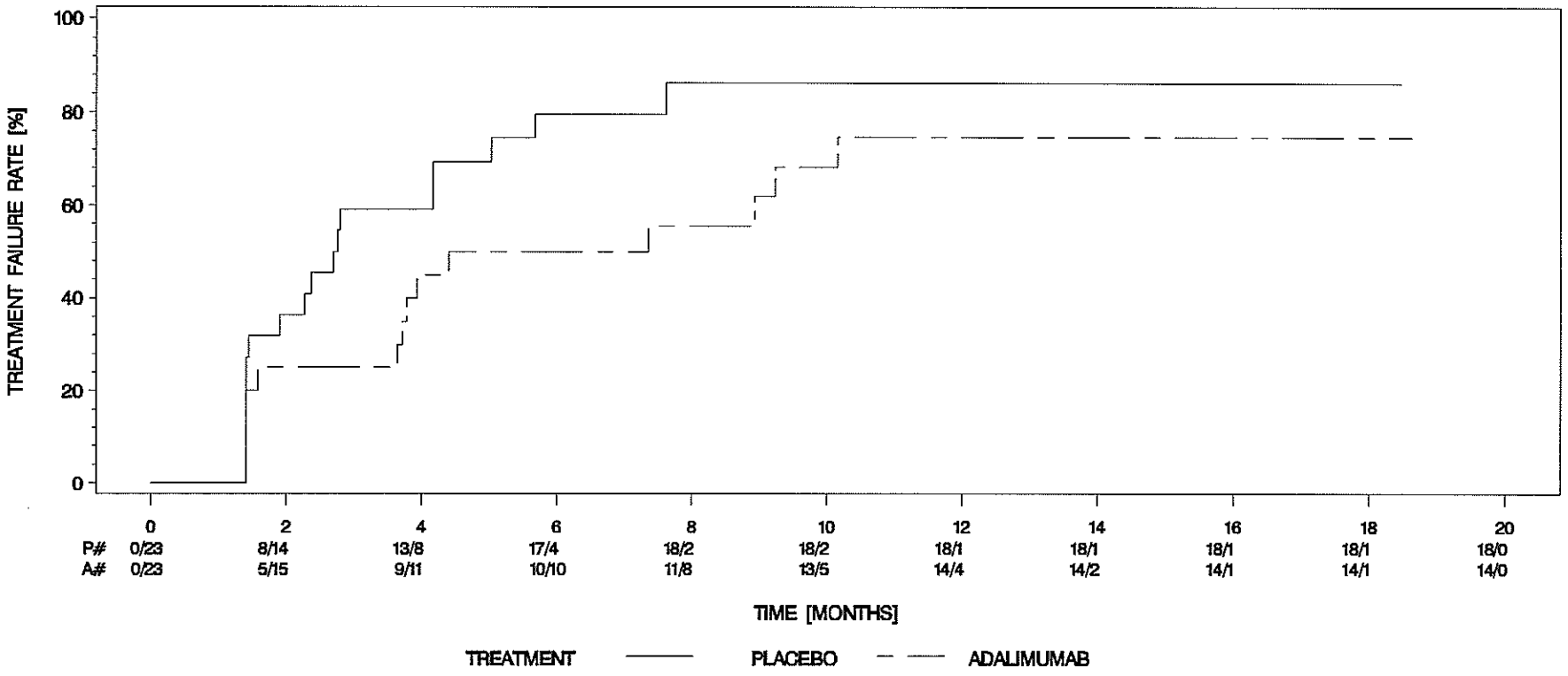
FIGURE 14.2__1000.1.1.4.2.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

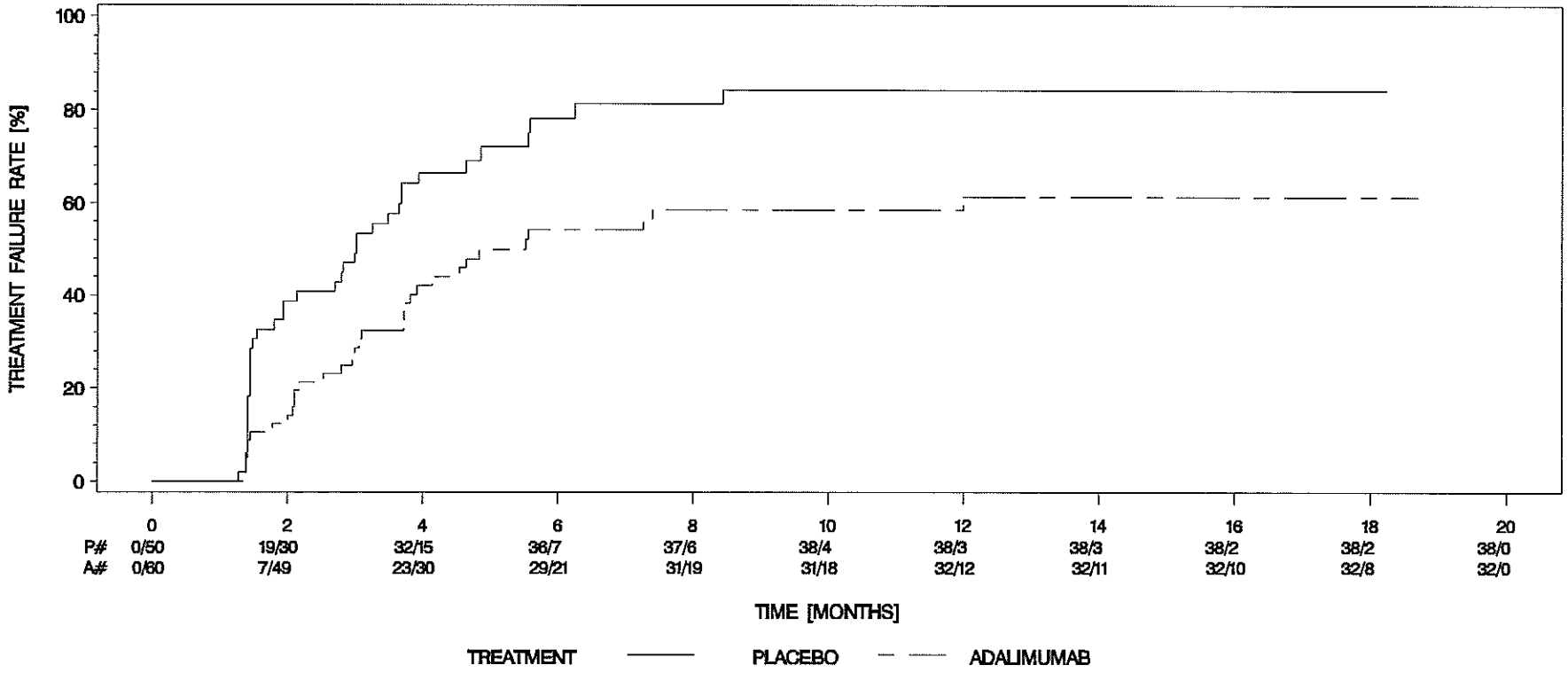
FIGURE 14.2__1000.1.1.4.3.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

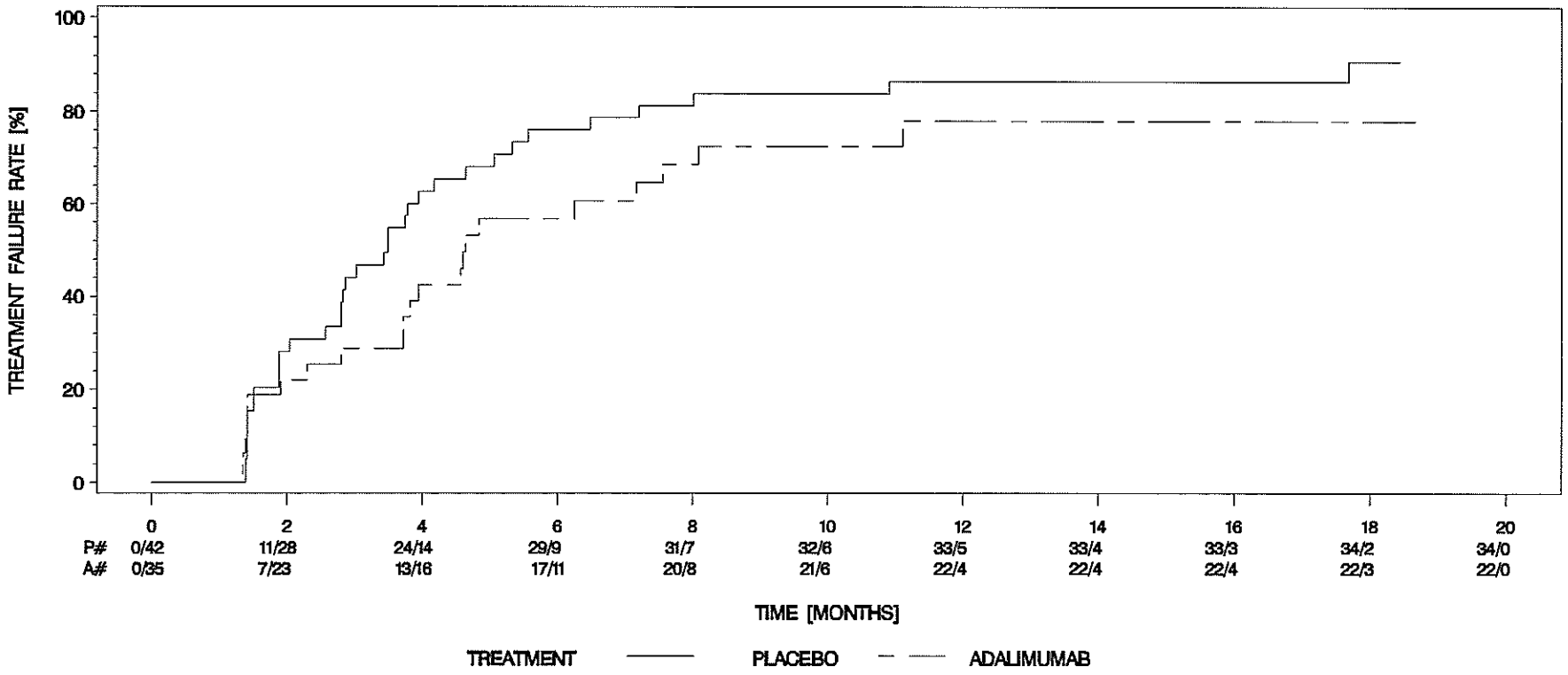
FIGURE 14.2__1000.1.1.4.4.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

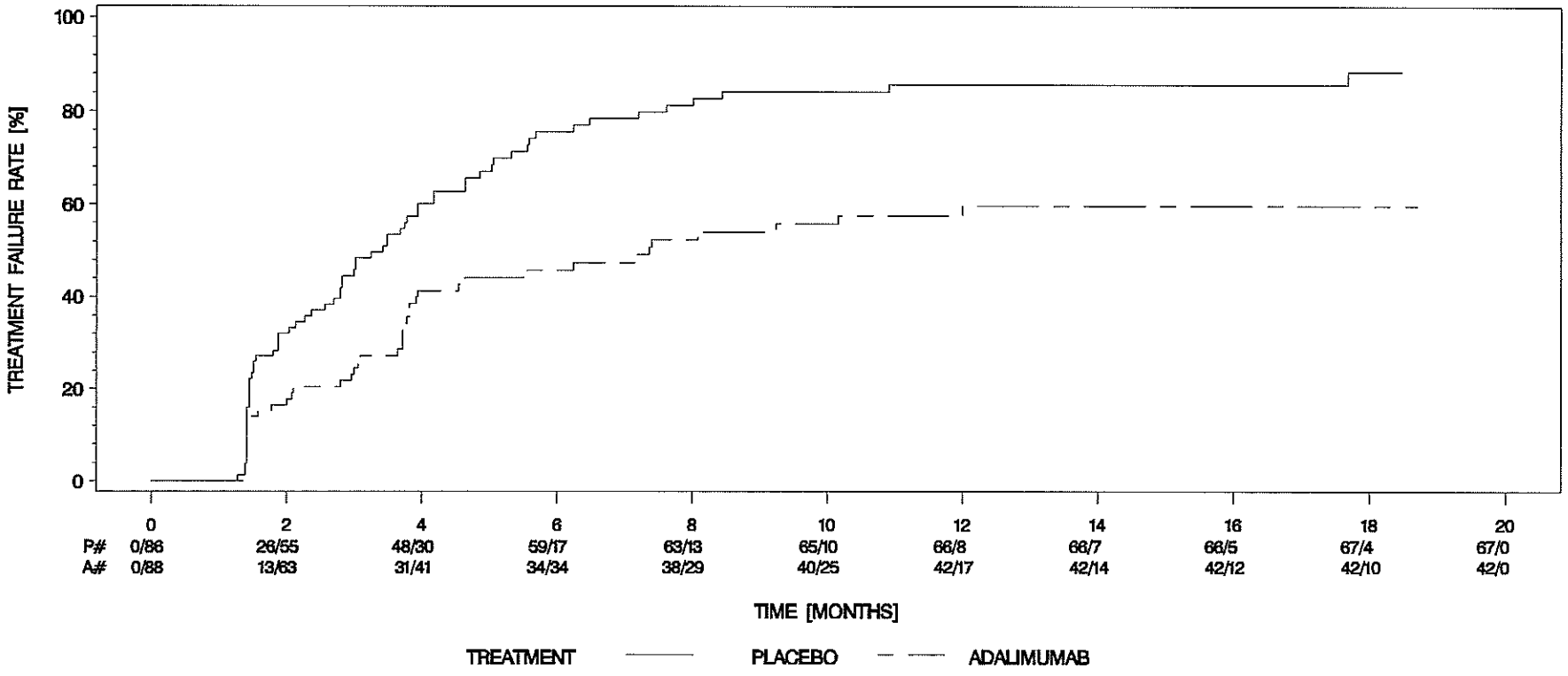
FIGURE 14.2__1000.1.1.4.5.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

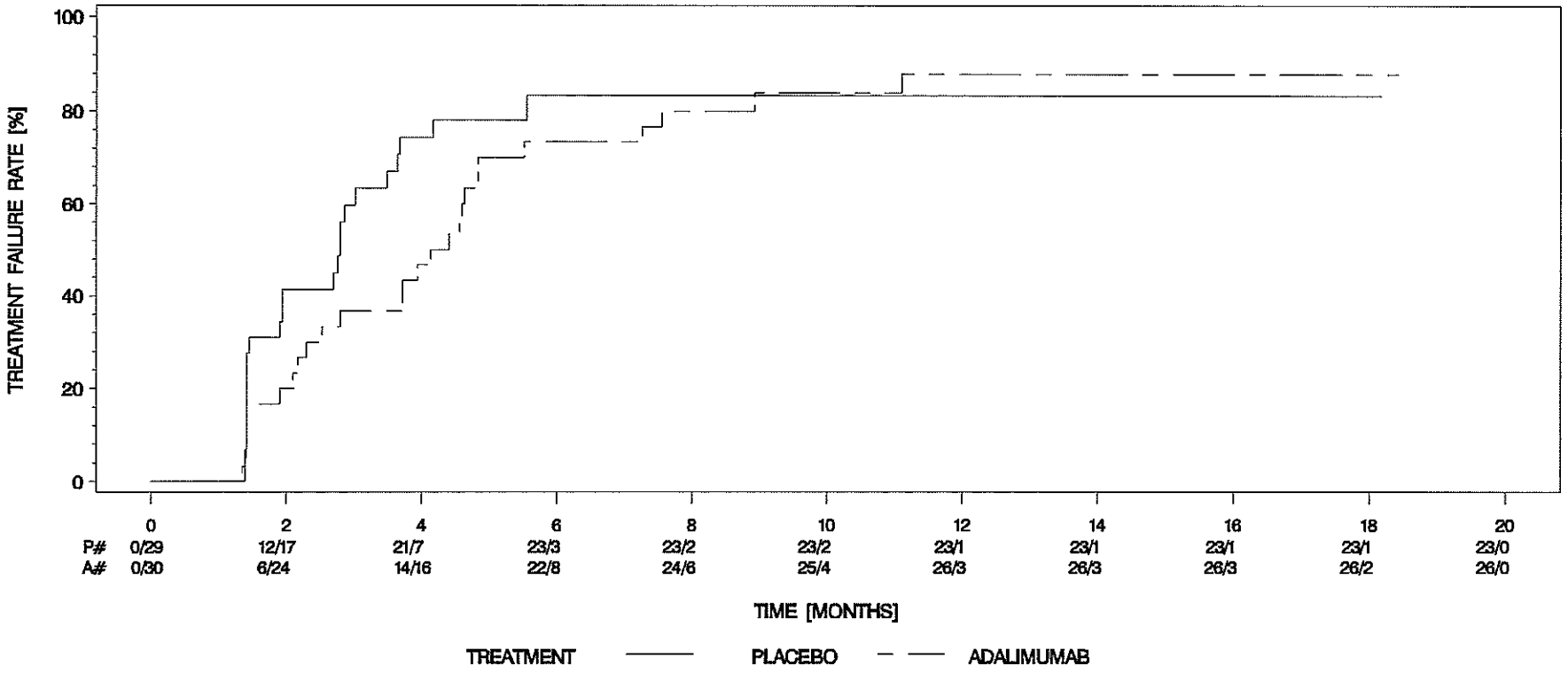
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.6.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

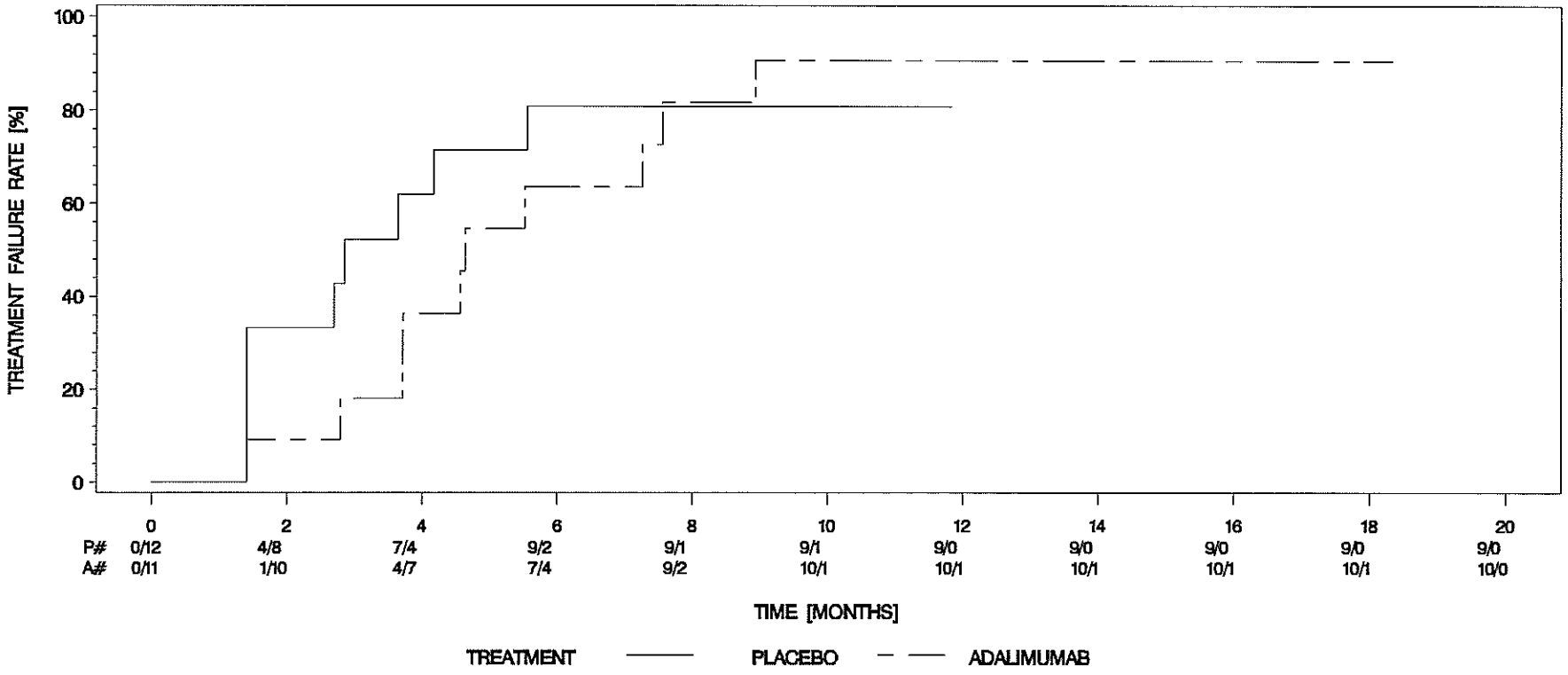
FIGURE 14.2__1000.1.1.4.7.1.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

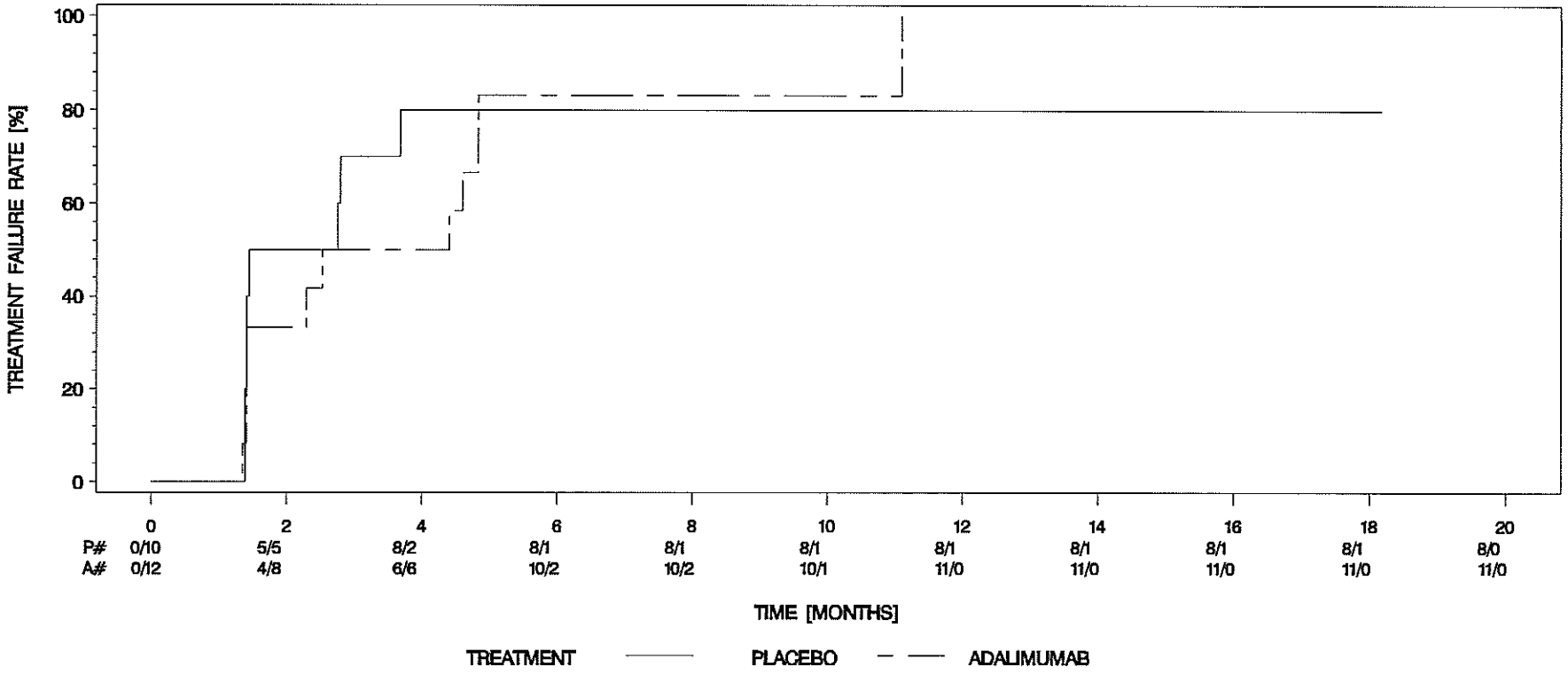
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.7.2.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: BLACK)



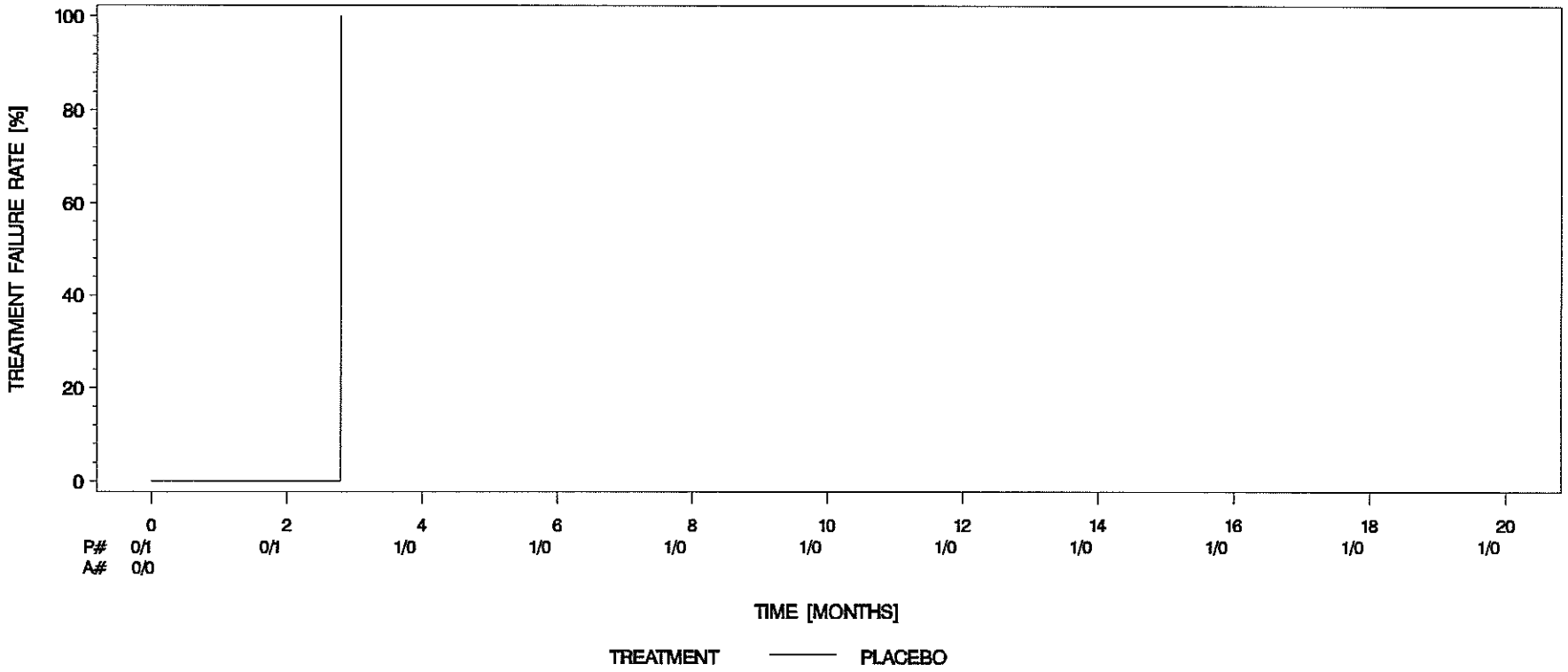
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.7.3.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ASIAN)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.7.4.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AMERICAN INDIAN/ALASKA NATIVE)

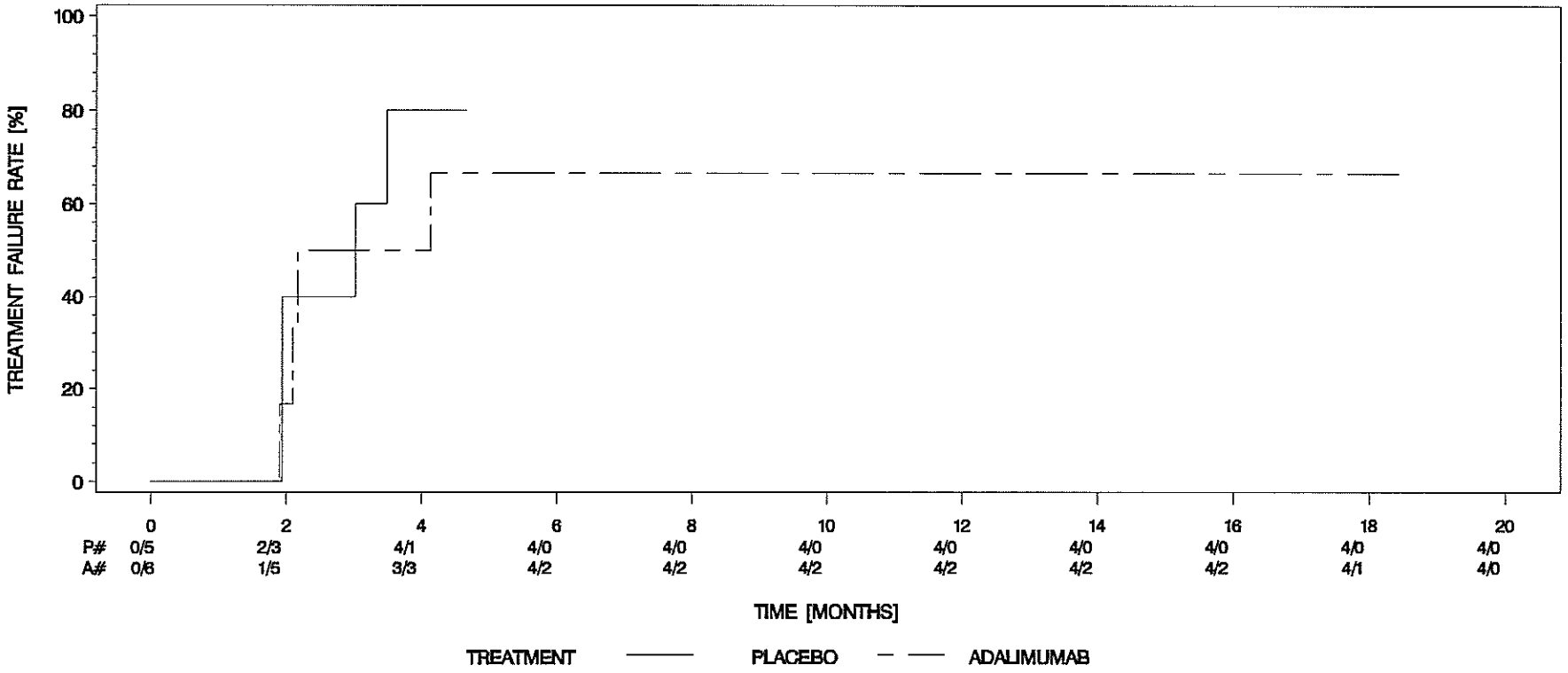


NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.7.5.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

** NO DATA IN THIS SEGMENT OR PART OF THIS FIGURE. **

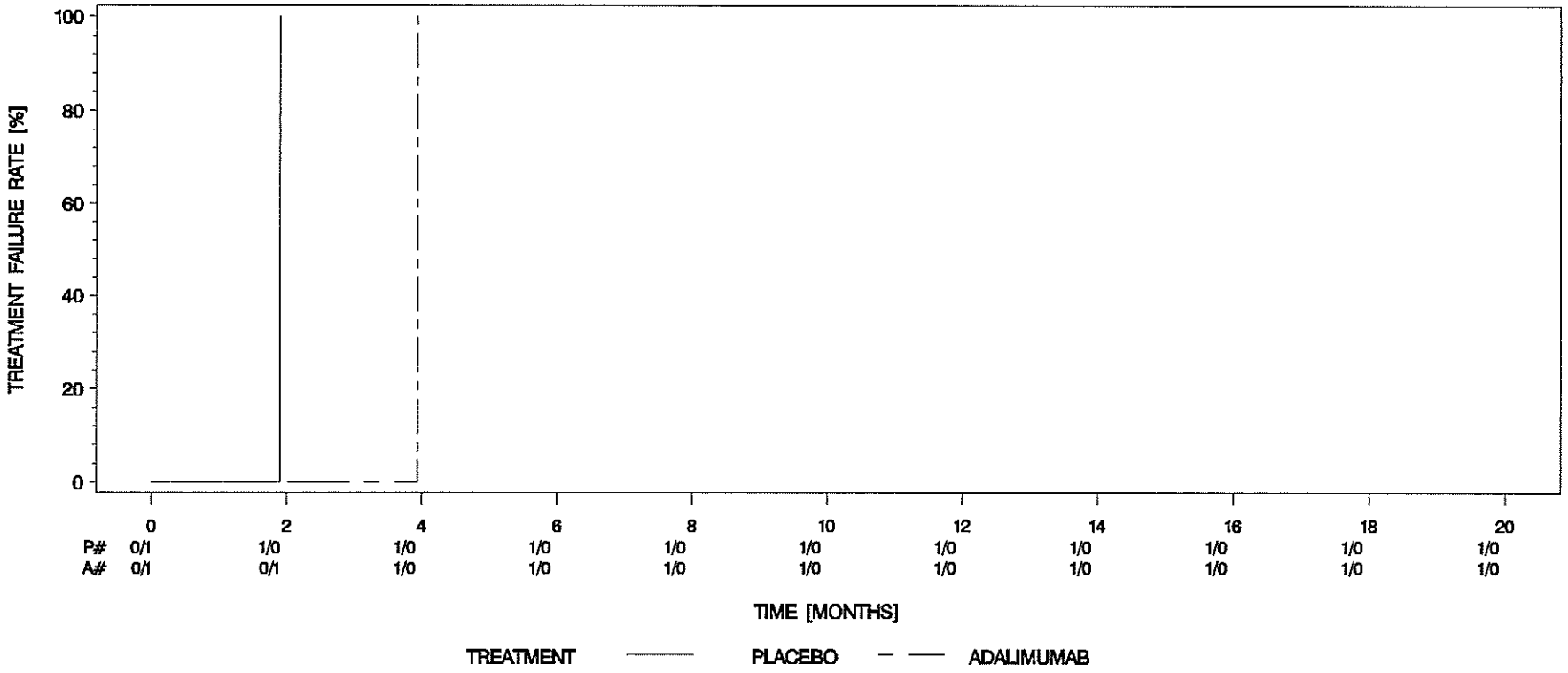
FIGURE 14.2__1000.1.1.4.7.6.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OTHER)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

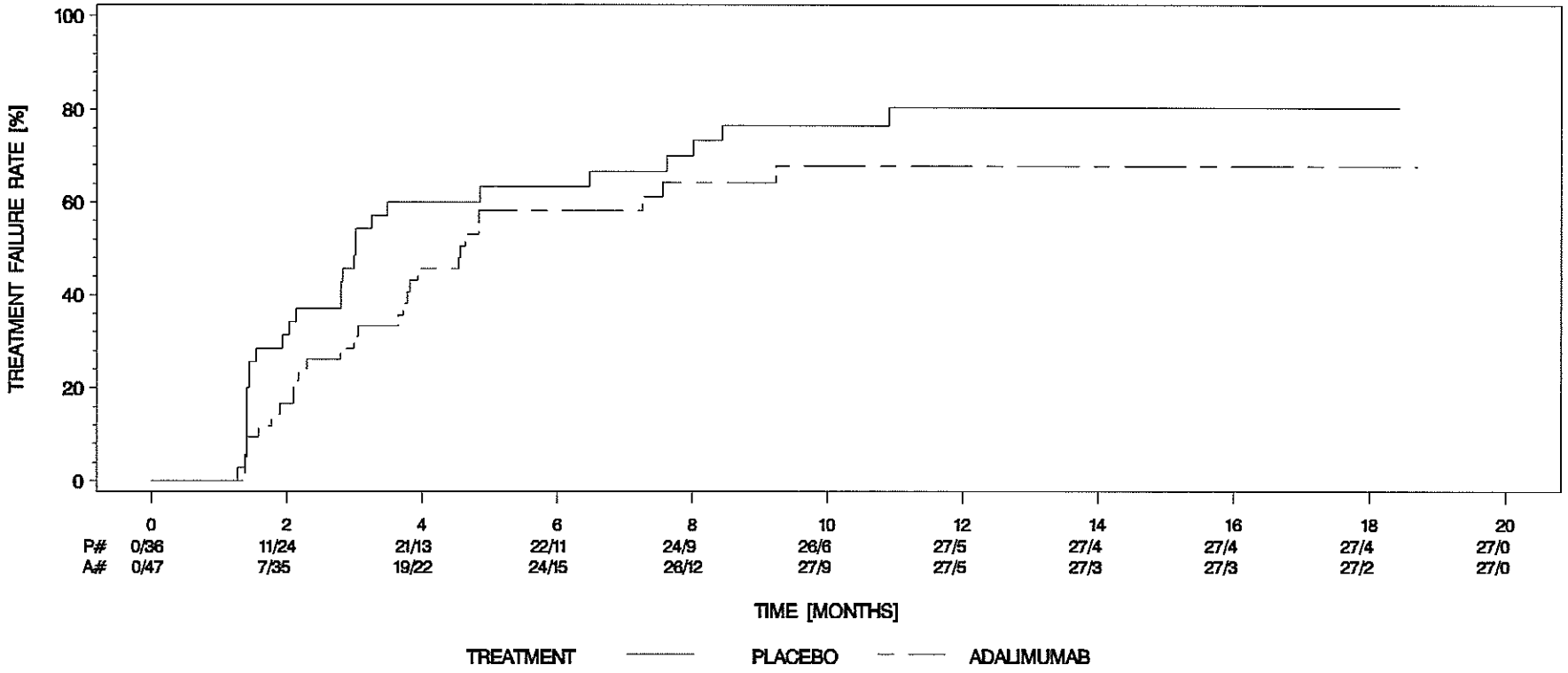
FIGURE 14.2__1000.1.1.4.7.7.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: MULTI RACE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

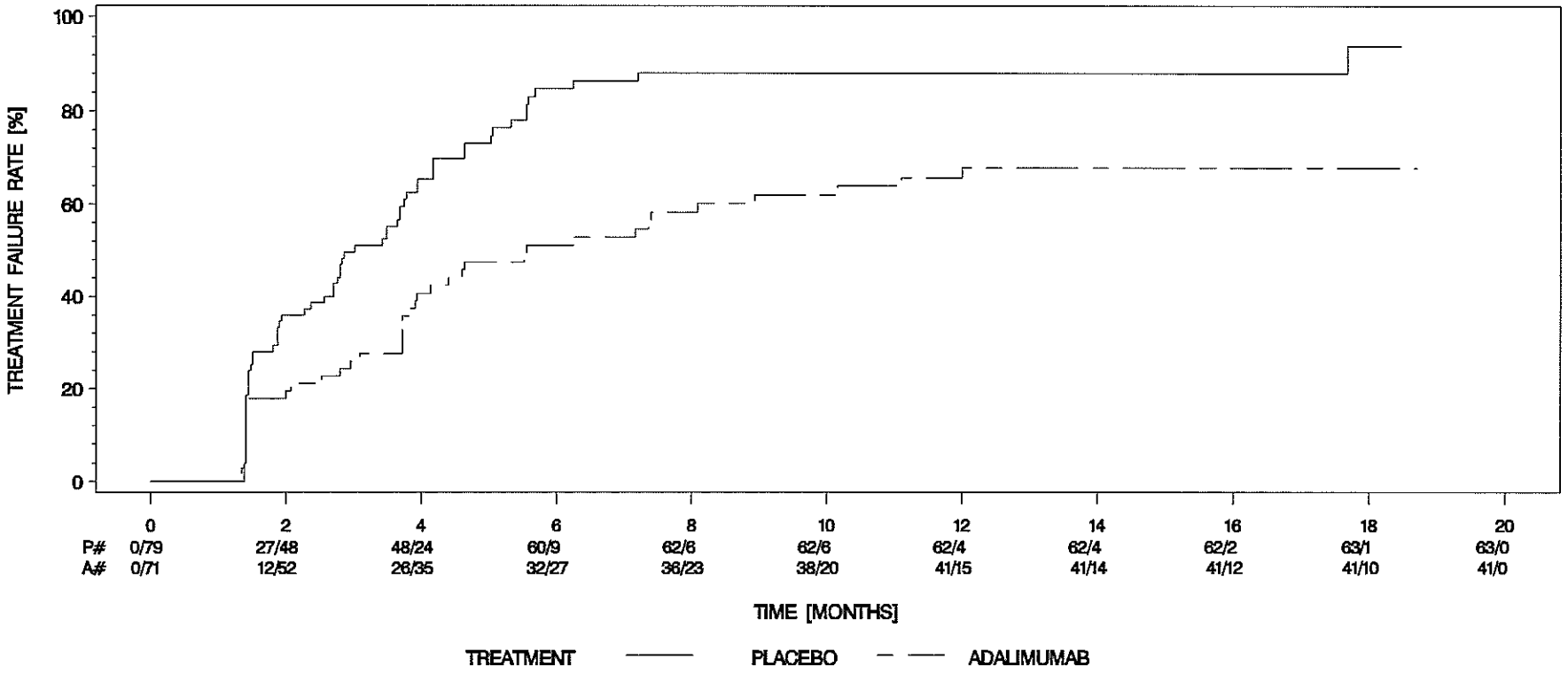
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.8.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)



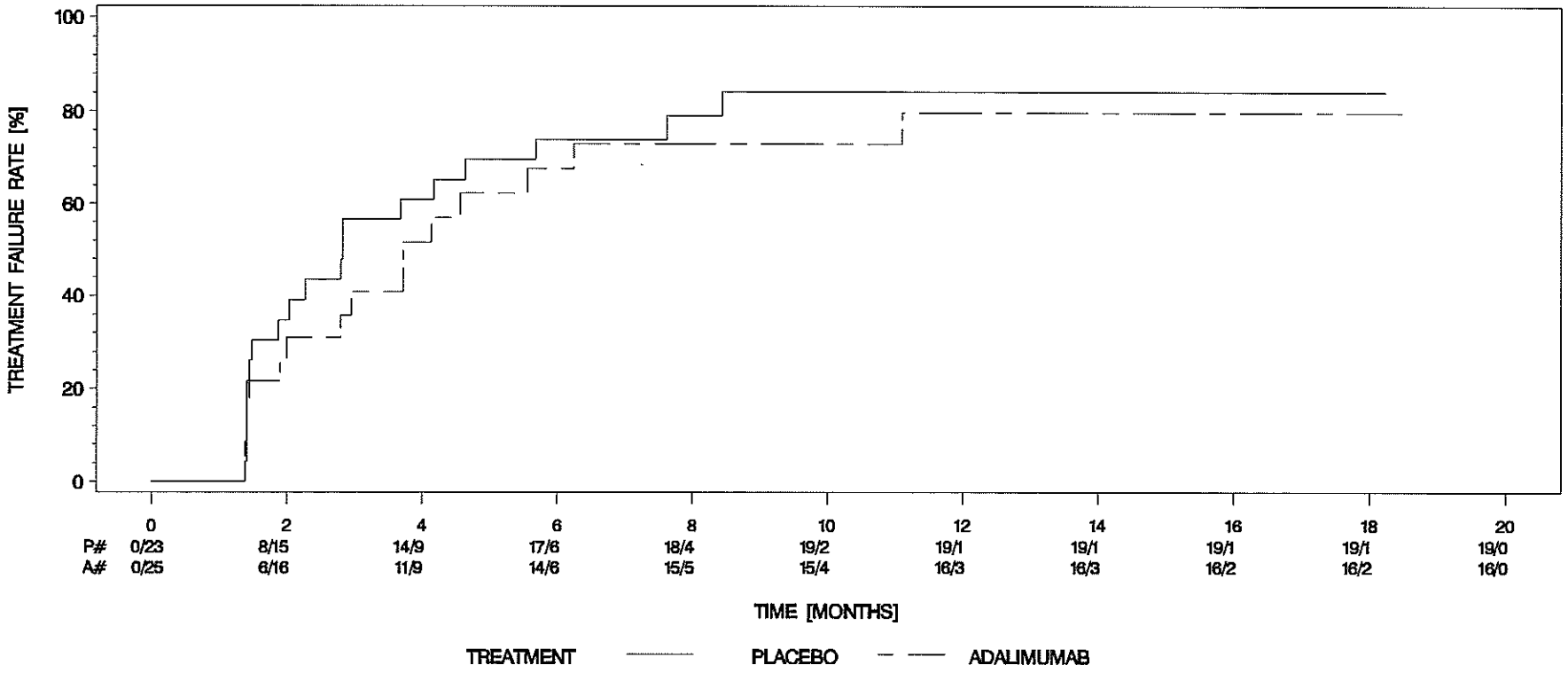
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.9.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)



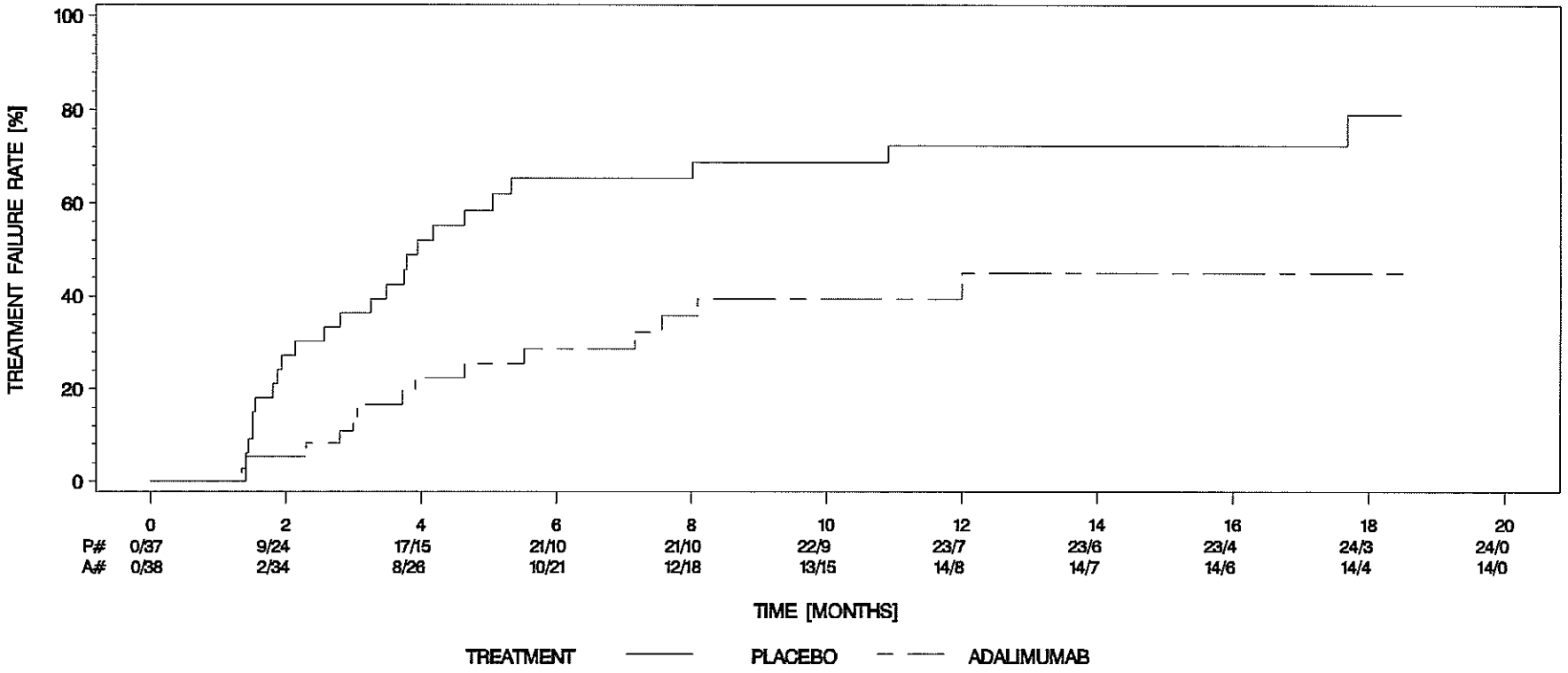
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.10.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)



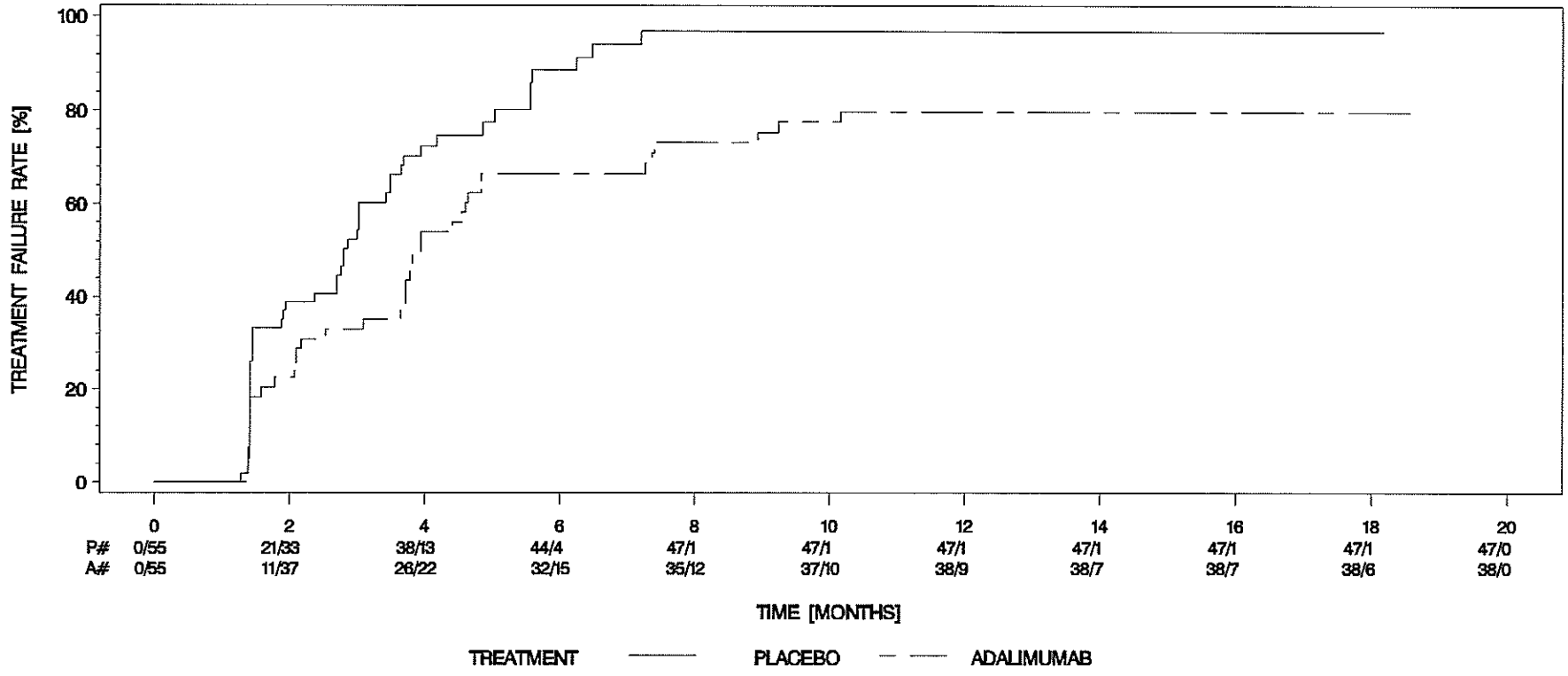
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.11.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

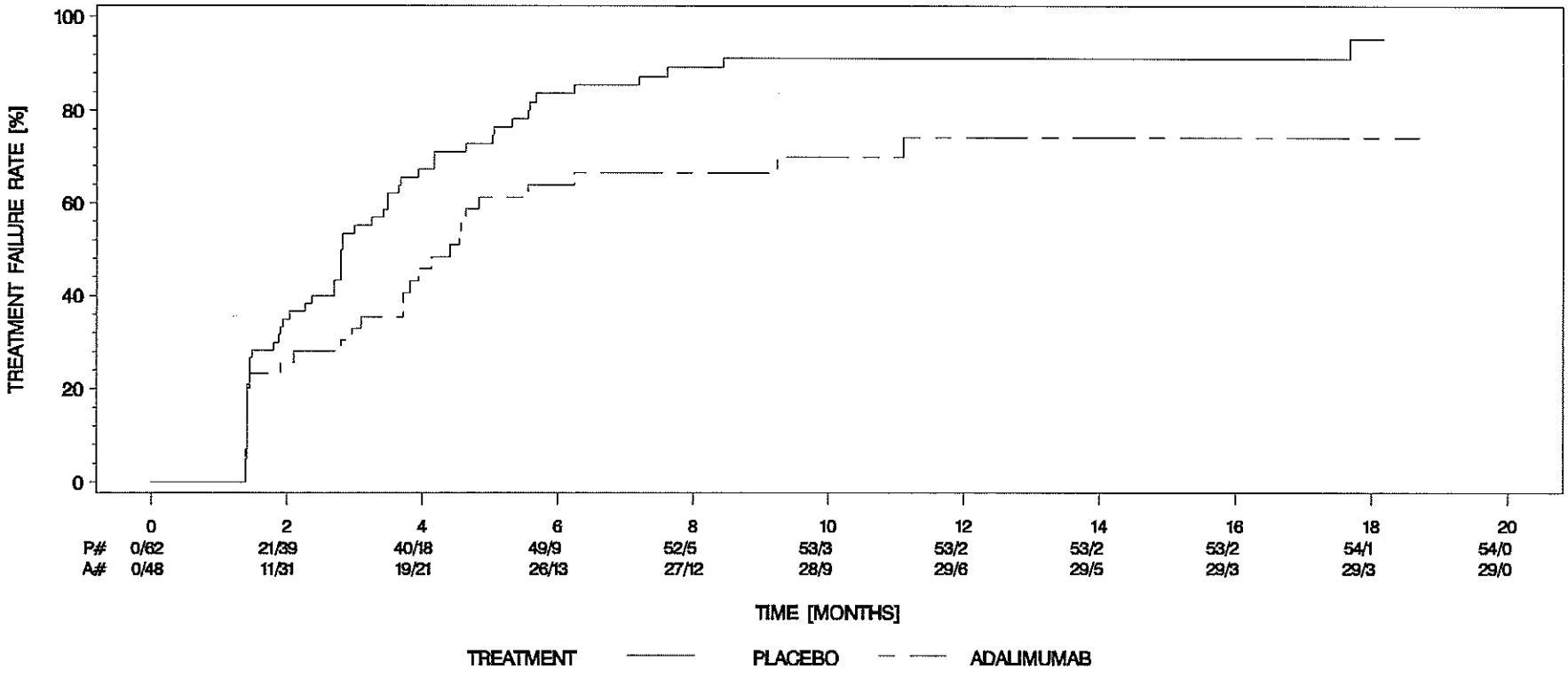
FIGURE 14.2__1000.1.1.4.12.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

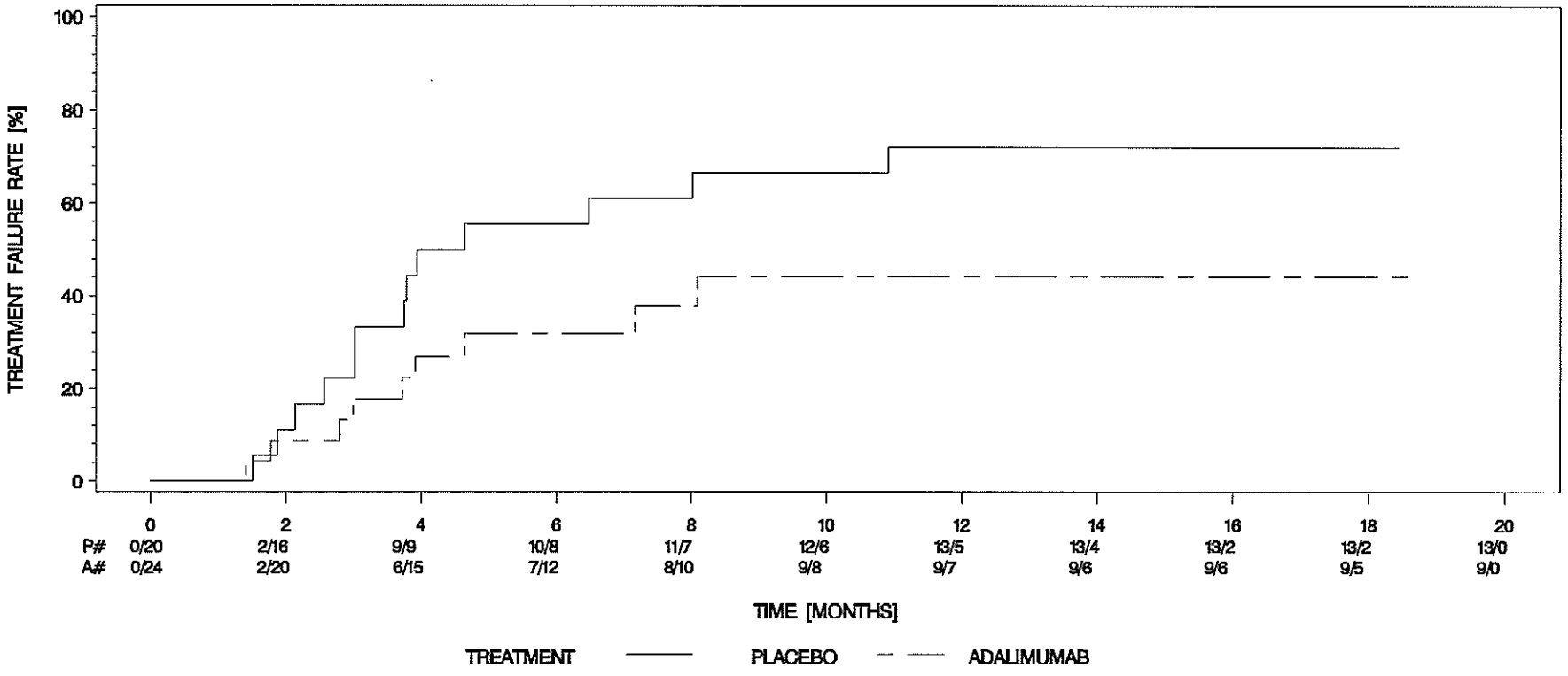
FIGURE 14.2__1000.1.1.4.13.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

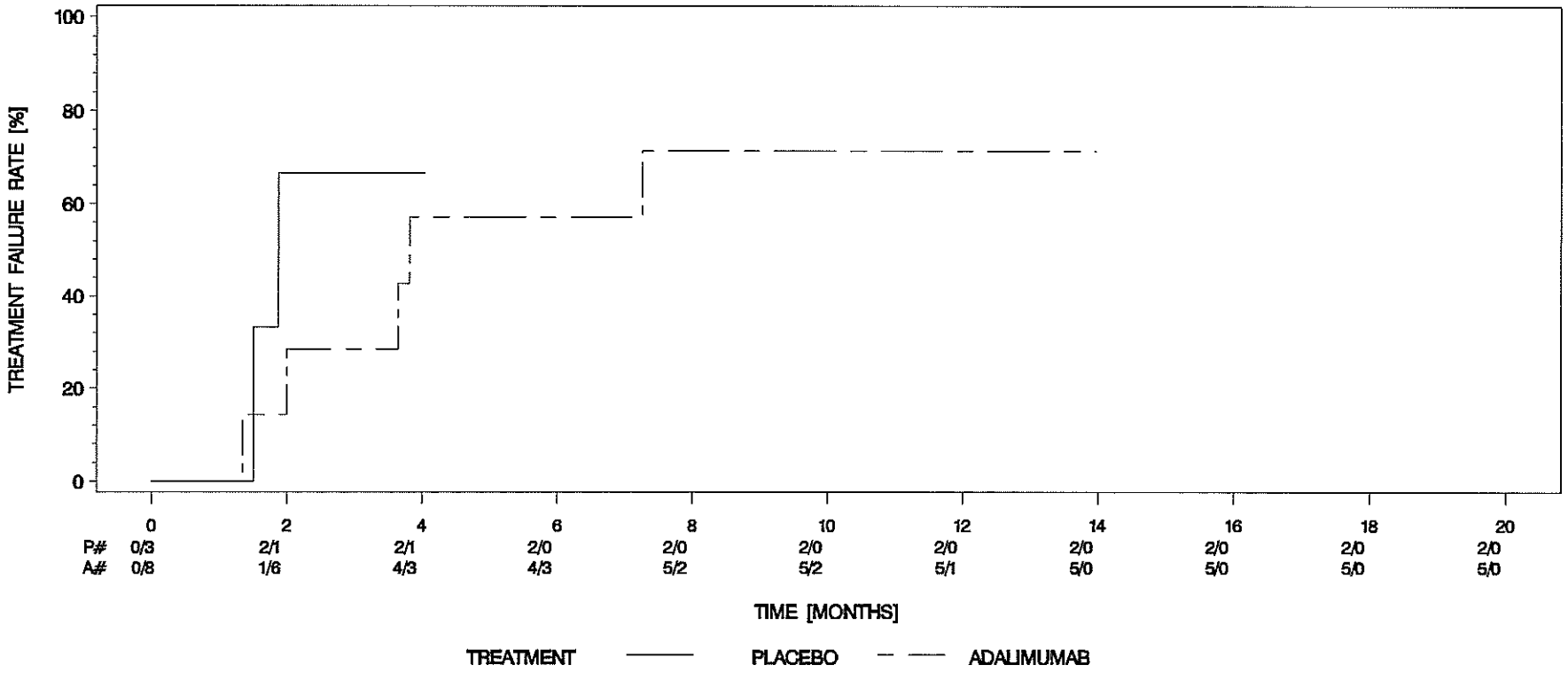
FIGURE 14.2__1000.1.1.4.14.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

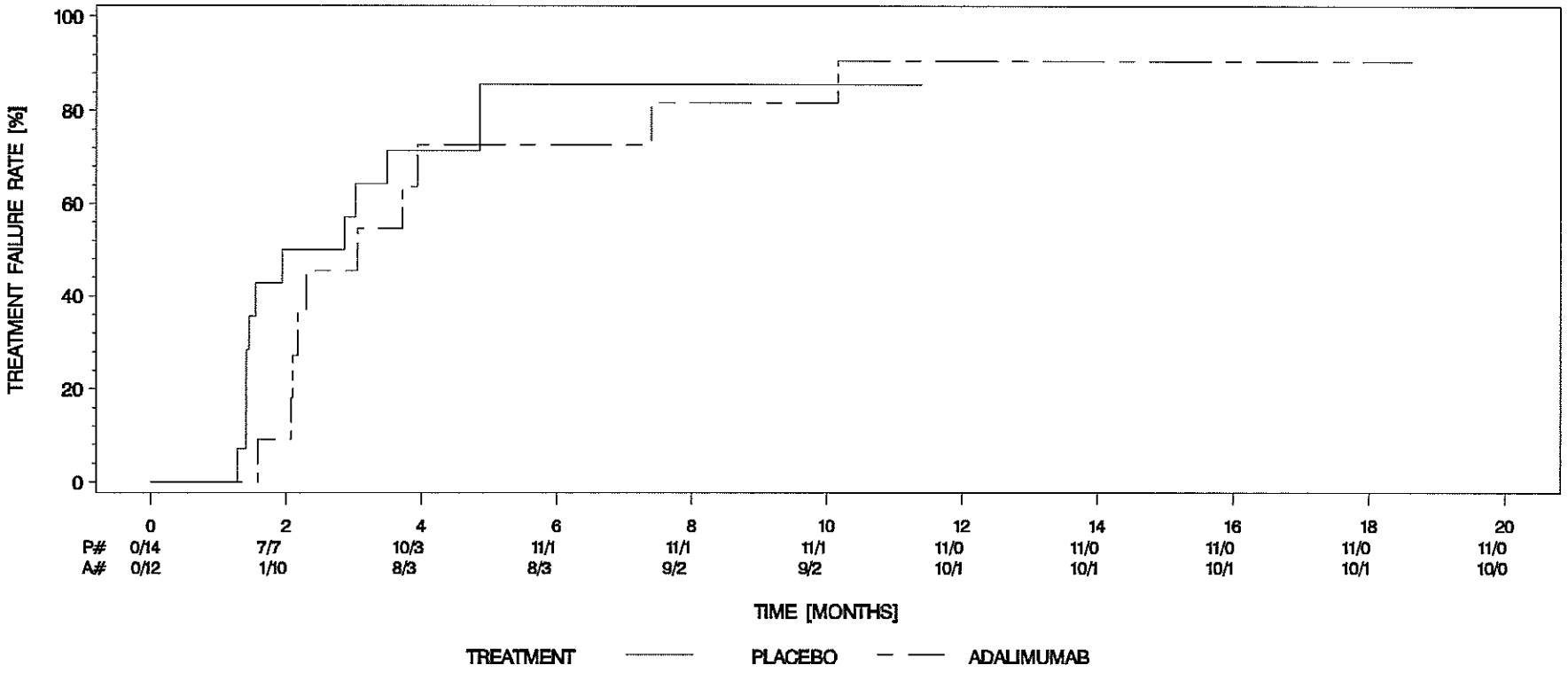
FIGURE 14.2__1000.1.1.4.15.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

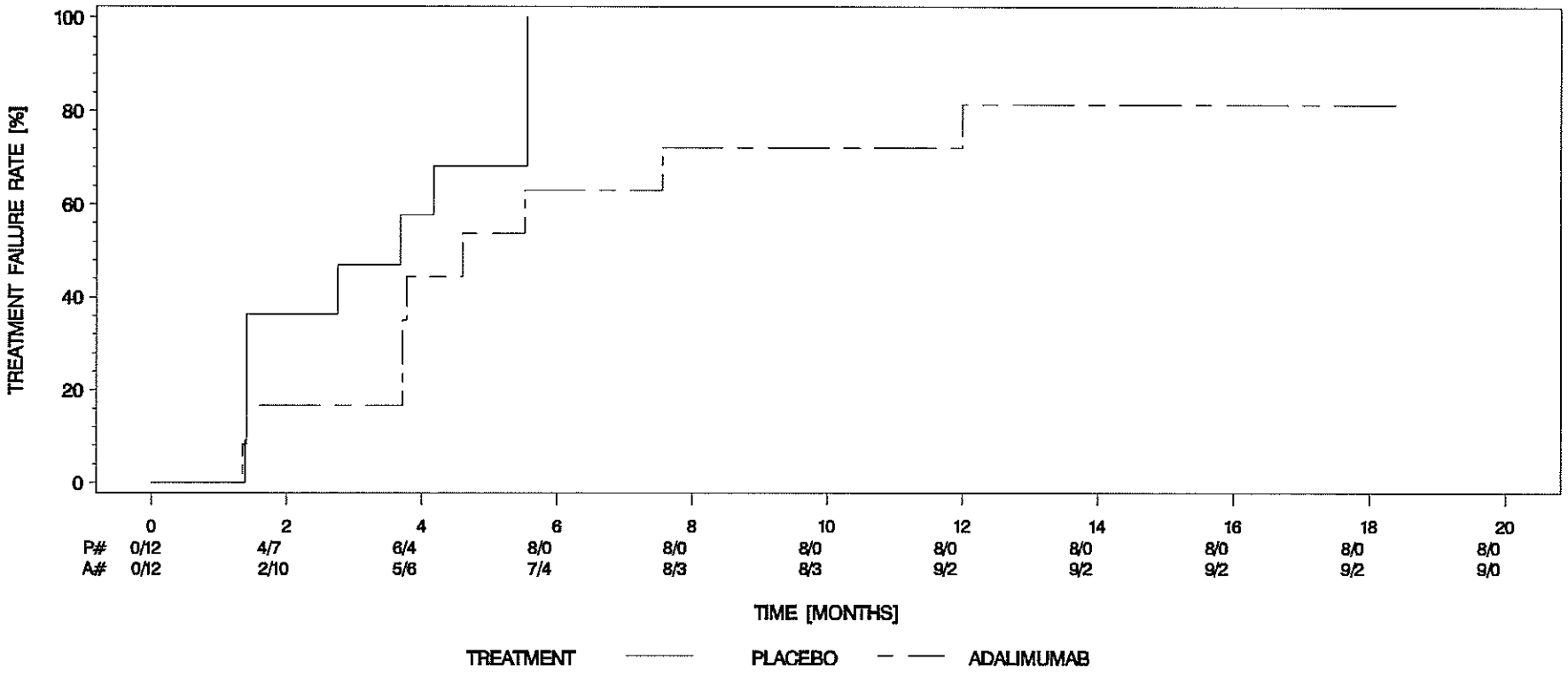
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.16.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)



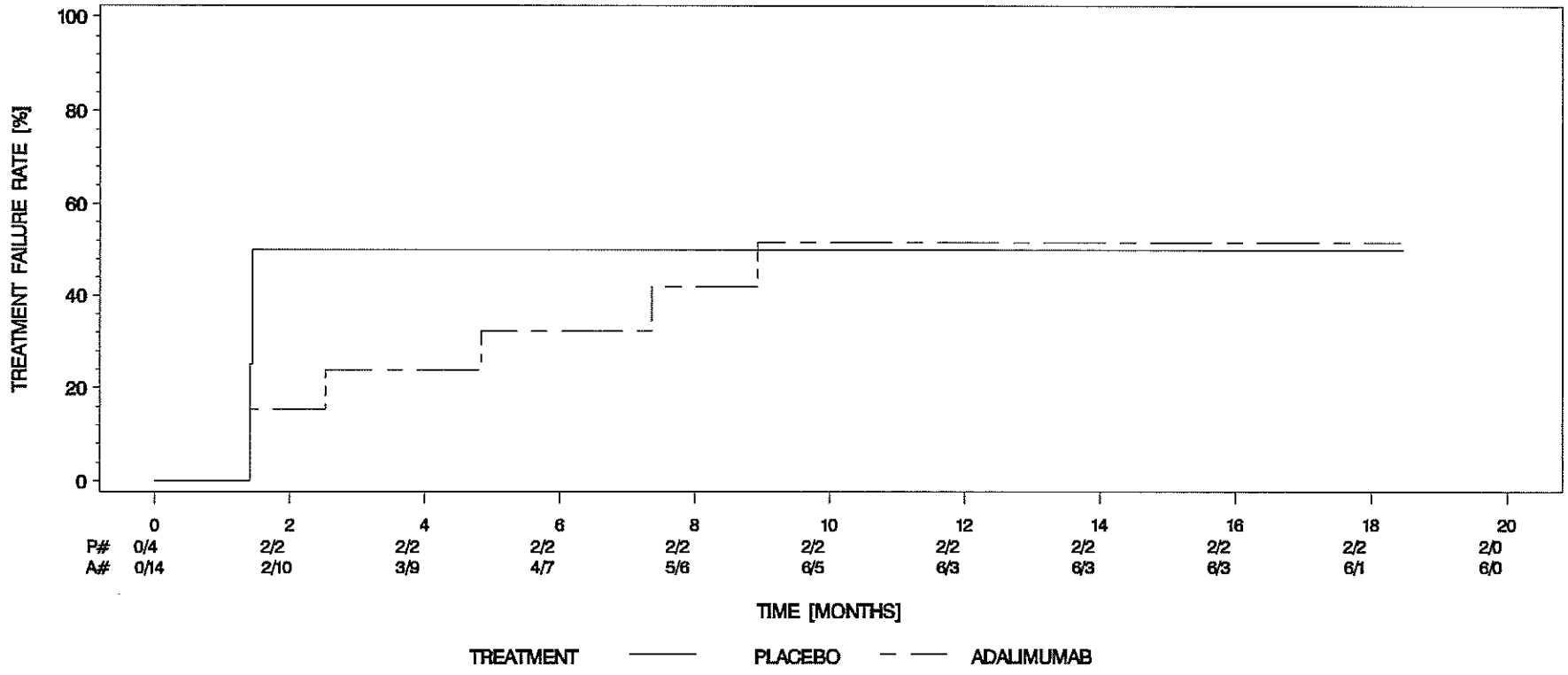
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.17.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

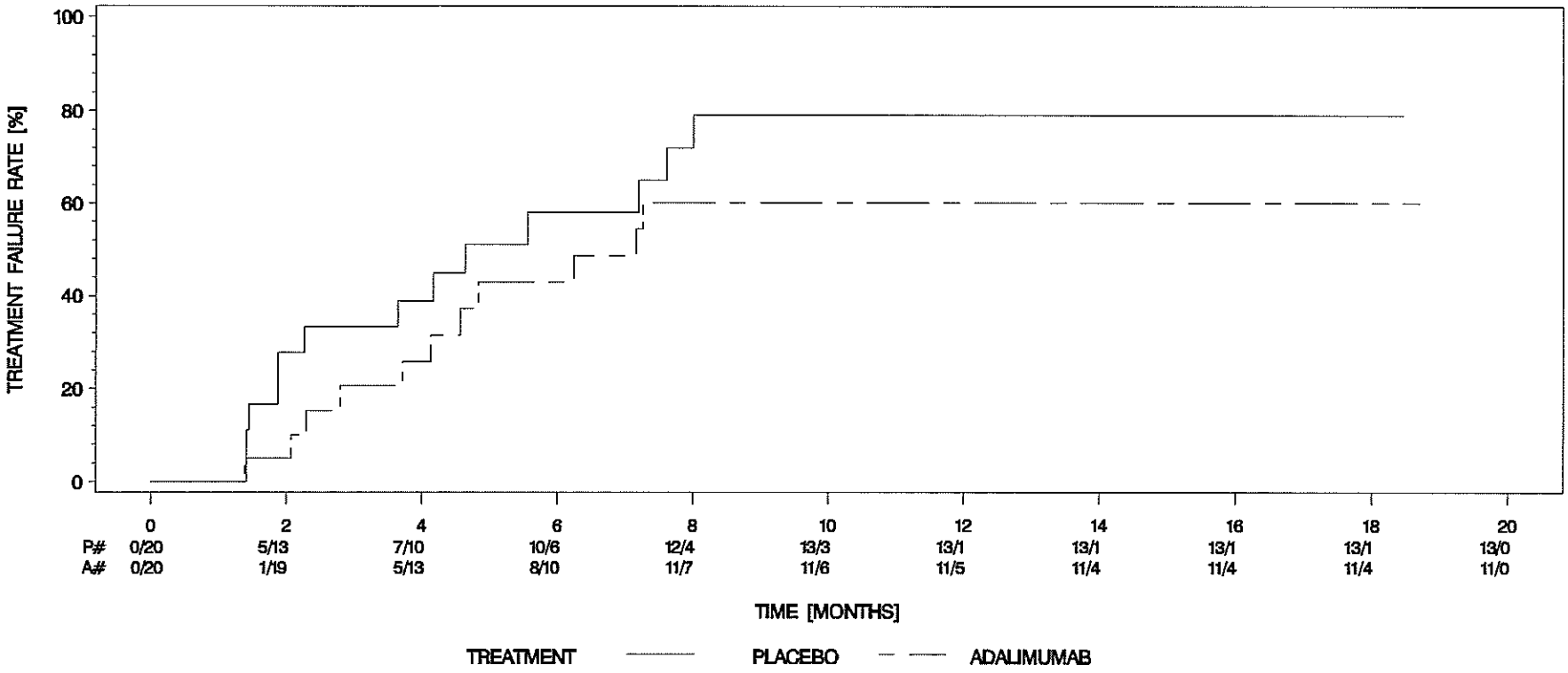
FIGURE 14.2__1000.1.1.4.18.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

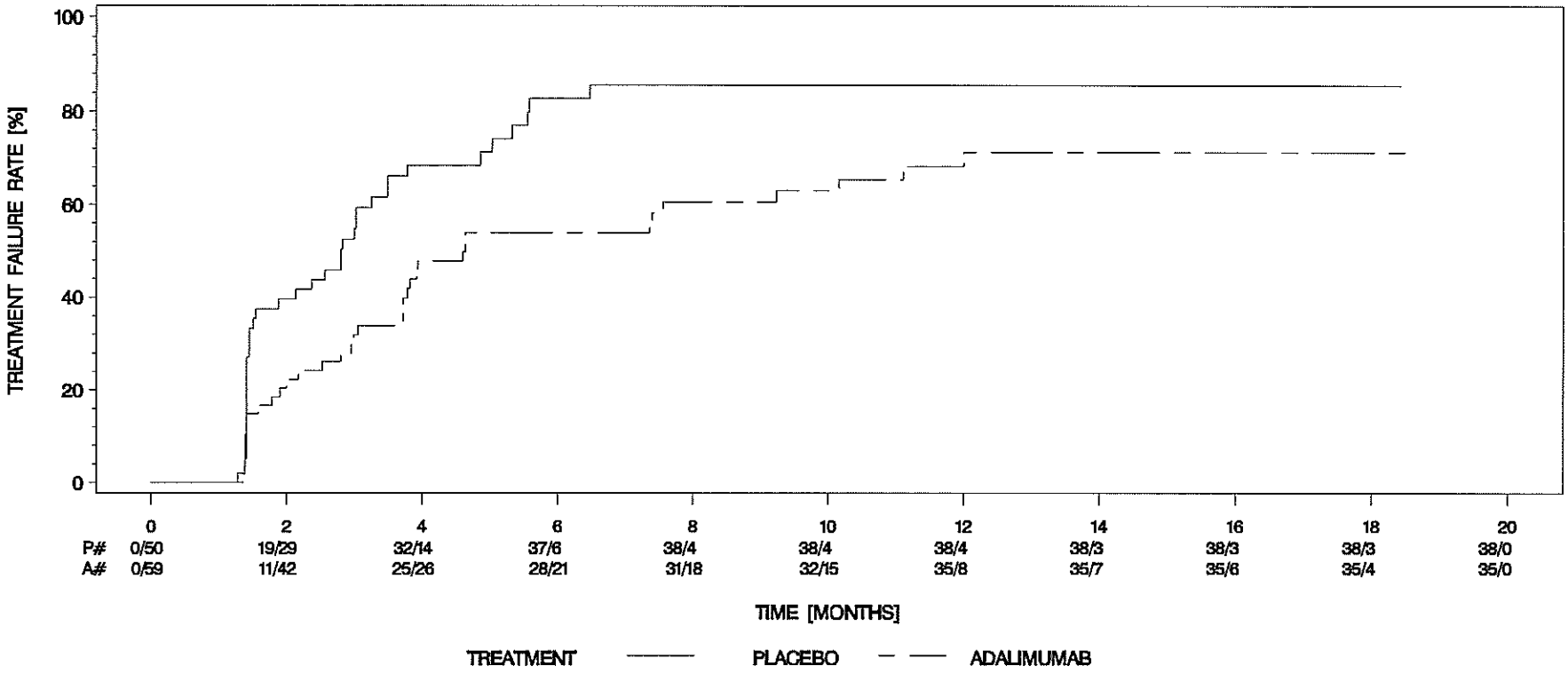
FIGURE 14.2__1000.1.1.4.19.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

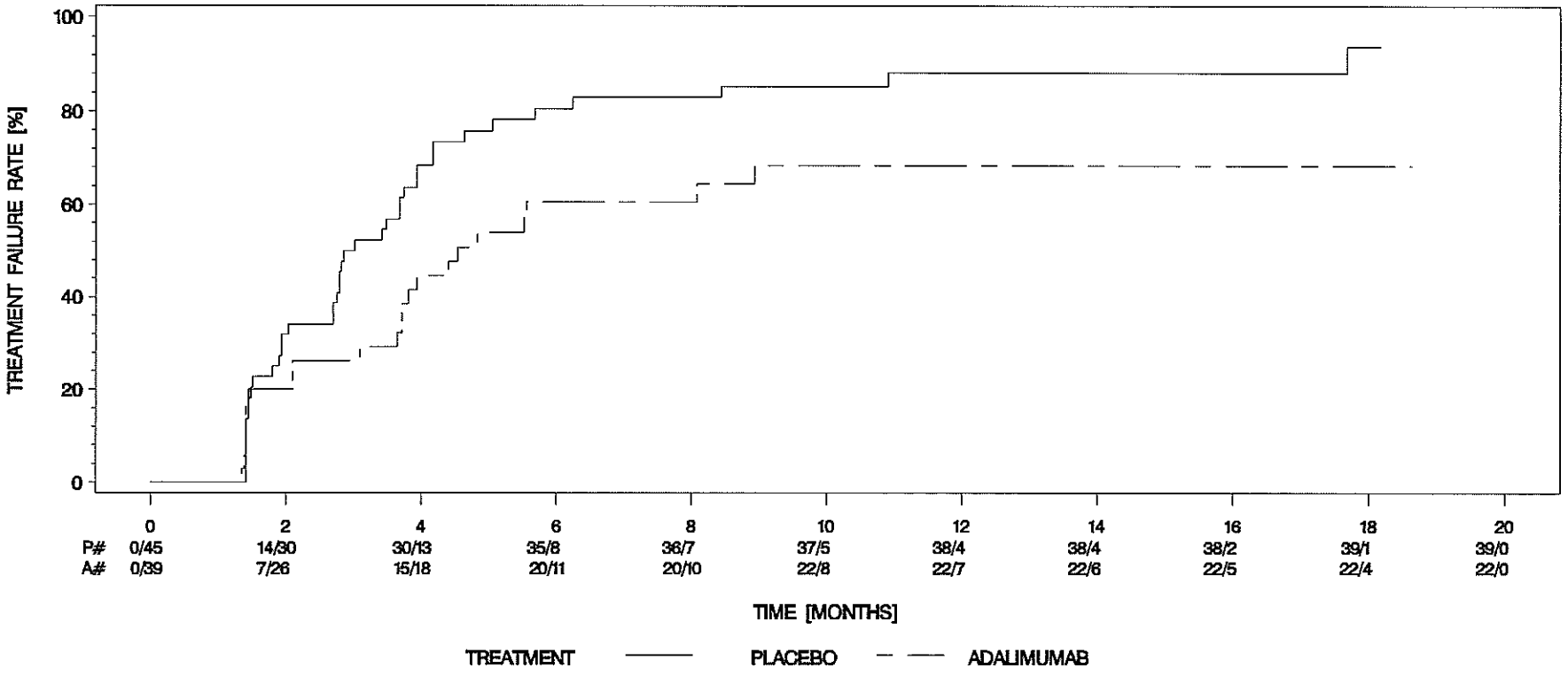
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.20.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

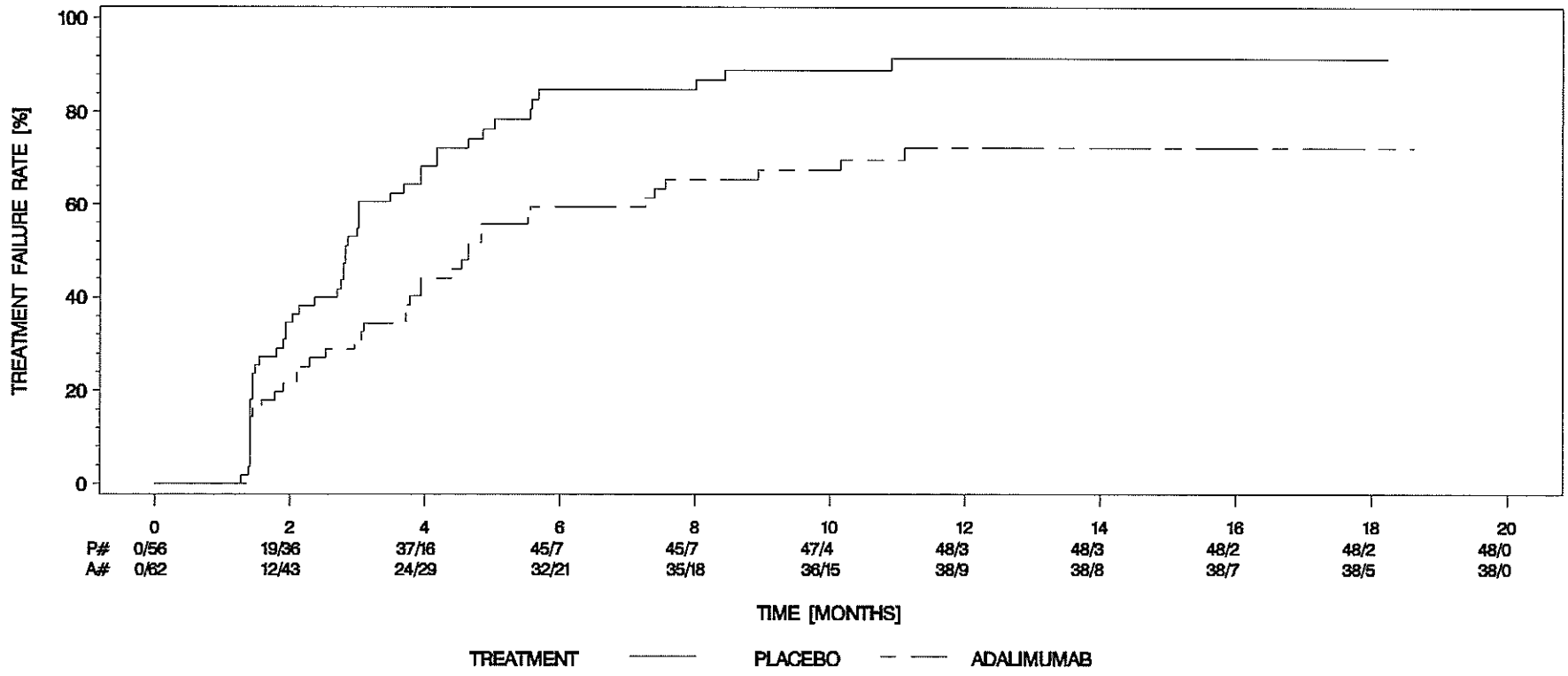
FIGURE 14.2__1000.1.1.4.21.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

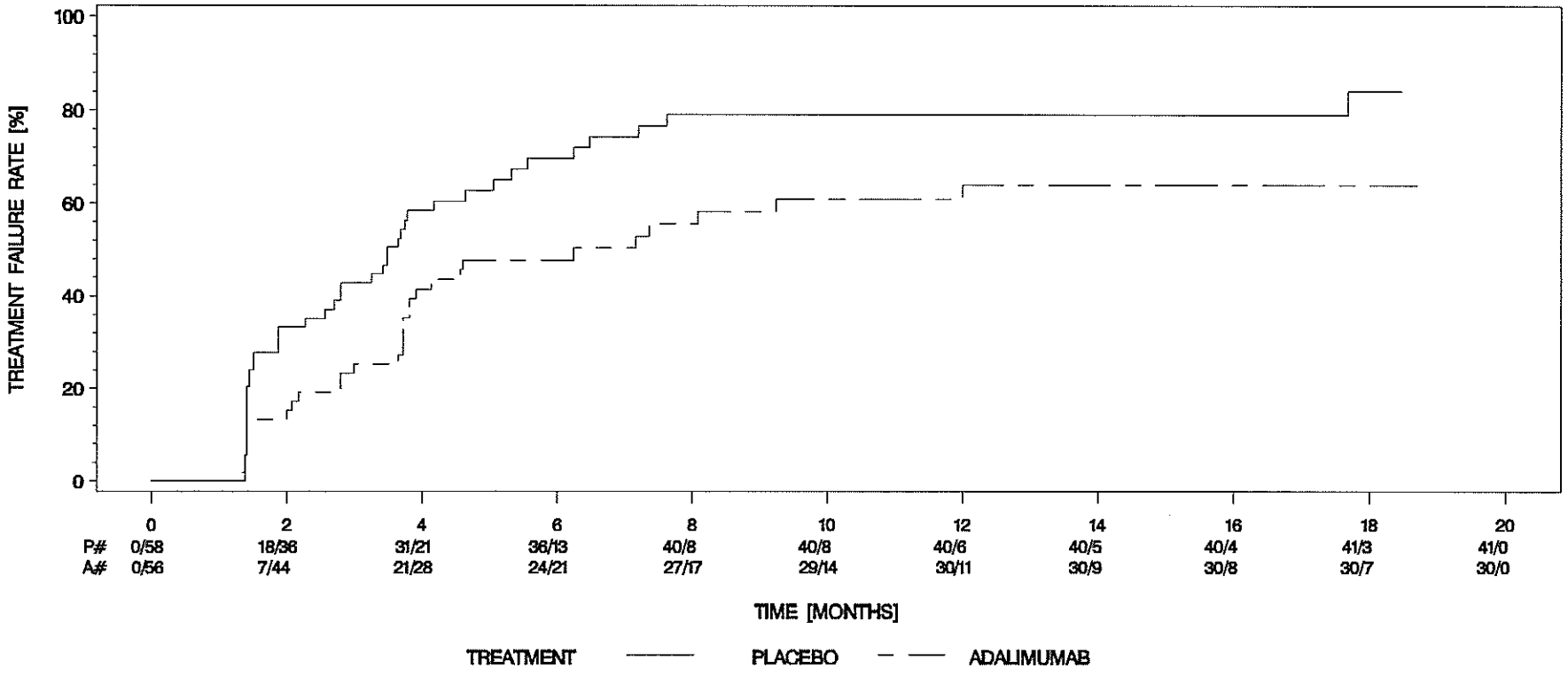
FIGURE 14.2__1000.1.1.4.22.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

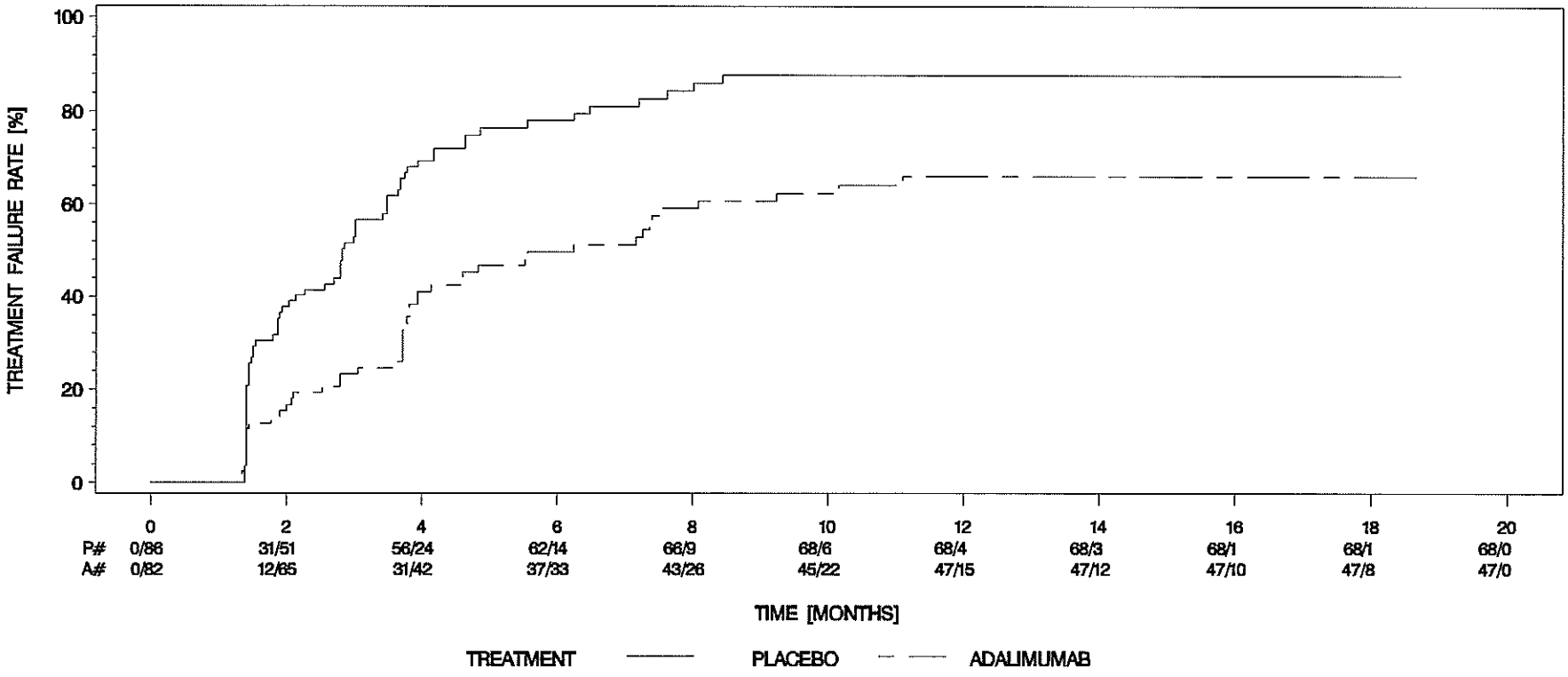
FIGURE 14.2__1000.1.1.4.23.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

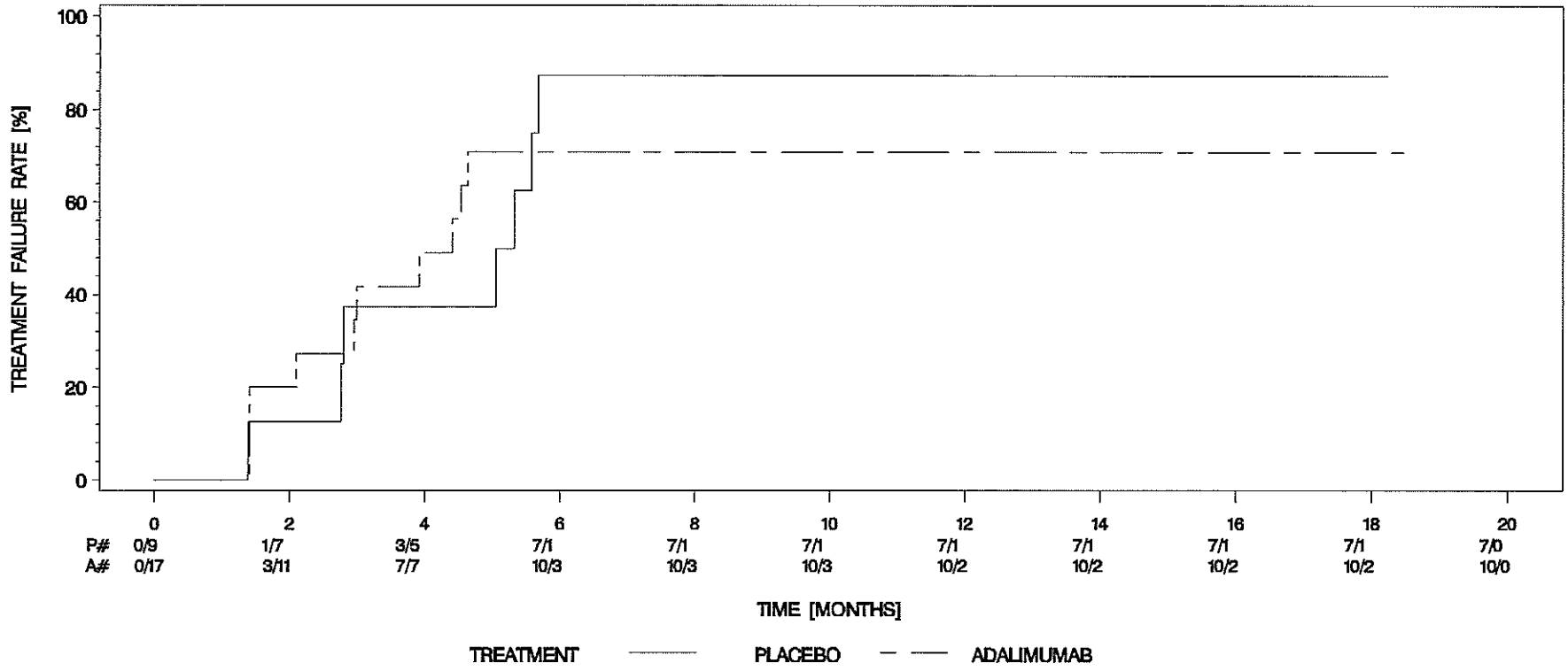
FIGURE 14.2__1000.1.1.4.24.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

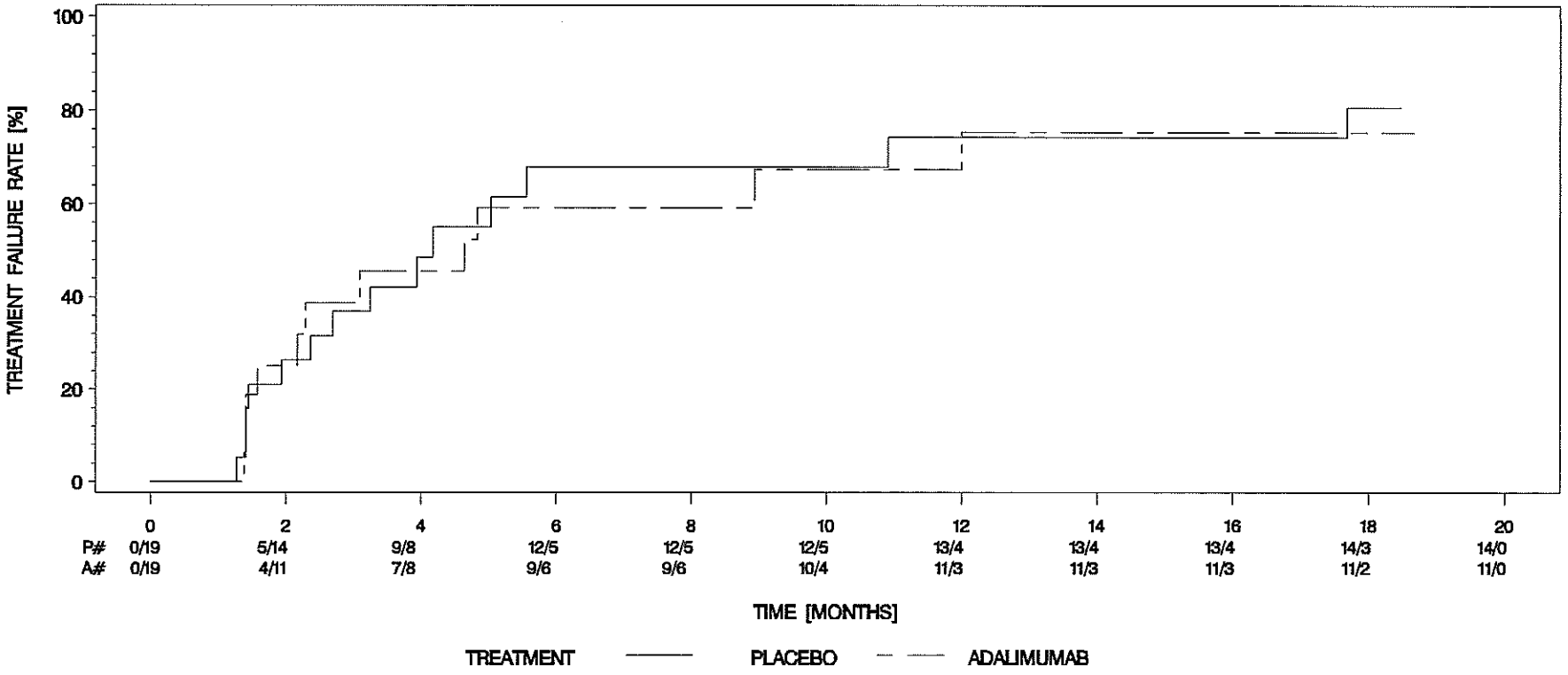
FIGURE 14.2__1000.1.1.4.25.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

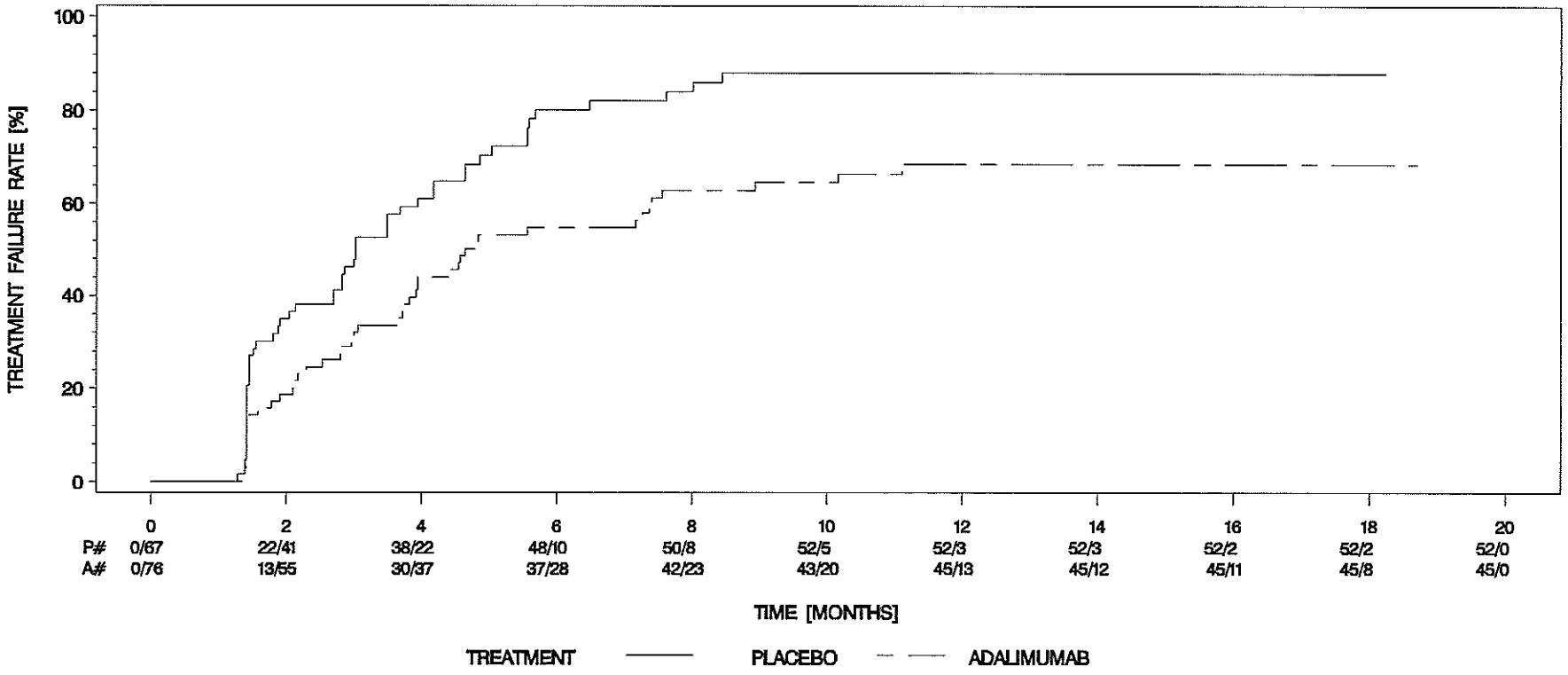
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.26.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

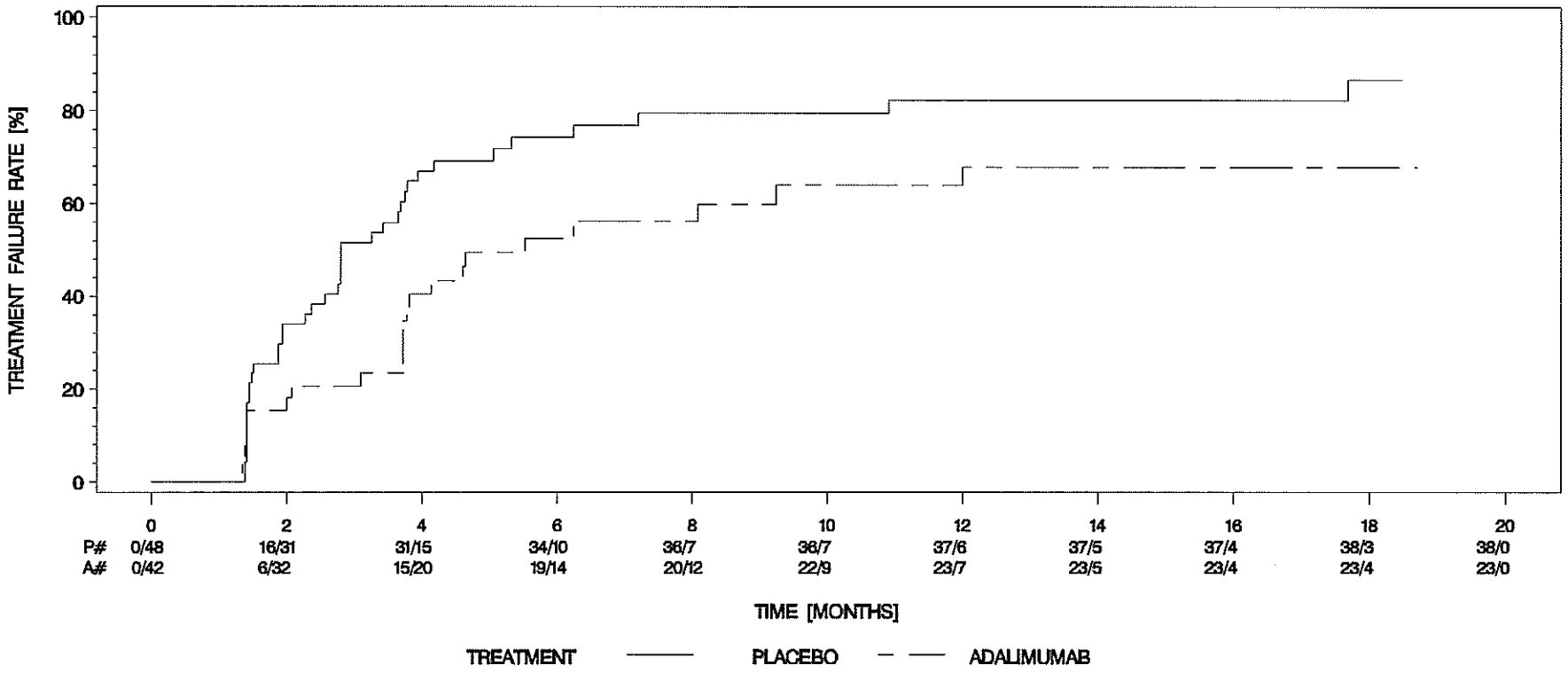
FIGURE 14.2__1000.1.1.4.27.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

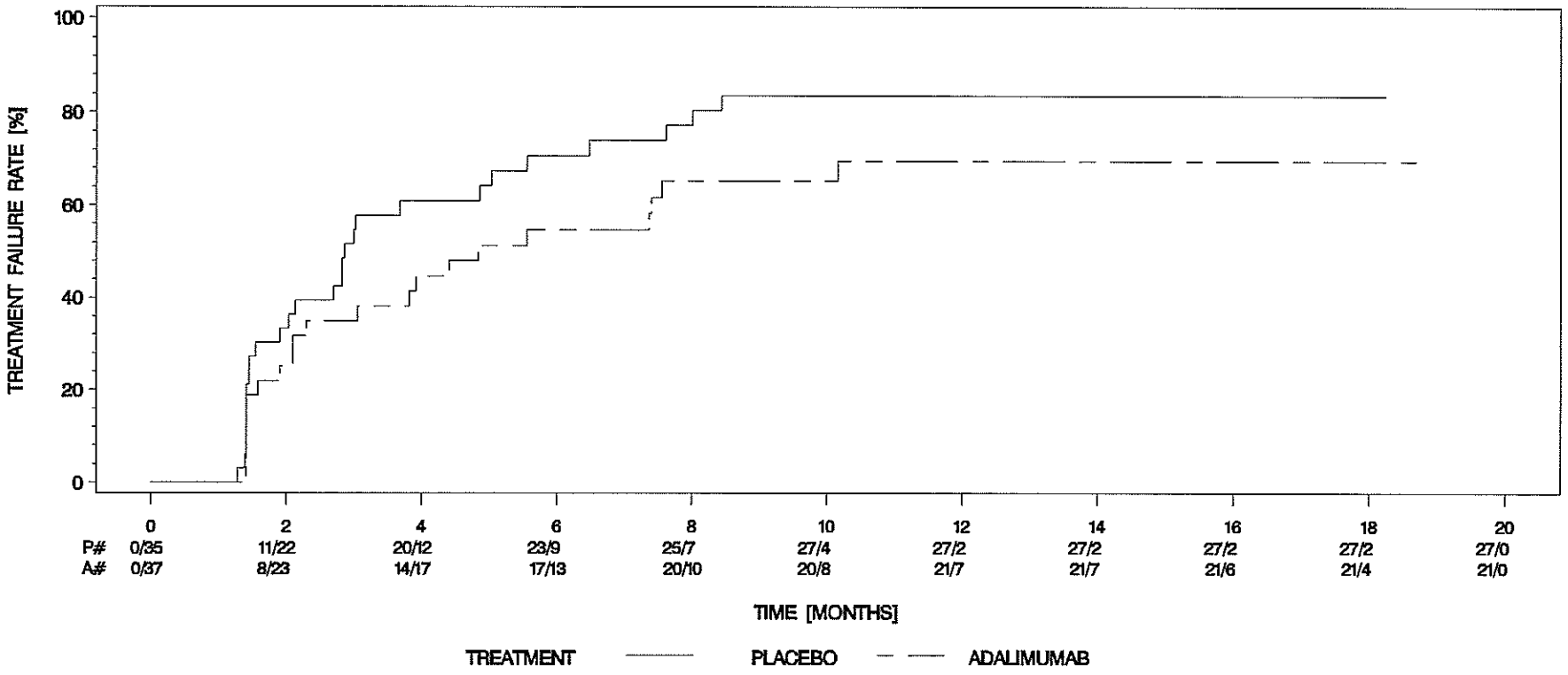
FIGURE 14.2__1000.1.1.4.28.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

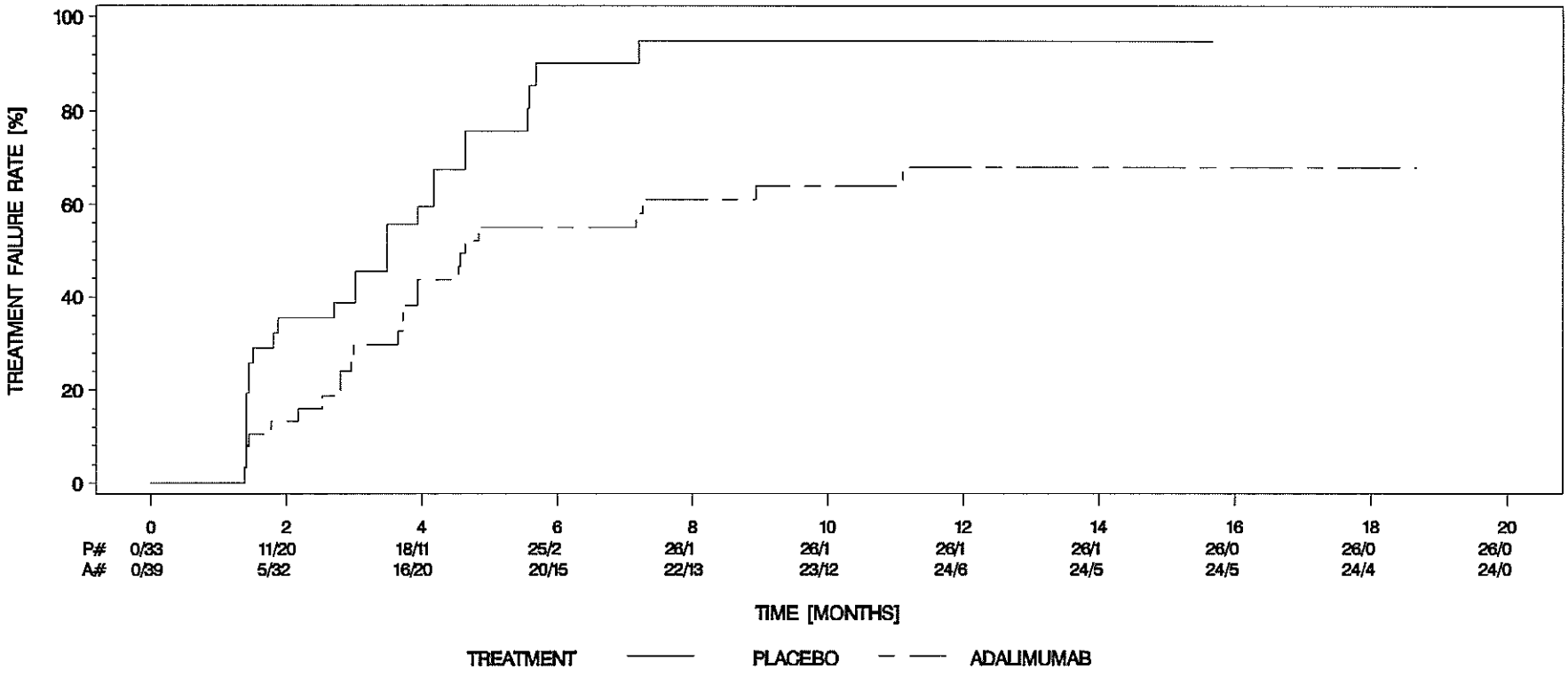
FIGURE 14.2__1000.1.1.4.29.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

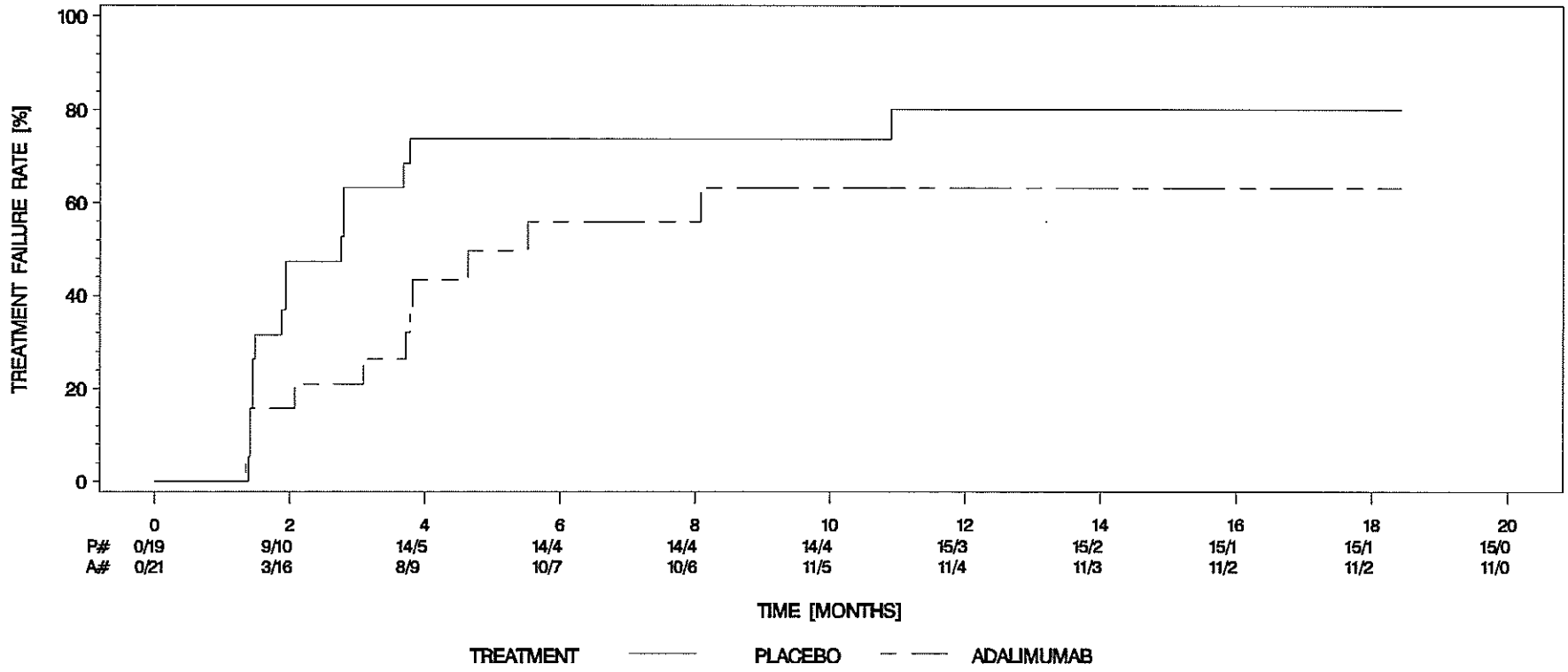
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.30.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)



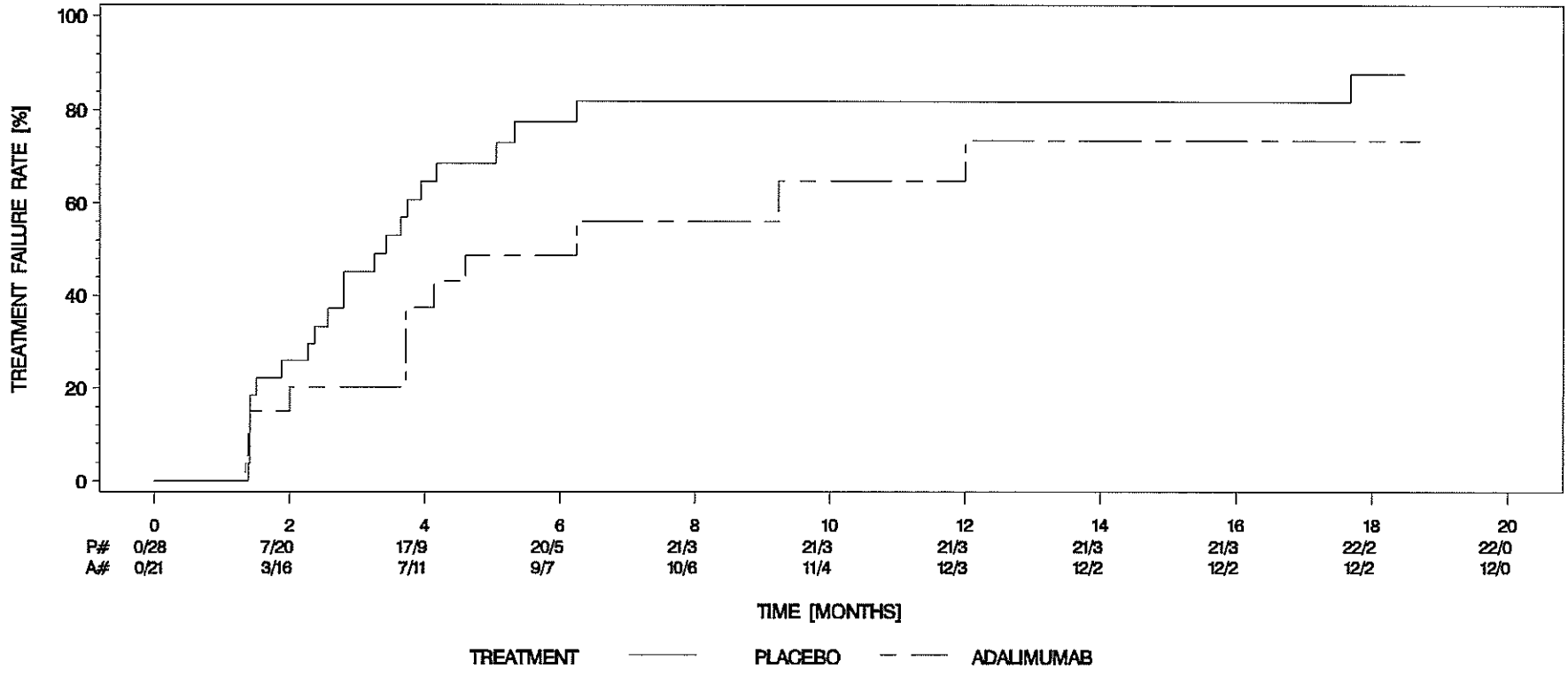
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.31.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

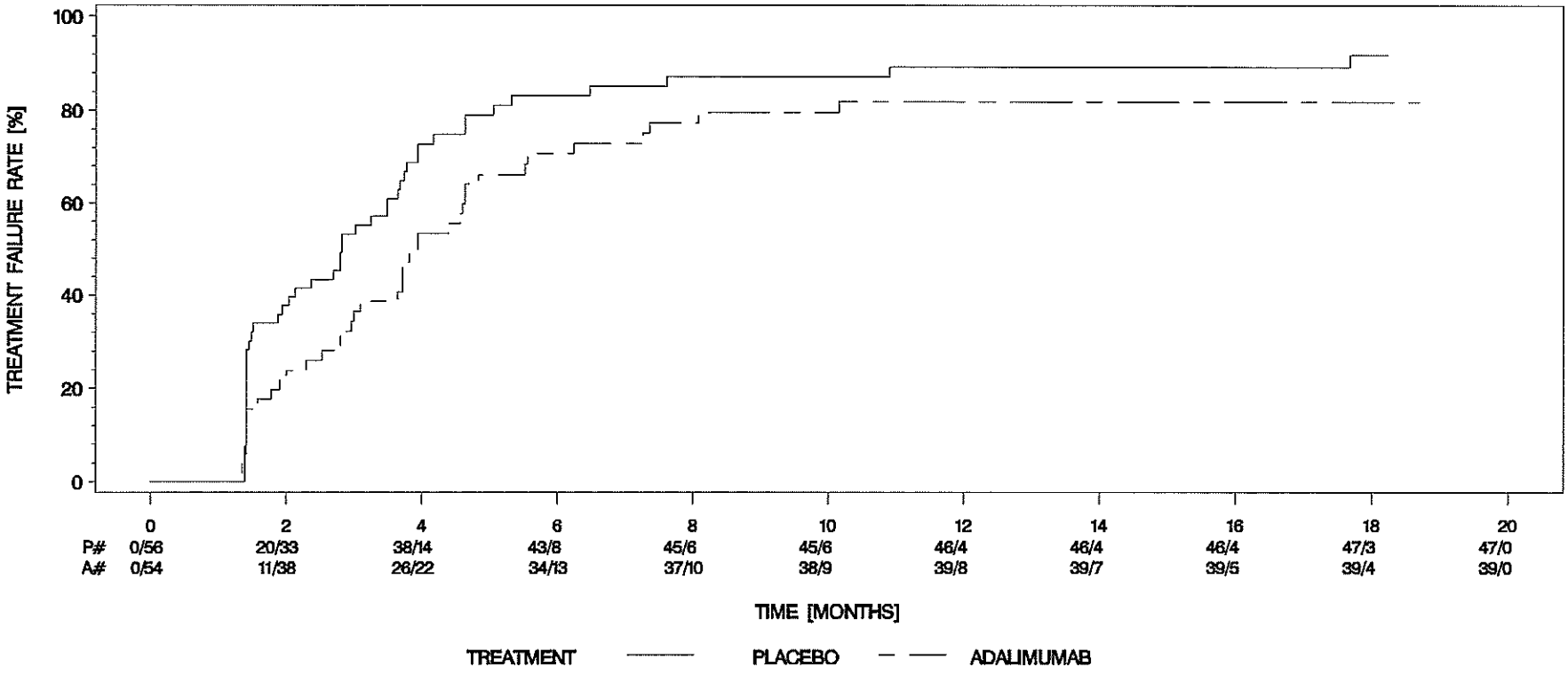
FIGURE 14.2__1000.1.1.4.32.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

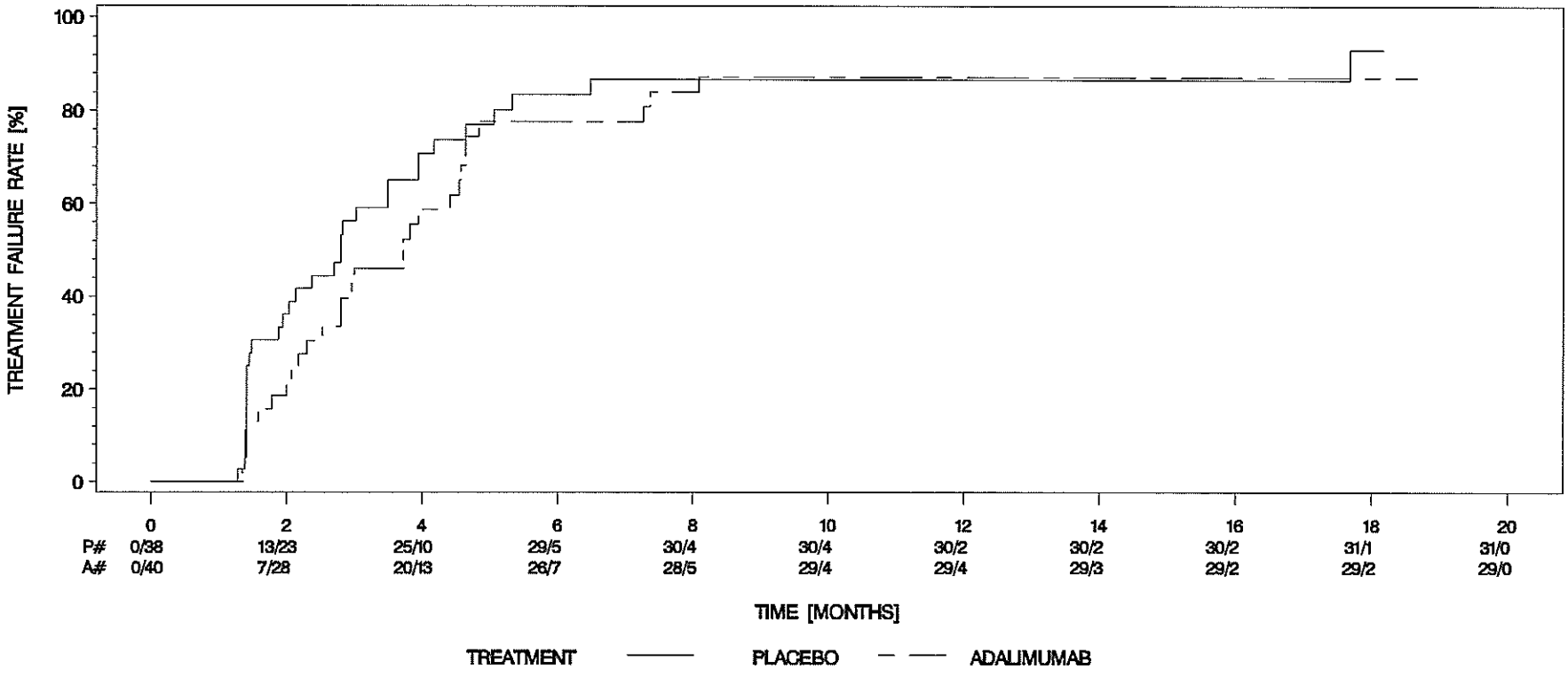
FIGURE 14.2__1000.1.1.4.33.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

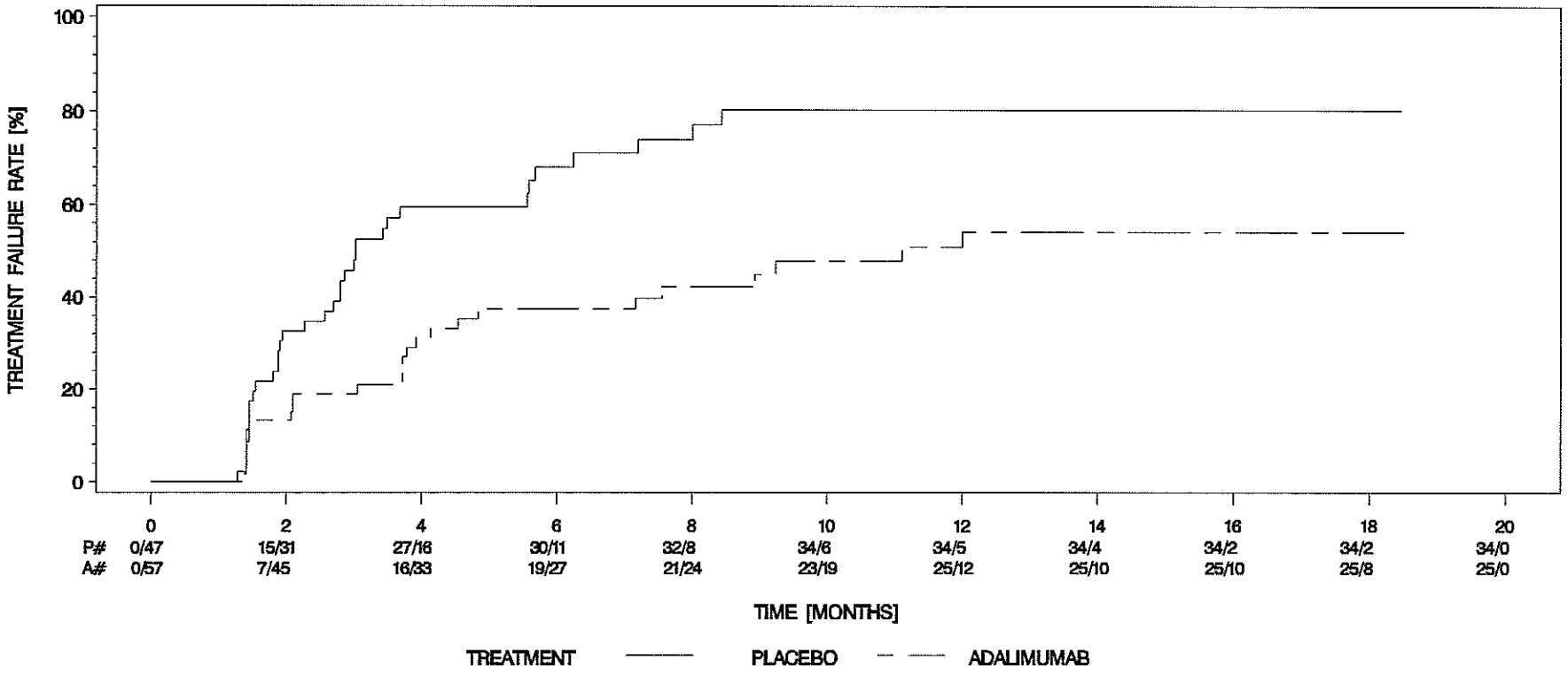
FIGURE 14.2__1000.1.1.4.33.I.PH
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

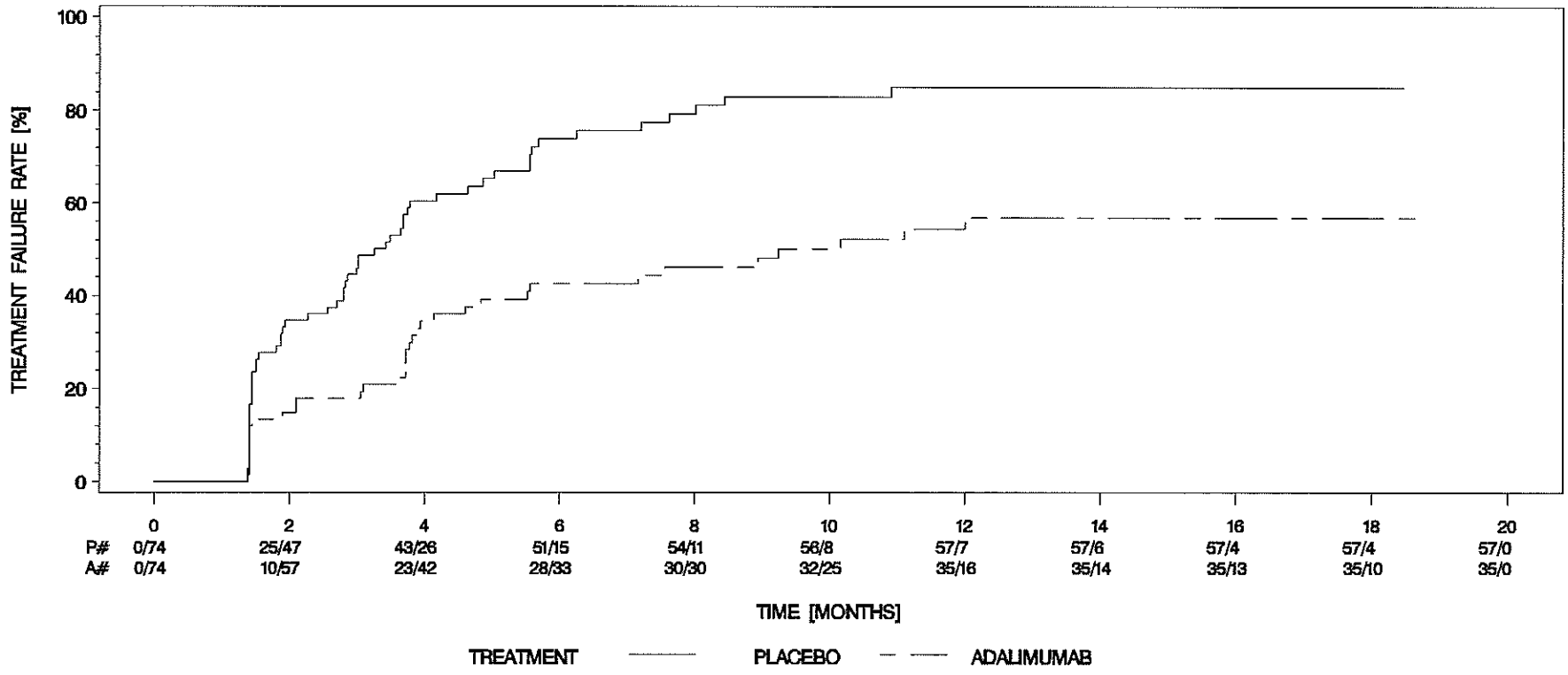
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.34.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

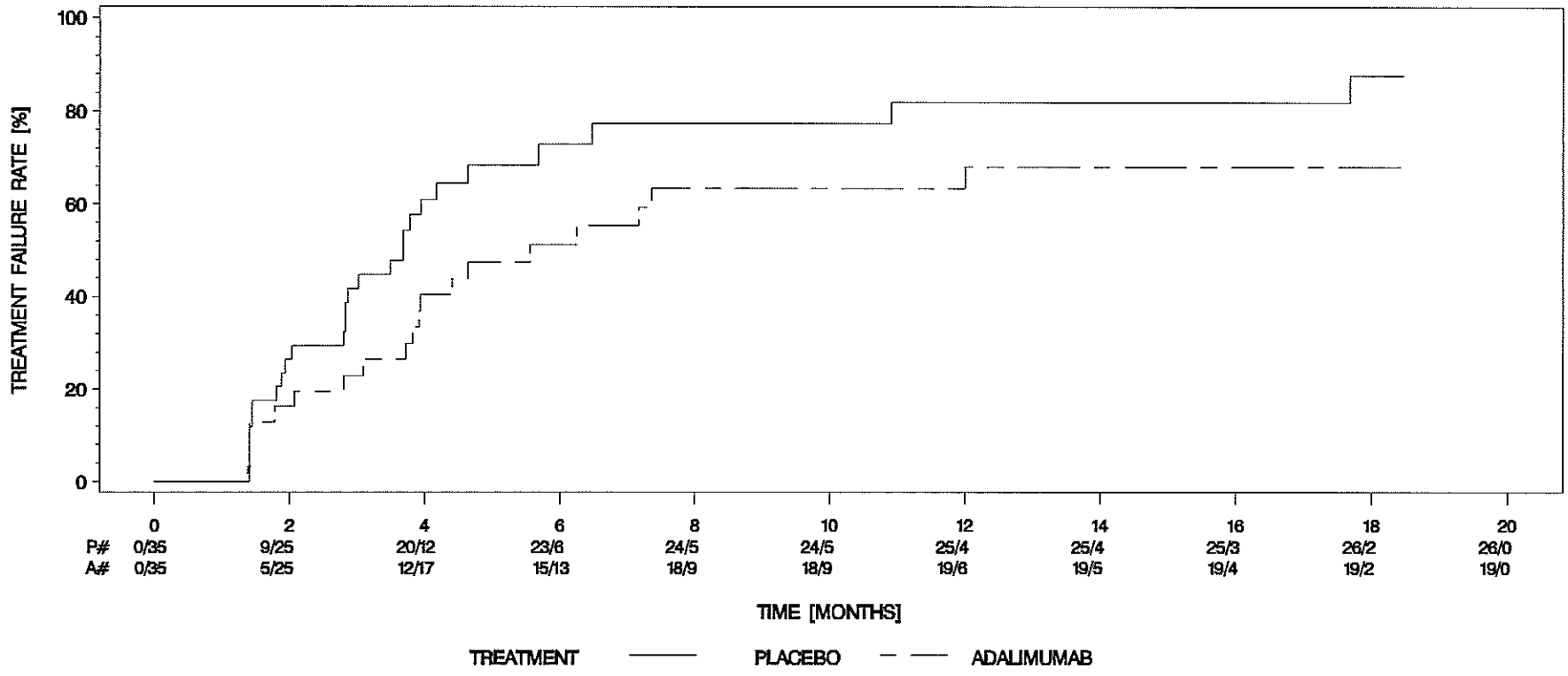
FIGURE 14.2__1000.1.1.4.34.I.PH
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

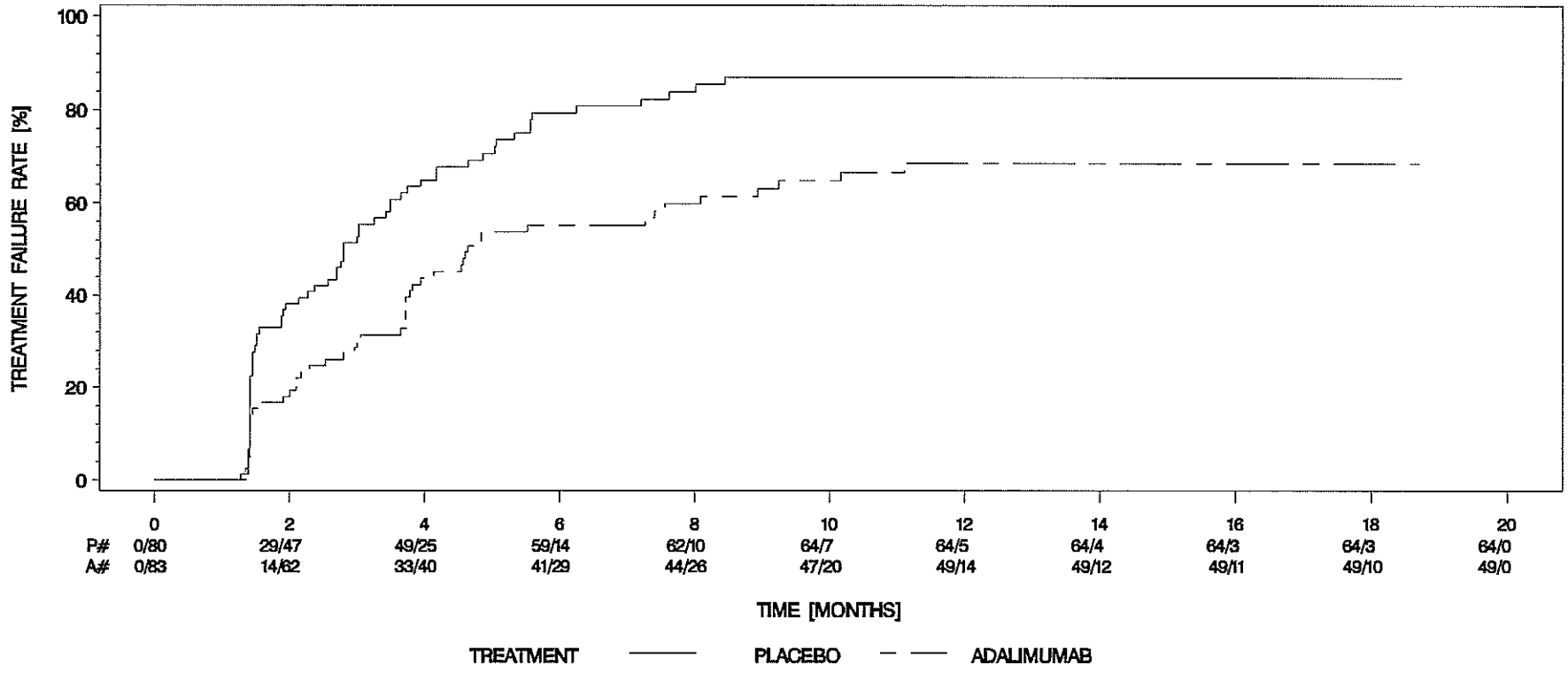
FIGURE 14.2__1000.1.1.4.35.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

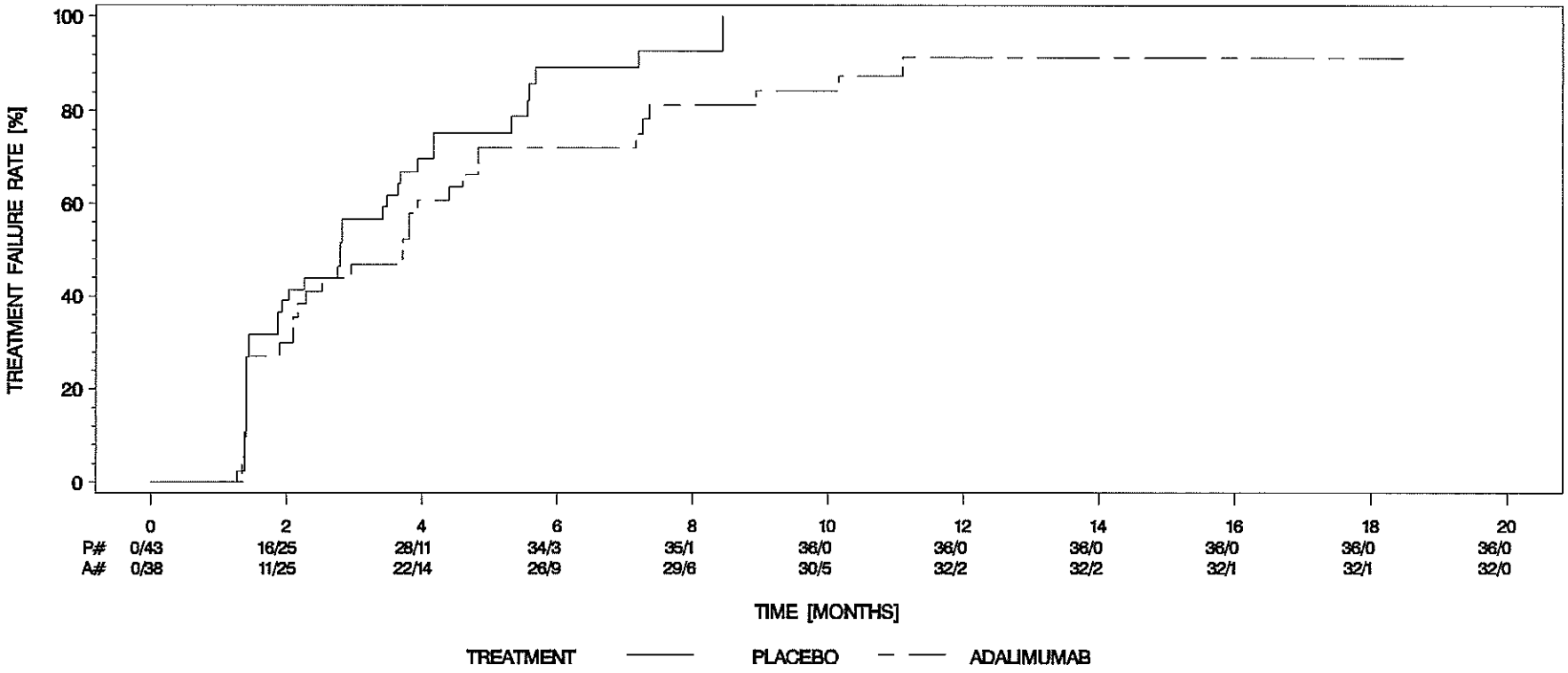
FIGURE 14.2__1000.1.1.4.36.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

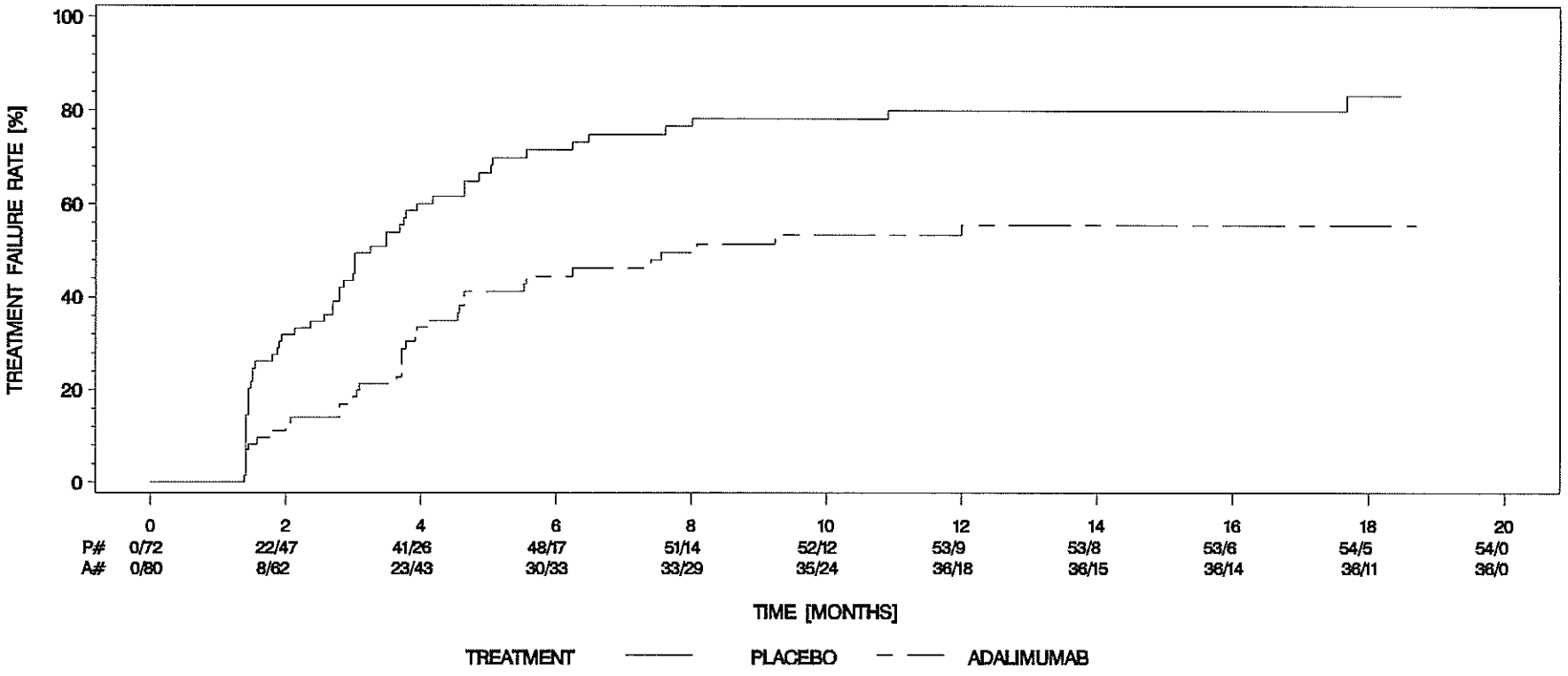
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.37.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)



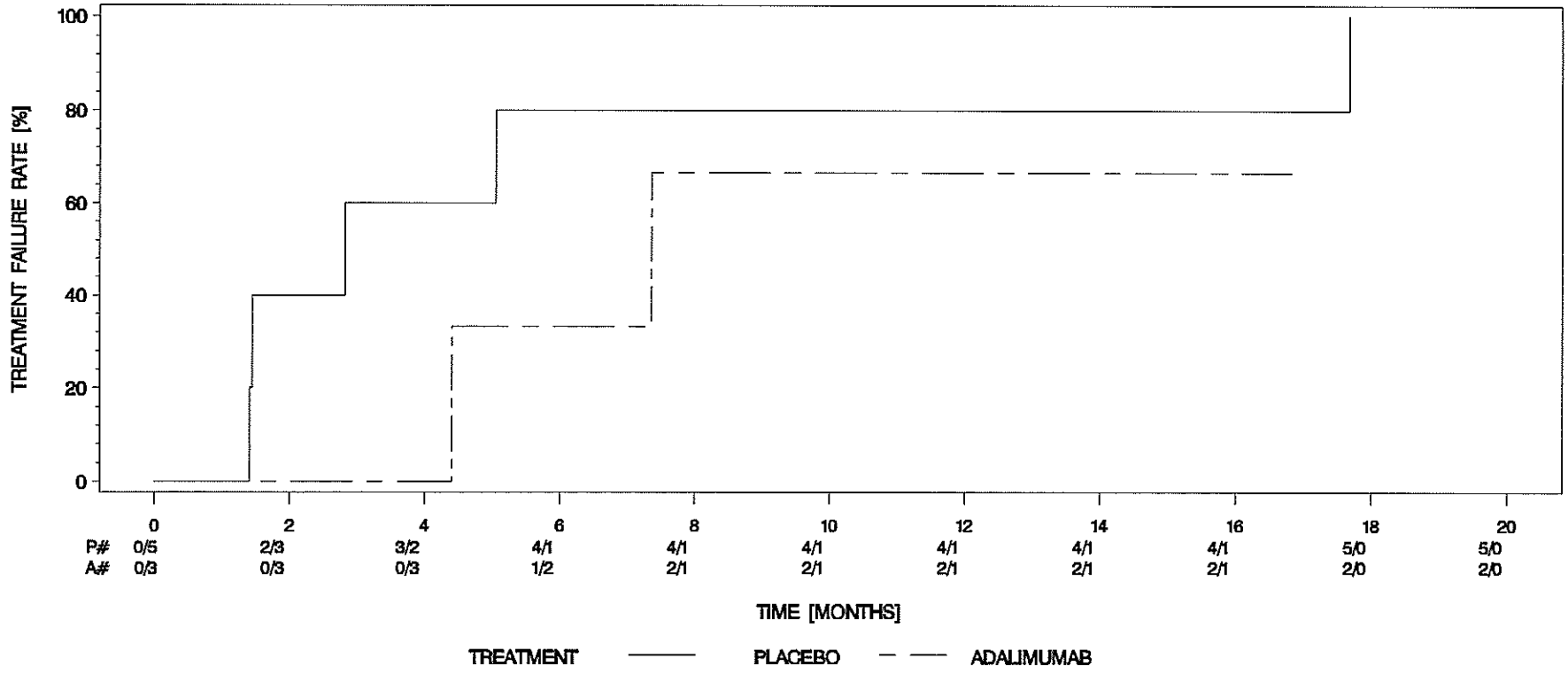
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.38.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

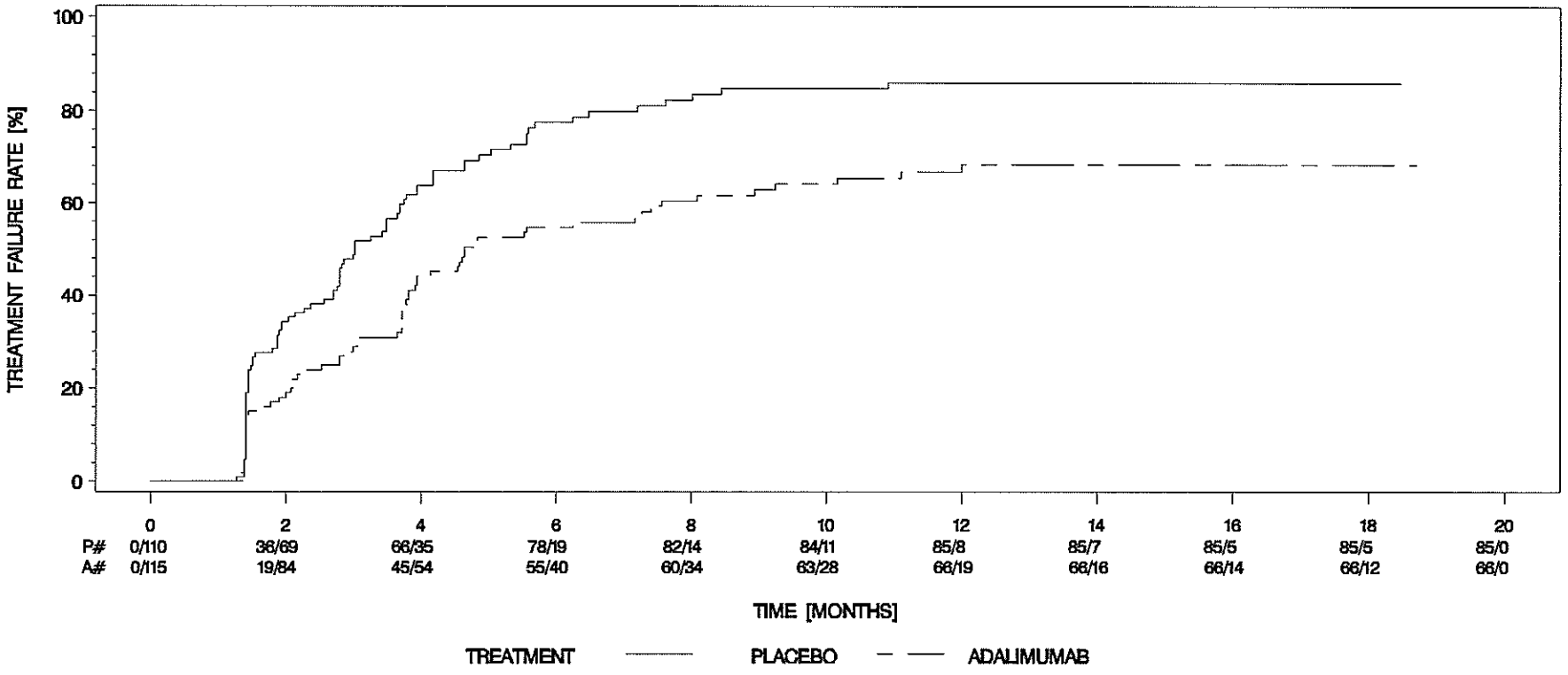
FIGURE 14.2__1000.1.1.4.39.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

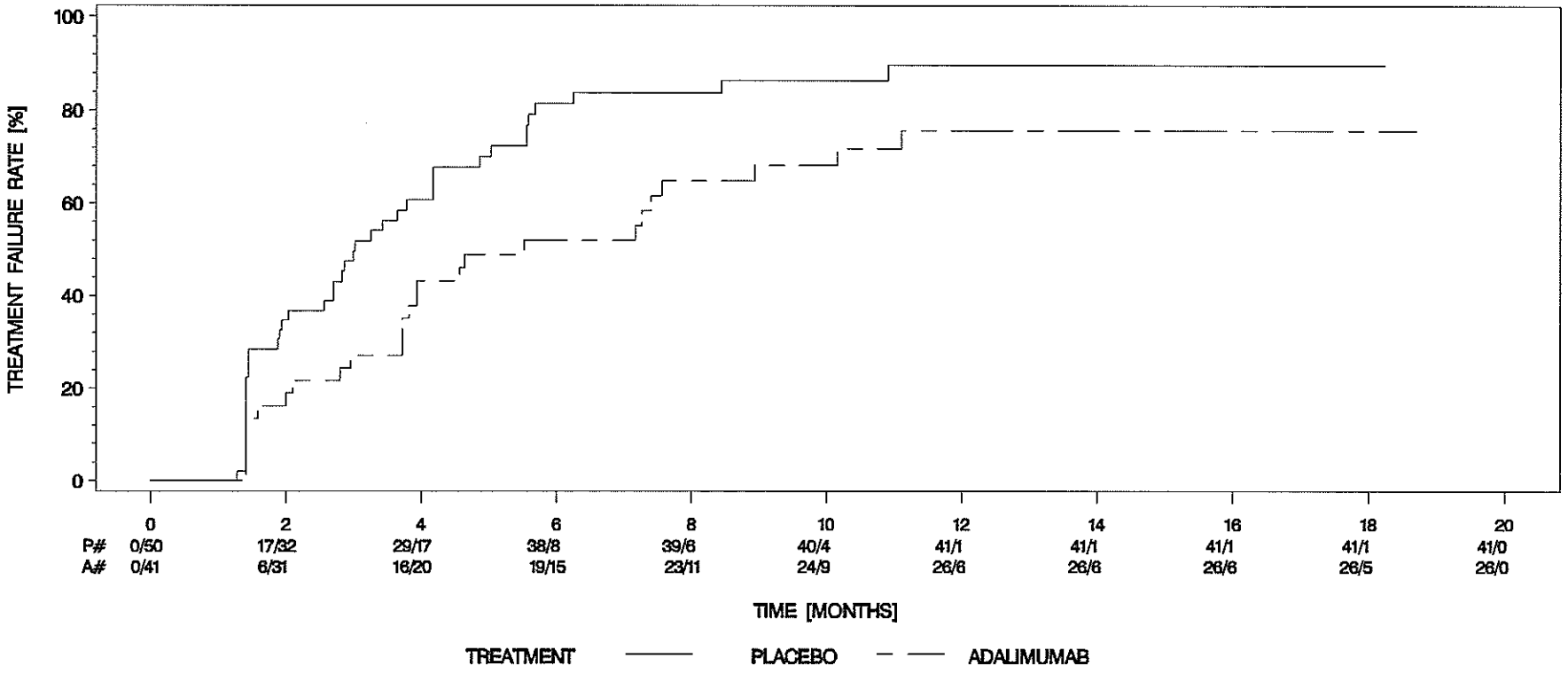
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.1.1.4.40.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)



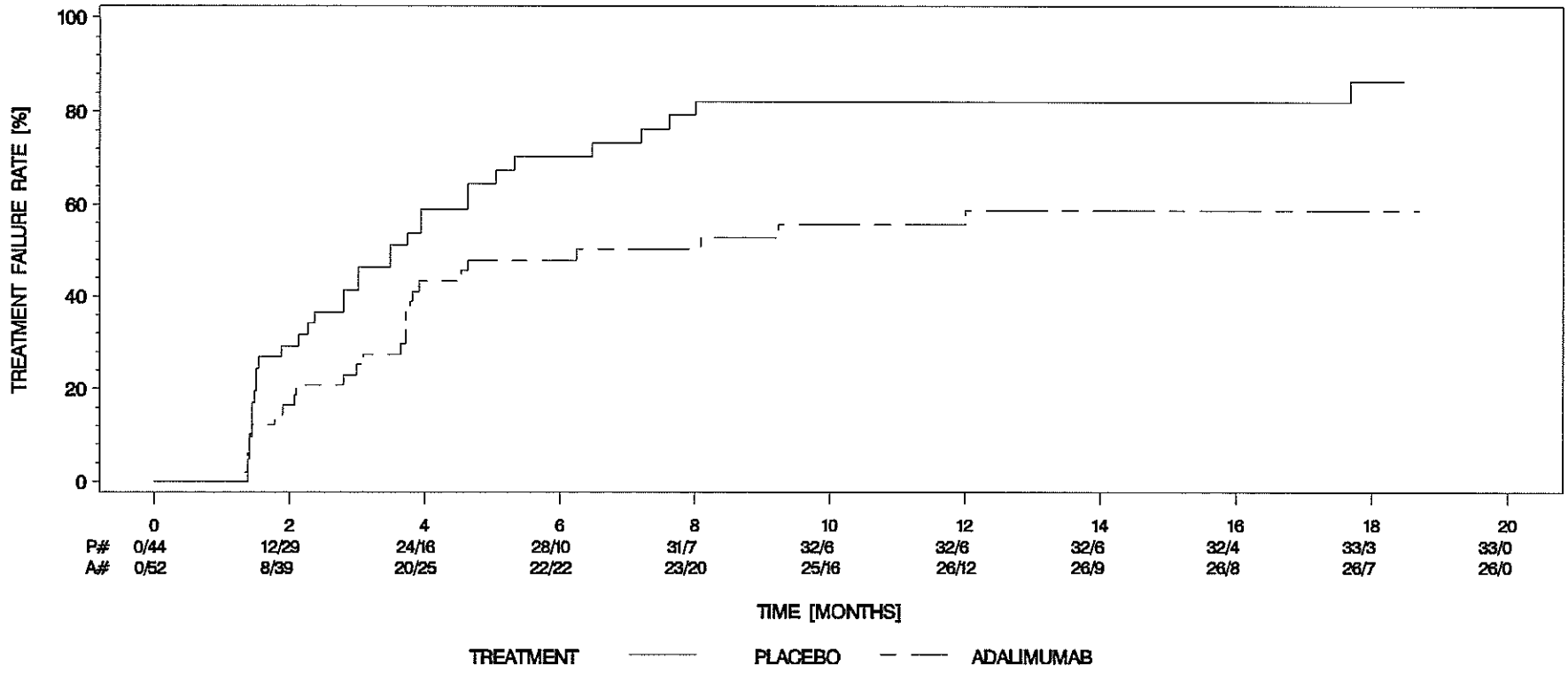
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.1.1.4.41.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

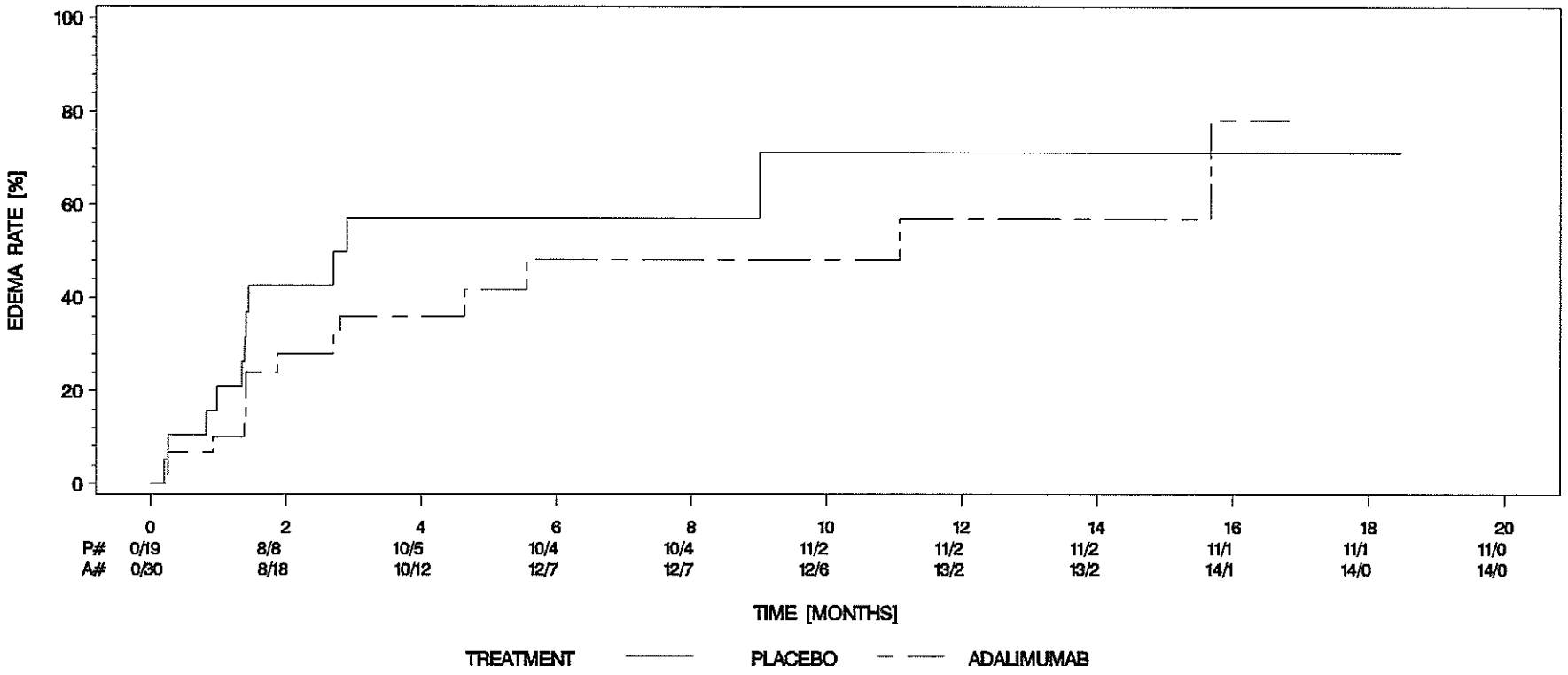
FIGURE 14.2__1000.1.1.4.42.I
KAPLAN-MEIER CURVE TIME TO TREATMENT FAILURE ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

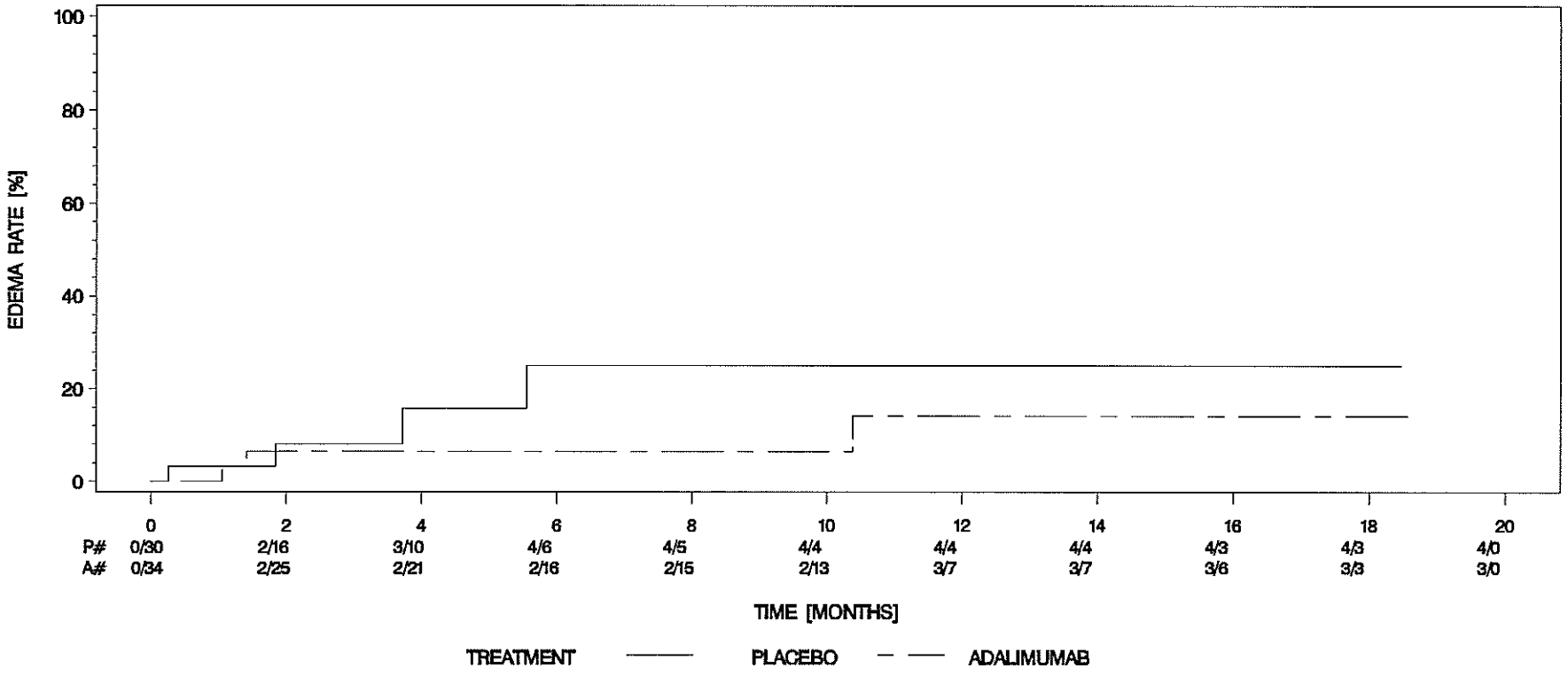
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.1.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)



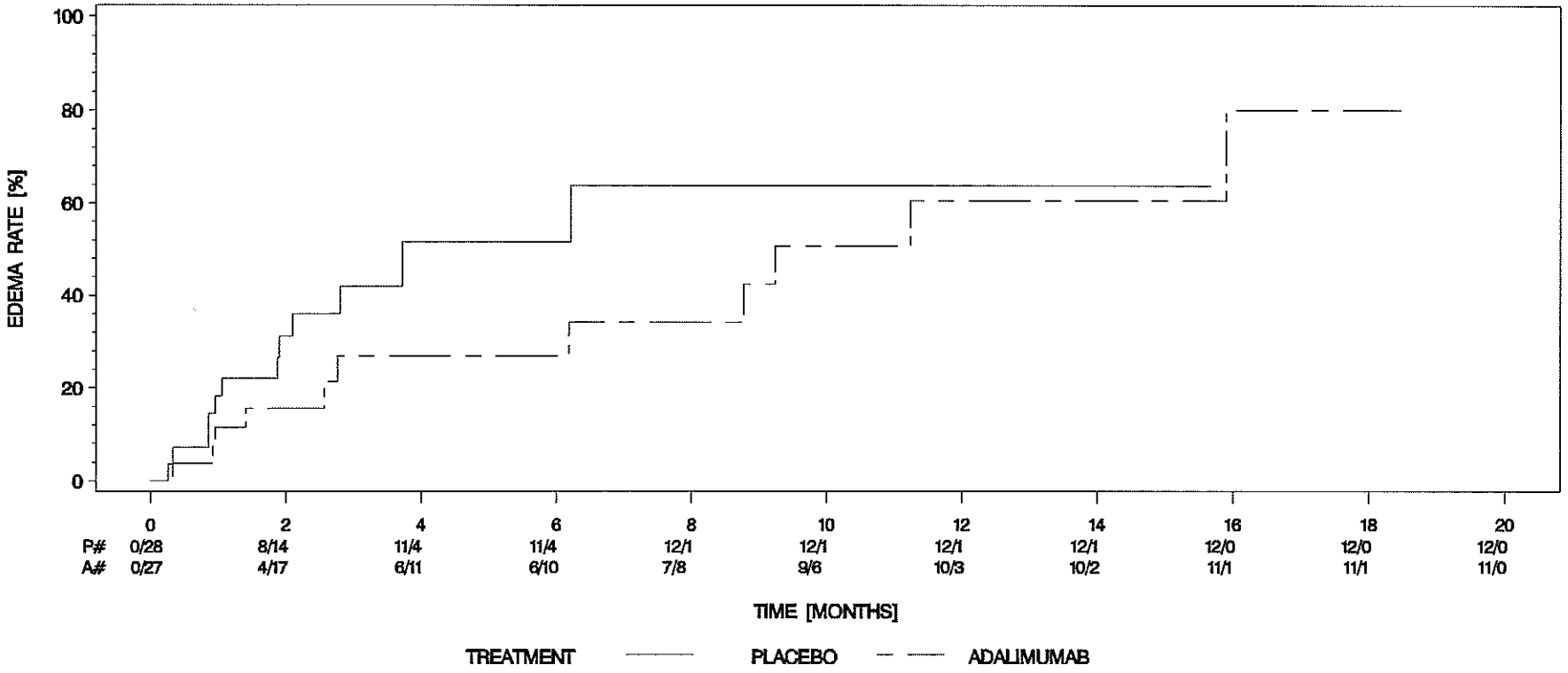
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.1.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

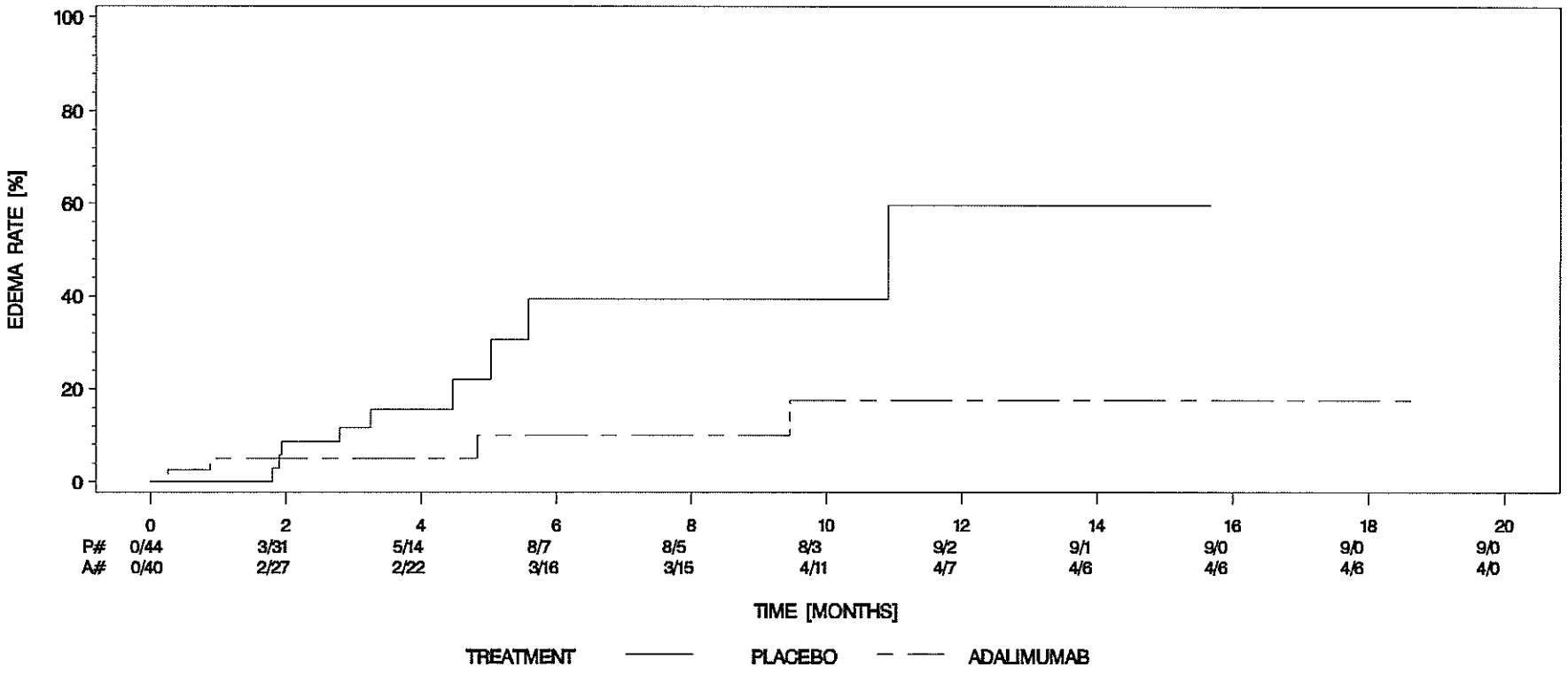
FIGURE 14.2__1000.3.1.2.2.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

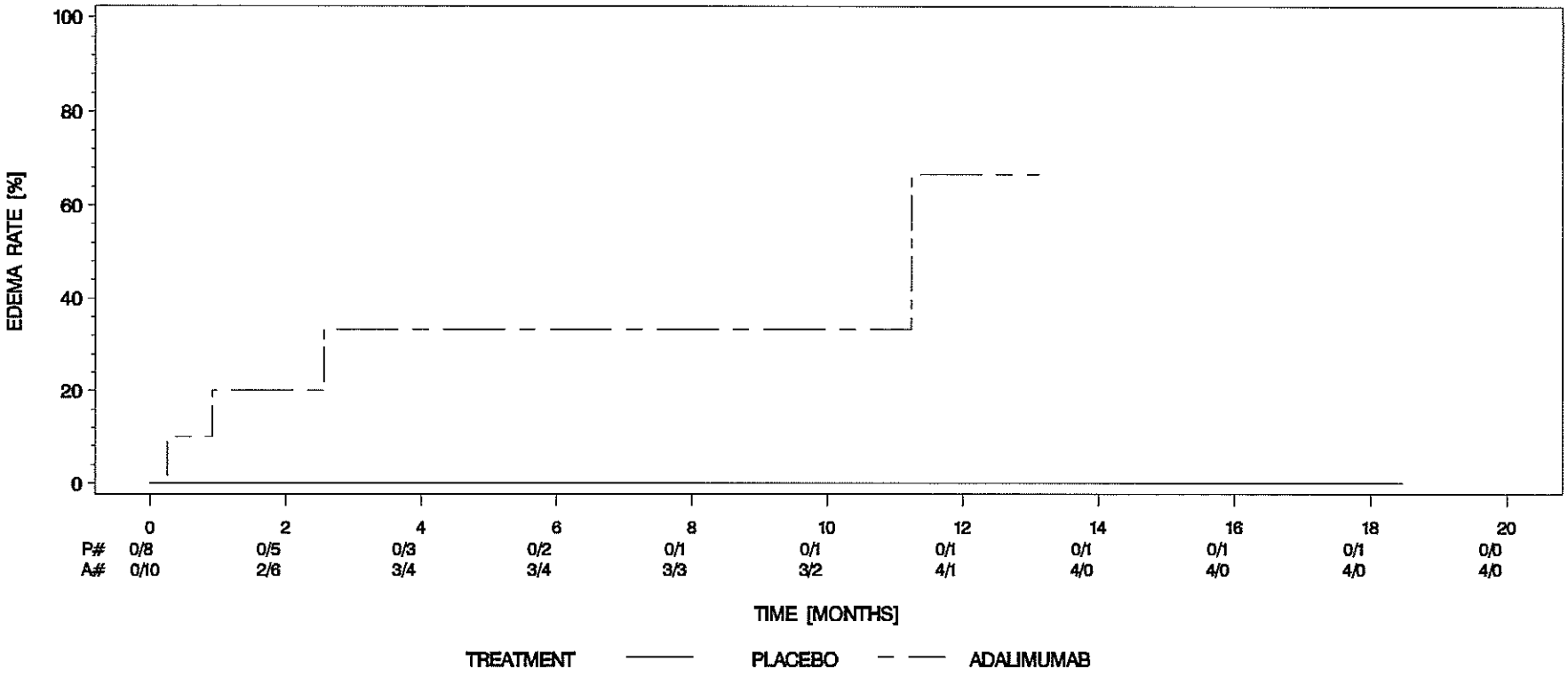
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.2.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)



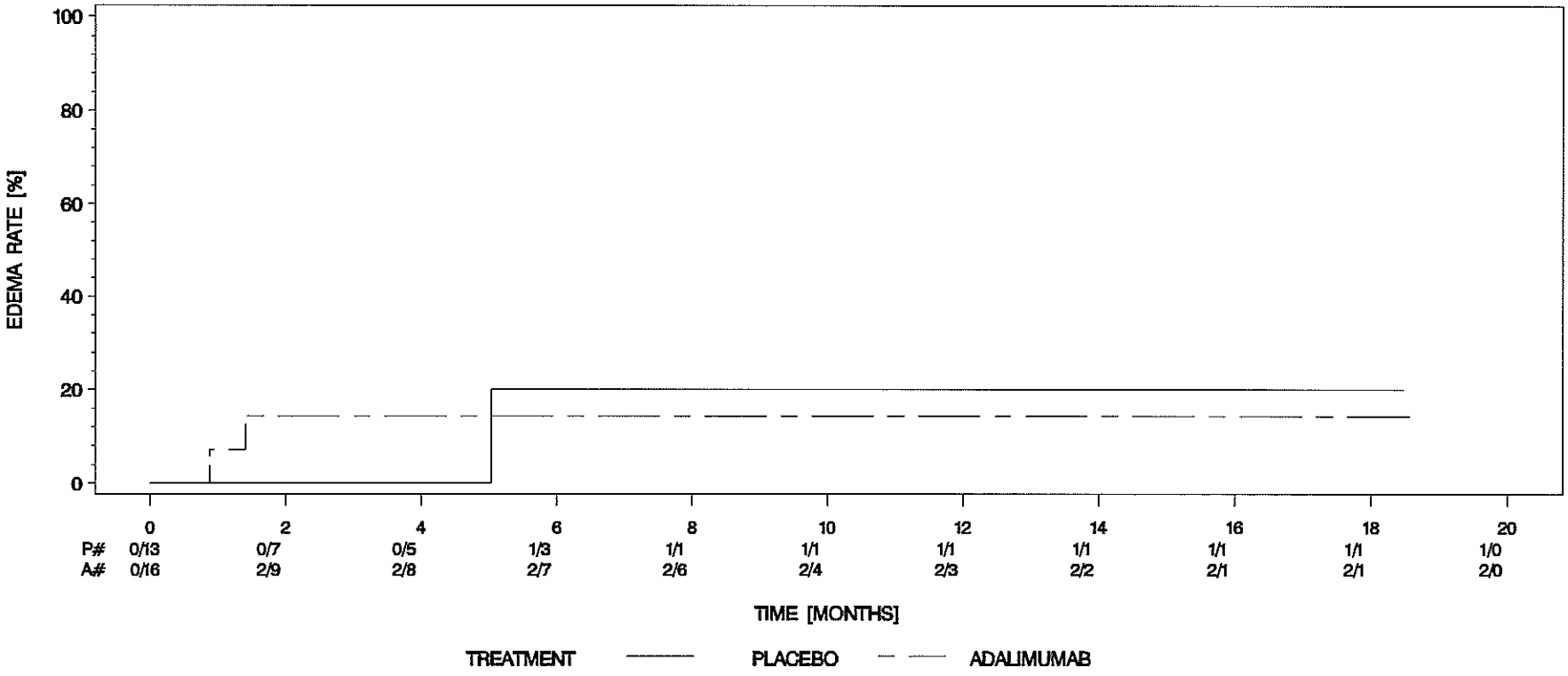
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.3.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)



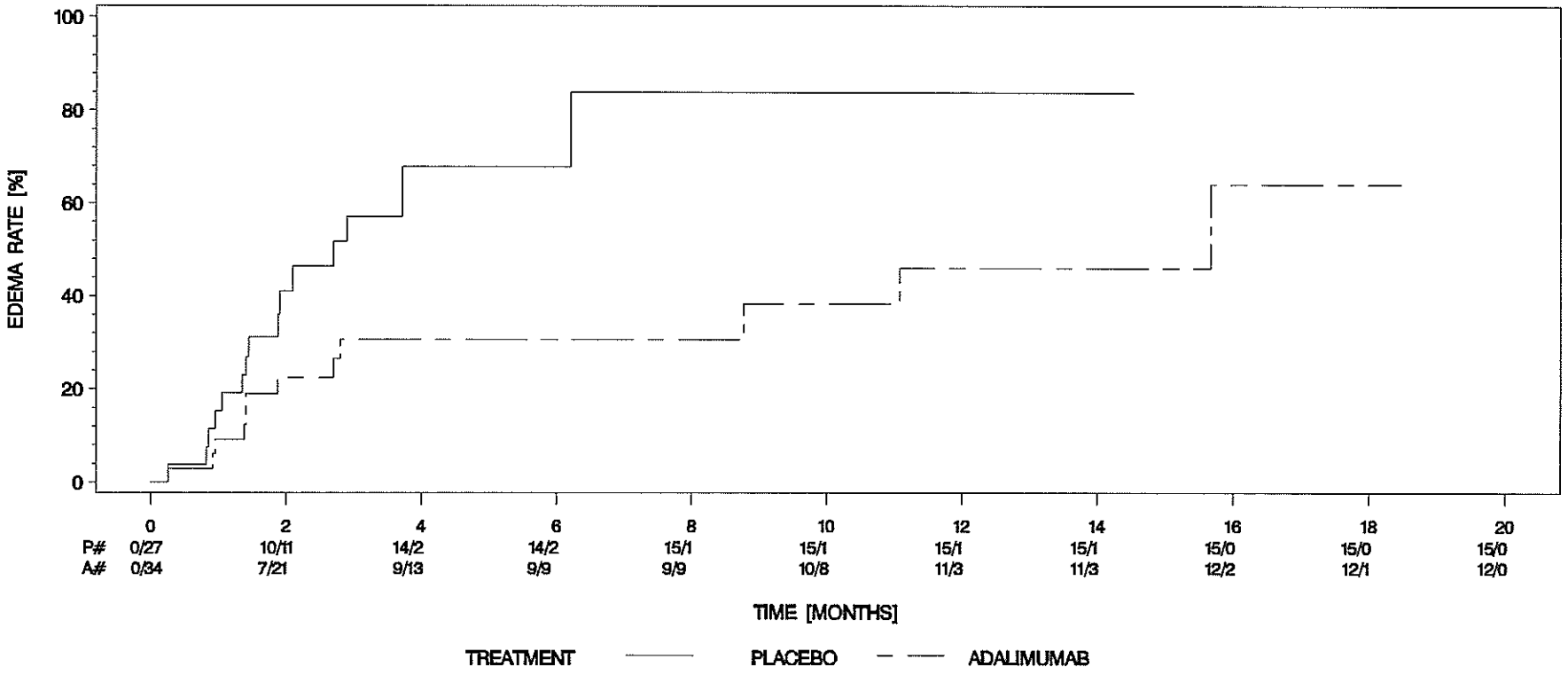
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.3.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)



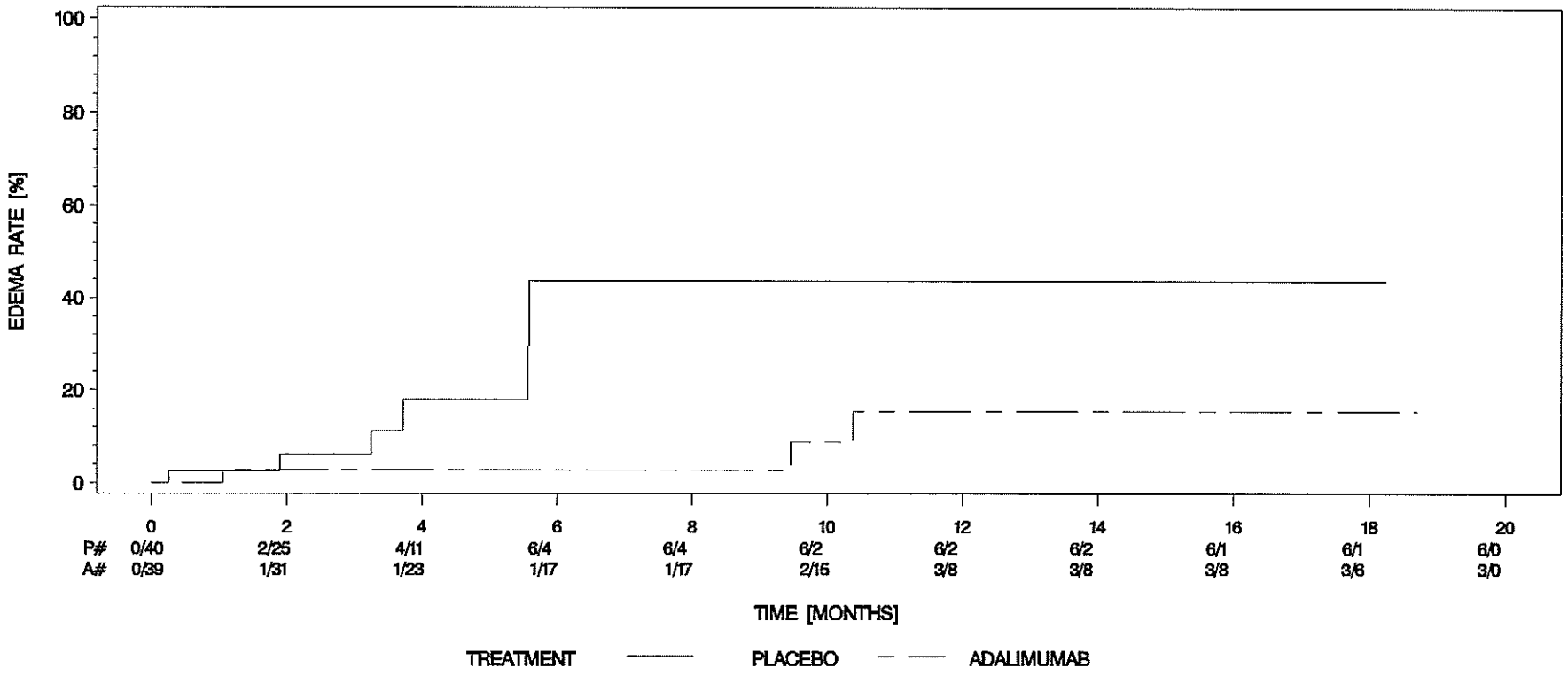
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.4.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)



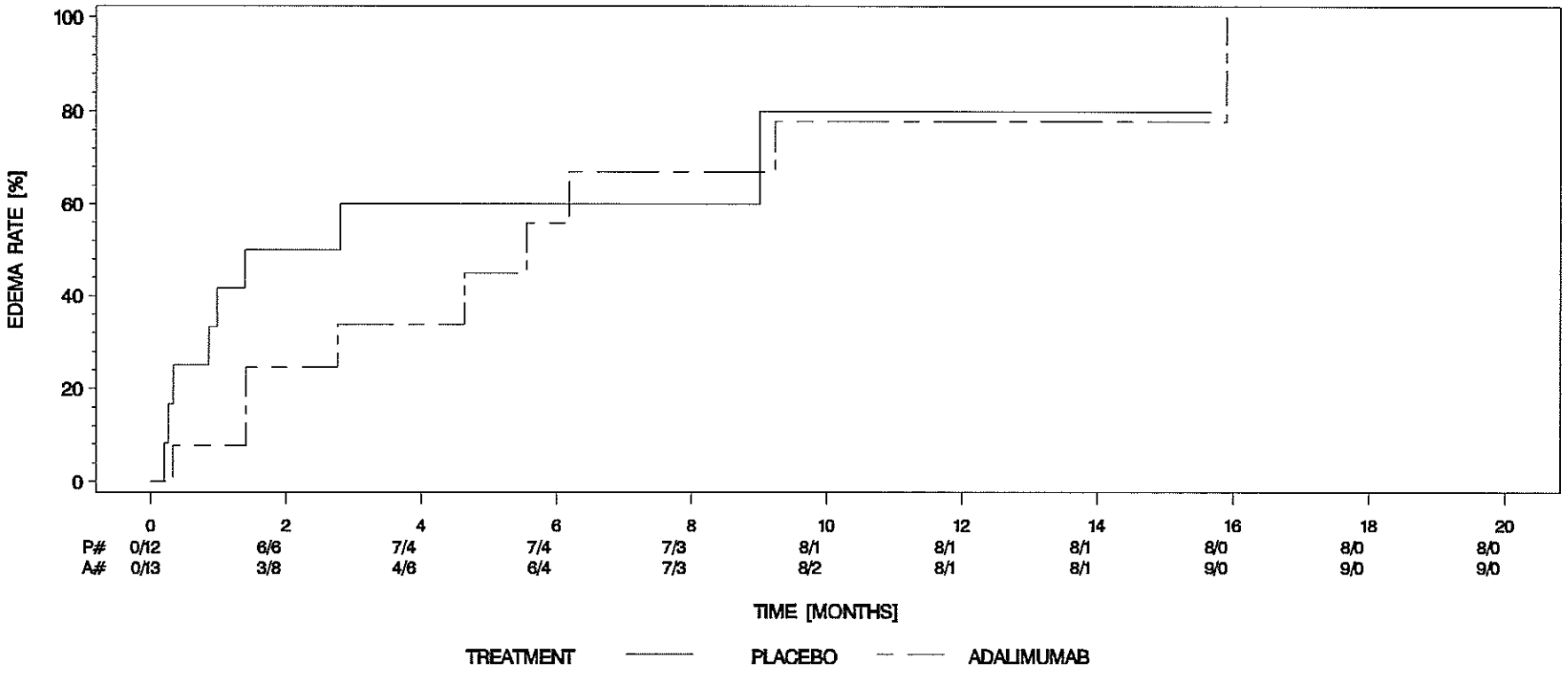
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.4.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)



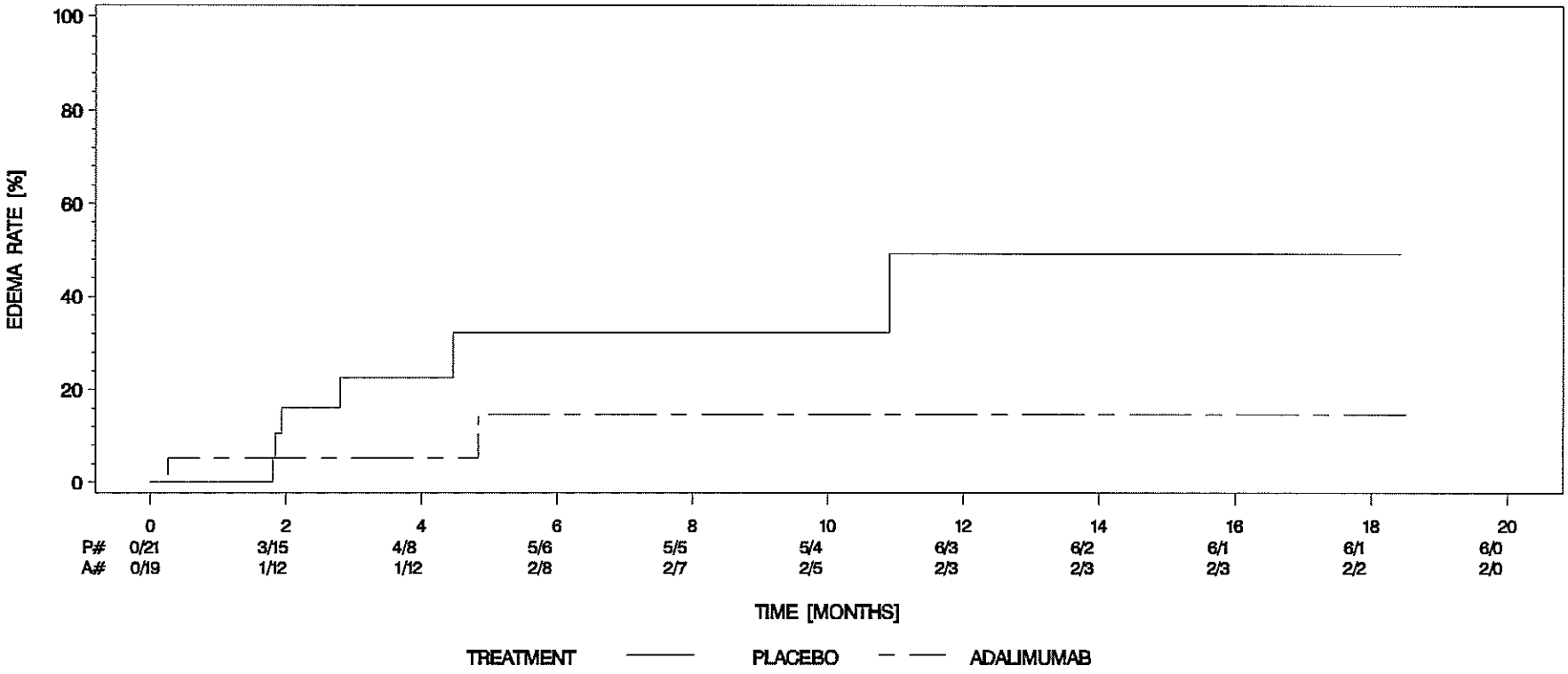
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.5.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)



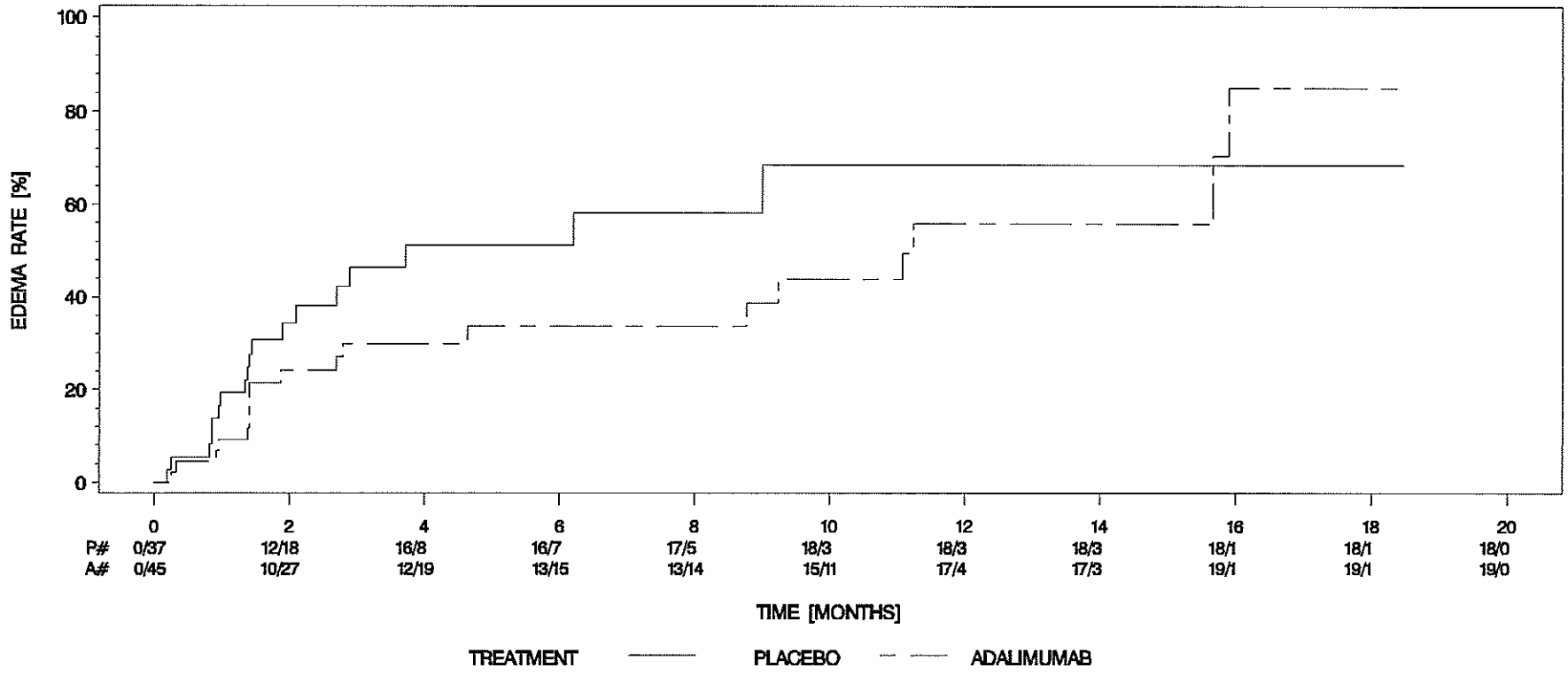
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.5.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)



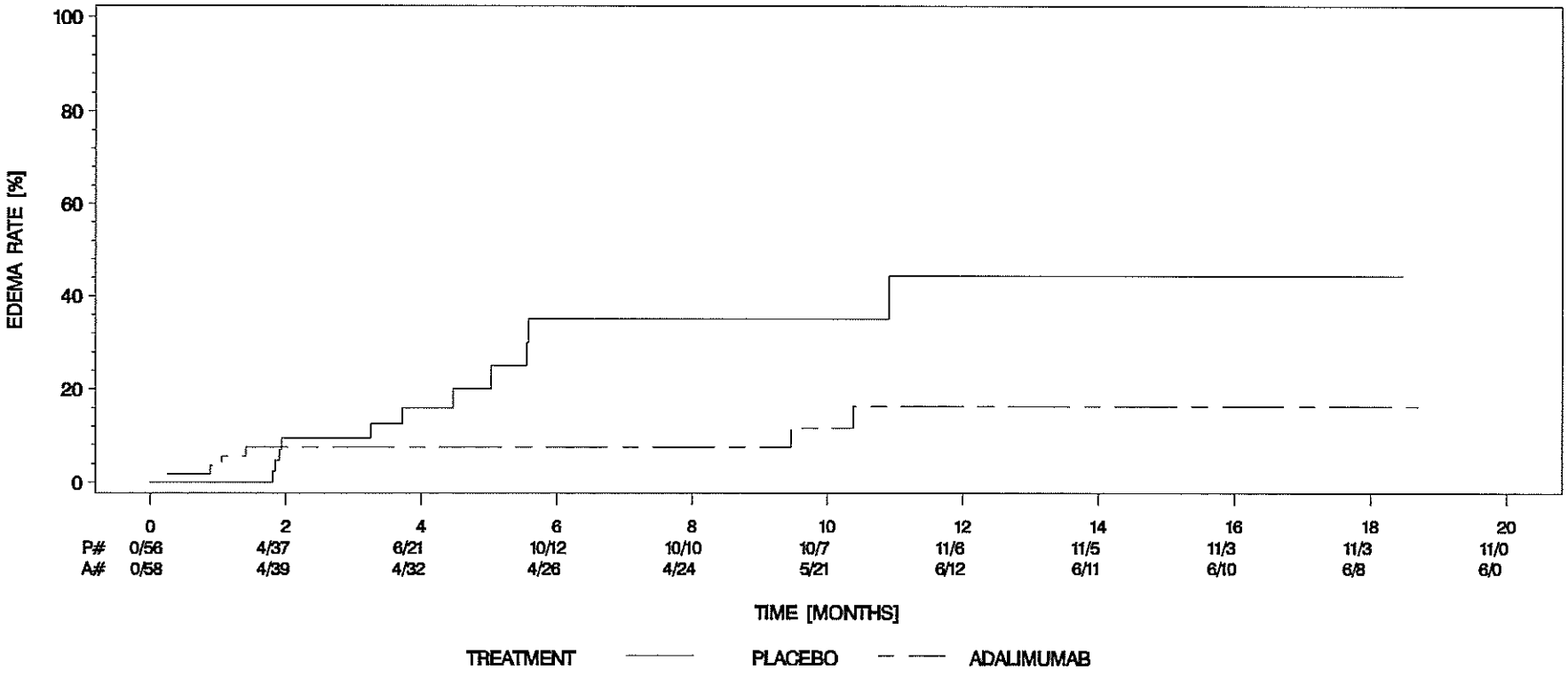
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.6.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)



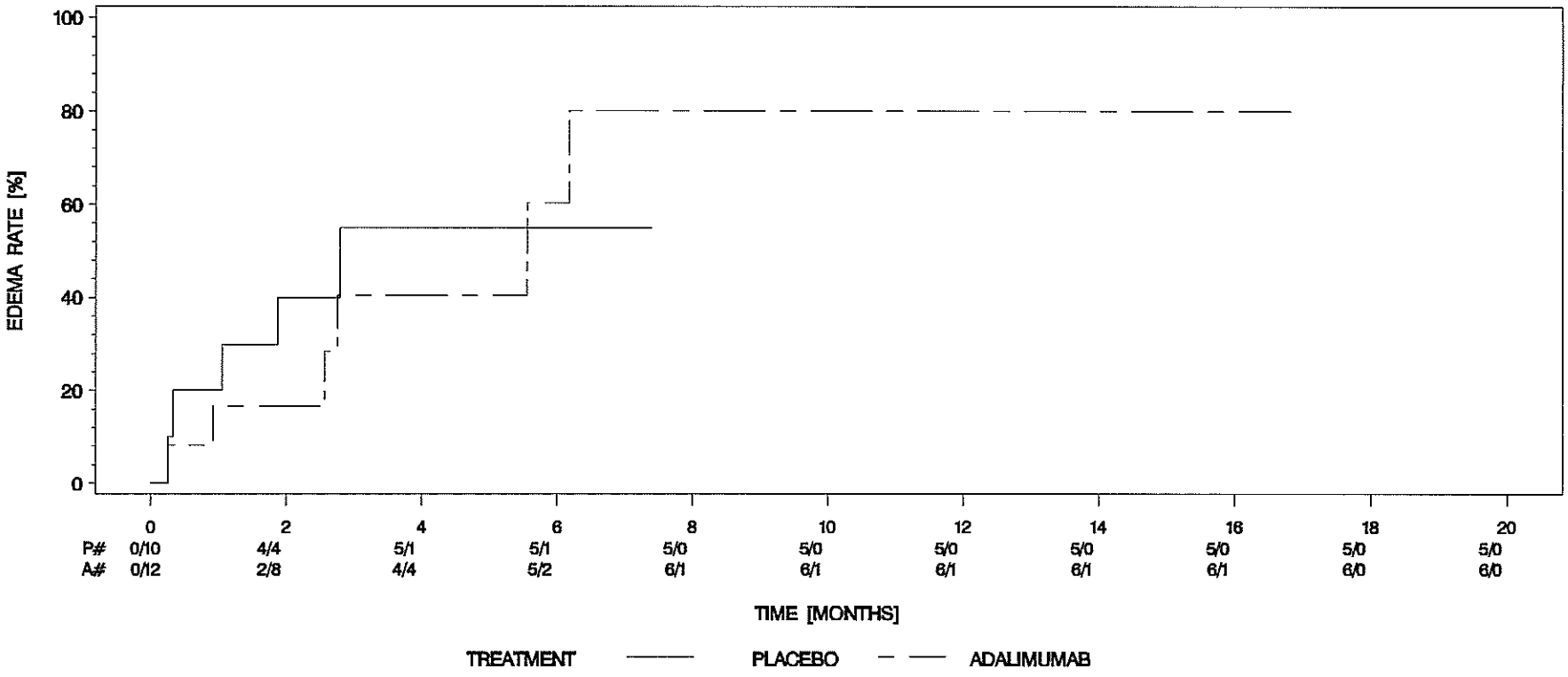
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.6.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)



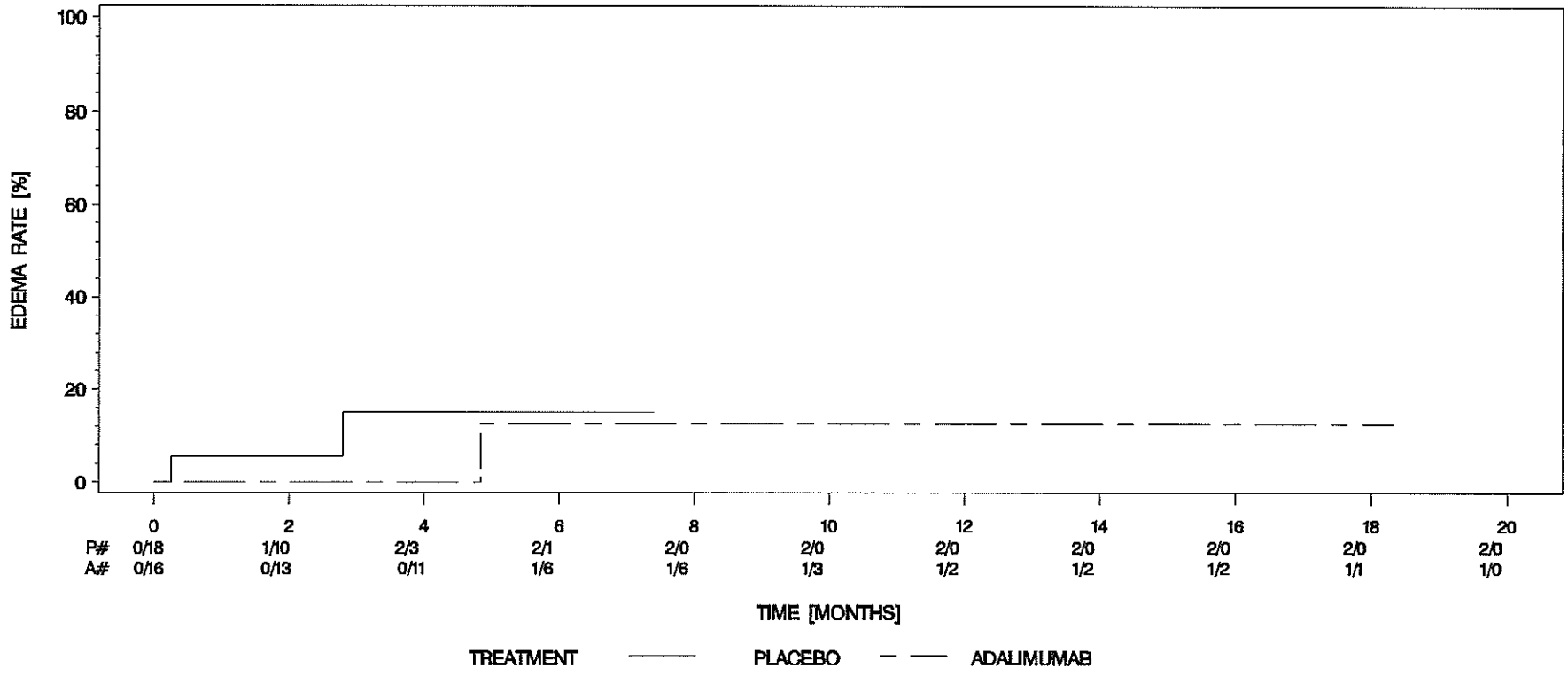
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.1.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)



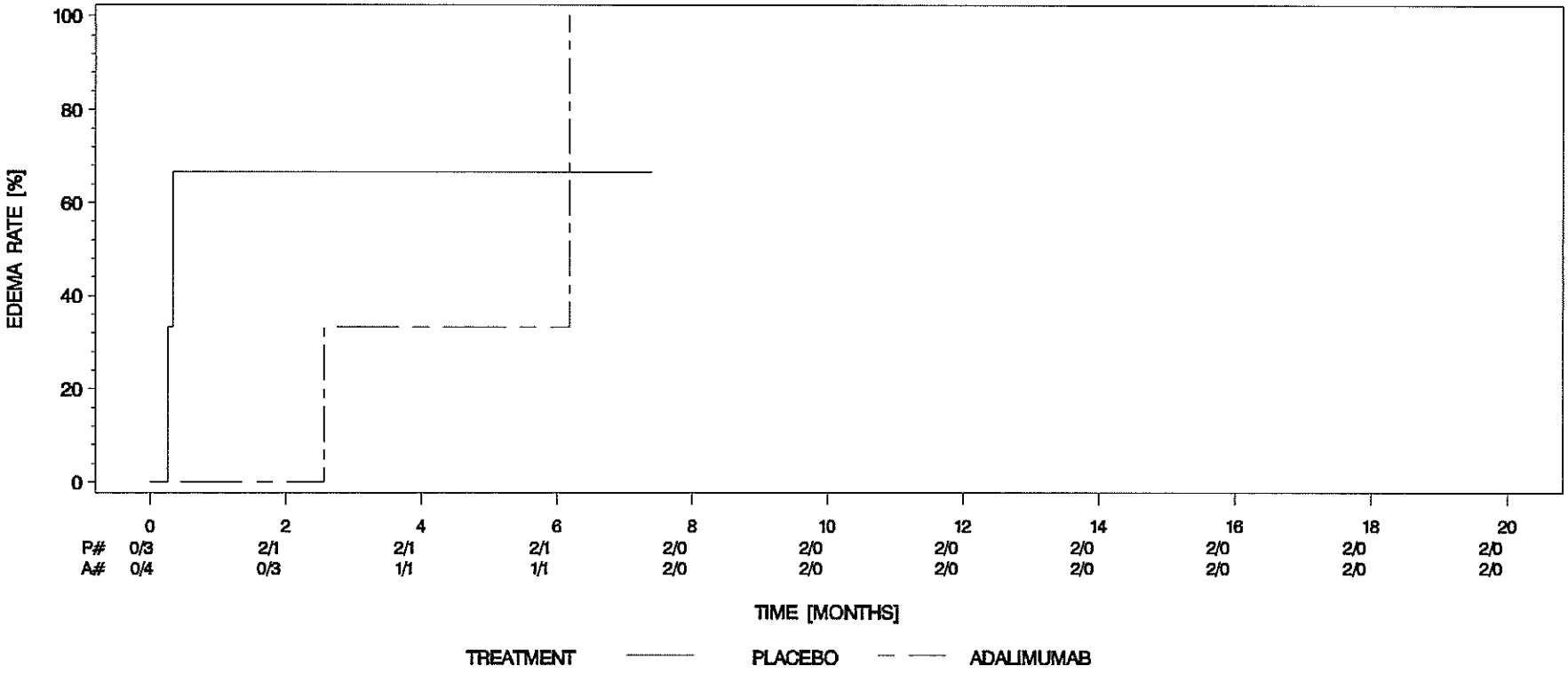
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.1.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)



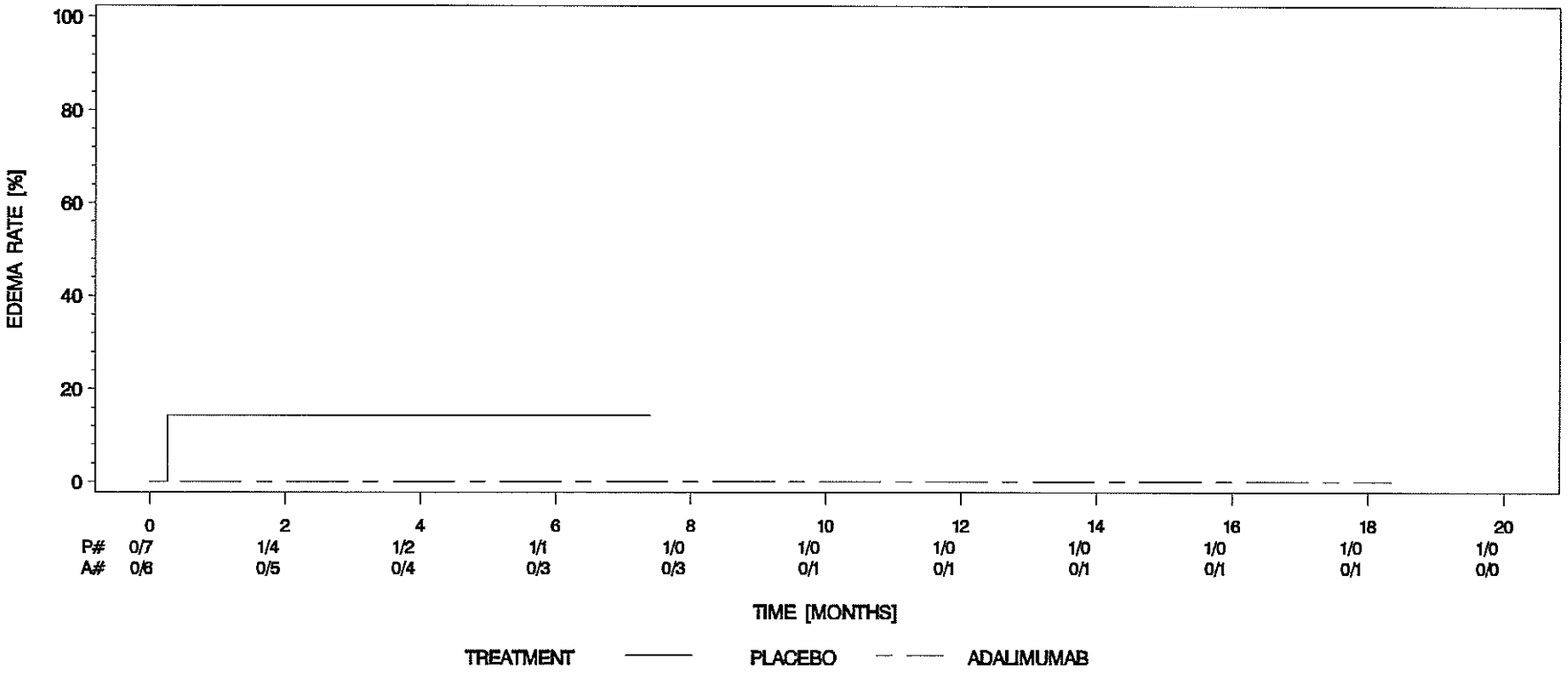
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.2.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: BLACK)



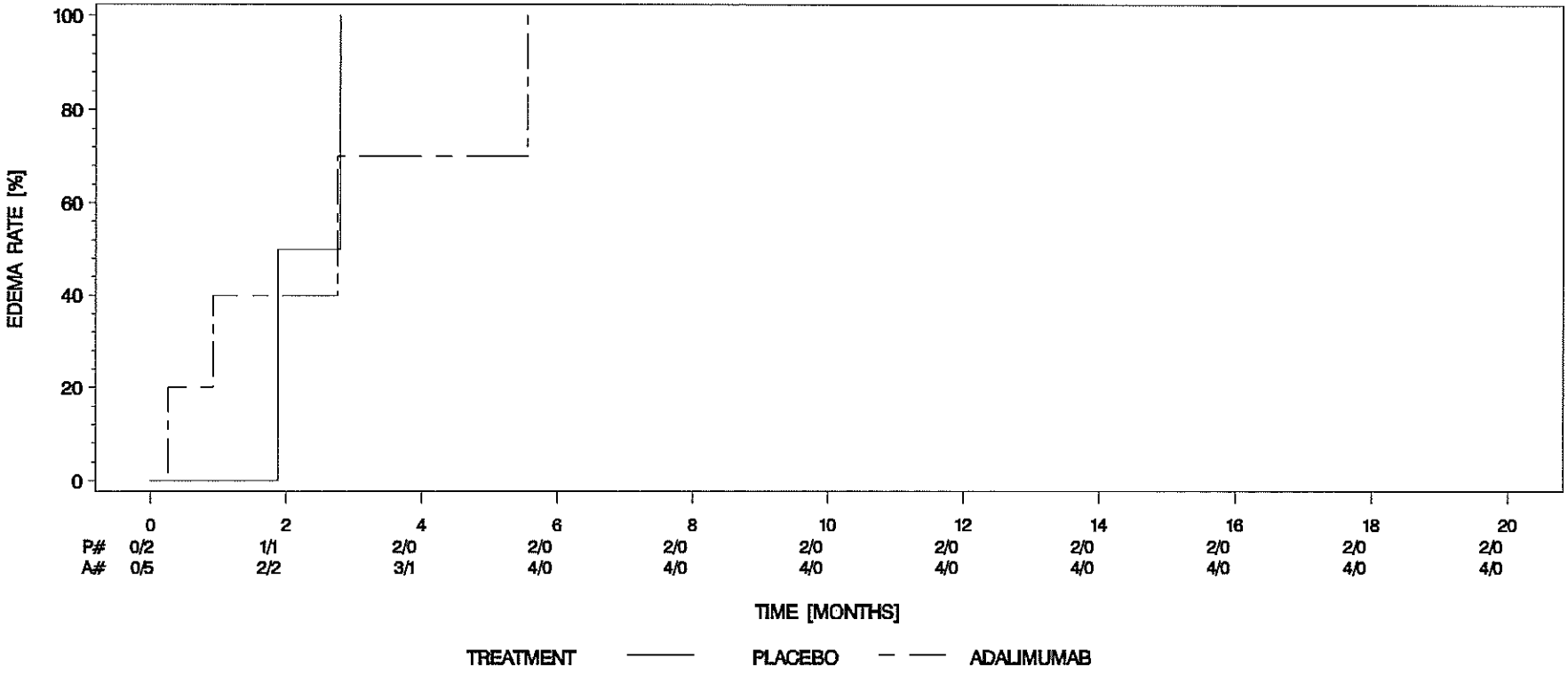
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.2.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: BLACK)



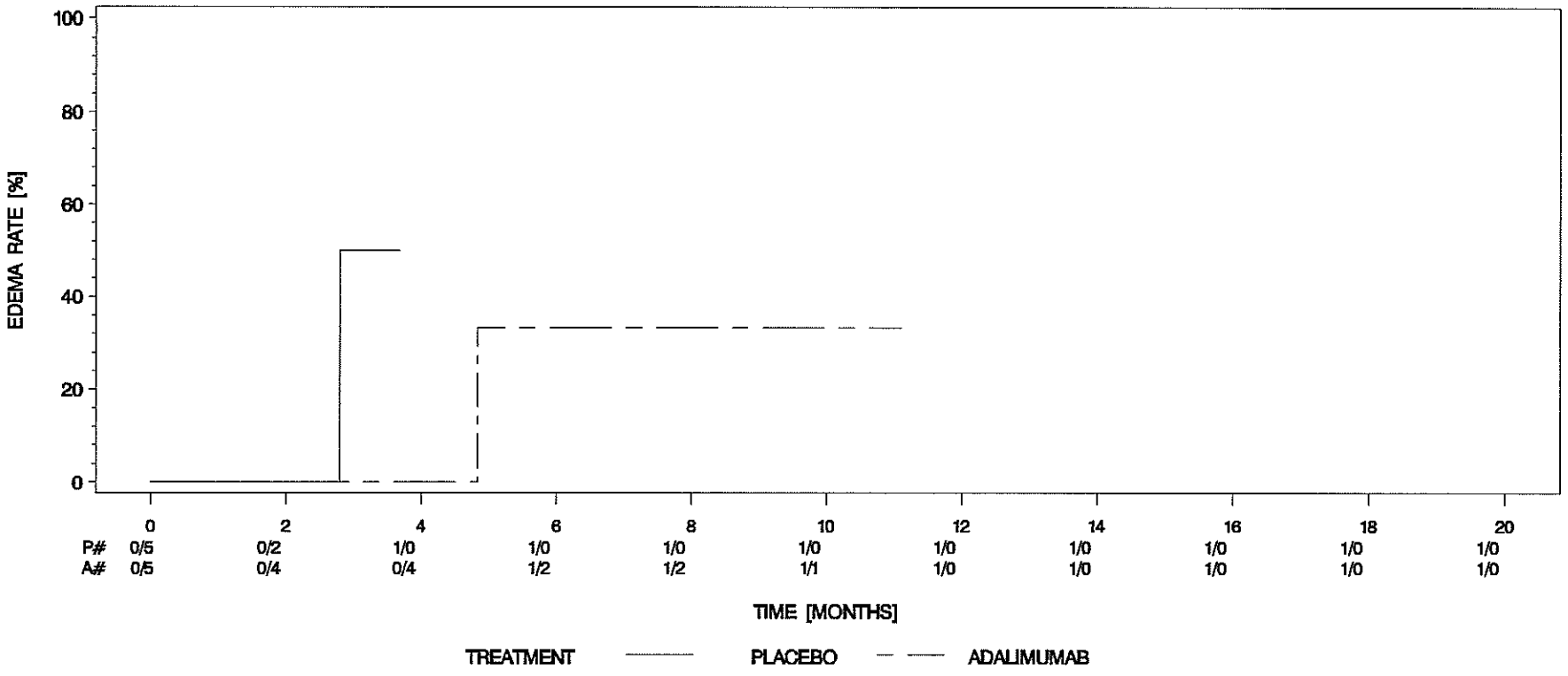
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.3.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ASIAN)



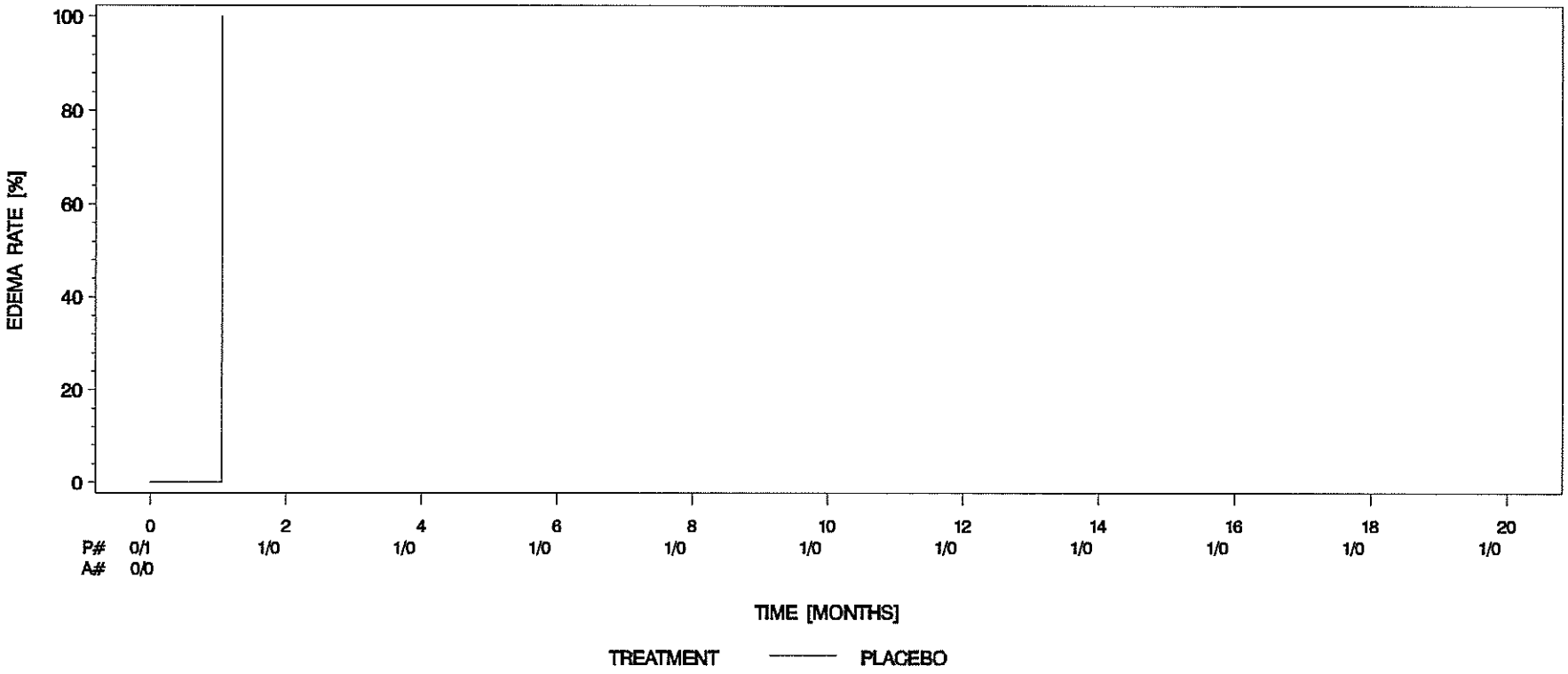
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.3.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ASIAN)



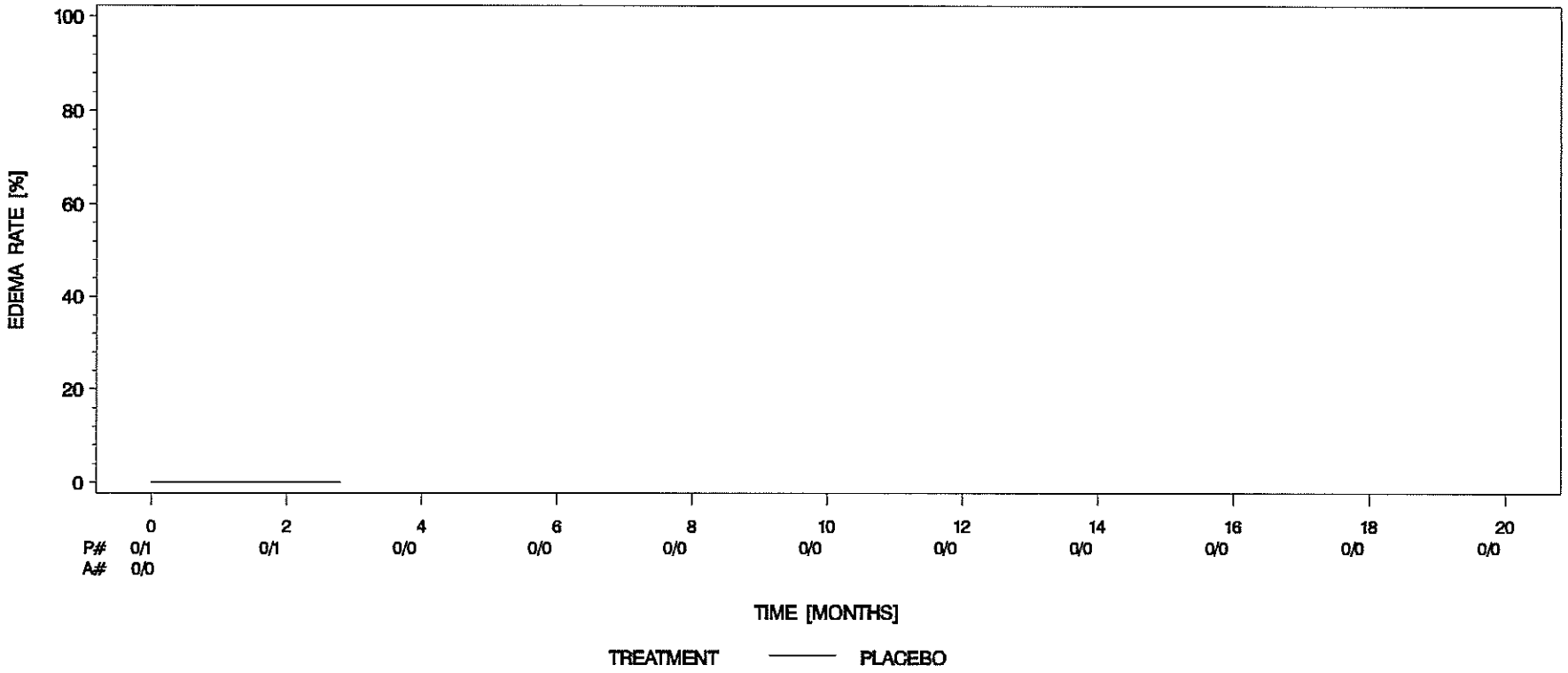
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.4.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AMERICAN INDIAN/ALASKA NATIVE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.4.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AMERICAN INDIAN/ALASKA NATIVE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

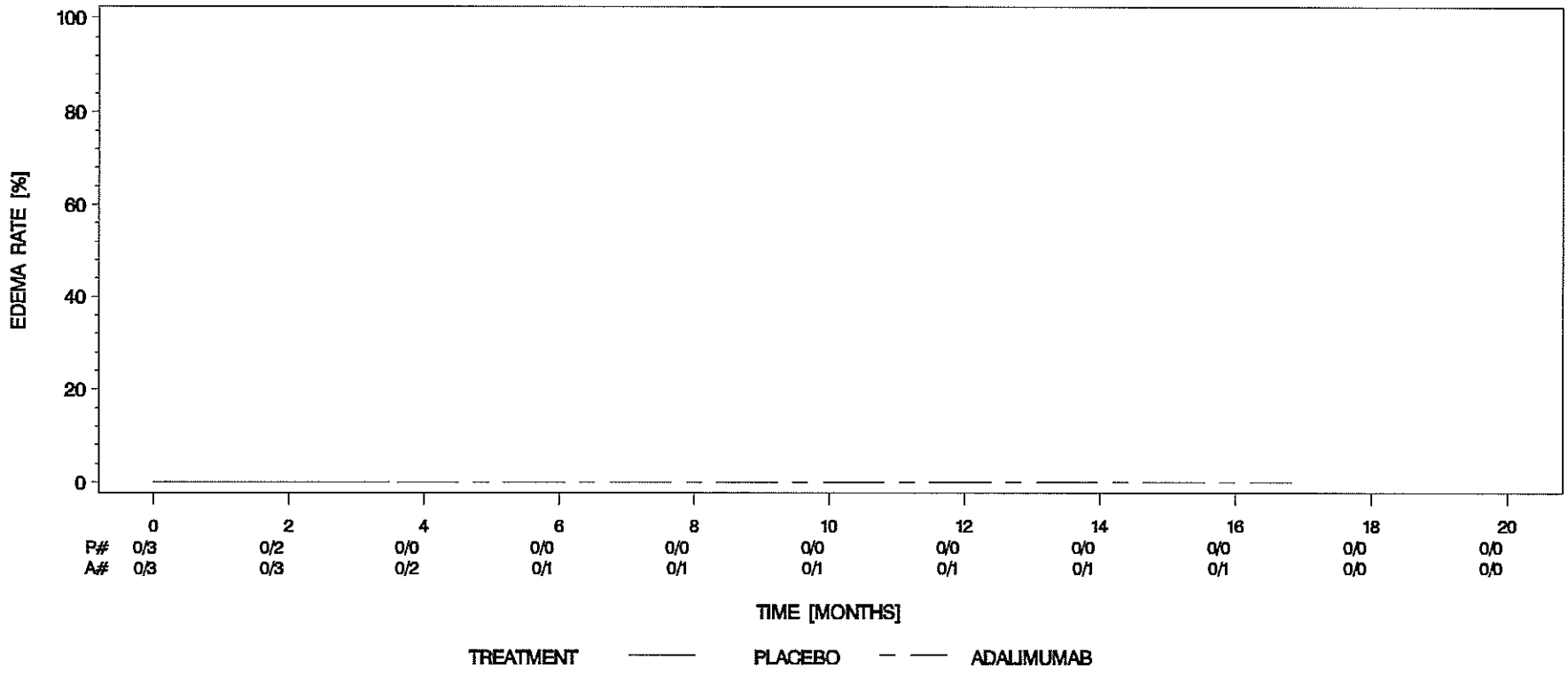
FIGURE 14.2__1000.3.1.2.7.5.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

** NO DATA IN THIS SEGMENT OR PART OF THIS FIGURE. **

FIGURE 14.2__1000.3.1.2.7.5.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

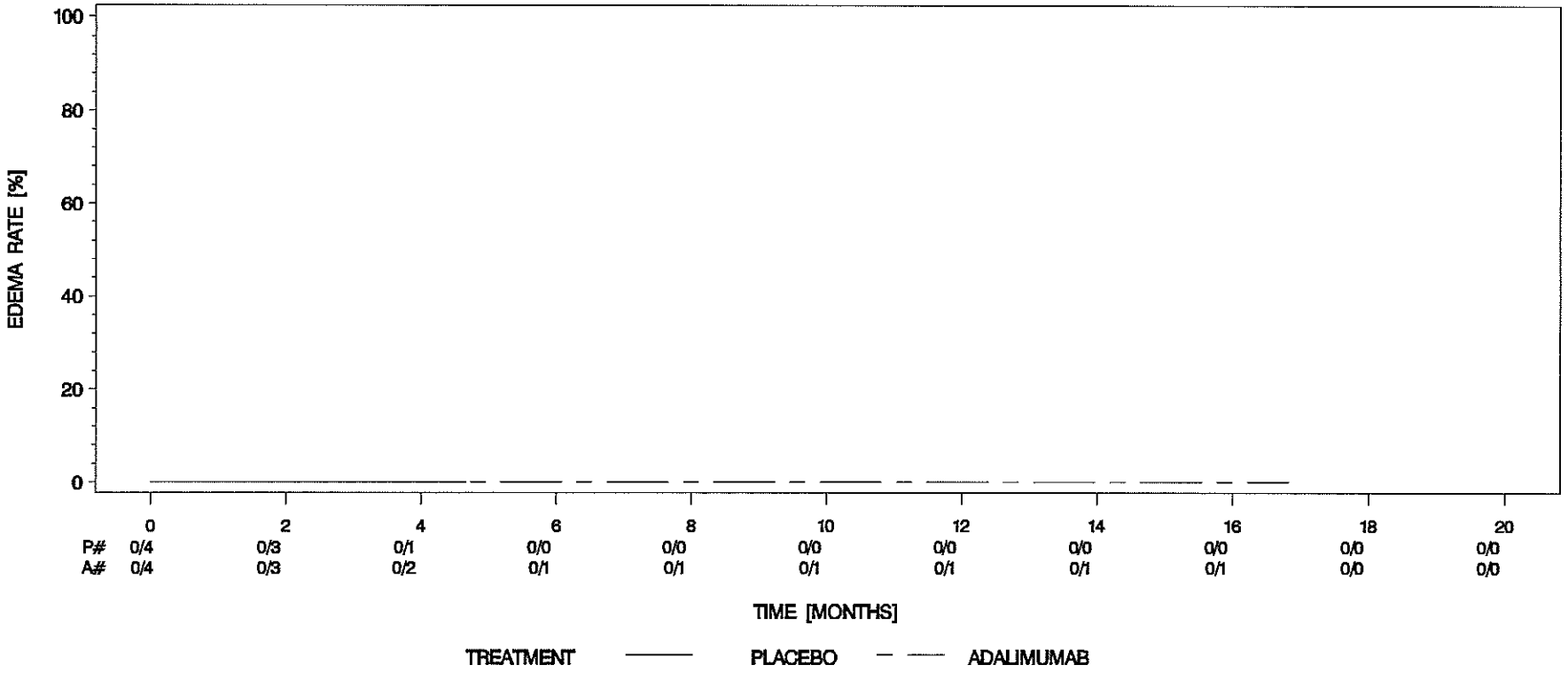
** NO DATA IN THE SEGMENT OR PART OF THE FIGURE. **

FIGURE 14.2__1000.3.1.2.7.6.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OTHER)



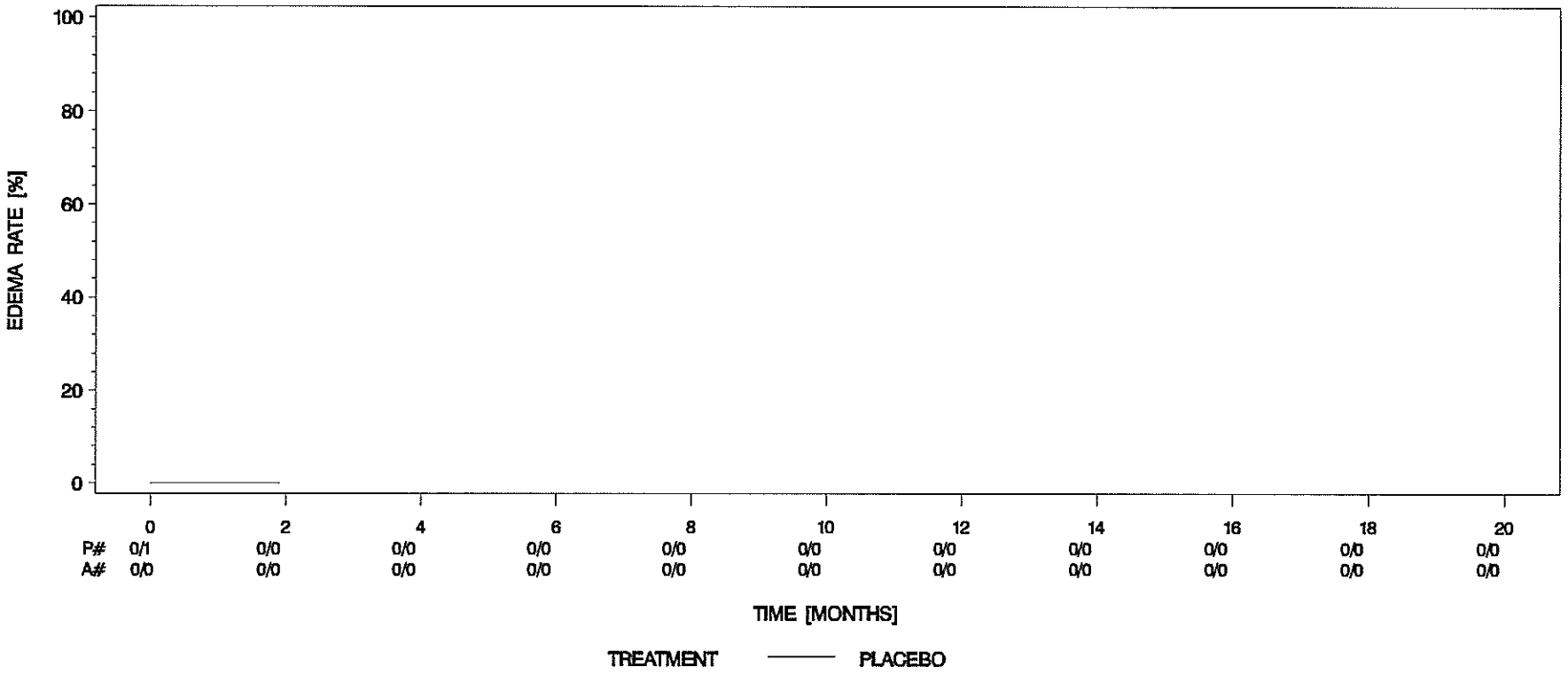
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.6.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OTHER)



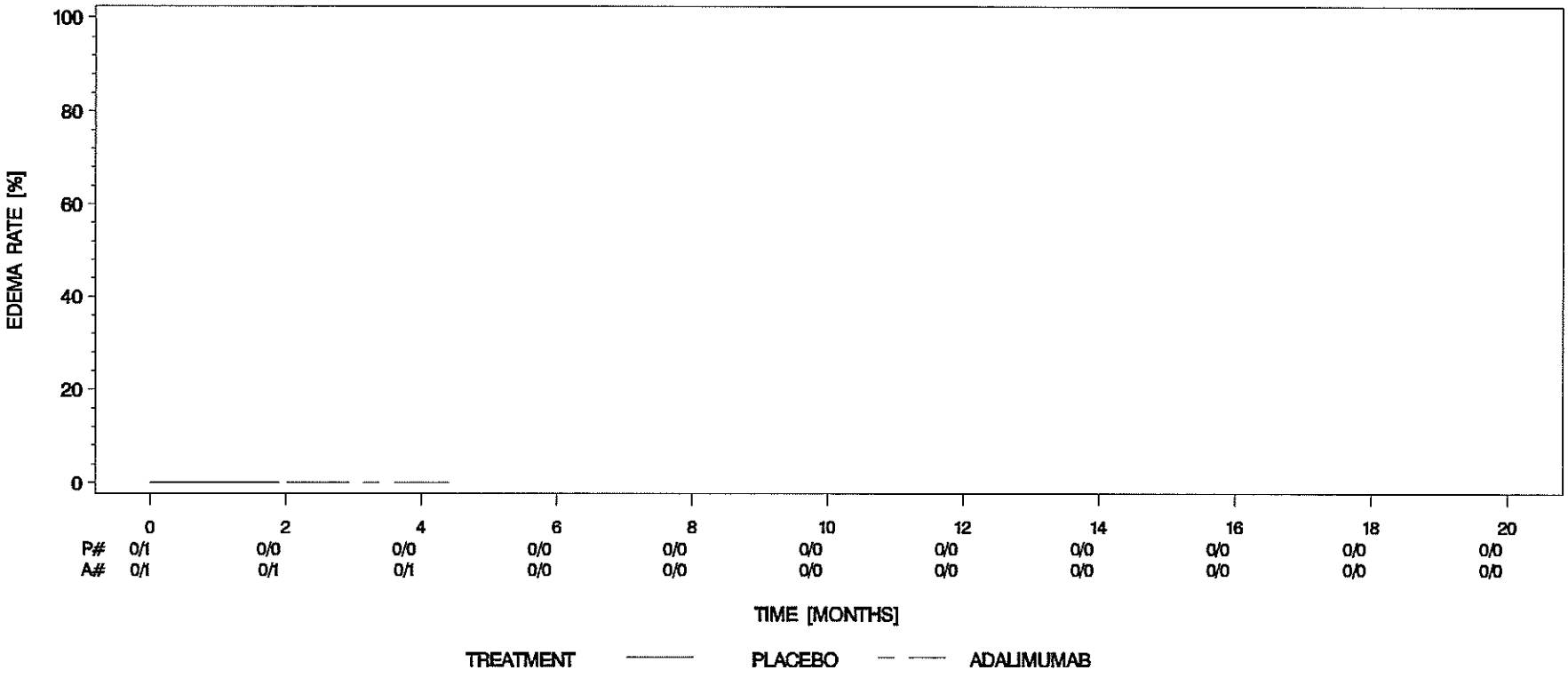
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.7.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: MULTI RACE)



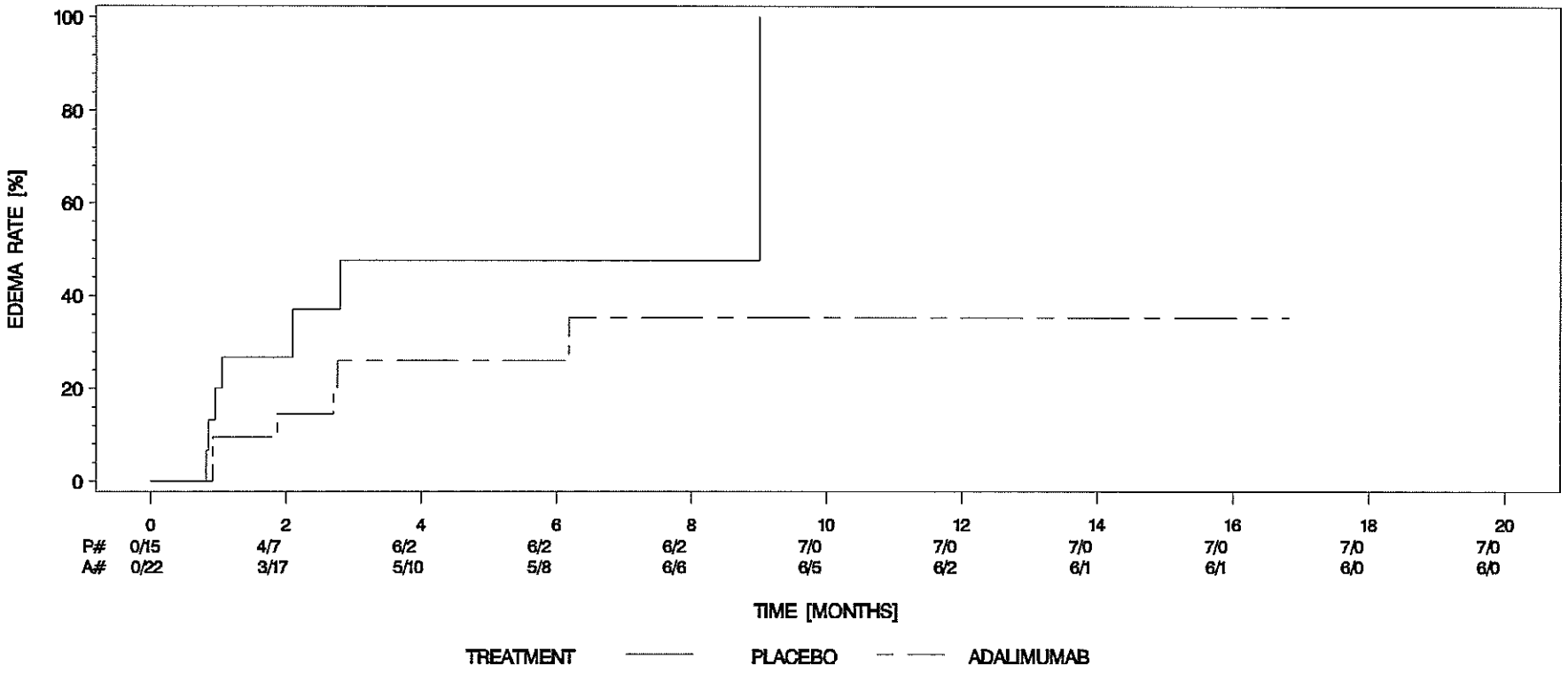
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.7.7.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: MULTI RACE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

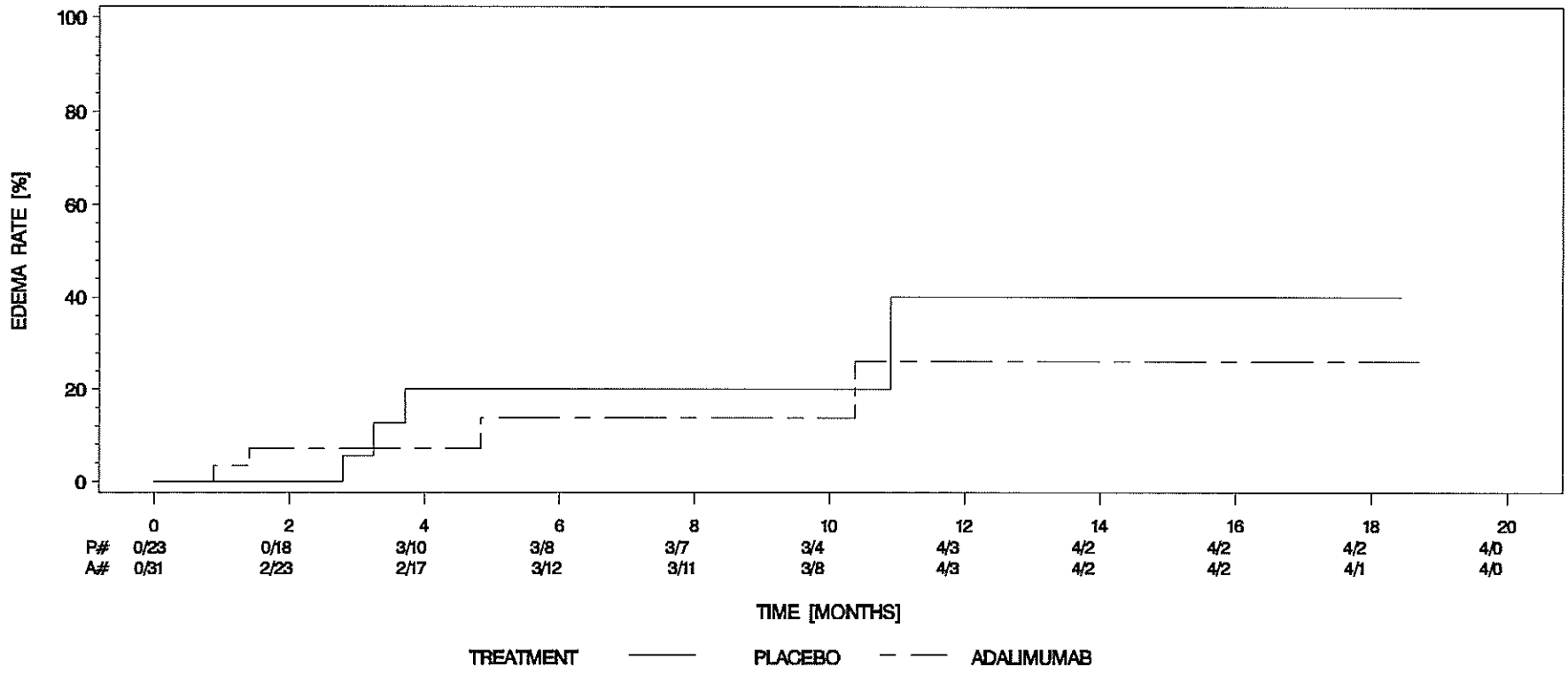
FIGURE 14.2__1000.3.1.2.8.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

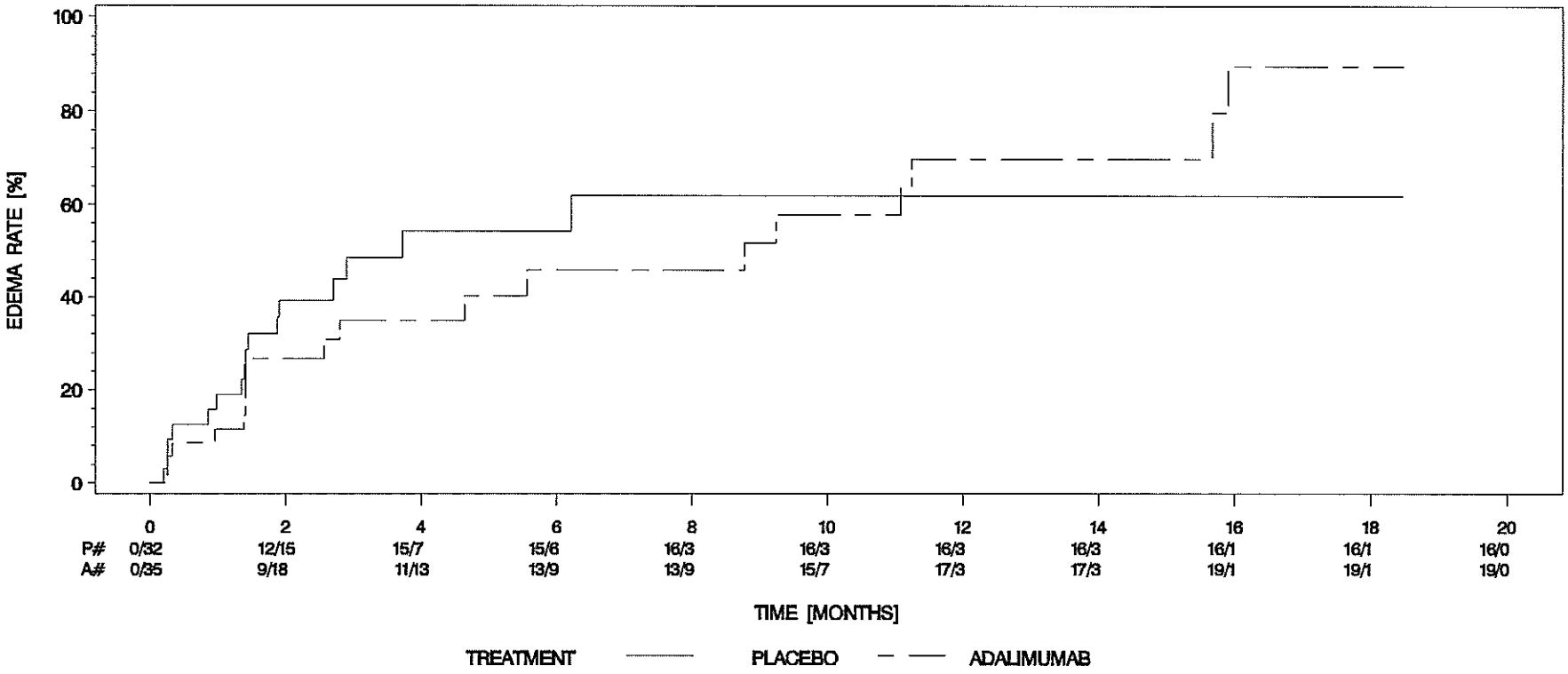
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.8.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)



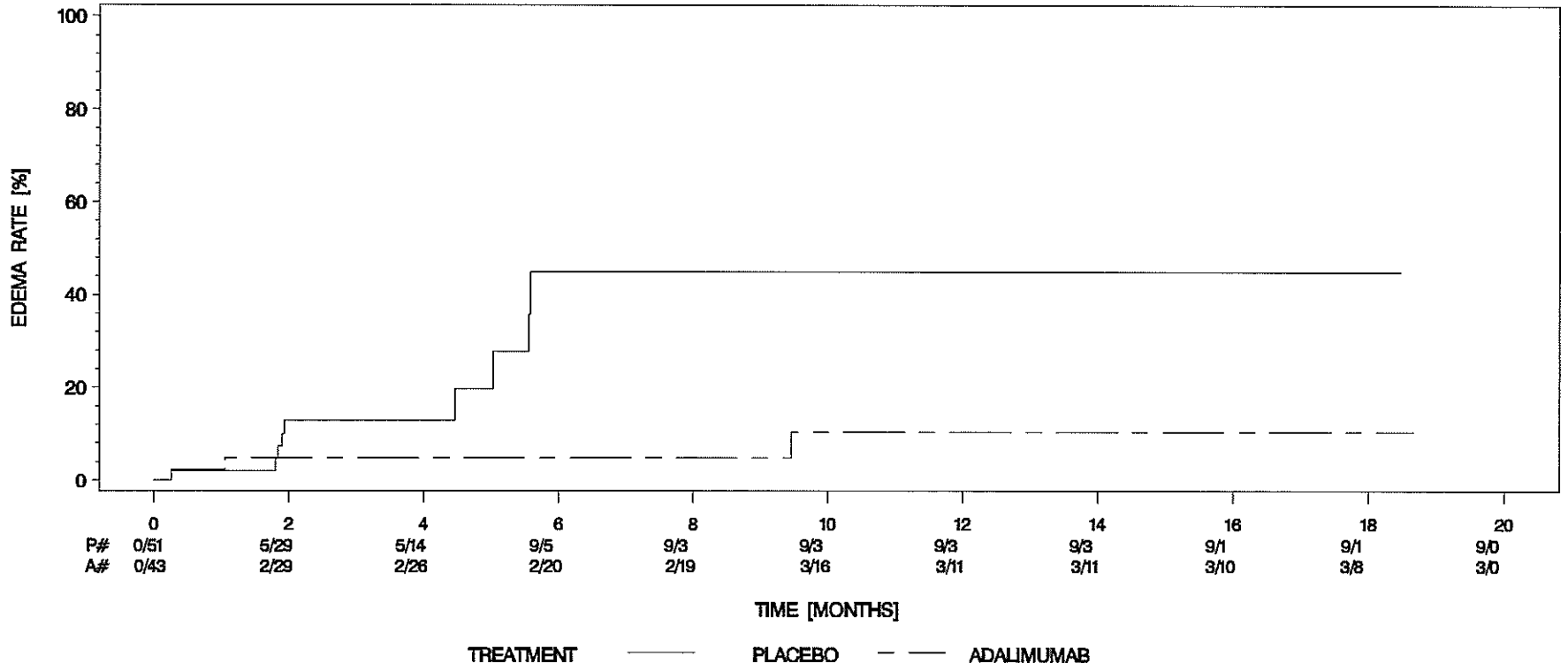
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.9.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)



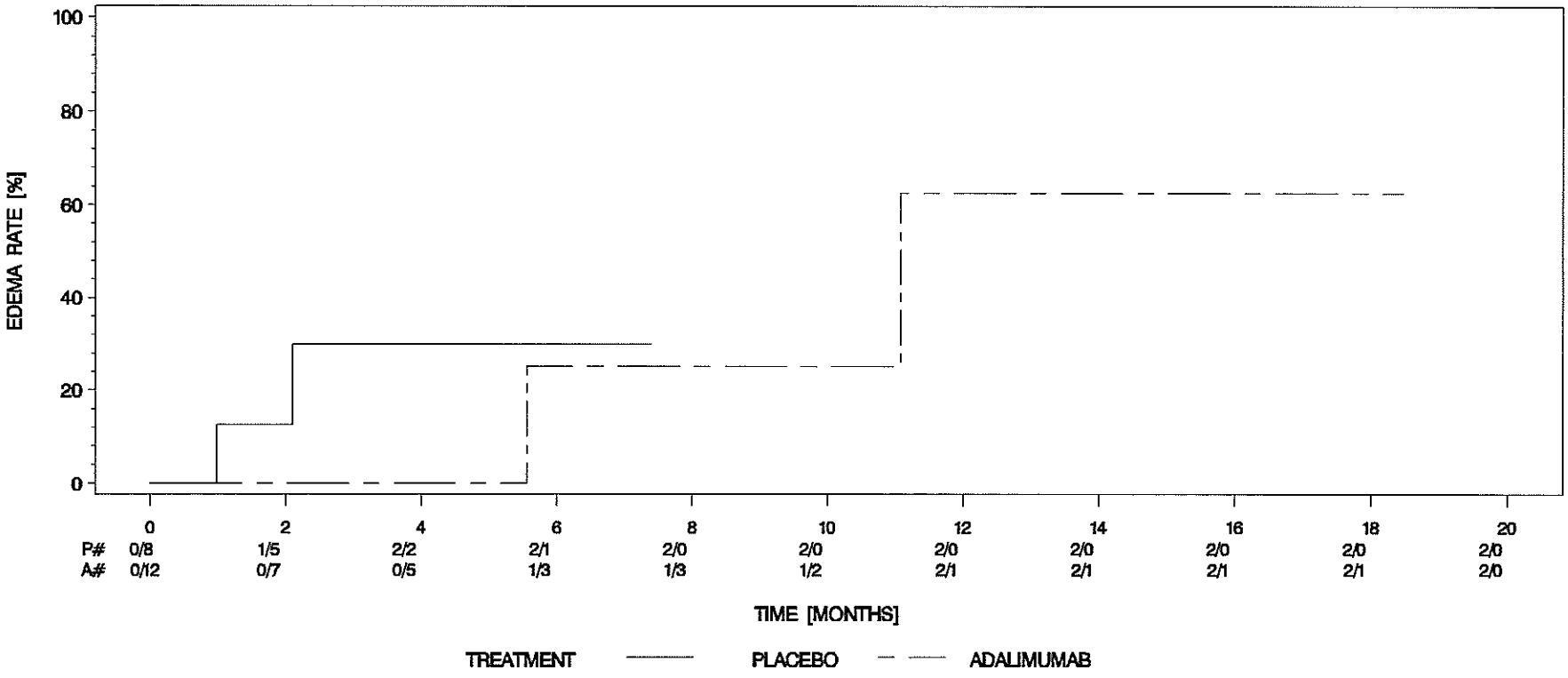
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.9.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)



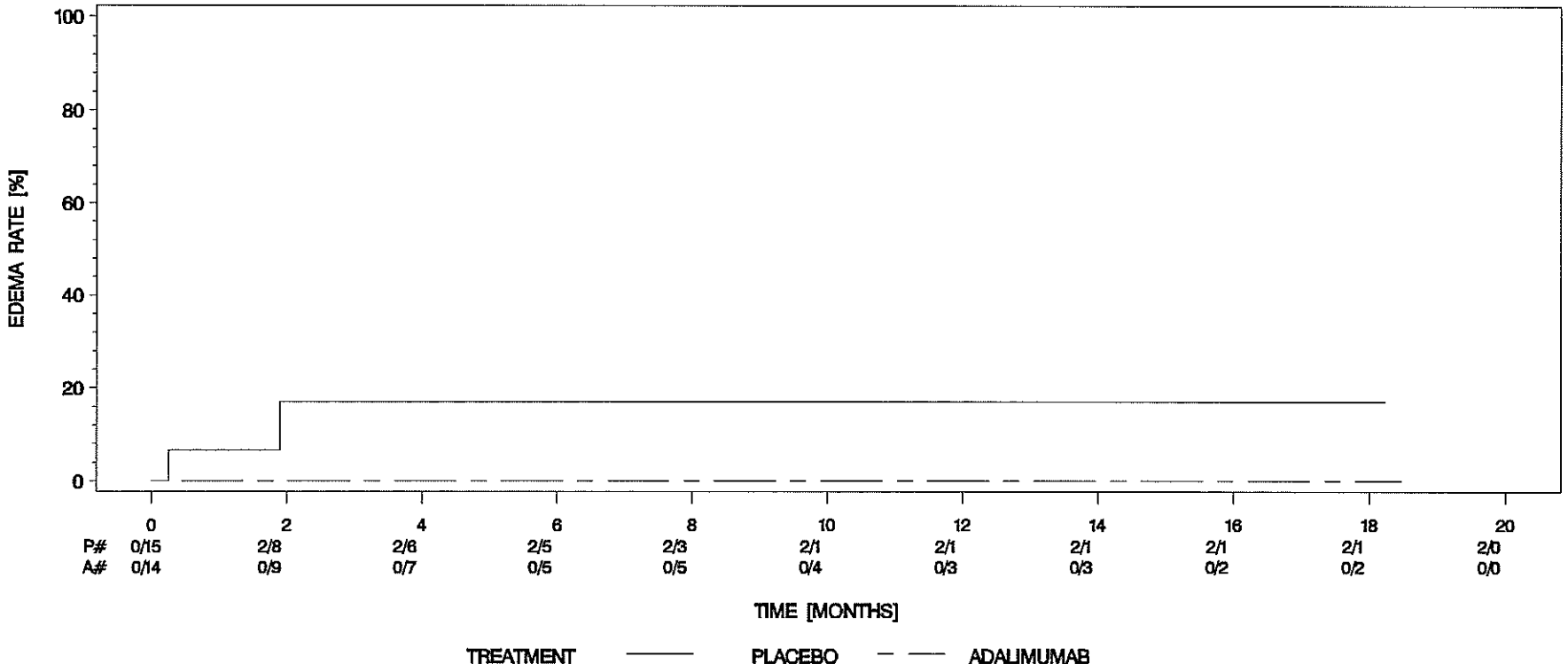
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.10.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)



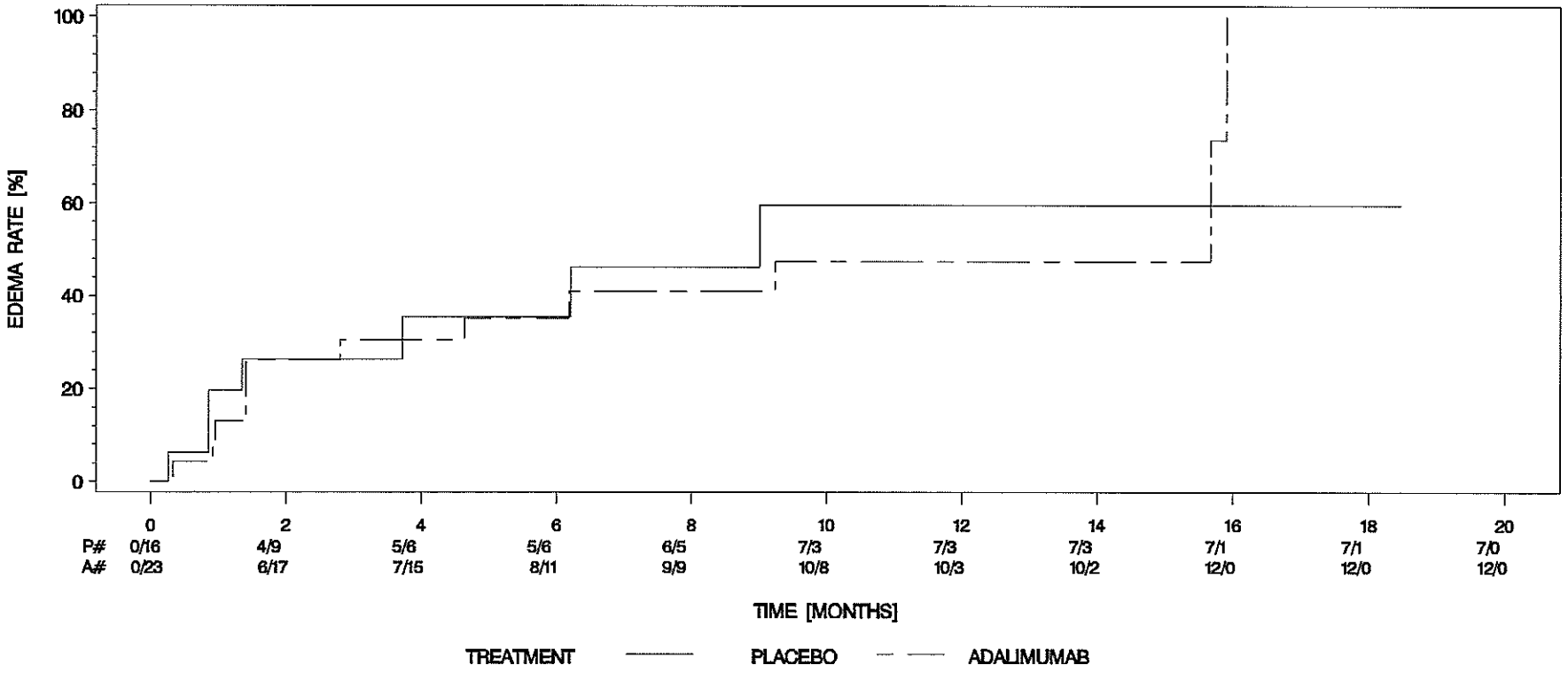
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.10.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

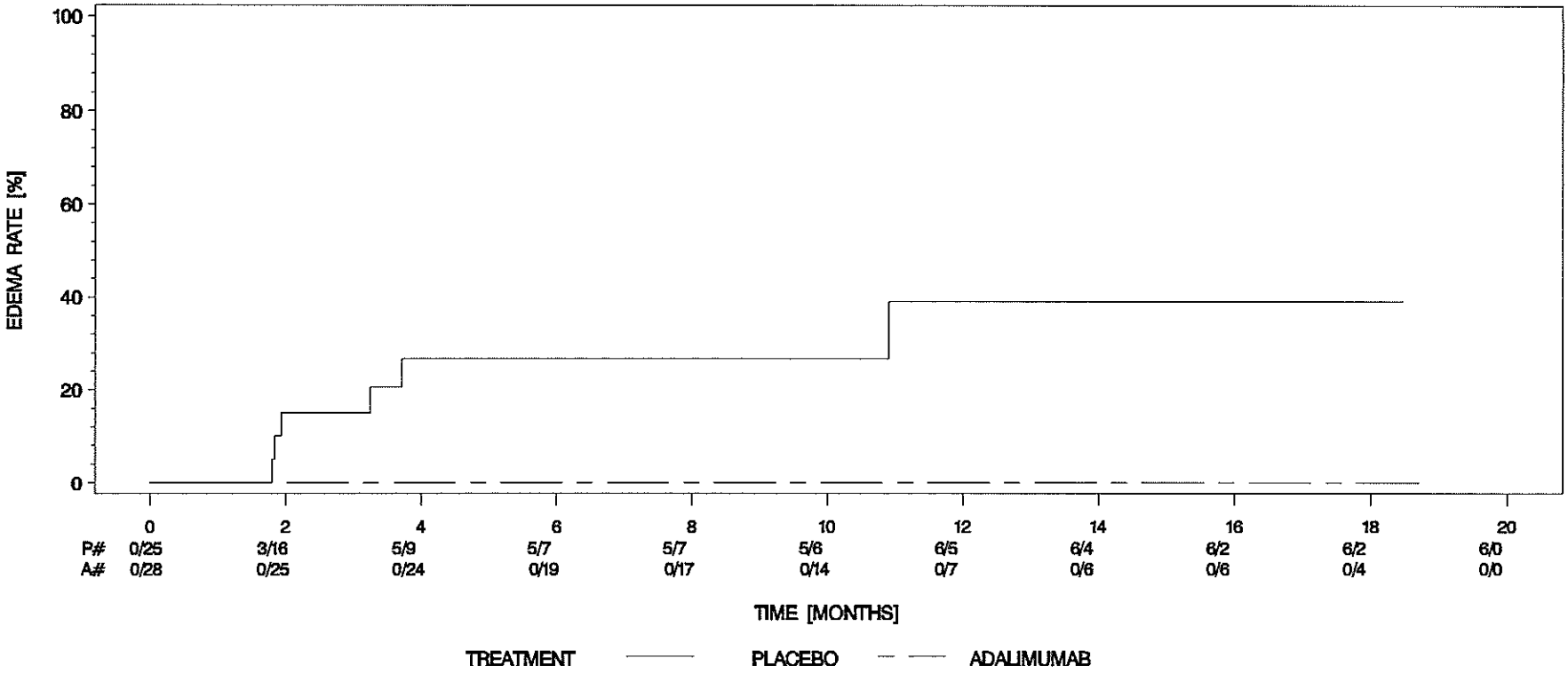
FIGURE 14.2__1000.3.1.2.11.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

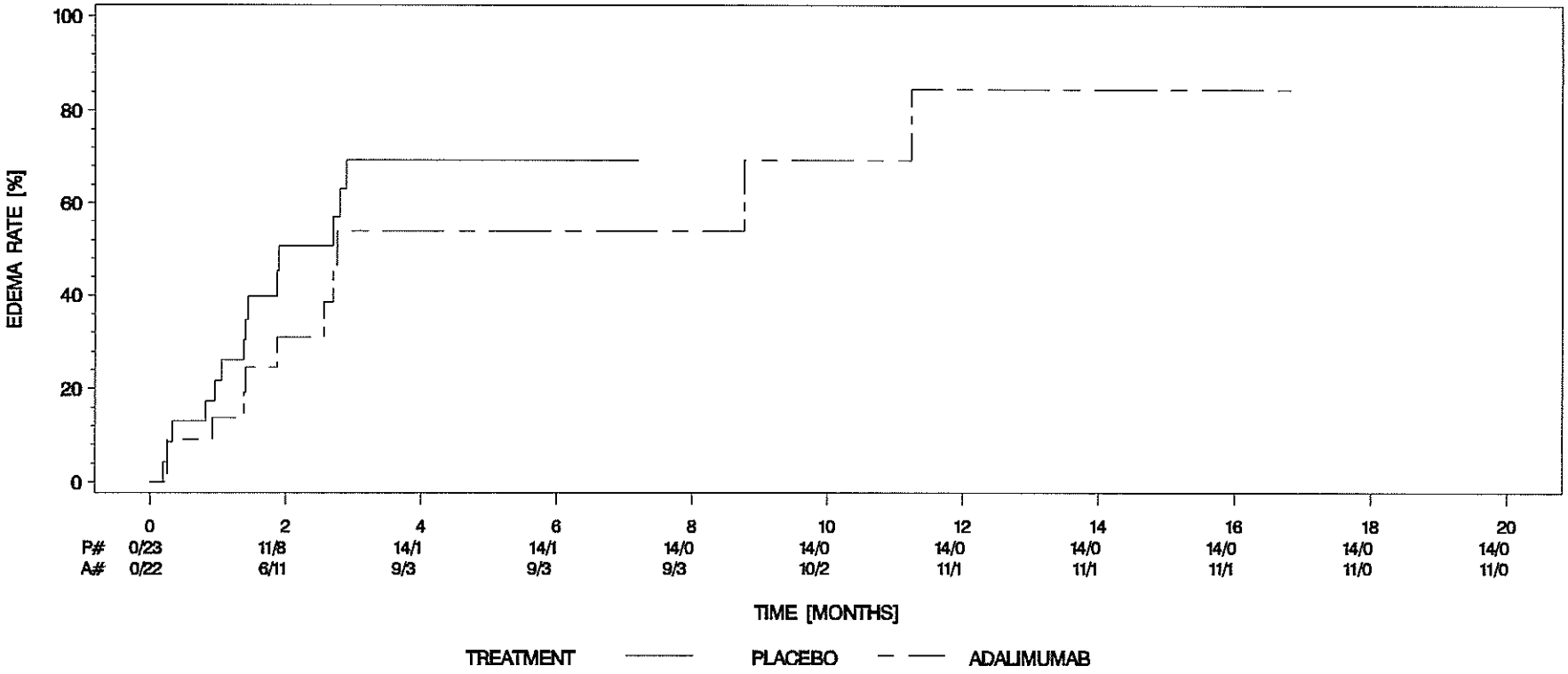
FIGURE 14.2__1000.3.1.2.11.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

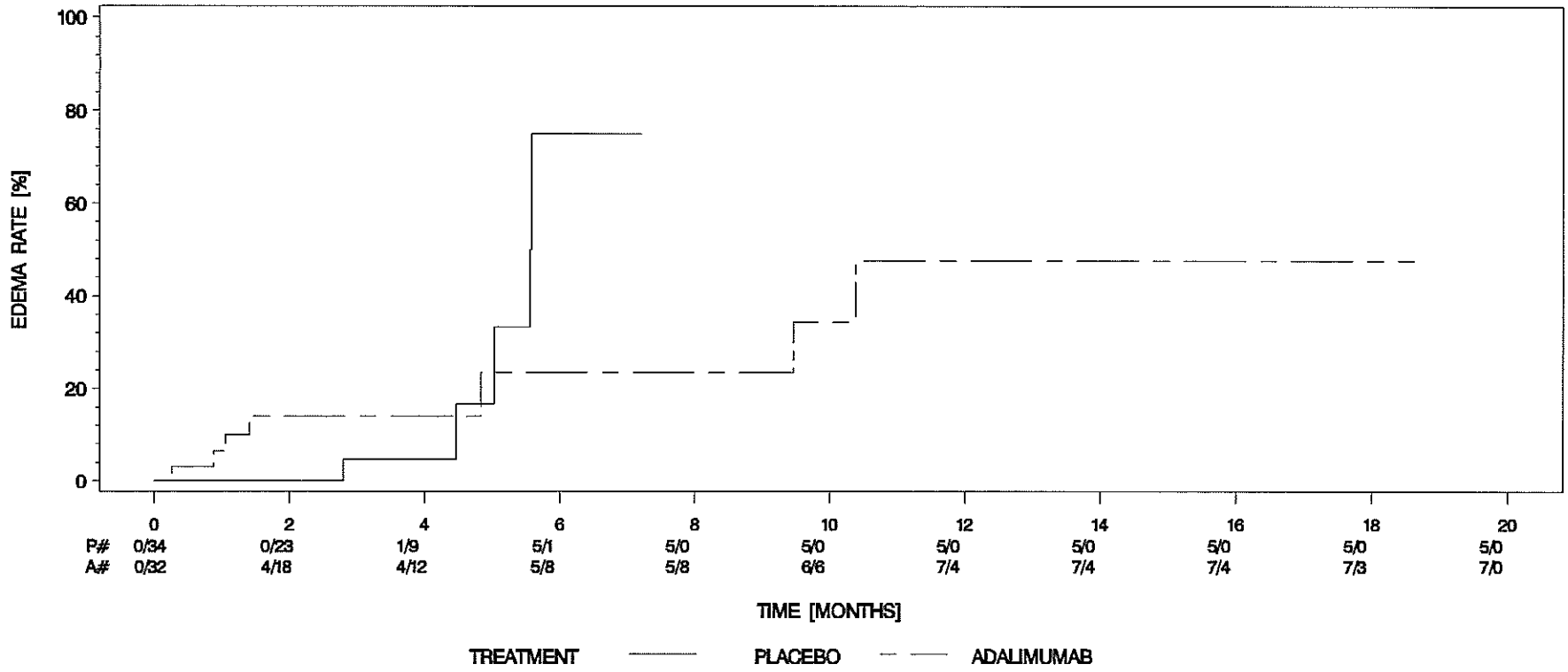
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.12.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)



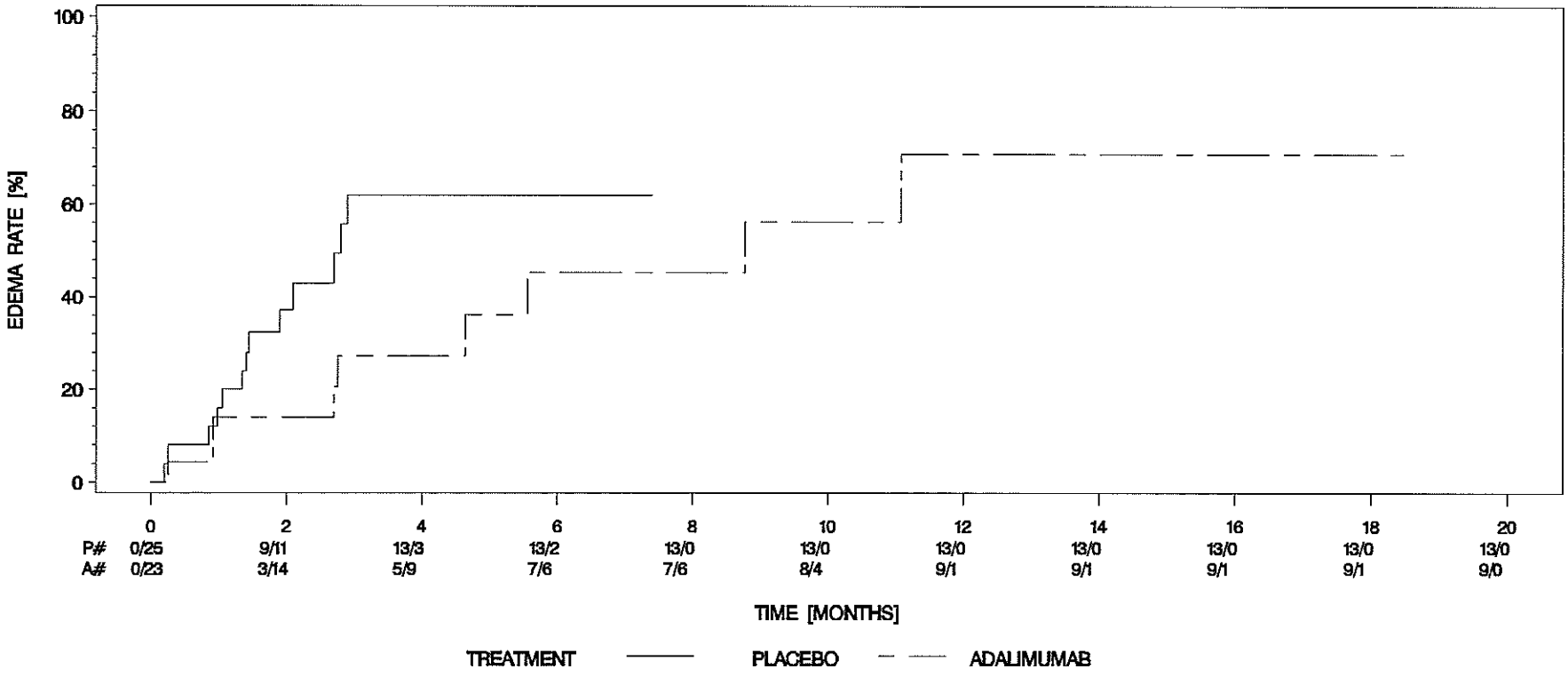
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.12.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

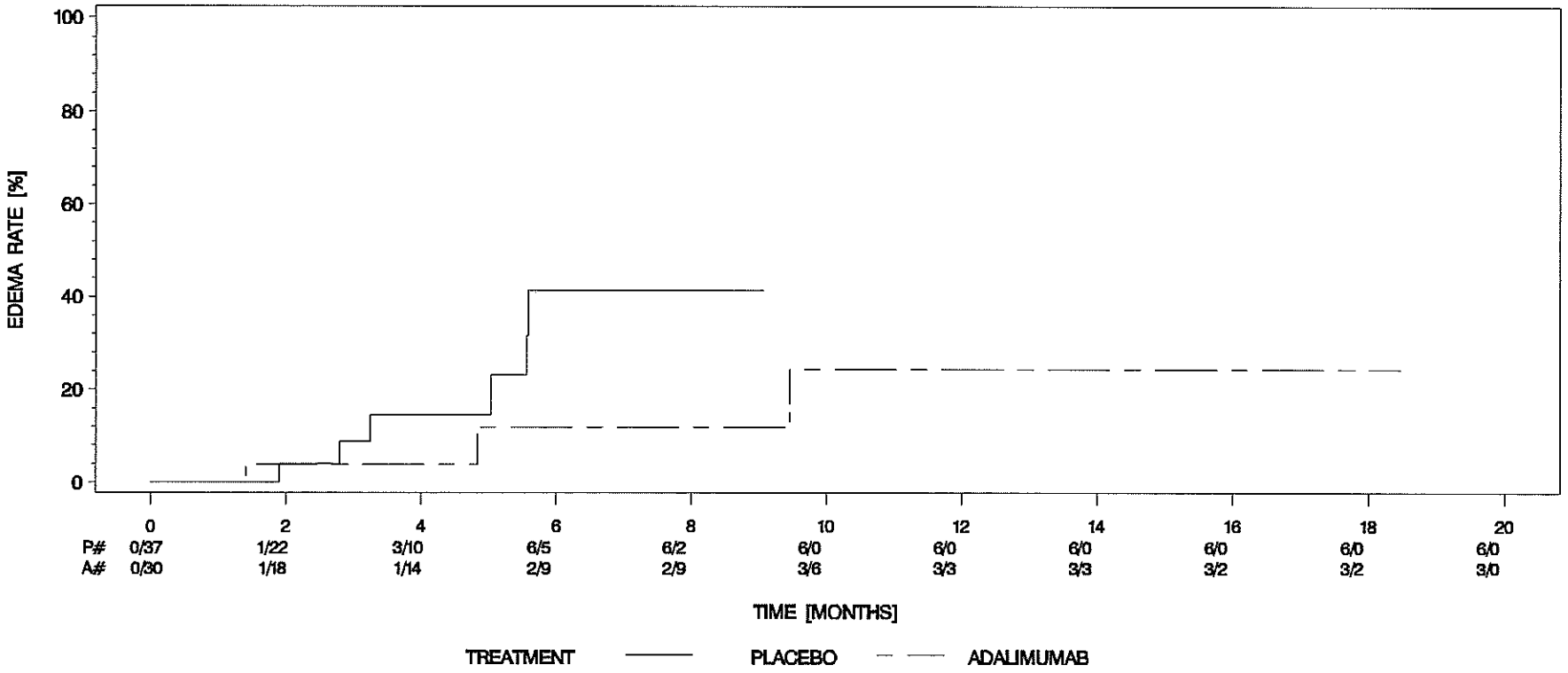
FIGURE 14.2__1000.3.1.2.13.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

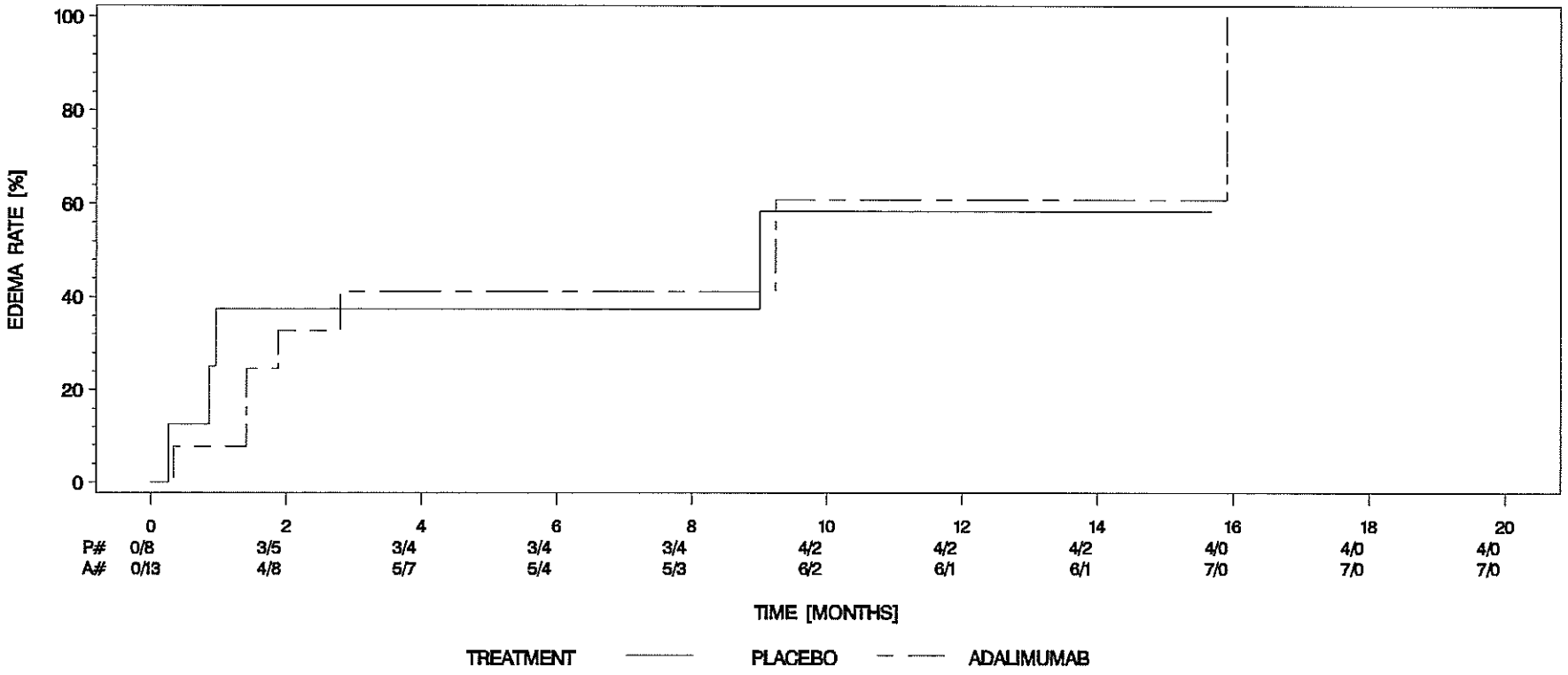
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.13.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)



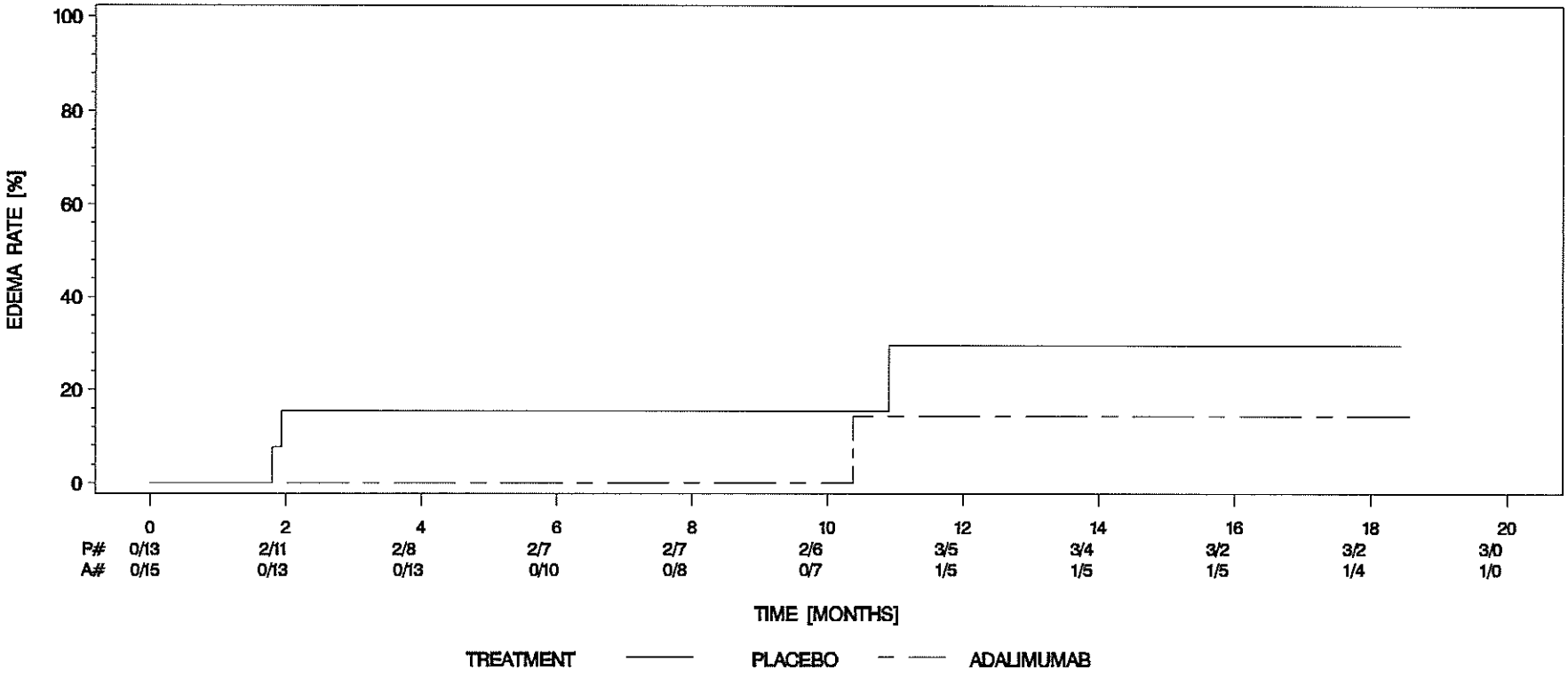
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.14.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)



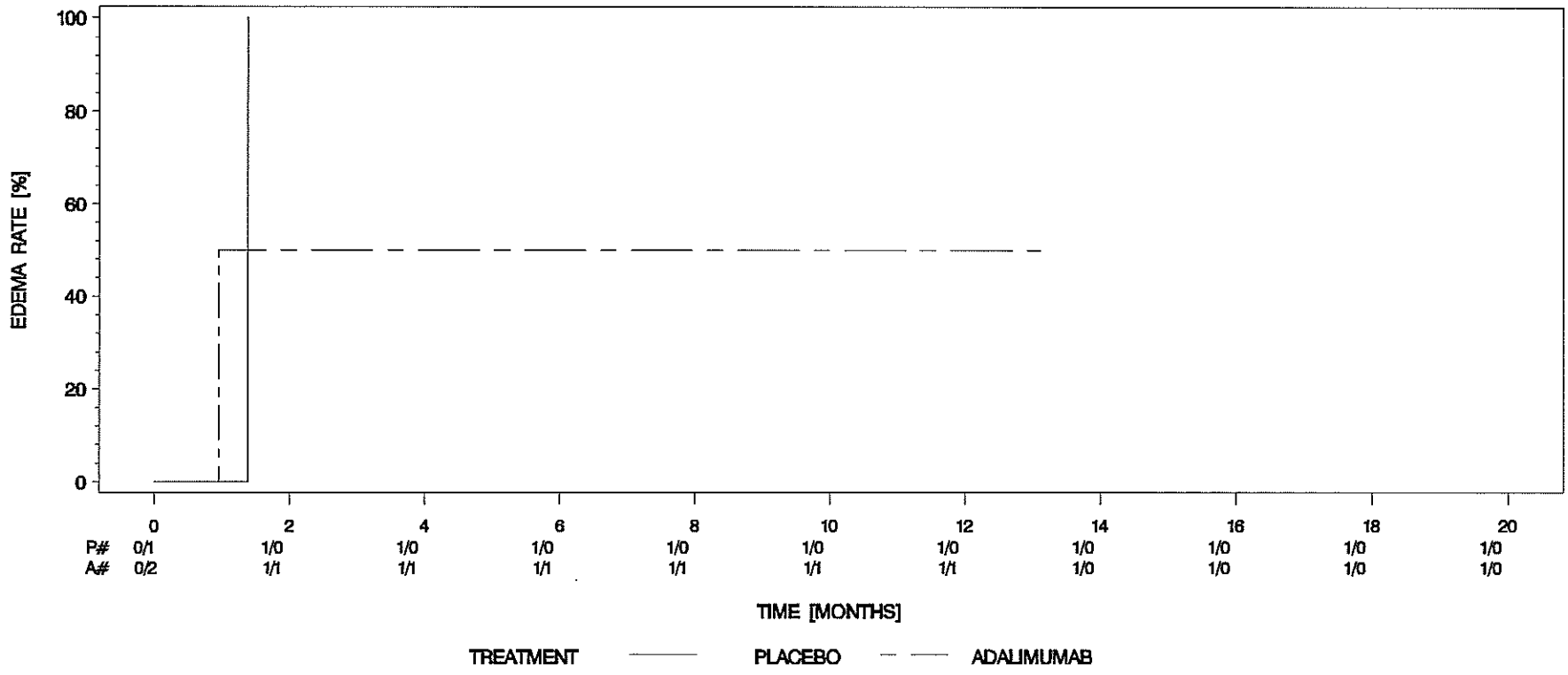
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.14.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)



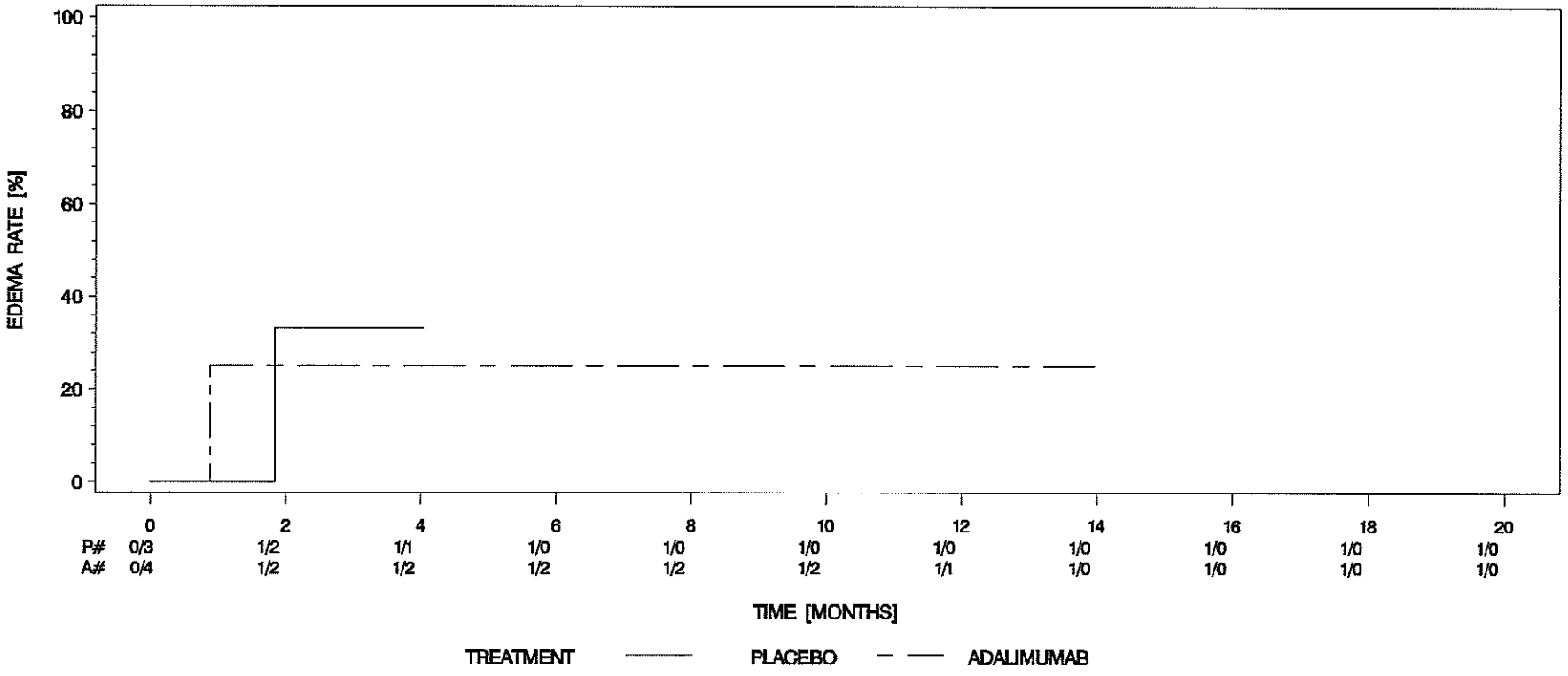
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.15.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

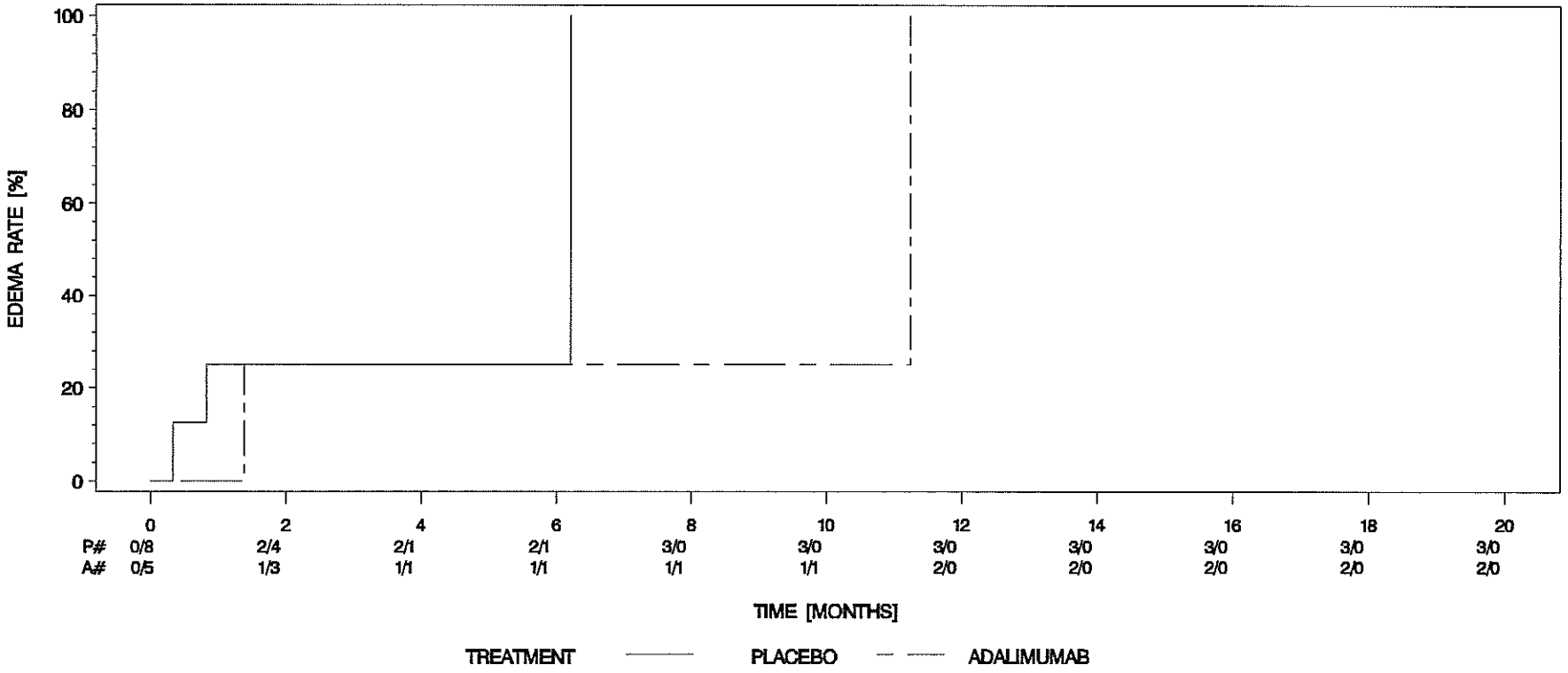
FIGURE 14.2__1000.3.1.2.15.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

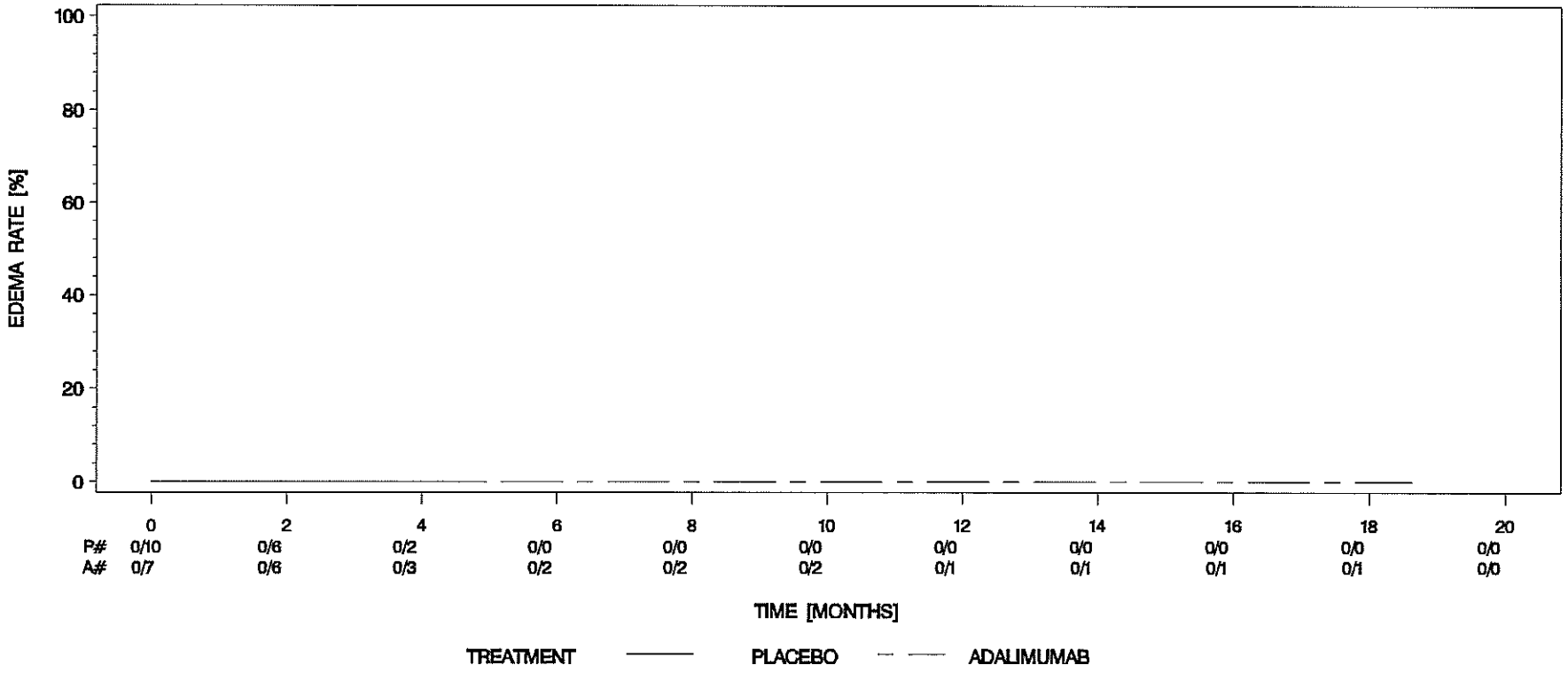
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.16.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)



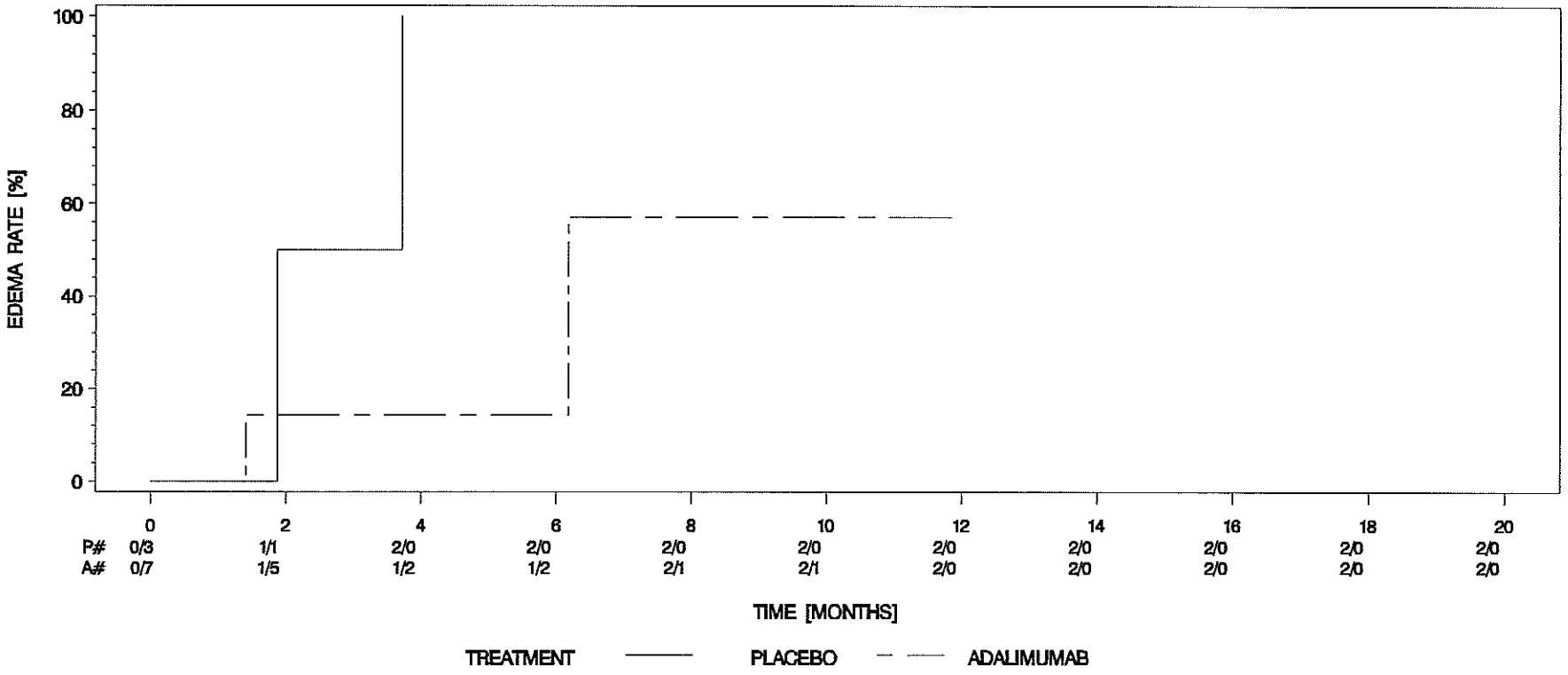
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.16.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)



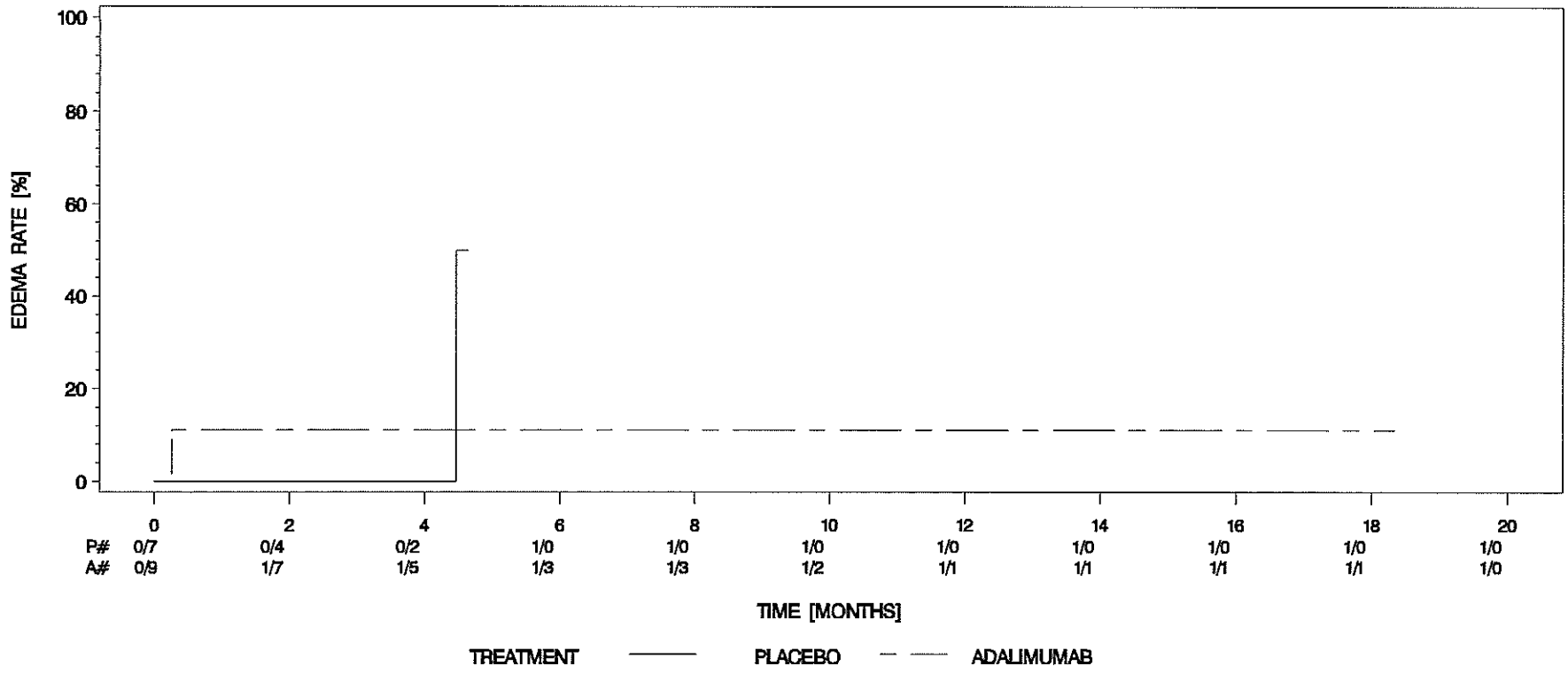
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.17.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)



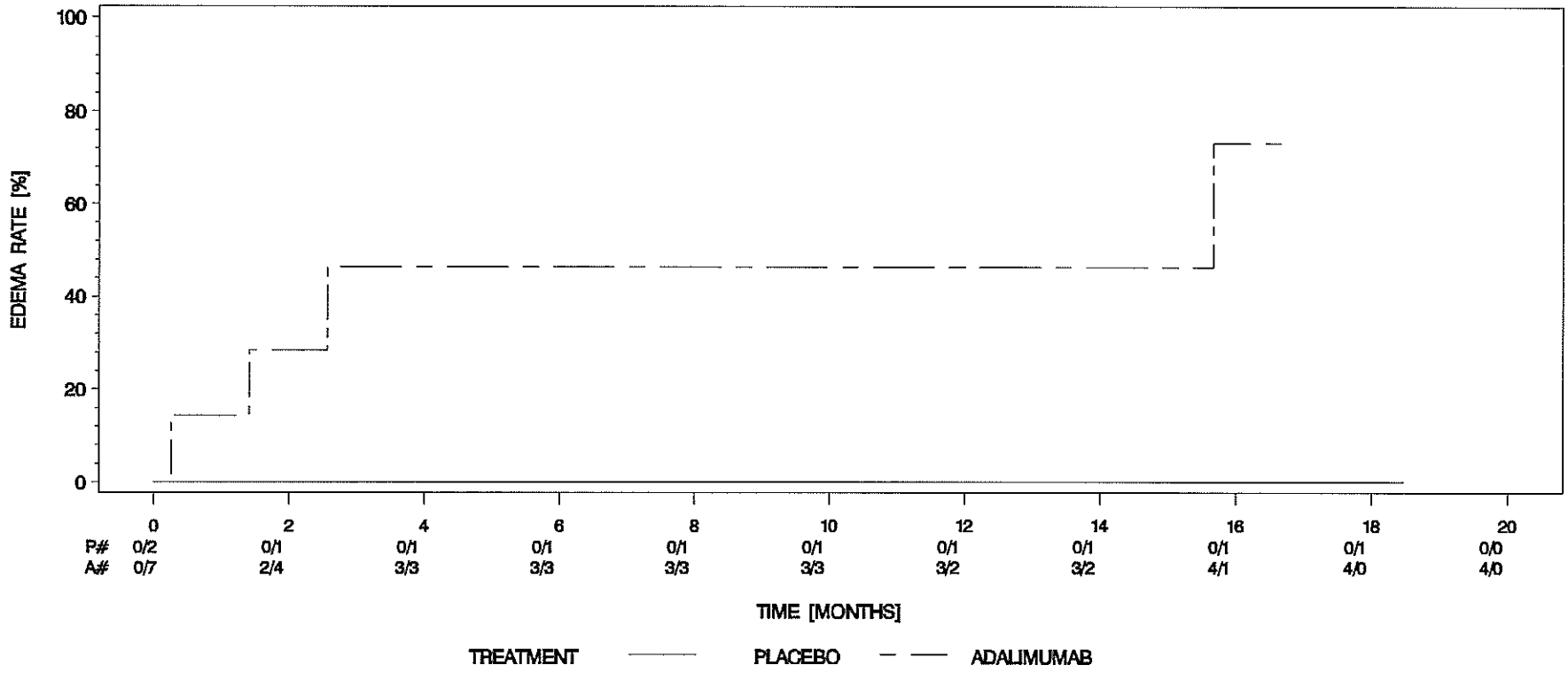
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.17.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

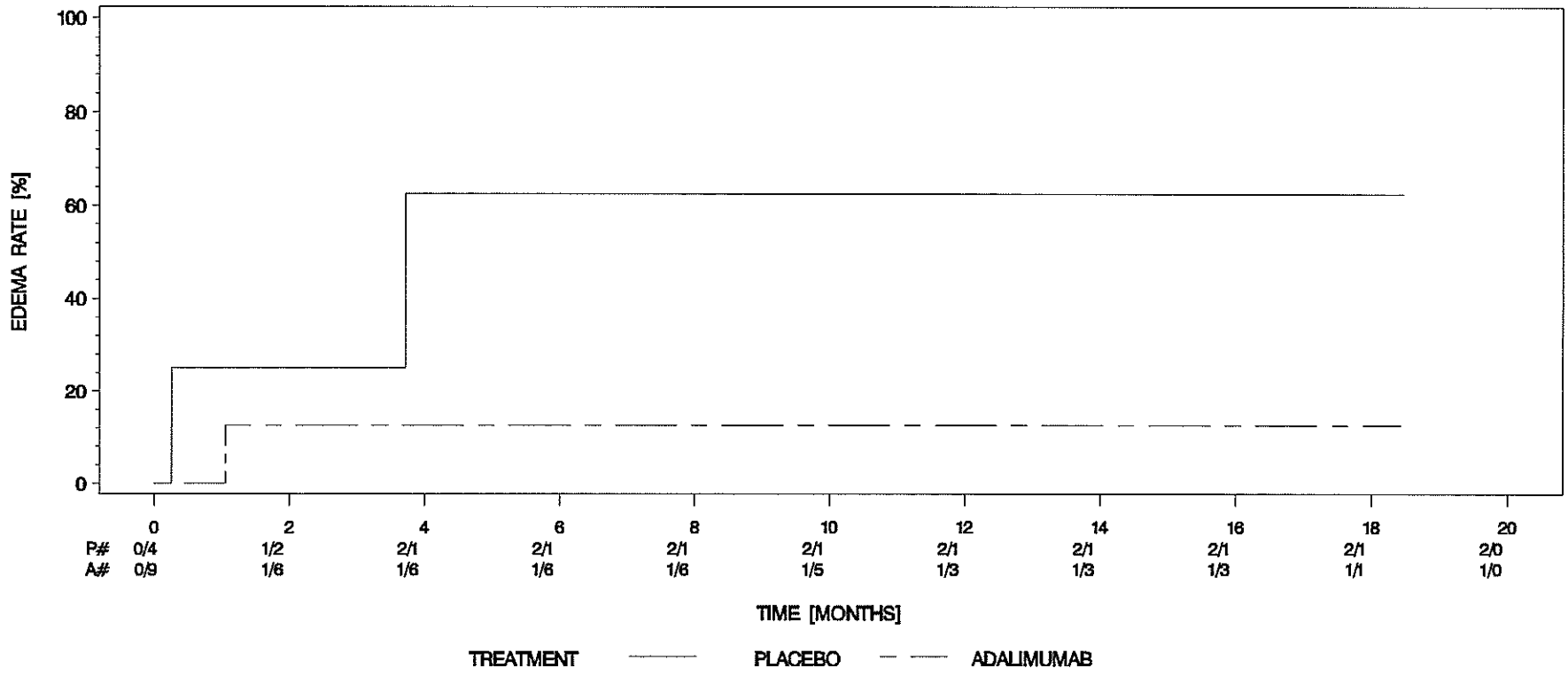
FIGURE 14.2__1000.3.1.2.18.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

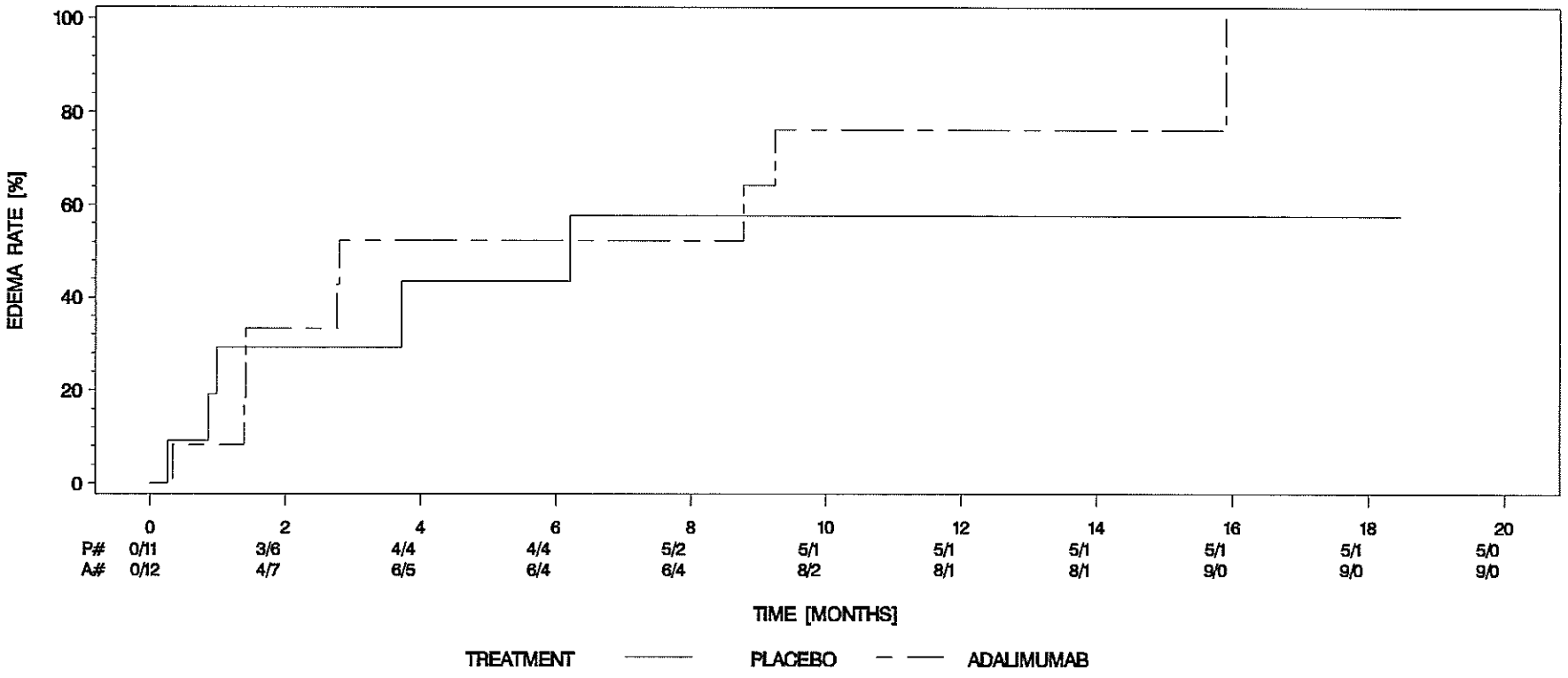
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.18.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)



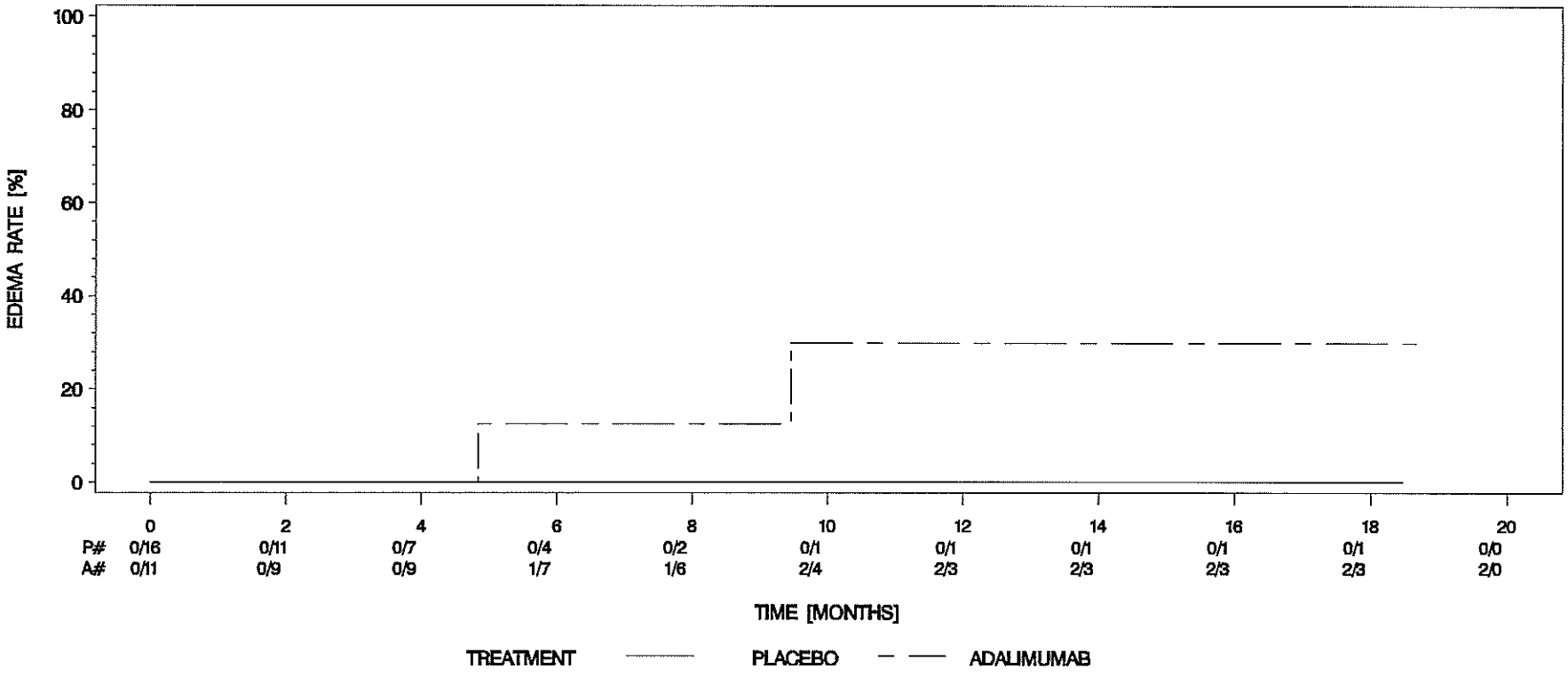
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.19.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

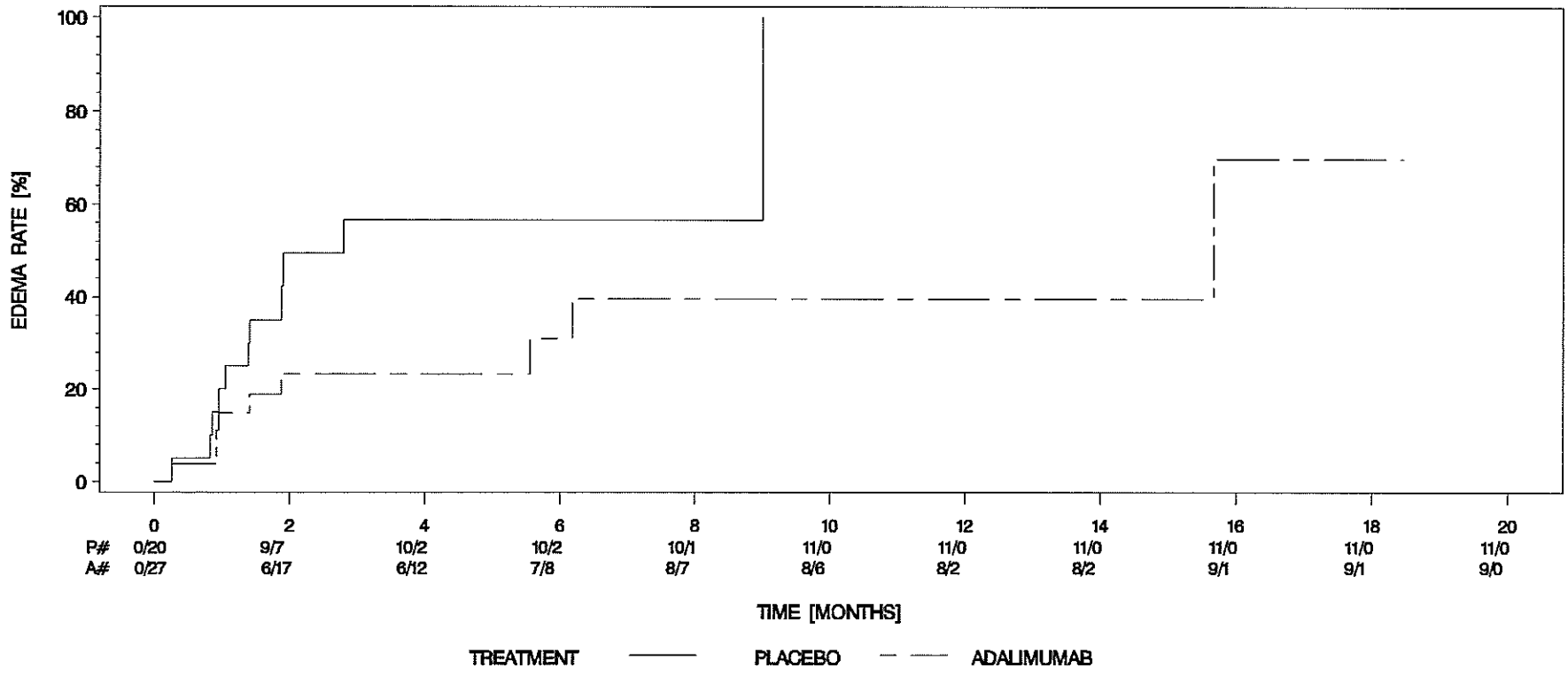
FIGURE 14.2__1000.3.1.2.19.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

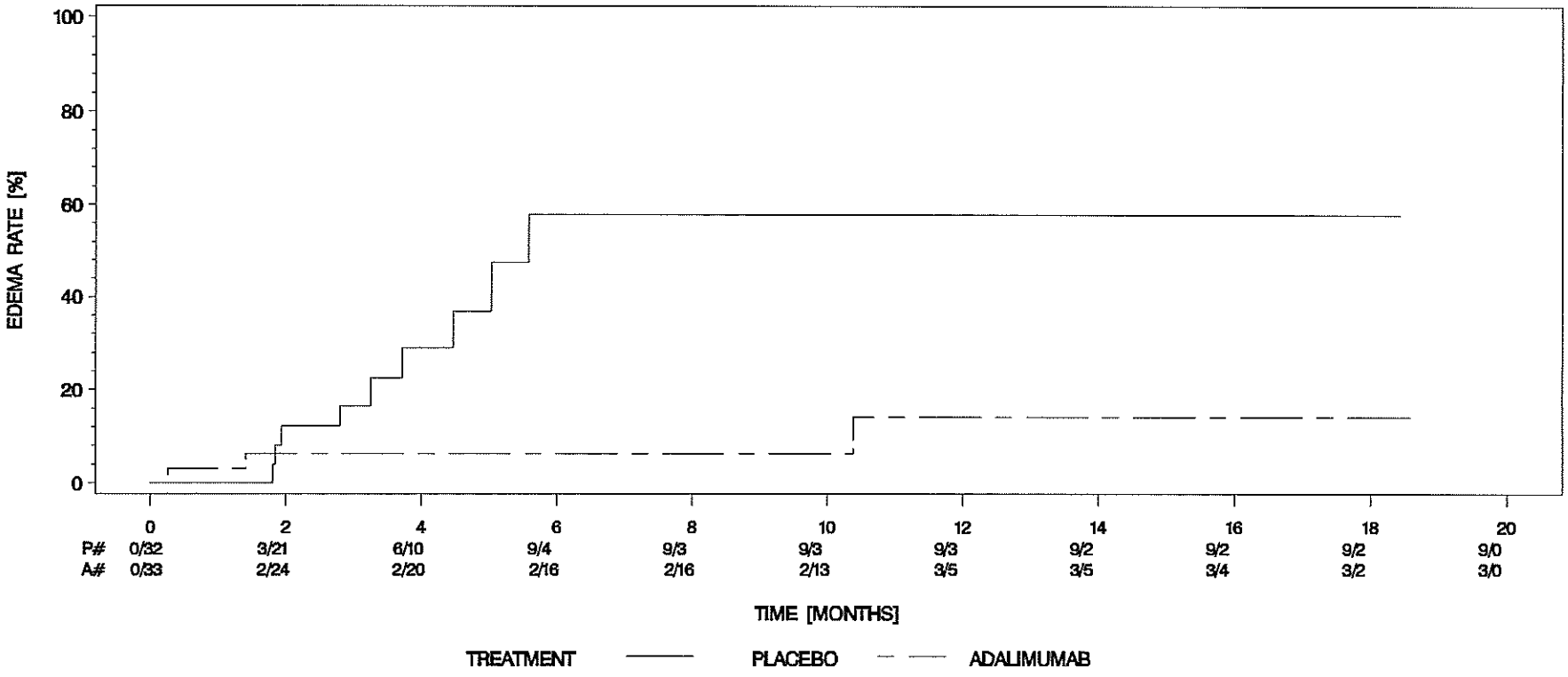
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.20.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)



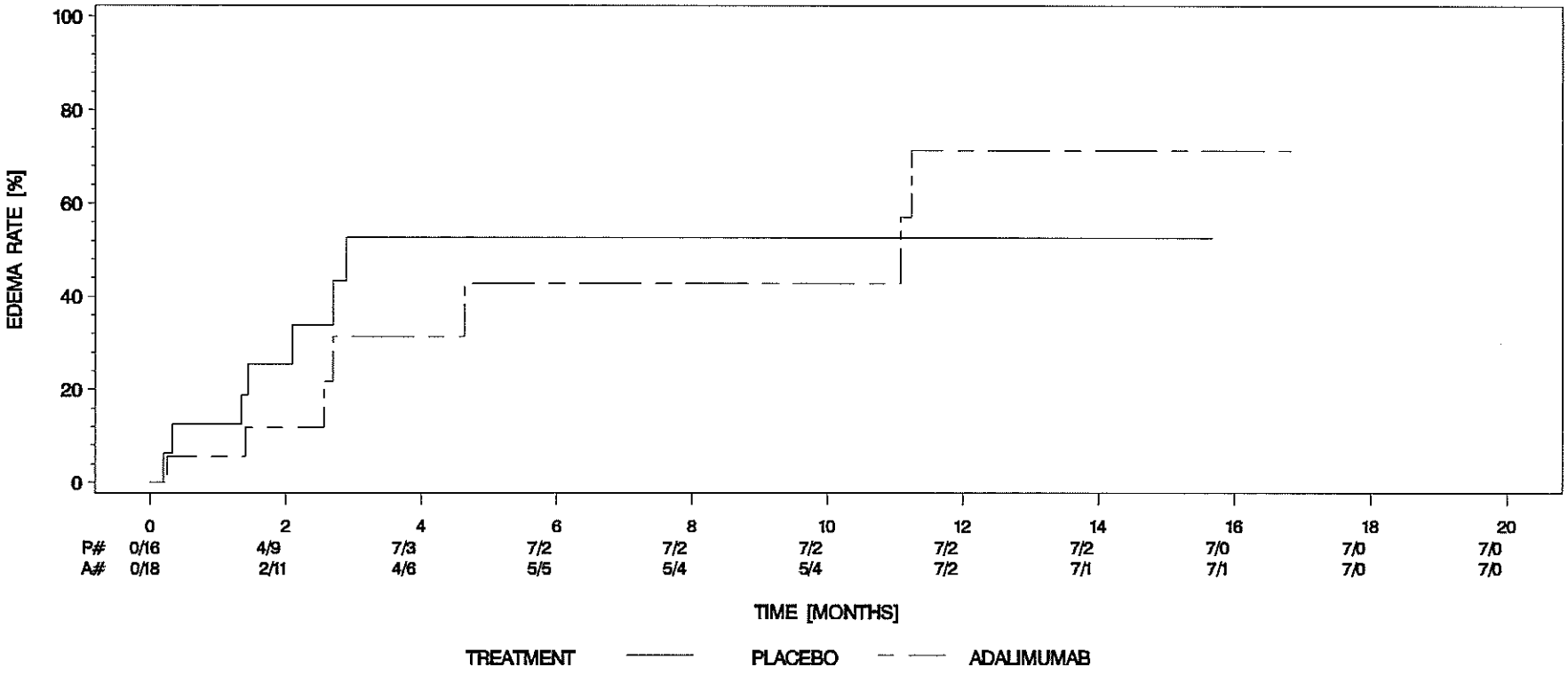
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.20.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)



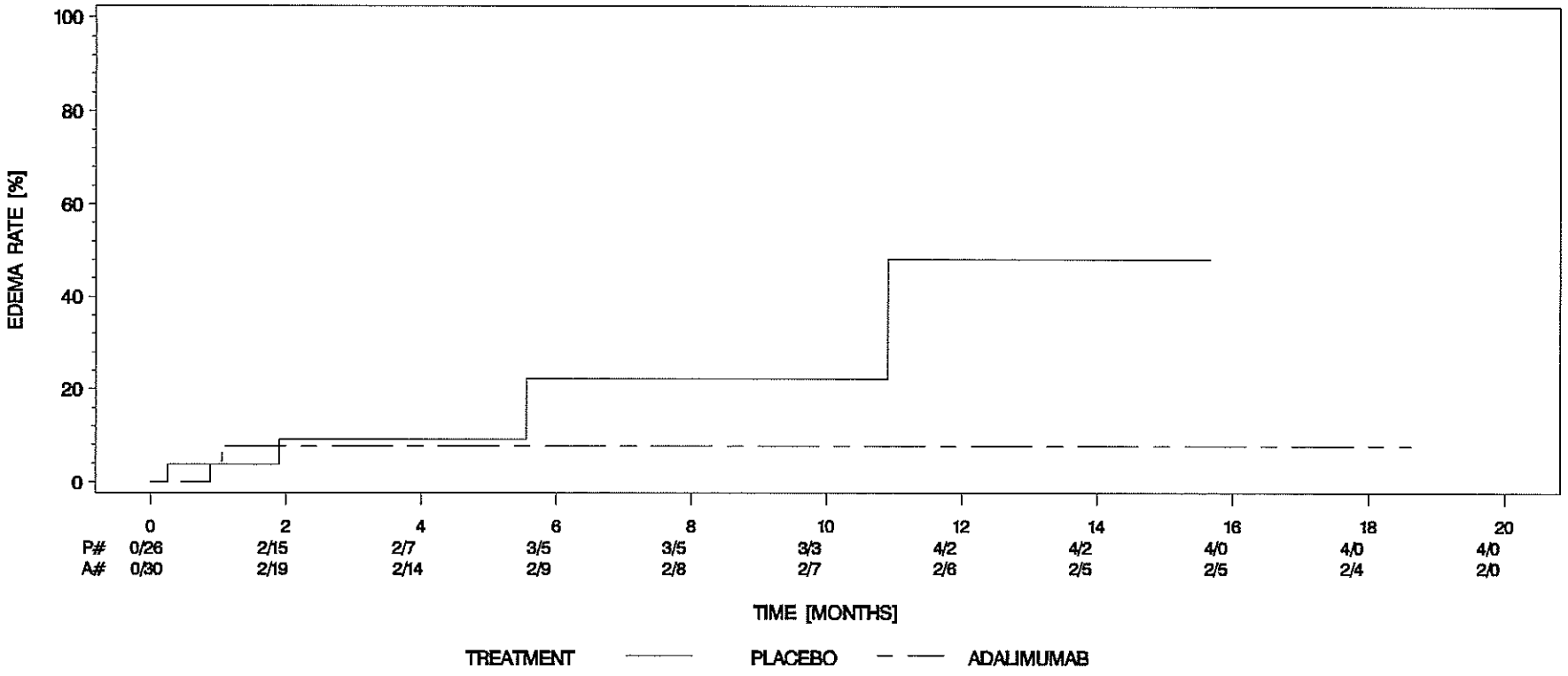
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.21.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)



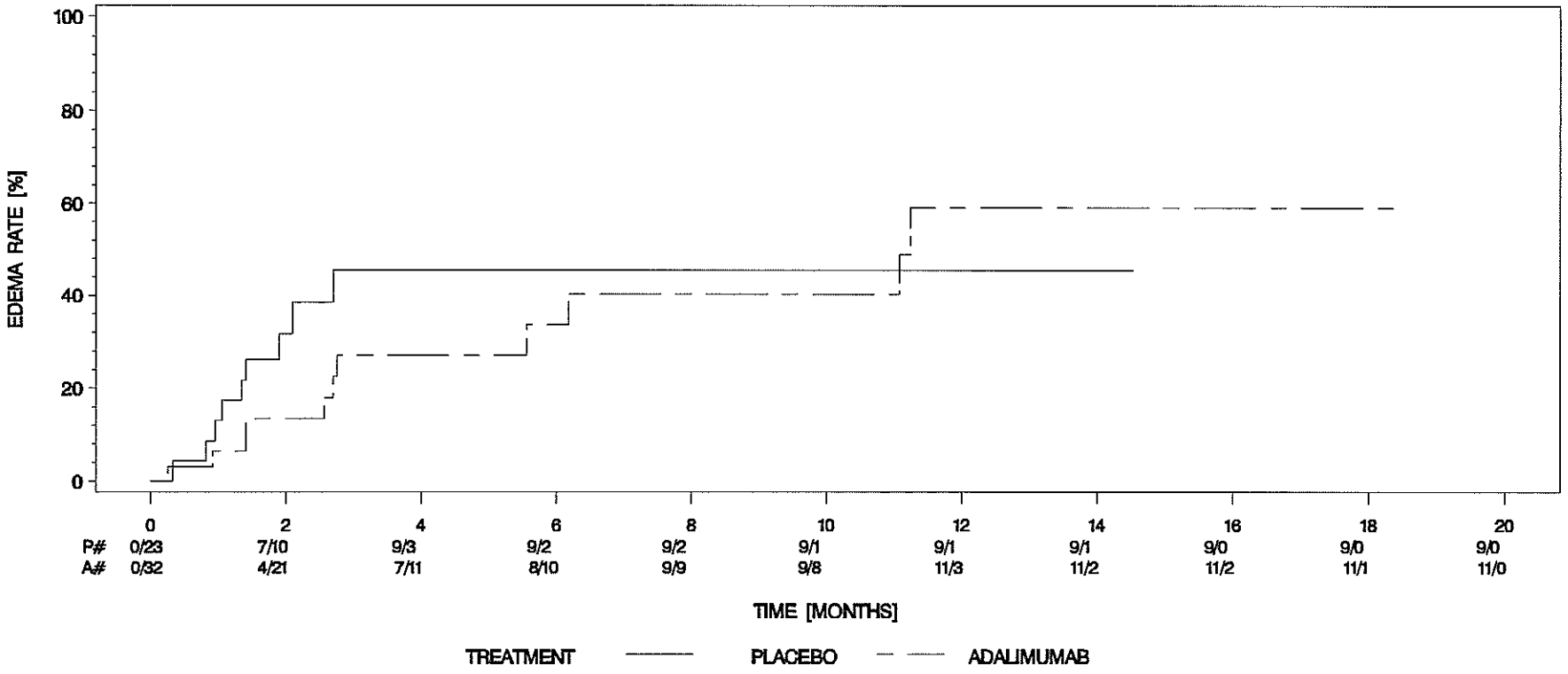
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.21.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)



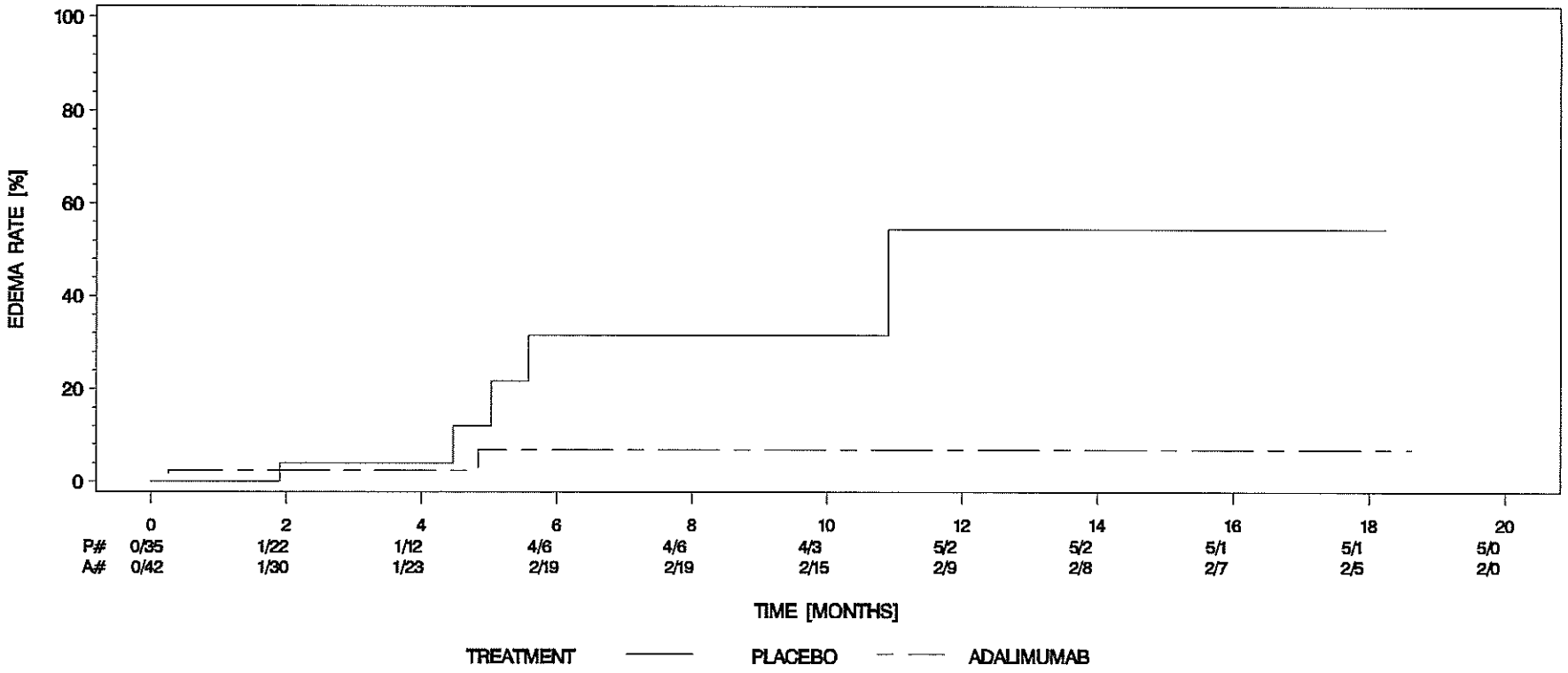
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.22.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)



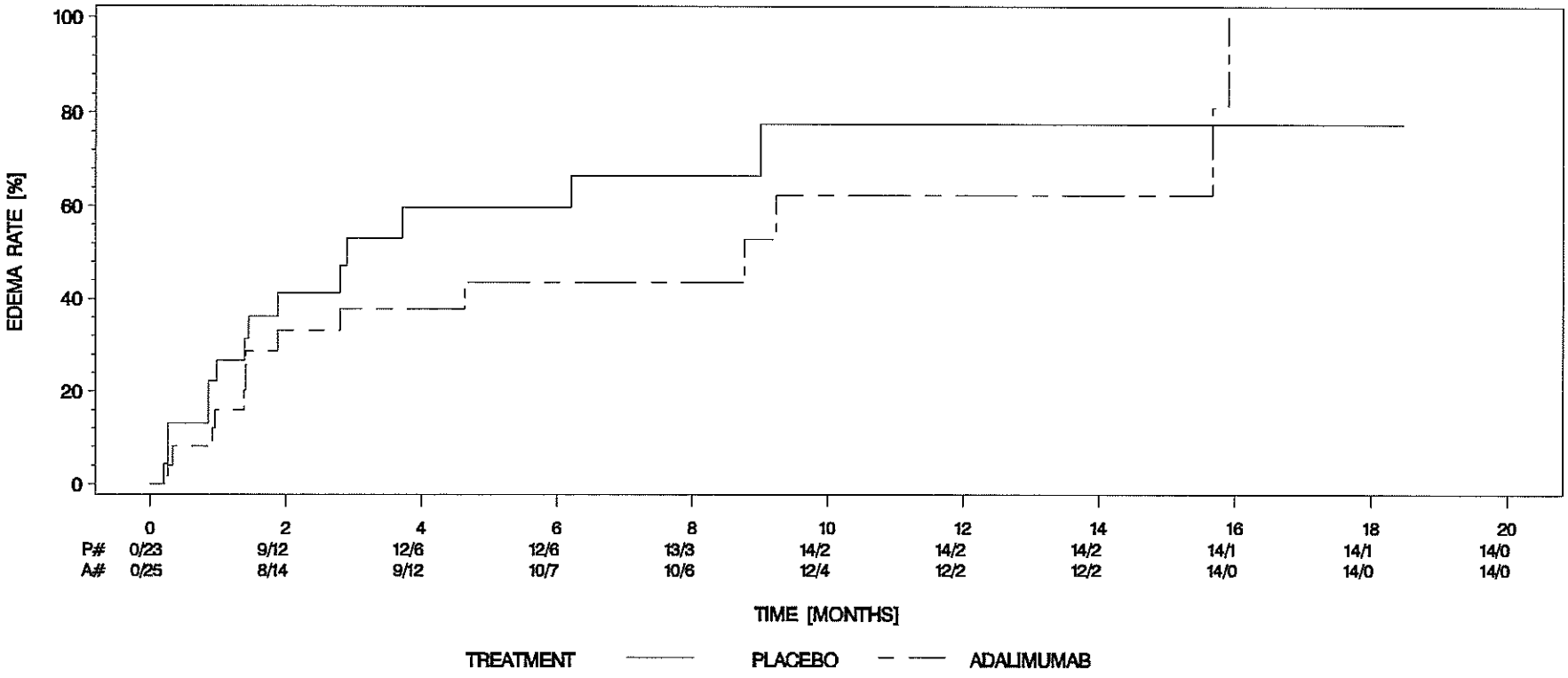
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.22.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

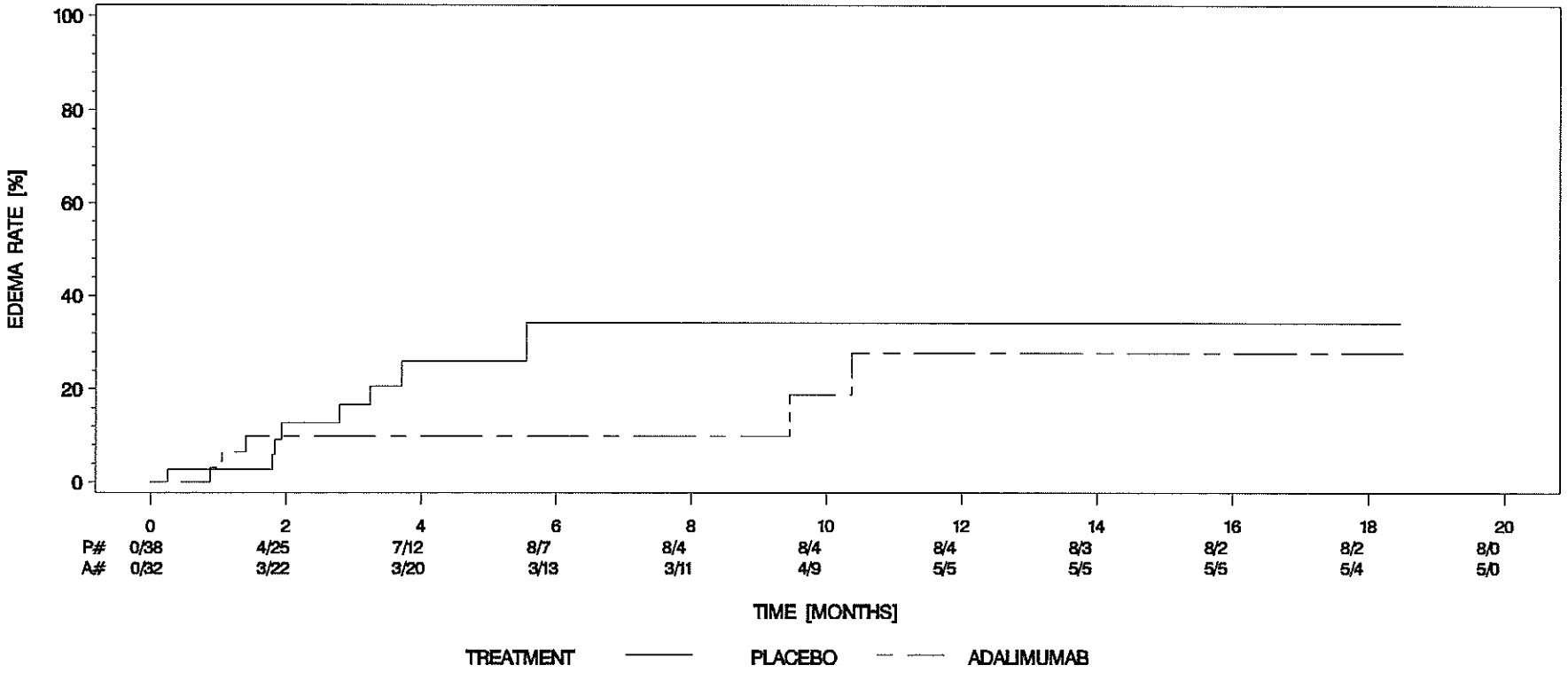
FIGURE 14.2__1000.3.1.2.23.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

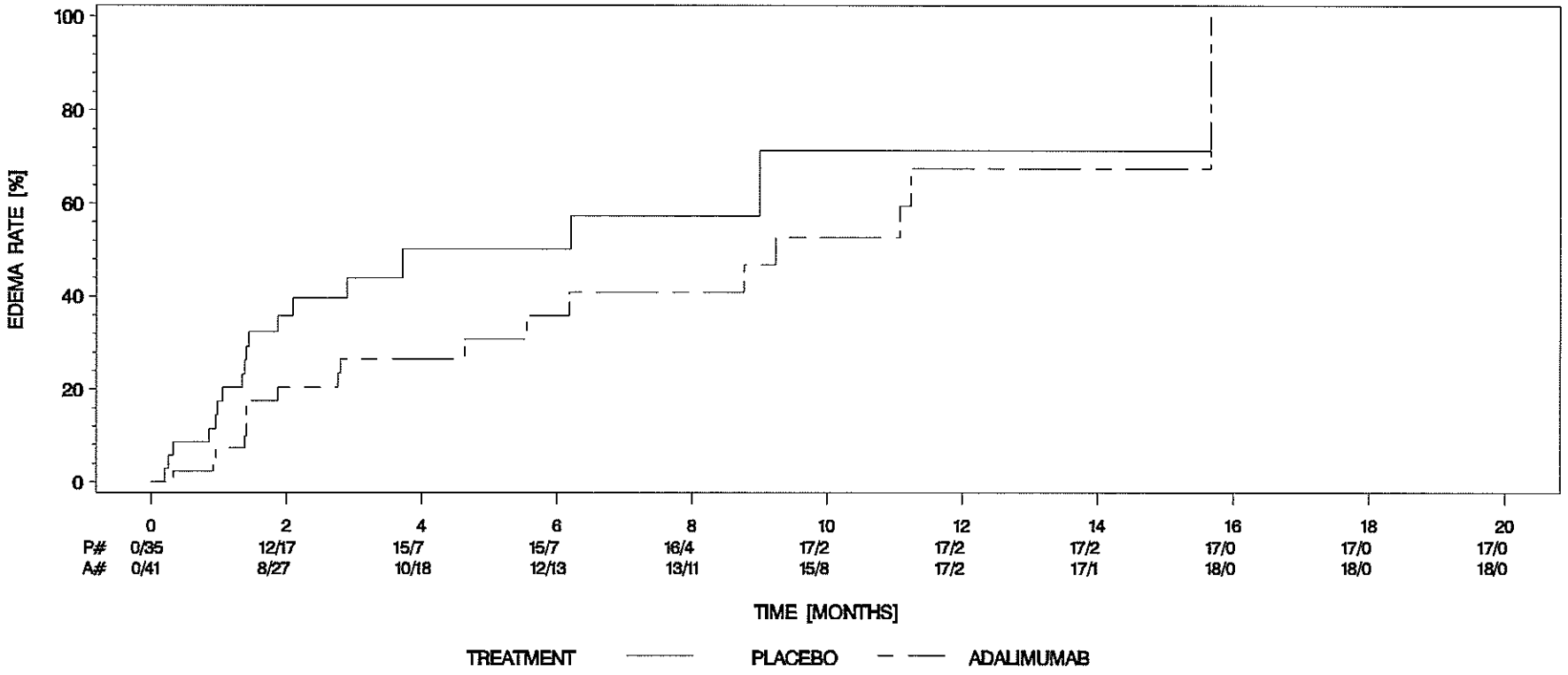
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.23.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)



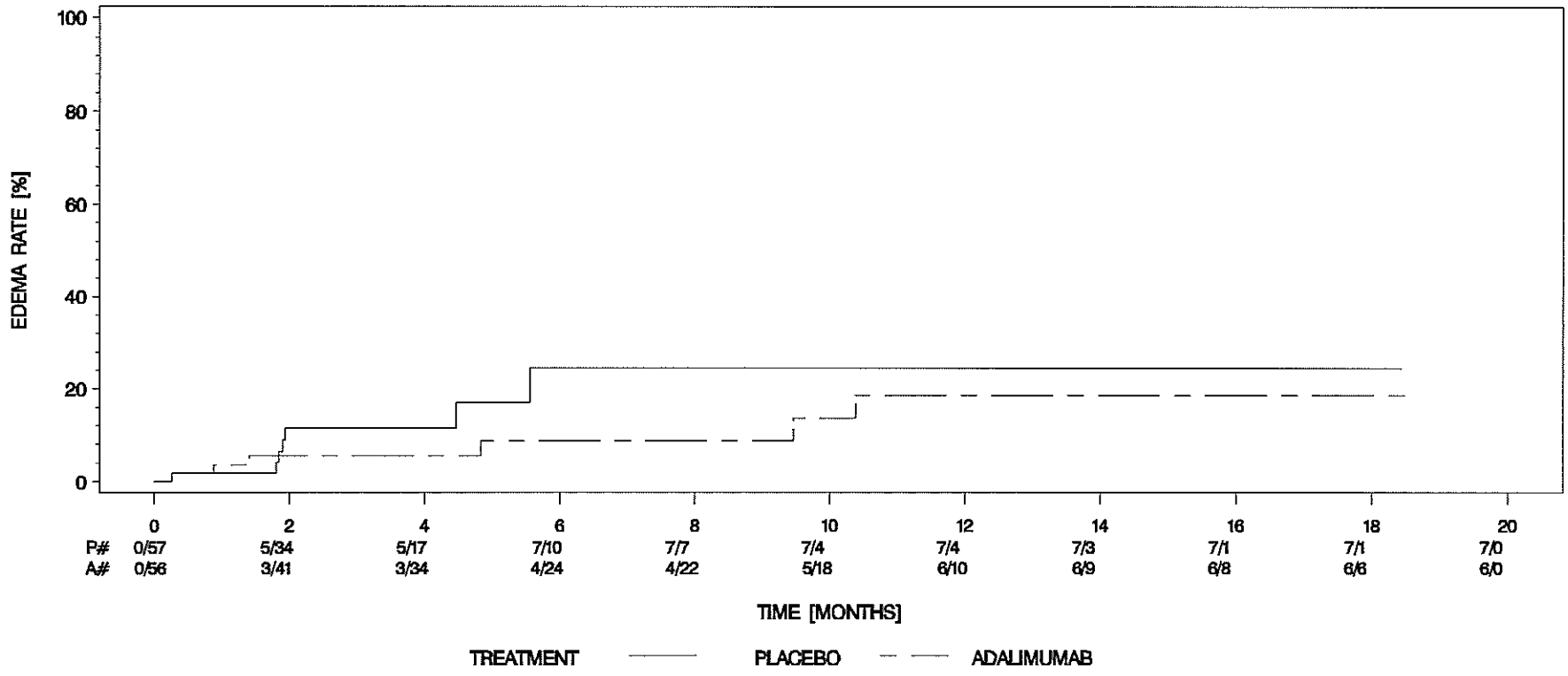
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.24.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)



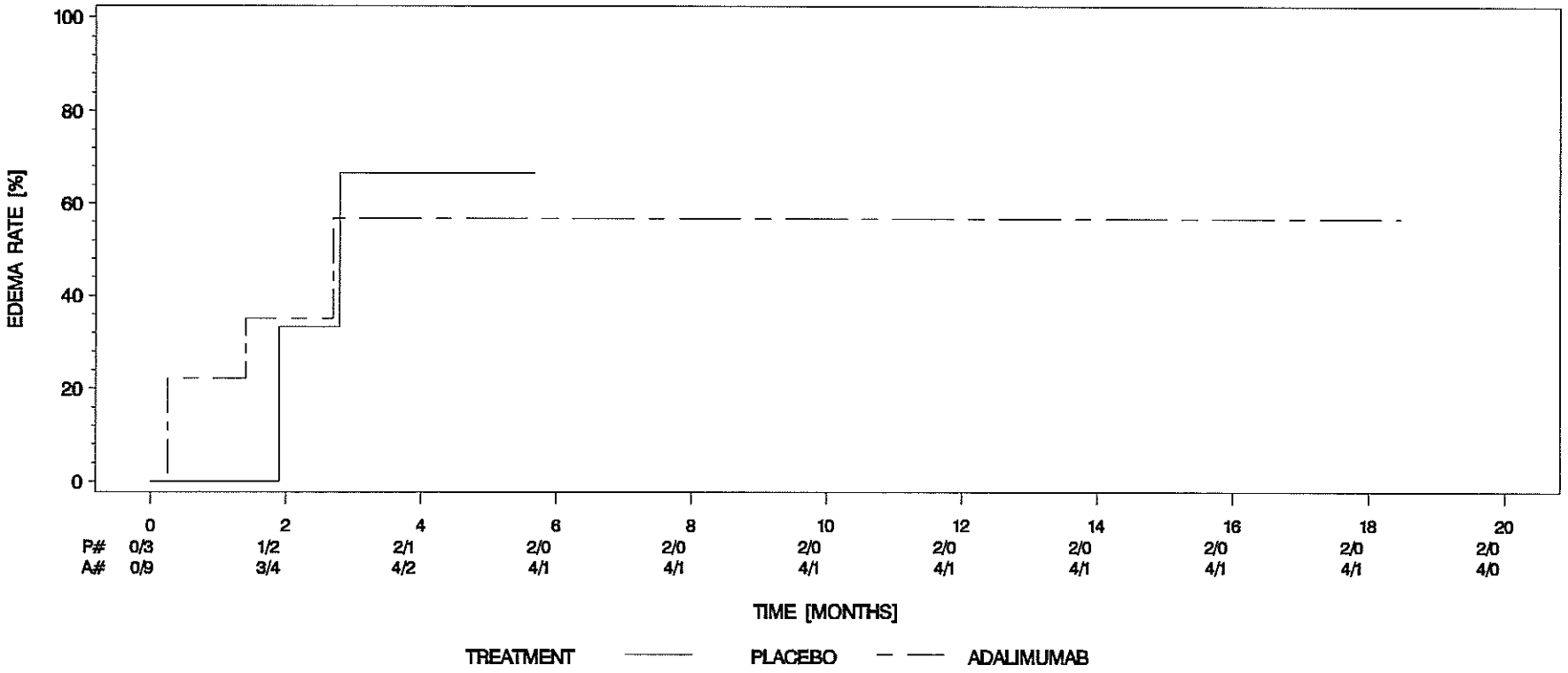
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.24.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)



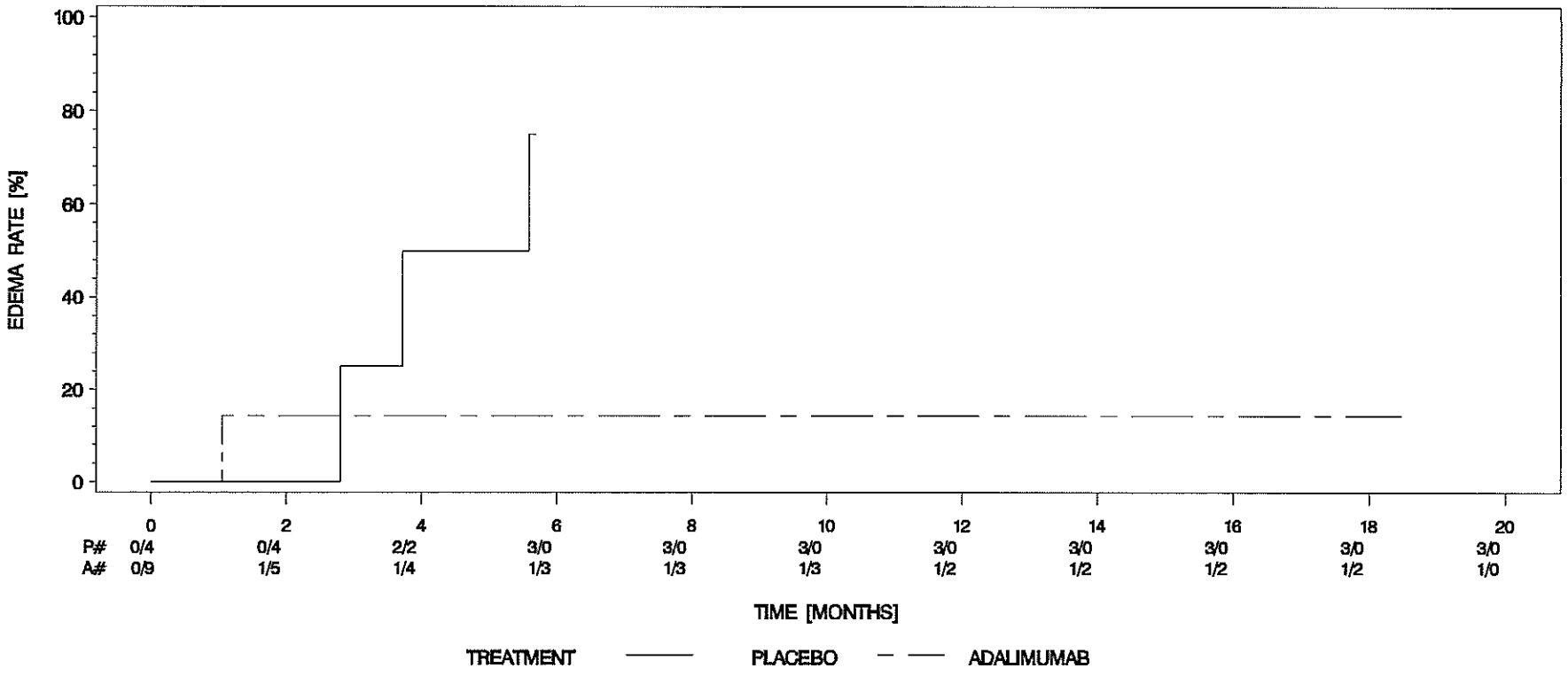
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.25.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)



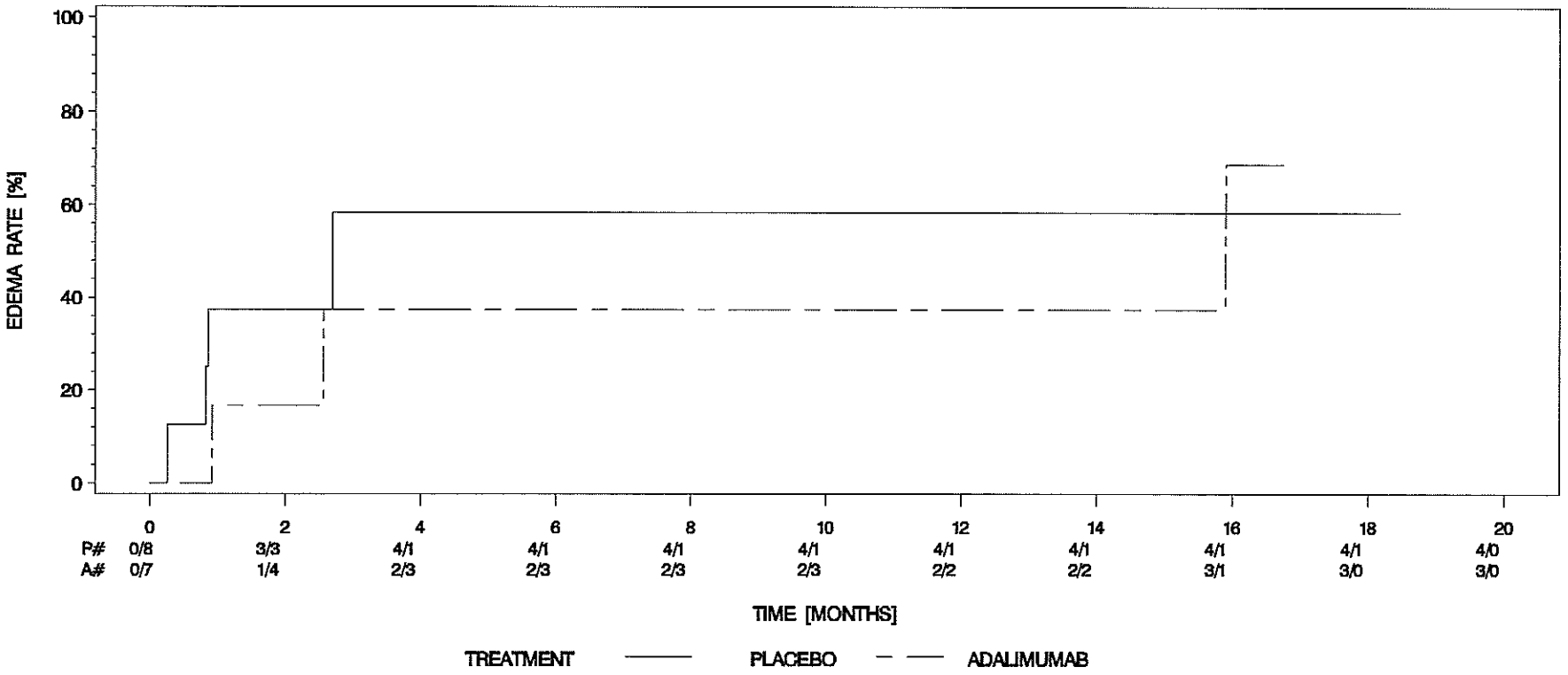
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.25.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)



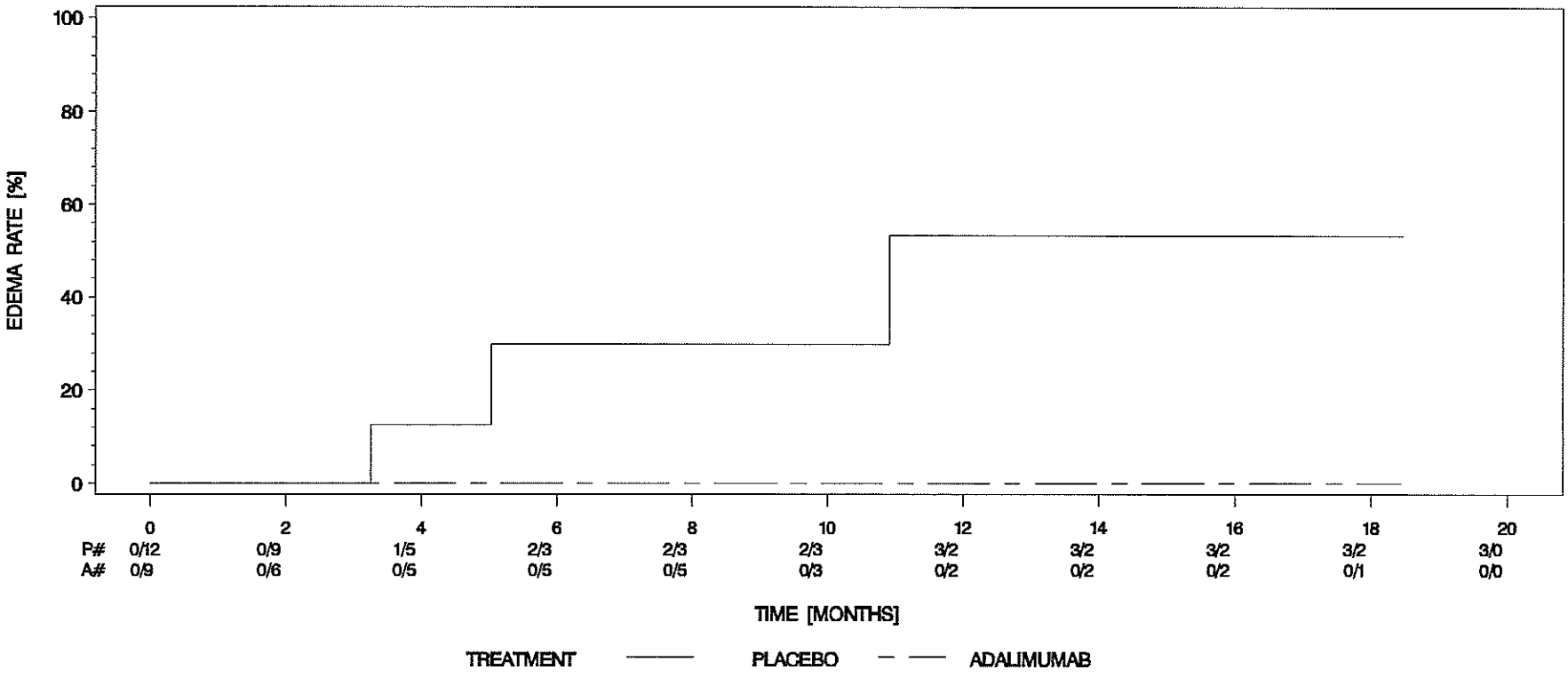
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.26.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)



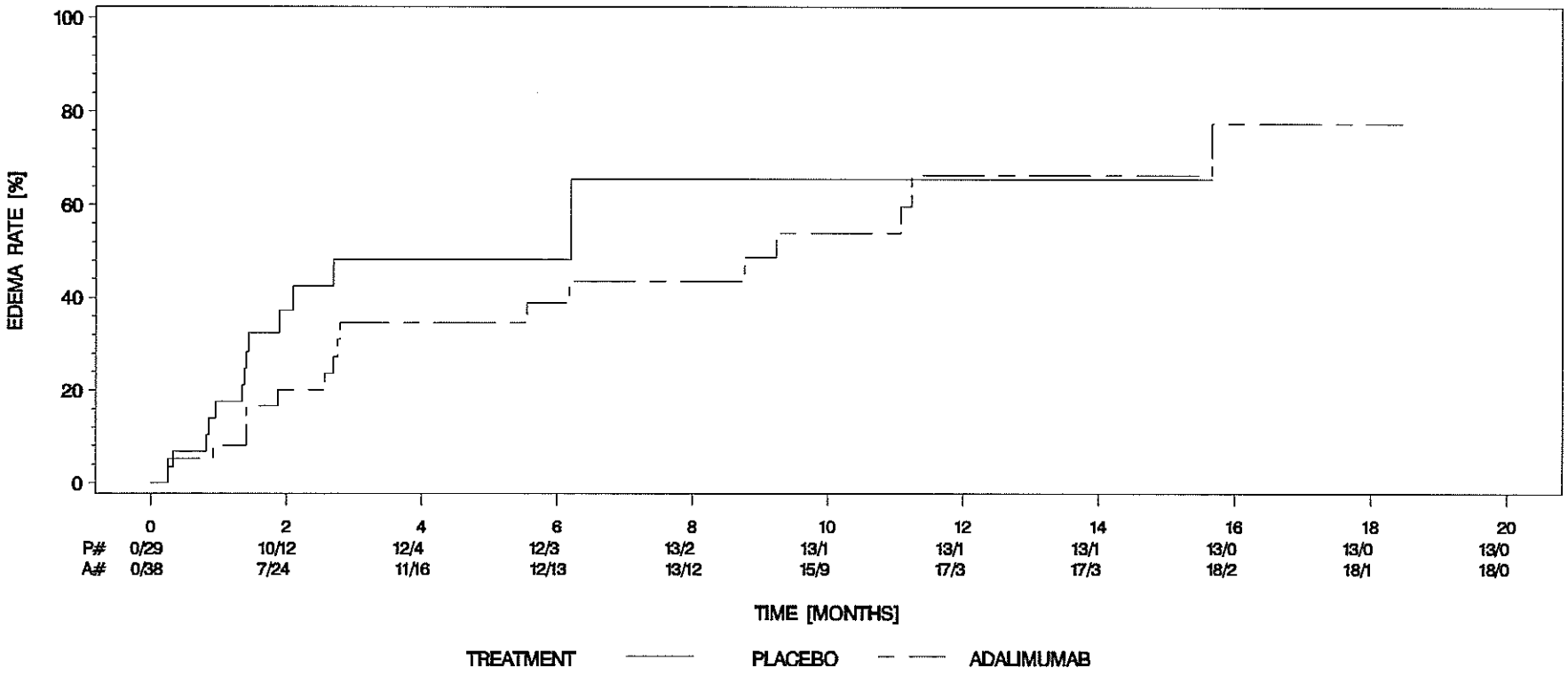
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.26.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)



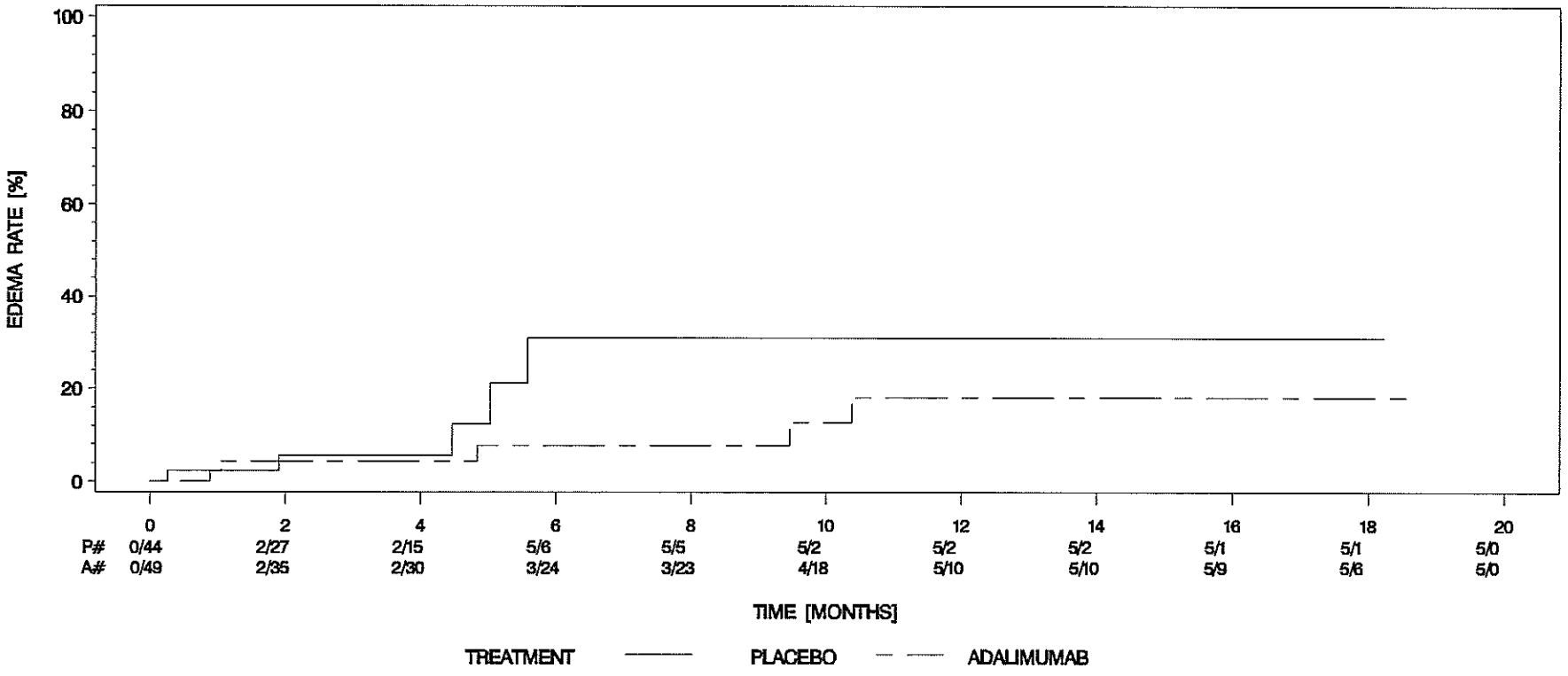
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.27.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

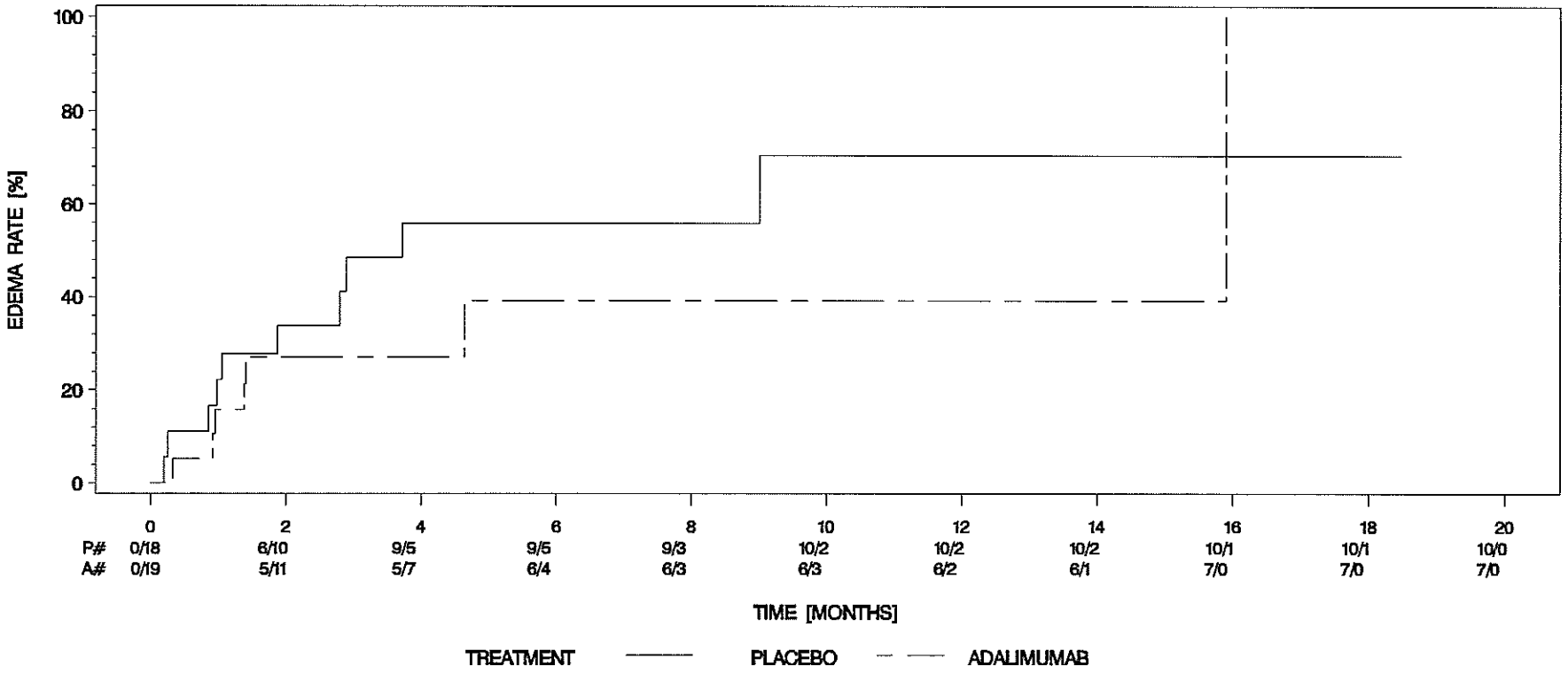
FIGURE 14.2__1000.3.1.2.27.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

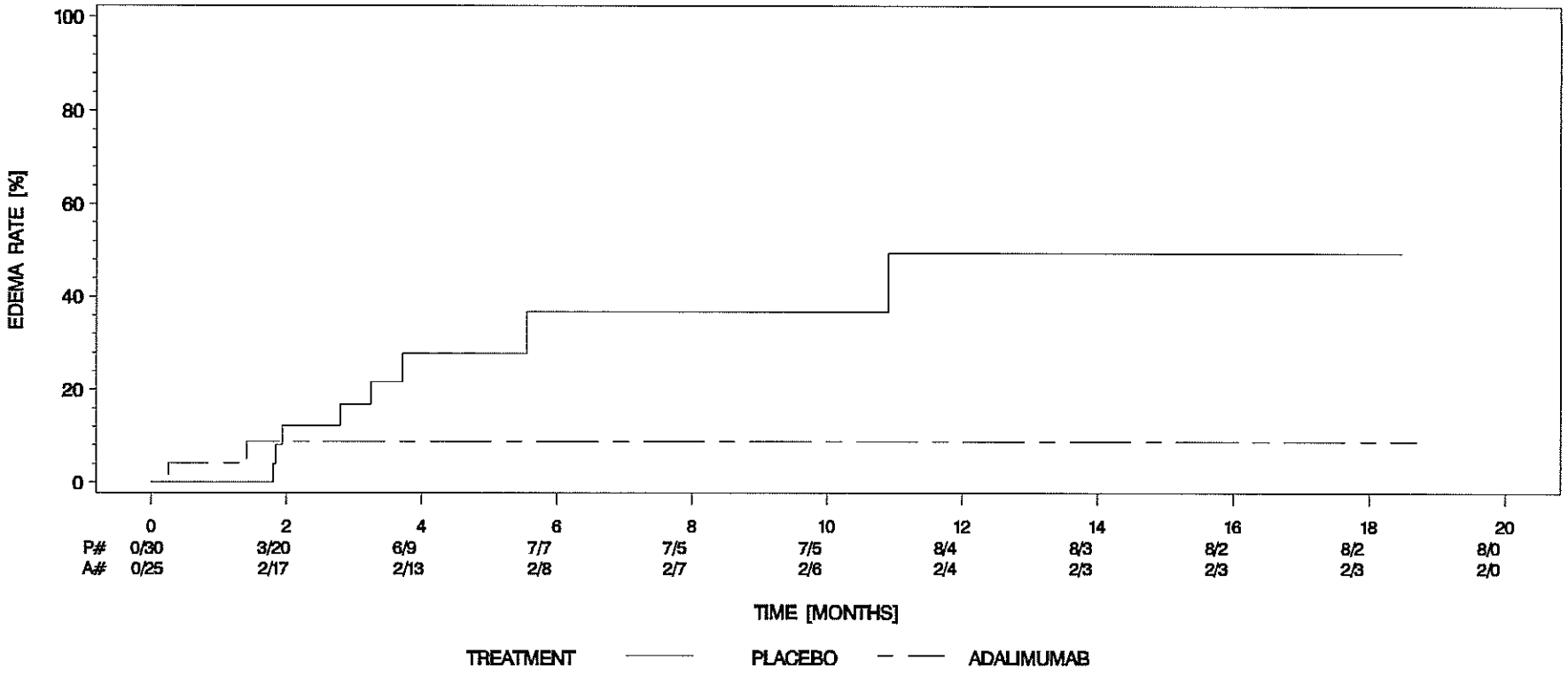
FIGURE 14.2__1000.3.1.2.28.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

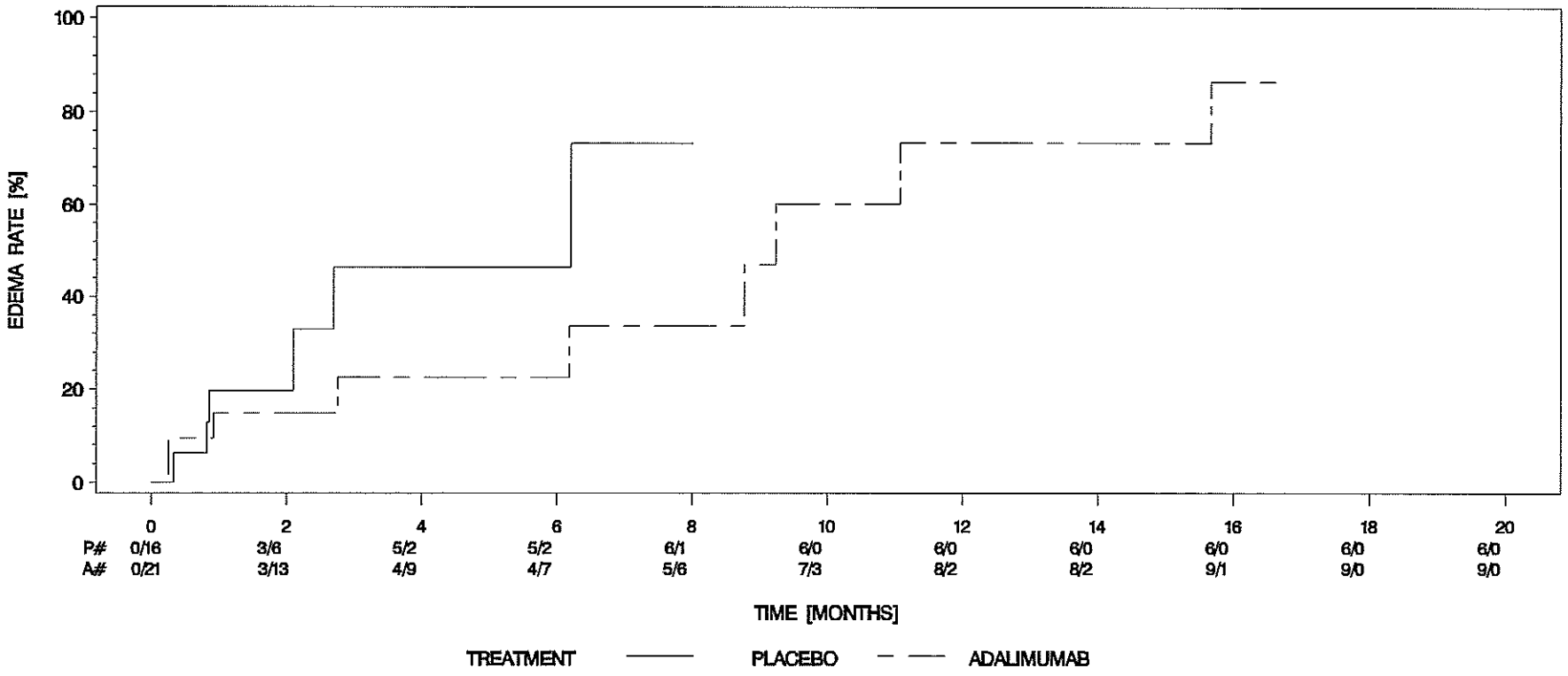
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.28.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)



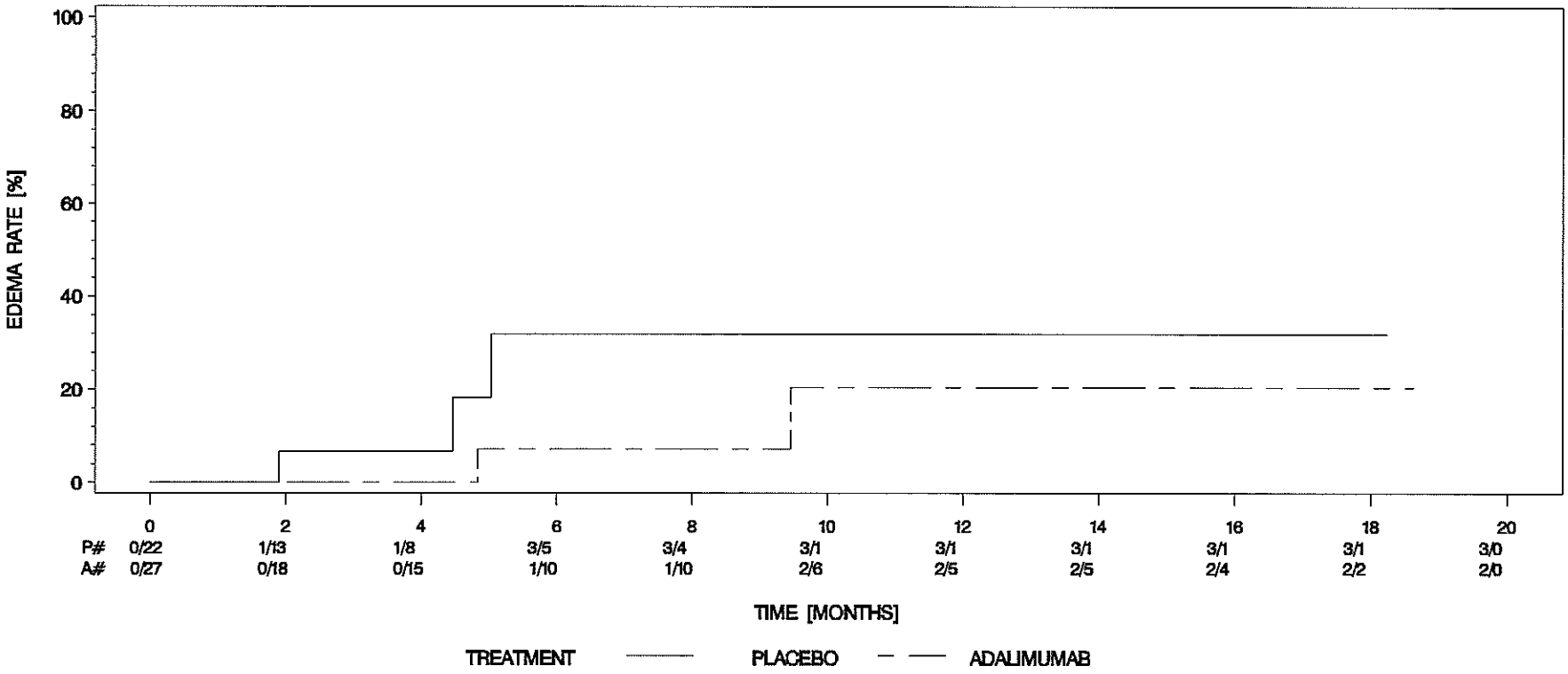
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.29.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)



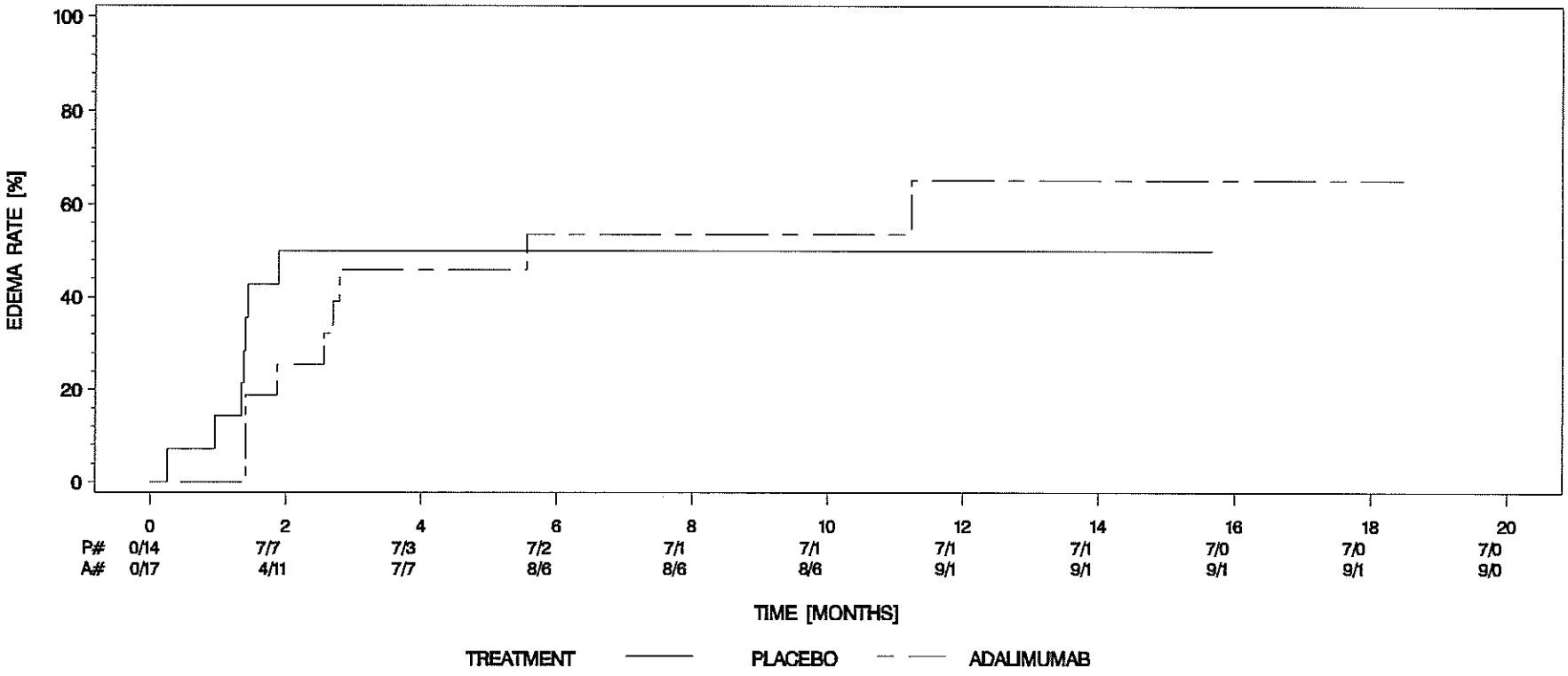
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.29.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)



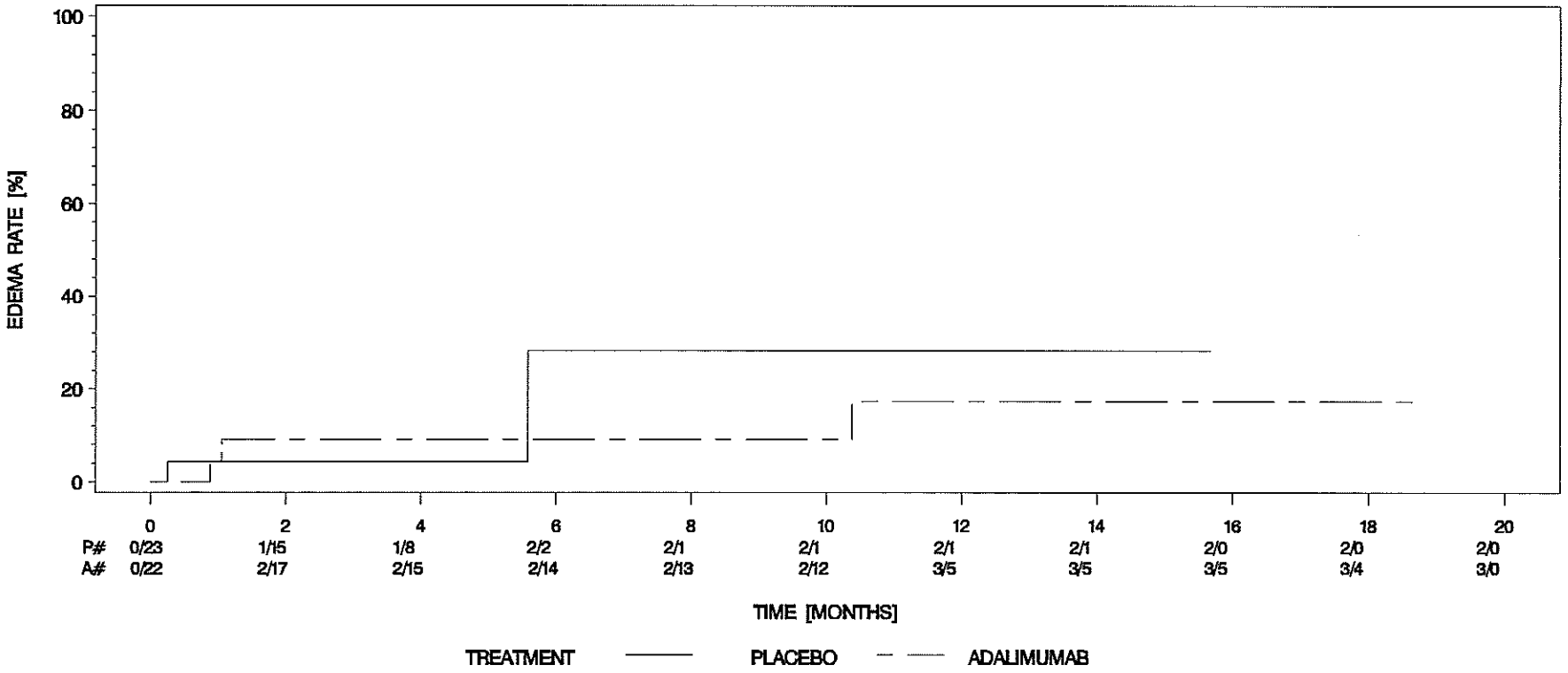
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.30.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)



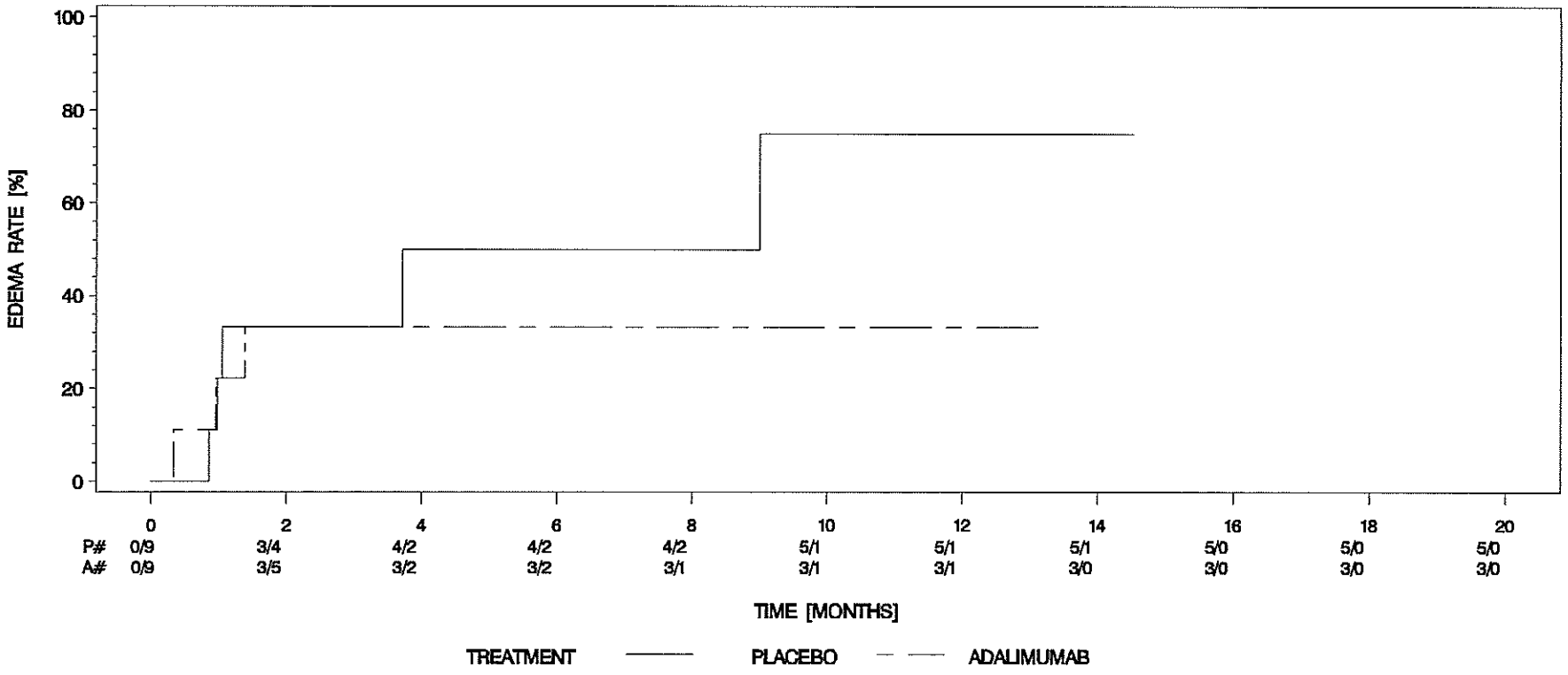
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.30.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)



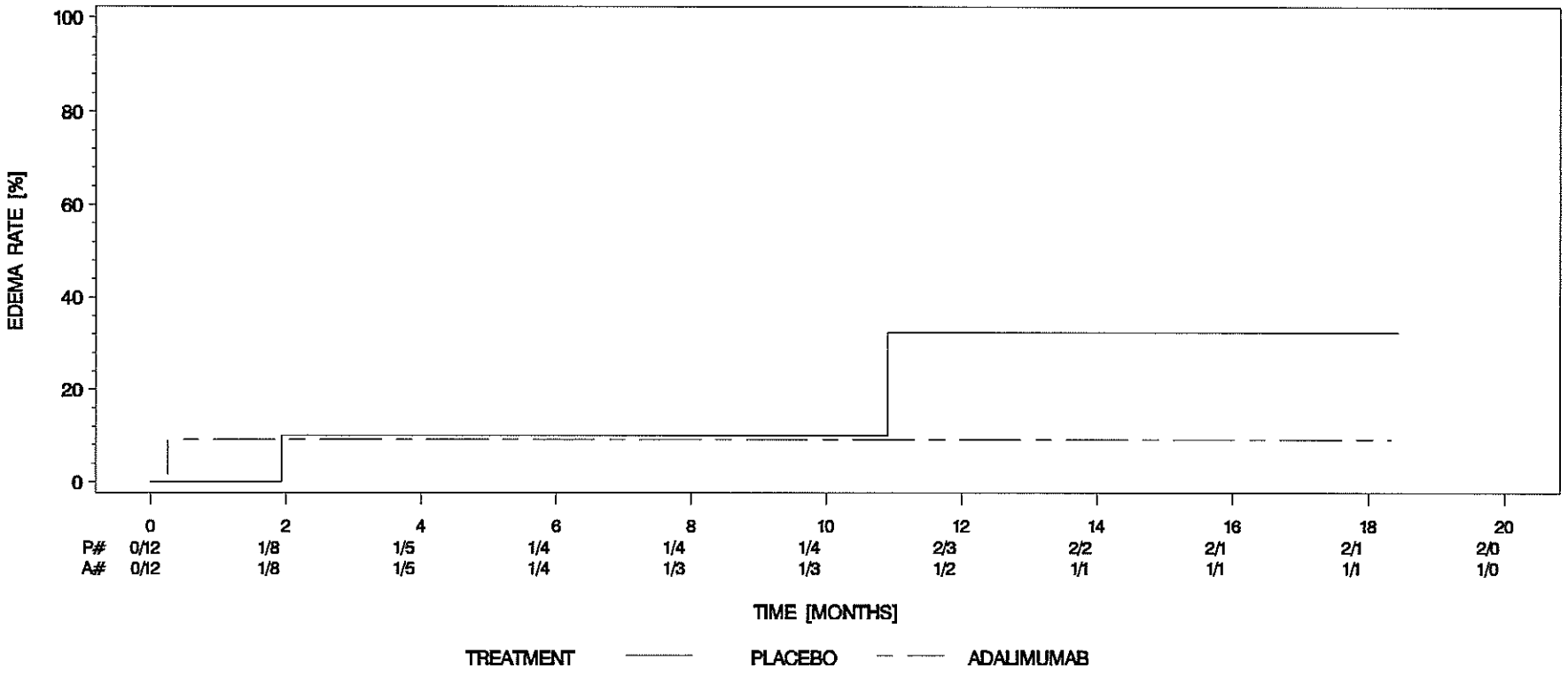
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.31.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)



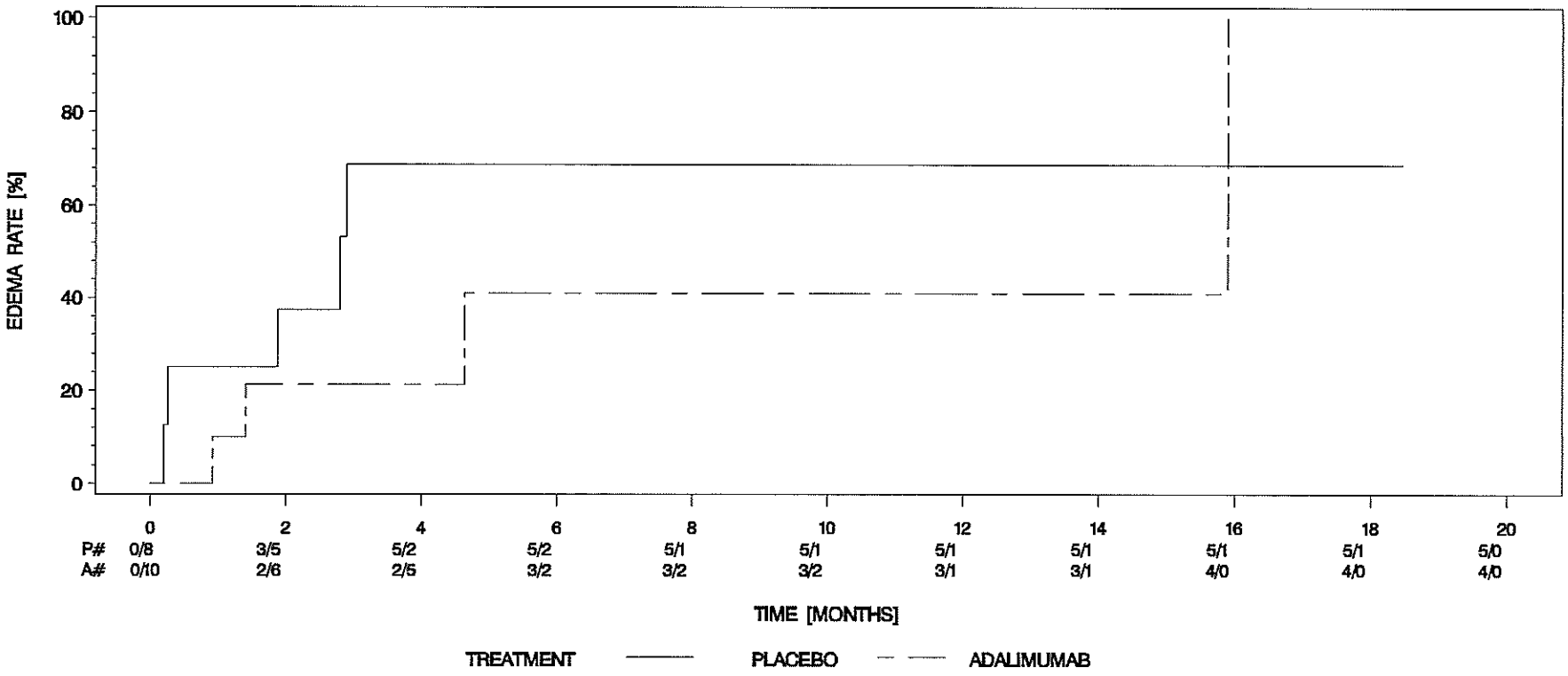
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.31.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

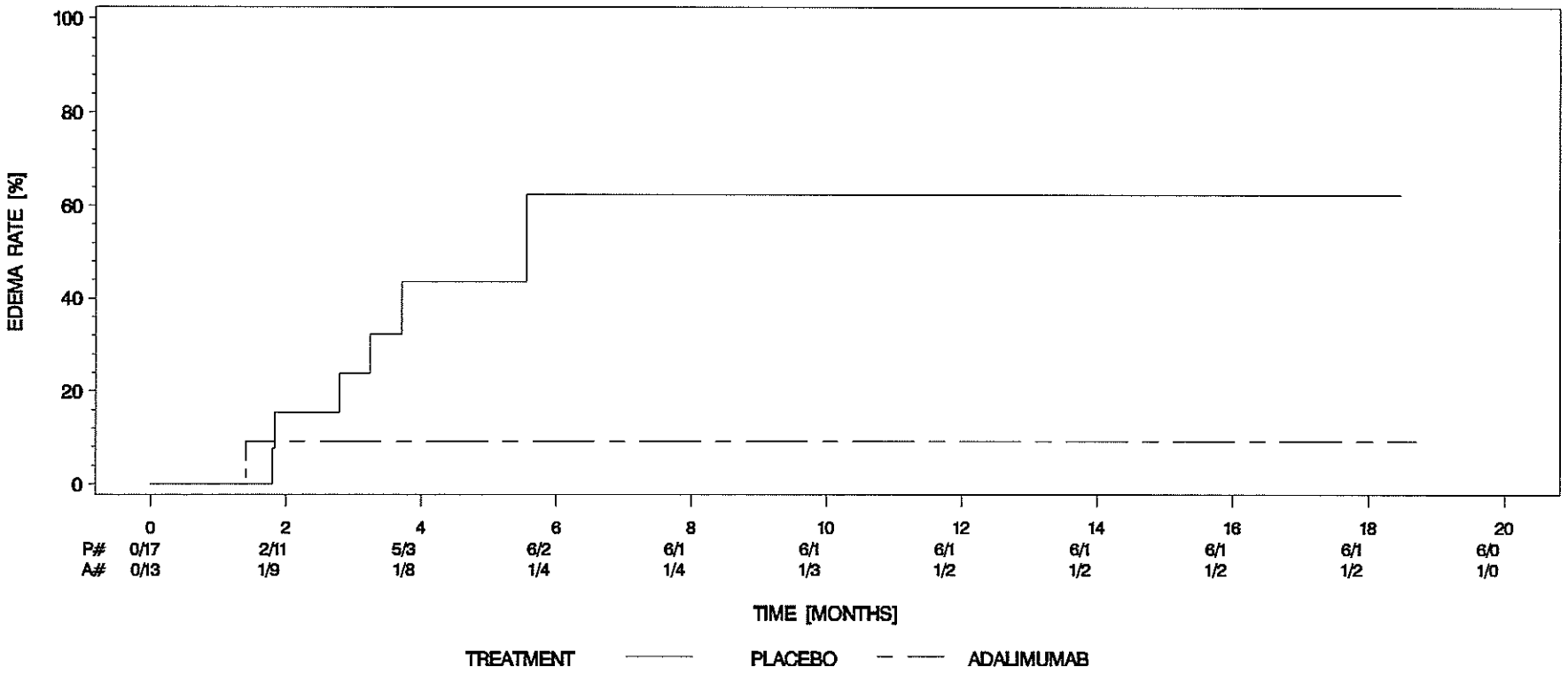
FIGURE 14.2__1000.3.1.2.32.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.32.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.33.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

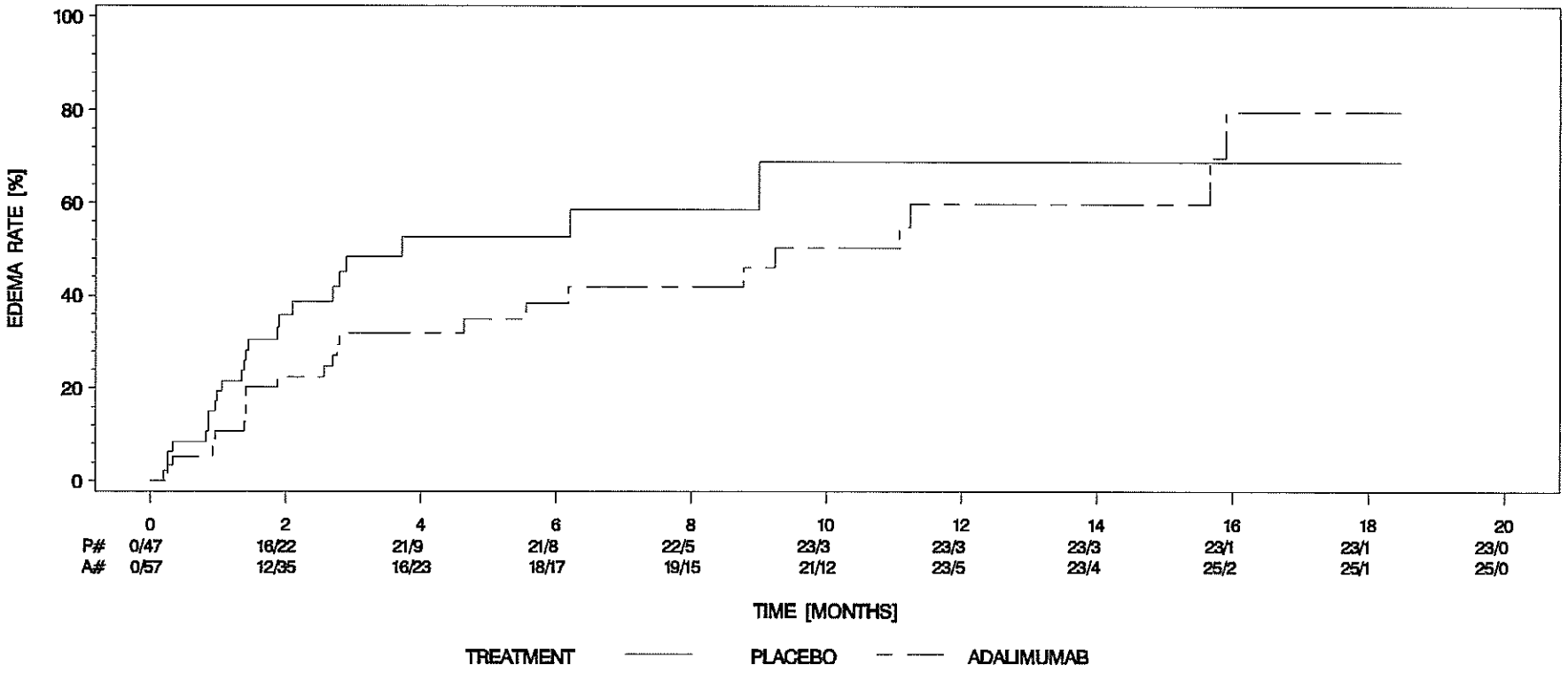
** ENDPOINT IS NOT DEFINED FOR THIS SUBGROUP. **

FIGURE 14.2__1000.3.1.2.33.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

** ENDPOINT IS NOT DEFINED FOR THIS SUBGROUP. **

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

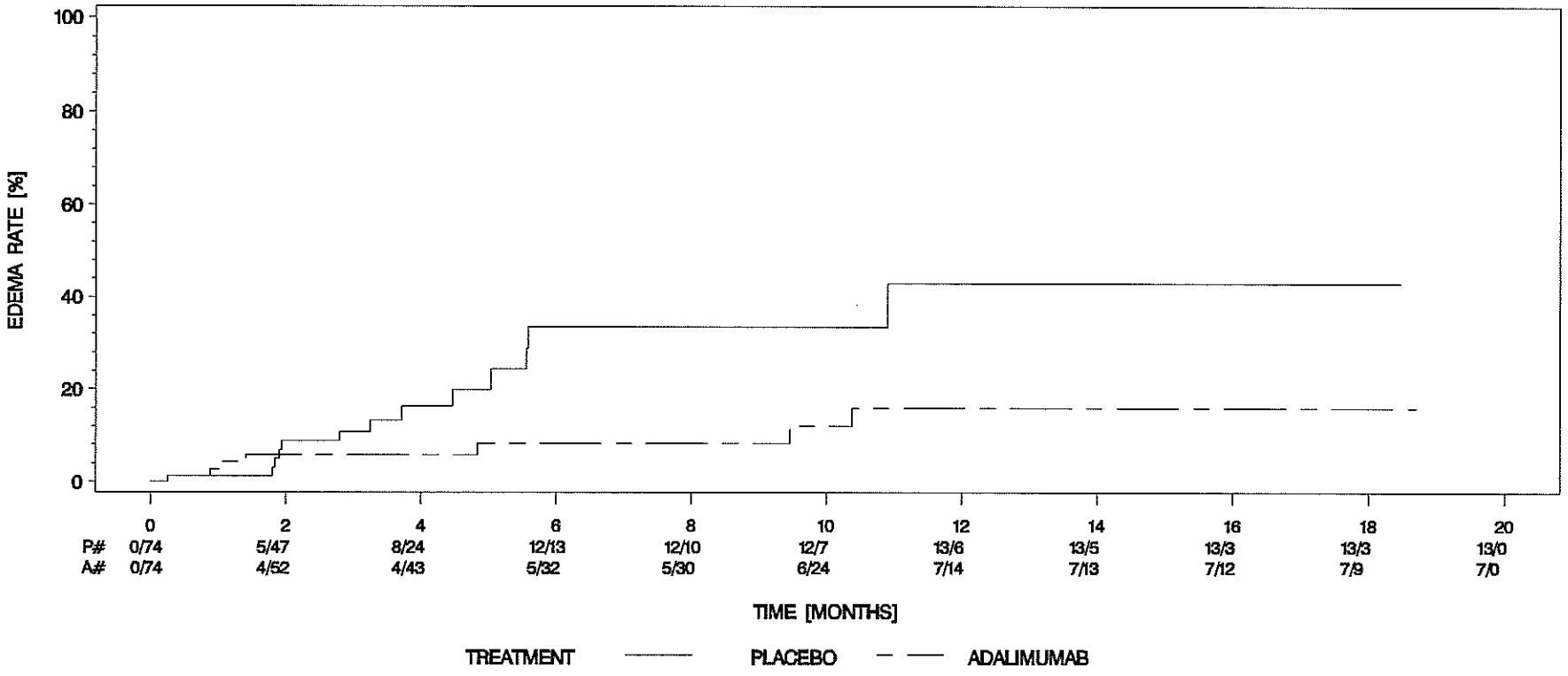
FIGURE 14.2__1000.3.1.2.34.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

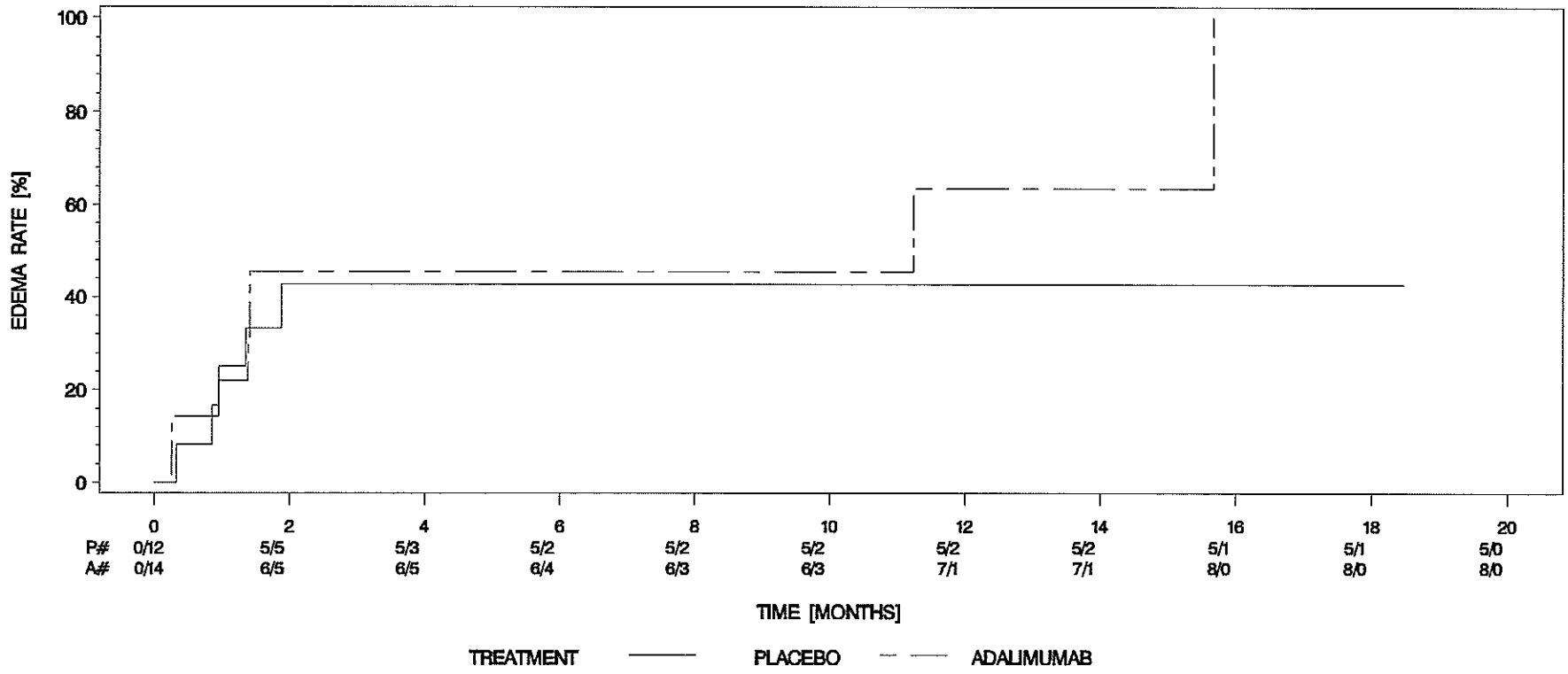
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.34.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)



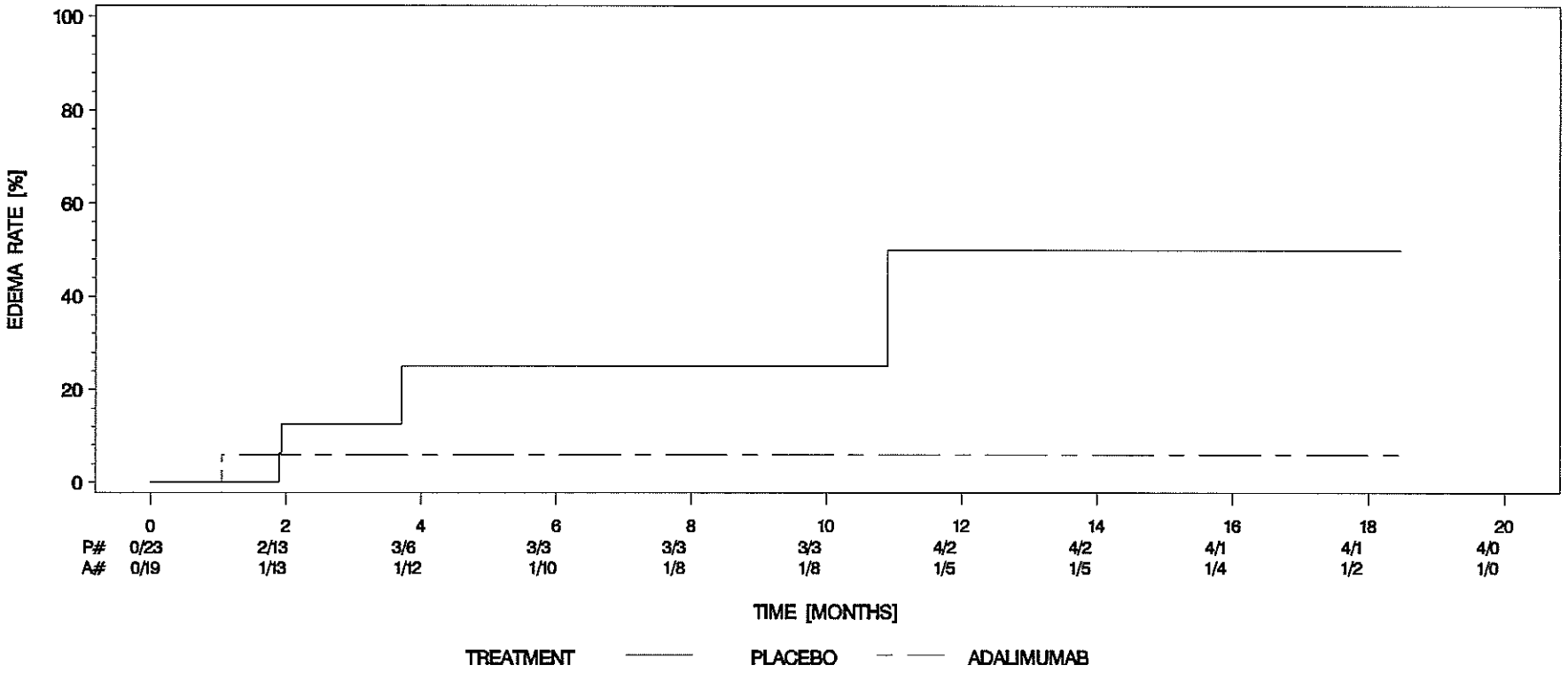
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.35.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)



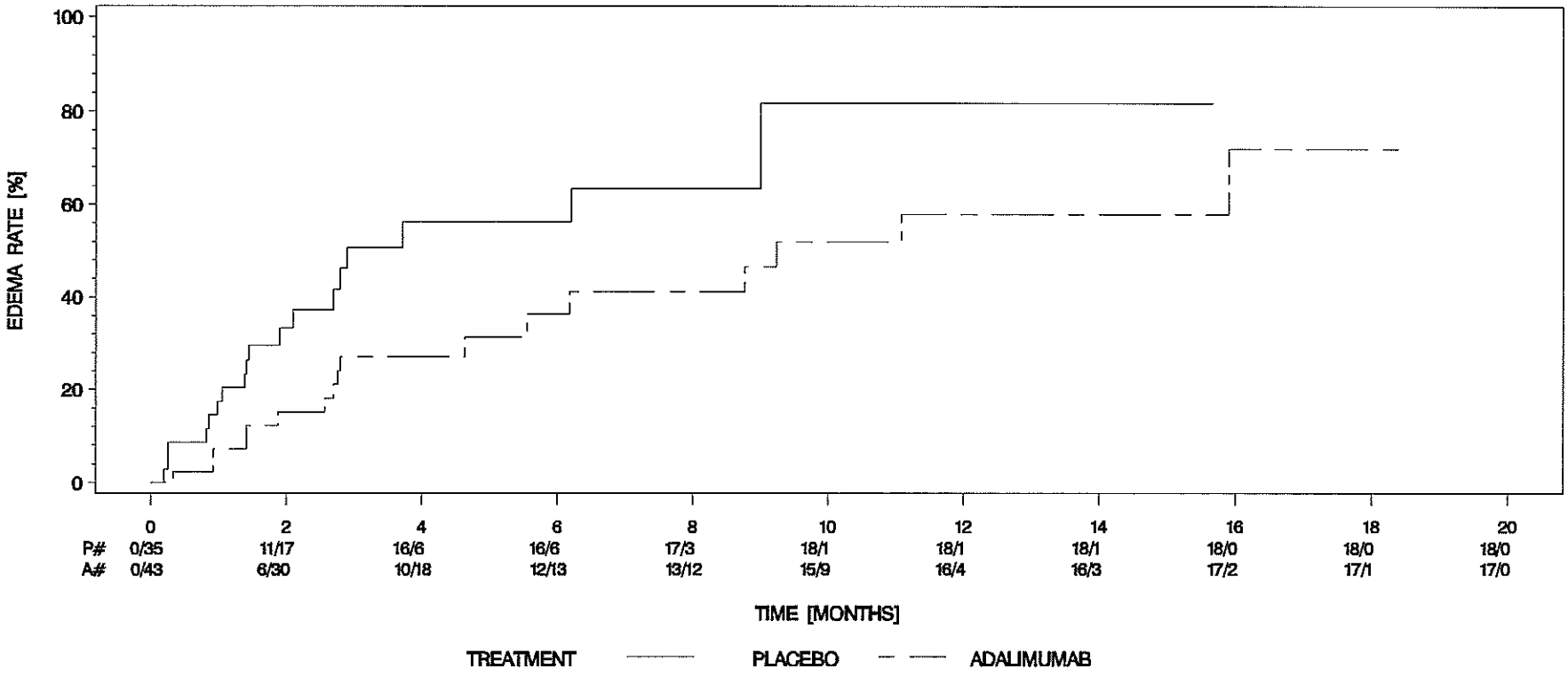
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.35.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)



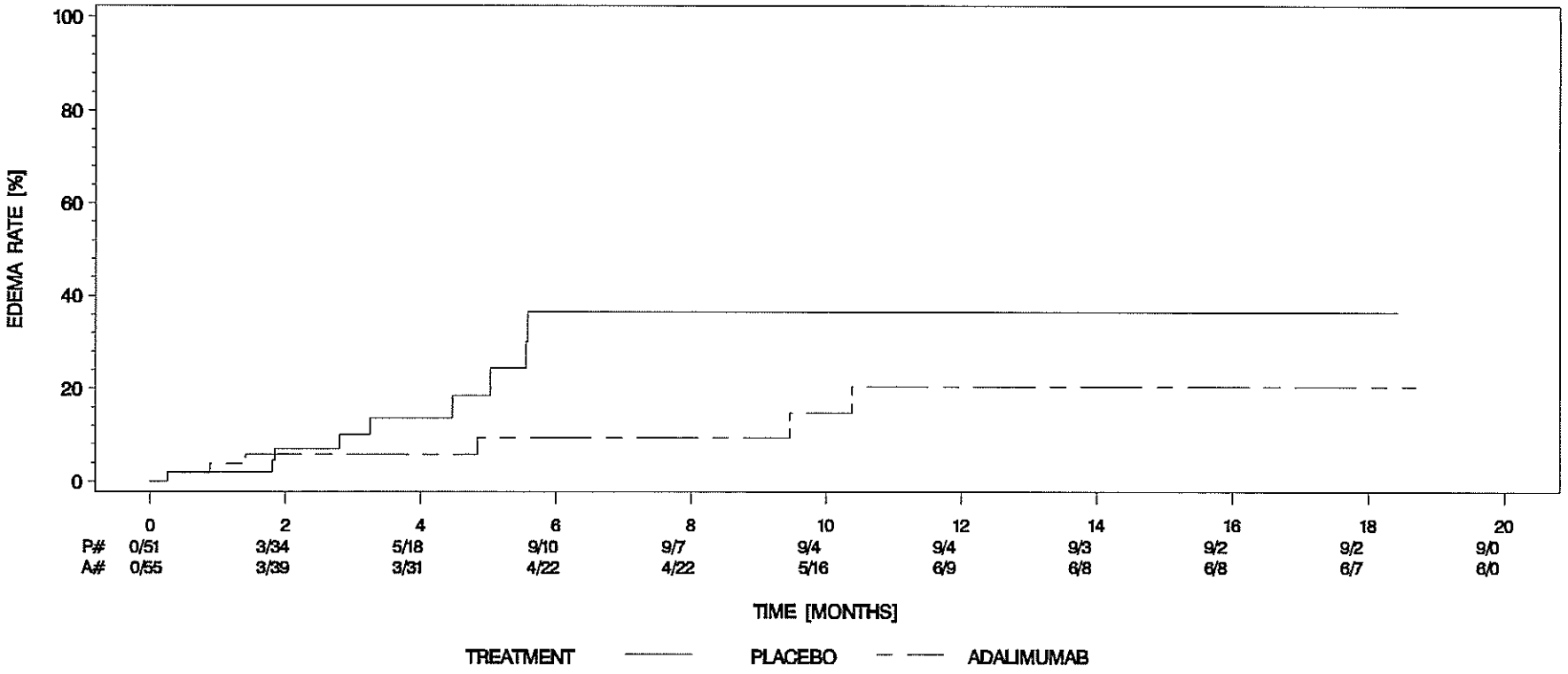
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.36.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

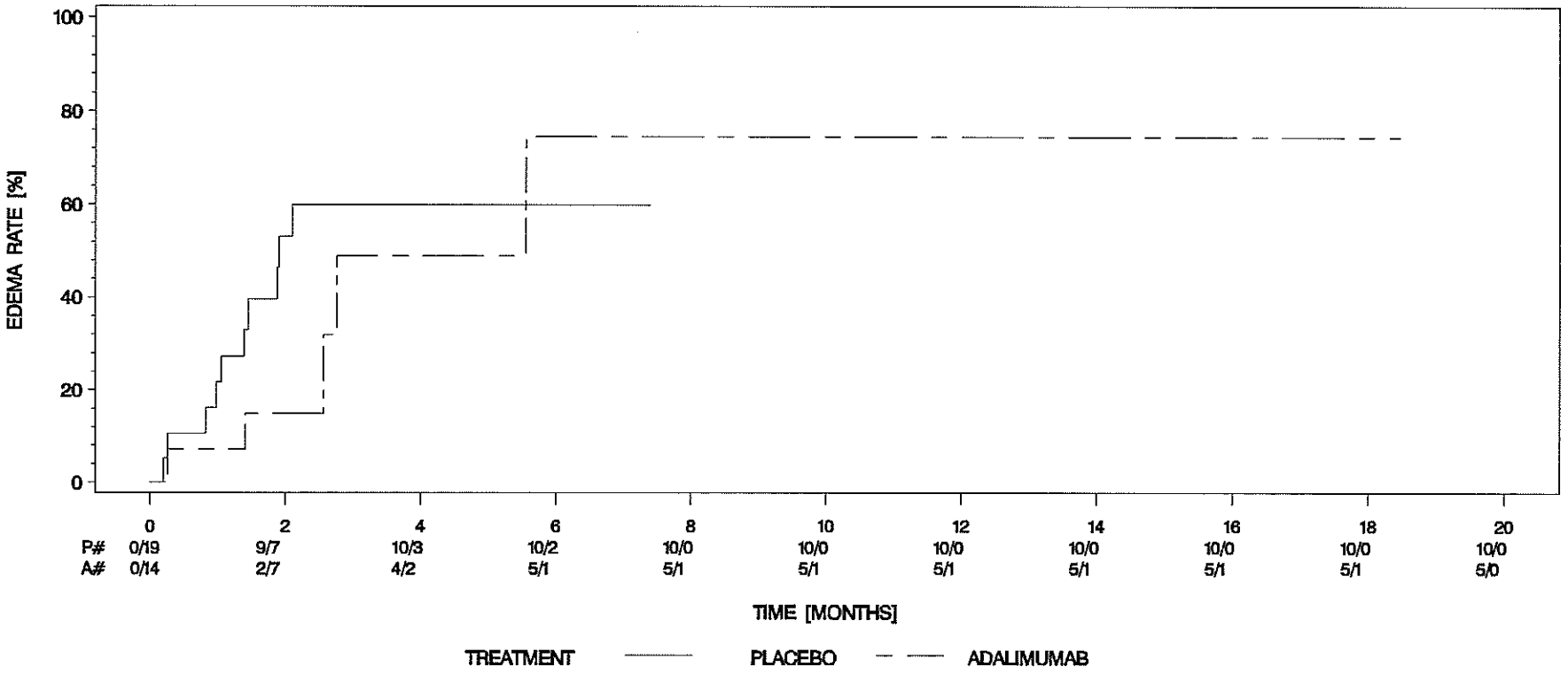
FIGURE 14.2__1000.3.1.2.36.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

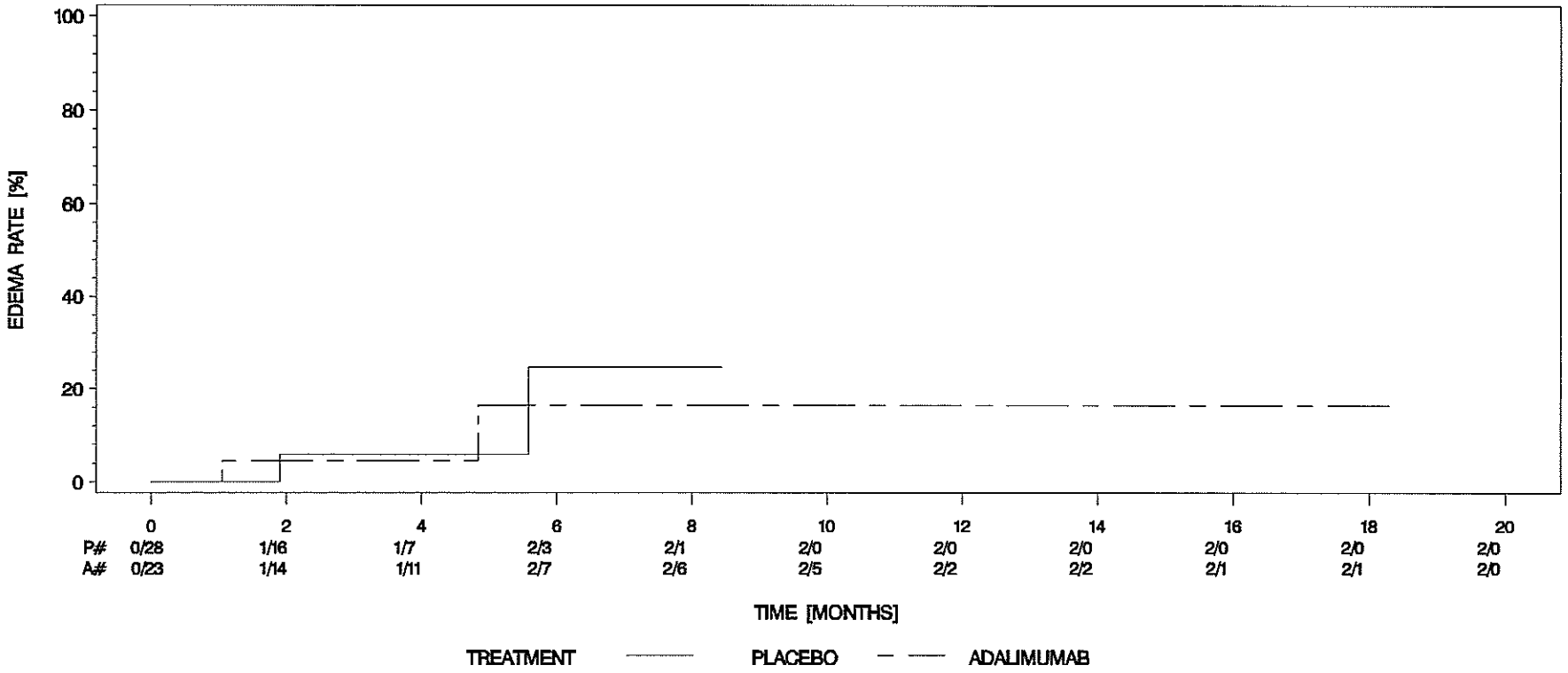
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.37.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)



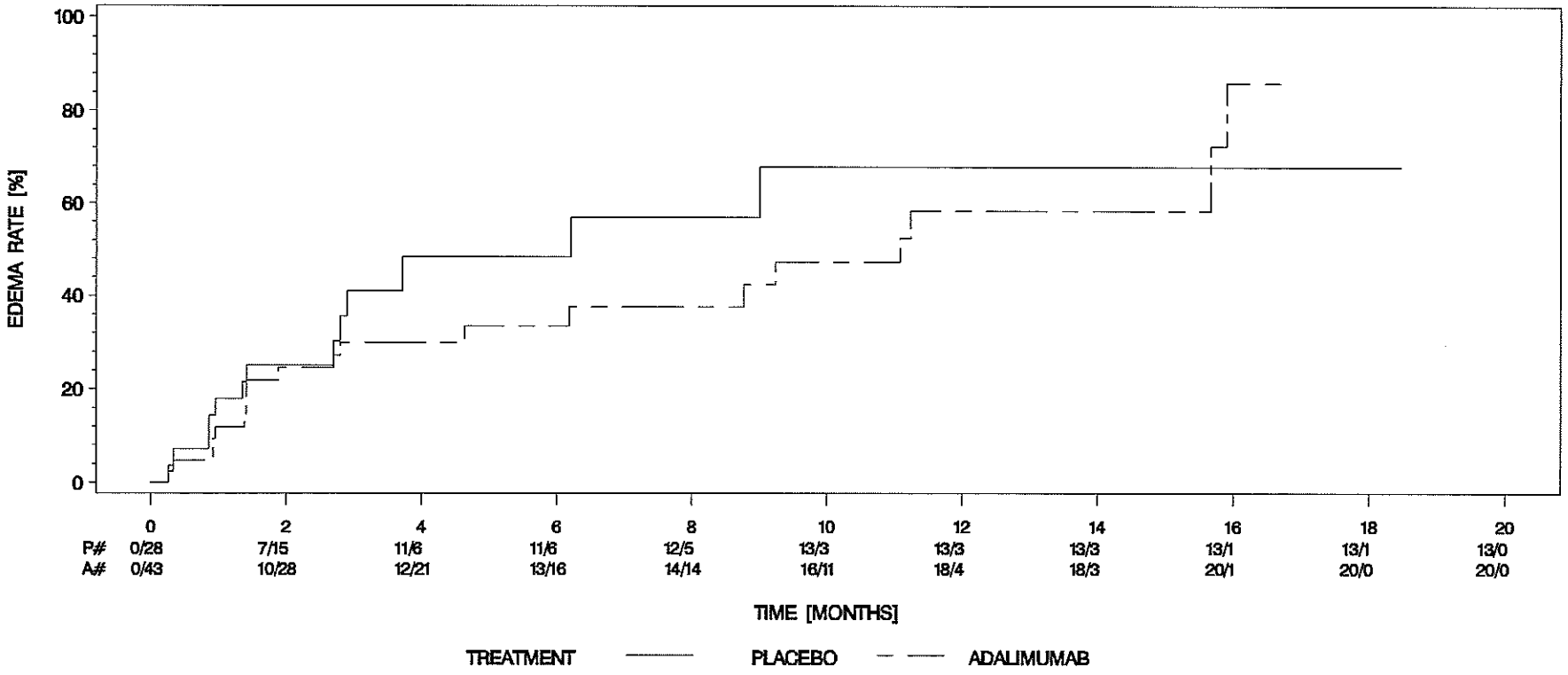
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.37.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)



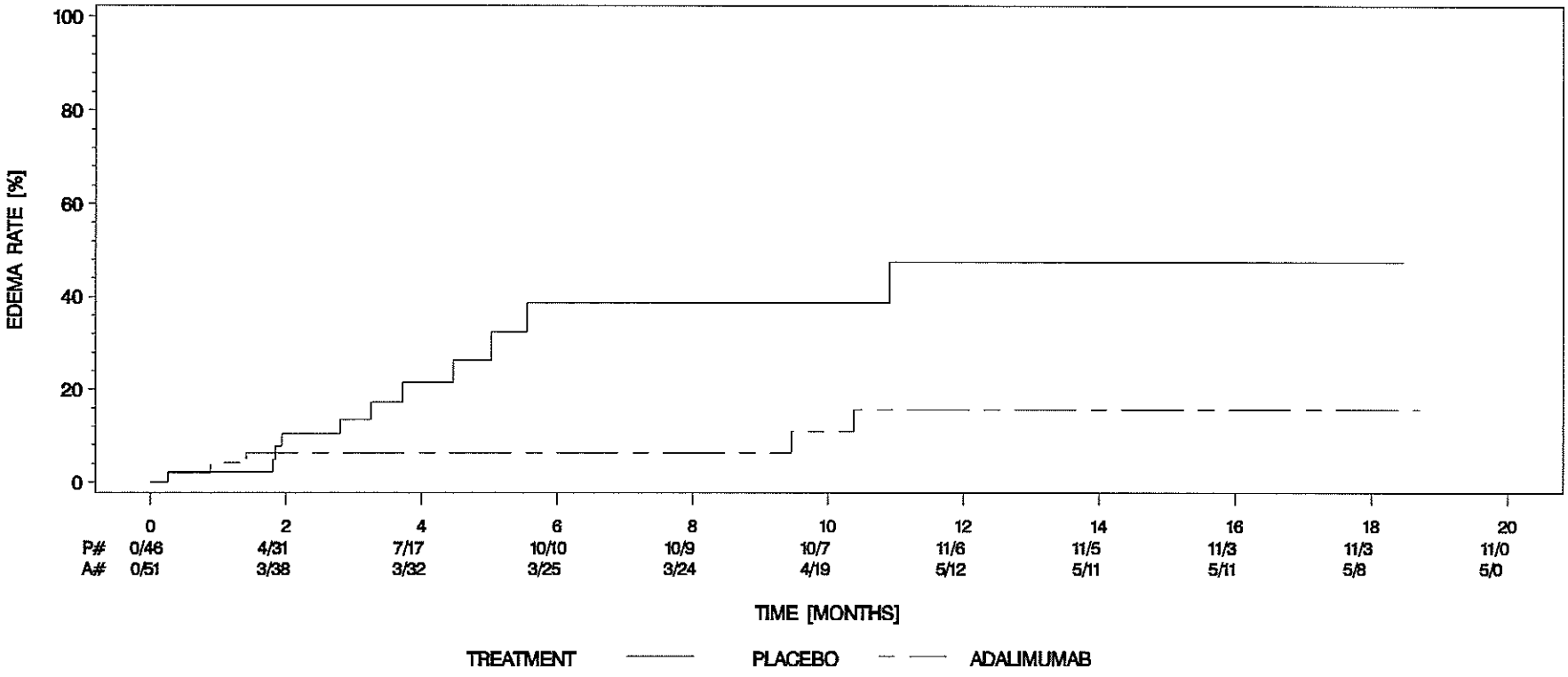
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.38.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

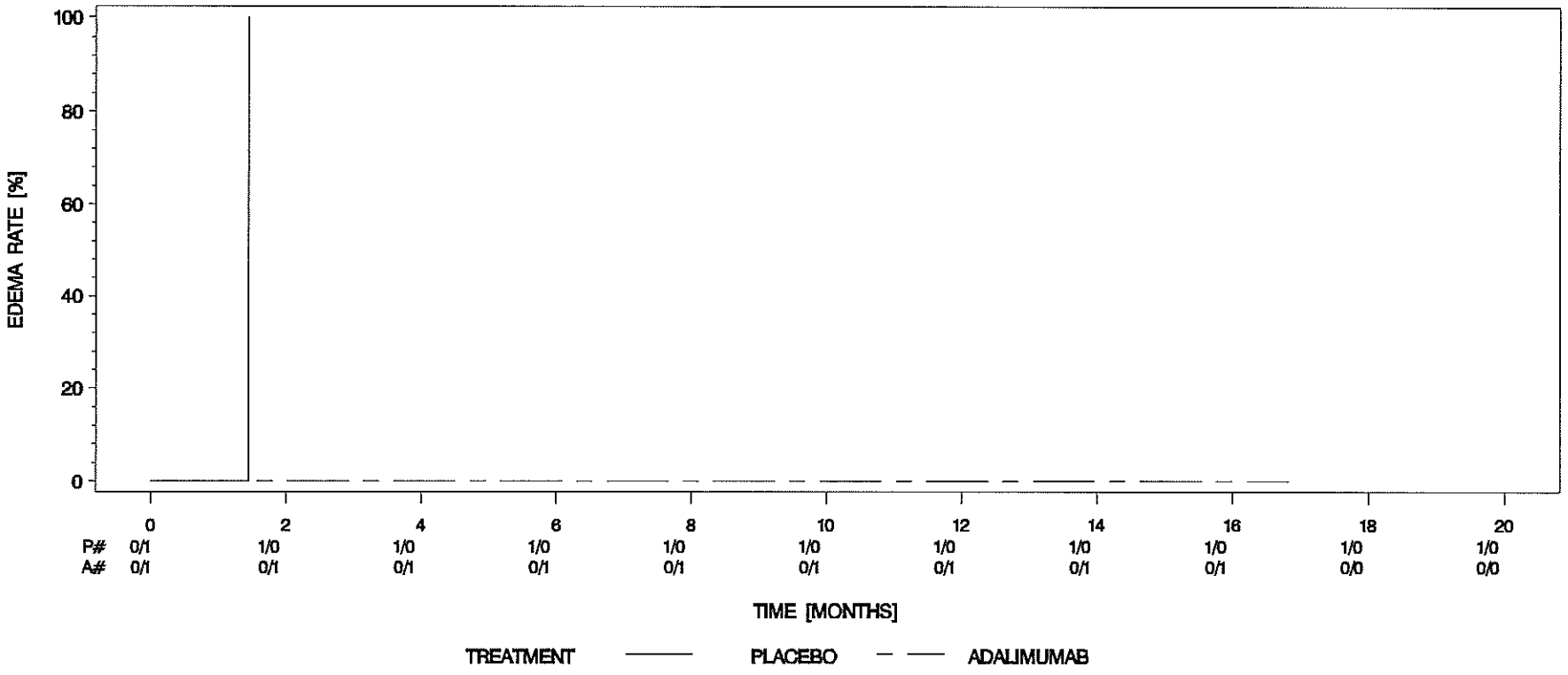
FIGURE 14.2__1000.3.1.2.38.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.39.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)



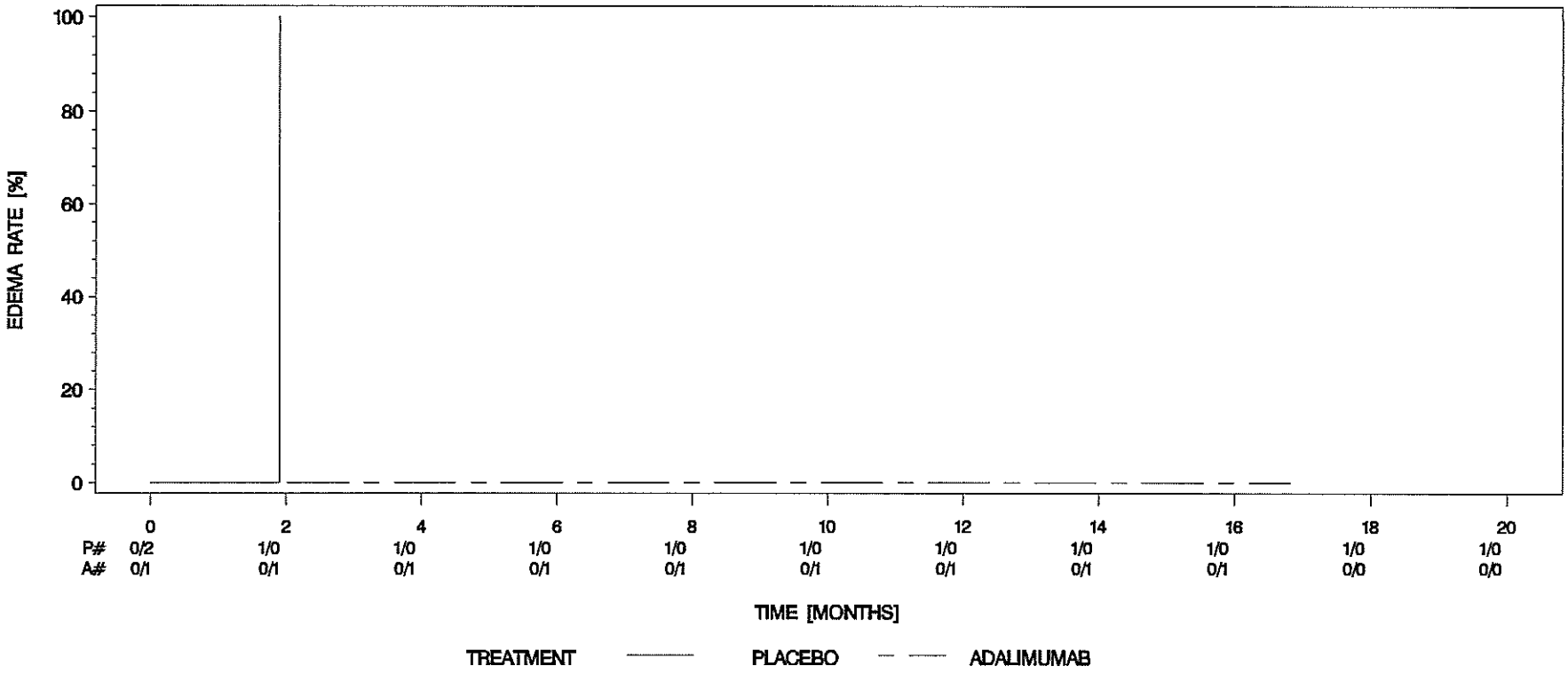
NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

FIGURE 14.2__1000.3.1.2.39.I.PH

KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6

ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)

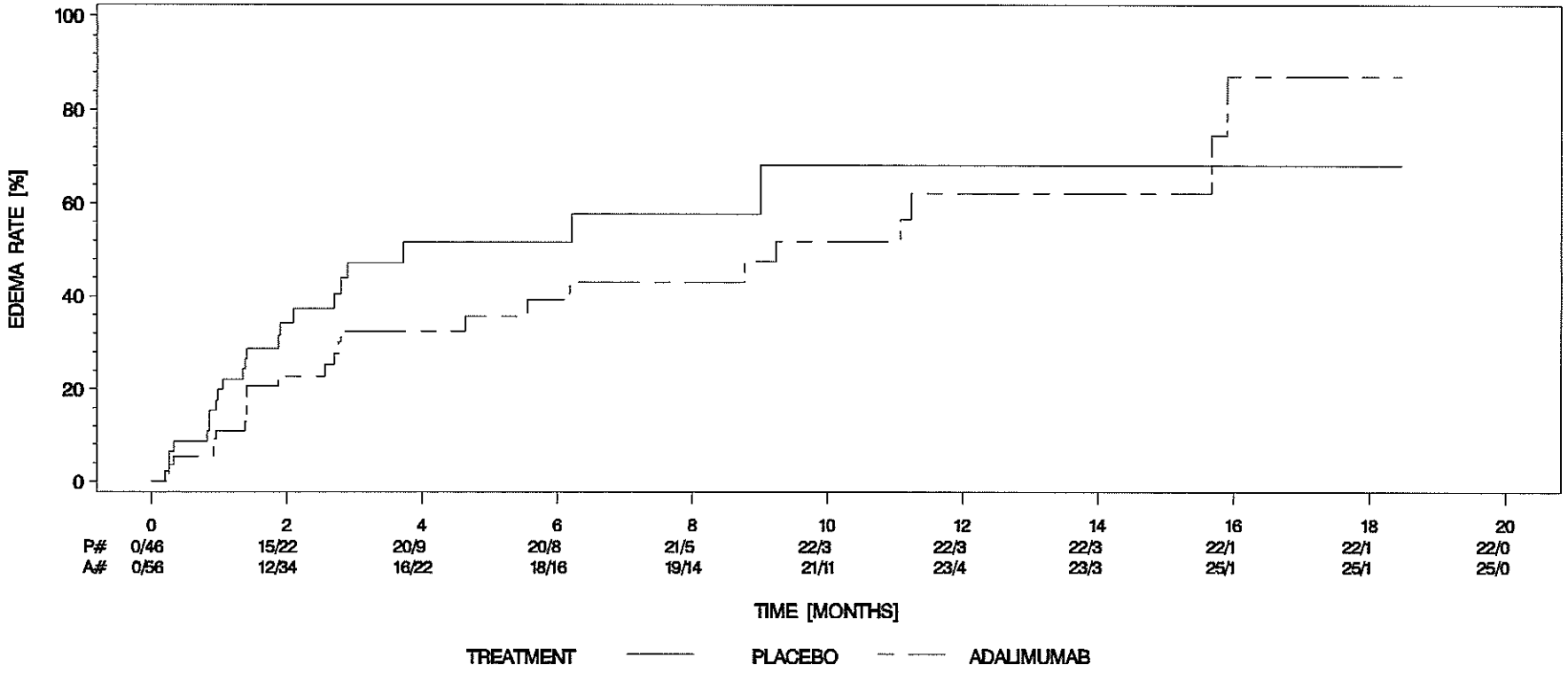
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)

Program Source Code: [redacted]

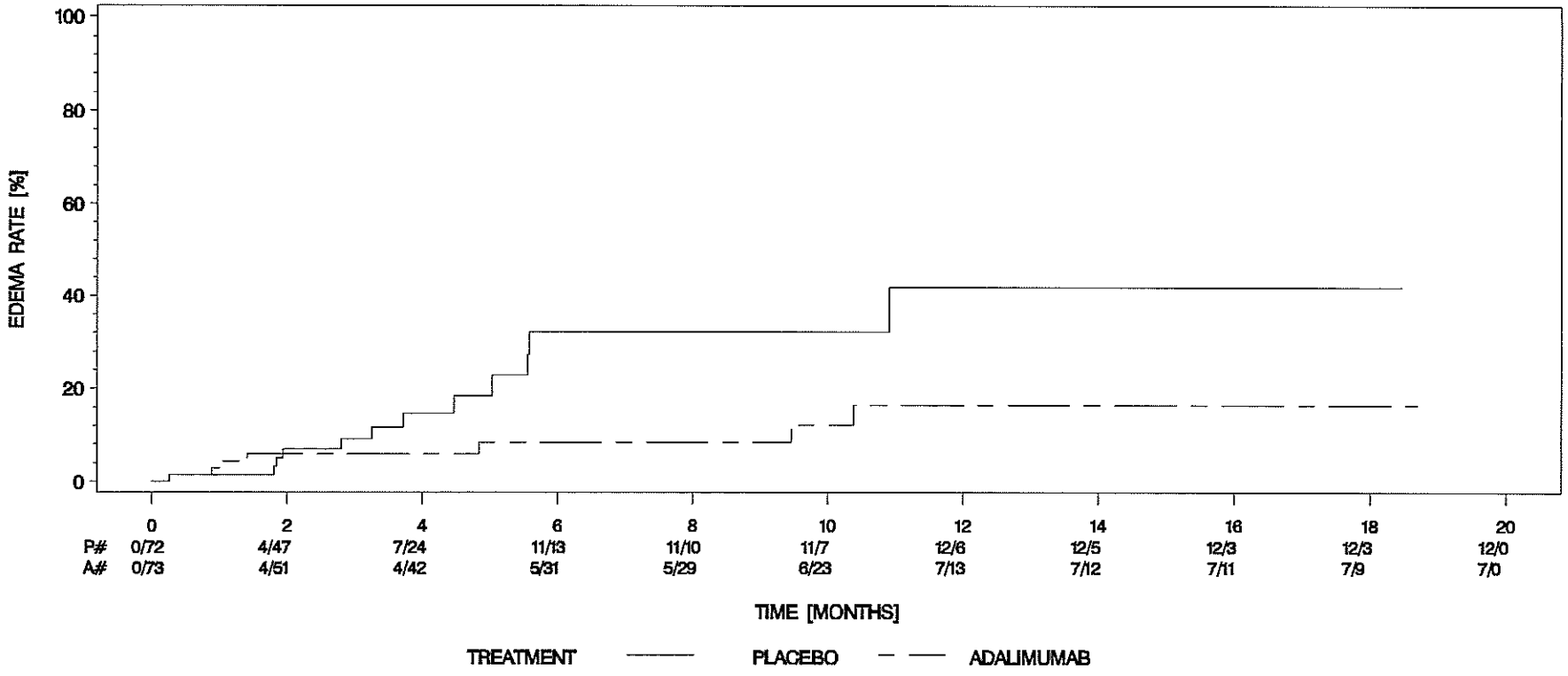
FIGURE 14.2__1000.3.1.2.40.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

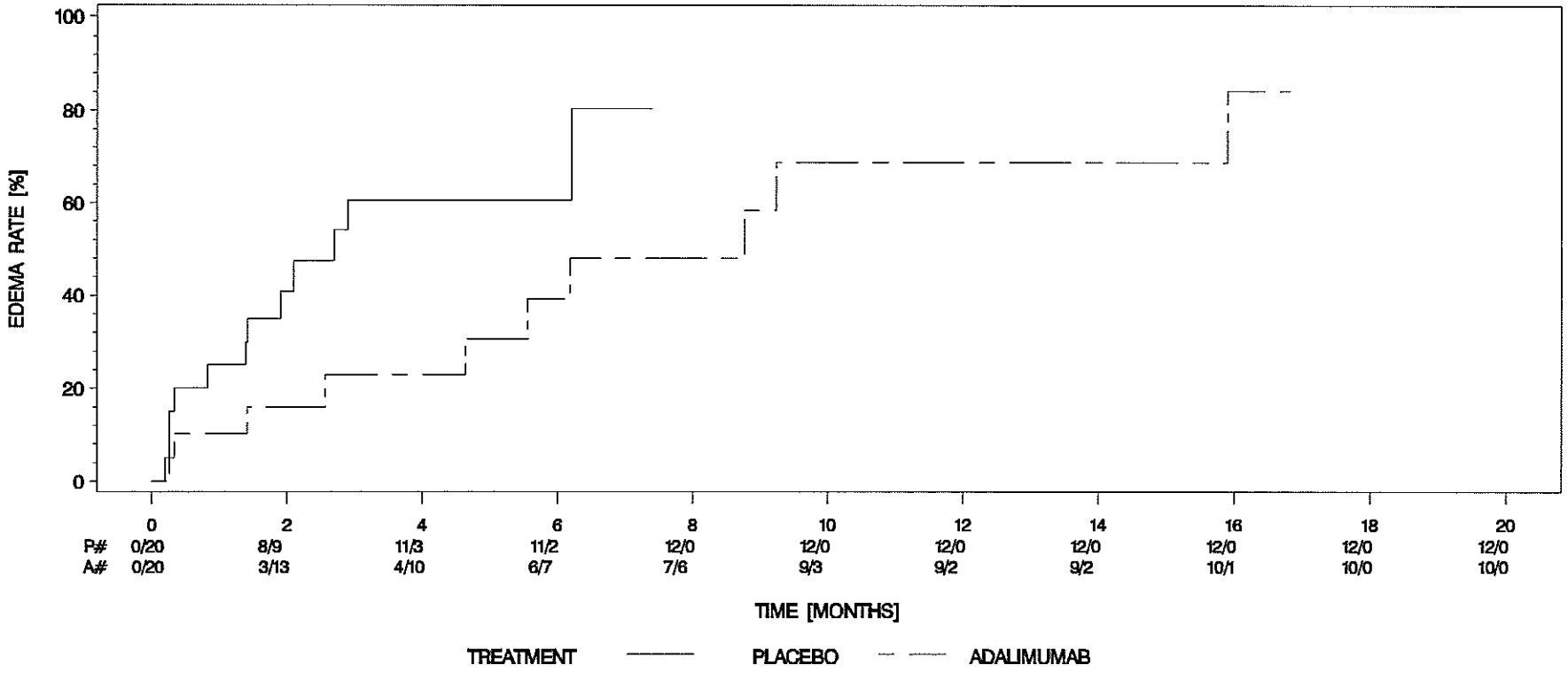
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ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.40.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

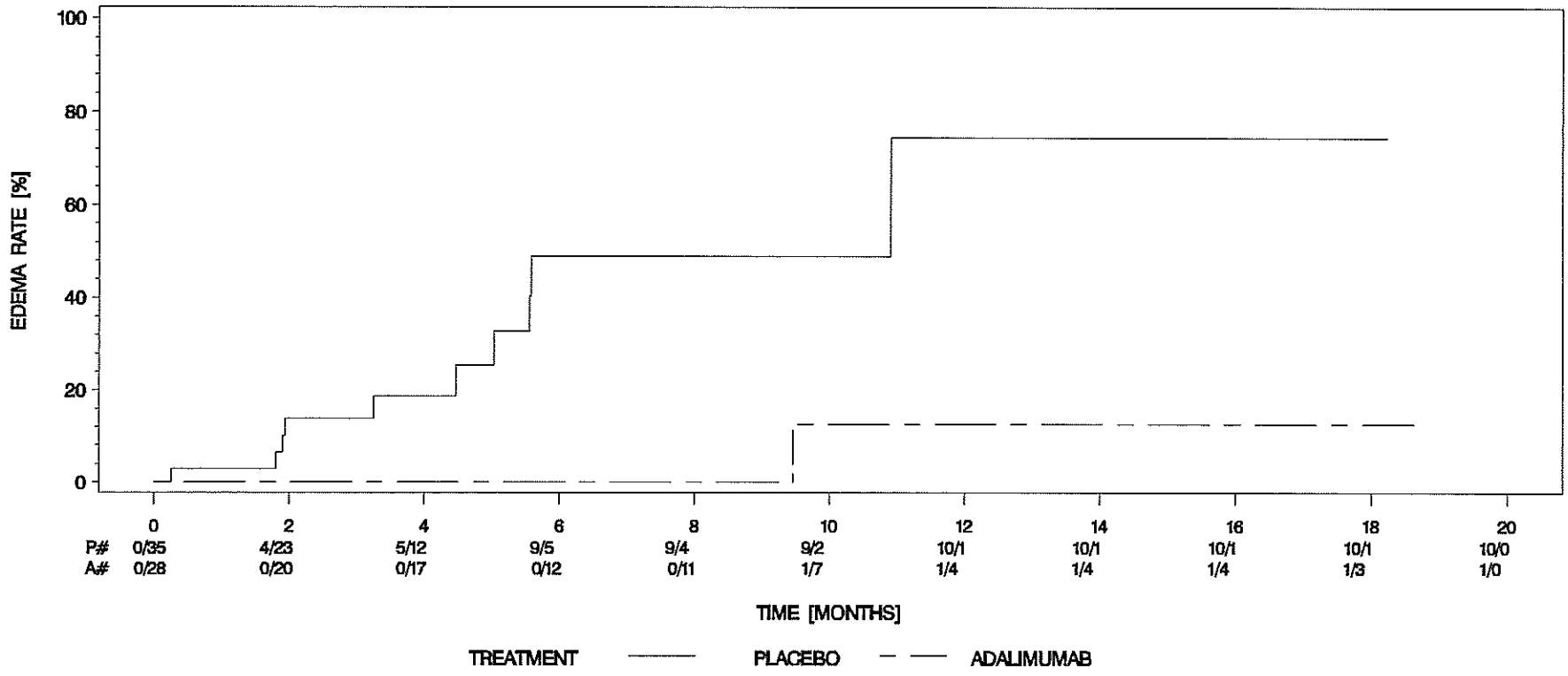
FIGURE 14.2__1000.3.1.2.41.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

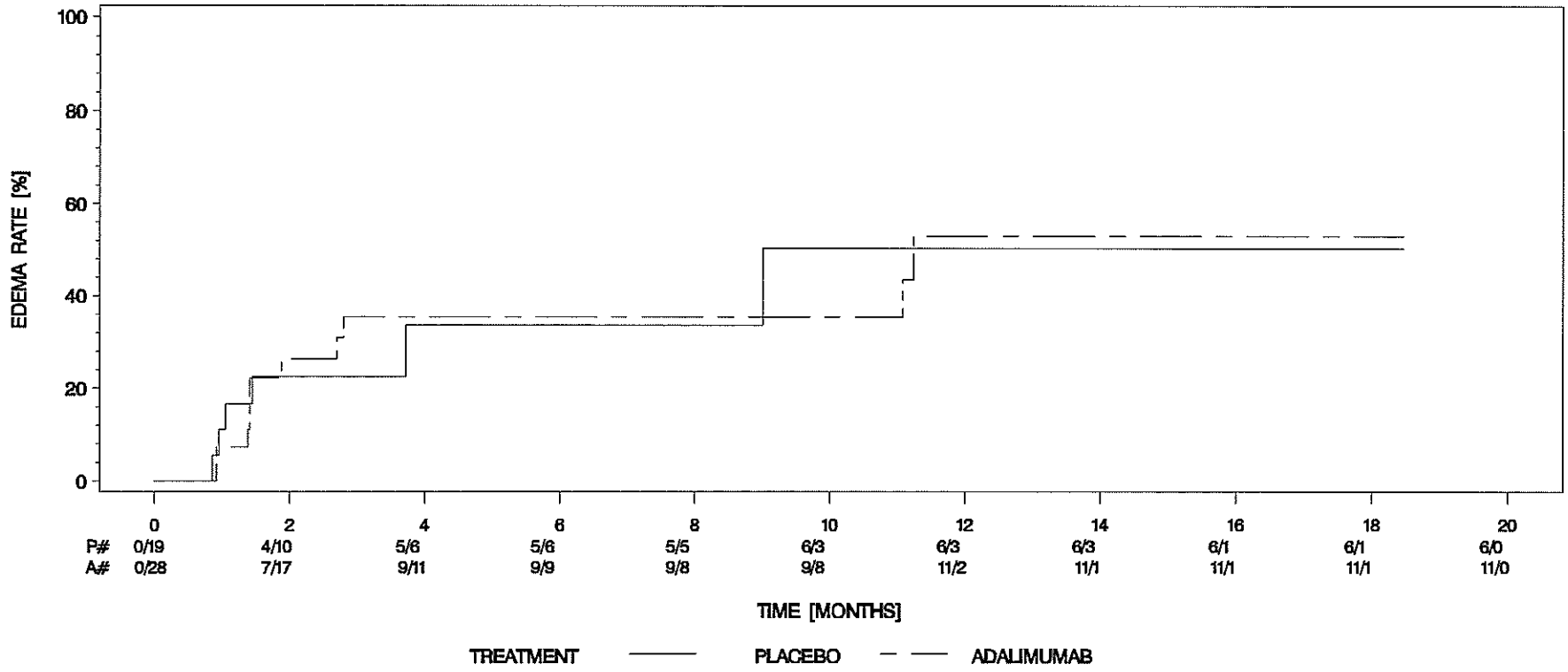
[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.41.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

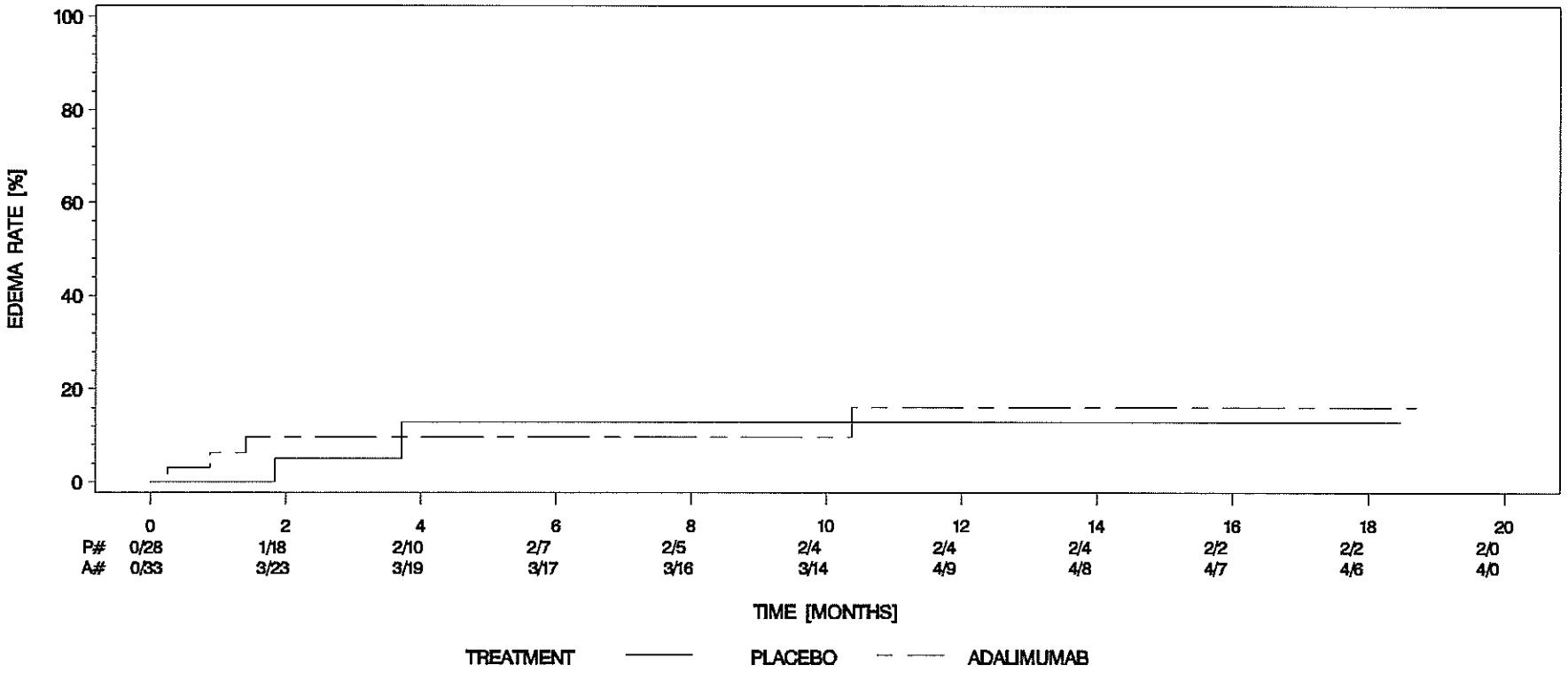
FIGURE 14.2__1000.3.1.2.42.I
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714- CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1000.3.1.2.42.I.PH
KAPLAN-MEIER CURVE TIME TO MACULAR EDEMA BASED ON CRT ON OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (ONLY IN SUBJ. WITHOUT EDEMA BASED ON CRT AT BSL AND WITHOUT MACULAR HOLE A/O RETINAL DETACHMENT)
(STUDY M10-877, INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)



NOTE: P# - PLACEBO (NUMBER OF EVENTS/NUMBER AT RISK), A# - ADALIMUMAB (NUMBER OF EVENTS/NUMBER AT RISK)
Program Source Code: [redacted]

2.7.3.6.2.2　M10-880 試験の併合解析集団での部分集団解析

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__2000.1.1.1.1.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

TREATMENT	N	FAILURE N	(%)	CENSORED N	(%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	45	32	(71.1)	13	(28.9)	1.8	3.7	9.0			
ADALIMUMAB	56	24	(42.9)	32	(57.1)	3.9	13.8	*			
TOTAL	101	56	(55.4)	45	(44.6)	3.0	7.4	*	0.39	(0.23, 0.67)	<0.001

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.2.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	82	43	(52.4)	39	(47.6)	2.8	9.0	*			
ADALIMUMAB	75	33	(44.0)	42	(56.0)	3.7	*	*			
TOTAL	157	76	(48.4)	81	(51.6)	3.1	11.5	*	0.71	(0.45, 1.11)	0.131

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.3.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	27	17	(63.0)	10	(37.0)	2.5	7.6	*			
ADALIMUMAB	21	9	(42.9)	12	(57.1)	3.7	*	*			
TOTAL	48	26	(54.2)	22	(45.8)	3.0	8.5	*	0.56	(0.25, 1.26)	0.154

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.4.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	58	34	(58.6)	24	(41.4)	2.8	4.8	*			
ADALIMUMAB	64	22	(34.4)	42	(65.6)	7.7	*	*			
TOTAL	122	56	(45.9)	66	(54.1)	3.7	11.5	*	0.37	(0.22, 0.64)	<0.001

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

[redacted]
ADALIMUMAB (UVEITIS)
CLINICAL SUMMARY OF EFFICACY (JAPAN)
R&D/15/0714 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__2000.1.1.1.5.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	42	24	(57.1)	18	(42.9)	2.4	8.3	*			
ADALIMUMAB	46	26	(56.5)	20	(43.5)	3.0	7.1	*			
TOTAL	88	50	(56.8)	38	(43.2)	2.8	7.3	*	1.01	(0.58, 1.76)	0.982

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.6.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	93	52 (55.9)	41 (44.1)	2.8	8.3	*			
ADALIMUMAB	96	37 (38.5)	59 (61.5)	5.4	*	*			
TOTAL	189	89 (47.1)	100 (52.9)	3.8	11.0	*	0.55	(0.36, 0.84)	0.005

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.7.1.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	34	23	(67.6)	11	(32.4)	1.9	3.3	12.7			
ADALIMUMAB	35	20	(57.1)	15	(42.9)	2.7	9.2	*			
TOTAL	69	43	(62.3)	26	(37.7)	2.4	3.7	*	0.60	(0.33, 1.10)	0.092

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.7.2.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	8	2	(25.0)	6	(75.0)	11.4	*	*
ADALIMUMAB	6	2	(33.3)	4	(66.7)	2.8	*	*
TOTAL	14	4	(28.6)	10	(71.4)	11.4	*	*

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE
WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.7.3.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	19	16	(84.2)	3	(15.8)	1.4	2.8	3.4
ADALIMUMAB	19	13	(68.4)	6	(31.6)	2.4	3.7	*
TOTAL	38	29	(76.3)	9	(23.7)	1.9	2.8	9.2

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.7.4.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	1	(100)	0		1.7	1.7	1.7
ADALIMUMAB	0							
TOTAL	1	1	(100)	0		1.7	1.7	1.7

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.7.5.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	0					
ADALIMUMAB	0					
TOTAL	0					

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE
WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.7.6.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	5	3	(60.0)	2	(40.0)	4.2	4.2	12.7
ADALIMUMAB	9	4	(44.4)	5	(55.6)	5.6	12.0	*
TOTAL	14	7	(50.0)	7	(50.0)	4.2	10.4	12.7

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.7.7.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	1	(100)	0		2.0	2.0	2.0
ADALIMUMAB	1	1	(100)	0		2.4	2.4	2.4
TOTAL	2	2	(100)	0		2.0	2.2	2.4

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.8.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	24	18	(75.0)	6	(25.0)	2.0	4.7	13.6			
ADALIMUMAB	22	8	(36.4)	14	(63.6)	3.7	13.8	*			
TOTAL	46	26	(56.5)	20	(43.5)	2.8	7.7	*	0.36	(0.16, 0.84)	0.014

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.9.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	103	57 (55.3)	46 (44.7)	2.8	7.6	*			
ADALIMUMAB	109	49 (45.0)	60 (55.0)	3.9	12.0	*			
TOTAL	212	106 (50.0)	106 (50.0)	3.0	10.1	*	0.63	(0.43, 0.93)	0.017

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.10.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	30	20	(66.7)	10	(33.3)	3.4	4.8	9.0			
ADALIMUMAB	17	9	(52.9)	8	(47.1)	3.0	7.3	11.5			
TOTAL	47	29	(61.7)	18	(38.3)	3.4	7.2	11.0	0.63	(0.29, 1.40)	0.250

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.11.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	35	13	(37.1)	22	(62.9)	4.2	*	*			
ADALIMUMAB	41	14	(34.1)	27	(65.9)	3.9	*	*			
TOTAL	76	27	(35.5)	49	(64.5)	4.2	*	*	0.95	(0.45, 2.03)	0.902

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.12.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	61	41	(67.2)	20	(32.8)	1.9	3.7	13.8			
ADALIMUMAB	71	33	(46.5)	38	(53.5)	3.8	*	*			
TOTAL	132	74	(56.1)	58	(43.9)	2.7	7.1	*	0.46	(0.29, 0.73)	<0.001

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.13.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	54	35 (64.8)	19 (35.2)	2.8	5.1	12.0			
ADALIMUMAB	45	19 (42.2)	26 (57.8)	5.4	*	*			
TOTAL	99	54 (54.5)	45 (45.5)	3.7	9.0	*	0.44	(0.25, 0.77)	0.003

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.14.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	15	4	(26.7)	11	(73.3)	8.3	*	*
ADALIMUMAB	15	2	(13.3)	13	(86.7)	*	*	*
TOTAL	30	6	(20.0)	24	(80.0)	9.0	*	*

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.15.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	2	2	(100)	0		3.7	4.9	6.1
ADALIMUMAB	5	2	(40.0)	3	(60.0)	8.8	*	*
TOTAL	7	4	(57.1)	3	(42.9)	3.8	10.0	*

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.16.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	29	19 (65.5)	10 (34.5)	2.0	3.5	13.8			
ADALIMUMAB	34	20 (58.8)	14 (41.2)	2.7	7.7	*			
TOTAL	63	39 (61.9)	24 (38.1)	2.4	4.2	*	0.69	(0.37, 1.30)	0.250

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.17.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	20	11	(55.0)	9	(45.0)	2.0	3.4	*			
ADALIMUMAB	22	14	(63.6)	8	(36.4)	2.6	5.6	10.2			
TOTAL	42	25	(59.5)	17	(40.5)	2.2	4.7	*	1.09	(0.49, 2.41)	0.826

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.18.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	7	4	(57.1)	3	(42.9)	1.4	4.0	*
ADALIMUMAB	10	0		10	(100)	*	*	*
TOTAL	17	4	(23.5)	13	(76.5)	6.2	*	*

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE
WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.19.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=0-1)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	51	23	(45.1)	28	(54.9)	3.7	11.4	*			
ADALIMUMAB	57	26	(45.6)	31	(54.4)	3.9	*	*			
TOTAL	108	49	(45.4)	59	(54.6)	3.7	11.5	*	0.89	(0.51, 1.56)	0.674

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.20.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	45	27	(60.0)	18	(40.0)	3.3	7.6	13.8			
ADALIMUMAB	46	14	(30.4)	32	(69.6)	7.7	*	*			
TOTAL	91	41	(45.1)	50	(54.9)	4.2	12.0	*	0.40	(0.21, 0.77)	0.004

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.21.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

TREATMENT	N	FAILURE N	(%)	CENSORED N	(%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	31	25	(80.6)	6	(19.4)	1.2	2.4	3.9			
ADALIMUMAB	28	17	(60.7)	11	(39.3)	2.8	7.2	*			
TOTAL	59	42	(71.2)	17	(28.8)	1.9	3.7	*	0.41	(0.22, 0.77)	0.004

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.22.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	89	61	(68.5)	28	(31.5)	2.0	3.9	13.6			
ADALIMUMAB	84	36	(42.9)	48	(57.1)	3.7	13.8	*			
TOTAL	173	97	(56.1)	76	(43.9)	2.7	7.2	*	0.46	(0.31, 0.70)	<0.001

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.23.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	38	14 (36.8)	24 (63.2)	6.1	*	*			
ADALIMUMAB	47	21 (44.7)	26 (55.3)	4.7	*	*			
TOTAL	85	35 (41.2)	50 (58.8)	5.1	*	*	1.05	(0.54, 2.07)	0.880

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.24.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	95	52 (54.7)	43 (45.3)	3.0	8.3	*			
ADALIMUMAB	103	42 (40.8)	61 (59.2)	4.4	*	*			
TOTAL	198	94 (47.5)	104 (52.5)	3.6	10.4	*	0.64	(0.42, 0.96)	0.028

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.25.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

TREATMENT	N	FAILURE N	(%)	CENSORED N	(%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	29	21	(72.4)	8	(27.6)	1.6	2.8	7.6			
ADALIMUMAB	22	13	(59.1)	9	(40.9)	3.0	10.1	*			
TOTAL	51	34	(66.7)	17	(33.3)	2.3	4.2	*	0.48	(0.24, 0.96)	0.034

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.26.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	3	2	(66.7)	1	(33.3)	2.0	2.6	*
ADALIMUMAB	6	2	(33.3)	4	(66.7)	8.3	*	*
TOTAL	9	4	(44.4)	5	(55.6)	7.4	*	*

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.27.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	17	13 (76.5)	4 (23.5)	1.6	2.3	11.0			
ADALIMUMAB	26	18 (69.2)	8 (30.8)	2.8	4.6	13.8			
TOTAL	43	31 (72.1)	12 (27.9)	2.2	3.8	12.0	0.64	(0.31, 1.31)	0.217

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.28.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	106	59 (55.7)	47 (44.3)	2.8	6.2	*			
ADALIMUMAB	102	38 (37.3)	64 (62.7)	5.6	*	*			
TOTAL	208	97 (46.6)	111 (53.4)	3.6	10.8	*	0.52	(0.35, 0.78)	0.001

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.29.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	54	24 (44.4)	30 (55.6)	3.5	12.7	*			
ADALIMUMAB	56	17 (30.4)	39 (69.6)	8.5	*	*			
TOTAL	110	41 (37.3)	69 (62.7)	4.7	*	*	0.51	(0.27, 0.95)	0.029

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.30.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	73	51	(69.9)	22	(30.1)	2.4	4.2	11.0			
ADALIMUMAB	75	40	(53.3)	35	(46.7)	3.0	7.7	*			
TOTAL	148	91	(61.5)	57	(38.5)	2.7	5.6	*	0.61	(0.40, 0.92)	0.016

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.31.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ORAL PREDNISONE USAGE AT BASELINE >20 MG/DAY)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	25	18 (72.0)	7 (28.0)	1.8	2.8	8.3			
ADALIMUMAB	23	13 (56.5)	10 (43.5)	3.8	7.7	*			
TOTAL	48	31 (64.6)	17 (35.4)	2.6	4.6	13.8	0.45	(0.22, 0.92)	0.024

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.32.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ORAL PREDNISONE USAGE AT BASELINE <=20 MG/DAY)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	102	57 (55.9)	45 (44.1)	2.8	7.6	*			
ADALIMUMAB	108	44 (40.7)	64 (59.3)	4.6	*	*			
TOTAL	210	101 (48.1)	109 (51.9)	3.5	11.0	*	0.60	(0.40, 0.89)	0.009

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.33.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	42	27 (64.3)	15 (35.7)	1.6	2.8	9.0			
ADALIMUMAB	32	22 (68.8)	10 (31.3)	2.4	5.6	12.0			
TOTAL	74	49 (66.2)	25 (33.8)	1.9	3.5	12.0	0.71	(0.40, 1.25)	0.227

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.34.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	85	48 (56.5)	37 (43.5)	3.7	8.3	*			
ADALIMUMAB	99	35 (35.4)	64 (64.6)	5.6	*	*			
TOTAL	184	83 (45.1)	101 (54.9)	4.2	13.6	*	0.52	(0.34, 0.81)	0.003

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.35.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

TREATMENT	N	FAILURE N	FAILURE (%)	CENSORED N	CENSORED (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	1	(100)	0		3.0	3.0	3.0
ADALIMUMAB	3	0		3	(100)	*	*	*
TOTAL	4	1	(25.0)	3	(75.0)	*	*	*

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.36.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	126	74 (58.7)	52 (41.3)	2.6	5.6	*			
ADALIMUMAB	128	57 (44.5)	71 (55.5)	3.8	13.8	*			
TOTAL	254	131 (51.6)	123 (48.4)	3.0	9.0	*	0.59	(0.42, 0.83)	0.002

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.37.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	37	22 (59.5)	15 (40.5)	2.6	5.6	*			
ADALIMUMAB	33	13 (39.4)	20 (60.6)	3.8	*	*			
TOTAL	70	35 (50.0)	35 (50.0)	3.4	8.5	*	0.51	(0.25, 1.01)	0.047

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.1.38.I

TIME TO TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

TREATMENT	N	FAILURE N (%)	CENSORED N (%)	TIME TO FAILURE (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	55	29 (52.7)	26 (47.3)	3.7	9.0	*			
ADALIMUMAB	64	23 (35.9)	41 (64.1)	5.4	*	*			
TOTAL	119	52 (43.7)	67 (56.3)	4.4	12.0	*	0.58	(0.33, 1.00)	0.048

NOTE: TREATMENT FAILURE AT OR AFTER WEEK 2 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN TREATMENT FAILURE WERE CENSORED AT THE TIME OF DROPPING OUT.
$ HAZARD RATIO OF ADALIMUMAB VS PLACEBO FROM PROPORTIONAL HAZARDS REGRESSION WITH TREATMENT AS FACTOR.
# 95% CONFIDENCE INTERVAL FOR HAZARD RATIO.
@ TWO-SIDED P-VALUE FROM LOG RANK TEST.
* NOT ESTIMABLE

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.1.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

VARIABLE	PLACEBO (N=45) n	(%)	ADALIMUMAB (N=56) n	(%)	TOTAL (N=101) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	13	(28.9)	6	(10.7)	19	(18.8)
NO	32	(71.1)	50	(89.3)	82	(81.2)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	13	(28.9)	14	(25.0)	27	(26.7)
NO	32	(71.1)	42	(75.0)	74	(73.3)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	9	(20.0)	8	(14.3)	17	(16.8)
NO	36	(80.0)	48	(85.7)	84	(83.2)
MISSING	0		0		0	
VISUAL ACUITY						
YES	11	(24.4)	5	(8.9)	16	(15.8)
NO	34	(75.6)	51	(91.1)	85	(84.2)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	13	(28.9)	32	(57.1)	45	(44.6)
1	21	(46.7)	17	(30.4)	38	(37.6)
2	8	(17.8)	5	(8.9)	13	(12.9)
3	3	(6.7)	2	(3.6)	5	(5.0)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.2.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

VARIABLE	PLACEBO (N=82) n	(%)	ADALIMUMAB (N=75) n	(%)	TOTAL (N=157) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	11	(13.4)	10	(13.3)	21	(13.4)
NO	71	(86.6)	65	(86.7)	136	(86.6)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	24	(29.3)	21	(28.0)	45	(28.7)
NO	58	(70.7)	54	(72.0)	112	(71.3)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	8	(9.8)	3	(4.0)	11	(7.0)
NO	74	(90.2)	72	(96.0)	146	(93.0)
MISSING	0		0		0	
VISUAL ACUITY						
YES	16	(19.5)	8	(10.7)	24	(15.3)
NO	66	(80.5)	67	(89.3)	133	(84.7)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	39	(47.6)	42	(56.0)	81	(51.6)
1	30	(36.6)	25	(33.3)	55	(35.0)
2	10	(12.2)	7	(9.3)	17	(10.8)
3	3	(3.7)	1	(1.3)	4	(2.5)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.3.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

VARIABLE	PLACEBO (N=27) n	(%)	ADALIMUMAB (N=21) n	(%)	TOTAL (N=48) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	7	(25.9)	1	(4.8)	8	(16.7)
NO	20	(74.1)	20	(95.2)	40	(83.3)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	9	(33.3)	6	(28.6)	15	(31.3)
NO	18	(66.7)	15	(71.4)	33	(68.8)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	4	(14.8)	1	(4.8)	5	(10.4)
NO	23	(85.2)	20	(95.2)	43	(89.6)
MISSING	0		0		0	
VISUAL ACUITY						
YES	6	(22.2)	3	(14.3)	9	(18.8)
NO	21	(77.8)	18	(85.7)	39	(81.3)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	10	(37.0)	12	(57.1)	22	(45.8)
1	9	(33.3)	7	(33.3)	16	(33.3)
2	7	(25.9)	2	(9.5)	9	(18.8)
3	1	(3.7)	0		1	(2.1)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.4.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

VARIABLE	PLACEBO (N=58) n	(%)	ADALIMUMAB (N=64) n	(%)	TOTAL (N=122) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	7	(12.1)	6	(9.4)	13	(10.7)
NO	51	(87.9)	58	(90.6)	109	(89.3)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	21	(36.2)	14	(21.9)	35	(28.7)
NO	37	(63.8)	50	(78.1)	87	(71.3)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	7	(12.1)	6	(9.4)	13	(10.7)
NO	51	(87.9)	58	(90.6)	109	(89.3)
MISSING	0		0		0	
VISUAL ACUITY						
YES	13	(22.4)	5	(7.8)	18	(14.8)
NO	45	(77.6)	59	(92.2)	104	(85.2)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	24	(41.4)	42	(65.6)	66	(54.1)
1	23	(39.7)	15	(23.4)	38	(31.1)
2	8	(13.8)	5	(7.8)	13	(10.7)
3	3	(5.2)	2	(3.1)	5	(4.1)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.5.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

VARIABLE	PLACEBO (N=42) n	(%)	ADALIMUMAB (N=46) n	(%)	TOTAL (N=88) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	10	(23.8)	9	(19.6)	19	(21.6)
NO	32	(76.2)	37	(80.4)	69	(78.4)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	7	(16.7)	15	(32.6)	22	(25.0)
NO	35	(83.3)	31	(67.4)	66	(75.0)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	6	(14.3)	4	(8.7)	10	(11.4)
NO	36	(85.7)	42	(91.3)	78	(88.6)
MISSING	0		0		0	
VISUAL ACUITY						
YES	8	(19.0)	5	(10.9)	13	(14.8)
NO	34	(81.0)	41	(89.1)	75	(85.2)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	18	(42.9)	20	(43.5)	38	(43.2)
1	19	(45.2)	20	(43.5)	39	(44.3)
2	3	(7.1)	5	(10.9)	8	(9.1)
3	2	(4.8)	1	(2.2)	3	(3.4)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.6.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

VARIABLE	PLACEBO (N=93) n	(%)	ADALIMUMAB (N=96) n	(%)	TOTAL (N=189) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	15	(16.1)	12	(12.5)	27	(14.3)
NO	78	(83.9)	84	(87.5)	162	(85.7)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	23	(24.7)	20	(20.8)	43	(22.8)
NO	70	(75.3)	76	(79.2)	146	(77.2)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	11	(11.8)	10	(10.4)	21	(11.1)
NO	82	(88.2)	86	(89.6)	168	(88.9)
MISSING	0		0		0	
VISUAL ACUITY						
YES	21	(22.6)	9	(9.4)	30	(15.9)
NO	72	(77.4)	87	(90.6)	159	(84.1)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	41	(44.1)	59	(61.5)	100	(52.9)
1	37	(39.8)	25	(26.0)	62	(32.8)
2	12	(12.9)	10	(10.4)	22	(11.6)
3	3	(3.2)	2	(2.1)	5	(2.6)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.7.1.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

VARIABLE	PLACEBO (N=34) n	(%)	ADALIMUMAB (N=35) n	(%)	TOTAL (N=69) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	9	(26.5)	4	(11.4)	13	(18.8)
NO	25	(73.5)	31	(88.6)	56	(81.2)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	14	(41.2)	15	(42.9)	29	(42.0)
NO	20	(58.8)	20	(57.1)	40	(58.0)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	6	(17.6)	1	(2.9)	7	(10.1)
NO	28	(82.4)	34	(97.1)	62	(89.9)
MISSING	0		0		0	
VISUAL ACUITY						
YES	6	(17.6)	4	(11.4)	10	(14.5)
NO	28	(82.4)	31	(88.6)	59	(85.5)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	11	(32.4)	15	(42.9)	26	(37.7)
1	14	(41.2)	17	(48.6)	31	(44.9)
2	6	(17.6)	2	(5.7)	8	(11.6)
3	3	(8.8)	1	(2.9)	4	(5.8)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.7.2.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VARIABLE	PLACEBO (N=8) n	(%)	ADALIMUMAB (N=6) n	(%)	TOTAL (N=14) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	0		0		0	
NO	8	(100)	6	(100)	14	(100)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	2	(25.0)	2	(33.3)	4	(28.6)
NO	6	(75.0)	4	(66.7)	10	(71.4)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	0		0		0	
NO	8	(100)	6	(100)	14	(100)
MISSING	0		0		0	
VISUAL ACUITY						
YES	0		0		0	
NO	8	(100)	6	(100)	14	(100)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	6	(75.0)	4	(66.7)	10	(71.4)
1	2	(25.0)	2	(33.3)	4	(28.6)
2	0		0		0	
3	0		0		0	
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.7.3.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

VARIABLE	PLACEBO (N=19) n	(%)	ADALIMUMAB (N=19) n	(%)	TOTAL (N=38) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	7	(36.8)	4	(21.1)	11	(28.9)
NO	12	(63.2)	15	(78.9)	27	(71.1)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	9	(47.4)	9	(47.4)	18	(47.4)
NO	10	(52.6)	10	(52.6)	20	(52.6)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	6	(31.6)	0		6	(15.8)
NO	13	(68.4)	19	(100)	32	(84.2)
MISSING	0		0		0	
VISUAL ACUITY						
YES	4	(21.1)	3	(15.8)	7	(18.4)
NO	15	(78.9)	16	(84.2)	31	(81.6)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	3	(15.8)	6	(31.6)	9	(23.7)
1	9	(47.4)	11	(57.9)	20	(52.6)
2	4	(21.1)	1	(5.3)	5	(13.2)
3	3	(15.8)	1	(5.3)	4	(10.5)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.7.4.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

VARIABLE	PLACEBO (N=1) n	(%)	ADALIMUMAB (N=0) n	(%)	TOTAL (N=1) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	0		0		0	
NO	1	(100)	0		1	(100)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	1	(100)	0		1	(100)
NO	0		0		0	
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	0		0		0	
NO	1	(100)	0		1	(100)
MISSING	0		0		0	
VISUAL ACUITY						
YES	0		0		0	
NO	1	(100)	0		1	(100)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	0		0		0	
1	1	(100)	0		1	(100)
2	0		0		0	
3	0		0		0	
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.7.5.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

VARIABLE	PLACEBO (N=0) n (%)	ADALIMUMAB (N=0) n (%)	TOTAL (N=0) n (%)

** NO DATA IN THIS SEGMENT OR PART OF THIS TABLE. **

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.7.6.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

VARIABLE	PLACEBO (N=5) n	(%)	ADALIMUMAB (N=9) n	(%)	TOTAL (N=14) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	1	(20.0)	0		1	(7.1)
NO	4	(80.0)	9	(100)	13	(92.9)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	1	(20.0)	3	(33.3)	4	(28.6)
NO	4	(80.0)	6	(66.7)	10	(71.4)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	0		1	(11.1)	1	(7.1)
NO	5	(100)	8	(88.9)	13	(92.9)
MISSING	0		0		0	
VISUAL ACUITY						
YES	2	(40.0)	1	(11.1)	3	(21.4)
NO	3	(60.0)	8	(88.9)	11	(78.6)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	2	(40.0)	5	(55.6)	7	(50.0)
1	2	(40.0)	3	(33.3)	5	(35.7)
2	1	(20.0)	1	(11.1)	2	(14.3)
3	0		0		0	
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.7.7.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

VARIABLE	PLACEBO (N=1) n	(%)	ADALIMUMAB (N=1) n	(%)	TOTAL (N=2) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	1	(100)	0		1	(50.0)
NO	0		1	(100)	1	(50.0)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	1	(100)	1	(100)	2	(100)
NO	0		0		0	
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	0		0		0	
NO	1	(100)	1	(100)	2	(100)
MISSING	0		0		0	
VISUAL ACUITY						
YES	0		0		0	
NO	1	(100)	1	(100)	2	(100)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	0		0		0	
1	0		1	(100)	1	(50.0)
2	1	(100)	0		1	(50.0)
3	0		0		0	
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.8.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

VARIABLE	PLACEBO (N=24) n	(%)	ADALIMUMAB (N=22) n	(%)	TOTAL (N=46) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	5	(20.8)	3	(13.6)	8	(17.4)
NO	19	(79.2)	19	(86.4)	38	(82.6)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	10	(41.7)	7	(31.8)	17	(37.0)
NO	14	(58.3)	15	(68.2)	29	(63.0)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	4	(16.7)	0		4	(8.7)
NO	20	(83.3)	22	(100)	42	(91.3)
MISSING	0		0		0	
VISUAL ACUITY						
YES	6	(25.0)	2	(9.1)	8	(17.4)
NO	18	(75.0)	20	(90.9)	38	(82.6)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	6	(25.0)	14	(63.6)	20	(43.5)
1	12	(50.0)	4	(18.2)	16	(34.8)
2	5	(20.8)	4	(18.2)	9	(19.6)
3	1	(4.2)	0		1	(2.2)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.9.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

VARIABLE	PLACEBO (N=103) n	(%)	ADALIMUMAB (N=109) n	(%)	TOTAL (N=212) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	19	(18.4)	13	(11.9)	32	(15.1)
NO	84	(81.6)	96	(88.1)	180	(84.9)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	27	(26.2)	28	(25.7)	55	(25.9)
NO	76	(73.8)	81	(74.3)	157	(74.1)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	13	(12.6)	11	(10.1)	24	(11.3)
NO	90	(87.4)	98	(89.9)	188	(88.7)
MISSING	0		0		0	
VISUAL ACUITY						
YES	21	(20.4)	11	(10.1)	32	(15.1)
NO	82	(79.6)	98	(89.9)	180	(84.9)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	46	(44.7)	60	(55.0)	106	(50.0)
1	39	(37.9)	38	(34.9)	77	(36.3)
2	13	(12.6)	8	(7.3)	21	(9.9)
3	5	(4.9)	3	(2.8)	8	(3.8)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.10.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

VARIABLE	PLACEBO (N=30) n	(%)	ADALIMUMAB (N=17) n	(%)	TOTAL (N=47) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	7	(23.3)	2	(11.8)	9	(19.1)
NO	23	(76.7)	15	(88.2)	38	(80.9)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	10	(33.3)	4	(23.5)	14	(29.8)
NO	20	(66.7)	13	(76.5)	33	(70.2)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	4	(13.3)	5	(29.4)	9	(19.1)
NO	26	(86.7)	12	(70.6)	38	(80.9)
MISSING	0		0		0	
VISUAL ACUITY						
YES	2	(6.7)	0		2	(4.3)
NO	28	(93.3)	17	(100)	45	(95.7)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	10	(33.3)	8	(47.1)	18	(38.3)
1	17	(56.7)	7	(41.2)	24	(51.1)
2	3	(10.0)	2	(11.8)	5	(10.6)
3	0		0		0	
4	0		0		0	

NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.11.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

VARIABLE	PLACEBO (N=35) n	(%)	ADALIMUMAB (N=41) n	(%)	TOTAL (N=76) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	4	(11.4)	4	(9.8)	8	(10.5)
NO	31	(88.6)	37	(90.2)	68	(89.5)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	3	(8.6)	10	(24.4)	13	(17.1)
NO	32	(91.4)	31	(75.6)	63	(82.9)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	2	(5.7)	4	(9.8)	6	(7.9)
NO	33	(94.3)	37	(90.2)	70	(92.1)
MISSING	0		0		0	
VISUAL ACUITY						
YES	5	(14.3)	5	(12.2)	10	(13.2)
NO	30	(85.7)	36	(87.8)	66	(86.8)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	22	(62.9)	27	(65.9)	49	(64.5)
1	12	(34.3)	7	(17.1)	19	(25.0)
2	1	(2.9)	5	(12.2)	6	(7.9)
3	0		2	(4.9)	2	(2.6)
4	0		0		0	

NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.12.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

VARIABLE	PLACEBO (N=61) n	(%)	ADALIMUMAB (N=71) n	(%)	TOTAL (N=132) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	13	(21.3)	9	(12.7)	22	(16.7)
NO	48	(78.7)	62	(87.3)	110	(83.3)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	23	(37.7)	21	(29.6)	44	(33.3)
NO	38	(62.3)	50	(70.4)	88	(66.7)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	11	(18.0)	2	(2.8)	13	(9.8)
NO	50	(82.0)	69	(97.2)	119	(90.2)
MISSING	0		0		0	
VISUAL ACUITY						
YES	20	(32.8)	7	(9.9)	27	(20.5)
NO	41	(67.2)	64	(90.1)	105	(79.5)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	20	(32.8)	38	(53.5)	58	(43.9)
1	21	(34.4)	28	(39.4)	49	(37.1)
2	14	(23.0)	4	(5.6)	18	(13.6)
3	6	(9.8)	1	(1.4)	7	(5.3)
4	0		0		0	

NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.13.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

VARIABLE	PLACEBO (N=54) n	(%)	ADALIMUMAB (N=45) n	(%)	TOTAL (N=99) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	10	(18.5)	6	(13.3)	16	(16.2)
NO	44	(81.5)	39	(86.7)	83	(83.8)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	16	(29.6)	8	(17.8)	24	(24.2)
NO	38	(70.4)	37	(82.2)	75	(75.8)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	11	(20.4)	7	(15.6)	18	(18.2)
NO	43	(79.6)	38	(84.4)	81	(81.8)
MISSING	0		0		0	
VISUAL ACUITY						
YES	9	(16.7)	4	(8.9)	13	(13.1)
NO	45	(83.3)	41	(91.1)	86	(86.9)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	19	(35.2)	26	(57.8)	45	(45.5)
1	26	(48.1)	13	(28.9)	39	(39.4)
2	7	(13.0)	6	(13.3)	13	(13.1)
3	2	(3.7)	0		2	(2.0)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.14.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

VARIABLE	PLACEBO (N=15) n	(%)	ADALIMUMAB (N=15) n	(%)	TOTAL (N=30) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	4	(26.7)	2	(13.3)	6	(20.0)
NO	11	(73.3)	13	(86.7)	24	(80.0)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	0		0		0	
NO	15	(100)	15	(100)	30	(100)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	0		0		0	
NO	15	(100)	15	(100)	30	(100)
MISSING	0		0		0	
VISUAL ACUITY						
YES	0		0		0	
NO	15	(100)	15	(100)	30	(100)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	11	(73.3)	13	(86.7)	24	(80.0)
1	4	(26.7)	2	(13.3)	6	(20.0)
2	0		0		0	
3	0		0		0	
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.15.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

VARIABLE	PLACEBO (N=2) n	(%)	ADALIMUMAB (N=5) n	(%)	TOTAL (N=7) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	0		0		0	
NO	2	(100)	5	(100)	7	(100)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	0		1	(20.0)	1	(14.3)
NO	2	(100)	4	(80.0)	6	(85.7)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	0		1	(20.0)	1	(14.3)
NO	2	(100)	4	(80.0)	6	(85.7)
MISSING	0		0		0	
VISUAL ACUITY						
YES	2	(100)	0		2	(28.6)
NO	0		5	(100)	5	(71.4)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	0		3	(60.0)	3	(42.9)
1	2	(100)	2	(40.0)	4	(57.1)
2	0		0		0	
3	0		0		0	
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.16.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

VARIABLE	PLACEBO (N=29) n	(%)	ADALIMUMAB (N=34) n	(%)	TOTAL (N=63) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	1	(3.4)	3	(8.8)	4	(6.3)
NO	28	(96.6)	31	(91.2)	59	(93.7)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	15	(51.7)	15	(44.1)	30	(47.6)
NO	14	(48.3)	19	(55.9)	33	(52.4)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	2	(6.9)	2	(5.9)	4	(6.3)
NO	27	(93.1)	32	(94.1)	59	(93.7)
MISSING	0		0		0	
VISUAL ACUITY						
YES	11	(37.9)	7	(20.6)	18	(28.6)
NO	18	(62.1)	27	(79.4)	45	(71.4)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	10	(34.5)	14	(41.2)	24	(38.1)
1	11	(37.9)	14	(41.2)	25	(39.7)
2	6	(20.7)	5	(14.7)	11	(17.5)
3	2	(6.9)	1	(2.9)	3	(4.8)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.17.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

VARIABLE	PLACEBO (N=20) n	(%)	ADALIMUMAB (N=22) n	(%)	TOTAL (N=42) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	6	(30.0)	5	(22.7)	11	(26.2)
NO	14	(70.0)	17	(77.3)	31	(73.8)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	4	(20.0)	11	(50.0)	15	(35.7)
NO	16	(80.0)	11	(50.0)	27	(64.3)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	3	(15.0)	1	(4.5)	4	(9.5)
NO	17	(85.0)	21	(95.5)	38	(90.5)
MISSING	0		0		0	
VISUAL ACUITY						
YES	3	(15.0)	2	(9.1)	5	(11.9)
NO	17	(85.0)	20	(90.9)	37	(88.1)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	9	(45.0)	8	(36.4)	17	(40.5)
1	7	(35.0)	11	(50.0)	18	(42.9)
2	3	(15.0)	1	(4.5)	4	(9.5)
3	1	(5.0)	2	(9.1)	3	(7.1)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.18.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

VARIABLE	PLACEBO (N=7) n (%)	ADALIMUMAB (N=10) n (%)	TOTAL (N=17) n (%)
CHORIORETINAL/RETINAL VASCULAR LESIONS			
YES	3 (42.9)	0	3 (17.6)
NO	4 (57.1)	10 (100)	14 (82.4)
MISSING	0	0	0
ANTERIOR CHAMBER CELL GRADE			
YES	2 (28.6)	0	2 (11.8)
NO	5 (71.4)	10 (100)	15 (88.2)
MISSING	0	0	0
VITREOUS HAZE GRADE			
YES	1 (14.3)	0	1 (5.9)
NO	6 (85.7)	10 (100)	16 (94.1)
MISSING	0	0	0
VISUAL ACUITY			
YES	2 (28.6)	0	2 (11.8)
NO	5 (71.4)	10 (100)	15 (88.2)
MISSING	0	0	0
NUMBER OF REASONS MET			
0	3 (42.9)	10 (100)	13 (76.5)
1	1 (14.3)	0	1 (5.9)
2	2 (28.6)	0	2 (11.8)
3	1 (14.3)	0	1 (5.9)
4	0	0	0

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.19.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=0-1)

VARIABLE	PLACEBO (N=51) n	(%)	ADALIMUMAB (N=57) n	(%)	TOTAL (N=108) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	8	(15.7)	6	(10.5)	14	(13.0)
NO	43	(84.3)	51	(89.5)	94	(87.0)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	9	(17.6)	15	(26.3)	24	(22.2)
NO	42	(82.4)	42	(73.7)	84	(77.8)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	7	(13.7)	7	(12.3)	14	(13.0)
NO	44	(86.3)	50	(87.7)	94	(87.0)
MISSING	0		0		0	
VISUAL ACUITY						
YES	10	(19.6)	7	(12.3)	17	(15.7)
NO	41	(80.4)	50	(87.7)	91	(84.3)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	28	(54.9)	31	(54.4)	59	(54.6)
1	15	(29.4)	18	(31.6)	33	(30.6)
2	5	(9.8)	7	(12.3)	12	(11.1)
3	3	(5.9)	1	(1.8)	4	(3.7)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.20.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

VARIABLE	PLACEBO (N=45) n	(%)	ADALIMUMAB (N=46) n	(%)	TOTAL (N=91) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	8	(17.8)	5	(10.9)	13	(14.3)
NO	37	(82.2)	41	(89.1)	78	(85.7)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	13	(28.9)	10	(21.7)	23	(25.3)
NO	32	(71.1)	36	(78.3)	68	(74.7)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	4	(8.9)	0		4	(4.4)
NO	41	(91.1)	46	(100)	87	(95.6)
MISSING	0		0		0	
VISUAL ACUITY						
YES	9	(20.0)	5	(10.9)	14	(15.4)
NO	36	(80.0)	41	(89.1)	77	(84.6)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	18	(40.0)	32	(69.6)	50	(54.9)
1	21	(46.7)	9	(19.6)	30	(33.0)
2	5	(11.1)	4	(8.7)	9	(9.9)
3	1	(2.2)	1	(2.2)	2	(2.2)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.21.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

VARIABLE	PLACEBO (N=31) n	(%)	ADALIMUMAB (N=28) n	(%)	TOTAL (N=59) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	8	(25.8)	5	(17.9)	13	(22.0)
NO	23	(74.2)	23	(82.1)	46	(78.0)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	15	(48.4)	10	(35.7)	25	(42.4)
NO	16	(51.6)	18	(64.3)	34	(57.6)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	6	(19.4)	4	(14.3)	10	(16.9)
NO	25	(80.6)	24	(85.7)	49	(83.1)
MISSING	0		0		0	
VISUAL ACUITY						
YES	8	(25.8)	1	(3.6)	9	(15.3)
NO	23	(74.2)	27	(96.4)	50	(84.7)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	6	(19.4)	11	(39.3)	17	(28.8)
1	15	(48.4)	15	(53.6)	30	(50.8)
2	8	(25.8)	1	(3.6)	9	(15.3)
3	2	(6.5)	1	(3.6)	3	(5.1)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.22.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

VARIABLE	PLACEBO (N=89) n	(%)	ADALIMUMAB (N=84) n	(%)	TOTAL (N=173) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	20	(22.5)	12	(14.3)	32	(18.5)
NO	69	(77.5)	72	(85.7)	141	(81.5)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	30	(33.7)	23	(27.4)	53	(30.6)
NO	59	(66.3)	61	(72.6)	120	(69.4)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	14	(15.7)	6	(7.1)	20	(11.6)
NO	75	(84.3)	78	(92.9)	153	(88.4)
MISSING	0		0		0	
VISUAL ACUITY						
YES	22	(24.7)	8	(9.5)	30	(17.3)
NO	67	(75.3)	76	(90.5)	143	(82.7)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	28	(31.5)	48	(57.1)	76	(43.9)
1	41	(46.1)	26	(31.0)	67	(38.7)
2	15	(16.9)	7	(8.3)	22	(12.7)
3	5	(5.6)	3	(3.6)	8	(4.6)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.23.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

VARIABLE	PLACEBO (N=38) n	(%)	ADALIMUMAB (N=47) n	(%)	TOTAL (N=85) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	4	(10.5)	4	(8.5)	8	(9.4)
NO	34	(89.5)	43	(91.5)	77	(90.6)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	7	(18.4)	12	(25.5)	19	(22.4)
NO	31	(81.6)	35	(74.5)	66	(77.6)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	3	(7.9)	5	(10.6)	8	(9.4)
NO	35	(92.1)	42	(89.4)	77	(90.6)
MISSING	0		0		0	
VISUAL ACUITY						
YES	5	(13.2)	5	(10.6)	10	(11.8)
NO	33	(86.8)	42	(89.4)	75	(88.2)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	24	(63.2)	26	(55.3)	50	(58.8)
1	10	(26.3)	16	(34.0)	26	(30.6)
2	3	(7.9)	5	(10.6)	8	(9.4)
3	1	(2.6)	0		1	(1.2)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.24.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

VARIABLE	PLACEBO (N=95) n	(%)	ADALIMUMAB (N=103) n	(%)	TOTAL (N=198) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	15	(15.8)	13	(12.6)	28	(14.1)
NO	80	(84.2)	90	(87.4)	170	(85.9)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	24	(25.3)	27	(26.2)	51	(25.8)
NO	71	(74.7)	76	(73.8)	147	(74.2)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	12	(12.6)	5	(4.9)	17	(8.6)
NO	83	(87.4)	98	(95.1)	181	(91.4)
MISSING	0		0		0	
VISUAL ACUITY						
YES	20	(21.1)	12	(11.7)	32	(16.2)
NO	75	(78.9)	91	(88.3)	166	(83.8)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	43	(45.3)	61	(59.2)	104	(52.5)
1	37	(38.9)	30	(29.1)	67	(33.8)
2	11	(11.6)	9	(8.7)	20	(10.1)
3	4	(4.2)	3	(2.9)	7	(3.5)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.25.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

VARIABLE	PLACEBO (N=29) n	(%)	ADALIMUMAB (N=22) n	(%)	TOTAL (N=51) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	9	(31.0)	2	(9.1)	11	(21.6)
NO	20	(69.0)	20	(90.9)	40	(78.4)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	11	(37.9)	7	(31.8)	18	(35.3)
NO	18	(62.1)	15	(68.2)	33	(64.7)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	5	(17.2)	5	(22.7)	10	(19.6)
NO	24	(82.8)	17	(77.3)	41	(80.4)
MISSING	0		0		0	
VISUAL ACUITY						
YES	6	(20.7)	1	(4.5)	7	(13.7)
NO	23	(79.3)	21	(95.5)	44	(86.3)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	8	(27.6)	9	(40.9)	17	(33.3)
1	13	(44.8)	11	(50.0)	24	(47.1)
2	6	(20.7)	2	(9.1)	8	(15.7)
3	2	(6.9)	0		2	(3.9)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.26.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

VARIABLE	PLACEBO (N=3) n (%)	ADALIMUMAB (N=6) n (%)	TOTAL (N=9) n (%)
CHORIORETINAL/RETINAL VASCULAR LESIONS			
YES	0	1 (16.7)	1 (11.1)
NO	3 (100)	5 (83.3)	8 (88.9)
MISSING	0	0	0
ANTERIOR CHAMBER CELL GRADE			
YES	2 (66.7)	1 (16.7)	3 (33.3)
NO	1 (33.3)	5 (83.3)	6 (66.7)
MISSING	0	0	0
VITREOUS HAZE GRADE			
YES	0	1 (16.7)	1 (11.1)
NO	3 (100)	5 (83.3)	8 (88.9)
MISSING	0	0	0
VISUAL ACUITY			
YES	1 (33.3)	0	1 (11.1)
NO	2 (66.7)	6 (100)	8 (88.9)
MISSING	0	0	0
NUMBER OF REASONS MET			
0	1 (33.3)	4 (66.7)	5 (55.6)
1	1 (33.3)	1 (16.7)	2 (22.2)
2	1 (33.3)	1 (16.7)	2 (22.2)
3	0	0	0
4	0	0	0

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.27.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

VARIABLE	PLACEBO (N=17) n	(%)	ADALIMUMAB (N=26) n	(%)	TOTAL (N=43) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	7	(41.2)	8	(30.8)	15	(34.9)
NO	10	(58.8)	18	(69.2)	28	(65.1)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	4	(23.5)	6	(23.1)	10	(23.3)
NO	13	(76.5)	20	(76.9)	33	(76.7)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	1	(5.9)	5	(19.2)	6	(14.0)
NO	16	(94.1)	21	(80.8)	37	(86.0)
MISSING	0		0		0	
VISUAL ACUITY						
YES	5	(29.4)	3	(11.5)	8	(18.6)
NO	12	(70.6)	23	(88.5)	35	(81.4)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	4	(23.5)	8	(30.8)	12	(27.9)
1	9	(52.9)	15	(57.7)	24	(55.8)
2	4	(23.5)	2	(7.7)	6	(14.0)
3	0		1	(3.8)	1	(2.3)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.28.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

VARIABLE	PLACEBO (N=106) n	(%)	ADALIMUMAB (N=102) n	(%)	TOTAL (N=208) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	16	(15.1)	7	(6.9)	23	(11.1)
NO	90	(84.9)	95	(93.1)	185	(88.9)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	32	(30.2)	29	(28.4)	61	(29.3)
NO	74	(69.8)	73	(71.6)	147	(70.7)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	15	(14.2)	6	(5.9)	21	(10.1)
NO	91	(85.8)	96	(94.1)	187	(89.9)
MISSING	0		0		0	
VISUAL ACUITY						
YES	21	(19.8)	10	(9.8)	31	(14.9)
NO	85	(80.2)	92	(90.2)	177	(85.1)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	47	(44.3)	64	(62.7)	111	(53.4)
1	40	(37.7)	26	(25.5)	66	(31.7)
2	13	(12.3)	10	(9.8)	23	(11.1)
3	6	(5.7)	2	(2.0)	8	(3.8)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.29.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

VARIABLE	PLACEBO (N=54) n	(%)	ADALIMUMAB (N=56) n	(%)	TOTAL (N=110) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	7	(13.0)	3	(5.4)	10	(9.1)
NO	47	(87.0)	53	(94.6)	100	(90.9)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	10	(18.5)	9	(16.1)	19	(17.3)
NO	44	(81.5)	47	(83.9)	91	(82.7)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	3	(5.6)	5	(8.9)	8	(7.3)
NO	51	(94.4)	51	(91.1)	102	(92.7)
MISSING	0		0		0	
VISUAL ACUITY						
YES	11	(20.4)	2	(3.6)	13	(11.8)
NO	43	(79.6)	54	(96.4)	97	(88.2)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	30	(55.6)	39	(69.6)	69	(62.7)
1	18	(33.3)	15	(26.8)	33	(30.0)
2	5	(9.3)	2	(3.6)	7	(6.4)
3	1	(1.9)	0		1	(0.9)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.30.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

VARIABLE	PLACEBO (N=73) n	(%)	ADALIMUMAB (N=75) n	(%)	TOTAL (N=148) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	17	(23.3)	13	(17.3)	30	(20.3)
NO	56	(76.7)	62	(82.7)	118	(79.7)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	27	(37.0)	26	(34.7)	53	(35.8)
NO	46	(63.0)	49	(65.3)	95	(64.2)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	14	(19.2)	6	(8.0)	20	(13.5)
NO	59	(80.8)	69	(92.0)	128	(86.5)
MISSING	0		0		0	
VISUAL ACUITY						
YES	16	(21.9)	11	(14.7)	27	(18.2)
NO	57	(78.1)	64	(85.3)	121	(81.8)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	22	(30.1)	35	(46.7)	57	(38.5)
1	33	(45.2)	27	(36.0)	60	(40.5)
2	13	(17.8)	10	(13.3)	23	(15.5)
3	5	(6.8)	3	(4.0)	8	(5.4)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.31.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ORAL PREDNISONE USAGE AT BASELINE >20 MG/DAY)

VARIABLE	PLACEBO (N=25) n	(%)	ADALIMUMAB (N=23) n	(%)	TOTAL (N=48) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	7	(28.0)	3	(13.0)	10	(20.8)
NO	18	(72.0)	20	(87.0)	38	(79.2)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	10	(40.0)	9	(39.1)	19	(39.6)
NO	15	(60.0)	14	(60.9)	29	(60.4)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	5	(20.0)	2	(8.7)	7	(14.6)
NO	20	(80.0)	21	(91.3)	41	(85.4)
MISSING	0		0		0	
VISUAL ACUITY						
YES	8	(32.0)	3	(13.0)	11	(22.9)
NO	17	(68.0)	20	(87.0)	37	(77.1)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	7	(28.0)	10	(43.5)	17	(35.4)
1	9	(36.0)	10	(43.5)	19	(39.6)
2	6	(24.0)	2	(8.7)	8	(16.7)
3	3	(12.0)	1	(4.3)	4	(8.3)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.32.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ORAL PREDNISONE USAGE AT BASELINE <=20 MG/DAY)

VARIABLE	PLACEBO (N=102) n	(%)	ADALIMUMAB (N=108) n	(%)	TOTAL (N=210) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	17	(16.7)	13	(12.0)	30	(14.3)
NO	85	(83.3)	95	(88.0)	180	(85.7)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	27	(26.5)	26	(24.1)	53	(25.2)
NO	75	(73.5)	82	(75.9)	157	(74.8)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	12	(11.8)	9	(8.3)	21	(10.0)
NO	90	(88.2)	99	(91.7)	189	(90.0)
MISSING	0		0		0	
VISUAL ACUITY						
YES	19	(18.6)	10	(9.3)	29	(13.8)
NO	83	(81.4)	98	(90.7)	181	(86.2)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	45	(44.1)	64	(59.3)	109	(51.9)
1	42	(41.2)	32	(29.6)	74	(35.2)
2	12	(11.8)	10	(9.3)	22	(10.5)
3	3	(2.9)	2	(1.9)	5	(2.4)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.33.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

VARIABLE	PLACEBO (N=42) n	(%)	ADALIMUMAB (N=32) n	(%)	TOTAL (N=74) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	8	(19.0)	4	(12.5)	12	(16.2)
NO	34	(81.0)	28	(87.5)	62	(83.8)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	16	(38.1)	16	(50.0)	32	(43.2)
NO	26	(61.9)	16	(50.0)	42	(56.8)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	8	(19.0)	3	(9.4)	11	(14.9)
NO	34	(81.0)	29	(90.6)	63	(85.1)
MISSING	0		0		0	
VISUAL ACUITY						
YES	10	(23.8)	5	(15.6)	15	(20.3)
NO	32	(76.2)	27	(84.4)	59	(79.7)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	15	(35.7)	10	(31.3)	25	(33.8)
1	16	(38.1)	17	(53.1)	33	(44.6)
2	7	(16.7)	4	(12.5)	11	(14.9)
3	4	(9.5)	1	(3.1)	5	(6.8)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.34.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

VARIABLE	PLACEBO (N=85) n	(%)	ADALIMUMAB (N=99) n	(%)	TOTAL (N=184) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	16	(18.8)	12	(12.1)	28	(15.2)
NO	69	(81.2)	87	(87.9)	156	(84.8)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	21	(24.7)	19	(19.2)	40	(21.7)
NO	64	(75.3)	80	(80.8)	144	(78.3)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	9	(10.6)	8	(8.1)	17	(9.2)
NO	76	(89.4)	91	(91.9)	167	(90.8)
MISSING	0		0		0	
VISUAL ACUITY						
YES	17	(20.0)	8	(8.1)	25	(13.6)
NO	68	(80.0)	91	(91.9)	159	(86.4)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	37	(43.5)	64	(64.6)	101	(54.9)
1	35	(41.2)	25	(25.3)	60	(32.6)
2	11	(12.9)	8	(8.1)	19	(10.3)
3	2	(2.4)	2	(2.0)	4	(2.2)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.35.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

VARIABLE	PLACEBO (N=1) n (%)	ADALIMUMAB (N=3) n (%)	TOTAL (N=4) n (%)
CHORIORETINAL/RETINAL VASCULAR LESIONS			
YES	0	0	0
NO	1 (100)	3 (100)	4 (100)
MISSING	0	0	0
ANTERIOR CHAMBER CELL GRADE			
YES	1 (100)	0	1 (25.0)
NO	0	3 (100)	3 (75.0)
MISSING	0	0	0
VITREOUS HAZE GRADE			
YES	0	0	0
NO	1 (100)	3 (100)	4 (100)
MISSING	0	0	0
VISUAL ACUITY			
YES	1 (100)	0	1 (25.0)
NO	0	3 (100)	3 (75.0)
MISSING	0	0	0
NUMBER OF REASONS MET			
0	0	3 (100)	3 (75.0)
1	0	0	0
2	1 (100)	0	1 (25.0)
3	0	0	0
4	0	0	0

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.36.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

VARIABLE	PLACEBO (N=126) n	(%)	ADALIMUMAB (N=128) n	(%)	TOTAL (N=254) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	24	(19.0)	16	(12.5)	40	(15.7)
NO	102	(81.0)	112	(87.5)	214	(84.3)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	36	(28.6)	35	(27.3)	71	(28.0)
NO	90	(71.4)	93	(72.7)	183	(72.0)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	17	(13.5)	11	(8.6)	28	(11.0)
NO	109	(86.5)	117	(91.4)	226	(89.0)
MISSING	0		0		0	
VISUAL ACUITY						
YES	26	(20.6)	13	(10.2)	39	(15.4)
NO	100	(79.4)	115	(89.8)	215	(84.6)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	52	(41.3)	71	(55.5)	123	(48.4)
1	51	(40.5)	42	(32.8)	93	(36.6)
2	17	(13.5)	12	(9.4)	29	(11.4)
3	6	(4.8)	3	(2.3)	9	(3.5)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.37.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

VARIABLE	PLACEBO (N=37) n	(%)	ADALIMUMAB (N=33) n	(%)	TOTAL (N=70) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	5	(13.5)	1	(3.0)	6	(8.6)
NO	32	(86.5)	32	(97.0)	64	(91.4)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	13	(35.1)	10	(30.3)	23	(32.9)
NO	24	(64.9)	23	(69.7)	47	(67.1)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	1	(2.7)	3	(9.1)	4	(5.7)
NO	36	(97.3)	30	(90.9)	66	(94.3)
MISSING	0		0		0	
VISUAL ACUITY						
YES	6	(16.2)	0		6	(8.6)
NO	31	(83.8)	33	(100)	64	(91.4)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	15	(40.5)	20	(60.6)	35	(50.0)
1	19	(51.4)	12	(36.4)	31	(44.3)
2	3	(8.1)	1	(3.0)	4	(5.7)
3	0		0		0	
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.2.38.I

REASON FOR TREATMENT FAILURE AT OR AFTER WEEK 2
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

VARIABLE	PLACEBO (N=55) n	(%)	ADALIMUMAB (N=64) n	(%)	TOTAL (N=119) n	(%)
CHORIORETINAL/RETINAL VASCULAR LESIONS						
YES	11	(20.0)	11	(17.2)	22	(18.5)
NO	44	(80.0)	53	(82.8)	97	(81.5)
MISSING	0		0		0	
ANTERIOR CHAMBER CELL GRADE						
YES	11	(20.0)	11	(17.2)	22	(18.5)
NO	44	(80.0)	53	(82.8)	97	(81.5)
MISSING	0		0		0	
VITREOUS HAZE GRADE						
YES	8	(14.5)	5	(7.8)	13	(10.9)
NO	47	(85.5)	59	(92.2)	106	(89.1)
MISSING	0		0		0	
VISUAL ACUITY						
YES	8	(14.5)	5	(7.8)	13	(10.9)
NO	47	(85.5)	59	(92.2)	106	(89.1)
MISSING	0		0		0	
NUMBER OF REASONS MET						
0	26	(47.3)	41	(64.1)	67	(56.3)
1	21	(38.2)	15	(23.4)	36	(30.3)
2	7	(12.7)	7	(10.9)	14	(11.8)
3	1	(1.8)	1	(1.6)	2	(1.7)
4	0		0		0	

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.1.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	45	17	4	24	40.70	(27.57, 57.11)
	ADALIMUMAB	56	7	5	44	13.21	(6.52, 25.74)
	TOTAL	101	24	9	68	25.16	(17.62, 35.17)
MONTH 6							
	PLACEBO	45	27	5	13	65.99	(51.46, 80.00)
	ADALIMUMAB	56	16	9	31	31.70	(20.71, 46.55)
	TOTAL	101	43	14	44	46.90	(37.22, 57.71)
MONTH 9							
	PLACEBO	45	29	5	11	71.22	(56.85, 84.21)
	ADALIMUMAB	56	20	11	25	41.05	(28.60, 56.37)
	TOTAL	101	49	16	36	54.40	(44.36, 65.08)
MONTH 12							
	PLACEBO	45	32	6	7	79.07	(65.34, 90.06)
	ADALIMUMAB	56	23	14	19	48.42	(35.10, 63.72)
	TOTAL	101	55	20	26	62.16	(51.95, 72.43)
MONTH 18							
	PLACEBO	45	32	6	7	79.07	(65.34, 90.06)
	ADALIMUMAB	56	24	19	13	51.46	(37.70, 66.84)
	TOTAL	101	56	25	20	63.73	(53.45, 73.95)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.2.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	82	21	5	56	26.39	(18.07, 37.56)
	ADALIMUMAB	75	15	3	57	20.64	(12.99, 31.90)
	TOTAL	157	36	8	113	23.63	(17.65, 31.22)
MONTH 6							
	PLACEBO	82	33	11	38	42.91	(32.66, 54.83)
	ADALIMUMAB	75	25	7	43	35.07	(25.20, 47.38)
	TOTAL	157	58	18	81	39.12	(31.75, 47.52)
MONTH 9							
	PLACEBO	82	36	21	25	48.24	(37.36, 60.43)
	ADALIMUMAB	75	30	12	33	43.08	(32.33, 55.66)
	TOTAL	157	66	33	58	45.87	(37.99, 54.53)
MONTH 12							
	PLACEBO	82	40	23	19	57.00	(45.04, 69.57)
	ADALIMUMAB	75	33	17	25	48.88	(37.45, 61.69)
	TOTAL	157	73	40	44	53.02	(44.59, 61.96)
MONTH 18							
	PLACEBO	82	43	29	10	64.32	(51.69, 76.78)
	ADALIMUMAB	75	33	24	18	48.88	(37.45, 61.69)
	TOTAL	157	76	53	28	56.38	(47.72, 65.40)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.3.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	27	9	1	17	33.33	(18.94, 54.29)
	ADALIMUMAB	21	3	1	17	15.00	(5.10, 39.62)
	TOTAL	48	12	2	34	25.41	(15.30, 40.41)
MONTH 6							
	PLACEBO	27	11	3	13	41.18	(25.27, 61.96)
	ADALIMUMAB	21	7	2	12	36.25	(19.16, 61.43)
	TOTAL	48	18	5	25	39.31	(26.79, 55.04)
MONTH 9							
	PLACEBO	27	14	5	8	56.12	(37.48, 76.42)
	ADALIMUMAB	21	8	4	9	42.63	(23.85, 67.78)
	TOTAL	48	22	9	17	50.24	(36.24, 66.11)
MONTH 12							
	PLACEBO	27	15	5	7	61.61	(42.26, 81.14)
	ADALIMUMAB	21	9	5	7	49.80	(29.26, 74.64)
	TOTAL	48	24	10	14	56.29	(41.65, 71.95)
MONTH 18							
	PLACEBO	27	17	8	2	74.40	(53.74, 91.01)
	ADALIMUMAB	21	9	7	5	49.80	(29.26, 74.64)
	TOTAL	48	26	15	7	64.23	(48.46, 79.71)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.4.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	58	16	7	35	30.23	(19.71, 44.58)
	ADALIMUMAB	64	9	3	52	14.48	(7.81, 25.99)
	TOTAL	122	25	10	87	21.72	(15.23, 30.44)
MONTH 6							
	PLACEBO	58	30	10	18	60.29	(46.90, 74.01)
	ADALIMUMAB	64	14	7	43	23.09	(14.35, 35.91)
	TOTAL	122	44	17	61	39.79	(31.30, 49.63)
MONTH 9							
	PLACEBO	58	30	14	14	60.29	(46.90, 74.01)
	ADALIMUMAB	64	18	8	38	30.29	(20.24, 43.78)
	TOTAL	122	48	22	52	43.95	(35.14, 53.89)
MONTH 12							
	PLACEBO	58	33	14	11	68.80	(54.89, 81.81)
	ADALIMUMAB	64	21	13	30	36.39	(25.32, 50.38)
	TOTAL	122	54	27	41	50.81	(41.53, 60.86)
MONTH 18							
	PLACEBO	58	34	16	8	71.64	(57.69, 84.21)
	ADALIMUMAB	64	22	22	20	38.58	(27.17, 52.73)
	TOTAL	122	56	38	28	53.27	(43.84, 63.33)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.5.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	42	13	1	28	31.71	(19.81, 48.26)
	ADALIMUMAB	46	10	4	32	22.84	(12.98, 38.34)
	TOTAL	88	23	5	60	26.93	(18.78, 37.71)
MONTH 6							
	PLACEBO	42	19	3	20	46.57	(32.73, 62.88)
	ADALIMUMAB	46	20	7	19	47.61	(33.75, 63.77)
	TOTAL	88	39	10	39	46.82	(36.73, 58.15)
MONTH 9							
	PLACEBO	42	21	7	14	52.55	(38.00, 68.73)
	ADALIMUMAB	46	24	11	11	60.56	(45.26, 76.22)
	TOTAL	88	45	18	25	56.22	(45.43, 67.59)
MONTH 12							
	PLACEBO	42	24	10	8	64.10	(47.93, 79.97)
	ADALIMUMAB	46	26	13	7	68.13	(52.16, 83.02)
	TOTAL	88	50	23	15	65.83	(54.33, 77.03)
MONTH 18							
	PLACEBO	42	24	11	7	64.10	(47.93, 79.97)
	ADALIMUMAB	46	26	14	6	68.13	(52.16, 83.02)
	TOTAL	88	50	25	13	65.83	(54.33, 77.03)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.6.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	93	24	5	64	26.80	(18.84, 37.28)
	ADALIMUMAB	96	11	6	79	11.92	(6.78, 20.50)
	TOTAL	189	35	11	143	19.20	(14.18, 25.71)
MONTH 6							
	PLACEBO	93	39	11	43	44.69	(34.93, 55.80)
	ADALIMUMAB	96	26	12	58	29.46	(21.07, 40.23)
	TOTAL	189	65	23	101	36.94	(30.24, 44.58)
MONTH 9							
	PLACEBO	93	44	19	30	52.06	(41.67, 63.31)
	ADALIMUMAB	96	34	18	44	39.92	(30.30, 51.27)
	TOTAL	189	78	37	74	45.90	(38.62, 53.85)
MONTH 12							
	PLACEBO	93	50	22	21	61.93	(50.94, 73.00)
	ADALIMUMAB	96	36	24	36	42.85	(32.92, 54.34)
	TOTAL	189	86	46	57	52.02	(44.42, 60.08)
MONTH 18							
	PLACEBO	93	52	27	14	65.84	(54.60, 76.80)
	ADALIMUMAB	96	37	32	27	44.48	(34.36, 56.07)
	TOTAL	189	89	59	41	54.67	(46.91, 62.80)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.7.1.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	34	14	4	16	43.99	(28.79, 62.82)
	ADALIMUMAB	35	11	2	22	32.59	(19.52, 51.13)
	TOTAL	69	25	6	38	38.17	(27.61, 51.10)
MONTH 6							
	PLACEBO	34	21	5	8	69.99	(52.93, 85.38)
	ADALIMUMAB	35	15	4	16	45.01	(30.01, 63.30)
	TOTAL	69	36	9	24	56.61	(44.78, 69.09)
MONTH 9							
	PLACEBO	34	21	7	6	69.99	(52.93, 85.38)
	ADALIMUMAB	35	16	5	14	48.45	(32.99, 66.60)
	TOTAL	69	37	12	20	58.42	(46.52, 70.78)
MONTH 12							
	PLACEBO	34	22	7	5	75.00	(57.52, 89.40)
	ADALIMUMAB	35	20	7	8	65.39	(47.90, 82.22)
	TOTAL	69	42	14	13	69.88	(57.35, 81.54)
MONTH 18							
	PLACEBO	34	23	8	3	80.00	(62.46, 92.89)
	ADALIMUMAB	35	20	11	4	65.39	(47.90, 82.22)
	TOTAL	69	43	19	7	72.19	(59.66, 83.54)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.7.2.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	8	0	1	7	0.00
	ADALIMUMAB	6	2	0	4	33.33
	TOTAL	14	2	1	11	15.38
MONTH 6						
	PLACEBO	8	1	2	5	16.67
	ADALIMUMAB	6	2	1	3	33.33
	TOTAL	14	3	3	8	23.85
MONTH 9						
	PLACEBO	8	1	3	4	16.67
	ADALIMUMAB	6	2	1	3	33.33
	TOTAL	14	3	4	7	23.85
MONTH 12						
	PLACEBO	8	2	3	3	37.50
	ADALIMUMAB	6	2	2	2	33.33
	TOTAL	14	4	5	5	36.54
MONTH 18						
	PLACEBO	8	2	4	2	37.50
	ADALIMUMAB	6	2	2	2	33.33
	TOTAL	14	4	6	4	36.54

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.7.3.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	19	11	1	7	60.09
	ADALIMUMAB	19	8	0	11	42.11
	TOTAL	38	19	1	18	51.00
MONTH 6						
	PLACEBO	19	16	1	2	88.60
	ADALIMUMAB	19	10	0	9	52.63
	TOTAL	38	26	1	11	70.05
MONTH 9						
	PLACEBO	19	16	2	1	88.60
	ADALIMUMAB	19	11	1	7	57.89
	TOTAL	38	27	3	8	72.78
MONTH 12						
	PLACEBO	19	16	2	1	88.60
	ADALIMUMAB	19	13	2	4	71.93
	TOTAL	38	29	4	5	80.55
MONTH 18						
	PLACEBO	19	16	2	1	88.60
	ADALIMUMAB	19	13	4	2	71.93
	TOTAL	38	29	6	3	80.55

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.7.4.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	0				
	TOTAL	1	1	0	0	100
MONTH 6						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	0				
	TOTAL	1	1	0	0	100
MONTH 9						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	0				
	TOTAL	1	1	0	0	100
MONTH 12						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	0				
	TOTAL	1	1	0	0	100
MONTH 18						
	PLACEBO	1	1	0	0	100
	TOTAL	1	1	0	0	100

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.7.5.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)

** NO DATA IN THIS SEGMENT OR PART OF THIS TABLE. **

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.7.6.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	5	1	2	2	20.00
	ADALIMUMAB	9	0	2	7	0.00
	TOTAL	14	1	4	9	7.14
MONTH 6						
	PLACEBO	5	2	2	1	60.00
	ADALIMUMAB	9	2	3	4	31.43
	TOTAL	14	4	5	5	39.81
MONTH 9						
	PLACEBO	5	2	2	1	60.00
	ADALIMUMAB	9	2	3	4	31.43
	TOTAL	14	4	5	5	39.81
MONTH 12						
	PLACEBO	5	2	2	1	60.00
	ADALIMUMAB	9	4	3	2	65.71
	TOTAL	14	6	5	3	63.89
MONTH 18						
	PLACEBO	5	3	2	0	100.00
	ADALIMUMAB	9	4	5	0	65.71
	TOTAL	14	7	7	0	75.93

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.7.7.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	1	1	0	0	100
	TOTAL	2	2	0	0	100
MONTH 6						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	1	1	0	0	100
	TOTAL	2	2	0	0	100
MONTH 9						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	1	1	0	0	100
	TOTAL	2	2	0	0	100
MONTH 12						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	1	1	0	0	100
	TOTAL	2	2	0	0	100
MONTH 18						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	1	1	0	0	100
	TOTAL	2	2	0	0	100

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.8.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	24	9	0	15	37.50	(21.58, 59.70)
	ADALIMUMAB	22	3	2	17	14.79	(5.02, 39.19)
	TOTAL	46	12	2	32	26.95	(16.29, 42.58)
MONTH 6							
	PLACEBO	24	15	1	8	62.96	(44.26, 81.51)
	ADALIMUMAB	22	5	4	13	25.15	(11.29, 50.35)
	TOTAL	46	20	5	21	45.90	(32.46, 61.78)
MONTH 9							
	PLACEBO	24	16	2	6	67.59	(48.75, 85.03)
	ADALIMUMAB	22	7	6	9	38.25	(20.03, 64.63)
	TOTAL	46	23	8	15	54.38	(40.00, 70.05)
MONTH 12							
	PLACEBO	24	17	3	4	72.99	(53.87, 89.09)
	ADALIMUMAB	22	7	9	6	38.25	(20.03, 64.63)
	TOTAL	46	24	12	10	57.64	(42.90, 73.20)
MONTH 18							
	PLACEBO	24	18	5	1	82.00	(60.40, 95.81)
	ADALIMUMAB	22	8	11	3	50.60	(26.84, 79.63)
	TOTAL	46	26	16	4	68.23	(51.04, 84.13)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.9.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	103	29	9	65	29.76	(21.71, 39.93)
	ADALIMUMAB	109	19	6	84	18.01	(11.89, 26.79)
	TOTAL	212	48	15	149	23.64	(18.37, 30.11)
MONTH 6							
	PLACEBO	103	45	15	43	47.84	(38.23, 58.49)
	ADALIMUMAB	109	36	12	61	35.23	(26.80, 45.39)
	TOTAL	212	81	27	104	41.22	(34.66, 48.50)
MONTH 9							
	PLACEBO	103	49	24	30	53.41	(43.38, 64.15)
	ADALIMUMAB	109	43	17	49	43.04	(33.91, 53.45)
	TOTAL	212	92	41	79	47.98	(41.06, 55.41)
MONTH 12							
	PLACEBO	103	55	26	22	62.99	(52.35, 73.62)
	ADALIMUMAB	109	49	22	38	50.28	(40.65, 60.78)
	TOTAL	212	104	48	60	56.16	(48.92, 63.66)
MONTH 18							
	PLACEBO	103	57	30	16	66.44	(55.66, 76.91)
	ADALIMUMAB	109	49	32	28	50.28	(40.65, 60.78)
	TOTAL	212	106	62	44	57.66	(50.36, 65.17)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.10.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	30	6	3	21	21.01	(10.02, 40.95)
	ADALIMUMAB	17	3	2	12	18.55	(6.35, 47.37)
	TOTAL	47	9	5	33	20.04	(10.95, 35.02)
MONTH 6							
	PLACEBO	30	15	5	10	57.21	(39.29, 76.40)
	ADALIMUMAB	17	5	4	8	33.63	(15.31, 63.65)
	TOTAL	47	20	9	18	48.93	(34.67, 65.37)
MONTH 9							
	PLACEBO	30	17	7	6	66.72	(48.07, 84.24)
	ADALIMUMAB	17	7	4	6	50.23	(27.34, 78.22)
	TOTAL	47	24	11	12	60.95	(45.75, 76.44)
MONTH 12							
	PLACEBO	30	20	8	2	83.36	(64.54, 95.50)
	ADALIMUMAB	17	9	6	2	75.11	(46.26, 95.56)
	TOTAL	47	29	14	4	80.47	(64.11, 92.60)
MONTH 18							
	PLACEBO	30	20	8	2	83.36	(64.54, 95.50)
	ADALIMUMAB	17	9	6	2	75.11	(46.26, 95.56)
	TOTAL	47	29	14	4	80.47	(64.11, 92.60)

NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.11.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	35	7	3	25	21.44	(10.84, 39.79)
	ADALIMUMAB	41	3	5	33	8.12	(2.69, 23.12)
	TOTAL	76	10	8	58	14.17	(7.88, 24.76)
MONTH 6							
	PLACEBO	35	9	4	22	27.72	(15.49, 46.55)
	ADALIMUMAB	41	10	7	24	28.07	(16.18, 45.95)
	TOTAL	76	19	11	46	27.68	(18.61, 39.94)
MONTH 9							
	PLACEBO	35	10	8	17	31.74	(18.38, 51.22)
	ADALIMUMAB	41	13	12	16	38.86	(24.48, 57.78)
	TOTAL	76	23	20	33	35.11	(24.75, 48.21)
MONTH 12							
	PLACEBO	35	12	9	14	40.04	(24.72, 60.19)
	ADALIMUMAB	41	14	14	13	42.94	(27.70, 62.11)
	TOTAL	76	26	23	27	41.41	(30.05, 55.04)
MONTH 18							
	PLACEBO	35	13	13	9	44.32	(28.18, 64.51)
	ADALIMUMAB	41	14	17	10	42.94	(27.70, 62.11)
	TOTAL	76	27	30	19	43.58	(31.92, 57.33)

NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.12.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	61	25	3	33	42.18	(30.80, 55.74)
	ADALIMUMAB	71	16	1	54	22.81	(14.65, 34.51)
	TOTAL	132	41	4	87	31.68	(24.41, 40.45)
MONTH 6							
	PLACEBO	61	35	7	19	60.87	(48.39, 73.58)
	ADALIMUMAB	71	25	5	41	36.23	(26.10, 48.78)
	TOTAL	132	60	12	60	47.33	(39.02, 56.44)
MONTH 9							
	PLACEBO	61	37	11	13	65.11	(52.51, 77.43)
	ADALIMUMAB	71	29	7	35	42.62	(31.82, 55.31)
	TOTAL	132	66	18	48	52.90	(44.33, 62.00)
MONTH 12							
	PLACEBO	61	39	12	10	70.72	(57.65, 82.72)
	ADALIMUMAB	71	32	10	29	47.79	(36.52, 60.53)
	TOTAL	132	71	22	39	58.03	(49.25, 67.09)
MONTH 18							
	PLACEBO	61	41	14	6	77.23	(63.68, 88.48)
	ADALIMUMAB	71	33	19	19	49.80	(38.31, 62.59)
	TOTAL	132	74	33	25	61.54	(52.59, 70.58)

NOTE: 3 SUBJECTS HAD INTERMEDIATE AND POSTERIOR UVEITIS.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.13.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	54	14	4	36	27.14	(17.05, 41.50)
	ADALIMUMAB	45	5	2	38	11.33	(4.88, 25.11)
	TOTAL	99	19	6	74	19.81	(13.12, 29.29)
MONTH 6							
	PLACEBO	54	26	9	19	53.11	(39.78, 67.72)
	ADALIMUMAB	45	11	4	30	25.60	(15.05, 41.48)
	TOTAL	99	37	13	49	40.14	(30.89, 50.96)
MONTH 9							
	PLACEBO	54	28	11	15	58.62	(44.78, 73.06)
	ADALIMUMAB	45	16	6	23	38.48	(25.53, 55.09)
	TOTAL	99	44	17	38	49.29	(39.31, 60.29)
MONTH 12							
	PLACEBO	54	34	12	8	75.93	(61.67, 87.94)
	ADALIMUMAB	45	19	8	18	47.01	(32.87, 63.66)
	TOTAL	99	53	20	26	61.89	(51.38, 72.50)
MONTH 18							
	PLACEBO	54	35	13	6	78.94	(64.84, 90.18)
	ADALIMUMAB	45	19	14	12	47.01	(32.87, 63.66)
	TOTAL	99	54	27	18	63.48	(52.91, 74.01)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.14.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	15	1	1	13	7.14
	ADALIMUMAB	15	0	2	13	0.00
	TOTAL	30	1	3	26	3.57
MONTH 6						
	PLACEBO	15	2	2	11	14.88
	ADALIMUMAB	15	1	4	10	7.69
	TOTAL	30	3	6	21	11.49
MONTH 9						
	PLACEBO	15	3	5	7	25.52
	ADALIMUMAB	15	2	8	5	20.88
	TOTAL	30	5	13	12	23.30
MONTH 12						
	PLACEBO	15	4	5	6	36.16
	ADALIMUMAB	15	2	9	4	20.88
	TOTAL	30	6	14	10	29.69
MONTH 18						
	PLACEBO	15	4	6	5	36.16
	ADALIMUMAB	15	2	10	3	20.88
	TOTAL	30	6	16	8	29.69

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.15.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	2	0	0	2	0.00
	ADALIMUMAB	5	0	1	4	0.00
	TOTAL	7	0	1	6	0.00
MONTH 6						
	PLACEBO	2	1	0	1	50.00
	ADALIMUMAB	5	1	1	3	25.00
	TOTAL	7	2	1	4	33.33
MONTH 9						
	PLACEBO	2	2	0	0	100.00
	ADALIMUMAB	5	1	1	3	25.00
	TOTAL	7	3	1	3	50.00
MONTH 12						
	PLACEBO	2	2	0	0	100.00
	ADALIMUMAB	5	1	1	3	25.00
	TOTAL	7	3	1	3	50.00
MONTH 18						
	PLACEBO	2	2	0	0	100.00
	ADALIMUMAB	5	2	1	2	50.00
	TOTAL	7	4	1	2	66.67

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.16.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	29	13	3	13	47.59	(30.90, 67.66)
	ADALIMUMAB	34	10	1	23	30.17	(17.51, 48.83)
	TOTAL	63	23	4	36	38.03	(27.12, 51.51)
MONTH 6							
	PLACEBO	29	17	3	9	63.71	(45.79, 81.34)
	ADALIMUMAB	34	16	2	16	48.72	(33.28, 66.79)
	TOTAL	63	33	5	25	55.43	(43.31, 68.35)
MONTH 9							
	PLACEBO	29	17	4	8	63.71	(45.79, 81.34)
	ADALIMUMAB	34	18	2	14	55.13	(39.18, 72.52)
	TOTAL	63	35	6	22	58.99	(46.80, 71.61)
MONTH 12							
	PLACEBO	29	17	4	8	63.71	(45.79, 81.34)
	ADALIMUMAB	34	20	6	8	63.19	(46.32, 79.91)
	TOTAL	63	37	10	16	63.24	(50.84, 75.61)
MONTH 18							
	PLACEBO	29	19	8	2	75.12	(55.88, 90.60)
	ADALIMUMAB	34	20	8	6	63.19	(46.32, 79.91)
	TOTAL	63	39	16	8	68.55	(55.69, 80.69)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.17.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	20	7	0	13	35.00	(18.47, 59.70)
	ADALIMUMAB	22	7	1	14	32.12	(16.77, 55.86)
	TOTAL	42	14	1	27	33.50	(21.38, 49.93)
MONTH 6							
	PLACEBO	20	11	1	8	56.36	(36.17, 78.39)
	ADALIMUMAB	22	12	4	6	61.71	(40.42, 83.12)
	TOTAL	42	23	5	14	58.10	(43.14, 73.81)
MONTH 9							
	PLACEBO	20	11	4	5	56.36	(36.17, 78.39)
	ADALIMUMAB	22	13	5	4	68.09	(46.38, 87.68)
	TOTAL	42	24	9	9	61.09	(45.99, 76.46)
MONTH 12							
	PLACEBO	20	11	6	3	56.36	(36.17, 78.39)
	ADALIMUMAB	22	14	5	3	76.07	(53.48, 93.09)
	TOTAL	42	25	11	6	65.41	(49.62, 80.68)
MONTH 18							
	PLACEBO	20	11	6	3	56.36	(36.17, 78.39)
	ADALIMUMAB	22	14	5	3	76.07	(53.48, 93.09)
	TOTAL	42	25	11	6	65.41	(49.62, 80.68)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.18.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	7	3	1	3	50.00
	ADALIMUMAB	10	0	1	9	0.00
	TOTAL	17	3	2	12	18.75
MONTH 6						
	PLACEBO	7	3	1	3	50.00
	ADALIMUMAB	10	0	1	9	0.00
	TOTAL	17	3	2	12	18.75
MONTH 9						
	PLACEBO	7	4	2	1	66.67
	ADALIMUMAB	10	0	1	9	0.00
	TOTAL	17	4	3	10	25.52
MONTH 12						
	PLACEBO	7	4	2	1	66.67
	ADALIMUMAB	10	0	2	8	0.00
	TOTAL	17	4	4	9	25.52
MONTH 18						
	PLACEBO	7	4	2	1	66.67
	ADALIMUMAB	10	0	5	5	0.00
	TOTAL	17	4	7	6	25.52

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.19.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=0~1)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	51	10	6	35	21.33	(12.08, 36.03)
	ADALIMUMAB	57	11	1	45	19.34	(11.21, 32.19)
	TOTAL	108	21	7	80	20.23	(13.68, 29.32)
MONTH 6							
	PLACEBO	51	17	8	26	37.22	(24.98, 52.94)
	ADALIMUMAB	57	19	4	34	34.17	(23.30, 48.25)
	TOTAL	108	36	12	60	35.54	(27.05, 45.73)
MONTH 9							
	PLACEBO	51	18	12	21	40.07	(27.31, 56.03)
	ADALIMUMAB	57	22	7	28	40.15	(28.49, 54.43)
	TOTAL	108	40	19	49	40.11	(31.17, 50.51)
MONTH 12							
	PLACEBO	51	22	14	15	51.84	(37.42, 67.98)
	ADALIMUMAB	57	26	11	20	49.20	(36.47, 63.63)
	TOTAL	108	48	25	35	50.34	(40.55, 61.02)
MONTH 18							
	PLACEBO	51	23	17	11	55.05	(40.27, 71.09)
	ADALIMUMAB	57	26	18	13	49.20	(36.47, 63.63)
	TOTAL	108	49	35	24	51.76	(41.86, 62.46)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.20.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	45	9	3	33	20.83	(11.42, 36.25)
	ADALIMUMAB	46	4	6	36	9.67	(3.74, 23.78)
	TOTAL	91	13	9	69	15.24	(9.14, 24.82)
MONTH 6							
	PLACEBO	45	18	7	20	43.55	(29.97, 60.06)
	ADALIMUMAB	46	9	11	26	23.15	(12.71, 39.95)
	TOTAL	91	27	18	46	33.50	(24.26, 45.06)
MONTH 9							
	PLACEBO	45	22	11	12	56.18	(41.02, 72.46)
	ADALIMUMAB	46	12	15	19	33.49	(20.31, 51.95)
	TOTAL	91	34	26	31	45.01	(34.30, 57.33)
MONTH 12							
	PLACEBO	45	25	11	9	67.14	(51.08, 82.31)
	ADALIMUMAB	46	13	18	15	37.65	(23.39, 56.72)
	TOTAL	91	38	29	24	52.64	(41.12, 65.16)
MONTH 18							
	PLACEBO	45	27	14	4	75.35	(58.95, 88.95)
	ADALIMUMAB	46	14	20	12	41.81	(26.63, 61.19)
	TOTAL	91	41	34	16	58.81	(46.80, 71.26)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.21.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	31	19	0	12	61.29	(44.85, 77.99)
	ADALIMUMAB	28	7	1	20	25.00	(12.79, 45.39)
	TOTAL	59	26	1	32	44.12	(32.57, 57.66)
MONTH 6							
	PLACEBO	31	25	1	5	82.40	(66.92, 93.47)
	ADALIMUMAB	28	13	1	14	47.50	(30.91, 67.46)
	TOTAL	59	38	2	19	65.71	(53.46, 77.65)
MONTH 9							
	PLACEBO	31	25	3	3	82.40	(66.92, 93.47)
	ADALIMUMAB	28	16	1	11	58.75	(41.28, 77.07)
	TOTAL	59	41	4	14	71.43	(59.32, 82.53)
MONTH 12							
	PLACEBO	31	25	4	2	82.40	(66.92, 93.47)
	ADALIMUMAB	28	17	2	9	62.88	(45.17, 80.48)
	TOTAL	59	42	6	11	73.63	(61.54, 84.42)
MONTH 18							
	PLACEBO	31	25	4	2	82.40	(66.92, 93.47)
	ADALIMUMAB	28	17	5	6	62.88	(45.17, 80.48)
	TOTAL	59	42	9	8	73.63	(61.54, 84.42)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.22.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	89	35	5	49	40.37	(30.90, 51.49)
	ADALIMUMAB	84	14	7	63	17.65	(10.84, 27.99)
	TOTAL	173	49	12	112	29.42	(23.11, 36.99)
MONTH 6							
	PLACEBO	89	52	8	29	61.72	(51.39, 72.15)
	ADALIMUMAB	84	27	14	43	35.51	(25.84, 47.47)
	TOTAL	173	79	22	72	49.13	(41.63, 57.19)
MONTH 9							
	PLACEBO	89	55	14	20	66.28	(55.83, 76.45)
	ADALIMUMAB	84	33	19	32	45.46	(34.62, 57.89)
	TOTAL	173	88	33	52	56.30	(48.50, 64.40)
MONTH 12							
	PLACEBO	89	59	16	14	73.34	(62.70, 83.00)
	ADALIMUMAB	84	35	23	26	49.10	(37.89, 61.60)
	TOTAL	173	94	39	40	61.60	(53.61, 69.65)
MONTH 18							
	PLACEBO	89	61	20	8	77.63	(66.81, 86.90)
	ADALIMUMAB	84	36	30	18	51.22	(39.75, 63.82)
	TOTAL	173	97	50	26	64.77	(56.62, 72.83)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.23.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	38	3	4	31	8.59	(2.85, 24.33)
	ADALIMUMAB	47	8	1	38	17.13	(8.96, 31.35)
	TOTAL	85	11	5	69	13.53	(7.73, 23.11)
MONTH 6							
	PLACEBO	38	8	8	22	24.37	(12.94, 43.04)
	ADALIMUMAB	47	14	2	31	30.46	(19.29, 45.99)
	TOTAL	85	22	10	53	27.92	(19.33, 39.29)
MONTH 9							
	PLACEBO	38	10	12	16	32.05	(18.47, 51.86)
	ADALIMUMAB	47	17	4	26	37.27	(25.03, 52.99)
	TOTAL	85	27	16	42	35.05	(25.47, 46.92)
MONTH 12							
	PLACEBO	38	13	13	12	45.12	(28.62, 65.63)
	ADALIMUMAB	47	21	8	18	48.05	(34.27, 64.02)
	TOTAL	85	34	21	30	46.70	(35.75, 59.14)
MONTH 18							
	PLACEBO	38	14	15	9	49.69	(32.42, 70.01)
	ADALIMUMAB	47	21	13	13	48.05	(34.27, 64.02)
	TOTAL	85	35	28	22	48.48	(37.36, 60.94)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.24.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	95	22	7	66	24.06	(16.55, 34.23)
	ADALIMUMAB	103	17	8	78	17.30	(11.12, 26.36)
	TOTAL	198	39	15	144	20.54	(15.45, 27.03)
MONTH 6							
	PLACEBO	95	40	13	42	45.73	(35.89, 56.83)
	ADALIMUMAB	103	31	14	58	32.79	(24.28, 43.31)
	TOTAL	198	71	27	100	38.96	(32.26, 46.51)
MONTH 9							
	PLACEBO	95	43	21	31	50.15	(39.93, 61.37)
	ADALIMUMAB	103	38	21	44	41.55	(32.11, 52.52)
	TOTAL	198	81	42	75	45.71	(38.58, 53.49)
MONTH 12							
	PLACEBO	95	49	24	22	60.07	(49.13, 71.26)
	ADALIMUMAB	103	42	27	34	47.21	(37.22, 58.39)
	TOTAL	198	91	51	56	53.27	(45.74, 61.20)
MONTH 18							
	PLACEBO	95	52	29	14	65.88	(54.57, 76.90)
	ADALIMUMAB	103	42	38	23	47.21	(37.22, 58.39)
	TOTAL	198	94	67	37	55.90	(48.21, 63.90)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.25.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	29	14	2	13	51.85	(34.81, 71.31)
	ADALIMUMAB	22	5	0	17	22.73	(10.15, 46.26)
	TOTAL	51	19	2	30	38.78	(26.77, 53.82)
MONTH 6							
	PLACEBO	29	18	3	8	67.08	(49.40, 83.66)
	ADALIMUMAB	22	10	2	10	46.97	(28.47, 69.90)
	TOTAL	51	28	5	18	58.02	(44.57, 72.10)
MONTH 9							
	PLACEBO	29	20	5	4	75.99	(58.22, 90.30)
	ADALIMUMAB	22	10	2	10	46.97	(28.47, 69.90)
	TOTAL	51	30	7	14	62.83	(49.21, 76.44)
MONTH 12							
	PLACEBO	29	21	5	3	82.00	(63.71, 94.50)
	ADALIMUMAB	22	12	3	7	58.75	(38.39, 80.20)
	TOTAL	51	33	8	10	71.41	(57.43, 84.04)
MONTH 18							
	PLACEBO	29	21	6	2	82.00	(63.71, 94.50)
	ADALIMUMAB	22	13	4	5	65.63	(44.27, 85.78)
	TOTAL	51	34	10	7	74.58	(60.51, 86.73)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.26.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	3	2	0	1	66.67
	ADALIMUMAB	6	0	0	6	0.00
	TOTAL	9	2	0	7	22.22
MONTH 6						
	PLACEBO	3	2	0	1	66.67
	ADALIMUMAB	6	0	0	6	0.00
	TOTAL	9	2	0	7	22.22
MONTH 9						
	PLACEBO	3	2	0	1	66.67
	ADALIMUMAB	6	2	0	4	33.33
	TOTAL	9	4	0	5	44.44
MONTH 12						
	PLACEBO	3	2	0	1	66.67
	ADALIMUMAB	6	2	1	3	33.33
	TOTAL	9	4	1	4	44.44
MONTH 18						
	PLACEBO	3	2	0	1	66.67
	ADALIMUMAB	6	2	1	3	33.33
	TOTAL	9	4	1	4	44.44

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.27.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	17	9	1	7	56.25	(34.44, 80.19)
	ADALIMUMAB	26	7	1	18	27.47	(14.14, 49.19)
	TOTAL	43	16	2	25	38.35	(25.52, 54.80)
MONTH 6							
	PLACEBO	17	10	2	5	62.50	(40.23, 84.58)
	ADALIMUMAB	26	15	3	8	61.32	(42.60, 80.31)
	TOTAL	43	25	5	13	61.53	(46.81, 76.44)
MONTH 9							
	PLACEBO	17	11	2	4	70.00	(47.03, 89.79)
	ADALIMUMAB	26	15	4	7	61.32	(42.60, 80.31)
	TOTAL	43	26	6	11	64.49	(49.66, 79.03)
MONTH 12							
	PLACEBO	17	13	2	2	85.00	(62.61, 97.42)
	ADALIMUMAB	26	17	5	4	74.21	(53.82, 90.72)
	TOTAL	43	30	7	6	78.69	(63.51, 90.67)
MONTH 18							
	PLACEBO	17	13	2	2	85.00	(62.61, 97.42)
	ADALIMUMAB	26	18	6	2	80.66	(60.23, 94.65)
	TOTAL	43	31	8	4	82.24	(67.33, 93.08)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.28.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	106	28	7	71	27.49	(19.86, 37.28)
	ADALIMUMAB	102	15	7	80	15.39	(9.57, 24.24)
	TOTAL	208	43	14	151	21.54	(16.44, 27.92)
MONTH 6							
	PLACEBO	106	47	13	46	47.76	(38.38, 58.15)
	ADALIMUMAB	102	25	13	64	26.39	(18.65, 36.55)
	TOTAL	208	72	26	110	37.23	(30.81, 44.50)
MONTH 9							
	PLACEBO	106	51	23	32	52.93	(43.17, 63.38)
	ADALIMUMAB	102	34	18	50	37.29	(28.18, 48.20)
	TOTAL	208	85	41	82	45.33	(38.41, 52.87)
MONTH 12							
	PLACEBO	106	56	26	24	60.46	(50.19, 70.92)
	ADALIMUMAB	102	38	25	39	42.67	(33.00, 53.82)
	TOTAL	208	94	51	63	51.62	(44.37, 59.29)
MONTH 18							
	PLACEBO	106	59	32	15	65.70	(55.09, 76.08)
	ADALIMUMAB	102	38	35	29	42.67	(33.00, 53.82)
	TOTAL	208	97	67	44	54.05	(46.66, 61.80)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.29.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	54	10	5	39	19.56	(11.03, 33.32)
	ADALIMUMAB	56	2	5	49	3.92	(1.00, 14.78)
	TOTAL	110	12	10	88	11.46	(6.67, 19.30)
MONTH 6							
	PLACEBO	54	17	9	28	34.78	(23.19, 49.96)
	ADALIMUMAB	56	10	8	38	20.22	(11.42, 34.36)
	TOTAL	110	27	17	66	27.24	(19.53, 37.22)
MONTH 9							
	PLACEBO	54	18	15	21	37.19	(25.20, 52.52)
	ADALIMUMAB	56	13	11	32	26.76	(16.47, 41.64)
	TOTAL	110	31	26	53	31.97	(23.60, 42.37)
MONTH 12							
	PLACEBO	54	22	16	16	49.49	(35.34, 65.69)
	ADALIMUMAB	56	17	12	27	35.99	(24.04, 51.51)
	TOTAL	110	39	28	43	42.40	(32.84, 53.45)
MONTH 18							
	PLACEBO	54	24	17	13	55.80	(40.94, 71.80)
	ADALIMUMAB	56	17	22	17	35.99	(24.04, 51.51)
	TOTAL	110	41	39	30	45.19	(35.36, 56.32)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.30.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	73	28	4	41	39.67	(29.34, 52.07)
	ADALIMUMAB	75	20	3	52	27.29	(18.54, 39.05)
	TOTAL	148	48	7	93	33.35	(26.29, 41.71)
MONTH 6							
	PLACEBO	73	43	7	23	62.32	(50.96, 73.74)
	ADALIMUMAB	75	31	8	36	43.29	(32.70, 55.62)
	TOTAL	148	74	15	59	52.68	(44.64, 61.21)
MONTH 9							
	PLACEBO	73	47	11	15	69.79	(58.25, 80.61)
	ADALIMUMAB	75	37	12	26	53.58	(42.14, 65.92)
	TOTAL	148	84	23	41	61.55	(53.25, 69.93)
MONTH 12							
	PLACEBO	73	50	13	10	76.00	(64.46, 86.03)
	ADALIMUMAB	75	39	19	17	57.56	(45.80, 69.86)
	TOTAL	148	89	32	27	66.60	(58.18, 74.81)
MONTH 18							
	PLACEBO	73	51	18	4	78.67	(66.97, 88.40)
	ADALIMUMAB	75	40	21	14	60.06	(47.98, 72.44)
	TOTAL	148	91	39	18	69.22	(60.64, 77.44)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.31.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ORAL PREDNISONE USAGE AT BASELINE >20 MG/DAY)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	25	13	2	10	56.52	(37.88, 76.71)
	ADALIMUMAB	23	3	0	20	13.04	(4.40, 35.19)
	TOTAL	48	16	2	30	34.78	(22.96, 50.36)
MONTH 6							
	PLACEBO	25	16	2	7	69.57	(50.72, 86.46)
	ADALIMUMAB	23	10	4	9	46.64	(27.96, 69.98)
	TOTAL	48	26	6	16	57.78	(43.82, 72.45)
MONTH 9							
	PLACEBO	25	17	5	3	77.17	(56.74, 92.61)
	ADALIMUMAB	23	12	5	6	59.98	(38.77, 81.90)
	TOTAL	48	29	10	9	67.92	(52.92, 82.02)
MONTH 12							
	PLACEBO	25	18	5	2	84.78	(63.85, 96.93)
	ADALIMUMAB	23	12	6	5	59.98	(38.77, 81.90)
	TOTAL	48	30	11	7	71.49	(56.30, 85.07)
MONTH 18							
	PLACEBO	25	18	6	1	84.78	(63.85, 96.93)
	ADALIMUMAB	23	13	6	4	67.98	(45.40, 88.28)
	TOTAL	48	31	12	5	75.56	(60.08, 88.49)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.32.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: ORAL PREDNISONE USAGE AT BASELINE <=20 MG/DAY)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	102	25	7	70	25.34	(17.88, 35.16)
	ADALIMUMAB	108	19	8	81	18.43	(12.17, 27.37)
	TOTAL	210	44	15	151	21.78	(16.69, 28.14)
MONTH 6							
	PLACEBO	102	44	14	44	46.62	(37.07, 57.29)
	ADALIMUMAB	108	31	12	65	30.86	(22.79, 40.95)
	TOTAL	210	75	26	109	38.45	(31.99, 45.72)
MONTH 9							
	PLACEBO	102	48	21	33	51.92	(42.00, 62.64)
	ADALIMUMAB	108	38	18	52	38.71	(29.80, 49.20)
	TOTAL	210	86	39	85	45.12	(38.27, 52.58)
MONTH 12							
	PLACEBO	102	54	24	24	61.05	(50.55, 71.70)
	ADALIMUMAB	108	44	25	39	46.32	(36.72, 57.09)
	TOTAL	210	98	49	63	53.35	(46.10, 60.96)
MONTH 18							
	PLACEBO	102	57	29	16	66.21	(55.46, 76.68)
	ADALIMUMAB	108	44	37	27	46.32	(36.72, 57.09)
	TOTAL	210	101	66	43	55.70	(48.33, 63.35)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.33.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	42	21	4	17	52.06	(37.76, 68.02)
	ADALIMUMAB	32	11	2	19	35.58	(21.50, 55.01)
	TOTAL	74	32	6	36	44.96	(34.26, 57.25)
MONTH 6							
	PLACEBO	42	25	7	10	64.55	(49.28, 79.49)
	ADALIMUMAB	32	16	2	14	52.53	(36.24, 70.87)
	TOTAL	74	41	9	24	59.51	(48.04, 71.31)
MONTH 9							
	PLACEBO	42	26	12	4	68.49	(52.83, 83.05)
	ADALIMUMAB	32	18	3	11	59.31	(42.66, 76.64)
	TOTAL	74	44	15	15	64.96	(53.33, 76.38)
MONTH 12							
	PLACEBO	42	27	12	3	76.37	(57.52, 91.20)
	ADALIMUMAB	32	22	6	4	77.22	(59.28, 91.24)
	TOTAL	74	49	18	7	78.10	(65.53, 88.53)
MONTH 18							
	PLACEBO	42	27	13	2	76.37	(57.52, 91.20)
	ADALIMUMAB	32	22	7	3	77.22	(59.28, 91.24)
	TOTAL	74	49	20	5	78.10	(65.53, 88.53)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.34.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	85	17	5	63	20.99	(13.60, 31.58)
	ADALIMUMAB	99	11	6	82	11.58	(6.58, 19.94)
	TOTAL	184	28	11	145	15.87	(11.24, 22.16)
MONTH 6							
	PLACEBO	85	35	9	41	44.02	(33.89, 55.66)
	ADALIMUMAB	99	25	14	60	27.47	(19.44, 37.94)
	TOTAL	184	60	23	101	35.13	(28.45, 42.84)
MONTH 9							
	PLACEBO	85	39	14	32	50.06	(39.44, 61.75)
	ADALIMUMAB	99	32	20	47	36.57	(27.34, 47.75)
	TOTAL	184	71	34	79	42.80	(35.58, 50.83)
MONTH 12							
	PLACEBO	85	45	17	23	59.85	(48.67, 71.30)
	ADALIMUMAB	99	34	25	40	39.49	(29.89, 50.86)
	TOTAL	184	79	42	63	48.94	(41.35, 57.12)
MONTH 18							
	PLACEBO	85	48	22	15	65.17	(53.82, 76.31)
	ADALIMUMAB	99	35	36	28	41.12	(31.31, 52.64)
	TOTAL	184	83	58	43	52.33	(44.55, 60.59)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.35.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)
MONTH 3						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	3	0	0	3	0
	TOTAL	4	1	0	3	25
MONTH 6						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	3	0	1	2	0
	TOTAL	4	1	1	2	25
MONTH 9						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	3	0	2	1	0
	TOTAL	4	1	2	1	25
MONTH 12						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	3	0	2	1	0
	TOTAL	4	1	2	1	25
MONTH 18						
	PLACEBO	1	1	0	0	100
	ADALIMUMAB	3	0	2	1	0
	TOTAL	4	1	2	1	25

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.36.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	126	37	9	80	30.69	(23.28, 39.78)
	ADALIMUMAB	128	22	8	98	17.89	(12.16, 25.89)
	TOTAL	254	59	17	178	24.18	(19.28, 30.07)
MONTH 6							
	PLACEBO	126	59	16	51	50.57	(41.81, 60.02)
	ADALIMUMAB	128	41	15	72	34.44	(26.62, 43.77)
	TOTAL	254	100	31	123	42.35	(36.29, 48.97)
MONTH 9							
	PLACEBO	126	64	26	36	56.02	(46.97, 65.47)
	ADALIMUMAB	128	50	21	57	43.03	(34.52, 52.66)
	TOTAL	254	114	47	93	49.46	(43.10, 56.21)
MONTH 12							
	PLACEBO	126	71	29	26	64.87	(55.42, 74.19)
	ADALIMUMAB	128	56	29	43	49.55	(40.56, 59.33)
	TOTAL	254	127	58	69	56.97	(50.34, 63.79)
MONTH 18							
	PLACEBO	126	74	35	17	69.15	(59.55, 78.30)
	ADALIMUMAB	128	57	41	30	50.81	(41.72, 60.64)
	TOTAL	254	131	76	47	59.61	(52.88, 66.45)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.37.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	37	10	2	25	28.57	(16.52, 46.59)
	ADALIMUMAB	33	5	2	26	15.95	(6.96, 34.18)
	TOTAL	70	15	4	51	22.50	(14.22, 34.53)
MONTH 6							
	PLACEBO	37	18	3	16	52.38	(36.97, 69.65)
	ADALIMUMAB	33	9	4	20	29.19	(16.35, 48.67)
	TOTAL	70	27	7	36	41.27	(30.42, 54.19)
MONTH 9							
	PLACEBO	37	20	7	10	59.08	(43.10, 75.72)
	ADALIMUMAB	33	12	5	16	40.37	(25.15, 60.25)
	TOTAL	70	32	12	26	50.34	(38.64, 63.32)
MONTH 12							
	PLACEBO	37	22	8	7	67.77	(50.81, 83.59)
	ADALIMUMAB	33	12	7	14	40.37	(25.15, 60.25)
	TOTAL	70	34	15	21	54.32	(42.30, 67.25)
MONTH 18							
	PLACEBO	37	22	10	5	67.77	(50.81, 83.59)
	ADALIMUMAB	33	13	10	10	44.96	(28.75, 65.06)
	TOTAL	70	35	20	15	56.61	(44.36, 69.54)

Program Source Code: [redacted]

TABLE 14.2__2000.1.1.3.38.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	55	9	5	41	17.20	(9.34, 30.48)
	ADALIMUMAB	64	7	6	51	11.59	(5.69, 22.80)
	TOTAL	119	16	11	92	14.13	(8.90, 22.04)
MONTH 6							
	PLACEBO	55	19	10	26	38.42	(26.38, 53.57)
	ADALIMUMAB	64	17	11	36	30.22	(19.92, 44.16)
	TOTAL	119	36	21	62	34.00	(25.77, 43.98)
MONTH 9							
	PLACEBO	55	22	13	20	46.14	(32.99, 61.58)
	ADALIMUMAB	64	21	15	28	38.51	(26.92, 52.96)
	TOTAL	119	43	28	48	41.95	(32.93, 52.32)
MONTH 12							
	PLACEBO	55	27	15	13	60.32	(45.75, 75.28)
	ADALIMUMAB	64	23	17	24	42.91	(30.74, 57.48)
	TOTAL	119	50	32	37	50.62	(40.95, 61.15)
MONTH 18							
	PLACEBO	55	29	15	11	66.43	(51.56, 80.67)
	ADALIMUMAB	64	23	25	16	42.91	(30.74, 57.48)
	TOTAL	119	52	40	27	53.45	(43.55, 64.02)

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BSL VALUE	PLO	45	0.11	0.210	0.0	0.00	0.00	0.00	0.5			
	ADA	56	0.13	0.218	0.0	0.00	0.00	0.25	0.5			
	TOT	101	0.12	0.214	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	45	0.73	1.156	0.0	0.00	0.00	1.00	4.0			
	ADA	56	0.64	1.034	0.0	0.00	0.00	0.75	3.0			
	TOT	101	0.68	1.086	0.0	0.00	0.00	1.00	4.0			
CHG FROM BSL	PLO	45	0.62	1.124	-0.5	0.00	0.00	1.00	4.0			
	ADA	56	0.52	1.004	-0.5	0.00	0.00	0.75	3.0			
	TOT	101	0.56	1.055	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BSL VALUE	PLO	45	0.10	0.202	0.0	0.00	0.00	0.00	0.5			
	ADA	56	0.11	0.207	0.0	0.00	0.00	0.00	0.5			
	TOT	101	0.10	0.204	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	45	0.58	0.929	0.0	0.00	0.00	1.00	3.0			
	ADA	56	0.34	0.626	0.0	0.00	0.00	0.50	3.0			
	TOT	101	0.45	0.781	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	45	0.48	0.898	-0.5	0.00	0.00	0.50	3.0			
	ADA	56	0.23	0.618	-0.5	0.00	0.00	0.25	2.5			
	TOT	101	0.34	0.761	-0.5	0.00	0.00	0.50	3.0			
										-0.18	(-0.48, 0.13)	0.256A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BSL VALUE	PLO	45	0.20	0.248	0.0	0.00	0.00	0.50	0.5			
	ADA	56	0.17	0.239	0.0	0.00	0.00	0.50	0.5			
	TOT	101	0.18	0.242	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	45	0.81	0.996	0.0	0.00	0.50	1.00	4.0			
	ADA	56	0.49	0.717	0.0	0.00	0.00	1.00	3.0			
	TOT	101	0.63	0.863	0.0	0.00	0.50	1.00	4.0			
CHG FROM BSL	PLO	45	0.61	1.005	-0.5	0.00	0.00	0.50	4.0			
	ADA	56	0.32	0.690	-0.5	0.00	0.00	0.50	2.5			
	TOT	101	0.45	0.853	-0.5	0.00	0.00	0.50	4.0			
VH RIGHT EYE												
BSL VALUE	PLO	45	0.20	0.248	0.0	0.00	0.00	0.50	0.5			
	ADA	56	0.13	0.218	0.0	0.00	0.00	0.25	0.5			
	TOT	101	0.16	0.234	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	45	0.53	0.686	0.0	0.00	0.50	1.00	3.0			
	ADA	56	0.39	0.659	0.0	0.00	0.00	0.50	2.0			
	TOT	101	0.46	0.671	0.0	0.00	0.00	1.00	3.0			
CHG FROM BSL	PLO	45	0.33	0.657	-0.5	0.00	0.00	0.50	2.5			
	ADA	56	0.27	0.674	-0.5	0.00	0.00	0.50	2.0			
	TOT	101	0.30	0.664	-0.5	0.00	0.00	0.50	2.5			
										-0.18	(-0.43, 0.07)	0.158A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BSL VALUE	PLO	45	0.15	0.282	-0.26	-0.02	0.08	0.24	1.20			
	ADA	56	0.14	0.246	-0.28	-0.02	0.08	0.24	0.76			
	TOT	101	0.14	0.261	-0.28	-0.02	0.08	0.24	1.20			
FINAL/ET VALUE	PLO	45	0.26	0.447	-0.30	-0.02	0.14	0.52	1.78			
	ADA	56	0.18	0.379	-0.30	-0.07	0.10	0.31	2.08			
	TOT	101	0.22	0.411	-0.30	-0.06	0.10	0.38	2.08			
CHG FROM BSL	PLO	45	0.12	0.264	-0.10	-0.02	0.02	0.16	1.36			
	ADA	56	0.04	0.301	-0.28	-0.07	-0.01	0.04	1.98			
	TOT	101	0.07	0.286	-0.28	-0.04	0.00	0.06	1.98			
LOGMAR RIGHT EYE												
BSL VALUE	PLO	45	0.17	0.258	-0.16	0.00	0.08	0.32	0.90			
	ADA	56	0.08	0.157	-0.24	-0.02	0.04	0.14	0.58			
	TOT	101	0.12	0.212	-0.24	-0.02	0.04	0.20	0.90			
FINAL/ET VALUE	PLO	45	0.23	0.363	-0.18	0.02	0.12	0.36	1.62			
	ADA	56	0.08	0.191	-0.28	-0.04	0.03	0.19	0.78			
	TOT	101	0.15	0.290	-0.28	-0.02	0.06	0.24	1.62			
CHG FROM BSL	PLO	45	0.07	0.240	-0.16	-0.04	0.02	0.08	1.26			
	ADA	56	0.00	0.132	-0.40	-0.06	-0.02	0.09	0.36			
	TOT	101	0.03	0.190	-0.40	-0.06	0.00	0.08	1.26			
										-0.07	(-0.15, 0.00)	0.052A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BSL	PLO	42	9.5	24.63	-19.4	-2.2	1.3	7.6	105.6			
	ADA	55	11.1	37.41	-25.7	-6.5	-1.4	6.0	165.6			
	TOT	97	10.4	32.35	-25.7	-3.9	0.0	7.3	165.6			
CRT RIGHT EYE												
%CHG FROM BSL	PLO	43	7.5	20.21	-18.1	-2.8	2.2	9.4	81.4			
	ADA	54	6.8	31.13	-27.5	-4.2	0.5	3.8	140.9			
	TOT	97	7.1	26.72	-27.5	-3.6	0.9	6.8	140.9			
										-0.1	(-9.7, 9.4)	0.977A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.2.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BSL VALUE	PLO	81	0.10	0.200	0.0	0.00	0.00	0.00	0.5			
	ADA	75	0.10	0.201	0.0	0.00	0.00	0.00	0.5			
	TOT	156	0.10	0.200	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	81	0.70	0.977	0.0	0.00	0.00	1.00	3.0			
	ADA	75	0.51	0.973	0.0	0.00	0.00	0.50	4.0			
	TOT	156	0.61	0.976	0.0	0.00	0.00	1.00	4.0			
CHG FROM BSL	PLO	81	0.60	0.940	-0.5	0.00	0.00	1.00	3.0			
	ADA	75	0.41	0.994	-0.5	0.00	0.00	0.50	4.0			
	TOT	156	0.51	0.968	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BSL VALUE	PLO	81	0.10	0.200	0.0	0.00	0.00	0.00	0.5			
	ADA	75	0.12	0.215	0.0	0.00	0.00	0.00	0.5			
	TOT	156	0.11	0.207	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	81	0.77	1.110	0.0	0.00	0.00	2.00	3.0			
	ADA	75	0.72	1.104	0.0	0.00	0.00	2.00	3.0			
	TOT	156	0.74	1.103	0.0	0.00	0.00	2.00	3.0			
CHG FROM BSL	PLO	81	0.67	1.040	-0.5	0.00	0.00	1.50	3.0			
	ADA	75	0.60	1.115	-0.5	0.00	0.00	2.00	3.0			
	TOT	156	0.63	1.074	-0.5	0.00	0.00	1.50	3.0			
										-0.13	(-0.42, 0.17)	0.404A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.2.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BSL VALUE	PLO	81	0.12	0.213	0.0	0.00	0.00	0.00	0.5			
	ADA	75	0.19	0.243	0.0	0.00	0.00	0.50	0.5			
	TOT	156	0.15	0.230	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	81	0.32	0.502	0.0	0.00	0.00	0.50	2.0			
	ADA	75	0.25	0.529	0.0	0.00	0.00	0.00	2.0			
	TOT	156	0.29	0.514	0.0	0.00	0.00	0.50	2.0			
CHG FROM BSL	PLO	81	0.20	0.511	-0.5	0.00	0.00	0.50	2.0			
	ADA	75	0.07	0.528	-0.5	0.00	0.00	0.00	2.0			
	TOT	156	0.14	0.522	-0.5	0.00	0.00	0.00	2.0			
VH RIGHT EYE												
BSL VALUE	PLO	81	0.14	0.224	0.0	0.00	0.00	0.50	0.5			
	ADA	75	0.19	0.243	0.0	0.00	0.00	0.50	0.5			
	TOT	156	0.16	0.234	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	81	0.51	0.823	0.0	0.00	0.00	0.50	3.0			
	ADA	75	0.31	0.586	0.0	0.00	0.00	0.50	3.0			
	TOT	156	0.41	0.724	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	81	0.37	0.770	-0.5	0.00	0.00	0.50	3.0			
	ADA	75	0.12	0.538	-0.5	0.00	0.00	0.00	2.5			
	TOT	156	0.25	0.678	-0.5	0.00	0.00	0.50	3.0			
										-0.19	(-0.36, -0.02)	0.025A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.2.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BSL VALUE	PLO	81	0.18	0.277	-0.18	-0.02	0.10	0.24	1.24			
	ADA	75	0.16	0.266	-0.16	-0.04	0.08	0.24	1.04			
	TOT	156	0.17	0.271	-0.18	-0.02	0.10	0.24	1.24			
FINAL/ET VALUE	PLO	81	0.22	0.338	-0.20	-0.02	0.14	0.34	1.30			
	ADA	75	0.16	0.308	-0.18	-0.06	0.06	0.24	1.20			
	TOT	156	0.19	0.325	-0.20	-0.04	0.12	0.30	1.30			
CHG FROM BSL	PLO	81	0.04	0.205	-0.64	-0.06	0.00	0.12	0.70			
	ADA	75	0.00	0.184	-0.58	-0.08	-0.02	0.04	0.88			
	TOT	156	0.02	0.196	-0.64	-0.08	0.00	0.10	0.88			
LOGMAR RIGHT EYE												
BSL VALUE	PLO	81	0.16	0.261	-0.10	0.00	0.06	0.24	1.20			
	ADA	75	0.17	0.261	-0.18	-0.02	0.08	0.34	1.16			
	TOT	156	0.17	0.261	-0.18	0.00	0.07	0.29	1.20			
FINAL/ET VALUE	PLO	81	0.19	0.314	-0.20	0.00	0.12	0.30	1.30			
	ADA	75	0.18	0.354	-0.26	-0.06	0.04	0.34	1.48			
	TOT	156	0.18	0.333	-0.26	-0.04	0.10	0.31	1.48			
CHG FROM BSL	PLO	81	0.03	0.202	-0.52	-0.08	0.00	0.10	0.96			
	ADA	75	0.01	0.193	-0.42	-0.10	0.00	0.06	0.94			
	TOT	156	0.02	0.198	-0.52	-0.10	0.00	0.08	0.96			
										-0.03	(-0.08, 0.02)	0.269A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.2.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BSL	PLO	80	4.6	16.56	-46.1	-1.8	1.0	9.0	73.2			
	ADA	75	0.8	22.21	-61.7	-4.4	0.0	3.4	117.7			
	TOT	155	2.8	19.52	-61.7	-3.5	0.7	6.4	117.7			
CRT RIGHT EYE												
%CHG FROM BSL	PLO	81	11.1	35.19	-40.4	-1.0	1.7	9.8	232.5			
	ADA	75	1.8	34.90	-63.4	-7.0	-1.3	2.0	260.7			
	TOT	156	6.6	35.25	-63.4	-3.8	0.4	6.2	260.7			
										-7.0	(-14.1, 0.1)	0.055A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.3.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BSL VALUE	PLO	27	0.09	0.198	0.0	0.00	0.00	0.00	0.5			
	ADA	21	0.21	0.254	0.0	0.00	0.00	0.50	0.5			
	TOT	48	0.15	0.230	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	27	0.76	1.155	0.0	0.00	0.00	1.00	4.0			
	ADA	21	0.62	1.060	0.0	0.00	0.00	0.50	3.0			
	TOT	48	0.70	1.105	0.0	0.00	0.00	1.00	4.0			
CHG FROM BSL	PLO	27	0.67	1.135	-0.5	0.00	0.00	1.00	4.0			
	ADA	21	0.40	1.068	-0.5	-0.50	0.00	0.50	2.5			
	TOT	48	0.55	1.102	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BSL VALUE	PLO	27	0.07	0.181	0.0	0.00	0.00	0.00	0.5			
	ADA	21	0.24	0.256	0.0	0.00	0.00	0.50	0.5			
	TOT	48	0.15	0.230	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	27	0.87	1.214	0.0	0.00	0.00	2.00	3.0			
	ADA	21	0.69	1.134	0.0	0.00	0.00	0.50	3.0			
	TOT	48	0.79	1.171	0.0	0.00	0.00	2.00	3.0			
CHG FROM BSL	PLO	27	0.80	1.137	-0.5	0.00	0.00	2.00	3.0			
	ADA	21	0.45	1.060	-0.5	0.00	0.00	0.50	2.5			
	TOT	48	0.65	1.106	-0.5	0.00	0.00	1.75	3.0			
										-0.30	(-0.91, 0.30)	0.317A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.3.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BSL VALUE	PLO	27	0.15	0.233	0.0	0.00	0.00	0.50	0.5			
	ADA	21	0.29	0.254	0.0	0.00	0.50	0.50	0.5			
	TOT	48	0.21	0.249	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	27	0.48	0.714	0.0	0.00	0.00	1.00	3.0			
	ADA	21	0.38	0.705	0.0	0.00	0.00	0.50	3.0			
	TOT	48	0.44	0.704	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	27	0.33	0.679	-0.5	0.00	0.00	0.50	2.5			
	ADA	21	0.10	0.682	-0.5	-0.50	0.00	0.00	2.5			
	TOT	48	0.23	0.684	-0.5	0.00	0.00	0.50	2.5			
VH RIGHT EYE												
BSL VALUE	PLO	27	0.19	0.246	0.0	0.00	0.00	0.50	0.5			
	ADA	21	0.24	0.256	0.0	0.00	0.00	0.50	0.5			
	TOT	48	0.21	0.249	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	27	0.67	0.899	0.0	0.00	0.50	1.00	3.0			
	ADA	21	0.21	0.338	0.0	0.00	0.00	0.50	1.0			
	TOT	48	0.47	0.740	0.0	0.00	0.00	0.75	3.0			
CHG FROM BSL	PLO	27	0.48	0.814	-0.5	0.00	0.00	1.00	2.5			
	ADA	21	-0.02	0.335	-0.5	0.00	0.00	0.00	0.5			
	TOT	48	0.26	0.692	-0.5	0.00	0.00	0.50	2.5			
										-0.37	(-0.69, -0.05)	0.024A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.3.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BSL VALUE	PLO	27	0.08	0.271	-0.18	-0.06	0.02	0.10	1.20			
	ADA	21	0.16	0.225	-0.16	0.00	0.14	0.30	0.82			
	TOT	48	0.12	0.253	-0.18	-0.02	0.05	0.21	1.20			
FINAL/ET VALUE	PLO	27	0.12	0.401	-0.24	-0.12	0.00	0.22	1.68			
	ADA	21	0.15	0.229	-0.14	0.00	0.12	0.24	0.72			
	TOT	48	0.14	0.334	-0.24	-0.08	0.05	0.23	1.68			
CHG FROM BSL	PLO	27	0.04	0.210	-0.32	-0.08	-0.02	0.12	0.70			
	ADA	21	-0.01	0.196	-0.58	-0.08	-0.02	0.06	0.32			
	TOT	48	0.02	0.204	-0.58	-0.08	-0.02	0.08	0.70			
LOGMAR RIGHT EYE												
BSL VALUE	PLO	27	0.07	0.259	-0.16	-0.06	0.00	0.04	1.20			
	ADA	21	0.19	0.321	-0.14	-0.02	0.08	0.34	1.16			
	TOT	48	0.12	0.291	-0.16	-0.04	0.02	0.19	1.20			
FINAL/ET VALUE	PLO	27	0.16	0.443	-0.20	-0.02	0.02	0.24	1.62			
	ADA	21	0.18	0.395	-0.16	0.00	0.04	0.20	1.48			
	TOT	48	0.17	0.418	-0.20	-0.02	0.02	0.22	1.62			
CHG FROM BSL	PLO	27	0.10	0.298	-0.22	-0.04	0.00	0.10	1.26			
	ADA	21	-0.01	0.161	-0.42	-0.04	-0.02	0.08	0.32			
	TOT	48	0.05	0.251	-0.42	-0.04	0.00	0.09	1.26			
										-0.08	(-0.20, 0.03)	0.153A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.3.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BSL	PLO	26	2.6	6.05	-9.4	-1.3	1.5	8.0	15.1			
	ADA	21	5.5	37.85	-61.7	-5.6	0.0	2.8	117.7			
	TOT	47	3.9	25.40	-61.7	-2.2	1.1	5.8	117.7			
CRT RIGHT EYE												
%CHG FROM BSL	PLO	27	7.3	25.09	-30.4	-3.0	3.0	9.3	81.4			
	ADA	20	-0.5	29.48	-63.4	-4.8	0.0	4.4	64.9			
	TOT	47	4.0	27.01	-63.4	-3.7	0.7	8.6	81.4			
										-3.4	(-17.5, 10.6)	0.627A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.4.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BSL VALUE	PLO	58	0.11	0.210	0.0	0.00	0.00	0.00	0.5			
	ADA	64	0.09	0.190	0.0	0.00	0.00	0.00	0.5			
	TOT	122	0.10	0.200	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	58	0.81	1.143	0.0	0.00	0.00	2.00	4.0			
	ADA	64	0.44	0.898	0.0	0.00	0.00	0.50	4.0			
	TOT	122	0.61	1.034	0.0	0.00	0.00	1.00	4.0			
CHG FROM BSL	PLO	58	0.70	1.088	-0.5	0.00	0.00	1.50	4.0			
	ADA	64	0.35	0.903	-0.5	0.00	0.00	0.00	4.0			
	TOT	122	0.52	1.006	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BSL VALUE	PLO	58	0.10	0.204	0.0	0.00	0.00	0.00	0.5			
	ADA	64	0.09	0.190	0.0	0.00	0.00	0.00	0.5			
	TOT	122	0.09	0.196	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	58	0.70	1.034	0.0	0.00	0.00	1.00	3.0			
	ADA	64	0.41	0.854	0.0	0.00	0.00	0.50	3.0			
	TOT	122	0.55	0.951	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	58	0.59	0.975	-0.5	0.00	0.00	1.00	3.0			
	ADA	64	0.32	0.875	-0.5	0.00	0.00	0.00	3.0			
	TOT	122	0.45	0.930	-0.5	0.00	0.00	0.50	3.0			
										-0.31	(-0.61, -0.01)	0.041A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.4.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BSL VALUE	PLO	58	0.16	0.237	0.0	0.00	0.00	0.50	0.5			
	ADA	64	0.15	0.230	0.0	0.00	0.00	0.50	0.5			
	TOT	122	0.16	0.233	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	58	0.52	0.832	0.0	0.00	0.00	0.50	4.0			
	ADA	64	0.35	0.659	0.0	0.00	0.00	0.50	2.0			
	TOT	122	0.43	0.748	0.0	0.00	0.00	0.50	4.0			
CHG FROM BSL	PLO	58	0.35	0.811	-0.5	0.00	0.00	0.50	4.0			
	ADA	64	0.20	0.641	-0.5	0.00	0.00	0.00	2.0			
	TOT	122	0.27	0.728	-0.5	0.00	0.00	0.50	4.0			
VH RIGHT EYE												
BSL VALUE	PLO	58	0.15	0.230	0.0	0.00	0.00	0.50	0.5			
	ADA	64	0.13	0.223	0.0	0.00	0.00	0.50	0.5			
	TOT	122	0.14	0.225	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	58	0.39	0.593	0.0	0.00	0.00	0.50	3.0			
	ADA	64	0.29	0.562	0.0	0.00	0.00	0.50	2.0			
	TOT	122	0.34	0.577	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	58	0.24	0.548	-0.5	0.00	0.00	0.50	2.5			
	ADA	64	0.16	0.563	-0.5	0.00	0.00	0.00	2.0			
	TOT	122	0.20	0.555	-0.5	0.00	0.00	0.50	2.5			
										-0.12	(-0.32, 0.08)	0.245A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.4.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BSL VALUE	PLO	58	0.22	0.323	-0.26	-0.02	0.12	0.40	1.24			
	ADA	64	0.12	0.266	-0.28	-0.06	0.02	0.22	0.96			
	TOT	122	0.17	0.298	-0.28	-0.04	0.08	0.28	1.24			
FINAL/ET VALUE	PLO	58	0.30	0.425	-0.30	0.00	0.16	0.60	1.78			
	ADA	64	0.14	0.401	-0.30	-0.10	0.00	0.26	2.08			
	TOT	122	0.22	0.419	-0.30	-0.08	0.11	0.36	2.08			
CHG FROM BSL	PLO	58	0.08	0.245	-0.20	-0.06	0.00	0.14	1.36			
	ADA	64	0.02	0.289	-0.30	-0.08	-0.04	0.03	1.98			
	TOT	122	0.05	0.269	-0.30	-0.08	0.00	0.06	1.98			
LOGMAR RIGHT EYE												
BSL VALUE	PLO	58	0.20	0.274	-0.16	-0.02	0.10	0.40	1.00			
	ADA	64	0.11	0.227	-0.24	-0.04	0.03	0.19	0.88			
	TOT	122	0.15	0.253	-0.24	-0.02	0.04	0.26	1.00			
FINAL/ET VALUE	PLO	58	0.19	0.278	-0.20	-0.04	0.14	0.36	1.06			
	ADA	64	0.08	0.271	-0.28	-0.09	0.00	0.20	1.10			
	TOT	122	0.13	0.279	-0.28	-0.06	0.07	0.26	1.10			
CHG FROM BSL	PLO	58	0.00	0.156	-0.52	-0.08	0.00	0.04	0.52			
	ADA	64	-0.03	0.145	-0.40	-0.12	-0.04	0.04	0.44			
	TOT	122	-0.02	0.150	-0.52	-0.10	-0.02	0.04	0.52			
										-0.04	(-0.10, 0.02)	0.154A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.4.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BSL	PLO	56	8.6	23.65	-27.5	-2.1	1.6	10.2	105.6			
	ADA	63	7.2	31.40	-25.7	-4.9	-0.8	5.3	165.6			
	TOT	119	7.9	27.92	-27.5	-3.9	0.0	8.0	165.6			
CRT RIGHT EYE												
%CHG FROM BSL	PLO	56	8.4	17.20	-10.2	-0.6	3.1	11.5	101.1			
	ADA	63	2.2	21.37	-22.5	-4.3	0.4	2.8	127.1			
	TOT	119	5.1	19.68	-22.5	-2.9	0.8	6.8	127.1			
										-3.8	(-11.0, 3.5)	0.309A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.5.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BSL VALUE	PLO	41	0.10	0.201	0.0	0.00	0.00	0.00	0.5			
	ADA	46	0.10	0.201	0.0	0.00	0.00	0.00	0.5			
	TOT	87	0.10	0.199	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	41	0.54	0.778	0.0	0.00	0.00	1.00	3.0			
	ADA	46	0.73	1.094	0.0	0.00	0.00	1.00	3.0			
	TOT	87	0.64	0.957	0.0	0.00	0.00	1.00	3.0			
CHG FROM BSL	PLO	41	0.44	0.768	-0.5	0.00	0.00	0.50	3.0			
	ADA	46	0.63	1.082	-0.5	0.00	0.00	1.00	3.0			
	TOT	87	0.54	0.947	-0.5	0.00	0.00	1.00	3.0			
AC RIGHT EYE												
BSL VALUE	PLO	41	0.11	0.210	0.0	0.00	0.00	0.00	0.5			
	ADA	46	0.10	0.201	0.0	0.00	0.00	0.00	0.5			
	TOT	87	0.10	0.204	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	41	0.59	0.961	0.0	0.00	0.00	1.00	3.0			
	ADA	46	0.71	0.964	0.0	0.00	0.00	1.00	3.0			
	TOT	87	0.65	0.959	0.0	0.00	0.00	1.00	3.0			
CHG FROM BSL	PLO	41	0.48	0.915	-0.5	0.00	0.00	0.50	3.0			
	ADA	46	0.61	0.994	-0.5	0.00	0.00	1.00	3.0			
	TOT	87	0.55	0.954	-0.5	0.00	0.00	1.00	3.0			
										0.16	(-0.20, 0.52)	0.373A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.5.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BSL VALUE	PLO	41	0.12	0.217	0.0	0.00	0.00	0.00	0.5			
	ADA	46	0.17	0.241	0.0	0.00	0.00	0.50	0.5			
	TOT	87	0.15	0.230	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	41	0.48	0.670	0.0	0.00	0.00	1.00	3.0			
	ADA	46	0.35	0.546	0.0	0.00	0.00	1.00	2.0			
	TOT	87	0.41	0.608	0.0	0.00	0.00	1.00	3.0			
CHG FROM BSL	PLO	41	0.35	0.718	-0.5	0.00	0.00	0.50	3.0			
	ADA	46	0.17	0.550	-0.5	0.00	0.00	0.50	2.0			
	TOT	87	0.26	0.637	-0.5	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BSL VALUE	PLO	41	0.16	0.236	0.0	0.00	0.00	0.50	0.5			
	ADA	46	0.16	0.237	0.0	0.00	0.00	0.50	0.5			
	TOT	87	0.16	0.235	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	41	0.60	0.896	0.0	0.00	0.00	1.00	3.0			
	ADA	46	0.48	0.760	0.0	0.00	0.00	1.00	3.0			
	TOT	87	0.53	0.824	0.0	0.00	0.00	1.00	3.0			
CHG FROM BSL	PLO	41	0.44	0.875	-0.5	0.00	0.00	0.50	3.0			
	ADA	46	0.32	0.718	-0.5	0.00	0.00	0.50	2.5			
	TOT	87	0.37	0.793	-0.5	0.00	0.00	0.50	3.0			
										-0.15	(-0.42, 0.11)	0.259A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.5.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BSL VALUE	PLO	41	0.14	0.187	-0.12	0.02	0.12	0.22	0.56			
	ADA	46	0.19	0.257	-0.16	0.00	0.10	0.32	1.04			
	TOT	87	0.17	0.226	-0.16	0.02	0.10	0.24	1.04			
FINAL/ET VALUE	PLO	41	0.22	0.270	-0.12	0.06	0.16	0.34	1.18			
	ADA	46	0.22	0.284	-0.16	0.00	0.10	0.36	0.98			
	TOT	87	0.22	0.276	-0.16	0.00	0.14	0.36	1.18			
CHG FROM BSL	PLO	41	0.07	0.224	-0.64	0.00	0.04	0.14	0.66			
	ADA	46	0.03	0.183	-0.24	-0.06	0.00	0.04	0.88			
	TOT	87	0.05	0.203	-0.64	-0.02	0.02	0.10	0.88			
LOGMAR RIGHT EYE												
BSL VALUE	PLO	41	0.18	0.226	-0.10	0.02	0.12	0.28	0.90			
	ADA	46	0.13	0.168	-0.12	0.00	0.08	0.24	0.64			
	TOT	87	0.15	0.198	-0.12	0.00	0.10	0.24	0.90			
FINAL/ET VALUE	PLO	41	0.24	0.320	-0.14	0.06	0.14	0.34	1.30			
	ADA	46	0.19	0.281	-0.20	0.00	0.10	0.34	1.16			
	TOT	87	0.21	0.300	-0.20	0.00	0.12	0.34	1.30			
CHG FROM BSL	PLO	41	0.06	0.220	-0.48	-0.06	0.04	0.14	0.96			
	ADA	46	0.06	0.194	-0.18	-0.04	0.02	0.12	0.94			
	TOT	87	0.06	0.205	-0.48	-0.06	0.02	0.12	0.96			
										-0.03	(-0.10, 0.05)	0.499A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.5.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BSL	PLO	40	5.4	19.49	-46.1	-2.2	0.8	10.5	69.7			
	ADA	46	2.3	23.56	-50.9	-5.9	0.0	5.3	95.1			
	TOT	86	3.7	21.69	-50.9	-3.8	0.4	7.3	95.1			
CRT RIGHT EYE												
%CHG FROM BSL	PLO	41	13.6	45.57	-40.4	-3.1	0.8	7.0	232.5			
	ADA	46	8.1	46.21	-27.5	-6.9	-2.7	2.1	260.7			
	TOT	87	10.7	45.73	-40.4	-5.4	-0.4	5.7	260.7			
										-4.8	(-16.2, 6.6)	0.409A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.6.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BSL VALUE	PLO	92	0.09	0.195	0.0	0.00	0.00	0.00	0.5			
	ADA	96	0.10	0.200	0.0	0.00	0.00	0.00	0.5			
	TOT	188	0.10	0.197	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	92	0.59	1.002	0.0	0.00	0.00	1.00	4.0			
	ADA	96	0.49	0.940	0.0	0.00	0.00	0.50	3.0			
	TOT	188	0.54	0.969	0.0	0.00	0.00	0.50	4.0			
CHG FROM BSL	PLO	92	0.49	0.982	-0.5	0.00	0.00	0.50	4.0			
	ADA	96	0.39	0.949	-0.5	0.00	0.00	0.00	3.0			
	TOT	188	0.44	0.964	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BSL VALUE	PLO	92	0.09	0.191	0.0	0.00	0.00	0.00	0.5			
	ADA	96	0.11	0.211	0.0	0.00	0.00	0.00	0.5			
	TOT	188	0.10	0.201	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	92	0.61	1.049	0.0	0.00	0.00	0.75	3.0			
	ADA	96	0.43	0.785	0.0	0.00	0.00	0.50	3.0			
	TOT	188	0.52	0.926	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	92	0.53	0.990	-0.5	0.00	0.00	0.50	3.0			
	ADA	96	0.31	0.799	-0.5	0.00	0.00	0.50	3.0			
	TOT	188	0.42	0.901	-0.5	0.00	0.00	0.50	3.0			
										-0.16	(-0.40, 0.08)	0.189A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.6.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BSL VALUE	PLO	92	0.14	0.224	0.0	0.00	0.00	0.50	0.5			
	ADA	96	0.17	0.237	0.0	0.00	0.00	0.50	0.5			
	TOT	188	0.15	0.230	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	92	0.50	0.777	0.0	0.00	0.00	1.00	4.0			
	ADA	96	0.36	0.630	0.0	0.00	0.00	0.50	3.0			
	TOT	188	0.43	0.707	0.0	0.00	0.00	0.75	4.0			
CHG FROM BSL	PLO	92	0.36	0.788	-0.5	0.00	0.00	0.50	4.0			
	ADA	96	0.20	0.630	-0.5	0.00	0.00	0.50	2.5			
	TOT	188	0.28	0.715	-0.5	0.00	0.00	0.50	4.0			
VH RIGHT EYE												
BSL VALUE	PLO	92	0.15	0.229	0.0	0.00	0.00	0.50	0.5			
	ADA	96	0.15	0.228	0.0	0.00	0.00	0.50	0.5			
	TOT	188	0.15	0.228	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	92	0.45	0.665	0.0	0.00	0.00	0.75	3.0			
	ADA	96	0.34	0.618	0.0	0.00	0.00	0.50	3.0			
	TOT	188	0.39	0.642	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	92	0.30	0.642	-0.5	0.00	0.00	0.50	2.5			
	ADA	96	0.19	0.609	-0.5	0.00	0.00	0.25	2.5			
	TOT	188	0.24	0.626	-0.5	0.00	0.00	0.50	2.5			
										-0.14	(-0.30, 0.03)	0.104A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.6.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BSL VALUE	PLO	92	0.15	0.274	-0.26	-0.02	0.09	0.23	1.24			
	ADA	96	0.14	0.257	-0.28	-0.04	0.07	0.24	1.04			
	TOT	188	0.14	0.265	-0.28	-0.03	0.08	0.24	1.24			
FINAL/ET VALUE	PLO	92	0.21	0.386	-0.30	-0.04	0.12	0.32	1.78			
	ADA	96	0.16	0.350	-0.30	-0.07	0.04	0.25	2.08			
	TOT	188	0.18	0.368	-0.30	-0.04	0.08	0.28	2.08			
CHG FROM BSL	PLO	92	0.07	0.246	-0.64	-0.05	0.00	0.12	1.36			
	ADA	96	0.02	0.271	-0.58	-0.08	-0.02	0.04	1.98			
	TOT	188	0.04	0.259	-0.64	-0.06	0.00	0.07	1.98			
LOGMAR RIGHT EYE												
BSL VALUE	PLO	92	0.13	0.233	-0.16	-0.02	0.02	0.19	0.90			
	ADA	96	0.11	0.218	-0.24	-0.02	0.04	0.20	1.16			
	TOT	188	0.12	0.225	-0.24	-0.02	0.04	0.20	1.16			
FINAL/ET VALUE	PLO	92	0.16	0.294	-0.20	-0.02	0.09	0.26	1.62			
	ADA	96	0.11	0.277	-0.28	-0.06	0.01	0.24	1.48			
	TOT	188	0.13	0.285	-0.28	-0.04	0.05	0.26	1.62			
CHG FROM BSL	PLO	92	0.03	0.214	-0.52	-0.08	0.00	0.10	1.26			
	ADA	96	0.00	0.164	-0.42	-0.08	-0.02	0.06	0.94			
	TOT	188	0.01	0.190	-0.52	-0.08	0.00	0.08	1.26			
										-0.04	(-0.09, 0.01)	0.157A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.6.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BSL	PLO	89	8.3	21.71	-46.1	-1.6	1.8	9.0	105.6			
	ADA	96	3.9	30.19	-61.7	-5.8	-1.2	2.9	165.6			
	TOT	185	6.0	26.47	-61.7	-3.7	0.0	7.3	165.6			
CRT RIGHT EYE												
%CHG FROM BSL	PLO	90	8.1	30.93	-40.4	-1.9	2.0	8.6	232.5			
	ADA	95	2.8	26.33	-59.3	-5.1	-1.1	2.4	140.9			
	TOT	185	5.4	28.71	-59.3	-3.9	0.5	5.9	232.5			
										-5.3	(-11.8, 1.2)	0.109A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.7.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BSL VALUE	PLO	34	0.13	0.224	0.0	0.00	0.00	0.50	0.5			
	ADA	35	0.14	0.229	0.0	0.00	0.00	0.50	0.5			
	TOT	69	0.14	0.225	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	34	1.04	1.083	0.0	0.00	0.50	2.00	3.0			
	ADA	35	0.79	1.126	0.0	0.00	0.00	2.00	4.0			
	TOT	69	0.91	1.105	0.0	0.00	0.50	2.00	4.0			
CHG FROM BSL	PLO	34	0.91	1.019	0.0	0.00	0.50	2.00	3.0			
	ADA	35	0.64	1.109	-0.5	0.00	0.00	1.50	4.0			
	TOT	69	0.78	1.066	-0.5	0.00	0.00	1.50	4.0			
AC RIGHT EYE												
BSL VALUE	PLO	34	0.13	0.224	0.0	0.00	0.00	0.50	0.5			
	ADA	35	0.11	0.213	0.0	0.00	0.00	0.00	0.5			
	TOT	69	0.12	0.217	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	34	0.93	1.031	0.0	0.00	0.50	2.00	3.0			
	ADA	35	0.91	1.234	0.0	0.00	0.00	2.00	3.0			
	TOT	69	0.92	1.130	0.0	0.00	0.50	2.00	3.0			
CHG FROM BSL	PLO	34	0.79	0.986	-0.5	0.00	0.50	2.00	3.0			
	ADA	35	0.80	1.220	-0.5	0.00	0.00	2.00	3.0			
	TOT	69	0.80	1.103	-0.5	0.00	0.00	2.00	3.0			
										-0.13	(-0.59, 0.33)	0.569A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.7.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BSL VALUE	PLO	34	0.18	0.243	0.0	0.00	0.00	0.50	0.5			
	ADA	35	0.21	0.251	0.0	0.00	0.00	0.50	0.5			
	TOT	69	0.20	0.246	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	34	0.49	0.691	0.0	0.00	0.50	0.50	3.0			
	ADA	35	0.33	0.618	0.0	0.00	0.00	0.50	2.0			
	TOT	69	0.41	0.655	0.0	0.00	0.00	0.50	3.0			
CHG FROM BSL	PLO	34	0.31	0.640	-0.5	0.00	0.00	0.50	2.5			
	ADA	35	0.11	0.570	-0.5	0.00	0.00	0.00	1.5			
	TOT	69	0.21	0.609	-0.5	0.00	0.00	0.50	2.5			
VH RIGHT EYE												
BSL VALUE	PLO	34	0.19	0.247	0.0	0.00	0.00	0.50	0.5			
	ADA	35	0.20	0.249	0.0	0.00	0.00	0.50	0.5			
	TOT	69	0.20	0.246	0.0	0.00	0.00	0.50	0.5			
FINAL/ET VALUE	PLO	34	0.71	1.001	0.0	0.00	0.50	1.00	3.0			
	ADA	35	0.36	0.625	0.0	0.00	0.00	0.50	2.0			
	TOT	69	0.53	0.844	0.0	0.00	0.00	1.00	3.0			
CHG FROM BSL	PLO	34	0.51	0.917	-0.5	0.00	0.00	0.50	3.0			
	ADA	35	0.16	0.591	-0.5	0.00	0.00	0.50	2.0			
	TOT	69	0.33	0.784	-0.5	0.00	0.00	0.50	3.0			
										-0.28	(-0.56, 0.01)	0.059A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.7.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BSL VALUE	PLO	34	0.22	0.286	-0.12	0.02	0.16	0.32	1.00			
	ADA	35	0.18	0.257	-0.12	0.00	0.10	0.32	0.84			
	TOT	69	0.20	0.271	-0.12	0.00	0.12	0.32	1.00			
FINAL/ET VALUE	PLO	34	0.30	0.359	-0.16	0.08	0.18	0.48	1.30			
	ADA	35	0.19	0.311	-0.16	-0.06	0.12	0.32	1.20			
	TOT	69	0.25	0.338	-0.16	-0.02	0.14	0.42	1.30			
CHG FROM BSL	PLO	34	0.08	0.179	-0.16	-0.02	0.03	0.18	0.70			
	ADA	35	0.02	0.133	-0.20	-0.06	-0.02	0.06	0.36			
	TOT	69	0.05	0.159	-0.20	-0.04	0.00	0.10	0.70			
LOGMAR RIGHT EYE												
BSL VALUE	PLO	34	0.26	0.302	-0.10	0.04	0.19	0.36	1.20			
	ADA	35	0.18	0.248	-0.18	-0.02	0.12	0.32	0.88			
	TOT	69	0.22	0.277	-0.18	0.02	0.14	0.34	1.20			
FINAL/ET VALUE	PLO	34	0.33	0.394	-0.20	0.08	0.21	0.42	1.30			
	ADA	35	0.19	0.350	-0.26	0.00	0.06	0.30	1.10			
	TOT	69	0.26	0.376	-0.26	0.02	0.18	0.34	1.30			
CHG FROM BSL	PLO	34	0.07	0.224	-0.14	-0.04	0.03	0.06	0.96			
	ADA	35	0.01	0.186	-0.40	-0.10	0.00	0.12	0.52			
	TOT	69	0.04	0.206	-0.40	-0.06	0.02	0.08	0.96			
										-0.06	(-0.13, 0.01)	0.098A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AS FACTOR
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.7.1.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BSL	PLO	33	0.8	11.71	-27.5	-2.6	0.5	4.9	31.8			
	ADA	34	8.7	29.25	-47.1	-3.2	1.6	8.1	117.7			
	TOT	67	4.8	22.59	-47.1	-3.2	1.1	6.6	117.7			
CRT RIGHT EYE												
%CHG FROM BSL	PLO	34	14.5	30.37	-30.4	-0.7	2.8	18.4	132.9			
	ADA	34	7.0	48.19	-63.4	-4.5	0.2	3.4	260.7			
	TOT	68	10.8	40.16	-63.4	-2.8	0.7	9.8	260.7			
										-1.4	(-14.3, 11.4)	0.826A

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.
$ MEAN DIFFERENCE IN CHANGE FROM BASELINE TO FINAL/ET VISIT OF ADALIMUMAB MINUS PLACEBO.
# 95% CONFIDENCE INTERVAL FOR DIFFERENCE OF ADALIMUMAB MINUS PLACEBO.
@ P-VALUE FOR DIFFERENCES BETWEEN TREATMENT GROUPS.
A: FROM ANOVA OF CHANGE FROM BASELINE TO FINAL/ET VISIT WITH TREATMENT AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.7.2.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BSL VALUE	PLO	8	0.13	0.231	0.0	0.00	0.00	0.25	0.5
	ADA	6	0.08	0.204	0.0	0.00	0.00	0.00	0.5
	TOT	14	0.11	0.213	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	8	0.63	0.876	0.0	0.00	0.25	1.25	2.0
	ADA	6	0.25	0.418	0.0	0.00	0.00	0.50	1.0
	TOT	14	0.46	0.720	0.0	0.00	0.00	0.50	2.0
CHG FROM BSL	PLO	8	0.50	0.926	0.0	0.00	0.00	1.00	2.0
	ADA	6	0.17	0.408	0.0	0.00	0.00	0.00	1.0
	TOT	14	0.36	0.745	0.0	0.00	0.00	0.00	2.0
AC RIGHT EYE									
BSL VALUE	PLO	8	0.13	0.231	0.0	0.00	0.00	0.25	0.5
	ADA	6	0.08	0.204	0.0	0.00	0.00	0.00	0.5
	TOT	14	0.11	0.213	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	8	0.38	0.694	0.0	0.00	0.00	0.50	2.0
	ADA	6	1.08	1.497	0.0	0.00	0.25	3.00	3.0
	TOT	14	0.68	1.120	0.0	0.00	0.00	0.50	3.0
CHG FROM BSL	PLO	8	0.25	0.756	-0.5	0.00	0.00	0.25	2.0
	ADA	6	1.00	1.549	0.0	0.00	0.00	3.00	3.0
	TOT	14	0.57	1.174	-0.5	0.00	0.00	0.50	3.0

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__2000.2.1.1.7.2.I

CHANGE FROM BASELINE TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN ANTERIOR CHAMBER CELL GRADE, VITREOUS HAZE GRADE, CENTRAL RETINAL THICKNESS AND LOG(MAR) BCVA (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-880)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BSL VALUE	PLO	8	0.25	0.267	0.0	0.00	0.25	0.50	0.5
	ADA	6	0.33	0.258	0.0	0.00	0.50	0.50	0.5
	TOT	14	0.29	0.257	0.0	0.00	0.50	0.50	0.5
FINAL/ET VALUE	PLO	8	0.38	0.443	0.0	0.00	0.25	0.75	1.0
	ADA	6	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	14	0.21	0.378	0.0	0.00	0.00	0.50	1.0
CHG FROM BSL	PLO	8	0.13	0.231	0.0	0.00	0.00	0.25	0.5
	ADA	6	-0.33	0.258	-0.5	-0.50	-0.50	0.00	0.0
	TOT	14	-0.07	0.331	-0.5	-0.50	0.00	0.00	0.5
VH RIGHT EYE									
BSL VALUE	PLO	8	0.13	0.231	0.0	0.00	0.00	0.25	0.5
	ADA	6	0.25	0.274	0.0	0.00	0.25	0.50	0.5
	TOT	14	0.18	0.249	0.0	0.00	0.00	0.50	0.5
FINAL/ET VALUE	PLO	8	0.31	0.458	0.0	0.00	0.00	0.75	1.0
	ADA	6	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	14	0.18	0.372	0.0	0.00	0.00	0.00	1.0
CHG FROM BSL	PLO	8	0.19	0.259	0.0	0.00	0.00	0.50	0.5
	ADA	6	-0.25	0.274	-0.5	-0.50	-0.25	0.00	0.0
	TOT	14	0.00	0.340	-0.5	0.00	0.00	0.00	0.5

NOTE: ONLY SUBJECTS WITH BOTH BSL AND FINAL/ET VISIT VALUES ARE SHOWN.
NOTE: ANALYSIS OF CRT DONE EXCLUDING SUBJECTS WITH MACULAR HOLE AND/OR RETINAL DETACHMENT.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
AC=ANTERIOR CHAMBER CELL GRADE, VH=VITREOUS HAZE GRADE, CRT=CENTRAL RETINAL THICKNESS,
LOG(MAR) = LOG(MAR) BEST CORRECTED VISUAL ACUITY.

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]