TABLE 14.2__1000.1.1.3.21.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	45	22	1	22	50.00	(36.40, 65.41)
	ADALIMUMAB	39	9	6	24	26.15	(14.54, 44.30)
	TOTAL	84	31	7	46	39.83	(29.93, 51.60)
MONTH 6							
	PLACEBO	45	35	2	8	80.61	(67.64, 90.79)
	ADALIMUMAB	39	20	8	11	60.44	(44.33, 76.96)
	TOTAL	84	55	10	19	71.92	(61.51, 81.54)
MONTH 9							
	PLACEBO	45	37	2	6	85.45	(73.24, 94.04)
	ADALIMUMAB	39	22	9	8	68.35	(51.70, 83.78)
	TOTAL	84	59	11	14	78.16	(68.03, 86.86)
MONTH 12							
	PLACEBO	45	38	3	4	88.36	(76.46, 95.92)
	ADALIMUMAB	39	22	10	7	68.35	(51.70, 83.78)
	TOTAL	84	60	13	11	79.98	(69.90, 88.41)
MONTH 18							
	PLACEBO	45	39	5	1	94.18	(79.91, 99.35)
	ADALIMUMAB	39	22	13	4	68.35	(51.70, 83.78)
	TOTAL	84	61	18	5	83.32	(72.40, 91.72)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.22.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	56	30	2	24	54.81	(42.28, 68.26)
	ADALIMUMAB	62	17	8	37	30.68	(20.31, 44.65)
	TOTAL	118	47	10	61	42.71	(34.08, 52.51)
MONTH 6							
	PLACEBO	56	45	4	7	84.93	(73.65, 93.18)
	ADALIMUMAB	62	32	9	21	59.50	(46.73, 72.67)
	TOTAL	118	77	13	28	71.93	(63.11, 80.19)
MONTH 9							
	PLACEBO	56	47	4	5	89.23	(78.75, 95.95)
	ADALIMUMAB	62	36	11	15	67.46	(54.71, 79.62)
	TOTAL	118	83	15	20	78.09	(69.65, 85.52)
MONTH 12							
	PLACEBO	56	48	5	3	91.92	(81.71, 97.60)
	ADALIMUMAB	62	38	15	9	72.39	(59.51, 83.99)
	TOTAL	118	86	20	12	81.93	(73.62, 88.88)
MONTH 18							
	PLACEBO	56	48	6	2	91.92	(81.71, 97.60)
	ADALIMUMAB	62	38	19	5	72.39	(59.51, 83.99)
	TOTAL	118	86	25	7	81.93	(73.62, 88.88)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.23.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	58	23	5	30	42.81	(30.87, 57.08)
	ADALIMUMAB	56	13	6	37	25.24	(15.49, 39.51)
	TOTAL	114	36	11	67	34.13	(25.94, 44.05)
MONTH 6							
	PLACEBO	58	36	9	13	69.60	(56.55, 81.75)
	ADALIMUMAB	56	24	11	21	47.68	(34.95, 62.31)
	TOTAL	114	60	20	34	58.72	(49.26, 68.45)
MONTH 9							
	PLACEBO	58	40	10	8	79.21	(66.53, 89.51)
	ADALIMUMAB	56	28	13	15	58.14	(44.38, 72.55)
	TOTAL	114	68	23	23	68.82	(59.21, 78.01)
MONTH 12							
	PLACEBO	58	40	12	6	79.21	(66.53, 89.51)
	ADALIMUMAB	56	30	15	11	63.94	(49.74, 77.96)
	TOTAL	114	70	27	17	71.75	(62.08, 80.74)
MONTH 18							
	PLACEBO	58	41	14	3	84.41	(70.11, 94.28)
	ADALIMUMAB	56	30	19	7	63.94	(49.74, 77.96)
	TOTAL	114	71	33	10	74.31	(64.13, 83.51)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.24.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	86	43	6	37	52.79	(42.44, 63.95)
	ADALIMUMAB	82	18	7	57	23.29	(15.36, 34.40)
	TOTAL	168	61	13	94	38.46	(31.38, 46.51)
MONTH 6							
	PLACEBO	86	62	10	14	77.98	(68.10, 86.53)
	ADALIMUMAB	82	37	12	33	49.67	(38.91, 61.58)
	TOTAL	168	99	22	47	64.13	(56.49, 71.73)
MONTH 9							
	PLACEBO	86	68	11	7	87.89	(78.84, 94.33)
	ADALIMUMAB	82	44	15	23	60.68	(49.47, 72.10)
	TOTAL	168	112	26	30	74.40	(66.95, 81.30)
MONTH 12							
	PLACEBO	86	68	14	4	87.89	(78.84, 94.33)
	ADALIMUMAB	82	47	20	15	65.99	(54.62, 77.06)
	TOTAL	168	115	34	19	77.12	(69.74, 83.79)
MONTH 18							
	PLACEBO	86	68	17	1	87.89	(78.84, 94.33)
	ADALIMUMAB	82	47	27	8	65.99	(54.62, 77.06)
	TOTAL	168	115	44	9	77.12	(69.74, 83.79)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.25.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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 (%)
MONTH 3						
	PLACEBO	9	3	1	5	37.50
	ADALIMUMAB	17	6	3	8	41.82
	TOTAL	26	9	4	13	40.34
MONTH 6						
	PLACEBO	9	7	1	1	87.50
	ADALIMUMAB	17	10	4	3	70.91
	TOTAL	26	17	5	4	78.58
MONTH 9						
	PLACEBO	9	7	1	1	87.50
	ADALIMUMAB	17	10	4	3	70.91
	TOTAL	26	17	5	4	78.58
MONTH 12						
	PLACEBO	9	7	1	1	87.50
	ADALIMUMAB	17	10	5	2	70.91
	TOTAL	26	17	6	3	78.58
MONTH 18						
	PLACEBO	9	7	1	1	87.50
	ADALIMUMAB	17	10	5	2	70.91
	TOTAL	26	17	6	3	78.58

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.26.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	19	7	0	12	36.84
	ADALIMUMAB	19	6	4	9	38.64
	TOTAL	38	13	4	21	37.69
MONTH 6						
	PLACEBO	19	12	2	5	67.84
	ADALIMUMAB	19	9	4	6	59.09
	TOTAL	38	21	6	11	63.52
MONTH 9						
	PLACEBO	19	12	2	5	67.84
	ADALIMUMAB	19	10	5	4	67.27
	TOTAL	38	22	7	9	67.17
MONTH 12						
	PLACEBO	19	13	2	4	74.27
	ADALIMUMAB	19	11	5	3	75.45
	TOTAL	38	24	7	7	74.47
MONTH 18						
	PLACEBO	19	14	2	3	80.70
	ADALIMUMAB	19	11	6	2	75.45
	TOTAL	38	25	8	5	78.72

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.27.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	67	30	5	32	47.80	(36.32, 60.78)
	ADALIMUMAB	76	22	9	45	32.06	(22.40, 44.52)
	TOTAL	143	52	14	77	39.54	(31.76, 48.45)
MONTH 6							
	PLACEBO	67	48	9	10	80.29	(68.94, 89.53)
	ADALIMUMAB	76	37	11	28	54.81	(43.42, 66.97)
	TOTAL	143	85	20	38	66.60	(58.27, 74.74)
MONTH 9							
	PLACEBO	67	52	9	6	88.18	(77.97, 95.09)
	ADALIMUMAB	76	43	13	20	64.65	(53.10, 76.02)
	TOTAL	143	95	22	26	75.48	(67.49, 82.77)
MONTH 12							
	PLACEBO	67	52	12	3	88.18	(77.97, 95.09)
	ADALIMUMAB	76	45	18	13	68.52	(56.87, 79.57)
	TOTAL	143	97	30	16	77.58	(69.65, 84.67)
MONTH 18							
	PLACEBO	67	52	13	2	88.18	(77.97, 95.09)
	ADALIMUMAB	76	45	23	8	68.52	(56.87, 79.57)
	TOTAL	143	97	36	10	77.58	(69.65, 84.67)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.28.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	48	24	2	22	51.52	(38.15, 66.41)
	ADALIMUMAB	42	8	5	29	20.67	(10.91, 37.13)
	TOTAL	90	32	7	51	37.71	(28.35, 48.94)
MONTH 6							
	PLACEBO	48	34	4	10	74.29	(60.89, 85.99)
	ADALIMUMAB	42	19	9	14	52.53	(37.31, 69.54)
	TOTAL	90	53	13	24	64.53	(54.07, 74.85)
MONTH 9							
	PLACEBO	48	36	5	7	79.43	(66.35, 89.94)
	ADALIMUMAB	42	21	11	10	59.83	(43.82, 76.37)
	TOTAL	90	57	16	17	70.78	(60.29, 80.58)
MONTH 12							
	PLACEBO	48	37	5	6	82.37	(69.41, 92.14)
	ADALIMUMAB	42	23	12	7	67.87	(51.21, 83.40)
	TOTAL	90	60	17	13	75.93	(65.48, 85.15)
MONTH 18							
	PLACEBO	48	38	7	3	86.78	(73.16, 95.55)
	ADALIMUMAB	42	23	15	4	67.87	(51.21, 83.40)
	TOTAL	90	61	22	7	78.94	(67.90, 88.18)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.29.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	35	18	2	15	54.55	(38.79, 71.82)
	ADALIMUMAB	37	11	6	20	34.90	(21.04, 54.14)
	TOTAL	72	29	8	35	45.01	(33.84, 57.93)
MONTH 6							
	PLACEBO	35	23	3	9	70.63	(54.61, 85.05)
	ADALIMUMAB	37	17	7	13	54.66	(38.38, 72.53)
	TOTAL	72	40	10	22	62.87	(51.11, 74.62)
MONTH 9							
	PLACEBO	35	27	3	5	83.68	(68.96, 93.98)
	ADALIMUMAB	37	20	9	8	65.12	(48.42, 81.29)
	TOTAL	72	47	12	13	74.80	(63.45, 84.85)
MONTH 12							
	PLACEBO	35	27	6	2	83.68	(68.96, 93.98)
	ADALIMUMAB	37	21	9	7	69.48	(52.46, 84.96)
	TOTAL	72	48	15	9	76.90	(65.58, 86.64)
MONTH 18							
	PLACEBO	35	27	6	2	83.68	(68.96, 93.98)
	ADALIMUMAB	37	21	12	4	69.48	(52.46, 84.96)
	TOTAL	72	48	18	6	76.90	(65.58, 86.64)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.30.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	33	12	3	18	38.71	(24.15, 57.98)
	ADALIMUMAB	39	11	3	25	29.71	(17.66, 47.24)
	TOTAL	72	23	6	43	33.73	(23.84, 46.28)
MONTH 6							
	PLACEBO	33	25	6	2	90.26	(74.17, 98.18)
	ADALIMUMAB	39	20	4	15	55.01	(39.84, 71.51)
	TOTAL	72	45	10	17	69.41	(57.78, 80.34)
MONTH 9							
	PLACEBO	33	26	6	1	95.13	(80.30, 99.64)
	ADALIMUMAB	39	23	4	12	64.01	(48.51, 79.27)
	TOTAL	72	49	10	13	76.60	(65.32, 86.37)
MONTH 12							
	PLACEBO	33	26	6	1	95.13	(80.30, 99.64)
	ADALIMUMAB	39	24	9	6	68.01	(52.11, 82.86)
	TOTAL	72	50	15	7	78.94	(67.62, 88.38)
MONTH 18							
	PLACEBO	33	26	7	0	95.13	(80.30, 99.64)
	ADALIMUMAB	39	24	11	4	68.01	(52.11, 82.86)
	TOTAL	72	50	18	4	78.94	(67.62, 88.38)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.31.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	19	12	0	7	63.16	(42.52, 83.48)
	ADALIMUMAB	21	4	2	15	21.05	(8.47, 46.81)
	TOTAL	40	16	2	22	42.11	(28.31, 59.25)
MONTH 6							
	PLACEBO	19	14	1	4	73.68	(53.23, 90.42)
	ADALIMUMAB	21	10	4	7	55.92	(34.81, 79.15)
	TOTAL	40	24	5	11	64.63	(49.31, 79.60)
MONTH 9							
	PLACEBO	19	14	1	4	73.68	(53.23, 90.42)
	ADALIMUMAB	21	11	5	5	63.26	(41.02, 85.03)
	TOTAL	40	25	6	9	68.17	(52.65, 82.67)
MONTH 12							
	PLACEBO	19	15	1	3	80.26	(59.68, 94.49)
	ADALIMUMAB	21	11	6	4	63.26	(41.02, 85.03)
	TOTAL	40	26	7	7	71.71	(56.11, 85.57)
MONTH 18							
	PLACEBO	19	15	3	1	80.26	(59.68, 94.49)
	ADALIMUMAB	21	11	8	2	63.26	(41.02, 85.03)
	TOTAL	40	26	11	3	71.71	(56.11, 85.57)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.32.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	28	12	2	14	45.10	(28.60, 65.61)
	ADALIMUMAB	21	4	3	14	20.31	(8.14, 45.52)
	TOTAL	49	16	5	28	34.94	(23.03, 50.63)
MONTH 6							
	PLACEBO	28	20	3	5	77.59	(59.87, 91.37)
	ADALIMUMAB	21	9	5	7	48.77	(28.92, 73.03)
	TOTAL	49	29	8	12	65.88	(51.74, 79.55)
MONTH 9							
	PLACEBO	28	21	4	3	82.07	(64.76, 94.11)
	ADALIMUMAB	21	10	6	5	56.09	(34.69, 79.61)
	TOTAL	49	31	10	8	71.57	(57.36, 84.36)
MONTH 12							
	PLACEBO	28	21	4	3	82.07	(64.76, 94.11)
	ADALIMUMAB	21	12	6	3	73.65	(49.36, 92.68)
	TOTAL	49	33	10	6	78.68	(64.18, 90.23)
MONTH 18							
	PLACEBO	28	22	4	2	88.05	(70.56, 97.51)
	ADALIMUMAB	21	12	7	2	73.65	(49.36, 92.68)
	TOTAL	49	34	11	4	82.94	(68.17, 93.49)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.33.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	56	28	4	24	53.16	(40.46, 67.02)
	ADALIMUMAB	54	18	6	30	36.52	(24.76, 51.60)
	TOTAL	110	46	10	54	45.05	(35.98, 55.24)
MONTH 6							
	PLACEBO	56	43	5	8	83.18	(71.65, 91.97)
	ADALIMUMAB	54	34	7	13	70.66	(57.43, 82.80)
	TOTAL	110	77	12	21	77.07	(68.32, 84.83)
MONTH 9							
	PLACEBO	56	45	5	6	87.39	(76.56, 94.79)
	ADALIMUMAB	54	38	7	9	79.69	(67.13, 89.80)
	TOTAL	110	83	12	15	83.62	(75.53, 90.22)
MONTH 12							
	PLACEBO	56	46	6	4	89.49	(79.12, 96.08)
	ADALIMUMAB	54	39	7	8	81.94	(69.67, 91.42)
	TOTAL	110	85	13	12	85.80	(78.01, 91.92)
MONTH 18							
	PLACEBO	56	47	6	3	92.12	(82.04, 97.67)
	ADALIMUMAB	54	39	11	4	81.94	(69.67, 91.42)
	TOTAL	110	86	17	7	87.58	(79.69, 93.47)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.33.I.PH

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
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)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	38	20	3	15	56.14	(40.79, 72.64)
	ADALIMUMAB	40	16	7	17	45.95	(31.03, 63.90)
	TOTAL	78	36	10	32	50.89	(39.81, 63.07)
MONTH 6							
	PLACEBO	38	29	4	5	83.55	(69.15, 93.74)
	ADALIMUMAB	40	26	7	7	77.74	(62.34, 90.09)
	TOTAL	78	55	11	12	80.66	(70.28, 89.20)
MONTH 9							
	PLACEBO	38	30	4	4	86.84	(72.98, 95.69)
	ADALIMUMAB	40	29	7	4	87.28	(73.43, 95.96)
	TOTAL	78	59	11	8	87.11	(77.68, 93.91)
MONTH 12							
	PLACEBO	38	30	6	2	86.84	(72.98, 95.69)
	ADALIMUMAB	40	29	7	4	87.28	(73.43, 95.96)
	TOTAL	78	59	13	6	87.11	(77.68, 93.91)
MONTH 18							
	PLACEBO	38	31	6	1	93.42	(77.37, 99.32)
	ADALIMUMAB	40	29	9	2	87.28	(73.43, 95.96)
	TOTAL	78	60	15	3	90.33	(80.24, 96.55)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.34.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	47	22	2	23	48.00	(34.76, 63.26)
	ADALIMUMAB	57	10	6	41	18.99	(10.70, 32.43)
	TOTAL	104	32	8	64	32.57	(24.27, 42.81)
MONTH 6							
	PLACEBO	47	30	6	11	68.12	(53.84, 81.56)
	ADALIMUMAB	57	19	11	27	37.43	(25.70, 52.31)
	TOTAL	104	49	17	38	51.63	(41.92, 62.13)
MONTH 9							
	PLACEBO	47	34	7	6	80.44	(66.30, 91.35)
	ADALIMUMAB	57	22	15	20	45.00	(32.11, 60.26)
	TOTAL	104	56	22	26	61.13	(50.97, 71.44)
MONTH 12							
	PLACEBO	47	34	8	5	80.44	(66.30, 91.35)
	ADALIMUMAB	57	25	20	12	54.10	(39.88, 69.63)
	TOTAL	104	59	28	17	66.04	(55.62, 76.21)
MONTH 18							
	PLACEBO	47	34	11	2	80.44	(66.30, 91.35)
	ADALIMUMAB	57	25	24	8	54.10	(39.88, 69.63)
	TOTAL	104	59	35	10	66.04	(55.62, 76.21)

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__1000.1.1.3.34.I.PH

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
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)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	74	33	3	38	45.93	(35.26, 58.10)
	ADALIMUMAB	74	12	7	55	17.91	(10.59, 29.38)
	TOTAL	148	45	10	93	32.40	(25.31, 40.87)
MONTH 6							
	PLACEBO	74	51	8	15	73.98	(62.89, 83.93)
	ADALIMUMAB	74	28	13	33	42.65	(31.70, 55.55)
	TOTAL	148	79	21	48	58.54	(50.29, 67.02)
MONTH 9							
	PLACEBO	74	56	9	9	83.09	(72.62, 91.27)
	ADALIMUMAB	74	31	17	26	48.23	(36.70, 61.23)
	TOTAL	148	87	26	35	65.80	(57.48, 73.98)
MONTH 12							
	PLACEBO	74	57	10	7	85.20	(74.87, 92.89)
	ADALIMUMAB	74	35	23	16	56.88	(44.49, 69.94)
	TOTAL	148	92	33	23	71.15	(62.76, 79.08)
MONTH 18							
	PLACEBO	74	57	13	4	85.20	(74.87, 92.89)
	ADALIMUMAB	74	35	29	10	56.88	(44.49, 69.94)
	TOTAL	148	92	42	14	71.15	(62.76, 79.08)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.35.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	35	14	2	19	41.69	(27.16, 60.06)
	ADALIMUMAB	35	7	6	22	22.95	(11.65, 42.23)
	TOTAL	70	21	8	41	32.90	(22.82, 45.90)
MONTH 6							
	PLACEBO	35	23	6	6	72.90	(56.02, 87.44)
	ADALIMUMAB	35	15	7	13	51.22	(34.69, 70.16)
	TOTAL	70	38	13	19	62.32	(50.15, 74.56)
MONTH 9							
	PLACEBO	35	24	6	5	77.41	(60.46, 90.80)
	ADALIMUMAB	35	18	8	9	63.42	(45.85, 80.76)
	TOTAL	70	42	14	14	70.70	(58.41, 82.04)
MONTH 12							
	PLACEBO	35	25	6	4	81.93	(65.16, 93.77)
	ADALIMUMAB	35	19	10	6	67.99	(50.12, 84.51)
	TOTAL	70	44	16	10	75.20	(62.97, 85.88)
MONTH 18							
	PLACEBO	35	26	7	2	87.95	(70.72, 97.39)
	ADALIMUMAB	35	19	14	2	67.99	(50.12, 84.51)
	TOTAL	70	45	21	4	80.16	(66.24, 91.02)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.36.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	80	40	5	35	52.67	(41.99, 64.20)
	ADALIMUMAB	83	23	8	52	30.05	(21.08, 41.69)
	TOTAL	163	63	13	87	41.32	(33.97, 49.58)
MONTH 6							
	PLACEBO	80	59	7	14	79.40	(69.41, 87.85)
	ADALIMUMAB	83	41	13	29	55.15	(44.21, 66.76)
	TOTAL	163	100	20	43	67.24	(59.56, 74.74)
MONTH 9							
	PLACEBO	80	64	8	8	87.16	(78.08, 93.77)
	ADALIMUMAB	83	46	16	21	63.09	(51.92, 74.24)
	TOTAL	163	110	24	29	75.08	(67.65, 81.93)
MONTH 12							
	PLACEBO	80	64	11	5	87.16	(78.08, 93.77)
	ADALIMUMAB	83	49	20	14	68.57	(57.26, 79.32)
	TOTAL	163	113	31	19	77.83	(70.46, 84.44)
MONTH 18							
	PLACEBO	80	64	13	3	87.16	(78.08, 93.77)
	ADALIMUMAB	83	49	24	10	68.57	(57.26, 79.32)
	TOTAL	163	113	37	13	77.83	(70.46, 84.44)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.37.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	43	23	3	17	56.65	(42.18, 72.07)
	ADALIMUMAB	38	17	2	19	46.67	(32.11, 63.97)
	TOTAL	81	40	5	36	51.90	(41.29, 63.42)
MONTH 6							
	PLACEBO	43	34	6	3	89.35	(75.88, 97.06)
	ADALIMUMAB	38	26	3	9	71.93	(56.87, 85.33)
	TOTAL	81	60	9	12	80.49	(70.47, 88.81)
MONTH 9							
	PLACEBO	43	36	7	0	100.00	
	ADALIMUMAB	38	30	3	5	84.41	(70.42, 94.13)
	TOTAL	81	66	10	5	90.71	(81.94, 96.31)
MONTH 12							
	PLACEBO	43	36	7	0	100.00	
	ADALIMUMAB	38	32	4	2	91.68	(78.41, 98.23)
	TOTAL	81	68	11	2	95.04	(86.67, 98.87)
MONTH 18							
	PLACEBO	43	36	7	0	100.00	
	ADALIMUMAB	38	32	5	1	91.68	(78.41, 98.23)
	TOTAL	81	68	12	1	95.04	(86.67, 98.87)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.38.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	72	31	4	37	45.00	(34.17, 57.46)
	ADALIMUMAB	80	13	12	55	18.40	(11.12, 29.59)
	TOTAL	152	44	16	92	31.55	(24.53, 39.99)
MONTH 6							
	PLACEBO	72	48	7	17	71.55	(60.32, 81.91)
	ADALIMUMAB	80	30	17	33	44.45	(33.47, 57.16)
	TOTAL	152	78	24	50	57.82	(49.58, 66.33)
MONTH 9							
	PLACEBO	72	52	7	13	78.24	(67.45, 87.42)
	ADALIMUMAB	80	34	21	25	51.39	(39.87, 64.05)
	TOTAL	152	86	28	38	64.71	(56.44, 72.90)
MONTH 12							
	PLACEBO	72	53	10	9	80.06	(69.39, 88.87)
	ADALIMUMAB	80	36	26	18	55.56	(43.64, 68.24)
	TOTAL	152	89	36	27	67.76	(59.43, 75.83)
MONTH 18							
	PLACEBO	72	54	13	5	83.38	(72.06, 92.00)
	ADALIMUMAB	80	36	33	11	55.56	(43.64, 68.24)
	TOTAL	152	90	46	16	69.65	(60.96, 77.94)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.39.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	5	3	0	2	60.00
	ADALIMUMAB	3	0	0	3	0.00
	TOTAL	8	3	0	5	37.50
MONTH 6						
	PLACEBO	5	4	0	1	80.00
	ADALIMUMAB	3	1	0	2	33.33
	TOTAL	8	5	0	3	62.50
MONTH 9						
	PLACEBO	5	4	0	1	80.00
	ADALIMUMAB	3	2	0	1	66.67
	TOTAL	8	6	0	2	75.00
MONTH 12						
	PLACEBO	5	4	0	1	80.00
	ADALIMUMAB	3	2	0	1	66.67
	TOTAL	8	6	0	2	75.00
MONTH 18						
	PLACEBO	5	5	0	0	100.00
	ADALIMUMAB	3	2	1	0	66.67
	TOTAL	8	7	1	0	100.00

NOTE: CONFIDENCE INTERVAL IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.40.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	110	51	7	52	48.79	(39.69, 58.75)
	ADALIMUMAB	115	30	14	71	28.84	(21.13, 38.61)
	TOTAL	225	81	21	123	38.85	(32.60, 45.83)
MONTH 6							
	PLACEBO	110	78	13	19	77.48	(68.62, 85.30)
	ADALIMUMAB	115	55	20	40	54.60	(45.14, 64.61)
	TOTAL	225	133	33	59	65.93	(59.26, 72.50)
MONTH 9							
	PLACEBO	110	84	14	12	84.83	(76.59, 91.36)
	ADALIMUMAB	115	62	24	29	62.87	(53.22, 72.52)
	TOTAL	225	146	38	41	73.69	(67.20, 79.80)
MONTH 12							
	PLACEBO	110	85	17	8	86.21	(78.09, 92.46)
	ADALIMUMAB	115	66	30	19	68.37	(58.59, 77.75)
	TOTAL	225	151	47	27	77.20	(70.77, 83.09)
MONTH 18							
	PLACEBO	110	85	20	5	86.21	(78.09, 92.46)
	ADALIMUMAB	115	66	37	12	68.37	(58.59, 77.75)
	TOTAL	225	151	57	17	77.20	(70.77, 83.09)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.41.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

TIME	TREATMENT	N	FAILED	CENSORED	AT RISK	TF RATE (%)	95% CI
MONTH 3							
	PLACEBO	50	24	3	23	49.63	(36.57, 64.42)
	ADALIMUMAB	41	10	4	27	27.03	(15.56, 44.41)
	TOTAL	91	34	7	50	39.78	(30.29, 50.97)
MONTH 6							
	PLACEBO	50	38	4	8	81.51	(68.99, 91.22)
	ADALIMUMAB	41	19	7	15	51.92	(36.96, 68.73)
	TOTAL	91	57	11	23	68.56	(58.35, 78.31)
MONTH 9							
	PLACEBO	50	40	5	5	86.52	(74.62, 94.65)
	ADALIMUMAB	41	24	8	9	68.27	(52.40, 83.05)
	TOTAL	91	64	13	14	78.54	(68.74, 86.95)
MONTH 12							
	PLACEBO	50	41	8	1	89.89	(78.03, 96.87)
	ADALIMUMAB	41	26	9	6	75.82	(59.82, 89.04)
	TOTAL	91	67	17	7	83.79	(74.20, 91.32)
MONTH 18							
	PLACEBO	50	41	8	1	89.89	(78.03, 96.87)
	ADALIMUMAB	41	26	10	5	75.82	(59.82, 89.04)
	TOTAL	91	67	18	6	83.79	(74.20, 91.32)

Program Source Code: [redacted]

TABLE 14.2__1000.1.1.3.42.I

TREATMENT FAILURE RATES WITH 95 PERCENT CONFIDENCE INTERVALL (CI)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877)
(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	44	17	3	24	41.46	(28.18, 57.95)
	ADALIMUMAB	52	12	7	33	25.23	(15.16, 40.18)
	TOTAL	96	29	10	57	32.71	(24.00, 43.56)
MONTH 6							
	PLACEBO	44	28	6	10	70.33	(55.61, 83.77)
	ADALIMUMAB	52	22	8	22	47.88	(34.59, 63.23)
	TOTAL	96	50	14	32	58.18	(47.94, 68.79)
MONTH 9							
	PLACEBO	44	32	6	6	82.20	(68.26, 92.54)
	ADALIMUMAB	52	24	11	17	52.85	(39.13, 67.97)
	TOTAL	96	56	17	23	66.28	(55.98, 76.31)
MONTH 12							
	PLACEBO	44	32	6	6	82.20	(68.26, 92.54)
	ADALIMUMAB	52	26	14	12	58.79	(44.45, 73.73)
	TOTAL	96	58	20	18	69.36	(59.03, 79.15)
MONTH 18							
	PLACEBO	44	33	8	3	86.65	(72.36, 95.73)
	ADALIMUMAB	52	26	19	7	58.79	(44.45, 73.73)
	TOTAL	96	59	27	10	72.14	(61.24, 82.16)

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	43	0.16	0.303	0.0	0.00	0.00	0.50	1.0			
	ADA	48	0.13	0.334	0.0	0.00	0.00	0.00	2.0			
	TOT	91	0.14	0.319	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	43	0.76	1.066	0.0	0.00	0.50	1.00	4.0			
	ADA	48	0.30	0.666	0.0	0.00	0.00	0.25	3.0			
	TOT	91	0.52	0.902	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	43	0.59	0.984	-0.5	0.00	0.00	1.00	4.0			
	ADA	48	0.18	0.500	-0.5	0.00	0.00	0.00	2.0			
	TOT	91	0.37	0.791	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	43	0.23	0.467	0.0	0.00	0.00	0.50	2.0			
	ADA	48	0.09	0.223	0.0	0.00	0.00	0.00	1.0			
	TOT	91	0.16	0.364	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	43	0.91	1.197	0.0	0.00	0.50	2.00	4.0			
	ADA	48	0.23	0.461	0.0	0.00	0.00	0.50	2.0			
	TOT	91	0.55	0.946	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	43	0.67	1.063	-0.5	0.00	0.00	1.00	4.0			
	ADA	48	0.14	0.409	-0.5	0.00	0.00	0.25	1.5			
	TOT	91	0.39	0.829	-0.5	0.00	0.00	0.50	4.0			
										-0.48	(-0.77, -0.19)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	44	0.44	0.497	0.0	0.00	0.50	0.50	2.0			
	ADA	48	0.24	0.357	0.0	0.00	0.00	0.50	1.0			
	TOT	92	0.34	0.439	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	44	0.75	0.803	0.0	0.00	0.50	1.00	3.0			
	ADA	48	0.36	0.513	0.0	0.00	0.00	0.50	2.0			
	TOT	92	0.55	0.692	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	44	0.31	0.741	-0.5	0.00	0.00	0.50	3.0			
	ADA	48	0.13	0.511	-1.0	0.00	0.00	0.00	2.0			
	TOT	92	0.21	0.634	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	44	0.38	0.405	0.0	0.00	0.50	0.50	1.0			
	ADA	48	0.32	0.419	0.0	0.00	0.00	0.50	2.0			
	TOT	92	0.35	0.411	0.0	0.00	0.25	0.50	2.0			
FINAL/ET VALUE	PLO	44	0.91	1.007	0.0	0.00	0.50	1.00	4.0			
	ADA	48	0.43	0.516	0.0	0.00	0.50	0.75	2.0			
	TOT	92	0.66	0.822	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	44	0.53	0.879	-1.0	0.00	0.25	1.00	3.5			
	ADA	48	0.10	0.583	-1.5	0.00	0.00	0.50	1.5			
	TOT	92	0.31	0.766	-1.5	0.00	0.00	0.50	3.5			
										-0.31	(-0.54, -0.07)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	44	0.12	0.290	-0.26	-0.06	0.04	0.21	0.94			
	ADA	48	0.10	0.301	-0.18	-0.08	0.02	0.14	1.30			
	TOT	92	0.11	0.294	-0.26	-0.07	0.02	0.15	1.30			
FINAL/ET VALUE	PLO	44	0.22	0.302	-0.18	0.01	0.14	0.34	1.00			
	ADA	48	0.14	0.358	-0.26	-0.09	0.02	0.23	1.60			
	TOT	92	0.18	0.333	-0.26	-0.05	0.08	0.31	1.60			
CHG FROM BEST*	PLO	44	0.10	0.201	-0.62	0.02	0.06	0.15	0.80			
	ADA	48	0.04	0.118	-0.32	-0.02	0.02	0.08	0.38			
	TOT	92	0.07	0.165	-0.62	-0.01	0.04	0.11	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	44	0.16	0.329	-0.24	-0.07	0.05	0.35	1.16			
	ADA	48	0.11	0.240	-0.20	-0.08	0.01	0.24	0.76			
	TOT	92	0.13	0.286	-0.24	-0.08	0.01	0.26	1.16			
FINAL/ET VALUE	PLO	44	0.32	0.560	-0.20	-0.03	0.18	0.52	3.00			
	ADA	48	0.12	0.273	-0.22	-0.06	0.01	0.24	1.04			
	TOT	92	0.21	0.444	-0.22	-0.06	0.05	0.35	3.00			
CHG FROM BEST*	PLO	44	0.16	0.449	-0.18	0.00	0.05	0.17	2.82			
	ADA	48	0.01	0.109	-0.30	-0.05	0.00	0.06	0.32			
	TOT	92	0.08	0.327	-0.30	-0.04	0.04	0.08	2.82			
										-0.11	(-0.19, -0.03)	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.
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 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 ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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 BEST*	PLO	43	17.2	57.16	-28.4	0.0	3.4	8.1	291.1			
	ADA	48	4.0	25.13	-47.6	-3.6	0.6	4.9	121.5			
	TOT	91	10.2	43.58	-47.6	-1.3	1.9	6.6	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	43	13.3	35.95	-12.8	0.0	4.3	11.8	169.7			
	ADA	48	7.6	20.44	-18.3	-1.2	2.2	7.7	109.1			
	TOT	91	10.3	28.80	-18.3	-0.5	3.0	10.2	169.7			
										-8.7	(-21.6, 4.1)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.1.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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 BEST*	PLO	43	17.2	57.16	-28.4	0.0	3.4	8.1	291.1			
	ADA	47	1.5	18.40	-47.6	-4.7	0.4	4.1	58.6			
	TOT	90	9.0	42.18	-47.6	-1.3	1.9	6.5	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	43	13.3	35.95	-12.8	0.0	4.3	11.8	169.7			
	ADA	47	7.2	20.43	-18.3	-1.3	2.1	7.2	109.1			
	TOT	90	10.1	28.90	-18.3	-0.5	3.0	9.4	169.7			
										-10.4	(-23.1, 2.3)	0.109A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	67	0.07	0.200	0.0	0.00	0.00	0.00	1.0			
	ADA	61	0.10	0.238	0.0	0.00	0.00	0.00	1.0			
	TOT	128	0.09	0.218	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	67	0.61	0.908	0.0	0.00	0.00	1.00	4.0			
	ADA	61	0.58	0.891	0.0	0.00	0.00	1.00	3.0			
	TOT	128	0.60	0.896	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	67	0.54	0.872	-0.5	0.00	0.00	1.00	4.0			
	ADA	61	0.48	0.871	-1.0	0.00	0.00	0.50	3.0			
	TOT	128	0.51	0.868	-1.0	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	67	0.08	0.187	0.0	0.00	0.00	0.00	0.5			
	ADA	61	0.11	0.243	0.0	0.00	0.00	0.00	1.0			
	TOT	128	0.09	0.215	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	67	0.71	1.074	0.0	0.00	0.00	1.00	4.0			
	ADA	61	0.64	0.890	0.0	0.00	0.00	1.00	3.0			
	TOT	128	0.68	0.987	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	67	0.63	1.031	-0.5	0.00	0.00	1.00	3.5			
	ADA	61	0.53	0.865	-1.0	0.00	0.00	1.00	2.5			
	TOT	128	0.58	0.953	-1.0	0.00	0.00	1.00	3.5			
										-0.07	(-0.36, 0.21)	0.612A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	67	0.39	0.434	0.0	0.00	0.50	0.50	2.0			
	ADA	61	0.39	0.633	0.0	0.00	0.00	0.50	3.0			
	TOT	128	0.39	0.536	0.0	0.00	0.25	0.50	3.0			
FINAL/ET VALUE	PLO	67	0.75	0.827	0.0	0.00	0.50	1.00	3.0			
	ADA	61	0.50	0.842	0.0	0.00	0.00	0.50	4.0			
	TOT	128	0.63	0.840	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	67	0.36	0.632	-0.5	0.00	0.00	0.50	2.0			
	ADA	61	0.11	0.578	-1.0	0.00	0.00	0.50	2.0			
	TOT	128	0.24	0.618	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	67	0.37	0.473	0.0	0.00	0.00	0.50	2.0			
	ADA	61	0.36	0.439	0.0	0.00	0.00	0.50	2.0			
	TOT	128	0.36	0.456	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	67	0.83	0.890	0.0	0.00	0.50	1.00	3.0			
	ADA	61	0.56	0.725	0.0	0.00	0.50	1.00	3.0			
	TOT	128	0.70	0.824	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	67	0.46	0.775	-1.0	0.00	0.00	0.50	2.5			
	ADA	61	0.20	0.697	-1.0	0.00	0.00	0.50	2.5			
	TOT	128	0.34	0.748	-1.0	0.00	0.00	0.50	2.5			
										-0.26	(-0.47, -0.05)	0.017A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	67	0.14	0.267	-0.28	-0.06	0.08	0.26	0.88			
	ADA	61	0.17	0.289	-0.20	-0.02	0.10	0.28	1.12			
	TOT	128	0.15	0.277	-0.28	-0.06	0.10	0.27	1.12			
FINAL/ET VALUE	PLO	67	0.25	0.336	-0.20	0.00	0.16	0.46	1.22			
	ADA	61	0.26	0.376	-0.28	0.00	0.20	0.46	1.62			
	TOT	128	0.26	0.354	-0.28	0.00	0.16	0.46	1.62			
CHG FROM BEST*	PLO	67	0.11	0.164	-0.08	0.02	0.06	0.14	0.76			
	ADA	61	0.10	0.189	-0.22	-0.04	0.04	0.22	0.58			
	TOT	128	0.11	0.175	-0.22	0.00	0.06	0.18	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	67	0.19	0.295	-0.20	-0.02	0.10	0.38	0.98			
	ADA	61	0.17	0.251	-0.22	-0.04	0.12	0.32	0.90			
	TOT	128	0.18	0.274	-0.22	-0.04	0.12	0.33	0.98			
FINAL/ET VALUE	PLO	67	0.31	0.421	-0.20	-0.02	0.20	0.54	2.08			
	ADA	61	0.25	0.311	-0.26	0.00	0.18	0.44	0.94			
	TOT	128	0.28	0.373	-0.26	-0.01	0.19	0.48	2.08			
CHG FROM BEST*	PLO	67	0.12	0.218	-0.20	0.00	0.04	0.16	1.20			
	ADA	61	0.08	0.162	-0.50	0.00	0.06	0.14	0.56			
	TOT	128	0.10	0.193	-0.50	0.00	0.05	0.16	1.20			
										-0.02	(-0.07, 0.03)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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 BEST*	PLO	64	20.2	46.06	-16.5	1.0	6.0	14.5	283.9			
	ADA	60	21.9	68.04	-18.6	-1.1	2.6	14.0	483.1			
	TOT	124	21.0	57.52	-18.6	0.2	4.2	14.5	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	65	27.1	72.42	-11.3	0.9	6.7	18.2	514.8			
	ADA	61	19.9	73.92	-50.0	0.4	3.2	13.4	534.5			
	TOT	126	23.6	72.95	-50.0	0.5	5.3	14.4	534.5			
										-0.9	(-20.6, 18.7)	0.925A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.2.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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 BEST*	PLO	64	20.2	46.06	-16.5	1.0	6.0	14.5	283.9			
	ADA	59	22.3	68.57	-18.6	-1.3	3.0	15.9	483.1			
	TOT	123	21.2	57.72	-18.6	0.0	4.3	14.6	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	65	27.1	72.42	-11.3	0.9	6.7	18.2	514.8			
	ADA	60	20.0	74.54	-50.0	0.2	3.1	13.5	534.5			
	TOT	125	23.7	73.23	-50.0	0.5	5.3	14.4	534.5			
										-0.7	(-20.5, 19.1)	0.942A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	22	0.14	0.316	0.0	0.00	0.00	0.00	1.0			
	ADA	20	0.18	0.335	0.0	0.00	0.00	0.25	1.0			
	TOT	42	0.15	0.322	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	22	0.89	1.112	0.0	0.00	0.25	2.00	3.0			
	ADA	20	0.60	0.926	0.0	0.00	0.00	1.00	3.0			
	TOT	42	0.75	1.026	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	22	0.75	0.973	0.0	0.00	0.00	1.00	3.0			
	ADA	20	0.43	0.847	-1.0	0.00	0.00	0.75	2.0			
	TOT	42	0.60	0.919	-1.0	0.00	0.00	1.00	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	22	0.20	0.480	0.0	0.00	0.00	0.00	2.0			
	ADA	20	0.15	0.235	0.0	0.00	0.00	0.50	0.5			
	TOT	42	0.18	0.380	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	22	0.93	1.094	0.0	0.00	0.75	2.00	3.0			
	ADA	20	0.70	0.951	0.0	0.00	0.25	1.50	3.0			
	TOT	42	0.82	1.023	0.0	0.00	0.50	2.00	3.0			
CHG FROM BEST*	PLO	22	0.73	0.909	0.0	0.00	0.50	1.00	3.0			
	ADA	20	0.55	0.916	-0.5	0.00	0.00	1.00	2.5			
	TOT	42	0.64	0.906	-0.5	0.00	0.25	1.00	3.0			
										-0.25	(-0.76, 0.26)	0.324A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	22	0.39	0.435	0.0	0.00	0.25	1.00	1.0			
	ADA	20	0.20	0.377	0.0	0.00	0.00	0.25	1.0			
	TOT	42	0.30	0.414	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	22	0.84	0.822	0.0	0.00	0.75	2.00	2.0			
	ADA	20	0.23	0.380	0.0	0.00	0.00	0.50	1.0			
	TOT	42	0.55	0.714	0.0	0.00	0.00	1.00	2.0			
CHG FROM BEST*	PLO	22	0.45	0.770	-0.5	0.00	0.00	1.00	2.0			
	ADA	20	0.03	0.413	-1.0	0.00	0.00	0.00	1.0			
	TOT	42	0.25	0.656	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	22	0.39	0.435	0.0	0.00	0.25	1.00	1.0			
	ADA	20	0.18	0.335	0.0	0.00	0.00	0.25	1.0			
	TOT	42	0.29	0.400	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	22	1.00	0.951	0.0	0.00	1.00	2.00	3.0			
	ADA	20	0.33	0.406	0.0	0.00	0.00	0.50	1.0			
	TOT	42	0.68	0.810	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	22	0.61	0.816	-0.5	0.00	0.50	1.00	2.5			
	ADA	20	0.15	0.516	-1.0	0.00	0.00	0.50	1.0			
	TOT	42	0.39	0.720	-1.0	0.00	0.00	1.00	2.5			
										-0.45	(-0.81, -0.09)	0.016A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	22	0.08	0.266	-0.26	-0.10	0.01	0.20	0.62			
	ADA	20	0.12	0.235	-0.12	-0.08	0.03	0.24	0.78			
	TOT	42	0.10	0.249	-0.26	-0.08	0.02	0.22	0.78			
FINAL/ET VALUE	PLO	22	0.19	0.335	-0.20	-0.08	0.04	0.42	0.90			
	ADA	20	0.16	0.385	-0.28	-0.11	0.00	0.37	1.26			
	TOT	42	0.18	0.356	-0.28	-0.10	0.03	0.42	1.26			
CHG FROM BEST*	PLO	22	0.10	0.189	-0.08	0.00	0.04	0.16	0.80			
	ADA	20	0.05	0.194	-0.32	-0.04	0.00	0.09	0.48			
	TOT	42	0.08	0.191	-0.32	-0.02	0.02	0.14	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	22	0.12	0.295	-0.20	-0.08	0.00	0.16	0.74			
	ADA	20	0.14	0.234	-0.22	-0.06	0.13	0.28	0.70			
	TOT	42	0.13	0.264	-0.22	-0.08	0.03	0.26	0.74			
FINAL/ET VALUE	PLO	22	0.20	0.394	-0.20	-0.08	0.04	0.38	1.26			
	ADA	20	0.15	0.303	-0.26	-0.06	0.07	0.33	0.90			
	TOT	42	0.17	0.350	-0.26	-0.06	0.04	0.34	1.26			
CHG FROM BEST*	PLO	22	0.08	0.164	-0.20	-0.02	0.04	0.14	0.52			
	ADA	20	0.01	0.189	-0.50	-0.06	0.03	0.09	0.50			
	TOT	42	0.05	0.178	-0.50	-0.04	0.03	0.10	0.52			
										-0.06	(-0.15, 0.03)	0.184A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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 BEST*	PLO	21	27.3	77.17	-19.7	0.0	3.1	10.2	283.9			
	ADA	20	11.4	35.10	-18.6	-3.9	0.9	11.4	126.3			
	TOT	41	19.5	60.23	-19.7	-1.3	1.2	10.2	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	21	14.5	46.78	-12.8	-0.5	4.1	6.9	212.4			
	ADA	20	7.0	24.89	-50.0	-0.3	2.6	10.0	81.8			
	TOT	41	10.8	37.46	-50.0	-0.5	2.9	6.9	212.4			
										-10.2	(-33.9, 13.5)	0.391A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.3.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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 BEST*	PLO	21	27.3	77.17	-19.7	0.0	3.1	10.2	283.9			
	ADA	20	11.4	35.10	-18.6	-3.9	0.9	11.4	126.3			
	TOT	41	19.5	60.23	-19.7	-1.3	1.2	10.2	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	21	14.5	46.78	-12.8	-0.5	4.1	6.9	212.4			
	ADA	20	7.0	24.89	-50.0	-0.3	2.6	10.0	81.8			
	TOT	41	10.8	37.46	-50.0	-0.5	2.9	6.9	212.4			
										-10.2	(-33.9, 13.5)	0.391A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	48	0.11	0.236	0.0	0.00	0.00	0.00	1.0			
	ADA	57	0.11	0.310	0.0	0.00	0.00	0.00	2.0			
	TOT	105	0.11	0.277	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	48	0.58	0.788	0.0	0.00	0.25	1.00	3.0			
	ADA	57	0.46	0.896	0.0	0.00	0.00	0.50	3.0			
	TOT	105	0.52	0.846	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	48	0.47	0.761	-0.5	0.00	0.00	0.50	2.5			
	ADA	57	0.36	0.828	-0.5	0.00	0.00	0.50	3.0			
	TOT	105	0.41	0.796	-0.5	0.00	0.00	0.50	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	48	0.16	0.345	0.0	0.00	0.00	0.25	2.0			
	ADA	57	0.10	0.258	0.0	0.00	0.00	0.00	1.0			
	TOT	105	0.12	0.300	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	48	0.75	1.171	0.0	0.00	0.00	1.00	4.0			
	ADA	57	0.39	0.754	0.0	0.00	0.00	0.50	3.0			
	TOT	105	0.56	0.979	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	48	0.59	1.114	-0.5	0.00	0.00	0.50	4.0			
	ADA	57	0.30	0.700	-1.0	0.00	0.00	0.50	2.5			
	TOT	105	0.43	0.920	-1.0	0.00	0.00	0.50	4.0			
										-0.20	(-0.49, 0.09)	0.170A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	49	0.39	0.552	0.0	0.00	0.00	0.50	2.0			
	ADA	57	0.25	0.355	0.0	0.00	0.00	0.50	1.0			
	TOT	106	0.32	0.459	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	49	0.63	0.776	0.0	0.00	0.50	1.00	3.0			
	ADA	57	0.38	0.607	0.0	0.00	0.00	0.50	3.0			
	TOT	106	0.50	0.699	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	49	0.24	0.596	-0.5	0.00	0.00	0.50	3.0			
	ADA	57	0.12	0.577	-1.0	0.00	0.00	0.50	2.0			
	TOT	106	0.18	0.586	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	49	0.30	0.444	0.0	0.00	0.00	0.50	2.0			
	ADA	57	0.37	0.418	0.0	0.00	0.50	0.50	2.0			
	TOT	106	0.33	0.429	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	49	0.67	0.875	0.0	0.00	0.50	1.00	4.0			
	ADA	57	0.46	0.650	0.0	0.00	0.00	1.00	3.0			
	TOT	106	0.56	0.766	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	49	0.38	0.807	-1.0	0.00	0.00	0.50	3.5			
	ADA	57	0.09	0.662	-1.5	0.00	0.00	0.50	2.5			
	TOT	106	0.22	0.743	-1.5	0.00	0.00	0.50	3.5			
										-0.21	(-0.42, 0.01)	0.064A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	49	0.12	0.270	-0.28	-0.06	0.08	0.24	0.94			
	ADA	57	0.11	0.310	-0.20	-0.10	0.00	0.16	1.30			
	TOT	106	0.11	0.291	-0.28	-0.08	0.02	0.22	1.30			
FINAL/ET VALUE	PLO	49	0.23	0.285	-0.16	0.02	0.16	0.36	1.00			
	ADA	57	0.17	0.358	-0.26	-0.06	0.04	0.32	1.60			
	TOT	106	0.20	0.326	-0.26	-0.02	0.11	0.34	1.60			
CHG FROM BEST*	PLO	49	0.11	0.136	-0.08	0.04	0.06	0.14	0.60			
	ADA	57	0.06	0.135	-0.22	-0.02	0.04	0.10	0.48			
	TOT	106	0.08	0.137	-0.22	0.00	0.06	0.12	0.60			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	49	0.13	0.240	-0.20	-0.08	0.10	0.32	0.76			
	ADA	57	0.13	0.276	-0.20	-0.08	0.04	0.26	0.90			
	TOT	106	0.13	0.259	-0.20	-0.08	0.10	0.28	0.90			
FINAL/ET VALUE	PLO	49	0.29	0.523	-0.20	-0.06	0.12	0.48	3.00			
	ADA	57	0.17	0.323	-0.22	-0.06	0.02	0.36	1.04			
	TOT	106	0.23	0.429	-0.22	-0.06	0.09	0.46	3.00			
CHG FROM BEST*	PLO	49	0.16	0.430	-0.16	0.00	0.04	0.16	2.82			
	ADA	57	0.04	0.113	-0.30	-0.02	0.02	0.08	0.32			
	TOT	106	0.10	0.309	-0.30	-0.02	0.04	0.10	2.82			
										-0.09	(-0.15, -0.02)	0.012A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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 BEST*	PLO	48	15.3	46.87	-10.8	0.8	4.3	9.5	291.1			
	ADA	56	4.6	23.44	-47.6	-3.5	1.1	5.9	99.1			
	TOT	104	9.6	36.39	-47.6	-0.9	2.0	7.7	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	48	24.0	80.25	-11.3	0.9	5.6	11.4	514.8			
	ADA	57	4.8	21.98	-43.0	-3.2	1.2	6.6	109.1			
	TOT	105	13.6	57.12	-43.0	-0.5	3.0	8.4	514.8			
										-13.0	(-27.8, 1.9)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

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

TABLE 14.2__1000.2.1.1.4.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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 BEST*	PLO	48	15.3	46.87	-10.8	0.8	4.3	9.5	291.1			
	ADA	56	4.6	23.44	-47.6	-3.5	1.1	5.9	99.1			
	TOT	104	9.6	36.39	-47.6	-0.9	2.0	7.7	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	48	24.0	80.25	-11.3	0.9	5.6	11.4	514.8			
	ADA	57	4.8	21.98	-43.0	-3.2	1.2	6.6	109.1			
	TOT	105	13.6	57.12	-43.0	-0.5	3.0	8.4	514.8			
										-13.0	(-27.8, 1.9)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.5.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	40	0.09	0.223	0.0	0.00	0.00	0.00	1.0			
	ADA	32	0.08	0.184	0.0	0.00	0.00	0.00	0.5			
	TOT	72	0.08	0.206	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	40	0.65	1.087	0.0	0.00	0.00	1.00	4.0			
	ADA	32	0.36	0.527	0.0	0.00	0.00	0.50	2.0			
	TOT	72	0.52	0.890	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	40	0.56	1.045	0.0	0.00	0.00	1.00	4.0			
	ADA	32	0.28	0.491	-0.5	0.00	0.00	0.50	2.0			
	TOT	72	0.44	0.851	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	40	0.09	0.192	0.0	0.00	0.00	0.00	0.5			
	ADA	32	0.08	0.184	0.0	0.00	0.00	0.00	0.5			
	TOT	72	0.08	0.188	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	40	0.75	1.098	0.0	0.00	0.00	1.00	4.0			
	ADA	32	0.42	0.611	0.0	0.00	0.00	0.50	2.0			
	TOT	72	0.60	0.923	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	40	0.66	1.034	-0.5	0.00	0.00	1.00	4.0			
	ADA	32	0.34	0.641	-0.5	0.00	0.00	0.50	2.0			
	TOT	72	0.52	0.890	-0.5	0.00	0.00	1.00	4.0			
										-0.30	(-0.68, 0.08)	0.123A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.5.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	40	0.45	0.336	0.0	0.00	0.50	0.50	1.0			
	ADA	32	0.53	0.782	0.0	0.00	0.50	0.50	3.0			
	TOT	72	0.49	0.575	0.0	0.00	0.50	0.50	3.0			
FINAL/ET VALUE	PLO	40	0.84	0.858	0.0	0.00	0.50	1.00	3.0			
	ADA	32	0.69	0.965	0.0	0.00	0.50	1.00	4.0			
	TOT	72	0.77	0.904	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	40	0.39	0.712	-0.5	0.00	0.00	0.75	2.0			
	ADA	32	0.16	0.574	-1.0	0.00	0.00	0.50	1.5			
	TOT	72	0.28	0.660	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	40	0.45	0.450	0.0	0.00	0.50	0.50	2.0			
	ADA	32	0.41	0.483	0.0	0.00	0.50	0.50	2.0			
	TOT	72	0.43	0.462	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	40	1.01	0.977	0.0	0.25	1.00	1.50	3.0			
	ADA	32	0.69	0.716	0.0	0.00	0.50	1.00	3.0			
	TOT	72	0.87	0.880	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	40	0.56	0.826	-1.0	0.00	0.50	1.00	2.5			
	ADA	32	0.28	0.695	-1.0	0.00	0.00	0.50	2.0			
	TOT	72	0.44	0.778	-1.0	0.00	0.00	1.00	2.5			
										-0.26	(-0.55, 0.04)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.5.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	40	0.17	0.289	-0.18	-0.06	0.06	0.35	0.88			
	ADA	32	0.20	0.298	-0.10	0.03	0.10	0.30	1.12			
	TOT	72	0.18	0.292	-0.18	-0.02	0.10	0.30	1.12			
FINAL/ET VALUE	PLO	40	0.28	0.360	-0.14	0.00	0.16	0.46	1.22			
	ADA	32	0.31	0.381	-0.14	0.05	0.21	0.47	1.62			
	TOT	72	0.29	0.367	-0.14	0.02	0.17	0.46	1.62			
CHG FROM BEST*	PLO	40	0.11	0.219	-0.62	0.01	0.07	0.17	0.76			
	ADA	32	0.10	0.189	-0.20	-0.04	0.04	0.22	0.58			
	TOT	72	0.11	0.204	-0.62	-0.02	0.05	0.18	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	40	0.28	0.366	-0.24	-0.02	0.15	0.53	1.16			
	ADA	32	0.15	0.202	-0.16	0.00	0.11	0.32	0.70			
	TOT	72	0.22	0.309	-0.24	-0.01	0.12	0.39	1.16			
FINAL/ET VALUE	PLO	40	0.40	0.458	-0.16	0.04	0.35	0.63	2.08			
	ADA	32	0.25	0.257	-0.20	0.09	0.21	0.43	0.94			
	TOT	72	0.33	0.387	-0.20	0.08	0.25	0.49	2.08			
CHG FROM BEST*	PLO	40	0.13	0.243	-0.18	0.00	0.05	0.16	1.20			
	ADA	32	0.10	0.158	-0.14	0.00	0.06	0.16	0.56			
	TOT	72	0.11	0.209	-0.18	0.00	0.06	0.16	1.20			
										-0.02	(-0.10, 0.06)	0.661A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.5.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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 BEST*	PLO	38	19.0	35.52	-28.4	1.7	6.2	15.7	136.0			
	ADA	32	31.8	88.47	-4.7	-0.5	4.2	22.9	483.1			
	TOT	70	24.9	65.07	-28.4	0.8	6.1	19.3	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	39	22.5	35.19	-7.2	0.0	8.3	34.7	165.2			
	ADA	32	36.3	96.91	-5.5	2.1	5.7	22.8	534.5			
	TOT	71	28.7	69.84	-7.2	1.7	8.2	30.6	534.5			
										12.1	(-17.6, 41.8)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.5.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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 BEST*	PLO	38	19.0	35.52	-28.4	1.7	6.2	15.7	136.0			
	ADA	30	29.9	89.72	-4.7	-0.5	4.2	19.3	483.1			
	TOT	68	23.8	64.89	-28.4	0.8	6.1	17.5	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	39	22.5	35.19	-7.2	0.0	8.3	34.7	165.2			
	ADA	30	37.4	100.05	-5.5	2.0	5.4	17.3	534.5			
	TOT	69	29.0	70.83	-7.2	1.7	7.5	30.6	534.5			
										12.8	(-17.8, 43.5)	0.406A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	81	0.10	0.229	0.0	0.00	0.00	0.00	1.0			
	ADA	79	0.06	0.179	0.0	0.00	0.00	0.00	1.0			
	TOT	160	0.08	0.206	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	81	0.70	1.030	0.0	0.00	0.00	1.00	4.0			
	ADA	79	0.33	0.742	0.0	0.00	0.00	0.50	3.0			
	TOT	160	0.52	0.915	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	81	0.60	0.992	-0.5	0.00	0.00	1.00	4.0			
	ADA	79	0.27	0.737	-1.0	0.00	0.00	0.50	3.0			
	TOT	160	0.44	0.888	-1.0	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	81	0.13	0.304	0.0	0.00	0.00	0.00	2.0			
	ADA	79	0.09	0.228	0.0	0.00	0.00	0.00	1.0			
	TOT	160	0.11	0.269	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	81	0.76	1.121	0.0	0.00	0.00	1.00	4.0			
	ADA	79	0.39	0.734	0.0	0.00	0.00	0.50	3.0			
	TOT	160	0.58	0.965	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	81	0.63	1.063	-0.5	0.00	0.00	1.00	4.0			
	ADA	79	0.29	0.701	-1.0	0.00	0.00	0.50	2.5			
	TOT	160	0.46	0.916	-1.0	0.00	0.00	0.50	4.0			
										-0.33	(-0.58, -0.08)	0.010A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	82	0.40	0.443	0.0	0.00	0.50	0.50	2.0			
	ADA	79	0.34	0.586	0.0	0.00	0.00	0.50	3.0			
	TOT	161	0.37	0.517	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	82	0.76	0.810	0.0	0.00	0.50	1.00	3.0			
	ADA	79	0.41	0.756	0.0	0.00	0.00	0.50	4.0			
	TOT	161	0.59	0.801	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	82	0.37	0.694	-0.5	0.00	0.00	0.50	3.0			
	ADA	79	0.06	0.521	-1.0	0.00	0.00	0.00	2.0			
	TOT	161	0.22	0.632	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	82	0.34	0.415	0.0	0.00	0.00	0.50	2.0			
	ADA	79	0.37	0.444	0.0	0.00	0.50	0.50	2.0			
	TOT	161	0.35	0.428	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	82	0.81	0.891	0.0	0.00	0.50	1.00	4.0			
	ADA	79	0.49	0.623	0.0	0.00	0.50	1.00	3.0			
	TOT	161	0.66	0.785	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	82	0.47	0.822	-1.0	0.00	0.00	0.50	3.5			
	ADA	79	0.13	0.653	-1.5	0.00	0.00	0.50	2.5			
	TOT	161	0.30	0.761	-1.5	0.00	0.00	0.50	3.5			
										-0.32	(-0.50, -0.14)	<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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	82	0.10	0.224	-0.28	-0.06	0.04	0.20	0.82			
	ADA	79	0.12	0.260	-0.18	-0.04	0.04	0.20	1.12			
	TOT	161	0.11	0.242	-0.28	-0.06	0.04	0.20	1.12			
FINAL/ET VALUE	PLO	82	0.23	0.301	-0.16	0.00	0.16	0.42	1.22			
	ADA	79	0.16	0.324	-0.28	-0.06	0.04	0.32	1.62			
	TOT	161	0.19	0.314	-0.28	-0.02	0.10	0.34	1.62			
CHG FROM BEST*	PLO	82	0.13	0.183	-0.06	0.02	0.07	0.18	0.80			
	ADA	79	0.04	0.144	-0.32	-0.04	0.00	0.08	0.50			
	TOT	161	0.09	0.171	-0.32	-0.02	0.04	0.14	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	82	0.14	0.266	-0.24	-0.06	0.09	0.26	0.84			
	ADA	79	0.12	0.226	-0.22	-0.06	0.10	0.26	0.70			
	TOT	161	0.13	0.246	-0.24	-0.06	0.10	0.26	0.84			
FINAL/ET VALUE	PLO	82	0.27	0.446	-0.20	-0.06	0.18	0.48	3.00			
	ADA	79	0.16	0.283	-0.26	-0.06	0.10	0.32	0.94			
	TOT	161	0.21	0.378	-0.26	-0.06	0.12	0.40	3.00			
CHG FROM BEST*	PLO	82	0.13	0.341	-0.18	0.00	0.04	0.16	2.82			
	ADA	79	0.03	0.148	-0.50	-0.04	0.02	0.08	0.56			
	TOT	161	0.08	0.268	-0.50	-0.02	0.04	0.10	2.82			
										-0.09	(-0.15, -0.04)	<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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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 BEST*	PLO	80	22.6	56.61	-10.8	1.0	4.5	14.0	291.1			
	ADA	79	10.4	28.99	-40.8	-1.0	1.5	9.8	128.0			
	TOT	159	16.5	45.34	-40.8	0.0	3.2	11.8	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	81	23.4	67.46	-12.8	0.0	5.3	14.4	514.8			
	ADA	79	9.2	26.58	-50.0	0.0	2.7	8.2	145.8			
	TOT	160	16.4	51.83	-50.0	0.0	4.3	11.2	514.8			
										-12.3	(-23.7, -0.8)	0.036A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.6.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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 BEST*	PLO	80	22.6	56.61	-10.8	1.0	4.5	14.0	291.1			
	ADA	78	8.9	26.25	-40.8	-1.0	1.4	7.4	128.0			
	TOT	158	15.9	44.70	-40.8	0.0	3.2	10.5	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	81	23.4	67.46	-12.8	0.0	5.3	14.4	514.8			
	ADA	78	9.0	26.67	-50.0	0.0	2.7	7.8	145.8			
	TOT	159	16.3	51.99	-50.0	0.0	4.2	11.2	514.8			
										-13.0	(-24.5, -1.5)	0.027A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	29	0.14	0.296	0.0	0.00	0.00	0.00	1.0			
	ADA	30	0.25	0.431	0.0	0.00	0.00	0.50	2.0			
	TOT	59	0.19	0.372	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	29	0.59	0.791	0.0	0.00	0.50	1.00	3.0			
	ADA	30	0.80	0.887	0.0	0.00	0.50	1.00	3.0			
	TOT	59	0.69	0.841	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	29	0.45	0.646	0.0	0.00	0.00	1.00	2.5			
	ADA	30	0.55	0.735	-0.5	0.00	0.25	1.00	2.0			
	TOT	59	0.50	0.689	-0.5	0.00	0.00	1.00	2.5			
AC RIGHT EYE												
BEST VALUE*	PLO	29	0.17	0.407	0.0	0.00	0.00	0.00	2.0			
	ADA	30	0.12	0.252	0.0	0.00	0.00	0.00	1.0			
	TOT	59	0.14	0.335	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	29	0.86	1.141	0.0	0.00	0.50	1.00	4.0			
	ADA	30	0.65	0.800	0.0	0.00	0.50	1.00	3.0			
	TOT	59	0.75	0.980	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	29	0.69	0.986	0.0	0.00	0.50	1.00	3.5			
	ADA	30	0.53	0.776	-0.5	0.00	0.50	1.00	2.5			
	TOT	59	0.61	0.881	-0.5	0.00	0.50	1.00	3.5			
										-0.03	(-0.39, 0.33)	0.880A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	29	0.45	0.506	0.0	0.00	0.50	1.00	2.0			
	ADA	30	0.28	0.364	0.0	0.00	0.00	0.50	1.0			
	TOT	59	0.36	0.444	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	29	0.71	0.840	0.0	0.00	0.50	1.00	3.0			
	ADA	30	0.53	0.601	0.0	0.00	0.50	0.50	2.0			
	TOT	59	0.62	0.727	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	29	0.26	0.621	-0.5	0.00	0.00	0.50	2.0			
	ADA	30	0.25	0.598	-1.0	0.00	0.00	0.50	2.0			
	TOT	59	0.25	0.604	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	29	0.45	0.523	0.0	0.00	0.50	1.00	2.0			
	ADA	30	0.28	0.387	0.0	0.00	0.00	0.50	1.0			
	TOT	59	0.36	0.463	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	29	1.00	1.052	0.0	0.00	1.00	2.00	3.0			
	ADA	30	0.52	0.701	0.0	0.00	0.25	1.00	3.0			
	TOT	59	0.75	0.916	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	29	0.55	0.806	-0.5	0.00	0.00	1.00	2.5			
	ADA	30	0.23	0.640	-1.0	0.00	0.00	0.50	2.0			
	TOT	59	0.39	0.737	-1.0	0.00	0.00	1.00	2.5			
										-0.16	(-0.48, 0.15)	0.298A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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												
BEST VALUE*	PLO	29	0.23	0.373	-0.26	-0.06	0.10	0.56	0.94			
	ADA	30	0.19	0.371	-0.20	-0.08	0.07	0.32	1.30			
	TOT	59	0.21	0.369	-0.26	-0.06	0.10	0.36	1.30			
FINAL/ET VALUE	PLO	29	0.27	0.380	-0.20	0.00	0.12	0.58	1.02			
	ADA	30	0.35	0.453	-0.26	0.00	0.24	0.62	1.60			
	TOT	59	0.31	0.417	-0.26	0.00	0.16	0.62	1.60			
CHG FROM BEST*	PLO	29	0.04	0.146	-0.62	0.02	0.06	0.10	0.22			
	ADA	30	0.16	0.184	-0.14	0.04	0.09	0.30	0.58			
	TOT	59	0.10	0.176	-0.62	0.02	0.06	0.16	0.58			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	29	0.29	0.387	-0.20	-0.02	0.20	0.56	1.16			
	ADA	30	0.18	0.294	-0.20	-0.04	0.09	0.36	0.90			
	TOT	59	0.24	0.345	-0.20	-0.04	0.16	0.44	1.16			
FINAL/ET VALUE	PLO	29	0.44	0.549	-0.20	0.00	0.38	0.86	2.08			
	ADA	30	0.27	0.334	-0.22	-0.02	0.16	0.46	1.04			
	TOT	59	0.36	0.457	-0.22	-0.02	0.34	0.58	2.08			
CHG FROM BEST*	PLO	29	0.15	0.295	-0.20	0.00	0.06	0.14	1.20			
	ADA	30	0.09	0.132	-0.10	0.00	0.06	0.14	0.50			
	TOT	59	0.12	0.227	-0.20	0.00	0.06	0.14	1.20			
										0.03	(-0.05, 0.12)	0.451A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.1.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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 BEST*	PLO	27	8.1	22.94	-28.4	-1.3	4.2	10.8	96.7			
	ADA	29	23.7	92.99	-47.6	-2.4	0.0	12.1	483.1			
	TOT	56	16.2	68.65	-47.6	-2.1	3.1	11.4	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	27	16.5	33.90	-9.2	0.9	8.2	15.0	174.4			
	ADA	30	28.3	99.74	-43.0	-1.3	1.9	14.3	534.5			
	TOT	57	22.7	75.63	-43.0	-0.5	5.4	14.4	534.5			
										16.9	(-19.7, 53.5)	0.360A

* 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.
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 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 AND OCT MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.1.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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 BEST*	PLO	27	8.1	22.94	-28.4	-1.3	4.2	10.8	96.7			
	ADA	28	24.5	94.58	-47.6	-3.1	-0.2	14.6	483.1			
	TOT	55	16.5	69.24	-47.6	-2.1	3.1	12.0	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	27	16.5	33.90	-9.2	0.9	8.2	15.0	174.4			
	ADA	29	29.0	101.44	-43.0	-1.3	1.7	14.3	534.5			
	TOT	56	23.0	76.30	-43.0	-0.5	5.0	14.7	534.5			
										17.4	(-19.8, 54.6)	0.352A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	12	0.13	0.226	0.0	0.00	0.00	0.25	0.5
	ADA	11	0.41	0.625	0.0	0.00	0.00	0.50	2.0
	TOT	23	0.26	0.474	0.0	0.00	0.00	0.50	2.0
FINAL/ET VALUE	PLO	12	0.63	0.856	0.0	0.00	0.50	1.00	3.0
	ADA	11	1.18	1.055	0.0	0.50	1.00	2.00	3.0
	TOT	23	0.89	0.977	0.0	0.00	0.50	1.00	3.0
CHG FROM BEST*	PLO	12	0.50	0.769	0.0	0.00	0.00	1.00	2.5
	ADA	11	0.77	0.720	0.0	0.00	0.50	1.00	2.0
	TOT	23	0.63	0.742	0.0	0.00	0.50	1.00	2.5
AC RIGHT EYE									
BEST VALUE*	PLO	12	0.29	0.582	0.0	0.00	0.00	0.50	2.0
	ADA	11	0.14	0.323	0.0	0.00	0.00	0.00	1.0
	TOT	23	0.22	0.473	0.0	0.00	0.00	0.50	2.0
FINAL/ET VALUE	PLO	12	1.46	1.469	0.0	0.00	1.00	3.00	4.0
	ADA	11	1.00	0.949	0.0	0.50	0.50	2.00	3.0
	TOT	23	1.24	1.242	0.0	0.00	1.00	2.00	4.0
CHG FROM BEST*	PLO	12	1.17	1.285	0.0	0.00	1.00	2.25	3.5
	ADA	11	0.86	0.897	0.0	0.00	0.50	2.00	2.5
	TOT	23	1.02	1.102	0.0	0.00	0.50	2.00	3.5

* 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.
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__1000.2.1.1.7.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	12	0.58	0.597	0.0	0.00	0.50	1.00	2.0
	ADA	11	0.41	0.437	0.0	0.00	0.50	1.00	1.0
	TOT	23	0.50	0.522	0.0	0.00	0.50	1.00	2.0
FINAL/ET VALUE	PLO	12	0.83	0.835	0.0	0.00	1.00	1.50	2.0
	ADA	11	0.68	0.717	0.0	0.00	0.50	1.00	2.0
	TOT	23	0.76	0.767	0.0	0.00	0.50	1.00	2.0
CHG FROM BEST*	PLO	12	0.25	0.691	-0.5	0.00	0.00	0.50	2.0
	ADA	11	0.27	0.720	-1.0	0.00	0.00	1.00	1.5
	TOT	23	0.26	0.689	-1.0	0.00	0.00	0.50	2.0
VH RIGHT EYE									
BEST VALUE*	PLO	12	0.38	0.433	0.0	0.00	0.25	0.75	1.0
	ADA	11	0.27	0.410	0.0	0.00	0.00	0.50	1.0
	TOT	23	0.33	0.416	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	12	0.96	0.865	0.0	0.00	1.00	2.00	2.0
	ADA	11	0.50	0.894	0.0	0.00	0.00	0.50	3.0
	TOT	23	0.74	0.890	0.0	0.00	0.50	1.00	3.0
CHG FROM BEST*	PLO	12	0.58	0.733	-0.5	0.00	0.50	1.00	2.0
	ADA	11	0.23	0.786	-1.0	0.00	0.00	0.50	2.0
	TOT	23	0.41	0.764	-1.0	0.00	0.00	1.00	2.0

* 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.
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__1000.2.1.1.7.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	12	0.20	0.394	-0.26	-0.13	0.11	0.53	0.88
	ADA	11	0.27	0.329	-0.10	-0.02	0.12	0.56	0.82
	TOT	23	0.23	0.357	-0.26	-0.08	0.12	0.56	0.88
FINAL/ET VALUE	PLO	12	0.28	0.420	-0.20	-0.09	0.21	0.69	0.98
	ADA	11	0.49	0.421	0.04	0.14	0.44	0.84	1.26
	TOT	23	0.38	0.425	-0.20	0.04	0.32	0.74	1.26
CHG FROM BEST*	PLO	12	0.08	0.074	-0.08	0.04	0.07	0.14	0.18
	ADA	11	0.23	0.166	0.04	0.06	0.22	0.32	0.48
	TOT	23	0.15	0.145	-0.08	0.06	0.10	0.22	0.48
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	12	0.21	0.346	-0.16	-0.08	0.16	0.41	0.98
	ADA	11	0.24	0.318	-0.16	0.00	0.18	0.42	0.90
	TOT	23	0.23	0.326	-0.16	-0.04	0.18	0.42	0.98
FINAL/ET VALUE	PLO	12	0.33	0.501	-0.20	-0.05	0.21	0.67	1.32
	ADA	11	0.33	0.346	-0.04	-0.02	0.14	0.64	0.92
	TOT	23	0.33	0.424	-0.20	-0.02	0.14	0.64	1.32
CHG FROM BEST*	PLO	12	0.12	0.268	-0.20	-0.01	0.05	0.15	0.88
	ADA	11	0.09	0.162	-0.06	-0.02	0.02	0.18	0.50
	TOT	23	0.10	0.219	-0.20	-0.02	0.04	0.16	0.88

* 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.
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__1000.2.1.1.7.2.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	11	11.8	32.75	-19.7	-2.7	4.7	12.0	96.7
	ADA	10	10.9	44.28	-47.6	-3.8	2.7	12.1	126.3
	TOT	21	11.4	37.67	-47.6	-2.7	3.6	12.0	126.3
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	12	8.9	14.88	-9.2	-0.9	5.9	13.9	43.8
	ADA	11	-2.0	15.50	-43.0	-3.2	1.7	3.0	15.8
	TOT	23	3.7	15.84	-43.0	-1.3	2.2	12.7	43.8

* 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.
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__1000.2.1.1.7.2.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	11	11.8	32.75	-19.7	-2.7	4.7	12.0	96.7
	ADA	10	10.9	44.28	-47.6	-3.8	2.7	12.1	126.3
	TOT	21	11.4	37.67	-47.6	-2.7	3.6	12.0	126.3
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	12	8.9	14.88	-9.2	-0.9	5.9	13.9	43.8
	ADA	11	-2.0	15.50	-43.0	-3.2	1.7	3.0	15.8
	TOT	23	3.7	15.84	-43.0	-1.3	2.2	12.7	43.8

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	10	0.20	0.422	0.0	0.00	0.00	0.00	1.0
	ADA	12	0.13	0.226	0.0	0.00	0.00	0.25	0.5
	TOT	22	0.16	0.323	0.0	0.00	0.00	0.00	1.0
FINAL/ET VALUE	PLO	10	0.50	0.850	0.0	0.00	0.00	1.00	2.0
	ADA	12	0.67	0.718	0.0	0.00	0.50	1.00	2.0
	TOT	22	0.59	0.766	0.0	0.00	0.25	1.00	2.0
CHG FROM BEST*	PLO	10	0.30	0.483	0.0	0.00	0.00	1.00	1.0
	ADA	12	0.54	0.782	0.0	0.00	0.00	1.00	2.0
	TOT	22	0.43	0.660	0.0	0.00	0.00	1.00	2.0
AC RIGHT EYE									
BEST VALUE*	PLO	10	0.10	0.211	0.0	0.00	0.00	0.00	0.5
	ADA	12	0.04	0.144	0.0	0.00	0.00	0.00	0.5
	TOT	22	0.07	0.176	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	10	0.25	0.425	0.0	0.00	0.00	0.50	1.0
	ADA	12	0.54	0.582	0.0	0.00	0.50	0.75	2.0
	TOT	22	0.41	0.526	0.0	0.00	0.25	0.50	2.0
CHG FROM BEST*	PLO	10	0.15	0.242	0.0	0.00	0.00	0.50	0.5
	ADA	12	0.50	0.603	0.0	0.00	0.50	0.75	2.0
	TOT	22	0.34	0.497	0.0	0.00	0.00	0.50	2.0

* 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.
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__1000.2.1.1.7.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	10	0.45	0.438	0.0	0.00	0.50	1.00	1.0
	ADA	12	0.21	0.334	0.0	0.00	0.00	0.50	1.0
	TOT	22	0.32	0.395	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	10	0.85	1.001	0.0	0.00	0.75	1.00	3.0
	ADA	12	0.38	0.377	0.0	0.00	0.50	0.50	1.0
	TOT	22	0.59	0.750	0.0	0.00	0.50	1.00	3.0
CHG FROM BEST*	PLO	10	0.40	0.738	-0.5	0.00	0.00	1.00	2.0
	ADA	12	0.17	0.326	0.0	0.00	0.00	0.25	1.0
	TOT	22	0.27	0.550	-0.5	0.00	0.00	0.50	2.0
VH RIGHT EYE									
BEST VALUE*	PLO	10	0.70	0.632	0.0	0.00	0.75	1.00	2.0
	ADA	12	0.33	0.444	0.0	0.00	0.00	0.75	1.0
	TOT	22	0.50	0.556	0.0	0.00	0.50	1.00	2.0
FINAL/ET VALUE	PLO	10	1.55	1.301	0.0	0.50	1.00	3.00	3.0
	ADA	12	0.67	0.651	0.0	0.00	1.00	1.00	2.0
	TOT	22	1.07	1.072	0.0	0.00	1.00	1.00	3.0
CHG FROM BEST*	PLO	10	0.85	1.029	-0.5	0.00	0.75	2.00	2.5
	ADA	12	0.33	0.615	-0.5	0.00	0.00	1.00	1.5
	TOT	22	0.57	0.849	-0.5	0.00	0.00	1.00	2.5

* 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.
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__1000.2.1.1.7.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	10	0.29	0.442	-0.22	-0.06	0.06	0.78	0.94
	ADA	12	0.16	0.311	-0.14	-0.01	0.06	0.27	1.02
	TOT	22	0.22	0.372	-0.22	-0.02	0.06	0.32	1.02
FINAL/ET VALUE	PLO	10	0.29	0.428	-0.18	0.04	0.10	0.58	1.02
	ADA	12	0.26	0.354	-0.08	0.00	0.17	0.39	1.12
	TOT	22	0.27	0.380	-0.18	0.00	0.12	0.42	1.12
CHG FROM BEST*	PLO	10	-0.01	0.227	-0.62	0.02	0.05	0.08	0.22
	ADA	12	0.10	0.173	-0.08	0.01	0.06	0.14	0.58
	TOT	22	0.05	0.202	-0.62	0.02	0.05	0.10	0.58
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	10	0.50	0.465	-0.20	-0.02	0.63	0.88	1.16
	ADA	12	0.14	0.266	-0.20	-0.04	0.06	0.29	0.76
	TOT	22	0.31	0.405	-0.20	-0.02	0.24	0.70	1.16
FINAL/ET VALUE	PLO	10	0.70	0.661	-0.16	0.12	0.65	1.00	2.08
	ADA	12	0.29	0.328	-0.20	0.07	0.26	0.44	1.04
	TOT	22	0.47	0.536	-0.20	0.12	0.39	0.76	2.08
CHG FROM BEST*	PLO	10	0.19	0.396	-0.16	-0.02	0.05	0.14	1.20
	ADA	12	0.14	0.115	0.00	0.06	0.11	0.25	0.36
	TOT	22	0.17	0.273	-0.16	0.02	0.09	0.24	1.20

* 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.
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__1000.2.1.1.7.3.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	9	1.8	12.31	-28.4	1.2	3.1	8.4	13.7
	ADA	12	49.3	138.01	-6.6	-2.3	-0.1	30.2	483.1
	TOT	21	28.9	105.44	-28.4	-2.1	3.1	10.8	483.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	8	13.0	9.44	4.1	5.7	10.3	18.7	30.6
	ADA	12	69.6	150.70	-4.2	0.2	13.4	63.7	534.5
	TOT	20	47.0	118.28	-4.2	4.4	12.4	32.2	534.5

* 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.
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__1000.2.1.1.7.3.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	9	1.8	12.31	-28.4	1.2	3.1	8.4	13.7
	ADA	11	53.7	143.84	-6.6	-2.4	-0.5	39.1	483.1
	TOT	20	30.4	107.97	-28.4	-2.1	3.1	12.2	483.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	8	13.0	9.44	4.1	5.7	10.3	18.7	30.6
	ADA	11	75.0	156.82	-4.2	-0.8	14.3	81.8	534.5
	TOT	19	48.9	121.19	-4.2	4.1	12.4	33.7	534.5

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5
FINAL/ET VALUE	PLO	1	1.00		1.0	1.00	1.00	1.00	1.0
	ADA	0							
	TOT	1	1.00		1.0	1.00	1.00	1.00	1.0
CHG FROM BEST*	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5
AC RIGHT EYE									
BEST VALUE*	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5
FINAL/ET VALUE	PLO	1	1.00		1.0	1.00	1.00	1.00	1.0
	ADA	0							
	TOT	1	1.00		1.0	1.00	1.00	1.00	1.0
CHG FROM BEST*	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5

* 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.
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__1000.2.1.1.7.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5
FINAL/ET VALUE	PLO	1	1.00		1.0	1.00	1.00	1.00	1.0
	ADA	0							
	TOT	1	1.00		1.0	1.00	1.00	1.00	1.0
CHG FROM BEST*	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5
VH RIGHT EYE									
BEST VALUE*	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5
FINAL/ET VALUE	PLO	1	0.50		0.5	0.50	0.50	0.50	0.5
	ADA	0							
	TOT	1	0.50		0.5	0.50	0.50	0.50	0.5
CHG FROM BEST*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	0							
	TOT	1	0.00		0.0	0.00	0.00	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.
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__1000.2.1.1.7.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	1	0.22		0.22	0.22	0.22	0.22	0.22
	ADA	0							
	TOT	1	0.22		0.22	0.22	0.22	0.22	0.22
FINAL/ET VALUE	PLO	1	0.34		0.34	0.34	0.34	0.34	0.34
	ADA	0							
	TOT	1	0.34		0.34	0.34	0.34	0.34	0.34
CHG FROM BEST*	PLO	1	0.12		0.12	0.12	0.12	0.12	0.12
	ADA	0							
	TOT	1	0.12		0.12	0.12	0.12	0.12	0.12
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	1	0.20		0.20	0.20	0.20	0.20	0.20
	ADA	0							
	TOT	1	0.20		0.20	0.20	0.20	0.20	0.20
FINAL/ET VALUE	PLO	1	0.34		0.34	0.34	0.34	0.34	0.34
	ADA	0							
	TOT	1	0.34		0.34	0.34	0.34	0.34	0.34
CHG FROM BEST*	PLO	1	0.14		0.14	0.14	0.14	0.14	0.14
	ADA	0							
	TOT	1	0.14		0.14	0.14	0.14	0.14	0.14

* 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.
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__1000.2.1.1.7.4.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	1	3.4		3.4	3.4	3.4	3.4	3.4
	ADA	0							
	TOT	1	3.4		3.4	3.4	3.4	3.4	3.4
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	1	0.9		0.9	0.9	0.9	0.9	0.9
	ADA	0							
	TOT	1	0.9		0.9	0.9	0.9	0.9	0.9

* 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.
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__1000.2.1.1.7.4.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	1	3.4		3.4	3.4	3.4	3.4	3.4
	ADA	0							
	TOT	1	3.4		3.4	3.4	3.4	3.4	3.4
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	1	0.9		0.9	0.9	0.9	0.9	0.9
	ADA	0							
	TOT	1	0.9		0.9	0.9	0.9	0.9	0.9

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.5.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

VISIT	TREATMENT N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX

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

* 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.
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__1000.2.1.1.7.5.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

VISIT	TREATMENT N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX

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

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	5	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	6	0.17	0.258	0.0	0.00	0.00	0.50	0.5
	TOT	11	0.09	0.202	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	5	0.70	0.758	0.0	0.50	0.50	0.50	2.0
	ADA	6	0.17	0.258	0.0	0.00	0.00	0.50	0.5
	TOT	11	0.41	0.584	0.0	0.00	0.50	0.50	2.0
CHG FROM BEST*	PLO	5	0.70	0.758	0.0	0.50	0.50	0.50	2.0
	ADA	6	0.00	0.316	-0.5	0.00	0.00	0.00	0.5
	TOT	11	0.32	0.643	-0.5	0.00	0.00	0.50	2.0
AC RIGHT EYE									
BEST VALUE*	PLO	5	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	6	0.17	0.258	0.0	0.00	0.00	0.50	0.5
	TOT	11	0.09	0.202	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	5	0.80	0.758	0.0	0.50	0.50	1.00	2.0
	ADA	6	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	11	0.36	0.636	0.0	0.00	0.00	0.50	2.0
CHG FROM BEST*	PLO	5	0.80	0.758	0.0	0.50	0.50	1.00	2.0
	ADA	6	-0.17	0.258	-0.5	-0.50	0.00	0.00	0.0
	TOT	11	0.27	0.720	-0.5	0.00	0.00	0.50	2.0

* 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.
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__1000.2.1.1.7.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	5	0.20	0.447	0.0	0.00	0.00	0.00	1.0
	ADA	6	0.25	0.274	0.0	0.00	0.25	0.50	0.5
	TOT	11	0.23	0.344	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	5	0.20	0.447	0.0	0.00	0.00	0.00	1.0
	ADA	6	0.67	0.753	0.0	0.00	0.50	1.00	2.0
	TOT	11	0.45	0.650	0.0	0.00	0.00	1.00	2.0
CHG FROM BEST*	PLO	5	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	6	0.42	0.861	-0.5	0.00	0.25	0.50	2.0
	TOT	11	0.23	0.647	-0.5	0.00	0.00	0.50	2.0
VH RIGHT EYE									
BEST VALUE*	PLO	5	0.20	0.447	0.0	0.00	0.00	0.00	1.0
	ADA	6	0.25	0.274	0.0	0.00	0.25	0.50	0.5
	TOT	11	0.23	0.344	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	5	0.30	0.447	0.0	0.00	0.00	0.50	1.0
	ADA	6	0.33	0.408	0.0	0.00	0.25	0.50	1.0
	TOT	11	0.32	0.405	0.0	0.00	0.00	0.50	1.0
CHG FROM BEST*	PLO	5	0.10	0.224	0.0	0.00	0.00	0.00	0.5
	ADA	6	0.08	0.492	-0.5	0.00	0.00	0.00	1.0
	TOT	11	0.09	0.375	-0.5	0.00	0.00	0.00	1.0

* 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.
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__1000.2.1.1.7.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	5	0.23	0.277	0.00	0.10	0.10	0.24	0.70
	ADA	6	0.13	0.578	-0.20	-0.16	-0.09	0.04	1.30
	TOT	11	0.18	0.447	-0.20	-0.12	0.04	0.24	1.30
FINAL/ET VALUE	PLO	5	0.25	0.287	0.02	0.04	0.12	0.36	0.70
	ADA	6	0.29	0.684	-0.26	-0.18	0.13	0.34	1.60
	TOT	11	0.27	0.517	-0.26	-0.02	0.12	0.36	1.60
CHG FROM BEST*	PLO	5	0.02	0.072	-0.08	0.00	0.02	0.04	0.12
	ADA	6	0.16	0.236	-0.14	-0.02	0.17	0.30	0.48
	TOT	11	0.10	0.188	-0.14	-0.02	0.04	0.30	0.48
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	5	0.14	0.202	-0.02	0.00	0.10	0.16	0.48
	ADA	6	0.18	0.354	-0.12	-0.12	0.08	0.40	0.74
	TOT	11	0.16	0.281	-0.12	-0.10	0.10	0.40	0.74
FINAL/ET VALUE	PLO	5	0.32	0.390	0.00	0.10	0.10	0.48	0.94
	ADA	6	0.21	0.374	-0.22	-0.06	0.16	0.44	0.76
	TOT	11	0.26	0.367	-0.22	-0.04	0.10	0.48	0.94
CHG FROM BEST*	PLO	5	0.18	0.204	0.00	0.00	0.12	0.32	0.46
	ADA	6	0.03	0.069	-0.10	0.02	0.05	0.06	0.10
	TOT	11	0.10	0.159	-0.10	0.00	0.06	0.12	0.46

* 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.
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__1000.2.1.1.7.6.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	5	13.3	16.25	-2.2	3.9	6.8	19.4	38.7
	ADA	6	-2.3	13.09	-17.7	-14.2	-0.5	0.0	19.3
	TOT	11	4.8	16.05	-17.7	-2.2	0.0	19.3	38.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	5	46.9	72.31	5.8	8.9	9.4	35.8	174.4
	ADA	6	6.3	19.62	-10.9	-3.3	0.8	5.4	44.7
	TOT	11	24.7	52.29	-10.9	0.4	5.8	35.8	174.4

* 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.
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__1000.2.1.1.7.6.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	5	13.3	16.25	-2.2	3.9	6.8	19.4	38.7
	ADA	6	-2.3	13.09	-17.7	-14.2	-0.5	0.0	19.3
	TOT	11	4.8	16.05	-17.7	-2.2	0.0	19.3	38.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	5	46.9	72.31	5.8	8.9	9.4	35.8	174.4
	ADA	6	6.3	19.62	-10.9	-3.3	0.8	5.4	44.7
	TOT	11	24.7	52.29	-10.9	0.4	5.8	35.8	174.4

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.7.7.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.50		0.5	0.50	0.50	0.50	0.5
	TOT	2	0.25	0.354	0.0	0.00	0.25	0.50	0.5
FINAL/ET VALUE	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	2.00		2.0	2.00	2.00	2.00	2.0
	TOT	2	1.00	1.414	0.0	0.00	1.00	2.00	2.0
CHG FROM BEST*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	1.50		1.5	1.50	1.50	1.50	1.5
	TOT	2	0.75	1.061	0.0	0.00	0.75	1.50	1.5
AC RIGHT EYE									
BEST VALUE*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.50		0.5	0.50	0.50	0.50	0.5
	TOT	2	0.25	0.354	0.0	0.00	0.25	0.50	0.5
FINAL/ET VALUE	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	2.00		2.0	2.00	2.00	2.00	2.0
	TOT	2	1.00	1.414	0.0	0.00	1.00	2.00	2.0
CHG FROM BEST*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	1.50		1.5	1.50	1.50	1.50	1.5
	TOT	2	0.75	1.061	0.0	0.00	0.75	1.50	1.5

* 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.
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__1000.2.1.1.7.7.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.00		0.0	0.00	0.00	0.00	0.0
	TOT	2	0.00	0.000	0.0	0.00	0.00	0.00	0.0
FINAL/ET VALUE	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.00		0.0	0.00	0.00	0.00	0.0
	TOT	2	0.00	0.000	0.0	0.00	0.00	0.00	0.0
CHG FROM BEST*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.00		0.0	0.00	0.00	0.00	0.0
	TOT	2	0.00	0.000	0.0	0.00	0.00	0.00	0.0
VH RIGHT EYE									
BEST VALUE*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.00		0.0	0.00	0.00	0.00	0.0
	TOT	2	0.00	0.000	0.0	0.00	0.00	0.00	0.0
FINAL/ET VALUE	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.00		0.0	0.00	0.00	0.00	0.0
	TOT	2	0.00	0.000	0.0	0.00	0.00	0.00	0.0
CHG FROM BEST*	PLO	1	0.00		0.0	0.00	0.00	0.00	0.0
	ADA	1	0.00		0.0	0.00	0.00	0.00	0.0
	TOT	2	0.00	0.000	0.0	0.00	0.00	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.
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__1000.2.1.1.7.7.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	1	-0.04		-0.04	-0.04	-0.04	-0.04	-0.04
	ADA	1	-0.08		-0.08	-0.08	-0.08	-0.08	-0.08
	TOT	2	-0.06	0.028	-0.08	-0.08	-0.06	-0.04	-0.04
FINAL/ET VALUE	PLO	1	-0.08		-0.08	-0.08	-0.08	-0.08	-0.08
	ADA	1	0.00		0.00	0.00	0.00	0.00	0.00
	TOT	2	-0.04	0.057	-0.08	-0.08	-0.04	0.00	0.00
CHG FROM BEST*	PLO	1	-0.04		-0.04	-0.04	-0.04	-0.04	-0.04
	ADA	1	0.08		0.08	0.08	0.08	0.08	0.08
	TOT	2	0.02	0.085	-0.04	-0.04	0.02	0.08	0.08
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	1	-0.06		-0.06	-0.06	-0.06	-0.06	-0.06
	ADA	1	0.00		0.00	0.00	0.00	0.00	0.00
	TOT	2	-0.03	0.042	-0.06	-0.06	-0.03	0.00	0.00
FINAL/ET VALUE	PLO	1	-0.08		-0.08	-0.08	-0.08	-0.08	-0.08
	ADA	1	-0.04		-0.04	-0.04	-0.04	-0.04	-0.04
	TOT	2	-0.06	0.028	-0.08	-0.08	-0.06	-0.04	-0.04
CHG FROM BEST*	PLO	1	-0.02		-0.02	-0.02	-0.02	-0.02	-0.02
	ADA	1	-0.04		-0.04	-0.04	-0.04	-0.04	-0.04
	TOT	2	-0.03	0.014	-0.04	-0.04	-0.03	-0.02	-0.02

* 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.
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__1000.2.1.1.7.7.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	1	4.2		4.2	4.2	4.2	4.2	4.2
	ADA	1	0.0		0.0	0.0	0.0	0.0	0.0
	TOT	2	2.1	2.97	0.0	0.0	2.1	4.2	4.2
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	1	0.5		0.5	0.5	0.5	0.5	0.5
	ADA	1	-0.5		-0.5	-0.5	-0.5	-0.5	-0.5
	TOT	2	0.0	0.69	-0.5	-0.5	0.0	0.5	0.5

* 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.
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__1000.2.1.1.7.7.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	1	4.2		4.2	4.2	4.2	4.2	4.2
	ADA	1	0.0		0.0	0.0	0.0	0.0	0.0
	TOT	2	2.1	2.97	0.0	0.0	2.1	4.2	4.2
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	1	0.5		0.5	0.5	0.5	0.5	0.5
	ADA	1	-0.5		-0.5	-0.5	-0.5	-0.5	-0.5
	TOT	2	0.0	0.69	-0.5	-0.5	0.0	0.5	0.5

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.8.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	34	0.12	0.277	0.0	0.00	0.00	0.00	1.0			
	ADA	42	0.10	0.199	0.0	0.00	0.00	0.00	0.5			
	TOT	76	0.11	0.235	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	34	0.72	1.116	0.0	0.00	0.25	1.00	4.0			
	ADA	42	0.46	0.872	0.0	0.00	0.00	0.50	3.0			
	TOT	76	0.58	0.990	0.0	0.00	0.00	0.75	4.0			
CHG FROM BEST*	PLO	34	0.60	1.021	0.0	0.00	0.25	0.50	4.0			
	ADA	42	0.37	0.834	-0.5	0.00	0.00	0.50	3.0			
	TOT	76	0.47	0.923	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	34	0.16	0.403	0.0	0.00	0.00	0.00	2.0			
	ADA	42	0.11	0.235	0.0	0.00	0.00	0.00	1.0			
	TOT	76	0.13	0.320	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	34	0.74	1.169	0.0	0.00	0.00	1.00	4.0			
	ADA	42	0.44	0.751	0.0	0.00	0.00	0.50	3.0			
	TOT	76	0.57	0.965	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	34	0.57	1.038	0.0	0.00	0.00	0.50	4.0			
	ADA	42	0.33	0.678	-0.5	0.00	0.00	0.50	2.0			
	TOT	76	0.44	0.860	-0.5	0.00	0.00	0.50	4.0			
										-0.24	(-0.63, 0.15)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.8.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	35	0.41	0.462	0.0	0.00	0.50	0.50	2.0			
	ADA	42	0.33	0.548	0.0	0.00	0.00	0.50	3.0			
	TOT	77	0.37	0.509	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	35	0.60	0.775	0.0	0.00	0.50	1.00	3.0			
	ADA	42	0.38	0.593	0.0	0.00	0.00	0.50	2.0			
	TOT	77	0.48	0.686	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	35	0.19	0.530	-0.5	0.00	0.00	0.50	2.0			
	ADA	42	0.05	0.504	-1.0	0.00	0.00	0.50	1.5			
	TOT	77	0.11	0.517	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	35	0.36	0.479	0.0	0.00	0.00	0.50	2.0			
	ADA	42	0.30	0.495	0.0	0.00	0.00	0.50	2.0			
	TOT	77	0.32	0.485	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	35	0.73	0.886	0.0	0.00	0.50	1.00	3.0			
	ADA	42	0.43	0.640	0.0	0.00	0.00	1.00	3.0			
	TOT	77	0.56	0.771	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	35	0.37	0.586	-0.5	0.00	0.00	0.50	2.0			
	ADA	42	0.13	0.644	-1.5	0.00	0.00	0.50	2.0			
	TOT	77	0.24	0.626	-1.5	0.00	0.00	0.50	2.0			
										-0.19	(-0.41, 0.03)	0.095A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.8.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	35	0.09	0.220	-0.18	-0.02	0.06	0.12	0.80			
	ADA	42	0.11	0.291	-0.20	-0.08	0.02	0.20	1.30			
	TOT	77	0.10	0.260	-0.20	-0.06	0.04	0.14	1.30			
FINAL/ET VALUE	PLO	35	0.21	0.281	-0.14	0.04	0.12	0.30	1.02			
	ADA	42	0.21	0.382	-0.28	-0.06	0.08	0.34	1.60			
	TOT	77	0.21	0.338	-0.28	-0.02	0.12	0.34	1.60			
CHG FROM BEST*	PLO	35	0.12	0.236	-0.62	0.02	0.06	0.14	0.80			
	ADA	42	0.10	0.182	-0.20	-0.02	0.03	0.30	0.58			
	TOT	77	0.11	0.207	-0.62	0.00	0.04	0.22	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	35	0.14	0.298	-0.16	-0.06	0.08	0.20	1.16			
	ADA	42	0.13	0.268	-0.22	-0.08	0.05	0.30	0.74			
	TOT	77	0.13	0.280	-0.22	-0.08	0.06	0.24	1.16			
FINAL/ET VALUE	PLO	35	0.25	0.449	-0.18	-0.04	0.10	0.34	2.08			
	ADA	42	0.17	0.315	-0.26	-0.06	0.10	0.42	0.90			
	TOT	77	0.21	0.381	-0.26	-0.06	0.10	0.36	2.08			
CHG FROM BEST*	PLO	35	0.10	0.235	-0.16	0.00	0.06	0.14	1.20			
	ADA	42	0.05	0.141	-0.50	-0.02	0.04	0.10	0.36			
	TOT	77	0.07	0.190	-0.50	-0.02	0.04	0.14	1.20			
										-0.04	(-0.11, 0.04)	0.314A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.8.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	34	19.1	53.70	-28.4	0.4	4.7	15.5	291.1			
	ADA	41	17.3	78.34	-47.6	-1.8	2.1	7.4	483.1			
	TOT	75	18.1	67.85	-47.6	-0.6	3.4	12.0	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	34	15.8	41.06	-11.3	0.9	5.2	8.9	174.4			
	ADA	42	19.1	83.00	-43.0	0.4	2.5	12.7	534.5			
	TOT	76	17.6	67.16	-43.0	0.5	3.9	10.0	534.5			
										6.6	(-22.7, 35.8)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.8.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	34	19.1	53.70	-28.4	0.4	4.7	15.5	291.1			
	ADA	41	17.3	78.34	-47.6	-1.8	2.1	7.4	483.1			
	TOT	75	18.1	67.85	-47.6	-0.6	3.4	12.0	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	34	15.8	41.06	-11.3	0.9	5.2	8.9	174.4			
	ADA	42	19.1	83.00	-43.0	0.4	2.5	12.7	534.5			
	TOT	76	17.6	67.16	-43.0	0.5	3.9	10.0	534.5			
										6.6	(-22.7, 35.8)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.9.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	76	0.11	0.235	0.0	0.00	0.00	0.00	1.0			
	ADA	67	0.12	0.327	0.0	0.00	0.00	0.00	2.0			
	TOT	143	0.11	0.281	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	76	0.64	0.905	0.0	0.00	0.00	1.00	3.0			
	ADA	67	0.46	0.772	0.0	0.00	0.00	0.50	3.0			
	TOT	143	0.56	0.848	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	76	0.54	0.867	-0.5	0.00	0.00	1.00	3.0			
	ADA	67	0.34	0.687	-1.0	0.00	0.00	0.50	3.0			
	TOT	143	0.44	0.792	-1.0	0.00	0.00	1.00	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	76	0.13	0.299	0.0	0.00	0.00	0.00	2.0			
	ADA	67	0.10	0.234	0.0	0.00	0.00	0.00	1.0			
	TOT	143	0.12	0.270	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	76	0.81	1.107	0.0	0.00	0.00	1.00	4.0			
	ADA	67	0.47	0.768	0.0	0.00	0.00	0.50	3.0			
	TOT	143	0.65	0.975	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	76	0.68	1.045	-0.5	0.00	0.00	1.00	4.0			
	ADA	67	0.37	0.760	-1.0	0.00	0.00	0.50	2.5			
	TOT	143	0.53	0.932	-1.0	0.00	0.00	1.00	4.0			
										-0.25	(-0.50, -0.01)	0.043A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.9.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	76	0.41	0.460	0.0	0.00	0.50	0.50	2.0			
	ADA	67	0.32	0.527	0.0	0.00	0.00	0.50	3.0			
	TOT	143	0.37	0.493	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	76	0.82	0.828	0.0	0.00	0.50	2.00	3.0			
	ADA	67	0.48	0.785	0.0	0.00	0.00	0.50	4.0			
	TOT	143	0.66	0.823	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	76	0.41	0.724	-0.5	0.00	0.00	1.00	3.0			
	ADA	67	0.16	0.572	-1.0	0.00	0.00	0.50	2.0			
	TOT	143	0.29	0.667	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	76	0.38	0.433	0.0	0.00	0.50	0.50	2.0			
	ADA	67	0.37	0.383	0.0	0.00	0.50	0.50	1.0			
	TOT	143	0.37	0.409	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	76	0.92	0.956	0.0	0.00	1.00	1.00	4.0			
	ADA	67	0.54	0.644	0.0	0.00	0.50	1.00	3.0			
	TOT	143	0.74	0.843	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	76	0.55	0.899	-1.0	0.00	0.25	1.00	3.5			
	ADA	67	0.17	0.655	-1.0	0.00	0.00	0.50	2.5			
	TOT	143	0.37	0.813	-1.0	0.00	0.00	0.50	3.5			
										-0.31	(-0.52, -0.10)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.9.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	76	0.15	0.297	-0.28	-0.07	0.04	0.40	0.94			
	ADA	67	0.15	0.298	-0.18	-0.04	0.08	0.24	1.12			
	TOT	143	0.15	0.296	-0.28	-0.06	0.06	0.30	1.12			
FINAL/ET VALUE	PLO	76	0.26	0.340	-0.20	-0.01	0.17	0.51	1.22			
	ADA	67	0.21	0.368	-0.26	-0.04	0.10	0.36	1.62			
	TOT	143	0.23	0.353	-0.26	-0.02	0.12	0.42	1.62			
CHG FROM BEST*	PLO	76	0.10	0.146	-0.08	0.02	0.06	0.15	0.72			
	ADA	67	0.05	0.149	-0.32	-0.04	0.04	0.10	0.50			
	TOT	143	0.08	0.149	-0.32	-0.02	0.04	0.12	0.72			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	76	0.20	0.312	-0.24	-0.05	0.12	0.39	0.98			
	ADA	67	0.15	0.235	-0.20	-0.04	0.10	0.28	0.90			
	TOT	143	0.17	0.279	-0.24	-0.04	0.10	0.34	0.98			
FINAL/ET VALUE	PLO	76	0.34	0.492	-0.20	-0.02	0.29	0.59	3.00			
	ADA	67	0.20	0.294	-0.22	-0.04	0.12	0.34	1.04			
	TOT	143	0.28	0.416	-0.22	-0.04	0.18	0.46	3.00			
CHG FROM BEST*	PLO	76	0.15	0.364	-0.20	0.00	0.04	0.20	2.82			
	ADA	67	0.05	0.149	-0.30	-0.02	0.02	0.08	0.56			
	TOT	143	0.10	0.287	-0.30	-0.02	0.04	0.14	2.82			
										-0.07	(-0.13, -0.02)	0.013A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.9.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	73	18.9	49.44	-19.7	0.9	4.3	10.2	283.9			
	ADA	67	11.9	31.44	-34.0	-2.0	1.0	10.5	128.0			
	TOT	140	15.6	41.80	-34.0	0.0	2.3	10.3	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	74	24.3	68.00	-12.8	0.0	6.0	17.7	514.8			
	ADA	67	11.6	32.01	-50.0	-1.3	2.7	9.9	145.8			
	TOT	141	18.3	54.18	-50.0	-0.5	4.8	14.4	514.8			
										-9.5	(-21.3, 2.4)	0.117A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.9.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	73	18.9	49.44	-19.7	0.9	4.3	10.2	283.9			
	ADA	65	10.4	28.76	-34.0	-2.0	1.0	10.2	128.0			
	TOT	138	14.9	41.10	-34.0	0.0	2.3	10.2	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	74	24.3	68.00	-12.8	0.0	6.0	17.7	514.8			
	ADA	65	11.3	32.44	-50.0	-1.3	2.4	8.2	145.8			
	TOT	139	18.3	54.56	-50.0	-0.5	4.6	14.4	514.8			
										-10.2	(-22.2, 1.7)	0.093A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.10.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	23	0.07	0.172	0.0	0.00	0.00	0.00	0.5			
	ADA	23	0.11	0.211	0.0	0.00	0.00	0.00	0.5			
	TOT	46	0.09	0.192	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	23	0.76	1.166	0.0	0.00	0.00	2.00	4.0			
	ADA	23	0.46	0.706	0.0	0.00	0.00	1.00	2.0			
	TOT	46	0.61	0.966	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	23	0.70	1.175	-0.5	0.00	0.00	1.50	4.0			
	ADA	23	0.35	0.698	-0.5	0.00	0.00	0.50	2.0			
	TOT	46	0.52	0.972	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	23	0.11	0.211	0.0	0.00	0.00	0.00	0.5			
	ADA	23	0.11	0.259	0.0	0.00	0.00	0.00	1.0			
	TOT	46	0.11	0.234	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	23	0.89	1.243	0.0	0.00	0.00	2.00	4.0			
	ADA	23	0.41	0.685	0.0	0.00	0.00	0.50	2.0			
	TOT	46	0.65	1.021	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	23	0.78	1.223	-0.5	0.00	0.00	2.00	3.5			
	ADA	23	0.30	0.735	-1.0	0.00	0.00	0.50	2.0			
	TOT	46	0.54	1.026	-1.0	0.00	0.00	1.00	3.5			
										-0.41	(-0.97, 0.15)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.10.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	23	0.50	0.500	0.0	0.00	0.50	1.00	2.0			
	ADA	23	0.28	0.364	0.0	0.00	0.00	0.50	1.0			
	TOT	46	0.39	0.446	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	23	0.96	0.782	0.0	0.50	1.00	2.00	2.0			
	ADA	23	0.59	0.596	0.0	0.00	0.50	1.00	2.0			
	TOT	46	0.77	0.713	0.0	0.00	0.50	1.00	2.0			
CHG FROM BEST*	PLO	23	0.46	0.706	-0.5	0.00	0.00	1.00	2.0			
	ADA	23	0.30	0.579	-0.5	0.00	0.00	0.50	2.0			
	TOT	46	0.38	0.643	-0.5	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	23	0.43	0.529	0.0	0.00	0.50	1.00	2.0			
	ADA	23	0.50	0.399	0.0	0.00	0.50	1.00	1.0			
	TOT	46	0.47	0.464	0.0	0.00	0.50	1.00	2.0			
FINAL/ET VALUE	PLO	23	1.00	0.989	0.0	0.00	1.00	1.00	3.0			
	ADA	23	0.70	0.765	0.0	0.00	0.50	1.00	3.0			
	TOT	46	0.85	0.887	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	23	0.57	0.921	-1.0	0.00	0.50	1.00	2.5			
	ADA	23	0.20	0.703	-1.0	0.00	0.00	0.50	2.0			
	TOT	46	0.38	0.831	-1.0	0.00	0.00	1.00	2.5			
										-0.26	(-0.65, 0.13)	0.187A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.10.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	23	0.16	0.209	-0.18	0.00	0.10	0.40	0.48			
	ADA	23	0.12	0.287	-0.18	-0.10	0.04	0.20	0.92			
	TOT	46	0.14	0.249	-0.18	-0.04	0.08	0.26	0.92			
FINAL/ET VALUE	PLO	23	0.30	0.277	-0.20	0.10	0.32	0.52	0.84			
	ADA	23	0.17	0.362	-0.18	-0.10	0.10	0.32	1.26			
	TOT	46	0.24	0.325	-0.20	-0.02	0.21	0.46	1.26			
CHG FROM BEST*	PLO	23	0.14	0.141	-0.08	0.06	0.12	0.24	0.40			
	ADA	23	0.06	0.157	-0.32	-0.04	0.04	0.12	0.48			
	TOT	46	0.10	0.153	-0.32	-0.02	0.07	0.14	0.48			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	23	0.12	0.254	-0.16	-0.08	0.00	0.32	0.78			
	ADA	23	0.12	0.217	-0.20	-0.08	0.12	0.28	0.64			
	TOT	46	0.12	0.234	-0.20	-0.08	0.05	0.28	0.78			
FINAL/ET VALUE	PLO	23	0.24	0.391	-0.20	-0.06	0.14	0.58	1.08			
	ADA	23	0.20	0.286	-0.16	-0.06	0.14	0.44	0.94			
	TOT	46	0.22	0.340	-0.20	-0.06	0.14	0.46	1.08			
CHG FROM BEST*	PLO	23	0.12	0.184	-0.20	0.00	0.06	0.26	0.60			
	ADA	23	0.08	0.131	-0.08	-0.02	0.06	0.18	0.32			
	TOT	46	0.10	0.159	-0.20	0.00	0.06	0.20	0.60			
										-0.06	(-0.14, 0.01)	0.102A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.10.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	22	26.0	57.20	-16.5	-0.9	2.4	15.7	227.9			
	ADA	23	15.5	36.69	-12.0	0.0	2.0	11.9	126.3			
	TOT	45	20.7	47.56	-16.5	0.0	2.0	11.9	227.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	22	6.5	18.91	-12.8	-1.3	1.2	7.6	69.5			
	ADA	23	5.8	20.25	-24.9	-3.3	2.9	8.4	83.7			
	TOT	45	6.1	19.39	-24.9	-1.3	2.2	8.2	83.7			
										-5.9	(-23.3, 11.6)	0.500A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.10.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	22	26.0	57.20	-16.5	-0.9	2.4	15.7	227.9			
	ADA	21	11.2	29.79	-12.0	0.0	2.0	10.2	126.3			
	TOT	43	18.8	45.98	-16.5	0.0	2.0	11.9	227.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	22	6.5	18.91	-12.8	-1.3	1.2	7.6	69.5			
	ADA	21	4.5	20.58	-24.9	-3.3	2.7	6.6	83.7			
	TOT	43	5.5	19.53	-24.9	-1.6	2.2	7.6	83.7			
										-8.6	(-25.9, 8.7)	0.320A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.11.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	33	0.03	0.121	0.0	0.00	0.00	0.00	0.5			
	ADA	37	0.03	0.115	0.0	0.00	0.00	0.00	0.5			
	TOT	70	0.03	0.117	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	33	0.24	0.639	0.0	0.00	0.00	0.00	3.0			
	ADA	37	0.27	0.560	0.0	0.00	0.00	0.50	3.0			
	TOT	70	0.26	0.594	0.0	0.00	0.00	0.50	3.0			
CHG FROM BEST*	PLO	33	0.21	0.650	-0.5	0.00	0.00	0.00	3.0			
	ADA	37	0.24	0.573	-0.5	0.00	0.00	0.50	3.0			
	TOT	70	0.23	0.606	-0.5	0.00	0.00	0.00	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	33	0.05	0.146	0.0	0.00	0.00	0.00	0.5			
	ADA	37	0.04	0.138	0.0	0.00	0.00	0.00	0.5			
	TOT	70	0.04	0.141	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	33	0.29	0.750	0.0	0.00	0.00	0.00	4.0			
	ADA	37	0.23	0.494	0.0	0.00	0.00	0.50	2.0			
	TOT	70	0.26	0.624	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	33	0.24	0.751	-0.5	0.00	0.00	0.00	4.0			
	ADA	37	0.19	0.532	-0.5	0.00	0.00	0.50	2.0			
	TOT	70	0.21	0.640	-0.5	0.00	0.00	0.00	4.0			
										-0.01	(-0.27, 0.24)	0.931A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.11.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	33	0.39	0.446	0.0	0.00	0.50	0.50	2.0			
	ADA	37	0.32	0.615	0.0	0.00	0.00	0.50	3.0			
	TOT	70	0.36	0.539	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	33	0.50	0.661	0.0	0.00	0.50	0.50	2.0			
	ADA	37	0.41	0.725	0.0	0.00	0.00	0.50	3.0			
	TOT	70	0.45	0.692	0.0	0.00	0.00	0.50	3.0			
CHG FROM BEST*	PLO	33	0.11	0.527	-0.5	0.00	0.00	0.00	1.5			
	ADA	37	0.08	0.534	-1.0	0.00	0.00	0.00	1.5			
	TOT	70	0.09	0.527	-1.0	0.00	0.00	0.00	1.5			
VH RIGHT EYE												
BEST VALUE*	PLO	33	0.38	0.376	0.0	0.00	0.50	0.50	1.0			
	ADA	37	0.35	0.525	0.0	0.00	0.00	0.50	2.0			
	TOT	70	0.36	0.458	0.0	0.00	0.25	0.50	2.0			
FINAL/ET VALUE	PLO	33	0.62	0.820	0.0	0.00	0.50	1.00	4.0			
	ADA	37	0.35	0.469	0.0	0.00	0.00	0.50	2.0			
	TOT	70	0.48	0.667	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	33	0.24	0.811	-1.0	0.00	0.00	0.50	3.5			
	ADA	37	0.00	0.527	-1.5	0.00	0.00	0.00	1.0			
	TOT	70	0.11	0.682	-1.5	0.00	0.00	0.50	3.5			
										-0.13	(-0.38, 0.11)	0.275A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.11.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	33	0.04	0.209	-0.24	-0.10	0.02	0.10	0.70			
	ADA	37	0.06	0.238	-0.18	-0.10	0.00	0.14	1.12			
	TOT	70	0.05	0.223	-0.24	-0.10	0.01	0.12	1.12			
FINAL/ET VALUE	PLO	33	0.18	0.287	-0.16	-0.02	0.08	0.22	0.86			
	ADA	37	0.14	0.349	-0.28	-0.06	0.02	0.22	1.62			
	TOT	70	0.16	0.319	-0.28	-0.06	0.04	0.22	1.62			
CHG FROM BEST*	PLO	33	0.13	0.208	-0.04	0.02	0.06	0.16	0.80			
	ADA	37	0.07	0.165	-0.16	-0.04	0.04	0.12	0.58			
	TOT	70	0.10	0.188	-0.16	0.00	0.04	0.14	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	33	0.06	0.224	-0.24	-0.10	-0.02	0.16	0.70			
	ADA	37	0.07	0.228	-0.22	-0.10	0.02	0.18	0.90			
	TOT	70	0.06	0.225	-0.24	-0.10	0.01	0.18	0.90			
FINAL/ET VALUE	PLO	33	0.22	0.563	-0.20	-0.08	0.06	0.40	3.00			
	ADA	37	0.07	0.239	-0.26	-0.06	0.02	0.14	0.92			
	TOT	70	0.14	0.427	-0.26	-0.08	0.03	0.34	3.00			
CHG FROM BEST*	PLO	33	0.17	0.506	-0.16	-0.04	0.04	0.16	2.82			
	ADA	37	0.00	0.143	-0.50	-0.04	0.00	0.06	0.36			
	TOT	70	0.08	0.369	-0.50	-0.04	0.02	0.08	2.82			
										-0.11	(-0.21, -0.01)	0.032A

* 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.
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 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 ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.11.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	33	33.8	74.32	-8.6	1.7	6.6	15.5	291.1			
	ADA	37	23.7	83.29	-34.0	-2.1	1.4	7.0	483.1			
	TOT	70	28.5	78.78	-34.0	-0.9	2.7	14.6	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	33	20.3	42.94	-8.8	0.0	4.8	14.4	169.7			
	ADA	37	21.8	89.79	-18.3	-1.3	1.5	5.4	534.5			
	TOT	70	21.1	71.15	-18.3	-0.5	2.0	10.2	534.5			
										-5.2	(-37.4, 27.1)	0.750A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.11.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	33	33.8	74.32	-8.6	1.7	6.6	15.5	291.1			
	ADA	37	23.7	83.29	-34.0	-2.1	1.4	7.0	483.1			
	TOT	70	28.5	78.78	-34.0	-0.9	2.7	14.6	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	33	20.3	42.94	-8.8	0.0	4.8	14.4	169.7			
	ADA	37	21.8	89.79	-18.3	-1.3	1.5	5.4	534.5			
	TOT	70	21.1	71.15	-18.3	-0.5	2.0	10.2	534.5			
										-5.2	(-37.4, 27.1)	0.750A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.12.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	54	0.18	0.310	0.0	0.00	0.00	0.50	1.0			
	ADA	49	0.17	0.376	0.0	0.00	0.00	0.00	2.0			
	TOT	103	0.17	0.341	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	54	0.89	0.979	0.0	0.00	0.50	1.00	4.0			
	ADA	49	0.60	0.979	0.0	0.00	0.00	1.00	3.0			
	TOT	103	0.75	0.985	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	54	0.71	0.883	-0.5	0.00	0.50	1.00	4.0			
	ADA	49	0.43	0.872	-1.0	0.00	0.00	0.50	3.0			
	TOT	103	0.58	0.885	-1.0	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	54	0.21	0.430	0.0	0.00	0.00	0.50	2.0			
	ADA	49	0.14	0.270	0.0	0.00	0.00	0.00	1.0			
	TOT	103	0.18	0.363	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	54	1.05	1.175	0.0	0.00	0.50	2.00	4.0			
	ADA	49	0.65	0.903	0.0	0.00	0.00	1.00	3.0			
	TOT	103	0.86	1.067	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	54	0.83	1.055	-0.5	0.00	0.50	1.00	4.0			
	ADA	49	0.51	0.826	-0.5	0.00	0.00	1.00	2.5			
	TOT	103	0.68	0.962	-0.5	0.00	0.50	1.00	4.0			
										-0.30	(-0.62, 0.01)	0.058A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.12.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	55	0.38	0.451	0.0	0.00	0.50	0.50	2.0			
	ADA	49	0.35	0.542	0.0	0.00	0.00	0.50	3.0			
	TOT	104	0.37	0.494	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	55	0.81	0.884	0.0	0.00	0.50	1.00	3.0			
	ADA	49	0.40	0.764	0.0	0.00	0.00	0.50	4.0			
	TOT	104	0.62	0.851	0.0	0.00	0.25	1.00	4.0			
CHG FROM BEST*	PLO	55	0.43	0.716	-0.5	0.00	0.00	1.00	3.0			
	ADA	49	0.05	0.533	-1.0	0.00	0.00	0.00	2.0			
	TOT	104	0.25	0.661	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	55	0.34	0.452	0.0	0.00	0.00	0.50	2.0			
	ADA	49	0.27	0.340	0.0	0.00	0.00	0.50	1.0			
	TOT	104	0.30	0.403	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	55	0.95	0.965	0.0	0.00	1.00	1.00	3.0			
	ADA	49	0.52	0.677	0.0	0.00	0.50	1.00	3.0			
	TOT	104	0.75	0.865	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	55	0.61	0.750	-0.5	0.00	0.50	1.00	2.5			
	ADA	49	0.26	0.693	-1.0	0.00	0.00	0.50	2.5			
	TOT	104	0.44	0.742	-1.0	0.00	0.00	1.00	2.5			
										-0.37	(-0.59, -0.14)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.12.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	55	0.17	0.323	-0.28	-0.06	0.04	0.42	0.94			
	ADA	49	0.20	0.326	-0.20	0.00	0.10	0.32	1.30			
	TOT	104	0.19	0.323	-0.28	-0.04	0.10	0.32	1.30			
FINAL/ET VALUE	PLO	55	0.25	0.357	-0.18	0.00	0.12	0.36	1.22			
	ADA	49	0.28	0.387	-0.26	0.00	0.20	0.50	1.60			
	TOT	104	0.27	0.370	-0.26	0.00	0.15	0.42	1.60			
CHG FROM BEST*	PLO	55	0.08	0.172	-0.62	0.00	0.04	0.14	0.72			
	ADA	49	0.08	0.168	-0.22	-0.02	0.02	0.10	0.50			
	TOT	104	0.08	0.169	-0.62	0.00	0.04	0.13	0.72			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	55	0.28	0.341	-0.20	0.00	0.16	0.54	1.16			
	ADA	49	0.20	0.261	-0.20	0.00	0.18	0.34	0.76			
	TOT	104	0.24	0.307	-0.20	0.00	0.17	0.42	1.16			
FINAL/ET VALUE	PLO	55	0.40	0.450	-0.18	0.04	0.30	0.70	2.08			
	ADA	49	0.28	0.325	-0.22	0.00	0.18	0.46	1.04			
	TOT	104	0.34	0.399	-0.22	0.03	0.26	0.61	2.08			
CHG FROM BEST*	PLO	55	0.12	0.231	-0.18	0.00	0.04	0.14	1.20			
	ADA	49	0.07	0.148	-0.24	0.00	0.04	0.10	0.56			
	TOT	104	0.10	0.197	-0.24	0.00	0.04	0.14	1.20			
										-0.03	(-0.08, 0.03)	0.389A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.12.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	52	6.6	13.52	-28.4	1.3	4.3	8.9	63.6			
	ADA	48	5.6	23.14	-47.6	-2.0	1.1	10.0	73.7			
	TOT	100	6.1	18.67	-47.6	-0.5	3.3	9.6	73.7			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	53	28.8	78.51	-4.7	4.1	8.0	16.2	514.8			
	ADA	49	13.0	31.78	-50.0	0.6	3.9	15.8	145.8			
	TOT	102	21.2	60.96	-50.0	1.0	6.1	16.2	514.8			
										-7.5	(-21.0, 5.9)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.12.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	52	6.6	13.52	-28.4	1.3	4.3	8.9	63.6			
	ADA	48	5.6	23.14	-47.6	-2.0	1.1	10.0	73.7			
	TOT	100	6.1	18.67	-47.6	-0.5	3.3	9.6	73.7			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	53	28.8	78.51	-4.7	4.1	8.0	16.2	514.8			
	ADA	49	13.0	31.78	-50.0	0.6	3.9	15.8	145.8			
	TOT	102	21.2	60.96	-50.0	1.0	6.1	16.2	514.8			
										-7.5	(-21.0, 5.9)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.13.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	61	0.16	0.296	0.0	0.00	0.00	0.00	1.0			
	ADA	43	0.09	0.197	0.0	0.00	0.00	0.00	0.5			
	TOT	104	0.13	0.261	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	61	0.89	1.130	0.0	0.00	0.50	2.00	4.0			
	ADA	43	0.42	0.739	0.0	0.00	0.00	0.50	3.0			
	TOT	104	0.70	1.011	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	61	0.74	1.075	-0.5	0.00	0.00	1.00	4.0			
	ADA	43	0.33	0.706	-0.5	0.00	0.00	0.50	2.5			
	TOT	104	0.57	0.958	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	61	0.15	0.247	0.0	0.00	0.00	0.50	1.0			
	ADA	43	0.14	0.274	0.0	0.00	0.00	0.00	1.0			
	TOT	104	0.14	0.258	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	61	1.03	1.284	0.0	0.00	0.50	2.00	4.0			
	ADA	43	0.55	0.851	0.0	0.00	0.00	0.50	3.0			
	TOT	104	0.83	1.146	0.0	0.00	0.25	1.00	4.0			
CHG FROM BEST*	PLO	61	0.89	1.250	-0.5	0.00	0.50	1.50	4.0			
	ADA	43	0.41	0.826	-1.0	0.00	0.00	0.50	2.5			
	TOT	104	0.69	1.115	-1.0	0.00	0.00	1.00	4.0			
										-0.45	(-0.81, -0.08)	0.016A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.13.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	61	0.38	0.394	0.0	0.00	0.50	0.50	1.0			
	ADA	43	0.37	0.568	0.0	0.00	0.00	0.50	3.0			
	TOT	104	0.38	0.471	0.0	0.00	0.25	0.50	3.0			
FINAL/ET VALUE	PLO	61	0.77	0.844	0.0	0.00	0.50	1.00	3.0			
	ADA	43	0.49	0.582	0.0	0.00	0.50	1.00	2.0			
	TOT	104	0.65	0.757	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	61	0.39	0.742	-0.5	0.00	0.00	0.50	3.0			
	ADA	43	0.12	0.555	-1.0	0.00	0.00	0.50	2.0			
	TOT	104	0.28	0.682	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	61	0.35	0.441	0.0	0.00	0.00	0.50	2.0			
	ADA	43	0.49	0.529	0.0	0.00	0.50	1.00	2.0			
	TOT	104	0.41	0.482	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	61	0.93	1.023	0.0	0.00	0.50	1.00	4.0			
	ADA	43	0.64	0.667	0.0	0.00	0.50	1.00	3.0			
	TOT	104	0.81	0.901	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	61	0.58	0.932	-1.0	0.00	0.50	1.00	3.5			
	ADA	43	0.15	0.736	-1.5	0.00	0.00	0.50	2.0			
	TOT	104	0.40	0.879	-1.5	0.00	0.00	0.75	3.5			
										-0.35	(-0.61, -0.10)	0.006A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.13.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	61	0.16	0.295	-0.28	-0.06	0.04	0.44	0.94			
	ADA	43	0.16	0.281	-0.18	-0.02	0.10	0.22	0.92			
	TOT	104	0.16	0.288	-0.28	-0.06	0.06	0.32	0.94			
FINAL/ET VALUE	PLO	61	0.29	0.348	-0.20	0.00	0.22	0.58	1.22			
	ADA	43	0.21	0.355	-0.18	-0.06	0.14	0.36	1.26			
	TOT	104	0.26	0.352	-0.20	-0.02	0.17	0.48	1.26			
CHG FROM BEST*	PLO	61	0.13	0.206	-0.62	0.02	0.08	0.18	0.80			
	ADA	43	0.05	0.152	-0.32	-0.04	0.04	0.10	0.48			
	TOT	104	0.10	0.189	-0.62	-0.02	0.06	0.16	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	61	0.19	0.317	-0.24	-0.04	0.10	0.38	1.16			
	ADA	43	0.14	0.225	-0.20	-0.04	0.12	0.30	0.68			
	TOT	104	0.17	0.283	-0.24	-0.04	0.11	0.33	1.16			
FINAL/ET VALUE	PLO	61	0.37	0.520	-0.20	-0.02	0.30	0.62	3.00			
	ADA	43	0.22	0.302	-0.20	-0.04	0.14	0.44	0.94			
	TOT	104	0.31	0.447	-0.20	-0.04	0.21	0.54	3.00			
CHG FROM BEST*	PLO	61	0.18	0.400	-0.20	0.00	0.08	0.26	2.82			
	ADA	43	0.08	0.148	-0.24	0.00	0.06	0.14	0.56			
	TOT	104	0.14	0.324	-0.24	0.00	0.06	0.22	2.82			
										-0.09	(-0.17, -0.01)	0.024A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.13.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	58	16.2	50.24	-28.4	0.5	3.3	10.8	283.9			
	ADA	42	7.2	30.36	-40.8	-1.8	1.1	6.2	126.3			
	TOT	100	12.5	43.07	-40.8	0.0	2.8	10.1	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	60	27.2	74.82	-12.8	0.6	6.4	16.4	514.8			
	ADA	43	7.2	30.27	-50.0	-3.3	2.7	9.9	145.8			
	TOT	103	18.8	60.94	-50.0	0.0	5.1	14.3	514.8			
										-14.1	(-29.4, 1.2)	0.070A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.13.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	58	16.2	50.24	-28.4	0.5	3.3	10.8	283.9			
	ADA	40	4.6	25.01	-40.8	-2.1	1.1	5.9	126.3			
	TOT	98	11.5	42.05	-40.8	0.0	2.8	10.0	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	60	27.2	74.82	-12.8	0.6	6.4	16.4	514.8			
	ADA	41	6.6	30.83	-50.0	-3.3	2.4	8.2	145.8			
	TOT	101	18.8	61.53	-50.0	0.0	4.6	12.7	514.8			
										-16.0	(-31.4, -0.5)	0.043A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.14.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	18	0.00	0.000	0.0	0.00	0.00	0.00	0.0			
	ADA	23	0.00	0.000	0.0	0.00	0.00	0.00	0.0			
	TOT	41	0.00	0.000	0.0	0.00	0.00	0.00	0.0			
FINAL/ET VALUE	PLO	18	0.25	0.712	0.0	0.00	0.00	0.00	3.0			
	ADA	23	0.15	0.317	0.0	0.00	0.00	0.00	1.0			
	TOT	41	0.20	0.523	0.0	0.00	0.00	0.00	3.0			
CHG FROM BEST*	PLO	18	0.25	0.712	0.0	0.00	0.00	0.00	3.0			
	ADA	23	0.15	0.317	0.0	0.00	0.00	0.00	1.0			
	TOT	41	0.20	0.523	0.0	0.00	0.00	0.00	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	18	0.03	0.118	0.0	0.00	0.00	0.00	0.5			
	ADA	23	0.02	0.104	0.0	0.00	0.00	0.00	0.5			
	TOT	41	0.02	0.109	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	18	0.17	0.343	0.0	0.00	0.00	0.00	1.0			
	ADA	23	0.17	0.442	0.0	0.00	0.00	0.00	2.0			
	TOT	41	0.17	0.397	0.0	0.00	0.00	0.00	2.0			
CHG FROM BEST*	PLO	18	0.14	0.335	0.0	0.00	0.00	0.00	1.0			
	ADA	23	0.15	0.463	-0.5	0.00	0.00	0.00	2.0			
	TOT	41	0.15	0.407	-0.5	0.00	0.00	0.00	2.0			
										-0.04	(-0.31, 0.23)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.14.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	18	0.39	0.323	0.0	0.00	0.50	0.50	1.0			
	ADA	23	0.37	0.482	0.0	0.00	0.50	0.50	2.0			
	TOT	41	0.38	0.415	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	18	0.75	0.862	0.0	0.00	0.50	1.00	3.0			
	ADA	23	0.43	0.758	0.0	0.00	0.00	0.50	3.0			
	TOT	41	0.57	0.811	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	18	0.36	0.724	-0.5	0.00	0.00	0.50	2.0			
	ADA	23	0.07	0.529	-1.0	0.00	0.00	0.50	1.5			
	TOT	41	0.20	0.631	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	18	0.33	0.343	0.0	0.00	0.50	0.50	1.0			
	ADA	23	0.35	0.351	0.0	0.00	0.50	0.50	1.0			
	TOT	41	0.34	0.343	0.0	0.00	0.50	0.50	1.0			
FINAL/ET VALUE	PLO	18	0.56	0.450	0.0	0.00	0.50	1.00	1.0			
	ADA	23	0.37	0.527	0.0	0.00	0.00	0.50	2.0			
	TOT	41	0.45	0.498	0.0	0.00	0.50	1.00	2.0			
CHG FROM BEST*	PLO	18	0.22	0.521	-1.0	0.00	0.00	0.50	1.0			
	ADA	23	0.02	0.439	-1.0	0.00	0.00	0.50	1.0			
	TOT	41	0.11	0.481	-1.0	0.00	0.00	0.50	1.0			
										-0.25	(-0.57, 0.08)	0.132A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.14.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	18	0.01	0.125	-0.18	-0.10	0.02	0.10	0.20			
	ADA	23	0.12	0.276	-0.16	-0.04	0.04	0.22	1.12			
	TOT	41	0.07	0.227	-0.18	-0.06	0.04	0.14	1.12			
FINAL/ET VALUE	PLO	18	0.15	0.231	-0.14	0.00	0.11	0.28	0.86			
	ADA	23	0.18	0.386	-0.18	-0.06	0.04	0.22	1.62			
	TOT	41	0.17	0.323	-0.18	0.00	0.10	0.22	1.62			
CHG FROM BEST*	PLO	18	0.15	0.195	-0.04	0.04	0.09	0.20	0.76			
	ADA	23	0.06	0.134	-0.14	-0.02	0.02	0.08	0.50			
	TOT	41	0.10	0.167	-0.14	0.02	0.06	0.12	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	18	0.07	0.213	-0.20	-0.08	0.01	0.12	0.54			
	ADA	23	0.07	0.219	-0.22	-0.08	0.00	0.20	0.70			
	TOT	41	0.07	0.214	-0.22	-0.08	0.00	0.18	0.70			
FINAL/ET VALUE	PLO	18	0.12	0.243	-0.16	-0.08	0.04	0.32	0.70			
	ADA	23	0.09	0.230	-0.26	-0.06	0.06	0.24	0.84			
	TOT	41	0.10	0.234	-0.26	-0.06	0.04	0.26	0.84			
CHG FROM BEST*	PLO	18	0.06	0.081	-0.06	0.00	0.06	0.08	0.24			
	ADA	23	0.01	0.064	-0.14	-0.02	0.00	0.06	0.14			
	TOT	41	0.03	0.074	-0.14	0.00	0.02	0.06	0.24			
										-0.07	(-0.12, -0.01)	0.028A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.14.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	18	41.6	78.22	-8.6	0.8	3.7	63.6	291.1			
	ADA	23	22.7	35.26	-6.1	-1.5	6.1	37.4	128.0			
	TOT	41	31.0	58.09	-8.6	0.0	4.1	37.4	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	18	17.5	42.44	-8.8	0.0	3.4	8.3	169.7			
	ADA	23	14.5	29.19	-10.7	0.4	2.3	13.6	97.3			
	TOT	41	15.8	35.16	-10.7	0.0	2.3	11.2	169.7			
										-14.5	(-39.0, 10.0)	0.239A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.14.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	18	41.6	78.22	-8.6	0.8	3.7	63.6	291.1			
	ADA	23	22.7	35.26	-6.1	-1.5	6.1	37.4	128.0			
	TOT	41	31.0	58.09	-8.6	0.0	4.1	37.4	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	18	17.5	42.44	-8.8	0.0	3.4	8.3	169.7			
	ADA	23	14.5	29.19	-10.7	0.4	2.3	13.6	97.3			
	TOT	41	15.8	35.16	-10.7	0.0	2.3	11.2	169.7			
										-14.5	(-39.0, 10.0)	0.239A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.15.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	3	0.17	0.289	0.0	0.00	0.00	0.50	0.5
	ADA	7	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	10	0.05	0.158	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	3	0.67	1.155	0.0	0.00	0.00	2.00	2.0
	ADA	7	0.21	0.267	0.0	0.00	0.00	0.50	0.5
	TOT	10	0.35	0.626	0.0	0.00	0.00	0.50	2.0
CHG FROM BEST*	PLO	3	0.50	0.866	0.0	0.00	0.00	1.50	1.5
	ADA	7	0.21	0.267	0.0	0.00	0.00	0.50	0.5
	TOT	10	0.30	0.483	0.0	0.00	0.00	0.50	1.5
AC RIGHT EYE									
BEST VALUE*	PLO	3	0.17	0.289	0.0	0.00	0.00	0.50	0.5
	ADA	7	0.07	0.189	0.0	0.00	0.00	0.00	0.5
	TOT	10	0.10	0.211	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	3	0.67	1.155	0.0	0.00	0.00	2.00	2.0
	ADA	7	0.21	0.393	0.0	0.00	0.00	0.50	1.0
	TOT	10	0.35	0.669	0.0	0.00	0.00	0.50	2.0
CHG FROM BEST*	PLO	3	0.50	0.866	0.0	0.00	0.00	1.50	1.5
	ADA	7	0.14	0.378	0.0	0.00	0.00	0.00	1.0
	TOT	10	0.25	0.540	0.0	0.00	0.00	0.00	1.5

* 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.
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__1000.2.1.1.15.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	3	0.33	0.289	0.0	0.00	0.50	0.50	0.5
	ADA	7	0.50	0.408	0.0	0.00	0.50	1.00	1.0
	TOT	10	0.45	0.369	0.0	0.00	0.50	0.50	1.0
FINAL/ET VALUE	PLO	3	1.00	0.866	0.5	0.50	0.50	2.00	2.0
	ADA	7	0.79	1.075	0.0	0.00	0.50	1.00	3.0
	TOT	10	0.85	0.973	0.0	0.00	0.50	1.00	3.0
CHG FROM BEST*	PLO	3	0.67	0.764	0.0	0.00	0.50	1.50	1.5
	ADA	7	0.29	0.951	-0.5	-0.50	0.00	1.00	2.0
	TOT	10	0.40	0.876	-0.5	-0.50	0.25	1.00	2.0
VH RIGHT EYE									
BEST VALUE*	PLO	3	0.50	0.500	0.0	0.00	0.50	1.00	1.0
	ADA	7	0.29	0.267	0.0	0.00	0.50	0.50	0.5
	TOT	10	0.35	0.337	0.0	0.00	0.50	0.50	1.0
FINAL/ET VALUE	PLO	3	1.00	1.000	0.0	0.00	1.00	2.00	2.0
	ADA	7	0.79	1.075	0.0	0.00	0.50	1.00	3.0
	TOT	10	0.85	1.001	0.0	0.00	0.75	1.00	3.0
CHG FROM BEST*	PLO	3	0.50	0.866	0.0	0.00	0.00	1.50	1.5
	ADA	7	0.50	1.000	-0.5	0.00	0.00	1.00	2.5
	TOT	10	0.50	0.913	-0.5	0.00	0.00	1.00	2.5

* 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.
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__1000.2.1.1.15.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	3	-0.03	0.083	-0.12	-0.12	0.00	0.04	0.04
	ADA	7	0.20	0.262	-0.12	-0.02	0.20	0.32	0.66
	TOT	10	0.13	0.243	-0.12	-0.02	0.04	0.30	0.66
FINAL/ET VALUE	PLO	3	-0.01	0.058	-0.08	-0.08	0.02	0.02	0.02
	ADA	7	0.29	0.376	-0.28	0.02	0.32	0.62	0.70
	TOT	10	0.20	0.341	-0.28	0.02	0.03	0.62	0.70
CHG FROM BEST*	PLO	3	0.01	0.031	-0.02	-0.02	0.02	0.04	0.04
	ADA	7	0.09	0.170	-0.16	0.00	0.04	0.30	0.32
	TOT	10	0.07	0.145	-0.16	0.00	0.04	0.12	0.32
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	3	0.19	0.446	-0.10	-0.10	-0.04	0.70	0.70
	ADA	7	0.28	0.218	0.02	0.12	0.28	0.34	0.70
	TOT	10	0.25	0.279	-0.10	0.02	0.23	0.34	0.70
FINAL/ET VALUE	PLO	3	0.18	0.401	-0.10	-0.10	0.00	0.64	0.64
	ADA	7	0.29	0.356	-0.18	0.02	0.26	0.50	0.90
	TOT	10	0.26	0.352	-0.18	0.00	0.19	0.50	0.90
CHG FROM BEST*	PLO	3	-0.01	0.050	-0.06	-0.06	0.00	0.04	0.04
	ADA	7	0.01	0.248	-0.50	-0.06	0.10	0.20	0.22
	TOT	10	0.01	0.204	-0.50	-0.06	0.02	0.14	0.22

* 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.
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__1000.2.1.1.15.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	3	2.8	1.81	0.8	0.8	3.3	4.3	4.3
	ADA	7	22.9	45.71	-47.6	-1.3	3.2	72.8	73.7
	TOT	10	16.9	38.58	-47.6	0.8	3.2	56.5	73.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	3	12.3	20.01	-1.4	-1.4	3.0	35.3	35.3
	ADA	7	18.9	29.27	1.5	2.4	6.4	17.9	83.7
	TOT	10	16.9	25.89	-1.4	2.4	5.5	17.9	83.7

* 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.
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__1000.2.1.1.15.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	3	2.8	1.81	0.8	0.8	3.3	4.3	4.3
	ADA	7	22.9	45.71	-47.6	-1.3	3.2	72.8	73.7
	TOT	10	16.9	38.58	-47.6	0.8	3.2	56.5	73.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	3	12.3	20.01	-1.4	-1.4	3.0	35.3	35.3
	ADA	7	18.9	29.27	1.5	2.4	6.4	17.9	83.7
	TOT	10	16.9	25.89	-1.4	2.4	5.5	17.9	83.7

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.16.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	13	0.12	0.219	0.0	0.00	0.00	0.00	0.5
	ADA	11	0.14	0.234	0.0	0.00	0.00	0.50	0.5
	TOT	24	0.13	0.221	0.0	0.00	0.00	0.25	0.5
FINAL/ET VALUE	PLO	13	0.69	0.560	0.0	0.50	0.50	1.00	2.0
	ADA	11	1.36	1.286	0.0	0.00	1.00	3.00	3.0
	TOT	24	1.00	1.000	0.0	0.00	1.00	1.50	3.0
CHG FROM BEST*	PLO	13	0.58	0.572	0.0	0.00	0.50	1.00	2.0
	ADA	11	1.23	1.348	-0.5	0.00	1.00	3.00	3.0
	TOT	24	0.88	1.035	-0.5	0.00	0.50	1.25	3.0
AC RIGHT EYE									
BEST VALUE*	PLO	13	0.19	0.560	0.0	0.00	0.00	0.00	2.0
	ADA	11	0.18	0.252	0.0	0.00	0.00	0.50	0.5
	TOT	24	0.19	0.438	0.0	0.00	0.00	0.25	2.0
FINAL/ET VALUE	PLO	13	0.96	0.967	0.0	0.50	0.50	2.00	3.0
	ADA	11	0.82	0.874	0.0	0.00	1.00	2.00	2.0
	TOT	24	0.90	0.909	0.0	0.00	0.50	2.00	3.0
CHG FROM BEST*	PLO	13	0.77	0.780	0.0	0.00	0.50	1.00	2.0
	ADA	11	0.64	0.869	-0.5	0.00	0.50	1.50	2.0
	TOT	24	0.71	0.806	-0.5	0.00	0.50	1.25	2.0

* 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.
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__1000.2.1.1.16.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	14	0.46	0.746	0.0	0.00	0.00	1.00	2.0
	ADA	11	0.23	0.344	0.0	0.00	0.00	0.50	1.0
	TOT	25	0.36	0.604	0.0	0.00	0.00	0.50	2.0
FINAL/ET VALUE	PLO	14	0.54	0.746	0.0	0.00	0.00	1.00	2.0
	ADA	11	0.14	0.323	0.0	0.00	0.00	0.00	1.0
	TOT	25	0.36	0.621	0.0	0.00	0.00	0.50	2.0
CHG FROM BEST*	PLO	14	0.07	0.267	0.0	0.00	0.00	0.00	1.0
	ADA	11	-0.09	0.491	-1.0	-0.50	0.00	0.00	1.0
	TOT	25	0.00	0.382	-1.0	0.00	0.00	0.00	1.0
VH RIGHT EYE									
BEST VALUE*	PLO	14	0.29	0.426	0.0	0.00	0.00	0.50	1.0
	ADA	11	0.23	0.344	0.0	0.00	0.00	0.50	1.0
	TOT	25	0.26	0.385	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	14	0.46	0.458	0.0	0.00	0.50	1.00	1.0
	ADA	11	0.23	0.344	0.0	0.00	0.00	0.50	1.0
	TOT	25	0.36	0.421	0.0	0.00	0.00	0.50	1.0
CHG FROM BEST*	PLO	14	0.18	0.317	0.0	0.00	0.00	0.50	1.0
	ADA	11	0.00	0.500	-1.0	0.00	0.00	0.00	1.0
	TOT	25	0.10	0.408	-1.0	0.00	0.00	0.00	1.0

* 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.
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__1000.2.1.1.16.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	14	0.16	0.239	-0.06	0.00	0.10	0.18	0.88
	ADA	11	0.19	0.444	-0.20	-0.08	0.02	0.20	1.30
	TOT	25	0.17	0.336	-0.20	0.00	0.10	0.18	1.30
FINAL/ET VALUE	PLO	14	0.19	0.267	-0.08	0.02	0.13	0.22	0.98
	ADA	11	0.35	0.479	-0.10	0.00	0.28	0.52	1.60
	TOT	25	0.26	0.375	-0.10	0.00	0.16	0.34	1.60
CHG FROM BEST*	PLO	14	0.03	0.050	-0.08	0.00	0.02	0.06	0.12
	ADA	11	0.17	0.250	-0.22	-0.02	0.08	0.34	0.58
	TOT	25	0.09	0.180	-0.22	0.00	0.02	0.10	0.58
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	14	0.20	0.328	-0.18	-0.02	0.09	0.42	0.98
	ADA	11	0.21	0.253	-0.08	0.02	0.12	0.26	0.74
	TOT	25	0.20	0.291	-0.18	0.00	0.12	0.26	0.98
FINAL/ET VALUE	PLO	14	0.26	0.367	-0.08	0.02	0.10	0.48	1.00
	ADA	11	0.27	0.276	-0.06	-0.04	0.34	0.42	0.76
	TOT	25	0.26	0.324	-0.08	0.02	0.14	0.42	1.00
CHG FROM BEST*	PLO	14	0.05	0.126	-0.04	-0.02	0.01	0.06	0.46
	ADA	11	0.07	0.116	-0.08	0.02	0.04	0.10	0.36
	TOT	25	0.06	0.119	-0.08	0.00	0.02	0.10	0.46

* 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.
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__1000.2.1.1.16.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	14	11.6	14.94	-10.8	3.4	8.0	16.0	44.5
	ADA	11	46.5	145.07	-17.7	-0.4	6.9	9.8	483.1
	TOT	25	27.0	95.93	-17.7	0.0	6.9	13.9	483.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	14	16.9	45.66	-4.6	0.9	5.6	8.9	174.4
	ADA	11	57.2	158.85	-0.5	0.4	5.7	19.8	534.5
	TOT	25	34.6	109.82	-4.6	0.6	5.7	9.4	534.5

* 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.
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__1000.2.1.1.16.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	14	11.6	14.94	-10.8	3.4	8.0	16.0	44.5
	ADA	11	46.5	145.07	-17.7	-0.4	6.9	9.8	483.1
	TOT	25	27.0	95.93	-17.7	0.0	6.9	13.9	483.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	14	16.9	45.66	-4.6	0.9	5.6	8.9	174.4
	ADA	11	57.2	158.85	-0.5	0.4	5.7	19.8	534.5
	TOT	25	34.6	109.82	-4.6	0.6	5.7	9.4	534.5

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.17.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	11	0.05	0.151	0.0	0.00	0.00	0.00	0.5
	ADA	12	0.29	0.582	0.0	0.00	0.00	0.50	2.0
	TOT	23	0.17	0.442	0.0	0.00	0.00	0.00	2.0
FINAL/ET VALUE	PLO	11	0.32	0.405	0.0	0.00	0.00	0.50	1.0
	ADA	12	0.63	0.829	0.0	0.00	0.50	0.75	3.0
	TOT	23	0.48	0.665	0.0	0.00	0.50	0.50	3.0
CHG FROM BEST*	PLO	11	0.27	0.410	0.0	0.00	0.00	0.50	1.0
	ADA	12	0.33	0.389	0.0	0.00	0.25	0.50	1.0
	TOT	23	0.30	0.391	0.0	0.00	0.00	0.50	1.0
AC RIGHT EYE									
BEST VALUE*	PLO	11	0.27	0.607	0.0	0.00	0.00	0.50	2.0
	ADA	12	0.08	0.289	0.0	0.00	0.00	0.00	1.0
	TOT	23	0.17	0.467	0.0	0.00	0.00	0.00	2.0
FINAL/ET VALUE	PLO	11	0.55	0.907	0.0	0.00	0.00	1.00	3.0
	ADA	12	0.46	0.582	0.0	0.00	0.50	0.50	2.0
	TOT	23	0.50	0.739	0.0	0.00	0.50	0.50	3.0
CHG FROM BEST*	PLO	11	0.27	0.410	0.0	0.00	0.00	0.50	1.0
	ADA	12	0.38	0.569	0.0	0.00	0.25	0.50	2.0
	TOT	23	0.33	0.491	0.0	0.00	0.00	0.50	2.0

* 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.
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__1000.2.1.1.17.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	11	0.45	0.350	0.0	0.00	0.50	0.50	1.0
	ADA	12	0.38	0.856	0.0	0.00	0.00	0.50	3.0
	TOT	23	0.41	0.651	0.0	0.00	0.50	0.50	3.0
FINAL/ET VALUE	PLO	11	0.86	0.710	0.0	0.00	1.00	1.00	2.0
	ADA	12	0.67	1.193	0.0	0.00	0.25	0.50	4.0
	TOT	23	0.76	0.975	0.0	0.00	0.50	1.00	4.0
CHG FROM BEST*	PLO	11	0.41	0.584	-0.5	0.00	0.50	1.00	1.5
	ADA	12	0.29	0.498	0.0	0.00	0.00	0.50	1.5
	TOT	23	0.35	0.532	-0.5	0.00	0.00	0.50	1.5
VH RIGHT EYE									
BEST VALUE*	PLO	11	0.59	0.625	0.0	0.00	0.50	1.00	2.0
	ADA	12	0.21	0.334	0.0	0.00	0.00	0.50	1.0
	TOT	23	0.39	0.521	0.0	0.00	0.00	0.50	2.0
FINAL/ET VALUE	PLO	11	1.59	1.158	0.0	0.50	2.00	3.00	3.0
	ADA	12	0.50	0.640	0.0	0.00	0.25	1.00	2.0
	TOT	23	1.02	1.060	0.0	0.00	1.00	2.00	3.0
CHG FROM BEST*	PLO	11	1.00	0.775	0.0	0.50	1.00	1.50	2.5
	ADA	12	0.29	0.620	-0.5	0.00	0.00	0.75	1.5
	TOT	23	0.63	0.772	-0.5	0.00	0.50	1.00	2.5

* 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.
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__1000.2.1.1.17.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	11	0.20	0.385	-0.26	-0.12	0.10	0.64	0.80
	ADA	12	0.02	0.204	-0.16	-0.11	-0.05	0.10	0.56
	TOT	23	0.11	0.310	-0.26	-0.12	0.00	0.26	0.80
FINAL/ET VALUE	PLO	11	0.28	0.393	-0.18	-0.06	0.16	0.58	1.02
	ADA	12	0.12	0.288	-0.26	-0.10	0.06	0.27	0.64
	TOT	23	0.20	0.344	-0.26	-0.08	0.10	0.44	1.02
CHG FROM BEST*	PLO	11	0.08	0.081	-0.06	0.04	0.08	0.16	0.22
	ADA	12	0.10	0.175	-0.14	-0.02	0.07	0.15	0.50
	TOT	23	0.09	0.136	-0.14	0.00	0.08	0.16	0.50
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	11	0.31	0.353	-0.10	-0.06	0.32	0.56	0.88
	ADA	12	0.07	0.330	-0.20	-0.13	-0.07	0.19	0.90
	TOT	23	0.18	0.355	-0.20	-0.10	0.00	0.44	0.90
FINAL/ET VALUE	PLO	11	0.49	0.652	-0.08	0.00	0.46	0.54	2.08
	ADA	12	0.15	0.330	-0.22	-0.05	-0.02	0.36	0.92
	TOT	23	0.31	0.529	-0.22	-0.04	0.18	0.48	2.08
CHG FROM BEST*	PLO	11	0.19	0.370	-0.04	-0.02	0.04	0.16	1.20
	ADA	12	0.08	0.120	-0.10	0.00	0.06	0.12	0.32
	TOT	23	0.13	0.270	-0.10	-0.02	0.04	0.14	1.20

* 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.
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__1000.2.1.1.17.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	10	6.9	7.26	-2.7	1.2	6.6	9.4	21.9
	ADA	12	-0.9	6.08	-14.2	-3.0	0.2	1.9	10.2
	TOT	22	2.6	7.59	-14.2	-2.0	1.5	6.9	21.9
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	9	12.1	9.25	-0.5	3.8	11.8	14.9	27.5
	ADA	12	3.6	11.01	-10.9	-1.6	1.4	4.5	33.7
	TOT	21	7.2	10.94	-10.9	-0.5	3.0	12.7	33.7

* 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.
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__1000.2.1.1.17.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	10	6.9	7.26	-2.7	1.2	6.6	9.4	21.9
	ADA	12	-0.9	6.08	-14.2	-3.0	0.2	1.9	10.2
	TOT	22	2.6	7.59	-14.2	-2.0	1.5	6.9	21.9
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	9	12.1	9.25	-0.5	3.8	11.8	14.9	27.5
	ADA	12	3.6	11.01	-10.9	-1.6	1.4	4.5	33.7
	TOT	21	7.2	10.94	-10.9	-0.5	3.0	12.7	33.7

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.18.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	4	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	13	0.23	0.388	0.0	0.00	0.00	0.50	1.0
	TOT	17	0.18	0.351	0.0	0.00	0.00	0.00	1.0
FINAL/ET VALUE	PLO	4	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	13	0.35	0.851	0.0	0.00	0.00	0.00	3.0
	TOT	17	0.26	0.752	0.0	0.00	0.00	0.00	3.0
CHG FROM BEST*	PLO	4	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	13	0.12	0.712	-1.0	0.00	0.00	0.00	2.0
	TOT	17	0.09	0.618	-1.0	0.00	0.00	0.00	2.0
AC RIGHT EYE									
BEST VALUE*	PLO	4	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	13	0.08	0.188	0.0	0.00	0.00	0.00	0.5
	TOT	17	0.06	0.166	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	4	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	13	0.50	0.957	0.0	0.00	0.00	0.50	3.0
	TOT	17	0.38	0.857	0.0	0.00	0.00	0.00	3.0
CHG FROM BEST*	PLO	4	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	ADA	13	0.42	0.886	-0.5	0.00	0.00	0.50	2.5
	TOT	17	0.32	0.789	-0.5	0.00	0.00	0.00	2.5

* 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.
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__1000.2.1.1.18.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	4	0.75	0.957	0.0	0.00	0.50	1.50	2.0
	ADA	13	0.04	0.139	0.0	0.00	0.00	0.00	0.5
	TOT	17	0.21	0.532	0.0	0.00	0.00	0.00	2.0
FINAL/ET VALUE	PLO	4	0.63	0.946	0.0	0.00	0.25	1.25	2.0
	ADA	13	0.15	0.315	0.0	0.00	0.00	0.00	1.0
	TOT	17	0.26	0.534	0.0	0.00	0.00	0.50	2.0
CHG FROM BEST*	PLO	4	-0.13	0.250	-0.5	-0.25	0.00	0.00	0.0
	ADA	13	0.12	0.363	-0.5	0.00	0.00	0.00	1.0
	TOT	17	0.06	0.348	-0.5	0.00	0.00	0.00	1.0
VH RIGHT EYE									
BEST VALUE*	PLO	4	0.38	0.479	0.0	0.00	0.25	0.75	1.0
	ADA	13	0.12	0.219	0.0	0.00	0.00	0.00	0.5
	TOT	17	0.18	0.303	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	4	0.38	0.479	0.0	0.00	0.25	0.75	1.0
	ADA	13	0.35	0.591	0.0	0.00	0.00	0.50	2.0
	TOT	17	0.35	0.552	0.0	0.00	0.00	0.50	2.0
CHG FROM BEST*	PLO	4	0.00	0.408	-0.5	-0.25	0.00	0.25	0.5
	ADA	13	0.23	0.563	-0.5	0.00	0.00	0.50	1.5
	TOT	17	0.18	0.529	-0.5	0.00	0.00	0.50	1.5

* 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.
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__1000.2.1.1.18.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	4	0.04	0.158	-0.10	-0.07	-0.01	0.14	0.26
	ADA	13	0.14	0.331	-0.18	-0.06	0.00	0.24	1.02
	TOT	17	0.11	0.298	-0.18	-0.06	0.00	0.24	1.02
FINAL/ET VALUE	PLO	4	0.08	0.173	-0.08	-0.04	0.03	0.19	0.32
	ADA	13	0.17	0.398	-0.20	-0.04	0.00	0.24	1.12
	TOT	17	0.15	0.355	-0.20	-0.04	0.00	0.24	1.12
CHG FROM BEST*	PLO	4	0.04	0.016	0.02	0.03	0.04	0.05	0.06
	ADA	13	0.03	0.143	-0.10	-0.02	0.00	0.04	0.48
	TOT	17	0.04	0.124	-0.10	-0.02	0.00	0.04	0.48
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	4	0.10	0.202	-0.10	-0.07	0.09	0.27	0.32
	ADA	13	0.19	0.271	-0.20	-0.04	0.12	0.40	0.76
	TOT	17	0.17	0.254	-0.20	-0.04	0.12	0.32	0.76
FINAL/ET VALUE	PLO	4	0.08	0.222	-0.08	-0.07	0.00	0.23	0.40
	ADA	13	0.19	0.369	-0.20	-0.06	0.10	0.32	1.04
	TOT	17	0.17	0.337	-0.20	-0.06	0.06	0.32	1.04
CHG FROM BEST*	PLO	4	-0.02	0.106	-0.16	-0.10	0.00	0.06	0.08
	ADA	13	0.00	0.204	-0.30	-0.10	-0.04	0.06	0.50
	TOT	17	0.00	0.183	-0.30	-0.10	-0.04	0.06	0.50

* 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.
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__1000.2.1.1.18.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	4	25.0	48.24	-8.2	-1.8	5.8	51.9	96.7
	ADA	13	1.5	14.10	-17.3	-6.6	0.0	1.9	39.1
	TOT	17	7.0	26.30	-17.3	-6.6	1.1	4.5	96.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	4	2.7	10.88	-7.2	-3.9	-0.1	9.3	18.2
	ADA	13	10.0	30.72	-12.3	-1.4	1.2	6.0	109.1
	TOT	17	8.3	27.21	-12.3	-1.4	0.6	6.0	109.1

* 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.
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__1000.2.1.1.18.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	4	25.0	48.24	-8.2	-1.8	5.8	51.9	96.7
	ADA	13	1.5	14.10	-17.3	-6.6	0.0	1.9	39.1
	TOT	17	7.0	26.30	-17.3	-6.6	1.1	4.5	96.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	4	2.7	10.88	-7.2	-3.9	-0.1	9.3	18.2
	ADA	13	10.0	30.72	-12.3	-1.4	1.2	6.0	109.1
	TOT	17	8.3	27.21	-12.3	-1.4	0.6	6.0	109.1

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.19.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	18	0.03	0.118	0.0	0.00	0.00	0.00	0.5			
	ADA	20	0.05	0.154	0.0	0.00	0.00	0.00	0.5			
	TOT	38	0.04	0.137	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	18	0.33	0.748	0.0	0.00	0.00	0.50	3.0			
	ADA	20	0.23	0.525	0.0	0.00	0.00	0.00	2.0			
	TOT	38	0.28	0.633	0.0	0.00	0.00	0.00	3.0			
CHG FROM BEST*	PLO	18	0.31	0.645	0.0	0.00	0.00	0.50	2.5			
	ADA	20	0.18	0.406	0.0	0.00	0.00	0.00	1.5			
	TOT	38	0.24	0.529	0.0	0.00	0.00	0.00	2.5			
AC RIGHT EYE												
BEST VALUE*	PLO	18	0.19	0.489	0.0	0.00	0.00	0.00	2.0			
	ADA	20	0.05	0.154	0.0	0.00	0.00	0.00	0.5			
	TOT	38	0.12	0.357	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	18	0.72	1.320	0.0	0.00	0.00	1.00	4.0			
	ADA	20	0.28	0.638	0.0	0.00	0.00	0.00	2.0			
	TOT	38	0.49	1.030	0.0	0.00	0.00	0.00	4.0			
CHG FROM BEST*	PLO	18	0.53	1.021	0.0	0.00	0.00	1.00	3.5			
	ADA	20	0.23	0.595	-0.5	0.00	0.00	0.00	2.0			
	TOT	38	0.37	0.828	-0.5	0.00	0.00	0.00	3.5			
										-0.22	(-0.62, 0.19)	0.283A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.19.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	18	0.50	0.383	0.0	0.00	0.50	1.00	1.0			
	ADA	20	0.38	0.559	0.0	0.00	0.00	0.75	2.0			
	TOT	38	0.43	0.482	0.0	0.00	0.50	1.00	2.0			
FINAL/ET VALUE	PLO	18	0.58	0.733	0.0	0.00	0.50	1.00	2.0			
	ADA	20	0.50	0.874	0.0	0.00	0.00	0.75	3.0			
	TOT	38	0.54	0.800	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	18	0.08	0.691	-0.5	-0.50	0.00	0.00	1.5			
	ADA	20	0.13	0.686	-1.0	-0.25	0.00	0.25	2.0			
	TOT	38	0.11	0.679	-1.0	-0.50	0.00	0.00	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	18	0.47	0.401	0.0	0.00	0.50	1.00	1.0			
	ADA	20	0.33	0.406	0.0	0.00	0.00	0.50	1.0			
	TOT	38	0.39	0.405	0.0	0.00	0.50	0.50	1.0			
FINAL/ET VALUE	PLO	18	0.86	0.888	0.0	0.00	0.75	1.00	3.0			
	ADA	20	0.50	0.778	0.0	0.00	0.25	0.50	3.0			
	TOT	38	0.67	0.840	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	18	0.39	0.796	-0.5	0.00	0.00	0.50	2.5			
	ADA	20	0.18	0.674	-1.0	0.00	0.00	0.50	2.0			
	TOT	38	0.28	0.732	-1.0	0.00	0.00	0.50	2.5			
										-0.09	(-0.51, 0.34)	0.681A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.19.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	18	-0.02	0.115	-0.26	-0.10	-0.02	0.06	0.26			
	ADA	20	0.08	0.238	-0.16	-0.05	0.02	0.11	0.92			
	TOT	38	0.03	0.194	-0.26	-0.08	0.00	0.08	0.92			
FINAL/ET VALUE	PLO	18	0.05	0.180	-0.20	-0.08	-0.01	0.10	0.46			
	ADA	20	0.16	0.318	-0.18	-0.07	0.08	0.28	0.96			
	TOT	38	0.11	0.265	-0.20	-0.08	0.04	0.18	0.96			
CHG FROM BEST*	PLO	18	0.07	0.113	-0.08	-0.02	0.05	0.14	0.40			
	ADA	20	0.09	0.172	-0.14	-0.03	0.04	0.13	0.58			
	TOT	38	0.08	0.145	-0.14	-0.02	0.04	0.14	0.58			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	18	0.12	0.259	-0.18	-0.08	0.01	0.38	0.70			
	ADA	20	0.12	0.196	-0.16	-0.02	0.08	0.25	0.64			
	TOT	38	0.12	0.225	-0.18	-0.04	0.04	0.26	0.70			
FINAL/ET VALUE	PLO	18	0.23	0.431	-0.20	-0.08	0.04	0.50	1.32			
	ADA	20	0.16	0.237	-0.08	0.01	0.11	0.28	0.94			
	TOT	38	0.19	0.340	-0.20	-0.04	0.09	0.34	1.32			
CHG FROM BEST*	PLO	18	0.11	0.258	-0.20	-0.04	0.05	0.10	0.88			
	ADA	20	0.05	0.131	-0.24	-0.02	0.02	0.09	0.36			
	TOT	38	0.08	0.201	-0.24	-0.02	0.03	0.10	0.88			
										-0.02	(-0.12, 0.07)	0.606A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.19.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	18	10.9	32.12	-16.5	0.4	2.7	7.2	136.0			
	ADA	20	38.5	112.64	-47.6	-1.3	0.6	29.7	483.1			
	TOT	38	25.4	84.76	-47.6	-0.5	2.1	10.0	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	18	7.2	16.43	-9.2	0.0	3.4	11.8	67.6			
	ADA	20	37.2	120.93	-50.0	-2.3	2.5	24.9	534.5			
	TOT	38	23.0	88.67	-50.0	-1.2	2.7	14.9	534.5			
										20.5	(-33.8, 74.9)	0.448A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.19.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	18	10.9	32.12	-16.5	0.4	2.7	7.2	136.0
	ADA	19	34.1	113.97	-47.6	-1.5	0.4	26.6	483.1
	TOT	37	22.8	84.38	-47.6	-0.5	2.0	9.8	483.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	18	7.2	16.43	-9.2	0.0	3.4	11.8	67.6
	ADA	19	37.6	124.22	-50.0	-3.3	2.2	21.6	534.5
	TOT	37	22.8	89.89	-50.0	-1.2	2.7	13.6	534.5

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.20.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	48	0.18	0.282	0.0	0.00	0.00	0.50	1.0			
	ADA	54	0.09	0.219	0.0	0.00	0.00	0.00	1.0			
	TOT	102	0.13	0.253	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	48	0.65	0.887	0.0	0.00	0.25	1.00	3.0			
	ADA	54	0.44	0.740	0.0	0.00	0.00	0.50	3.0			
	TOT	102	0.53	0.815	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	48	0.47	0.788	-0.5	0.00	0.00	0.75	3.0			
	ADA	54	0.34	0.782	-1.0	0.00	0.00	0.50	3.0			
	TOT	102	0.40	0.784	-1.0	0.00	0.00	0.50	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	48	0.21	0.369	0.0	0.00	0.00	0.50	2.0			
	ADA	54	0.06	0.195	0.0	0.00	0.00	0.00	1.0			
	TOT	102	0.13	0.298	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	48	0.72	0.893	0.0	0.00	0.50	1.00	3.0			
	ADA	54	0.37	0.608	0.0	0.00	0.00	0.50	2.0			
	TOT	102	0.53	0.772	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	48	0.51	0.782	-0.5	0.00	0.25	1.00	3.0			
	ADA	54	0.31	0.655	-1.0	0.00	0.00	0.50	2.0			
	TOT	102	0.40	0.721	-1.0	0.00	0.00	0.50	3.0			
										-0.17	(-0.43, 0.10)	0.214A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.20.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	49	0.36	0.421	0.0	0.00	0.50	0.50	2.0			
	ADA	54	0.30	0.500	0.0	0.00	0.00	0.50	3.0			
	TOT	103	0.33	0.463	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	49	0.67	0.781	0.0	0.00	0.50	1.00	3.0			
	ADA	54	0.47	0.780	0.0	0.00	0.00	0.50	4.0			
	TOT	103	0.57	0.783	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	49	0.32	0.565	-0.5	0.00	0.00	0.50	2.0			
	ADA	54	0.18	0.542	-1.0	0.00	0.00	0.50	2.0			
	TOT	103	0.24	0.555	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	49	0.34	0.449	0.0	0.00	0.00	0.50	2.0			
	ADA	54	0.35	0.430	0.0	0.00	0.25	0.50	2.0			
	TOT	103	0.34	0.437	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	49	0.83	0.869	0.0	0.00	0.50	1.00	3.0			
	ADA	54	0.54	0.650	0.0	0.00	0.50	1.00	3.0			
	TOT	103	0.67	0.772	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	49	0.49	0.711	-1.0	0.00	0.50	1.00	2.5			
	ADA	54	0.19	0.661	-1.5	0.00	0.00	0.50	2.5			
	TOT	103	0.33	0.699	-1.5	0.00	0.00	0.50	2.5			
										-0.22	(-0.44, 0.00)	0.048A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.20.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	49	0.12	0.271	-0.28	-0.06	0.04	0.20	0.82			
	ADA	54	0.14	0.319	-0.18	-0.10	0.03	0.22	1.30			
	TOT	103	0.13	0.296	-0.28	-0.08	0.04	0.22	1.30			
FINAL/ET VALUE	PLO	49	0.21	0.300	-0.14	0.00	0.12	0.36	1.02			
	ADA	54	0.20	0.384	-0.26	-0.06	0.07	0.34	1.60			
	TOT	103	0.21	0.345	-0.26	-0.04	0.10	0.36	1.60			
CHG FROM BEST*	PLO	49	0.09	0.136	-0.08	0.02	0.04	0.12	0.60			
	ADA	54	0.06	0.153	-0.32	-0.04	0.03	0.10	0.50			
	TOT	103	0.07	0.146	-0.32	-0.02	0.04	0.12	0.60			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	49	0.19	0.308	-0.16	-0.04	0.10	0.32	0.88			
	ADA	54	0.14	0.265	-0.20	-0.08	0.09	0.34	0.76			
	TOT	103	0.16	0.286	-0.20	-0.08	0.10	0.34	0.88			
FINAL/ET VALUE	PLO	49	0.29	0.416	-0.20	0.00	0.18	0.48	2.08			
	ADA	54	0.20	0.311	-0.22	-0.06	0.13	0.44	1.04			
	TOT	103	0.24	0.366	-0.22	-0.04	0.14	0.46	2.08			
CHG FROM BEST*	PLO	49	0.10	0.214	-0.18	0.00	0.04	0.14	1.20			
	ADA	54	0.06	0.132	-0.30	0.00	0.04	0.10	0.56			
	TOT	103	0.08	0.176	-0.30	0.00	0.04	0.12	1.20			
										-0.04	(-0.09, 0.01)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.20.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	47	14.5	45.78	-10.8	1.3	4.3	10.8	291.1			
	ADA	53	11.1	28.41	-17.7	-2.4	1.4	12.0	126.3			
	TOT	100	12.7	37.42	-17.7	-1.1	3.1	11.4	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	48	28.7	82.04	-7.2	0.9	6.0	17.2	514.8			
	ADA	54	12.7	31.31	-43.0	-1.3	3.8	12.7	145.8			
	TOT	102	20.2	60.92	-43.0	0.0	5.4	13.9	514.8			
										-7.6	(-22.6, 7.4)	0.317A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.20.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	47	14.5	45.78	-10.8	1.3	4.3	10.8	291.1			
	ADA	52	11.4	28.64	-17.7	-2.4	1.4	12.1	126.3			
	TOT	99	12.9	37.59	-17.7	-1.3	3.2	12.0	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	48	28.7	82.04	-7.2	0.9	6.0	17.2	514.8			
	ADA	53	12.7	31.61	-43.0	-1.3	3.2	12.7	145.8			
	TOT	101	20.3	61.21	-43.0	0.0	5.3	13.9	514.8			
										-7.5	(-22.6, 7.6)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.21.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	44	0.07	0.231	0.0	0.00	0.00	0.00	1.0			
	ADA	35	0.17	0.401	0.0	0.00	0.00	0.00	2.0			
	TOT	79	0.11	0.320	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	44	0.83	1.110	0.0	0.00	0.25	2.00	4.0			
	ADA	35	0.63	1.003	0.0	0.00	0.00	0.50	3.0			
	TOT	79	0.74	1.062	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	44	0.76	1.092	0.0	0.00	0.00	1.00	4.0			
	ADA	35	0.46	0.826	-0.5	0.00	0.00	0.50	3.0			
	TOT	79	0.63	0.989	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	44	0.05	0.145	0.0	0.00	0.00	0.00	0.5			
	ADA	35	0.19	0.299	0.0	0.00	0.00	0.50	1.0			
	TOT	79	0.11	0.236	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	44	0.89	1.271	0.0	0.00	0.00	1.00	4.0			
	ADA	35	0.70	0.964	0.0	0.00	0.50	1.00	3.0			
	TOT	79	0.80	1.142	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	44	0.84	1.261	-0.5	0.00	0.00	1.00	4.0			
	ADA	35	0.51	0.879	-0.5	0.00	0.00	1.00	2.5			
	TOT	79	0.70	1.113	-0.5	0.00	0.00	1.00	4.0			
										-0.32	(-0.74, 0.11)	0.146A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.21.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	44	0.43	0.524	0.0	0.00	0.50	0.75	2.0			
	ADA	35	0.34	0.579	0.0	0.00	0.00	0.50	3.0			
	TOT	79	0.39	0.547	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	44	0.90	0.873	0.0	0.00	1.00	2.00	3.0			
	ADA	35	0.36	0.494	0.0	0.00	0.00	0.50	2.0			
	TOT	79	0.66	0.774	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	44	0.47	0.758	-0.5	0.00	0.00	1.00	3.0			
	ADA	35	0.01	0.462	-1.0	0.00	0.00	0.00	1.0			
	TOT	79	0.27	0.679	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	44	0.36	0.462	0.0	0.00	0.00	0.50	2.0			
	ADA	35	0.34	0.450	0.0	0.00	0.00	0.50	2.0			
	TOT	79	0.35	0.454	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	44	0.90	1.038	0.0	0.00	0.75	1.00	4.0			
	ADA	35	0.44	0.553	0.0	0.00	0.50	1.00	2.0			
	TOT	79	0.70	0.882	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	44	0.53	0.936	-1.0	0.00	0.25	0.75	3.5			
	ADA	35	0.10	0.628	-1.0	-0.50	0.00	0.50	2.0			
	TOT	79	0.34	0.838	-1.0	0.00	0.00	0.50	3.5			
										-0.44	(-0.71, -0.18)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.21.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	44	0.21	0.302	-0.24	-0.03	0.10	0.43	0.94			
	ADA	35	0.16	0.289	-0.20	-0.04	0.10	0.24	1.12			
	TOT	79	0.19	0.295	-0.24	-0.04	0.10	0.40	1.12			
FINAL/ET VALUE	PLO	44	0.35	0.352	-0.18	0.06	0.26	0.63	1.22			
	ADA	35	0.24	0.387	-0.28	0.00	0.14	0.46	1.62			
	TOT	79	0.30	0.369	-0.28	0.00	0.22	0.56	1.62			
CHG FROM BEST*	PLO	44	0.14	0.232	-0.62	0.03	0.08	0.19	0.80			
	ADA	35	0.08	0.177	-0.20	-0.02	0.02	0.12	0.50			
	TOT	79	0.12	0.210	-0.62	0.00	0.06	0.18	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	44	0.19	0.328	-0.24	-0.07	0.12	0.44	1.16			
	ADA	35	0.16	0.248	-0.22	0.00	0.10	0.30	0.90			
	TOT	79	0.18	0.294	-0.24	-0.04	0.10	0.32	1.16			
FINAL/ET VALUE	PLO	44	0.37	0.558	-0.20	-0.04	0.31	0.61	3.00			
	ADA	35	0.19	0.325	-0.26	-0.06	0.10	0.44	0.92			
	TOT	79	0.29	0.476	-0.26	-0.06	0.18	0.48	3.00			
CHG FROM BEST*	PLO	44	0.18	0.441	-0.16	0.00	0.05	0.25	2.82			
	ADA	35	0.04	0.173	-0.50	-0.04	0.00	0.10	0.50			
	TOT	79	0.12	0.354	-0.50	-0.02	0.04	0.20	2.82			
										-0.10	(-0.20, 0.00)	0.040A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.21.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	42	27.4	60.90	-28.4	0.9	6.0	23.7	283.9			
	ADA	35	4.2	19.27	-40.8	-0.6	1.8	6.9	72.8			
	TOT	77	16.9	47.99	-40.8	0.0	3.2	11.8	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	42	19.7	40.63	-12.8	0.0	5.8	15.0	174.4			
	ADA	35	4.3	15.00	-18.3	-0.4	1.2	5.4	81.8			
	TOT	77	12.7	32.42	-18.3	0.0	3.9	10.2	174.4			
										-19.7	(-32.8, -6.6)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.21.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	42	27.4	60.90	-28.4	0.9	6.0	23.7	283.9			
	ADA	35	4.2	19.27	-40.8	-0.6	1.8	6.9	72.8			
	TOT	77	16.9	47.99	-40.8	0.0	3.2	11.8	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	42	19.7	40.63	-12.8	0.0	5.8	15.0	174.4			
	ADA	35	4.3	15.00	-18.3	-0.4	1.2	5.4	81.8			
	TOT	77	12.7	32.42	-18.3	0.0	3.9	10.2	174.4			
										-19.7	(-32.8, -6.6)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

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

TABLE 14.2__1000.2.1.1.22.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	55	0.16	0.305	0.0	0.00	0.00	0.50	1.0			
	ADA	56	0.15	0.343	0.0	0.00	0.00	0.00	2.0			
	TOT	111	0.16	0.323	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	55	0.92	1.088	0.0	0.00	0.50	2.00	4.0			
	ADA	56	0.61	0.947	0.0	0.00	0.00	1.00	3.0			
	TOT	111	0.76	1.027	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	55	0.75	1.031	-0.5	0.00	0.50	1.00	4.0			
	ADA	56	0.46	0.844	-0.5	0.00	0.00	0.75	3.0			
	TOT	111	0.60	0.949	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	55	0.16	0.348	0.0	0.00	0.00	0.50	2.0			
	ADA	56	0.14	0.281	0.0	0.00	0.00	0.00	1.0			
	TOT	111	0.15	0.315	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	55	1.05	1.256	0.0	0.00	0.50	2.00	4.0			
	ADA	56	0.64	0.898	0.0	0.00	0.00	1.00	3.0			
	TOT	111	0.84	1.104	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	55	0.88	1.217	-0.5	0.00	0.50	1.50	4.0			
	ADA	56	0.50	0.869	-1.0	0.00	0.00	1.00	2.5			
	TOT	111	0.69	1.068	-1.0	0.00	0.00	1.00	4.0			
										-0.34	(-0.68, 0.00)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.22.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	55	0.36	0.435	0.0	0.00	0.50	0.50	2.0			
	ADA	56	0.39	0.623	0.0	0.00	0.00	0.50	3.0			
	TOT	111	0.38	0.536	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	55	0.74	0.781	0.0	0.00	0.50	1.00	3.0			
	ADA	56	0.41	0.695	0.0	0.00	0.00	0.50	4.0			
	TOT	111	0.57	0.753	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	55	0.37	0.633	-0.5	0.00	0.00	0.50	3.0			
	ADA	56	0.02	0.476	-1.0	0.00	0.00	0.00	1.5			
	TOT	111	0.19	0.585	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	55	0.35	0.438	0.0	0.00	0.00	0.50	2.0			
	ADA	56	0.37	0.481	0.0	0.00	0.00	0.50	2.0			
	TOT	111	0.36	0.458	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	55	0.90	0.988	0.0	0.00	1.00	1.00	4.0			
	ADA	56	0.46	0.602	0.0	0.00	0.50	0.50	2.0			
	TOT	111	0.68	0.842	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	55	0.55	0.889	-1.0	0.00	0.50	1.00	3.5			
	ADA	56	0.10	0.663	-1.5	0.00	0.00	0.50	2.0			
	TOT	111	0.32	0.811	-1.5	0.00	0.00	0.50	3.5			
										-0.40	(-0.61, -0.19)	<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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.22.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	55	0.17	0.286	-0.28	0.00	0.10	0.24	0.94			
	ADA	56	0.11	0.267	-0.20	-0.08	0.04	0.18	1.02			
	TOT	111	0.14	0.277	-0.28	-0.04	0.06	0.22	1.02			
FINAL/ET VALUE	PLO	55	0.30	0.341	-0.18	0.04	0.20	0.52	1.22			
	ADA	56	0.19	0.339	-0.28	-0.04	0.04	0.37	1.12			
	TOT	111	0.25	0.343	-0.28	0.00	0.16	0.46	1.22			
CHG FROM BEST*	PLO	55	0.14	0.210	-0.62	0.02	0.08	0.20	0.76			
	ADA	56	0.08	0.181	-0.32	-0.04	0.04	0.13	0.58			
	TOT	111	0.11	0.197	-0.62	0.00	0.06	0.18	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	55	0.22	0.307	-0.20	-0.02	0.14	0.44	1.16			
	ADA	56	0.11	0.249	-0.20	-0.08	0.05	0.25	0.90			
	TOT	111	0.17	0.284	-0.20	-0.04	0.10	0.32	1.16			
FINAL/ET VALUE	PLO	55	0.39	0.503	-0.16	0.04	0.32	0.64	3.00			
	ADA	56	0.18	0.321	-0.20	-0.06	0.09	0.39	1.04			
	TOT	111	0.28	0.433	-0.20	-0.04	0.18	0.46	3.00			
CHG FROM BEST*	PLO	55	0.17	0.397	-0.16	0.00	0.06	0.20	2.82			
	ADA	56	0.06	0.167	-0.50	-0.04	0.04	0.12	0.56			
	TOT	111	0.11	0.307	-0.50	0.00	0.06	0.16	2.82			
										-0.08	(-0.15, -0.01)	0.034A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.22.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	53	22.4	54.70	-28.4	1.2	4.7	13.9	291.1			
	ADA	55	12.5	66.87	-47.6	-1.8	1.2	6.9	483.1			
	TOT	108	17.4	61.12	-47.6	-0.4	2.7	11.0	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	53	29.5	81.62	-12.8	0.5	6.1	15.0	514.8			
	ADA	56	19.3	75.46	-43.0	0.0	3.0	9.6	534.5			
	TOT	109	24.3	78.32	-43.0	0.4	5.0	12.3	534.5			
										-5.2	(-28.1, 17.8)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

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__1000.2.1.1.22.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	53	22.4	54.70	-28.4	1.2	4.7	13.9	291.1			
	ADA	55	12.5	66.87	-47.6	-1.8	1.2	6.9	483.1			
	TOT	108	17.4	61.12	-47.6	-0.4	2.7	11.0	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	53	29.5	81.62	-12.8	0.5	6.1	15.0	514.8			
	ADA	56	19.3	75.46	-43.0	0.0	3.0	9.6	534.5			
	TOT	109	24.3	78.32	-43.0	0.4	5.0	12.3	534.5			
										-5.2	(-28.1, 17.8)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.23.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	54	0.06	0.159	0.0	0.00	0.00	0.00	0.5			
	ADA	53	0.07	0.197	0.0	0.00	0.00	0.00	1.0			
	TOT	107	0.06	0.178	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	54	0.43	0.773	0.0	0.00	0.00	0.50	3.0			
	ADA	53	0.30	0.599	0.0	0.00	0.00	0.50	3.0			
	TOT	107	0.36	0.692	0.0	0.00	0.00	0.50	3.0			
CHG FROM BEST*	PLO	54	0.37	0.741	-0.5	0.00	0.00	0.50	3.0			
	ADA	53	0.24	0.609	-1.0	0.00	0.00	0.50	3.0			
	TOT	107	0.30	0.679	-1.0	0.00	0.00	0.50	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	54	0.12	0.321	0.0	0.00	0.00	0.00	2.0			
	ADA	53	0.06	0.160	0.0	0.00	0.00	0.00	0.5			
	TOT	107	0.09	0.255	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	54	0.54	0.916	0.0	0.00	0.00	1.00	4.0			
	ADA	53	0.26	0.515	0.0	0.00	0.00	0.50	2.0			
	TOT	107	0.40	0.754	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	54	0.42	0.769	-0.5	0.00	0.00	1.00	3.5			
	ADA	53	0.21	0.504	-0.5	0.00	0.00	0.50	2.0			
	TOT	107	0.31	0.657	-0.5	0.00	0.00	0.50	3.5			
										-0.17	(-0.39, 0.04)	0.119A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.23.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	55	0.45	0.478	0.0	0.00	0.50	0.50	2.0			
	ADA	53	0.25	0.412	0.0	0.00	0.00	0.50	2.0			
	TOT	108	0.35	0.455	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	55	0.75	0.860	0.0	0.00	0.50	1.00	3.0			
	ADA	53	0.47	0.743	0.0	0.00	0.00	0.50	3.0			
	TOT	108	0.62	0.813	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	55	0.31	0.723	-0.5	0.00	0.00	0.50	2.0			
	ADA	53	0.22	0.601	-1.0	0.00	0.00	0.50	2.0			
	TOT	108	0.26	0.664	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	55	0.37	0.454	0.0	0.00	0.00	0.50	2.0			
	ADA	53	0.32	0.368	0.0	0.00	0.00	0.50	1.0			
	TOT	108	0.35	0.413	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	55	0.82	0.894	0.0	0.00	0.50	1.00	3.0			
	ADA	53	0.54	0.685	0.0	0.00	0.50	1.00	3.0			
	TOT	108	0.68	0.807	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	55	0.45	0.743	-1.0	0.00	0.00	1.00	2.5			
	ADA	53	0.22	0.632	-1.0	0.00	0.00	0.50	2.5			
	TOT	108	0.33	0.697	-1.0	0.00	0.00	0.50	2.5			
										-0.16	(-0.39, 0.07)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.23.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	55	0.10	0.264	-0.26	-0.10	0.00	0.26	0.80			
	ADA	53	0.17	0.321	-0.18	-0.04	0.10	0.26	1.30			
	TOT	108	0.13	0.294	-0.26	-0.08	0.03	0.26	1.30			
FINAL/ET VALUE	PLO	55	0.18	0.293	-0.20	-0.04	0.04	0.42	1.02			
	ADA	53	0.23	0.406	-0.26	-0.04	0.14	0.32	1.62			
	TOT	108	0.21	0.352	-0.26	-0.04	0.10	0.35	1.62			
CHG FROM BEST*	PLO	55	0.08	0.139	-0.08	0.00	0.04	0.14	0.80			
	ADA	53	0.06	0.144	-0.20	-0.02	0.02	0.10	0.50			
	TOT	108	0.07	0.141	-0.20	-0.02	0.04	0.12	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	55	0.14	0.306	-0.24	-0.10	0.02	0.32	0.88			
	ADA	53	0.17	0.244	-0.22	-0.04	0.12	0.32	0.74			
	TOT	108	0.15	0.276	-0.24	-0.08	0.10	0.32	0.88			
FINAL/ET VALUE	PLO	55	0.24	0.447	-0.20	-0.08	0.06	0.48	2.08			
	ADA	53	0.20	0.281	-0.26	0.00	0.14	0.34	0.94			
	TOT	108	0.22	0.374	-0.26	-0.05	0.12	0.43	2.08			
CHG FROM BEST*	PLO	55	0.10	0.244	-0.20	-0.02	0.04	0.10	1.20			
	ADA	53	0.04	0.119	-0.30	-0.02	0.02	0.08	0.34			
	TOT	108	0.07	0.195	-0.30	-0.02	0.03	0.10	1.20			
										-0.04	(-0.09, 0.01)	0.091A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.23.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	53	15.9	46.84	-19.7	0.8	4.3	10.8	283.9			
	ADA	53	15.4	36.63	-34.0	-2.1	1.4	11.9	128.0			
	TOT	106	15.7	41.85	-34.0	-0.9	3.3	11.9	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	54	14.3	28.12	-9.2	0.0	5.5	14.4	165.2			
	ADA	53	9.3	26.19	-50.0	-1.3	2.2	13.4	97.3			
	TOT	107	11.9	27.17	-50.0	-0.5	3.9	14.4	165.2			
										-2.7	(-13.3, 7.8)	0.609A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.23.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	53	15.9	46.84	-19.7	0.8	4.3	10.8	283.9			
	ADA	51	13.6	34.09	-34.0	-2.2	1.4	11.9	128.0			
	TOT	104	14.8	40.91	-34.0	-0.9	3.3	11.3	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	54	14.3	28.12	-9.2	0.0	5.5	14.4	165.2			
	ADA	51	9.0	26.58	-50.0	-2.1	2.1	13.4	97.3			
	TOT	105	11.7	27.38	-50.0	-0.5	3.3	13.6	165.2			
										-3.8	(-14.3, 6.8)	0.479A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.24.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	81	0.12	0.265	0.0	0.00	0.00	0.00	1.0			
	ADA	78	0.10	0.295	0.0	0.00	0.00	0.00	2.0			
	TOT	159	0.11	0.279	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	81	0.65	0.970	0.0	0.00	0.00	1.00	4.0			
	ADA	78	0.51	0.853	0.0	0.00	0.00	0.50	3.0			
	TOT	159	0.58	0.914	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	81	0.54	0.914	-0.5	0.00	0.00	1.00	4.0			
	ADA	78	0.41	0.793	-1.0	0.00	0.00	0.50	3.0			
	TOT	159	0.47	0.856	-1.0	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	81	0.14	0.309	0.0	0.00	0.00	0.00	2.0			
	ADA	78	0.09	0.224	0.0	0.00	0.00	0.00	1.0			
	TOT	159	0.12	0.271	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	81	0.78	1.126	0.0	0.00	0.00	1.00	4.0			
	ADA	78	0.46	0.742	0.0	0.00	0.00	0.50	3.0			
	TOT	159	0.63	0.968	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	81	0.64	1.061	-0.5	0.00	0.00	1.00	4.0			
	ADA	78	0.37	0.714	-0.5	0.00	0.00	0.50	2.0			
	TOT	159	0.51	0.915	-0.5	0.00	0.00	1.00	4.0			
										-0.20	(-0.45, 0.05)	0.114A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.24.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	82	0.41	0.472	0.0	0.00	0.50	0.50	2.0			
	ADA	78	0.35	0.583	0.0	0.00	0.00	0.50	3.0			
	TOT	160	0.38	0.528	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	82	0.73	0.783	0.0	0.00	0.50	1.00	3.0			
	ADA	78	0.49	0.787	0.0	0.00	0.00	1.00	4.0			
	TOT	160	0.62	0.792	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	82	0.32	0.605	-0.5	0.00	0.00	0.50	2.0			
	ADA	78	0.15	0.587	-1.0	0.00	0.00	0.50	2.0			
	TOT	160	0.24	0.601	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	82	0.37	0.431	0.0	0.00	0.25	0.50	2.0			
	ADA	78	0.34	0.445	0.0	0.00	0.00	0.50	2.0			
	TOT	160	0.35	0.437	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	82	0.80	0.909	0.0	0.00	0.50	1.00	4.0			
	ADA	78	0.56	0.684	0.0	0.00	0.50	1.00	3.0			
	TOT	160	0.68	0.814	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	82	0.44	0.810	-1.0	0.00	0.00	0.50	3.5			
	ADA	78	0.22	0.682	-1.5	0.00	0.00	0.50	2.5			
	TOT	160	0.33	0.756	-1.5	0.00	0.00	0.50	3.5			
										-0.20	(-0.38, -0.02)	0.034A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.24.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	82	0.13	0.281	-0.28	-0.08	0.06	0.26	0.94			
	ADA	78	0.13	0.284	-0.18	-0.04	0.04	0.20	1.12			
	TOT	160	0.13	0.281	-0.28	-0.06	0.04	0.22	1.12			
FINAL/ET VALUE	PLO	82	0.24	0.327	-0.20	0.00	0.15	0.46	1.22			
	ADA	78	0.19	0.359	-0.28	-0.04	0.09	0.32	1.62			
	TOT	160	0.22	0.342	-0.28	-0.02	0.11	0.42	1.62			
CHG FROM BEST*	PLO	82	0.11	0.165	-0.08	0.02	0.06	0.14	0.80			
	ADA	78	0.06	0.159	-0.32	-0.04	0.03	0.10	0.50			
	TOT	160	0.08	0.163	-0.32	-0.02	0.04	0.12	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	82	0.16	0.295	-0.20	-0.06	0.10	0.32	0.98			
	ADA	78	0.14	0.242	-0.22	-0.06	0.10	0.30	0.90			
	TOT	160	0.15	0.270	-0.22	-0.06	0.10	0.32	0.98			
FINAL/ET VALUE	PLO	82	0.29	0.473	-0.20	-0.06	0.16	0.50	3.00			
	ADA	78	0.19	0.301	-0.26	-0.04	0.12	0.34	1.04			
	TOT	160	0.24	0.400	-0.26	-0.04	0.12	0.45	3.00			
CHG FROM BEST*	PLO	82	0.12	0.344	-0.20	0.00	0.04	0.14	2.82			
	ADA	78	0.05	0.148	-0.50	-0.02	0.04	0.10	0.56			
	TOT	160	0.09	0.269	-0.50	-0.02	0.04	0.13	2.82			
										-0.06	(-0.12, -0.01)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.24.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	81	21.5	56.41	-19.7	0.8	4.1	11.8	291.1			
	ADA	78	9.4	29.85	-47.6	-2.0	1.3	9.8	128.0			
	TOT	159	15.6	45.63	-47.6	-0.6	3.1	10.0	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	81	12.3	24.30	-11.3	0.8	5.3	11.8	169.7			
	ADA	78	10.3	27.95	-50.0	-0.4	2.8	9.9	145.8			
	TOT	159	11.3	26.09	-50.0	0.0	4.3	11.8	169.7			
										-6.6	(-16.1, 3.0)	0.175A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.24.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	81	21.5	56.41	-19.7	0.8	4.1	11.8	291.1			
	ADA	76	8.1	27.28	-47.6	-2.1	1.3	8.6	128.0			
	TOT	157	15.0	45.11	-47.6	-0.6	3.1	9.8	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	81	12.3	24.30	-11.3	0.8	5.3	11.8	169.7			
	ADA	76	10.0	28.24	-50.0	-0.5	2.6	7.8	145.8			
	TOT	157	11.2	26.22	-50.0	0.0	4.3	11.3	169.7			
										-7.5	(-17.0, 2.1)	0.127A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.25.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	9	0.06	0.167	0.0	0.00	0.00	0.00	0.5
	ADA	15	0.10	0.207	0.0	0.00	0.00	0.00	0.5
	TOT	24	0.08	0.190	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	9	0.61	0.993	0.0	0.00	0.00	1.00	3.0
	ADA	15	0.23	0.563	0.0	0.00	0.00	0.00	2.0
	TOT	24	0.38	0.755	0.0	0.00	0.00	0.50	3.0
CHG FROM BEST*	PLO	9	0.56	1.014	0.0	0.00	0.00	1.00	3.0
	ADA	15	0.13	0.611	-0.5	0.00	0.00	0.00	2.0
	TOT	24	0.29	0.793	-0.5	0.00	0.00	0.00	3.0
AC RIGHT EYE									
BEST VALUE*	PLO	9	0.11	0.220	0.0	0.00	0.00	0.00	0.5
	ADA	15	0.17	0.309	0.0	0.00	0.00	0.50	1.0
	TOT	24	0.15	0.275	0.0	0.00	0.00	0.25	1.0
FINAL/ET VALUE	PLO	9	0.56	0.682	0.0	0.00	0.50	1.00	2.0
	ADA	15	0.27	0.530	0.0	0.00	0.00	0.50	2.0
	TOT	24	0.38	0.594	0.0	0.00	0.00	0.50	2.0
CHG FROM BEST*	PLO	9	0.44	0.726	-0.5	0.00	0.50	0.50	2.0
	ADA	15	0.10	0.660	-1.0	0.00	0.00	0.50	2.0
	TOT	24	0.23	0.691	-1.0	0.00	0.00	0.50	2.0

* 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.
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__1000.2.1.1.25.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	9	0.28	0.441	0.0	0.00	0.00	0.50	1.0
	ADA	15	0.30	0.368	0.0	0.00	0.00	0.50	1.0
	TOT	24	0.29	0.388	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	9	0.67	1.090	0.0	0.00	0.00	0.50	3.0
	ADA	15	0.40	0.573	0.0	0.00	0.00	0.50	2.0
	TOT	24	0.50	0.794	0.0	0.00	0.00	0.50	3.0
CHG FROM BEST*	PLO	9	0.39	0.928	-0.5	0.00	0.00	0.00	2.0
	ADA	15	0.10	0.471	-0.5	0.00	0.00	0.00	1.5
	TOT	24	0.21	0.674	-0.5	0.00	0.00	0.00	2.0
VH RIGHT EYE									
BEST VALUE*	PLO	9	0.44	0.726	0.0	0.00	0.00	1.00	2.0
	ADA	15	0.33	0.362	0.0	0.00	0.50	0.50	1.0
	TOT	24	0.38	0.516	0.0	0.00	0.00	0.50	2.0
FINAL/ET VALUE	PLO	9	1.39	1.364	0.0	0.00	1.00	3.00	3.0
	ADA	15	0.47	0.611	0.0	0.00	0.00	1.00	2.0
	TOT	24	0.81	1.041	0.0	0.00	0.50	1.00	3.0
CHG FROM BEST*	PLO	9	0.94	0.882	0.0	0.00	1.00	2.00	2.0
	ADA	15	0.13	0.640	-1.0	0.00	0.00	0.50	1.5
	TOT	24	0.44	0.825	-1.0	0.00	0.00	1.00	2.0

* 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.
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__1000.2.1.1.25.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	9	0.14	0.311	-0.22	-0.06	0.04	0.30	0.80
	ADA	15	0.05	0.191	-0.20	-0.16	0.00	0.24	0.32
	TOT	24	0.08	0.241	-0.22	-0.09	0.03	0.26	0.80
FINAL/ET VALUE	PLO	9	0.26	0.381	-0.18	0.04	0.22	0.26	1.02
	ADA	15	0.14	0.252	-0.20	-0.04	0.00	0.38	0.50
	TOT	24	0.19	0.305	-0.20	-0.04	0.14	0.37	1.02
CHG FROM BEST*	PLO	9	0.12	0.119	-0.04	0.04	0.10	0.22	0.32
	ADA	15	0.09	0.163	-0.10	-0.02	0.02	0.20	0.48
	TOT	24	0.10	0.146	-0.10	0.00	0.04	0.21	0.48
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	9	0.27	0.331	-0.02	0.00	0.18	0.34	0.88
	ADA	15	0.08	0.196	-0.20	-0.12	0.10	0.24	0.42
	TOT	24	0.15	0.265	-0.20	-0.03	0.11	0.25	0.88
FINAL/ET VALUE	PLO	9	0.59	0.703	-0.06	0.06	0.42	0.76	2.08
	ADA	15	0.13	0.252	-0.20	-0.08	0.06	0.36	0.58
	TOT	24	0.30	0.513	-0.20	-0.06	0.11	0.44	2.08
CHG FROM BEST*	PLO	9	0.32	0.409	-0.16	0.04	0.24	0.52	1.20
	ADA	15	0.04	0.129	-0.18	-0.04	0.04	0.10	0.32
	TOT	24	0.15	0.295	-0.18	-0.02	0.08	0.24	1.20

* 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.
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__1000.2.1.1.25.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	7	7.1	8.18	-8.2	1.2	10.2	14.4	14.6
	ADA	15	11.7	34.56	-40.8	-2.4	0.0	21.3	99.1
	TOT	22	10.2	28.64	-40.8	-0.9	1.9	14.4	99.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	7	83.3	192.35	-12.8	-7.2	-1.2	66.4	514.8
	ADA	15	6.0	22.04	-12.3	-2.5	0.6	8.2	81.8
	TOT	22	30.6	110.70	-12.8	-4.8	0.5	10.7	514.8

* 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.
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__1000.2.1.1.25.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	7	7.1	8.18	-8.2	1.2	10.2	14.4	14.6
	ADA	15	11.7	34.56	-40.8	-2.4	0.0	21.3	99.1
	TOT	22	10.2	28.64	-40.8	-0.9	1.9	14.4	99.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	7	83.3	192.35	-12.8	-7.2	-1.2	66.4	514.8
	ADA	15	6.0	22.04	-12.3	-2.5	0.6	8.2	81.8
	TOT	22	30.6	110.70	-12.8	-4.8	0.5	10.7	514.8

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.26.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
AC LEFT EYE									
BEST VALUE*	PLO	19	0.11	0.209	0.0	0.00	0.00	0.00	0.5
	ADA	16	0.16	0.301	0.0	0.00	0.00	0.25	1.0
	TOT	35	0.13	0.253	0.0	0.00	0.00	0.00	1.0
FINAL/ET VALUE	PLO	19	0.79	1.018	0.0	0.00	0.50	1.00	3.0
	ADA	16	0.41	0.779	0.0	0.00	0.00	0.50	3.0
	TOT	35	0.61	0.924	0.0	0.00	0.00	1.00	3.0
CHG FROM BEST*	PLO	19	0.68	0.916	0.0	0.00	0.00	1.00	2.5
	ADA	16	0.25	0.577	-0.5	0.00	0.00	0.50	2.0
	TOT	35	0.49	0.800	-0.5	0.00	0.00	1.00	2.5
AC RIGHT EYE									
BEST VALUE*	PLO	19	0.16	0.473	0.0	0.00	0.00	0.00	2.0
	ADA	16	0.09	0.202	0.0	0.00	0.00	0.00	0.5
	TOT	35	0.13	0.371	0.0	0.00	0.00	0.00	2.0
FINAL/ET VALUE	PLO	19	0.95	1.301	0.0	0.00	0.00	3.00	3.0
	ADA	16	0.63	0.992	0.0	0.00	0.25	0.75	3.0
	TOT	35	0.80	1.164	0.0	0.00	0.00	1.00	3.0
CHG FROM BEST*	PLO	19	0.79	1.110	0.0	0.00	0.00	1.00	3.0
	ADA	16	0.53	0.826	0.0	0.00	0.25	0.50	2.5
	TOT	35	0.67	0.985	0.0	0.00	0.00	1.00	3.0

* 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.
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__1000.2.1.1.26.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
VH LEFT EYE									
BEST VALUE*	PLO	19	0.45	0.405	0.0	0.00	0.50	1.00	1.0
	ADA	16	0.25	0.408	0.0	0.00	0.00	0.50	1.0
	TOT	35	0.36	0.413	0.0	0.00	0.00	0.50	1.0
FINAL/ET VALUE	PLO	19	0.84	0.867	0.0	0.00	0.50	1.00	3.0
	ADA	16	0.22	0.364	0.0	0.00	0.00	0.50	1.0
	TOT	35	0.56	0.745	0.0	0.00	0.50	1.00	3.0
CHG FROM BEST*	PLO	19	0.39	0.859	-0.5	0.00	0.00	1.00	3.0
	ADA	16	-0.03	0.386	-1.0	0.00	0.00	0.00	0.5
	TOT	35	0.20	0.709	-1.0	0.00	0.00	0.50	3.0
VH RIGHT EYE									
BEST VALUE*	PLO	19	0.32	0.342	0.0	0.00	0.50	0.50	1.0
	ADA	16	0.38	0.428	0.0	0.00	0.25	0.75	1.0
	TOT	35	0.34	0.379	0.0	0.00	0.50	0.50	1.0
FINAL/ET VALUE	PLO	19	0.84	0.800	0.0	0.00	1.00	1.00	3.0
	ADA	16	0.25	0.365	0.0	0.00	0.00	0.50	1.0
	TOT	35	0.57	0.698	0.0	0.00	0.50	1.00	3.0
CHG FROM BEST*	PLO	19	0.53	0.790	-0.5	0.00	0.50	1.00	2.5
	ADA	16	-0.13	0.387	-1.0	-0.50	0.00	0.00	0.5
	TOT	35	0.23	0.711	-1.0	0.00	0.00	0.50	2.5

* 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.
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__1000.2.1.1.26.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
LOGMAR LEFT EYE									
BEST VALUE*	PLO	19	0.14	0.255	-0.16	-0.04	0.06	0.24	0.78
	ADA	16	0.24	0.397	-0.14	-0.03	0.08	0.44	1.30
	TOT	35	0.19	0.326	-0.16	-0.04	0.06	0.36	1.30
FINAL/ET VALUE	PLO	19	0.25	0.292	-0.08	0.02	0.16	0.36	0.90
	ADA	16	0.35	0.496	-0.10	-0.04	0.16	0.64	1.60
	TOT	35	0.30	0.395	-0.10	0.00	0.16	0.58	1.60
CHG FROM BEST*	PLO	19	0.11	0.257	-0.62	0.02	0.10	0.16	0.76
	ADA	16	0.12	0.188	-0.08	0.00	0.05	0.16	0.58
	TOT	35	0.11	0.225	-0.62	0.00	0.06	0.16	0.76
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	19	0.22	0.358	-0.24	-0.04	0.08	0.48	1.16
	ADA	16	0.18	0.313	-0.20	-0.09	0.11	0.37	0.74
	TOT	35	0.20	0.334	-0.24	-0.08	0.10	0.44	1.16
FINAL/ET VALUE	PLO	19	0.32	0.357	-0.18	0.02	0.28	0.48	1.00
	ADA	16	0.25	0.347	-0.20	-0.04	0.21	0.53	0.84
	TOT	35	0.29	0.348	-0.20	-0.04	0.24	0.48	1.00
CHG FROM BEST*	PLO	19	0.10	0.175	-0.16	-0.02	0.06	0.28	0.46
	ADA	16	0.07	0.152	-0.10	0.00	0.03	0.07	0.50
	TOT	35	0.09	0.163	-0.16	0.00	0.04	0.08	0.50

* 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.
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__1000.2.1.1.26.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	18	13.4	28.44	-28.4	2.0	6.3	16.0	113.8
	ADA	15	39.7	123.78	-17.7	-1.5	5.6	17.1	483.1
	TOT	33	25.4	85.50	-28.4	0.0	6.0	16.0	483.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	19	39.9	68.79	-3.9	0.3	8.0	18.2	212.4
	ADA	16	42.9	133.96	-43.0	0.4	4.0	15.3	534.5
	TOT	35	41.3	102.10	-43.0	0.3	6.2	16.6	534.5

* 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.
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__1000.2.1.1.26.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX
CRT LEFT EYE									
%CHG FROM BEST*	PLO	18	13.4	28.44	-28.4	2.0	6.3	16.0	113.8
	ADA	15	39.7	123.78	-17.7	-1.5	5.6	17.1	483.1
	TOT	33	25.4	85.50	-28.4	0.0	6.0	16.0	483.1
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	19	39.9	68.79	-3.9	0.3	8.0	18.2	212.4
	ADA	16	42.9	133.96	-43.0	0.4	4.0	15.3	534.5
	TOT	35	41.3	102.10	-43.0	0.3	6.2	16.6	534.5

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.27.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	64	0.14	0.288	0.0	0.00	0.00	0.00	1.0			
	ADA	70	0.14	0.329	0.0	0.00	0.00	0.00	2.0			
	TOT	134	0.14	0.309	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	64	0.85	1.068	0.0	0.00	0.50	2.00	4.0			
	ADA	70	0.58	0.943	0.0	0.00	0.00	1.00	3.0			
	TOT	134	0.71	1.010	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	64	0.71	0.999	-0.5	0.00	0.25	1.00	4.0			
	ADA	70	0.44	0.875	-1.0	0.00	0.00	0.50	3.0			
	TOT	134	0.57	0.942	-1.0	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	64	0.17	0.401	0.0	0.00	0.00	0.00	2.0			
	ADA	70	0.11	0.258	0.0	0.00	0.00	0.00	1.0			
	TOT	134	0.14	0.334	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	64	0.97	1.218	0.0	0.00	0.50	2.00	4.0			
	ADA	70	0.54	0.802	0.0	0.00	0.00	1.00	3.0			
	TOT	134	0.75	1.040	0.0	0.00	0.25	1.00	4.0			
CHG FROM BEST*	PLO	64	0.80	1.133	-0.5	0.00	0.25	1.00	4.0			
	ADA	70	0.43	0.782	-1.0	0.00	0.00	0.50	2.5			
	TOT	134	0.60	0.979	-1.0	0.00	0.00	1.00	4.0			
										-0.32	(-0.61, -0.02)	0.034A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.27.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	64	0.39	0.475	0.0	0.00	0.50	0.50	2.0			
	ADA	70	0.29	0.357	0.0	0.00	0.00	0.50	1.0			
	TOT	134	0.34	0.419	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	64	0.69	0.799	0.0	0.00	0.50	1.00	3.0			
	ADA	70	0.36	0.519	0.0	0.00	0.00	0.50	2.0			
	TOT	134	0.51	0.685	0.0	0.00	0.25	1.00	3.0			
CHG FROM BEST*	PLO	64	0.30	0.700	-0.5	0.00	0.00	0.50	3.0			
	ADA	70	0.07	0.468	-1.0	0.00	0.00	0.00	1.5			
	TOT	134	0.18	0.599	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	64	0.32	0.392	0.0	0.00	0.00	0.50	1.0			
	ADA	70	0.32	0.417	0.0	0.00	0.00	0.50	2.0			
	TOT	134	0.32	0.404	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	64	0.80	0.872	0.0	0.00	0.50	1.00	4.0			
	ADA	70	0.46	0.618	0.0	0.00	0.50	0.50	3.0			
	TOT	134	0.62	0.766	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	64	0.48	0.753	-1.0	0.00	0.00	1.00	3.5			
	ADA	70	0.14	0.625	-1.5	0.00	0.00	0.50	2.0			
	TOT	134	0.30	0.707	-1.5	0.00	0.00	0.50	3.5			
										-0.28	(-0.47, -0.10)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.27.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	64	0.12	0.267	-0.28	-0.04	0.04	0.20	0.94			
	ADA	70	0.10	0.273	-0.20	-0.06	0.03	0.20	1.30			
	TOT	134	0.11	0.269	-0.28	-0.04	0.04	0.20	1.30			
FINAL/ET VALUE	PLO	64	0.22	0.312	-0.20	0.00	0.13	0.30	1.22			
	ADA	70	0.17	0.338	-0.20	-0.04	0.04	0.32	1.60			
	TOT	134	0.19	0.326	-0.20	-0.02	0.10	0.32	1.60			
CHG FROM BEST*	PLO	64	0.09	0.170	-0.62	0.02	0.06	0.14	0.72			
	ADA	70	0.07	0.166	-0.32	-0.04	0.02	0.10	0.58			
	TOT	134	0.08	0.168	-0.62	-0.02	0.04	0.14	0.72			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	64	0.15	0.295	-0.20	-0.04	0.08	0.28	1.16			
	ADA	70	0.13	0.247	-0.20	-0.08	0.07	0.26	0.76			
	TOT	134	0.14	0.270	-0.20	-0.06	0.08	0.26	1.16			
FINAL/ET VALUE	PLO	64	0.26	0.480	-0.20	-0.03	0.10	0.40	3.00			
	ADA	70	0.18	0.310	-0.20	-0.06	0.09	0.36	1.04			
	TOT	134	0.22	0.401	-0.20	-0.06	0.10	0.40	3.00			
CHG FROM BEST*	PLO	64	0.11	0.365	-0.20	0.00	0.04	0.14	2.82			
	ADA	70	0.06	0.144	-0.30	-0.04	0.04	0.10	0.56			
	TOT	134	0.09	0.273	-0.30	0.00	0.04	0.12	2.82			
										-0.04	(-0.10, 0.02)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.27.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	61	16.4	49.17	-28.4	0.9	4.1	9.8	291.1			
	ADA	70	12.5	61.01	-47.6	-2.0	1.1	7.4	483.1			
	TOT	131	14.3	55.64	-47.6	-0.6	2.3	9.8	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	63	21.9	72.45	-12.8	0.0	5.3	11.3	514.8			
	ADA	70	17.6	67.73	-14.1	0.0	2.5	10.7	534.5			
	TOT	133	19.7	69.78	-14.1	0.0	4.1	10.7	534.5			
										-0.7	(-19.5, 18.0)	0.938A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.27.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	61	16.4	49.17	-28.4	0.9	4.1	9.8	291.1			
	ADA	70	12.5	61.01	-47.6	-2.0	1.1	7.4	483.1			
	TOT	131	14.3	55.64	-47.6	-0.6	2.3	9.8	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	63	21.9	72.45	-12.8	0.0	5.3	11.3	514.8			
	ADA	70	17.6	67.73	-14.1	0.0	2.5	10.7	534.5			
	TOT	133	19.7	69.78	-14.1	0.0	4.1	10.7	534.5			
										-0.7	(-19.5, 18.0)	0.938A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.28.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	46	0.07	0.170	0.0	0.00	0.00	0.00	0.5			
	ADA	39	0.06	0.169	0.0	0.00	0.00	0.00	0.5			
	TOT	85	0.06	0.169	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	46	0.41	0.755	0.0	0.00	0.00	0.50	3.0			
	ADA	39	0.24	0.412	0.0	0.00	0.00	0.50	2.0			
	TOT	85	0.34	0.624	0.0	0.00	0.00	0.50	3.0			
CHG FROM BEST*	PLO	46	0.35	0.737	-0.5	0.00	0.00	0.50	3.0			
	ADA	39	0.18	0.371	-0.5	0.00	0.00	0.50	1.5			
	TOT	85	0.27	0.600	-0.5	0.00	0.00	0.50	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	46	0.10	0.201	0.0	0.00	0.00	0.00	0.5			
	ADA	39	0.08	0.183	0.0	0.00	0.00	0.00	0.5			
	TOT	85	0.09	0.192	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	46	0.53	0.927	0.0	0.00	0.00	1.00	4.0			
	ADA	39	0.31	0.655	0.0	0.00	0.00	0.50	3.0			
	TOT	85	0.43	0.817	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	46	0.43	0.860	-0.5	0.00	0.00	0.50	3.5			
	ADA	39	0.23	0.605	-0.5	0.00	0.00	0.50	2.5			
	TOT	85	0.34	0.757	-0.5	0.00	0.00	0.50	3.5			
										-0.19	(-0.44, 0.07)	0.150A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.28.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	47	0.44	0.438	0.0	0.00	0.50	0.50	2.0			
	ADA	39	0.40	0.754	0.0	0.00	0.00	0.50	3.0			
	TOT	86	0.42	0.598	0.0	0.00	0.25	0.50	3.0			
FINAL/ET VALUE	PLO	47	0.83	0.836	0.0	0.00	0.50	2.00	3.0			
	ADA	39	0.59	0.966	0.0	0.00	0.00	1.00	4.0			
	TOT	86	0.72	0.900	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	47	0.39	0.642	-0.5	0.00	0.00	1.00	2.0			
	ADA	39	0.19	0.665	-1.0	0.00	0.00	0.50	2.0			
	TOT	86	0.30	0.657	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	47	0.44	0.507	0.0	0.00	0.50	0.50	2.0			
	ADA	39	0.38	0.451	0.0	0.00	0.50	0.50	2.0			
	TOT	86	0.41	0.480	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	47	0.95	1.017	0.0	0.00	0.50	1.00	3.0			
	ADA	39	0.58	0.684	0.0	0.00	0.50	1.00	3.0			
	TOT	86	0.78	0.896	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	47	0.51	0.900	-1.0	0.00	0.00	0.50	2.5			
	ADA	39	0.19	0.694	-1.0	0.00	0.00	0.50	2.5			
	TOT	86	0.37	0.824	-1.0	0.00	0.00	0.50	2.5			
										-0.26	(-0.54, 0.02)	0.069A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.28.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	47	0.14	0.289	-0.22	-0.10	0.06	0.40	0.80			
	ADA	39	0.20	0.325	-0.16	-0.02	0.12	0.32	1.12			
	TOT	86	0.17	0.306	-0.22	-0.08	0.06	0.32	1.12			
FINAL/ET VALUE	PLO	47	0.27	0.335	-0.18	0.00	0.18	0.58	1.02			
	ADA	39	0.28	0.422	-0.28	-0.02	0.18	0.58	1.62			
	TOT	86	0.27	0.375	-0.28	0.00	0.18	0.58	1.62			
CHG FROM BEST*	PLO	47	0.13	0.189	-0.06	0.02	0.08	0.18	0.80			
	ADA	39	0.08	0.161	-0.16	-0.02	0.04	0.12	0.50			
	TOT	86	0.11	0.178	-0.16	0.00	0.04	0.16	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	47	0.22	0.323	-0.24	-0.06	0.16	0.44	0.88			
	ADA	39	0.16	0.248	-0.22	0.00	0.12	0.32	0.90			
	TOT	86	0.19	0.291	-0.24	-0.06	0.14	0.38	0.90			
FINAL/ET VALUE	PLO	47	0.38	0.475	-0.20	-0.02	0.36	0.60	2.08			
	ADA	39	0.20	0.289	-0.26	-0.02	0.18	0.34	0.94			
	TOT	86	0.30	0.409	-0.26	-0.02	0.21	0.50	2.08			
CHG FROM BEST*	PLO	47	0.16	0.273	-0.18	-0.02	0.06	0.30	1.20			
	ADA	39	0.04	0.148	-0.50	-0.02	0.02	0.10	0.32			
	TOT	86	0.10	0.232	-0.50	-0.02	0.04	0.14	1.20			
										-0.09	(-0.16, -0.02)	0.012A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.28.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	46	22.4	52.74	-10.8	0.8	5.6	14.6	283.9			
	ADA	38	16.7	38.25	-34.0	-1.3	1.9	21.3	128.0			
	TOT	84	19.8	46.56	-34.0	0.0	3.4	15.1	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	45	21.3	39.71	-7.2	0.8	8.2	21.3	174.4			
	ADA	39	8.8	29.47	-50.0	-1.3	2.7	12.4	97.3			
	TOT	84	15.5	35.68	-50.0	-0.4	5.0	14.7	174.4			
										-9.1	(-22.9, 4.7)	0.193A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.28.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	46	22.4	52.74	-10.8	0.8	5.6	14.6	283.9			
	ADA	36	14.2	34.91	-34.0	-1.4	1.9	15.9	128.0			
	TOT	82	18.8	45.70	-34.0	0.0	3.4	14.6	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	45	21.3	39.71	-7.2	0.8	8.2	21.3	174.4			
	ADA	37	8.2	30.10	-50.0	-1.3	2.4	7.8	97.3			
	TOT	82	15.4	36.09	-50.0	-0.5	4.5	14.6	174.4			
										-10.5	(-24.3, 3.4)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.29.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	33	0.12	0.280	0.0	0.00	0.00	0.00	1.0			
	ADA	32	0.11	0.245	0.0	0.00	0.00	0.00	1.0			
	TOT	65	0.12	0.262	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	33	0.80	1.038	0.0	0.00	0.50	1.00	4.0			
	ADA	32	0.61	0.965	0.0	0.00	0.00	1.00	3.0			
	TOT	65	0.71	1.000	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	33	0.68	0.942	0.0	0.00	0.50	1.00	4.0			
	ADA	32	0.50	0.976	-1.0	0.00	0.00	0.75	3.0			
	TOT	65	0.59	0.956	-1.0	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	33	0.15	0.405	0.0	0.00	0.00	0.00	2.0			
	ADA	32	0.09	0.235	0.0	0.00	0.00	0.00	1.0			
	TOT	65	0.12	0.331	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	33	0.86	1.214	0.0	0.00	0.00	2.00	4.0			
	ADA	32	0.58	0.843	0.0	0.00	0.00	0.75	3.0			
	TOT	65	0.72	1.050	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	33	0.71	1.083	0.0	0.00	0.00	1.00	3.5			
	ADA	32	0.48	0.808	-0.5	0.00	0.00	0.50	2.0			
	TOT	65	0.60	0.957	-0.5	0.00	0.00	1.00	3.5			
										-0.20	(-0.64, 0.23)	0.352A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.29.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	33	0.35	0.364	0.0	0.00	0.50	0.50	1.0			
	ADA	32	0.16	0.296	0.0	0.00	0.00	0.25	1.0			
	TOT	65	0.25	0.344	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	33	0.67	0.816	0.0	0.00	0.50	1.00	3.0			
	ADA	32	0.30	0.566	0.0	0.00	0.00	0.50	2.0			
	TOT	65	0.48	0.723	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	33	0.32	0.748	-0.5	0.00	0.00	0.50	3.0			
	ADA	32	0.14	0.406	-0.5	0.00	0.00	0.00	1.5			
	TOT	65	0.23	0.606	-0.5	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	33	0.27	0.377	0.0	0.00	0.00	0.50	1.0			
	ADA	32	0.16	0.296	0.0	0.00	0.00	0.25	1.0			
	TOT	65	0.22	0.342	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	33	0.71	0.781	0.0	0.00	0.50	1.00	3.0			
	ADA	32	0.33	0.394	0.0	0.00	0.00	0.50	1.0			
	TOT	65	0.52	0.646	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	33	0.44	0.682	-0.5	0.00	0.00	1.00	2.5			
	ADA	32	0.17	0.373	-0.5	0.00	0.00	0.50	1.0			
	TOT	65	0.31	0.564	-0.5	0.00	0.00	0.50	2.5			
										-0.22	(-0.47, 0.02)	0.075A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.29.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	33	0.09	0.231	-0.28	-0.04	0.04	0.12	0.88			
	ADA	32	0.07	0.203	-0.20	-0.06	0.01	0.13	0.74			
	TOT	65	0.08	0.216	-0.28	-0.04	0.02	0.12	0.88			
FINAL/ET VALUE	PLO	33	0.16	0.254	-0.20	0.00	0.12	0.22	0.98			
	ADA	32	0.12	0.216	-0.18	-0.05	0.04	0.29	0.68			
	TOT	65	0.14	0.235	-0.20	-0.02	0.10	0.28	0.98			
CHG FROM BEST*	PLO	33	0.07	0.170	-0.62	0.00	0.06	0.12	0.40			
	ADA	32	0.05	0.186	-0.32	-0.03	0.02	0.07	0.58			
	TOT	65	0.06	0.177	-0.62	-0.02	0.04	0.10	0.58			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	33	0.14	0.309	-0.18	-0.04	0.08	0.16	1.16			
	ADA	32	0.12	0.214	-0.16	-0.08	0.09	0.25	0.70			
	TOT	65	0.13	0.265	-0.18	-0.06	0.08	0.24	1.16			
FINAL/ET VALUE	PLO	33	0.20	0.315	-0.20	-0.04	0.10	0.32	1.00			
	ADA	32	0.18	0.242	-0.16	-0.03	0.14	0.35	0.84			
	TOT	65	0.19	0.280	-0.20	-0.04	0.14	0.34	1.00			
CHG FROM BEST*	PLO	33	0.06	0.119	-0.20	-0.02	0.04	0.08	0.34			
	ADA	32	0.06	0.126	-0.30	0.00	0.06	0.11	0.36			
	TOT	65	0.06	0.122	-0.30	0.00	0.06	0.10	0.36			
										-0.01	(-0.07, 0.06)	0.822A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.29.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	33	17.4	52.51	-28.4	1.3	4.5	9.4	291.1			
	ADA	32	17.2	85.89	-17.3	-2.2	0.3	5.6	483.1			
	TOT	65	17.3	70.37	-28.4	-0.9	2.1	8.1	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	33	20.3	46.70	-11.3	1.6	6.1	12.3	212.4			
	ADA	32	25.2	94.44	-14.1	1.1	5.3	13.0	534.5			
	TOT	65	22.7	73.60	-14.1	1.2	5.7	12.7	534.5			
										9.8	(-24.2, 43.8)	0.567A

* 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.
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 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 AND OCT MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

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__1000.2.1.1.29.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	33	17.4	52.51	-28.4	1.3	4.5	9.4	291.1			
	ADA	32	17.2	85.89	-17.3	-2.2	0.3	5.6	483.1			
	TOT	65	17.3	70.37	-28.4	-0.9	2.1	8.1	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	33	20.3	46.70	-11.3	1.6	6.1	12.3	212.4			
	ADA	32	25.2	94.44	-14.1	1.1	5.3	13.0	534.5			
	TOT	65	22.7	73.60	-14.1	1.2	5.7	12.7	534.5			
										9.8	(-24.2, 43.8)	0.567A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	32	0.16	0.296	0.0	0.00	0.00	0.25	1.0			
	ADA	38	0.16	0.387	0.0	0.00	0.00	0.00	2.0			
	TOT	70	0.16	0.346	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	32	0.88	1.107	0.0	0.00	0.50	2.00	4.0			
	ADA	38	0.55	0.936	0.0	0.00	0.00	1.00	3.0			
	TOT	70	0.70	1.023	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	32	0.72	1.062	-0.5	0.00	0.00	1.00	4.0			
	ADA	38	0.39	0.790	-0.5	0.00	0.00	0.50	3.0			
	TOT	70	0.54	0.932	-0.5	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	32	0.19	0.397	0.0	0.00	0.00	0.50	2.0			
	ADA	38	0.13	0.277	0.0	0.00	0.00	0.00	1.0			
	TOT	70	0.16	0.336	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	32	1.05	1.227	0.0	0.00	0.50	2.00	4.0			
	ADA	38	0.51	0.775	0.0	0.00	0.00	1.00	3.0			
	TOT	70	0.76	1.035	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	32	0.86	1.186	-0.5	0.00	0.50	1.25	4.0			
	ADA	38	0.38	0.766	-1.0	0.00	0.00	0.50	2.5			
	TOT	70	0.60	1.002	-1.0	0.00	0.00	1.00	4.0			
										-0.40	(-0.81, 0.01)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	32	0.42	0.570	0.0	0.00	0.00	0.75	2.0			
	ADA	38	0.39	0.370	0.0	0.00	0.50	0.50	1.0			
	TOT	70	0.41	0.469	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	32	0.69	0.791	0.0	0.00	0.50	1.00	2.0			
	ADA	38	0.41	0.477	0.0	0.00	0.50	0.50	2.0			
	TOT	70	0.54	0.650	0.0	0.00	0.50	1.00	2.0			
CHG FROM BEST*	PLO	32	0.27	0.647	-0.5	0.00	0.00	0.50	2.0			
	ADA	38	0.01	0.513	-1.0	-0.50	0.00	0.50	1.0			
	TOT	70	0.13	0.588	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	32	0.36	0.406	0.0	0.00	0.25	0.50	1.0			
	ADA	38	0.46	0.456	0.0	0.00	0.50	0.50	2.0			
	TOT	70	0.41	0.434	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	32	0.86	0.961	0.0	0.00	0.75	1.00	4.0			
	ADA	38	0.57	0.746	0.0	0.00	0.50	1.00	3.0			
	TOT	70	0.70	0.857	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	32	0.50	0.823	-1.0	0.00	0.25	0.75	3.5			
	ADA	38	0.11	0.781	-1.5	-0.50	0.00	0.50	2.0			
	TOT	70	0.29	0.819	-1.5	0.00	0.00	0.50	3.5			
										-0.32	(-0.60, -0.04)	0.025A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	32	0.15	0.298	-0.26	-0.05	0.04	0.36	0.94			
	ADA	38	0.13	0.320	-0.18	-0.08	0.05	0.22	1.30			
	TOT	70	0.14	0.308	-0.26	-0.06	0.04	0.28	1.30			
FINAL/ET VALUE	PLO	32	0.27	0.357	-0.16	0.00	0.18	0.48	1.22			
	ADA	38	0.22	0.412	-0.20	-0.04	0.03	0.44	1.60			
	TOT	70	0.24	0.386	-0.20	-0.02	0.11	0.44	1.60			
CHG FROM BEST*	PLO	32	0.12	0.166	-0.08	0.02	0.06	0.17	0.72			
	ADA	38	0.08	0.148	-0.14	-0.04	0.05	0.12	0.48			
	TOT	70	0.10	0.156	-0.14	0.00	0.06	0.14	0.72			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	32	0.16	0.280	-0.20	-0.04	0.06	0.36	0.76			
	ADA	38	0.13	0.275	-0.20	-0.06	0.01	0.26	0.76			
	TOT	70	0.14	0.276	-0.20	-0.04	0.02	0.32	0.76			
FINAL/ET VALUE	PLO	32	0.33	0.597	-0.20	0.00	0.11	0.66	3.00			
	ADA	38	0.19	0.360	-0.20	-0.06	0.02	0.44	1.04			
	TOT	70	0.25	0.485	-0.20	-0.06	0.08	0.46	3.00			
CHG FROM BEST*	PLO	32	0.17	0.499	-0.06	0.00	0.04	0.16	2.82			
	ADA	38	0.06	0.160	-0.18	-0.04	0.02	0.08	0.56			
	TOT	70	0.11	0.359	-0.18	-0.02	0.04	0.14	2.82			
										-0.08	(-0.17, 0.02)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.30.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	29	14.8	45.10	-19.7	0.8	3.3	10.2	227.9			
	ADA	38	8.4	26.92	-47.6	-1.0	1.9	11.9	99.1			
	TOT	67	11.2	35.77	-47.6	0.0	3.2	11.8	227.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	31	23.3	92.31	-12.8	0.0	4.8	10.2	514.8			
	ADA	38	11.3	31.50	-12.5	-0.8	1.9	8.2	145.8			
	TOT	69	16.7	65.84	-12.8	-0.5	2.3	9.4	514.8			
										-8.4	(-26.6, 9.9)	0.363A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

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

TABLE 14.2__1000.2.1.1.30.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	29	14.8	45.10	-19.7	0.8	3.3	10.2	227.9			
	ADA	38	8.4	26.92	-47.6	-1.0	1.9	11.9	99.1			
	TOT	67	11.2	35.77	-47.6	0.0	3.2	11.8	227.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	31	23.3	92.31	-12.8	0.0	4.8	10.2	514.8			
	ADA	38	11.3	31.50	-12.5	-0.8	1.9	8.2	145.8			
	TOT	69	16.7	65.84	-12.8	-0.5	2.3	9.4	514.8			
										-8.4	(-26.6, 9.9)	0.363A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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	DIFF.$	95% CI#	P-VALUE@
AC LEFT EYE												
BEST VALUE*	PLO	18	0.08	0.192	0.0	0.00	0.00	0.00	0.5			
	ADA	19	0.08	0.187	0.0	0.00	0.00	0.00	0.5			
	TOT	37	0.08	0.187	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	18	0.17	0.343	0.0	0.00	0.00	0.00	1.0			
	ADA	19	0.18	0.299	0.0	0.00	0.00	0.50	1.0			
	TOT	37	0.18	0.317	0.0	0.00	0.00	0.50	1.0			
CHG FROM BEST*	PLO	18	0.08	0.354	-0.5	0.00	0.00	0.00	1.0			
	ADA	19	0.11	0.315	-0.5	0.00	0.00	0.00	1.0			
	TOT	37	0.09	0.330	-0.5	0.00	0.00	0.00	1.0			
AC RIGHT EYE												
BEST VALUE*	PLO	18	0.17	0.243	0.0	0.00	0.00	0.50	0.5			
	ADA	19	0.05	0.158	0.0	0.00	0.00	0.00	0.5			
	TOT	37	0.11	0.209	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	18	0.39	0.698	0.0	0.00	0.00	1.00	2.0			
	ADA	19	0.37	0.797	0.0	0.00	0.00	0.50	3.0			
	TOT	37	0.38	0.740	0.0	0.00	0.00	0.50	3.0			
CHG FROM BEST*	PLO	18	0.22	0.669	-0.5	0.00	0.00	0.50	2.0			
	ADA	19	0.32	0.730	-0.5	0.00	0.00	0.50	2.5			
	TOT	37	0.27	0.693	-0.5	0.00	0.00	0.50	2.5			
										0.06	(-0.25, 0.37)	0.705A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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	DIFF.$	95% CI#	P-VALUE@
VH LEFT EYE												
BEST VALUE*	PLO	19	0.55	0.497	0.0	0.00	0.50	1.00	2.0			
	ADA	19	0.55	0.926	0.0	0.00	0.00	0.50	3.0			
	TOT	38	0.55	0.733	0.0	0.00	0.50	0.50	3.0			
FINAL/ET VALUE	PLO	19	0.92	0.838	0.0	0.00	1.00	2.00	2.0			
	ADA	19	0.61	1.137	0.0	0.00	0.00	0.50	4.0			
	TOT	38	0.76	0.998	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	19	0.37	0.642	-0.5	0.00	0.00	1.00	1.5			
	ADA	19	0.05	0.664	-1.0	0.00	0.00	0.00	2.0			
	TOT	38	0.21	0.664	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	19	0.63	0.597	0.0	0.00	0.50	1.00	2.0			
	ADA	19	0.47	0.513	0.0	0.00	0.50	0.50	2.0			
	TOT	38	0.55	0.555	0.0	0.00	0.50	1.00	2.0			
FINAL/ET VALUE	PLO	19	1.21	1.217	0.0	0.00	1.00	3.00	3.0			
	ADA	19	0.55	0.815	0.0	0.00	0.00	1.00	3.0			
	TOT	38	0.88	1.074	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	19	0.58	1.096	-1.0	0.00	0.50	1.00	2.5			
	ADA	19	0.08	0.821	-1.0	-0.50	0.00	0.00	2.5			
	TOT	38	0.33	0.988	-1.0	0.00	0.00	0.50	2.5			
										-0.41	(-0.90, 0.08)	0.101A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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	DIFF.$	95% CI#	P-VALUE@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	19	0.18	0.299	-0.22	-0.12	0.10	0.44	0.80			
	ADA	19	0.24	0.355	-0.12	-0.02	0.14	0.56	1.12			
	TOT	38	0.21	0.325	-0.22	-0.02	0.12	0.44	1.12			
FINAL/ET VALUE	PLO	19	0.35	0.353	-0.18	0.00	0.42	0.66	1.02			
	ADA	19	0.33	0.469	-0.28	0.02	0.26	0.60	1.62			
	TOT	38	0.34	0.410	-0.28	0.02	0.34	0.60	1.62			
CHG FROM BEST*	PLO	19	0.18	0.210	-0.04	0.04	0.12	0.24	0.76			
	ADA	19	0.09	0.189	-0.16	-0.04	0.04	0.22	0.50			
	TOT	38	0.14	0.201	-0.16	0.00	0.08	0.22	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	19	0.28	0.327	-0.20	-0.06	0.30	0.48	0.88			
	ADA	19	0.18	0.278	-0.22	0.00	0.10	0.34	0.90			
	TOT	38	0.23	0.304	-0.22	-0.02	0.20	0.42	0.90			
FINAL/ET VALUE	PLO	19	0.55	0.565	-0.16	0.02	0.46	0.94	2.08			
	ADA	19	0.20	0.314	-0.26	-0.02	0.14	0.46	0.92			
	TOT	38	0.37	0.484	-0.26	0.00	0.35	0.54	2.08			
CHG FROM BEST*	PLO	19	0.27	0.311	-0.06	0.02	0.14	0.46	1.20			
	ADA	19	0.03	0.167	-0.50	-0.02	0.04	0.10	0.32			
	TOT	38	0.15	0.274	-0.50	0.00	0.08	0.30	1.20			
										-0.16	(-0.28, -0.04)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.31.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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	DIFF.$	95% CI#	P-VALUE@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	18	17.8	39.06	-10.8	0.5	4.0	14.1	128.0			
	ADA	18	6.6	22.56	-34.0	-2.1	2.4	9.8	73.7			
	TOT	36	12.2	31.95	-34.0	-1.1	3.1	10.1	128.0			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	17	19.0	43.94	-3.2	0.8	1.9	10.1	174.4			
	ADA	19	1.5	13.94	-43.0	-0.4	4.6	7.8	19.8			
	TOT	36	9.8	32.58	-43.0	0.2	2.9	9.8	174.4			
										-17.8	(-33.9, -1.8)	0.030A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.31.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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
CRT LEFT EYE									
%CHG FROM BEST*	PLO	18	17.8	39.06	-10.8	0.5	4.0	14.1	128.0
	ADA	17	7.0	23.19	-34.0	-2.1	3.0	9.8	73.7
	TOT	35	12.6	32.35	-34.0	-1.7	3.2	10.5	128.0
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	17	19.0	43.94	-3.2	0.8	1.9	10.1	174.4
	ADA	18	1.0	14.19	-43.0	-0.4	3.8	6.4	19.8
	TOT	35	9.8	33.05	-43.0	0.0	2.7	9.8	174.4

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	27	0.06	0.160	0.0	0.00	0.00	0.00	0.5			
	ADA	20	0.05	0.154	0.0	0.00	0.00	0.00	0.5			
	TOT	47	0.05	0.156	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	27	0.59	0.910	0.0	0.00	0.00	1.00	3.0			
	ADA	20	0.30	0.497	0.0	0.00	0.00	0.50	2.0			
	TOT	47	0.47	0.769	0.0	0.00	0.00	0.50	3.0			
CHG FROM BEST*	PLO	27	0.54	0.876	0.0	0.00	0.00	1.00	3.0			
	ADA	20	0.25	0.414	0.0	0.00	0.00	0.50	1.5			
	TOT	47	0.41	0.725	0.0	0.00	0.00	0.50	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	27	0.06	0.160	0.0	0.00	0.00	0.00	0.5			
	ADA	20	0.10	0.205	0.0	0.00	0.00	0.00	0.5			
	TOT	47	0.07	0.180	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	27	0.65	1.064	0.0	0.00	0.00	1.00	4.0			
	ADA	20	0.25	0.500	0.0	0.00	0.00	0.50	2.0			
	TOT	47	0.48	0.884	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	27	0.59	0.961	0.0	0.00	0.00	1.00	3.5			
	ADA	20	0.15	0.462	-0.5	0.00	0.00	0.25	1.5			
	TOT	47	0.40	0.812	-0.5	0.00	0.00	0.50	3.5			
										-0.36	(-0.75, 0.02)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	27	0.37	0.382	0.0	0.00	0.50	0.50	1.0			
	ADA	20	0.25	0.526	0.0	0.00	0.00	0.25	2.0			
	TOT	47	0.32	0.448	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	27	0.80	0.846	0.0	0.00	0.50	1.00	3.0			
	ADA	20	0.58	0.799	0.0	0.00	0.25	1.00	3.0			
	TOT	47	0.70	0.825	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	27	0.43	0.661	-0.5	0.00	0.00	1.00	2.0			
	ADA	20	0.33	0.654	-0.5	0.00	0.00	1.00	2.0			
	TOT	47	0.38	0.653	-0.5	0.00	0.00	1.00	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	27	0.31	0.396	0.0	0.00	0.00	0.50	1.0			
	ADA	20	0.30	0.377	0.0	0.00	0.00	0.50	1.0			
	TOT	47	0.31	0.384	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	27	0.80	0.835	0.0	0.00	0.50	1.00	3.0			
	ADA	20	0.60	0.553	0.0	0.00	0.50	1.00	2.0			
	TOT	47	0.71	0.728	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	27	0.48	0.766	-0.5	0.00	0.00	0.50	2.5			
	ADA	20	0.30	0.548	-0.5	0.00	0.00	1.00	1.0			
	TOT	47	0.40	0.681	-0.5	0.00	0.00	0.50	2.5			
										-0.14	(-0.48, 0.20)	0.405A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	27	0.12	0.288	-0.18	-0.10	0.02	0.32	0.76			
	ADA	20	0.16	0.298	-0.16	-0.05	0.10	0.28	0.92			
	TOT	47	0.14	0.290	-0.18	-0.10	0.04	0.30	0.92			
FINAL/ET VALUE	PLO	27	0.23	0.319	-0.14	0.00	0.06	0.58	0.90			
	ADA	20	0.23	0.378	-0.18	-0.06	0.12	0.34	1.26			
	TOT	47	0.23	0.341	-0.18	-0.04	0.10	0.44	1.26			
CHG FROM BEST*	PLO	27	0.10	0.174	-0.06	0.00	0.04	0.16	0.80			
	ADA	20	0.07	0.133	-0.08	-0.02	0.04	0.10	0.48			
	TOT	47	0.09	0.157	-0.08	0.00	0.04	0.12	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	27	0.18	0.324	-0.24	-0.08	0.10	0.44	0.88			
	ADA	20	0.15	0.222	-0.20	-0.04	0.13	0.30	0.64			
	TOT	47	0.17	0.283	-0.24	-0.08	0.12	0.32	0.88			
FINAL/ET VALUE	PLO	27	0.27	0.377	-0.20	-0.06	0.18	0.54	1.32			
	ADA	20	0.20	0.271	-0.20	0.00	0.18	0.33	0.94			
	TOT	47	0.24	0.335	-0.20	-0.02	0.18	0.48	1.32			
CHG FROM BEST*	PLO	27	0.09	0.225	-0.18	-0.04	0.02	0.14	0.88			
	ADA	20	0.05	0.132	-0.24	-0.02	0.01	0.11	0.30			
	TOT	47	0.07	0.190	-0.24	-0.02	0.02	0.14	0.88			
										-0.04	(-0.11, 0.04)	0.310A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.32.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	27	26.2	61.40	-8.2	0.8	6.3	15.5	283.9			
	ADA	20	25.8	47.02	-18.6	-0.7	1.7	42.6	128.0			
	TOT	47	26.0	55.17	-18.6	0.0	6.0	21.9	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	27	23.1	38.36	-7.2	0.3	11.2	27.5	165.2			
	ADA	20	15.7	38.07	-50.0	-2.3	1.9	31.0	97.3			
	TOT	47	19.9	38.00	-50.0	-0.5	6.0	28.2	165.2			
										-2.1	(-24.3, 20.1)	0.850A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.32.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	27	26.2	61.40	-8.2	0.8	6.3	15.5	283.9			
	ADA	19	20.8	42.40	-18.6	-1.3	1.4	32.8	128.0			
	TOT	46	23.9	53.89	-18.6	0.0	5.2	21.3	283.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	27	23.1	38.36	-7.2	0.3	11.2	27.5	165.2			
	ADA	19	15.0	39.00	-50.0	-3.3	1.5	33.7	97.3			
	TOT	46	19.7	38.40	-50.0	-0.5	5.6	27.5	165.2			
										-5.0	(-27.4, 17.4)	0.656A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	52	0.09	0.237	0.0	0.00	0.00	0.00	1.0			
	ADA	51	0.14	0.247	0.0	0.00	0.00	0.50	1.0			
	TOT	103	0.11	0.242	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	52	0.63	1.038	0.0	0.00	0.00	1.00	4.0			
	ADA	51	0.56	0.712	0.0	0.00	0.50	1.00	3.0			
	TOT	103	0.59	0.888	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	52	0.54	0.974	0.0	0.00	0.00	1.00	4.0			
	ADA	51	0.42	0.744	-1.0	0.00	0.00	1.00	3.0			
	TOT	103	0.48	0.866	-1.0	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	52	0.10	0.199	0.0	0.00	0.00	0.00	0.5			
	ADA	51	0.13	0.220	0.0	0.00	0.00	0.50	0.5			
	TOT	103	0.11	0.209	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	52	0.75	1.157	0.0	0.00	0.00	1.00	4.0			
	ADA	51	0.71	0.826	0.0	0.00	0.50	1.00	3.0			
	TOT	103	0.73	1.002	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	52	0.65	1.096	-0.5	0.00	0.00	1.00	4.0			
	ADA	51	0.58	0.845	-0.5	0.00	0.50	1.00	2.5			
	TOT	103	0.62	0.976	-0.5	0.00	0.00	1.00	4.0			
										-0.10	(-0.42, 0.23)	0.563A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	53	0.53	0.513	0.0	0.00	0.50	1.00	2.0			
	ADA	51	0.38	0.580	0.0	0.00	0.00	0.50	3.0			
	TOT	104	0.46	0.549	0.0	0.00	0.50	0.50	3.0			
FINAL/ET VALUE	PLO	53	0.91	0.779	0.0	0.50	1.00	1.00	3.0			
	ADA	51	0.53	0.717	0.0	0.00	0.50	1.00	3.0			
	TOT	104	0.72	0.769	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	53	0.38	0.612	-0.5	0.00	0.00	0.50	2.0			
	ADA	51	0.15	0.568	-1.0	0.00	0.00	0.50	2.0			
	TOT	104	0.26	0.599	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	53	0.47	0.494	0.0	0.00	0.50	1.00	2.0			
	ADA	51	0.37	0.422	0.0	0.00	0.50	0.50	2.0			
	TOT	104	0.42	0.461	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	53	1.06	0.902	0.0	0.50	1.00	1.00	3.0			
	ADA	51	0.64	0.749	0.0	0.00	0.50	1.00	3.0			
	TOT	104	0.85	0.853	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	53	0.58	0.813	-1.0	0.00	0.50	1.00	2.5			
	ADA	51	0.26	0.703	-1.0	0.00	0.00	0.50	2.5			
	TOT	104	0.43	0.774	-1.0	0.00	0.00	0.75	2.5			
										-0.28	(-0.50, -0.05)	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.
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 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 ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	53	0.17	0.263	-0.28	0.00	0.10	0.40	0.80			
	ADA	51	0.25	0.316	-0.18	0.04	0.16	0.32	1.12			
	TOT	104	0.21	0.291	-0.28	0.01	0.12	0.40	1.12			
FINAL/ET VALUE	PLO	53	0.30	0.338	-0.20	0.02	0.20	0.54	1.22			
	ADA	51	0.35	0.403	-0.26	0.04	0.32	0.60	1.62			
	TOT	104	0.32	0.370	-0.26	0.04	0.22	0.57	1.62			
CHG FROM BEST*	PLO	53	0.13	0.217	-0.62	0.02	0.08	0.16	0.80			
	ADA	51	0.10	0.166	-0.32	0.00	0.06	0.20	0.58			
	TOT	104	0.12	0.193	-0.62	0.00	0.08	0.17	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	53	0.24	0.331	-0.24	-0.02	0.16	0.44	1.16			
	ADA	51	0.25	0.250	-0.20	0.10	0.24	0.38	0.90			
	TOT	104	0.24	0.293	-0.24	0.00	0.19	0.40	1.16			
FINAL/ET VALUE	PLO	53	0.37	0.448	-0.20	0.02	0.34	0.62	2.08			
	ADA	51	0.33	0.299	-0.22	0.12	0.32	0.48	1.04			
	TOT	104	0.35	0.381	-0.22	0.06	0.33	0.52	2.08			
CHG FROM BEST*	PLO	53	0.13	0.242	-0.20	0.00	0.06	0.20	1.20			
	ADA	51	0.08	0.148	-0.24	0.00	0.06	0.18	0.56			
	TOT	104	0.11	0.202	-0.24	0.00	0.06	0.19	1.20			
										-0.04	(-0.10, 0.02)	0.187A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	51	31.5	69.19	-28.4	0.8	6.3	23.7	291.1			
	ADA	50	28.9	75.98	-47.6	-0.6	6.7	37.4	483.1			
	TOT	101	30.2	72.28	-47.6	0.0	6.3	26.6	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	51	25.6	43.79	-9.2	1.8	7.6	35.3	174.4			
	ADA	51	25.2	81.57	-50.0	-0.8	3.8	17.3	534.5			
	TOT	102	25.4	65.14	-50.0	0.0	6.2	27.5	534.5			
										-1.1	(-25.4, 23.2)	0.928A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
AC LEFT EYE												
BEST VALUE*	PLO	35	0.09	0.226	0.0	0.00	0.00	0.00	1.0			
	ADA	38	0.11	0.237	0.0	0.00	0.00	0.00	1.0			
	TOT	73	0.10	0.231	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	35	0.83	1.194	0.0	0.00	0.00	1.00	4.0			
	ADA	38	0.37	0.541	0.0	0.00	0.00	0.50	2.0			
	TOT	73	0.59	0.937	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	35	0.74	1.114	0.0	0.00	0.00	1.00	4.0			
	ADA	38	0.26	0.578	-1.0	0.00	0.00	0.50	2.0			
	TOT	73	0.49	0.903	-1.0	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	35	0.21	0.504	0.0	0.00	0.00	0.00	2.0			
	ADA	38	0.04	0.137	0.0	0.00	0.00	0.00	0.5			
	TOT	73	0.12	0.371	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	35	1.01	1.269	0.0	0.00	0.50	2.00	4.0			
	ADA	38	0.50	0.688	0.0	0.00	0.00	1.00	2.0			
	TOT	73	0.75	1.035	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	35	0.80	1.093	-0.5	0.00	0.50	1.00	4.0			
	ADA	38	0.46	0.701	-0.5	0.00	0.00	0.50	2.0			
	TOT	73	0.62	0.920	-0.5	0.00	0.00	1.00	4.0			
										-0.41	(-0.80, -0.02)	0.038A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
VH LEFT EYE												
BEST VALUE*	PLO	36	0.39	0.465	0.0	0.00	0.50	0.50	2.0			
	ADA	38	0.37	0.475	0.0	0.00	0.00	0.50	2.0			
	TOT	74	0.38	0.467	0.0	0.00	0.25	0.50	2.0			
FINAL/ET VALUE	PLO	36	0.69	0.795	0.0	0.00	0.50	1.00	3.0			
	ADA	38	0.51	0.758	0.0	0.00	0.25	1.00	3.0			
	TOT	74	0.60	0.776	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	36	0.31	0.613	-0.5	0.00	0.00	0.50	2.0			
	ADA	38	0.14	0.580	-1.0	0.00	0.00	0.50	2.0			
	TOT	74	0.22	0.598	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	36	0.44	0.545	0.0	0.00	0.50	0.75	2.0			
	ADA	38	0.34	0.370	0.0	0.00	0.50	0.50	1.0			
	TOT	74	0.39	0.463	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	36	1.04	0.913	0.0	0.50	1.00	1.00	3.0			
	ADA	38	0.66	0.839	0.0	0.00	0.50	1.00	3.0			
	TOT	74	0.84	0.891	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	36	0.60	0.791	-1.0	0.00	0.50	1.00	2.5			
	ADA	38	0.32	0.748	-1.0	0.00	0.00	0.50	2.5			
	TOT	74	0.45	0.777	-1.0	0.00	0.00	1.00	2.5			
										-0.22	(-0.49, 0.05)	0.111A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	36	0.20	0.298	-0.28	-0.03	0.10	0.45	0.80			
	ADA	38	0.30	0.354	-0.18	0.06	0.21	0.48	1.30			
	TOT	74	0.25	0.329	-0.28	0.02	0.15	0.46	1.30			
FINAL/ET VALUE	PLO	36	0.31	0.331	-0.20	0.01	0.22	0.58	1.02			
	ADA	38	0.43	0.452	-0.26	0.12	0.35	0.60	1.62			
	TOT	74	0.37	0.400	-0.26	0.06	0.31	0.58	1.62			
CHG FROM BEST*	PLO	36	0.11	0.210	-0.62	0.00	0.08	0.16	0.80			
	ADA	38	0.13	0.175	-0.14	0.00	0.08	0.30	0.58			
	TOT	74	0.12	0.192	-0.62	0.00	0.08	0.22	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	36	0.25	0.346	-0.24	0.02	0.14	0.46	1.16			
	ADA	38	0.23	0.244	-0.20	0.10	0.24	0.36	0.76			
	TOT	74	0.24	0.296	-0.24	0.04	0.19	0.38	1.16			
FINAL/ET VALUE	PLO	36	0.40	0.459	-0.20	0.10	0.35	0.61	2.08			
	ADA	38	0.31	0.301	-0.22	0.12	0.33	0.46	1.04			
	TOT	74	0.36	0.386	-0.22	0.10	0.34	0.50	2.08			
CHG FROM BEST*	PLO	36	0.15	0.244	-0.20	0.01	0.08	0.22	1.20			
	ADA	38	0.08	0.147	-0.24	0.00	0.06	0.14	0.56			
	TOT	74	0.12	0.202	-0.24	0.00	0.07	0.18	1.20			
										-0.02	(-0.09, 0.05)	0.534A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.33.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	34	39.3	80.57	-28.4	1.3	7.7	33.7	291.1			
	ADA	37	31.2	86.43	-47.6	-0.6	10.0	39.1	483.1			
	TOT	71	35.1	83.18	-47.6	-0.3	9.1	38.7	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	34	36.5	50.05	-9.2	5.3	14.2	50.3	174.4			
	ADA	38	34.2	93.11	-50.0	0.6	9.5	43.6	534.5			
	TOT	72	35.3	75.39	-50.0	2.3	12.1	46.5	534.5			
										-5.4	(-39.3, 28.5)	0.751A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	46	0.10	0.227	0.0	0.00	0.00	0.00	1.0			
	ADA	53	0.08	0.321	0.0	0.00	0.00	0.00	2.0			
	TOT	99	0.09	0.280	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	46	0.76	0.976	0.0	0.00	0.50	1.00	3.0			
	ADA	53	0.35	0.841	0.0	0.00	0.00	0.00	3.0			
	TOT	99	0.54	0.925	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	46	0.66	0.931	-0.5	0.00	0.50	1.00	3.0			
	ADA	53	0.26	0.669	-0.5	0.00	0.00	0.00	3.0			
	TOT	99	0.45	0.822	-0.5	0.00	0.00	0.50	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	46	0.15	0.363	0.0	0.00	0.00	0.00	2.0			
	ADA	53	0.08	0.254	0.0	0.00	0.00	0.00	1.0			
	TOT	99	0.12	0.310	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	46	0.78	1.099	0.0	0.00	0.00	1.00	4.0			
	ADA	53	0.25	0.648	0.0	0.00	0.00	0.00	3.0			
	TOT	99	0.50	0.920	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	46	0.63	1.008	-0.5	0.00	0.00	1.00	4.0			
	ADA	53	0.17	0.563	-1.0	0.00	0.00	0.00	2.5			
	TOT	99	0.38	0.829	-1.0	0.00	0.00	0.50	4.0			
										-0.43	(-0.72, -0.14)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	46	0.29	0.374	0.0	0.00	0.00	0.50	1.0			
	ADA	53	0.29	0.504	0.0	0.00	0.00	0.50	3.0			
	TOT	99	0.29	0.446	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	46	0.59	0.825	0.0	0.00	0.25	1.00	3.0			
	ADA	53	0.40	0.736	0.0	0.00	0.00	0.50	4.0			
	TOT	99	0.48	0.781	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	46	0.29	0.757	-0.5	0.00	0.00	0.50	3.0			
	ADA	53	0.10	0.549	-1.0	0.00	0.00	0.00	2.0			
	TOT	99	0.19	0.657	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	46	0.26	0.376	0.0	0.00	0.00	0.50	1.0			
	ADA	53	0.32	0.440	0.0	0.00	0.00	0.50	2.0			
	TOT	99	0.29	0.410	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	46	0.59	0.878	0.0	0.00	0.50	1.00	4.0			
	ADA	53	0.39	0.516	0.0	0.00	0.00	0.50	2.0			
	TOT	99	0.48	0.710	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	46	0.33	0.797	-1.0	0.00	0.00	0.50	3.5			
	ADA	53	0.07	0.605	-1.5	-0.50	0.00	0.50	1.5			
	TOT	99	0.19	0.709	-1.5	0.00	0.00	0.50	3.5			
										-0.22	(-0.46, 0.01)	0.062A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	46	0.06	0.259	-0.24	-0.10	-0.01	0.10	0.88			
	ADA	53	0.00	0.130	-0.20	-0.10	0.00	0.04	0.36			
	TOT	99	0.03	0.202	-0.24	-0.10	0.00	0.10	0.88			
FINAL/ET VALUE	PLO	46	0.15	0.282	-0.16	-0.04	0.04	0.30	0.98			
	ADA	53	0.05	0.213	-0.28	-0.08	0.00	0.16	0.84			
	TOT	99	0.10	0.252	-0.28	-0.08	0.02	0.22	0.98			
CHG FROM BEST*	PLO	46	0.09	0.146	-0.08	0.00	0.04	0.14	0.60			
	ADA	53	0.05	0.152	-0.16	-0.04	0.02	0.06	0.50			
	TOT	99	0.07	0.150	-0.16	-0.02	0.02	0.10	0.60			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	46	0.10	0.257	-0.20	-0.06	0.00	0.20	0.98			
	ADA	53	0.02	0.180	-0.22	-0.10	0.00	0.10	0.64			
	TOT	99	0.06	0.222	-0.22	-0.08	0.00	0.16	0.98			
FINAL/ET VALUE	PLO	46	0.25	0.527	-0.18	-0.08	0.08	0.40	3.00			
	ADA	53	0.04	0.226	-0.26	-0.08	-0.02	0.10	0.94			
	TOT	99	0.14	0.407	-0.26	-0.08	0.02	0.26	3.00			
CHG FROM BEST*	PLO	46	0.15	0.432	-0.08	0.00	0.04	0.12	2.82			
	ADA	53	0.02	0.136	-0.50	-0.04	0.00	0.08	0.50			
	TOT	99	0.08	0.315	-0.50	-0.02	0.04	0.10	2.82			
										-0.08	(-0.16, -0.01)	0.035A

* 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.
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 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 ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	46	7.8	18.62	-8.4	1.5	4.0	7.2	120.6			
	ADA	53	1.3	11.93	-40.8	-2.0	0.4	2.3	42.9			
	TOT	99	4.3	15.67	-40.8	-0.5	1.9	6.0	120.6			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	46	16.2	75.73	-12.8	0.0	3.7	8.5	514.8			
	ADA	53	4.4	10.84	-12.3	-0.5	1.7	5.8	47.9			
	TOT	99	9.9	52.26	-12.8	0.0	2.1	7.2	514.8			
										-6.6	(-17.6, 4.5)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
AC LEFT EYE												
BEST VALUE*	PLO	72	0.11	0.255	0.0	0.00	0.00	0.00	1.0			
	ADA	67	0.11	0.312	0.0	0.00	0.00	0.00	2.0			
	TOT	139	0.11	0.283	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	72	0.60	0.860	0.0	0.00	0.00	1.00	3.0			
	ADA	67	0.46	0.872	0.0	0.00	0.00	0.50	3.0			
	TOT	139	0.54	0.865	0.0	0.00	0.00	1.00	3.0			
CHG FROM BEST*	PLO	72	0.49	0.807	-0.5	0.00	0.00	1.00	3.0			
	ADA	67	0.35	0.764	-0.5	0.00	0.00	0.50	3.0			
	TOT	139	0.42	0.787	-0.5	0.00	0.00	0.50	3.0			
AC RIGHT EYE												
BEST VALUE*	PLO	72	0.10	0.199	0.0	0.00	0.00	0.00	0.5			
	ADA	67	0.13	0.269	0.0	0.00	0.00	0.00	1.0			
	TOT	139	0.12	0.236	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	72	0.65	1.020	0.0	0.00	0.00	1.00	4.0			
	ADA	67	0.43	0.794	0.0	0.00	0.00	0.50	3.0			
	TOT	139	0.54	0.922	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	72	0.56	0.984	-0.5	0.00	0.00	0.75	4.0			
	ADA	67	0.29	0.744	-1.0	0.00	0.00	0.50	2.5			
	TOT	139	0.43	0.884	-1.0	0.00	0.00	0.50	4.0			
										-0.20	(-0.45, 0.05)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
VH LEFT EYE												
BEST VALUE*	PLO	72	0.41	0.454	0.0	0.00	0.50	0.50	2.0			
	ADA	67	0.31	0.576	0.0	0.00	0.00	0.50	3.0			
	TOT	139	0.36	0.517	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	72	0.77	0.826	0.0	0.00	0.50	1.00	3.0			
	ADA	67	0.40	0.708	0.0	0.00	0.00	0.50	4.0			
	TOT	139	0.59	0.791	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	72	0.36	0.708	-0.5	0.00	0.00	0.50	3.0			
	ADA	67	0.09	0.536	-1.0	0.00	0.00	0.50	2.0			
	TOT	139	0.23	0.643	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	72	0.33	0.386	0.0	0.00	0.00	0.50	1.0			
	ADA	67	0.34	0.456	0.0	0.00	0.00	0.50	2.0			
	TOT	139	0.33	0.419	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	72	0.74	0.904	0.0	0.00	0.50	1.00	4.0			
	ADA	67	0.40	0.496	0.0	0.00	0.00	1.00	2.0			
	TOT	139	0.57	0.753	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	72	0.41	0.811	-1.0	0.00	0.00	0.50	3.5			
	ADA	67	0.06	0.587	-1.5	-0.50	0.00	0.50	1.5			
	TOT	139	0.24	0.731	-1.5	0.00	0.00	0.50	3.5			
										-0.31	(-0.51, -0.11)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	72	0.09	0.256	-0.24	-0.07	0.02	0.17	0.94			
	ADA	67	0.03	0.169	-0.20	-0.10	0.00	0.10	0.60			
	TOT	139	0.06	0.220	-0.24	-0.10	0.00	0.12	0.94			
FINAL/ET VALUE	PLO	72	0.21	0.312	-0.16	0.00	0.10	0.33	1.22			
	ADA	67	0.07	0.230	-0.28	-0.08	0.00	0.22	0.84			
	TOT	139	0.14	0.282	-0.28	-0.06	0.04	0.28	1.22			
CHG FROM BEST*	PLO	72	0.11	0.165	-0.08	0.02	0.06	0.14	0.76			
	ADA	67	0.04	0.149	-0.32	-0.04	0.02	0.08	0.50			
	TOT	139	0.08	0.160	-0.32	-0.02	0.04	0.12	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	72	0.13	0.276	-0.20	-0.07	0.01	0.31	0.98			
	ADA	67	0.08	0.239	-0.22	-0.08	0.00	0.20	0.90			
	TOT	139	0.11	0.259	-0.22	-0.08	0.00	0.24	0.98			
FINAL/ET VALUE	PLO	72	0.25	0.475	-0.20	-0.06	0.08	0.47	3.00			
	ADA	67	0.12	0.290	-0.26	-0.06	0.00	0.26	0.94			
	TOT	139	0.19	0.401	-0.26	-0.06	0.04	0.36	3.00			
CHG FROM BEST*	PLO	72	0.12	0.367	-0.18	-0.02	0.04	0.11	2.82			
	ADA	67	0.04	0.145	-0.50	-0.04	0.02	0.08	0.50			
	TOT	139	0.08	0.285	-0.50	-0.02	0.04	0.10	2.82			
										-0.07	(-0.13, -0.01)	0.014A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.34.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877, 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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	72	9.6	22.58	-8.4	0.8	4.0	8.9	120.6			
	ADA	67	3.4	13.48	-15.4	-2.0	0.8	4.1	72.8			
	TOT	139	6.6	18.95	-15.4	-0.5	2.1	6.9	120.6			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	72	15.0	65.11	-12.8	0.0	4.3	8.7	514.8			
	ADA	67	3.4	10.62	-14.1	-1.2	1.7	5.4	47.9			
	TOT	139	9.5	47.63	-14.1	-0.4	2.4	6.9	514.8			
										-7.4	(-16.0, 1.1)	0.088A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	34	0.09	0.229	0.0	0.00	0.00	0.00	1.0			
	ADA	31	0.10	0.239	0.0	0.00	0.00	0.00	1.0			
	TOT	65	0.09	0.232	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	34	0.75	1.032	0.0	0.00	0.25	1.00	4.0			
	ADA	31	0.27	0.560	0.0	0.00	0.00	0.50	2.0			
	TOT	65	0.52	0.868	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	34	0.66	1.013	0.0	0.00	0.00	1.00	4.0			
	ADA	31	0.18	0.585	-1.0	0.00	0.00	0.00	2.0			
	TOT	65	0.43	0.865	-1.0	0.00	0.00	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	34	0.04	0.144	0.0	0.00	0.00	0.00	0.5			
	ADA	31	0.10	0.201	0.0	0.00	0.00	0.00	0.5			
	TOT	65	0.07	0.174	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	34	0.97	1.302	0.0	0.00	0.25	2.00	4.0			
	ADA	31	0.55	0.907	0.0	0.00	0.00	0.50	3.0			
	TOT	65	0.77	1.142	0.0	0.00	0.00	2.00	4.0			
CHG FROM BEST*	PLO	34	0.93	1.280	0.0	0.00	0.00	2.00	4.0			
	ADA	31	0.45	0.898	-0.5	0.00	0.00	0.50	2.5			
	TOT	65	0.70	1.131	-0.5	0.00	0.00	1.50	4.0			
										-0.48	(-0.91, -0.05)	0.030A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	34	0.37	0.414	0.0	0.00	0.25	0.50	1.0			
	ADA	31	0.29	0.461	0.0	0.00	0.00	0.50	2.0			
	TOT	65	0.33	0.436	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	34	0.81	0.798	0.0	0.00	0.50	1.00	3.0			
	ADA	31	0.44	0.824	0.0	0.00	0.00	0.50	3.0			
	TOT	65	0.63	0.826	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	34	0.44	0.660	-0.5	0.00	0.00	1.00	2.0			
	ADA	31	0.15	0.580	-1.0	0.00	0.00	0.00	2.0			
	TOT	65	0.30	0.636	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	34	0.26	0.353	0.0	0.00	0.00	0.50	1.0			
	ADA	31	0.34	0.351	0.0	0.00	0.50	0.50	1.0			
	TOT	65	0.30	0.351	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	34	0.90	1.036	0.0	0.00	0.50	1.00	4.0			
	ADA	31	0.48	0.652	0.0	0.00	0.50	0.50	3.0			
	TOT	65	0.70	0.892	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	34	0.63	0.907	-0.5	0.00	0.50	1.00	3.5			
	ADA	31	0.15	0.622	-1.0	0.00	0.00	0.50	2.5			
	TOT	65	0.40	0.816	-1.0	0.00	0.00	0.50	3.5			
										-0.39	(-0.71, -0.08)	0.016A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	34	0.22	0.316	-0.24	0.02	0.10	0.46	0.94			
	ADA	31	0.15	0.263	-0.18	-0.02	0.10	0.30	0.92			
	TOT	65	0.19	0.292	-0.24	0.00	0.10	0.32	0.94			
FINAL/ET VALUE	PLO	34	0.35	0.325	-0.16	0.08	0.29	0.58	1.00			
	ADA	31	0.17	0.301	-0.20	-0.08	0.06	0.38	0.96			
	TOT	65	0.26	0.325	-0.20	0.02	0.18	0.46	1.00			
CHG FROM BEST*	PLO	34	0.13	0.172	-0.08	0.02	0.07	0.18	0.76			
	ADA	31	0.01	0.115	-0.32	-0.04	0.00	0.04	0.32			
	TOT	65	0.07	0.157	-0.32	-0.02	0.04	0.10	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	34	0.23	0.321	-0.24	-0.04	0.17	0.52	0.98			
	ADA	31	0.16	0.212	-0.22	0.02	0.18	0.32	0.64			
	TOT	65	0.20	0.275	-0.24	0.00	0.18	0.38	0.98			
FINAL/ET VALUE	PLO	34	0.39	0.575	-0.18	0.00	0.39	0.58	3.00			
	ADA	31	0.19	0.285	-0.26	-0.06	0.14	0.34	0.94			
	TOT	65	0.30	0.468	-0.26	0.00	0.18	0.46	3.00			
CHG FROM BEST*	PLO	34	0.16	0.491	-0.18	0.00	0.05	0.16	2.82			
	ADA	31	0.03	0.163	-0.30	-0.08	0.04	0.08	0.56			
	TOT	65	0.10	0.376	-0.30	-0.02	0.04	0.10	2.82			
										-0.12	(-0.22, -0.02)	0.016A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.35.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	32	16.5	32.12	-8.2	0.4	5.7	14.9	136.0			
	ADA	31	16.3	36.02	-18.6	-0.9	1.8	26.6	128.0			
	TOT	63	16.4	33.82	-18.6	0.0	3.9	15.7	136.0			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	33	19.4	36.32	-12.8	0.0	7.5	18.2	165.2			
	ADA	31	15.5	36.30	-50.0	-0.5	4.0	19.8	145.8			
	TOT	64	17.5	36.07	-50.0	0.0	5.9	19.0	165.2			
										-2.7	(-17.1, 11.6)	0.704A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.35.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	32	16.5	32.12	-8.2	0.4	5.7	14.9	136.0			
	ADA	29	13.3	31.24	-18.6	-0.9	1.8	9.8	128.0			
	TOT	61	15.0	31.48	-18.6	0.0	3.9	14.1	136.0			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	33	19.4	36.32	-12.8	0.0	7.5	18.2	165.2			
	ADA	29	15.2	37.48	-50.0	-0.5	3.0	8.4	145.8			
	TOT	62	17.4	36.62	-50.0	0.0	5.4	18.2	165.2			
										-4.9	(-19.1, 9.2)	0.487A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	76	0.12	0.256	0.0	0.00	0.00	0.00	1.0			
	ADA	78	0.12	0.301	0.0	0.00	0.00	0.00	2.0			
	TOT	154	0.12	0.279	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	76	0.63	0.946	0.0	0.00	0.00	1.00	4.0			
	ADA	78	0.53	0.880	0.0	0.00	0.00	0.50	3.0			
	TOT	154	0.58	0.912	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	76	0.51	0.868	-0.5	0.00	0.00	1.00	4.0			
	ADA	78	0.42	0.791	-0.5	0.00	0.00	0.50	3.0			
	TOT	154	0.46	0.829	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	76	0.18	0.382	0.0	0.00	0.00	0.50	2.0			
	ADA	78	0.10	0.247	0.0	0.00	0.00	0.00	1.0			
	TOT	154	0.14	0.322	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	76	0.70	1.030	0.0	0.00	0.00	1.00	4.0			
	ADA	78	0.42	0.694	0.0	0.00	0.00	0.50	3.0			
	TOT	154	0.56	0.884	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	76	0.52	0.892	-0.5	0.00	0.00	1.00	4.0			
	ADA	78	0.32	0.650	-1.0	0.00	0.00	0.50	2.5			
	TOT	154	0.42	0.783	-1.0	0.00	0.00	0.50	4.0			
										-0.15	(-0.38, 0.09)	0.213A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	77	0.43	0.478	0.0	0.00	0.50	0.50	2.0			
	ADA	78	0.34	0.561	0.0	0.00	0.00	0.50	3.0			
	TOT	155	0.38	0.522	0.0	0.00	0.50	0.50	3.0			
FINAL/ET VALUE	PLO	77	0.72	0.825	0.0	0.00	0.50	1.00	3.0			
	ADA	78	0.44	0.674	0.0	0.00	0.00	0.50	4.0			
	TOT	155	0.58	0.763	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	77	0.29	0.680	-0.5	0.00	0.00	0.50	3.0			
	ADA	78	0.10	0.537	-1.0	0.00	0.00	0.50	2.0			
	TOT	155	0.20	0.618	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	77	0.42	0.476	0.0	0.00	0.50	0.50	2.0			
	ADA	78	0.35	0.458	0.0	0.00	0.00	0.50	2.0			
	TOT	155	0.38	0.467	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	77	0.84	0.893	0.0	0.00	0.50	1.00	3.0			
	ADA	78	0.51	0.642	0.0	0.00	0.50	1.00	3.0			
	TOT	155	0.67	0.793	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	77	0.43	0.768	-1.0	0.00	0.00	0.50	2.5			
	ADA	78	0.16	0.662	-1.5	0.00	0.00	0.50	2.0			
	TOT	155	0.29	0.727	-1.5	0.00	0.00	0.50	2.5			
										-0.23	(-0.41, -0.05)	0.012A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	77	0.09	0.247	-0.28	-0.08	0.02	0.20	0.82			
	ADA	78	0.13	0.308	-0.20	-0.08	0.02	0.22	1.30			
	TOT	155	0.11	0.279	-0.28	-0.08	0.02	0.22	1.30			
FINAL/ET VALUE	PLO	77	0.19	0.311	-0.20	-0.02	0.10	0.32	1.22			
	ADA	78	0.23	0.397	-0.28	-0.04	0.11	0.34	1.62			
	TOT	155	0.21	0.356	-0.28	-0.04	0.10	0.34	1.62			
CHG FROM BEST*	PLO	77	0.10	0.182	-0.62	0.02	0.06	0.14	0.80			
	ADA	78	0.09	0.174	-0.22	-0.02	0.04	0.14	0.58			
	TOT	155	0.10	0.178	-0.62	0.00	0.06	0.14	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	77	0.16	0.300	-0.20	-0.06	0.08	0.26	1.16			
	ADA	78	0.13	0.260	-0.20	-0.08	0.07	0.26	0.90			
	TOT	155	0.14	0.280	-0.20	-0.08	0.08	0.26	1.16			
FINAL/ET VALUE	PLO	77	0.28	0.429	-0.20	-0.04	0.12	0.48	2.08			
	ADA	78	0.19	0.309	-0.22	-0.04	0.11	0.42	1.04			
	TOT	155	0.23	0.375	-0.22	-0.04	0.12	0.44	2.08			
CHG FROM BEST*	PLO	77	0.12	0.226	-0.20	0.00	0.04	0.14	1.20			
	ADA	78	0.06	0.138	-0.50	-0.02	0.03	0.10	0.50			
	TOT	155	0.09	0.189	-0.50	-0.02	0.04	0.14	1.20			
										-0.03	(-0.08, 0.01)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.36.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	75	20.0	56.82	-28.4	1.2	4.2	11.8	291.1			
	ADA	77	13.0	59.86	-47.6	-2.0	1.2	10.2	483.1			
	TOT	152	16.5	58.29	-47.6	-0.6	3.0	10.3	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	75	22.7	69.01	-11.3	0.5	5.3	12.7	514.8			
	ADA	78	14.1	63.65	-43.0	-0.6	2.4	10.7	534.5			
	TOT	153	18.3	66.25	-43.0	0.0	3.8	12.4	534.5			
										-5.4	(-22.2, 11.4)	0.528A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

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__1000.2.1.1.36.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	75	20.0	56.82	-28.4	1.2	4.2	11.8	291.1			
	ADA	77	13.0	59.86	-47.6	-2.0	1.2	10.2	483.1			
	TOT	152	16.5	58.29	-47.6	-0.6	3.0	10.3	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	75	22.7	69.01	-11.3	0.5	5.3	12.7	514.8			
	ADA	78	14.1	63.65	-43.0	-0.6	2.4	10.7	534.5			
	TOT	153	18.3	66.25	-43.0	0.0	3.8	12.4	534.5			
										-5.4	(-22.2, 11.4)	0.528A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	42	0.18	0.309	0.0	0.00	0.00	0.50	1.0			
	ADA	37	0.26	0.419	0.0	0.00	0.00	0.50	2.0			
	TOT	79	0.22	0.364	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	42	0.99	1.045	0.0	0.00	0.75	2.00	4.0			
	ADA	37	0.70	0.939	0.0	0.00	0.50	1.00	3.0			
	TOT	79	0.85	1.000	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	42	0.81	0.969	0.0	0.00	0.50	1.00	4.0			
	ADA	37	0.45	0.840	-1.0	0.00	0.00	1.00	2.5			
	TOT	79	0.64	0.923	-1.0	0.00	0.50	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	42	0.20	0.383	0.0	0.00	0.00	0.50	2.0			
	ADA	37	0.18	0.317	0.0	0.00	0.00	0.50	1.0			
	TOT	79	0.19	0.352	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	42	1.10	1.185	0.0	0.00	0.75	2.00	4.0			
	ADA	37	0.65	0.857	0.0	0.00	0.50	1.00	3.0			
	TOT	79	0.89	1.062	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	42	0.89	1.068	-0.5	0.00	0.50	1.00	3.5			
	ADA	37	0.47	0.833	-1.0	0.00	0.00	1.00	2.5			
	TOT	79	0.70	0.982	-1.0	0.00	0.50	1.00	3.5			
										-0.39	(-0.77, -0.01)	0.045A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	42	0.33	0.361	0.0	0.00	0.50	0.50	1.0			
	ADA	37	0.35	0.388	0.0	0.00	0.50	0.50	1.0			
	TOT	79	0.34	0.372	0.0	0.00	0.50	0.50	1.0			
FINAL/ET VALUE	PLO	42	0.73	0.775	0.0	0.00	0.50	1.00	2.0			
	ADA	37	0.46	0.582	0.0	0.00	0.50	0.50	3.0			
	TOT	79	0.60	0.700	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	42	0.39	0.640	-0.5	0.00	0.00	1.00	2.0			
	ADA	37	0.11	0.516	-1.0	0.00	0.00	0.50	2.0			
	TOT	79	0.26	0.598	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	42	0.31	0.441	0.0	0.00	0.00	0.50	2.0			
	ADA	37	0.34	0.374	0.0	0.00	0.50	0.50	1.0			
	TOT	79	0.32	0.409	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	42	0.98	1.024	0.0	0.00	0.75	1.00	3.0			
	ADA	37	0.58	0.722	0.0	0.00	0.50	1.00	3.0			
	TOT	79	0.79	0.911	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	42	0.67	0.846	0.0	0.00	0.50	1.00	2.5			
	ADA	37	0.24	0.723	-1.0	0.00	0.00	0.50	2.5			
	TOT	79	0.47	0.814	-1.0	0.00	0.00	1.00	2.5			
										-0.35	(-0.62, -0.08)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	42	0.17	0.290	-0.28	-0.02	0.10	0.30	0.94			
	ADA	37	0.20	0.351	-0.20	-0.02	0.10	0.32	1.30			
	TOT	79	0.19	0.318	-0.28	-0.02	0.10	0.32	1.30			
FINAL/ET VALUE	PLO	42	0.26	0.319	-0.18	0.02	0.19	0.46	1.02			
	ADA	37	0.30	0.437	-0.20	0.00	0.26	0.42	1.60			
	TOT	79	0.28	0.377	-0.20	0.00	0.22	0.46	1.60			
CHG FROM BEST*	PLO	42	0.09	0.114	-0.08	0.02	0.06	0.14	0.40			
	ADA	37	0.10	0.196	-0.32	-0.04	0.04	0.18	0.58			
	TOT	79	0.09	0.157	-0.32	0.00	0.06	0.14	0.58			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	42	0.23	0.294	-0.20	0.00	0.14	0.44	0.88			
	ADA	37	0.18	0.247	-0.20	0.00	0.12	0.34	0.76			
	TOT	79	0.21	0.272	-0.20	0.00	0.14	0.40	0.88			
FINAL/ET VALUE	PLO	42	0.38	0.473	-0.20	0.02	0.34	0.58	2.08			
	ADA	37	0.28	0.320	-0.20	-0.02	0.26	0.46	1.04			
	TOT	79	0.33	0.409	-0.20	0.00	0.34	0.54	2.08			
CHG FROM BEST*	PLO	42	0.15	0.263	-0.18	0.00	0.05	0.20	1.20			
	ADA	37	0.10	0.147	-0.18	0.00	0.06	0.14	0.50			
	TOT	79	0.12	0.217	-0.18	0.00	0.06	0.20	1.20			
										-0.02	(-0.09, 0.05)	0.549A

* 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.
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 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 ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.37.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	39	8.2	12.91	-4.0	1.2	4.5	10.2	63.2			
	ADA	37	20.6	83.07	-47.6	-2.0	0.9	10.2	483.1			
	TOT	76	14.2	58.61	-47.6	-0.5	3.3	10.2	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	40	27.2	85.52	-12.8	-0.2	6.5	15.0	514.8			
	ADA	37	25.6	89.34	-14.1	-0.5	3.2	14.3	534.5			
	TOT	77	26.4	86.80	-14.1	-0.5	5.4	14.9	534.5			
										9.1	(-20.9, 39.0)	0.549A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.37.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	39	8.2	12.91	-4.0	1.2	4.5	10.2	63.2			
	ADA	36	21.1	84.18	-47.6	-2.1	1.2	11.1	483.1			
	TOT	75	14.4	58.99	-47.6	-0.5	3.4	10.2	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	40	27.2	85.52	-12.8	-0.2	6.5	15.0	514.8			
	ADA	36	26.0	90.57	-14.1	-0.6	3.1	15.1	534.5			
	TOT	76	26.7	87.36	-14.1	-0.5	5.4	15.0	534.5			
										9.5	(-20.9, 39.8)	0.536A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	68	0.07	0.191	0.0	0.00	0.00	0.00	1.0			
	ADA	72	0.03	0.128	0.0	0.00	0.00	0.00	0.5			
	TOT	140	0.05	0.162	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	68	0.47	0.872	0.0	0.00	0.00	0.50	4.0			
	ADA	72	0.33	0.707	0.0	0.00	0.00	0.50	3.0			
	TOT	140	0.40	0.792	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	68	0.40	0.848	-0.5	0.00	0.00	0.50	4.0			
	ADA	72	0.30	0.690	-0.5	0.00	0.00	0.50	3.0			
	TOT	140	0.35	0.770	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	68	0.10	0.294	0.0	0.00	0.00	0.00	2.0			
	ADA	72	0.06	0.167	0.0	0.00	0.00	0.00	0.5			
	TOT	140	0.08	0.237	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	68	0.60	1.045	0.0	0.00	0.00	1.00	4.0			
	ADA	72	0.36	0.688	0.0	0.00	0.00	0.50	3.0			
	TOT	140	0.48	0.884	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	68	0.49	0.998	-0.5	0.00	0.00	0.75	4.0			
	ADA	72	0.30	0.664	-0.5	0.00	0.00	0.50	2.5			
	TOT	140	0.39	0.846	-0.5	0.00	0.00	0.50	4.0			
										-0.15	(-0.39, 0.09)	0.216A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	69	0.46	0.505	0.0	0.00	0.50	0.50	2.0			
	ADA	72	0.31	0.596	0.0	0.00	0.00	0.50	3.0			
	TOT	141	0.38	0.556	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	69	0.76	0.843	0.0	0.00	0.50	1.00	3.0			
	ADA	72	0.43	0.780	0.0	0.00	0.00	0.50	4.0			
	TOT	141	0.59	0.825	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	69	0.30	0.698	-0.5	0.00	0.00	0.50	3.0			
	ADA	72	0.12	0.566	-1.0	0.00	0.00	0.50	2.0			
	TOT	141	0.21	0.639	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	69	0.41	0.448	0.0	0.00	0.50	0.50	2.0			
	ADA	72	0.35	0.457	0.0	0.00	0.00	0.50	2.0			
	TOT	141	0.38	0.452	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	69	0.79	0.876	0.0	0.00	0.50	1.00	4.0			
	ADA	72	0.46	0.598	0.0	0.00	0.50	1.00	3.0			
	TOT	141	0.62	0.763	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	69	0.38	0.782	-1.0	0.00	0.00	0.50	3.5			
	ADA	72	0.11	0.606	-1.5	0.00	0.00	0.50	2.0			
	TOT	141	0.24	0.709	-1.5	0.00	0.00	0.50	3.5			
										-0.23	(-0.42, -0.04)	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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	69	0.11	0.265	-0.26	-0.08	0.02	0.20	0.88			
	ADA	72	0.10	0.257	-0.18	-0.07	0.02	0.17	1.12			
	TOT	141	0.10	0.260	-0.26	-0.08	0.02	0.18	1.12			
FINAL/ET VALUE	PLO	69	0.23	0.326	-0.20	0.00	0.12	0.32	1.22			
	ADA	72	0.16	0.327	-0.28	-0.06	0.05	0.28	1.62			
	TOT	141	0.19	0.327	-0.28	-0.02	0.10	0.32	1.62			
CHG FROM BEST*	PLO	69	0.12	0.208	-0.62	0.02	0.08	0.16	0.80			
	ADA	72	0.06	0.144	-0.22	-0.02	0.02	0.08	0.50			
	TOT	141	0.09	0.180	-0.62	-0.02	0.04	0.12	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	69	0.15	0.314	-0.24	-0.08	0.04	0.24	1.16			
	ADA	72	0.12	0.246	-0.22	-0.08	0.09	0.26	0.90			
	TOT	141	0.13	0.281	-0.24	-0.08	0.08	0.26	1.16			
FINAL/ET VALUE	PLO	69	0.27	0.482	-0.20	-0.06	0.12	0.46	3.00			
	ADA	72	0.14	0.282	-0.26	-0.06	0.09	0.28	0.94			
	TOT	141	0.21	0.397	-0.26	-0.06	0.10	0.34	3.00			
CHG FROM BEST*	PLO	69	0.12	0.364	-0.20	0.00	0.04	0.14	2.82			
	ADA	72	0.03	0.139	-0.50	-0.04	0.02	0.08	0.56			
	TOT	141	0.07	0.277	-0.50	-0.02	0.04	0.10	2.82			
										-0.08	(-0.14, -0.02)	0.007A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.38.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	68	25.2	62.01	-28.4	0.8	4.4	14.0	291.1			
	ADA	71	10.5	29.41	-40.8	-1.8	1.4	10.2	128.0			
	TOT	139	17.7	48.58	-40.8	-0.4	3.0	12.0	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	68	18.4	40.09	-9.2	0.5	4.9	13.3	212.4			
	ADA	72	8.8	28.41	-50.0	-0.8	2.3	8.1	145.8			
	TOT	140	13.4	34.79	-50.0	0.0	3.5	11.5	212.4			
										-11.8	(-22.9, -0.6)	0.038A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.38.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	68	25.2	62.01	-28.4	0.8	4.4	14.0	291.1			
	ADA	70	8.9	26.39	-40.8	-1.8	1.3	10.0	128.0			
	TOT	138	16.9	47.94	-40.8	-0.4	2.7	11.8	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	68	18.4	40.09	-9.2	0.5	4.9	13.3	212.4			
	ADA	71	8.5	28.52	-50.0	-1.2	2.3	7.8	145.8			
	TOT	139	13.3	34.89	-50.0	0.0	3.3	11.3	212.4			
										-12.6	(-23.7, -1.5)	0.027A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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
AC LEFT EYE									
BEST VALUE*	PLO	5	0.10	0.224	0.0	0.00	0.00	0.00	0.5
	ADA	3	0.33	0.577	0.0	0.00	0.00	1.00	1.0
	TOT	8	0.19	0.372	0.0	0.00	0.00	0.25	1.0
FINAL/ET VALUE	PLO	5	1.20	0.837	0.0	1.00	1.00	2.00	2.0
	ADA	3	0.67	1.155	0.0	0.00	0.00	2.00	2.0
	TOT	8	1.00	0.926	0.0	0.00	1.00	2.00	2.0
CHG FROM BEST*	PLO	5	1.10	0.894	0.0	0.50	1.00	2.00	2.0
	ADA	3	0.33	1.528	-1.0	-1.00	0.00	2.00	2.0
	TOT	8	0.81	1.132	-1.0	0.00	0.75	2.00	2.0
AC RIGHT EYE									
BEST VALUE*	PLO	5	0.10	0.224	0.0	0.00	0.00	0.00	0.5
	ADA	3	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	8	0.06	0.177	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	5	1.40	1.140	0.0	1.00	1.00	2.00	3.0
	ADA	3	1.33	1.155	0.0	0.00	2.00	2.00	2.0
	TOT	8	1.38	1.061	0.0	0.50	1.50	2.00	3.0
CHG FROM BEST*	PLO	5	1.30	1.095	0.0	1.00	1.00	1.50	3.0
	ADA	3	1.33	1.155	0.0	0.00	2.00	2.00	2.0
	TOT	8	1.31	1.033	0.0	0.50	1.25	2.00	3.0

* 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.
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__1000.2.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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
VH LEFT EYE									
BEST VALUE*	PLO	5	0.30	0.274	0.0	0.00	0.50	0.50	0.5
	ADA	3	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	8	0.19	0.259	0.0	0.00	0.00	0.50	0.5
FINAL/ET VALUE	PLO	5	0.70	0.758	0.0	0.50	0.50	0.50	2.0
	ADA	3	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	8	0.44	0.678	0.0	0.00	0.25	0.50	2.0
CHG FROM BEST*	PLO	5	0.40	0.652	0.0	0.00	0.00	0.50	1.5
	ADA	3	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	8	0.25	0.535	0.0	0.00	0.00	0.25	1.5
VH RIGHT EYE									
BEST VALUE*	PLO	5	0.10	0.224	0.0	0.00	0.00	0.00	0.5
	ADA	3	0.00	0.000	0.0	0.00	0.00	0.00	0.0
	TOT	8	0.06	0.177	0.0	0.00	0.00	0.00	0.5
FINAL/ET VALUE	PLO	5	0.90	1.194	0.0	0.50	0.50	0.50	3.0
	ADA	3	0.17	0.289	0.0	0.00	0.00	0.50	0.5
	TOT	8	0.63	0.991	0.0	0.00	0.50	0.50	3.0
CHG FROM BEST*	PLO	5	0.80	0.975	0.0	0.50	0.50	0.50	2.5
	ADA	3	0.17	0.289	0.0	0.00	0.00	0.50	0.5
	TOT	8	0.56	0.821	0.0	0.00	0.50	0.50	2.5

* 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.
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__1000.2.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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
LOGMAR LEFT EYE									
BEST VALUE*	PLO	5	0.14	0.275	-0.14	-0.08	0.06	0.40	0.46
	ADA	3	0.21	0.270	-0.06	-0.06	0.22	0.48	0.48
	TOT	8	0.17	0.256	-0.14	-0.07	0.14	0.43	0.48
FINAL/ET VALUE	PLO	5	0.34	0.424	-0.10	0.00	0.22	0.72	0.84
	ADA	3	0.27	0.254	-0.02	-0.02	0.42	0.42	0.42
	TOT	8	0.31	0.349	-0.10	-0.01	0.32	0.57	0.84
CHG FROM BEST*	PLO	5	0.20	0.158	-0.02	0.14	0.16	0.32	0.38
	ADA	3	0.06	0.131	-0.06	-0.06	0.04	0.20	0.20
	TOT	8	0.15	0.156	-0.06	0.01	0.15	0.26	0.38
LOGMAR RIGHT EYE									
BEST VALUE*	PLO	5	0.16	0.442	-0.24	-0.20	0.10	0.32	0.84
	ADA	3	0.18	0.255	-0.10	-0.10	0.24	0.40	0.40
	TOT	8	0.17	0.361	-0.24	-0.15	0.17	0.36	0.84
FINAL/ET VALUE	PLO	5	0.42	0.417	-0.18	0.18	0.58	0.62	0.88
	ADA	3	0.26	0.269	-0.04	-0.04	0.34	0.48	0.48
	TOT	8	0.36	0.356	-0.18	0.07	0.41	0.60	0.88
CHG FROM BEST*	PLO	5	0.25	0.223	0.02	0.04	0.26	0.42	0.52
	ADA	3	0.08	0.020	0.06	0.06	0.08	0.10	0.10
	TOT	8	0.19	0.191	0.02	0.05	0.09	0.34	0.52

* 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.
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__1000.2.1.1.39.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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
CRT LEFT EYE									
%CHG FROM BEST*	PLO	5	10.1	9.34	1.8	2.2	8.0	14.6	23.9
	ADA	3	12.6	38.25	-17.3	-17.3	-0.6	55.7	55.7
	TOT	8	11.0	21.67	-17.3	0.6	5.1	19.3	55.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	5	55.9	65.90	5.6	7.6	34.7	66.4	165.2
	ADA	3	34.6	42.01	1.2	1.2	20.9	81.8	81.8
	TOT	8	47.9	55.74	1.2	6.6	27.8	74.1	165.2

* 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.
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__1000.2.1.1.39.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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
CRT LEFT EYE									
%CHG FROM BEST*	PLO	5	10.1	9.34	1.8	2.2	8.0	14.6	23.9
	ADA	3	12.6	38.25	-17.3	-17.3	-0.6	55.7	55.7
	TOT	8	11.0	21.67	-17.3	0.6	5.1	19.3	55.7
CRT RIGHT EYE									
%CHG FROM BEST*	PLO	5	55.9	65.90	5.6	7.6	34.7	66.4	165.2
	ADA	3	34.6	42.01	1.2	1.2	20.9	81.8	81.8
	TOT	8	47.9	55.74	1.2	6.6	27.8	74.1	165.2

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,

TESTSTATISTICAL ANALYSIS IS OMITTED DUE TO SMALL N.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	105	0.11	0.250	0.0	0.00	0.00	0.00	1.0			
	ADA	106	0.10	0.274	0.0	0.00	0.00	0.00	2.0			
	TOT	211	0.11	0.261	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	105	0.64	0.972	0.0	0.00	0.00	1.00	4.0			
	ADA	106	0.45	0.803	0.0	0.00	0.00	0.50	3.0			
	TOT	211	0.55	0.894	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	105	0.53	0.910	-0.5	0.00	0.00	1.00	4.0			
	ADA	106	0.35	0.724	-0.5	0.00	0.00	0.50	3.0			
	TOT	211	0.44	0.825	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	105	0.14	0.338	0.0	0.00	0.00	0.00	2.0			
	ADA	106	0.10	0.236	0.0	0.00	0.00	0.00	1.0			
	TOT	211	0.12	0.291	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	105	0.76	1.118	0.0	0.00	0.00	1.00	4.0			
	ADA	106	0.43	0.737	0.0	0.00	0.00	0.50	3.0			
	TOT	211	0.59	0.958	0.0	0.00	0.00	1.00	4.0			
CHG FROM BEST*	PLO	105	0.61	1.031	-0.5	0.00	0.00	1.00	4.0			
	ADA	106	0.33	0.700	-1.0	0.00	0.00	0.50	2.5			
	TOT	211	0.47	0.890	-1.0	0.00	0.00	0.50	4.0			
										-0.23	(-0.44, -0.03)	0.028A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	106	0.42	0.465	0.0	0.00	0.50	0.50	2.0			
	ADA	106	0.33	0.538	0.0	0.00	0.00	0.50	3.0			
	TOT	212	0.38	0.503	0.0	0.00	0.00	0.50	3.0			
FINAL/ET VALUE	PLO	106	0.75	0.820	0.0	0.00	0.50	1.00	3.0			
	ADA	106	0.45	0.722	0.0	0.00	0.00	0.50	4.0			
	TOT	212	0.60	0.785	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	106	0.33	0.679	-0.5	0.00	0.00	0.50	3.0			
	ADA	106	0.12	0.554	-1.0	0.00	0.00	0.50	2.0			
	TOT	212	0.23	0.628	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	106	0.38	0.450	0.0	0.00	0.50	0.50	2.0			
	ADA	106	0.35	0.431	0.0	0.00	0.25	0.50	2.0			
	TOT	212	0.37	0.440	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	106	0.86	0.928	0.0	0.00	0.50	1.00	4.0			
	ADA	106	0.51	0.647	0.0	0.00	0.50	1.00	3.0			
	TOT	212	0.68	0.817	0.0	0.00	0.50	1.00	4.0			
CHG FROM BEST*	PLO	106	0.48	0.809	-1.0	0.00	0.00	1.00	3.5			
	ADA	106	0.16	0.656	-1.5	0.00	0.00	0.50	2.5			
	TOT	212	0.32	0.752	-1.5	0.00	0.00	0.50	3.5			
										-0.27	(-0.43, -0.11)	<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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	106	0.13	0.277	-0.28	-0.06	0.04	0.24	0.94			
	ADA	106	0.14	0.296	-0.20	-0.06	0.04	0.22	1.30			
	TOT	212	0.13	0.286	-0.28	-0.06	0.04	0.23	1.30			
FINAL/ET VALUE	PLO	106	0.24	0.318	-0.20	0.00	0.15	0.42	1.22			
	ADA	106	0.21	0.375	-0.28	-0.04	0.09	0.34	1.62			
	TOT	212	0.22	0.348	-0.28	-0.02	0.12	0.37	1.62			
CHG FROM BEST*	PLO	106	0.10	0.179	-0.62	0.02	0.06	0.14	0.80			
	ADA	106	0.07	0.165	-0.32	-0.02	0.04	0.12	0.58			
	TOT	212	0.09	0.173	-0.62	0.00	0.04	0.13	0.80			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	106	0.18	0.303	-0.20	-0.04	0.10	0.38	1.16			
	ADA	106	0.14	0.248	-0.22	-0.06	0.10	0.28	0.90			
	TOT	212	0.16	0.277	-0.22	-0.06	0.10	0.32	1.16			
FINAL/ET VALUE	PLO	106	0.31	0.483	-0.20	-0.02	0.18	0.50	3.00			
	ADA	106	0.19	0.303	-0.26	-0.06	0.12	0.36	1.04			
	TOT	212	0.25	0.407	-0.26	-0.04	0.13	0.44	3.00			
CHG FROM BEST*	PLO	106	0.13	0.332	-0.20	0.00	0.04	0.16	2.82			
	ADA	106	0.05	0.147	-0.50	-0.02	0.03	0.10	0.56			
	TOT	212	0.09	0.259	-0.50	-0.02	0.04	0.13	2.82			
										-0.06	(-0.10, -0.01)	0.017A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.40.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	102	19.4	51.74	-28.4	0.8	4.4	12.0	291.1			
	ADA	105	14.0	54.47	-47.6	-1.8	1.4	10.2	483.1			
	TOT	207	16.7	53.08	-47.6	-0.4	3.2	10.8	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	103	20.0	60.34	-12.8	0.0	5.3	14.4	514.8			
	ADA	106	13.9	57.47	-50.0	-0.6	2.5	9.9	534.5			
	TOT	209	16.9	58.84	-50.0	0.0	4.1	12.4	534.5			
										-4.7	(-17.6, 8.3)	0.476A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.40.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	102	19.4	51.74	-28.4	0.8	4.4	12.0	291.1			
	ADA	103	13.1	53.93	-47.6	-2.0	1.4	10.2	483.1			
	TOT	205	16.2	52.82	-47.6	-0.4	3.2	10.5	483.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	103	20.0	60.34	-12.8	0.0	5.3	14.4	514.8			
	ADA	104	13.8	58.00	-50.0	-0.7	2.4	8.3	534.5			
	TOT	207	16.9	59.11	-50.0	0.0	4.0	12.4	534.5			
										-5.0	(-18.0, 8.0)	0.451A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	49	0.19	0.320	0.0	0.00	0.00	0.50	1.0			
	ADA	37	0.16	0.392	0.0	0.00	0.00	0.00	2.0			
	TOT	86	0.18	0.351	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	49	0.91	1.064	0.0	0.00	0.50	2.00	4.0			
	ADA	37	0.85	1.073	0.0	0.00	0.50	1.00	3.0			
	TOT	86	0.88	1.062	0.0	0.00	0.50	2.00	4.0			
CHG FROM BEST*	PLO	49	0.71	1.010	-0.5	0.00	0.50	1.00	4.0			
	ADA	37	0.69	0.923	0.0	0.00	0.50	1.00	3.0			
	TOT	86	0.70	0.968	-0.5	0.00	0.50	1.00	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	49	0.21	0.445	0.0	0.00	0.00	0.50	2.0			
	ADA	37	0.12	0.274	0.0	0.00	0.00	0.00	1.0			
	TOT	86	0.17	0.382	0.0	0.00	0.00	0.00	2.0			
FINAL/ET VALUE	PLO	49	1.02	1.225	0.0	0.00	0.50	2.00	4.0			
	ADA	37	0.68	0.884	0.0	0.00	0.50	1.00	3.0			
	TOT	86	0.87	1.099	0.0	0.00	0.50	2.00	4.0			
CHG FROM BEST*	PLO	49	0.81	1.094	-0.5	0.00	0.50	1.00	3.5			
	ADA	37	0.55	0.780	-0.5	0.00	0.50	0.50	2.5			
	TOT	86	0.70	0.974	-0.5	0.00	0.50	1.00	3.5			
										-0.14	(-0.51, 0.23)	0.459A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	50	0.40	0.484	0.0	0.00	0.50	0.50	2.0			
	ADA	37	0.27	0.384	0.0	0.00	0.00	0.50	1.0			
	TOT	87	0.34	0.447	0.0	0.00	0.00	0.50	2.0			
FINAL/ET VALUE	PLO	50	0.86	0.839	0.0	0.00	1.00	2.00	3.0			
	ADA	37	0.49	0.546	0.0	0.00	0.50	1.00	2.0			
	TOT	87	0.70	0.749	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	50	0.46	0.741	-0.5	0.00	0.00	1.00	3.0			
	ADA	37	0.22	0.507	-1.0	0.00	0.00	0.50	1.5			
	TOT	87	0.36	0.660	-1.0	0.00	0.00	0.50	3.0			
VH RIGHT EYE												
BEST VALUE*	PLO	50	0.23	0.338	0.0	0.00	0.00	0.50	1.0			
	ADA	37	0.24	0.384	0.0	0.00	0.00	0.50	1.0			
	TOT	87	0.24	0.356	0.0	0.00	0.00	0.50	1.0			
FINAL/ET VALUE	PLO	50	0.69	0.769	0.0	0.00	0.50	1.00	3.0			
	ADA	37	0.47	0.645	0.0	0.00	0.50	1.00	3.0			
	TOT	87	0.60	0.723	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	50	0.46	0.669	-1.0	0.00	0.50	1.00	2.5			
	ADA	37	0.23	0.608	-1.0	0.00	0.00	0.50	2.0			
	TOT	87	0.36	0.650	-1.0	0.00	0.00	0.50	2.5			
										-0.24	(-0.48, 0.01)	0.058A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	50	0.16	0.286	-0.26	-0.04	0.05	0.28	0.94			
	ADA	37	0.14	0.257	-0.18	-0.06	0.06	0.22	0.82			
	TOT	87	0.15	0.272	-0.26	-0.06	0.06	0.26	0.94			
FINAL/ET VALUE	PLO	50	0.29	0.351	-0.20	0.00	0.22	0.44	1.22			
	ADA	37	0.21	0.324	-0.14	0.00	0.12	0.32	1.26			
	TOT	87	0.25	0.340	-0.20	0.00	0.14	0.42	1.26			
CHG FROM BEST*	PLO	50	0.13	0.178	-0.08	0.02	0.07	0.18	0.76			
	ADA	37	0.07	0.152	-0.22	-0.02	0.04	0.10	0.48			
	TOT	87	0.10	0.169	-0.22	0.00	0.06	0.16	0.76			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	50	0.17	0.291	-0.20	-0.06	0.09	0.38	0.98			
	ADA	37	0.17	0.266	-0.16	-0.04	0.12	0.28	0.90			
	TOT	87	0.17	0.279	-0.20	-0.04	0.10	0.34	0.98			
FINAL/ET VALUE	PLO	50	0.28	0.370	-0.20	-0.04	0.19	0.50	1.32			
	ADA	37	0.25	0.329	-0.20	-0.02	0.12	0.50	0.94			
	TOT	87	0.27	0.351	-0.20	-0.04	0.14	0.50	1.32			
CHG FROM BEST*	PLO	50	0.11	0.185	-0.20	0.00	0.05	0.14	0.88			
	ADA	37	0.08	0.146	-0.10	0.00	0.02	0.12	0.56			
	TOT	87	0.09	0.169	-0.20	0.00	0.04	0.14	0.88			
										-0.04	(-0.10, 0.01)	0.131A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.41.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	48	18.9	42.22	-19.7	0.3	6.1	14.9	227.9			
	ADA	36	6.5	25.43	-47.6	-2.0	1.6	6.7	126.3			
	TOT	84	13.6	36.34	-47.6	-0.7	3.3	12.0	227.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	50	25.9	80.69	-12.8	0.5	5.7	14.9	514.8			
	ADA	37	8.8	28.68	-43.0	0.0	2.4	12.7	145.8			
	TOT	87	18.6	64.23	-43.0	0.0	4.1	13.9	514.8			
										-12.7	(-28.8, 3.3)	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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

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__1000.2.1.1.41.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	48	18.9	42.22	-19.7	0.3	6.1	14.9	227.9			
	ADA	36	6.5	25.43	-47.6	-2.0	1.6	6.7	126.3			
	TOT	84	13.6	36.34	-47.6	-0.7	3.3	12.0	227.9			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	50	25.9	80.69	-12.8	0.5	5.7	14.9	514.8			
	ADA	37	8.8	28.68	-43.0	0.0	2.4	12.7	145.8			
	TOT	87	18.6	64.23	-43.0	0.0	4.1	13.9	514.8			
										-12.7	(-28.8, 3.3)	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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
AC LEFT EYE												
BEST VALUE*	PLO	41	0.04	0.132	0.0	0.00	0.00	0.00	0.5			
	ADA	49	0.05	0.153	0.0	0.00	0.00	0.00	0.5			
	TOT	90	0.04	0.143	0.0	0.00	0.00	0.00	0.5			
FINAL/ET VALUE	PLO	41	0.49	0.905	0.0	0.00	0.00	0.50	4.0			
	ADA	49	0.16	0.373	0.0	0.00	0.00	0.00	2.0			
	TOT	90	0.31	0.685	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	41	0.45	0.872	0.0	0.00	0.00	0.50	4.0			
	ADA	49	0.11	0.357	-0.5	0.00	0.00	0.00	1.5			
	TOT	90	0.27	0.663	-0.5	0.00	0.00	0.50	4.0			
AC RIGHT EYE												
BEST VALUE*	PLO	41	0.09	0.190	0.0	0.00	0.00	0.00	0.5			
	ADA	49	0.11	0.234	0.0	0.00	0.00	0.00	1.0			
	TOT	90	0.10	0.215	0.0	0.00	0.00	0.00	1.0			
FINAL/ET VALUE	PLO	41	0.49	0.905	0.0	0.00	0.00	0.50	4.0			
	ADA	49	0.27	0.605	0.0	0.00	0.00	0.50	3.0			
	TOT	90	0.37	0.760	0.0	0.00	0.00	0.50	4.0			
CHG FROM BEST*	PLO	41	0.40	0.875	-0.5	0.00	0.00	0.50	4.0			
	ADA	49	0.15	0.606	-1.0	0.00	0.00	0.00	2.5			
	TOT	90	0.27	0.747	-1.0	0.00	0.00	0.50	4.0			
										-0.29	(-0.57, -0.02)	0.036A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
VH LEFT EYE												
BEST VALUE*	PLO	41	0.43	0.396	0.0	0.00	0.50	0.50	1.0			
	ADA	49	0.46	0.676	0.0	0.00	0.50	0.50	3.0			
	TOT	90	0.44	0.563	0.0	0.00	0.50	0.50	3.0			
FINAL/ET VALUE	PLO	41	0.61	0.712	0.0	0.00	0.50	1.00	3.0			
	ADA	49	0.49	0.893	0.0	0.00	0.00	0.50	4.0			
	TOT	90	0.54	0.813	0.0	0.00	0.25	1.00	4.0			
CHG FROM BEST*	PLO	41	0.18	0.567	-0.5	0.00	0.00	0.50	2.0			
	ADA	49	0.03	0.599	-1.0	-0.50	0.00	0.00	2.0			
	TOT	90	0.10	0.586	-1.0	0.00	0.00	0.50	2.0			
VH RIGHT EYE												
BEST VALUE*	PLO	41	0.46	0.466	0.0	0.00	0.50	1.00	2.0			
	ADA	49	0.46	0.455	0.0	0.00	0.50	0.50	2.0			
	TOT	90	0.46	0.457	0.0	0.00	0.50	0.50	2.0			
FINAL/ET VALUE	PLO	41	0.77	0.742	0.0	0.50	0.50	1.00	3.0			
	ADA	49	0.54	0.683	0.0	0.00	0.50	1.00	3.0			
	TOT	90	0.64	0.716	0.0	0.00	0.50	1.00	3.0			
CHG FROM BEST*	PLO	41	0.30	0.706	-1.0	0.00	0.00	0.50	2.5			
	ADA	49	0.08	0.738	-1.5	-0.50	0.00	0.50	2.5			
	TOT	90	0.18	0.728	-1.5	0.00	0.00	0.50	2.5			
										-0.19	(-0.42, 0.05)	0.113A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
LOGMAR LEFT EYE												
BEST VALUE*	PLO	41	0.08	0.225	-0.28	-0.06	0.02	0.12	0.62			
	ADA	49	0.12	0.296	-0.20	-0.10	0.04	0.20	1.12			
	TOT	90	0.10	0.265	-0.28	-0.08	0.03	0.16	1.12			
FINAL/ET VALUE	PLO	41	0.17	0.278	-0.14	-0.02	0.06	0.28	0.90			
	ADA	49	0.20	0.387	-0.28	-0.08	0.04	0.46	1.62			
	TOT	90	0.19	0.340	-0.28	-0.04	0.05	0.34	1.62			
CHG FROM BEST*	PLO	41	0.10	0.125	-0.06	0.02	0.06	0.14	0.48			
	ADA	49	0.08	0.176	-0.32	-0.04	0.02	0.12	0.50			
	TOT	90	0.08	0.154	-0.32	0.00	0.04	0.14	0.50			
LOGMAR RIGHT EYE												
BEST VALUE*	PLO	41	0.10	0.243	-0.24	-0.08	0.08	0.18	0.76			
	ADA	49	0.10	0.229	-0.22	-0.10	0.08	0.26	0.70			
	TOT	90	0.10	0.234	-0.24	-0.10	0.08	0.24	0.76			
FINAL/ET VALUE	PLO	41	0.18	0.294	-0.20	-0.06	0.10	0.40	1.00			
	ADA	49	0.12	0.273	-0.26	-0.08	0.06	0.32	0.94			
	TOT	90	0.15	0.282	-0.26	-0.08	0.09	0.34	1.00			
CHG FROM BEST*	PLO	41	0.08	0.155	-0.18	-0.02	0.04	0.14	0.52			
	ADA	49	0.03	0.135	-0.50	-0.04	0.04	0.08	0.32			
	TOT	90	0.05	0.147	-0.50	-0.04	0.04	0.10	0.52			
										-0.04	(-0.09, 0.02)	0.162A

* 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.
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 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
ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.42.I

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 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 M10-877)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	40	24.3	67.63	-8.6	1.0	3.3	7.0	291.1			
	ADA	49	14.6	34.51	-40.8	-1.3	1.2	19.3	128.0			
	TOT	89	19.0	51.96	-40.8	-0.3	2.3	10.5	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	40	19.8	42.00	-8.8	0.0	4.3	11.9	169.7			
	ADA	49	7.0	24.44	-50.0	-1.3	2.0	6.4	97.3			
	TOT	89	12.7	33.89	-50.0	-0.5	2.4	8.9	169.7			
										-9.3	(-24.7, 6.1)	0.232A

* 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.
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 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.2.1.1.42.I.PH

CHANGE FROM BEST STATE ACHIEVED PRIOR TO WEEK 6 TO FINAL/EARLY TERMINATION VISIT (LEFT/RIGHT EYE)
IN CENTRAL RETINAL THICKNESS (LOCF)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
(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@
CRT LEFT EYE												
%CHG FROM BEST*	PLO	40	24.3	67.63	-8.6	1.0	3.3	7.0	291.1			
	ADA	48	12.4	31.11	-40.8	-1.6	1.1	15.6	128.0			
	TOT	88	17.8	51.07	-40.8	-0.3	2.1	10.3	291.1			
CRT RIGHT EYE												
%CHG FROM BEST*	PLO	40	19.8	42.00	-8.8	0.0	4.3	11.9	169.7			
	ADA	48	6.5	24.50	-50.0	-1.4	1.8	6.2	97.3			
	TOT	88	12.6	34.05	-50.0	-0.5	2.4	8.3	169.7			
										-10.6	(-26.0, 4.8)	0.175A

* 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.
PLO=PLACEBO, ADA=ADALIMUMAB, TOT=TOTAL
CRT=CENTRAL RETINAL THICKNESS,
$ 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 AND OCT
MACHINE AS FACTORS ADJUSTED FOR CLUSTERED OBSERVATIONS.

Program Source Code: [redacted]

TABLE 14.2__1000.3.1.1.1.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	19	11	(57.9)	8	(42.1)	1.3	2.9	*				
ADALIMUMAB	30	14	(46.7)	16	(53.3)	1.9	11.1	15.7				
TOTAL	49	25	(51.0)	24	(49.0)	1.4	5.6	*	0.66	(0.30,	1.46)	0.299

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.1.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=MALE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	30	4	(13.3)	26	(86.7)	5.6	*	*			
ADALIMUMAB	34	3	(8.8)	31	(91.2)	*	*	*			
TOTAL	64	7	(10.9)	57	(89.1)	*	*	*	0.49	(0.11, 2.23)	0.344

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.2.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	28	12	(42.9)	16	(57.1)	1.9	3.7	*			
ADALIMUMAB	27	11	(40.7)	16	(59.3)	2.8	9.2	15.9			
TOTAL	55	23	(41.8)	32	(58.2)	2.1	8.8	15.9	0.56	(0.23, 1.35)	0.190

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.2.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GENDER=FEMALE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	44	9	(20.5)	35	(79.5)	5.0	10.9	*			
ADALIMUMAB	40	4	(10.0)	36	(90.0)	*	*	*			
TOTAL	84	13	(15.5)	71	(84.5)	9.5	*	*	0.31	(0.09, 1.04)	0.047

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.3.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	8	0		8	(100)	*	*	*
ADALIMUMAB	10	4	(40.0)	6	(60.0)	2.6	11.2	*
TOTAL	18	4	(22.2)	14	(77.8)	11.2	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.3.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE < 30 YEARS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	13	1	(7.7)	12	(92.3)	*	*	*
ADALIMUMAB	16	2	(12.5)	14	(87.5)	*	*	*
TOTAL	29	3	(10.3)	26	(89.7)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.4.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	27	15	(55.6)	12	(44.4)	1.4	2.7	6.2			
ADALIMUMAB	34	12	(35.3)	22	(64.7)	2.7	15.7	*			
TOTAL	61	27	(44.3)	34	(55.7)	1.9	6.2	*	0.40	(0.18, 0.90)	0.021

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.4.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 30 TO < 50 YEARS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	40	6	(15.0)	34	(85.0)	5.6	*	*				
ADALIMUMAB	39	3	(7.7)	36	(92.3)	*	*	*				
TOTAL	79	9	(11.4)	70	(88.6)	10.4	*	*	0.20	(0.05,	0.89)	0.023

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.5.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	12	8	(66.7)	4	(33.3)	0.6	2.1	9.0
ADALIMUMAB	13	9	(69.2)	4	(30.8)	2.8	5.6	9.2
TOTAL	25	17	(68.0)	8	(32.0)	1.4	4.6	9.2

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.5.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: AGE >= 50 YEARS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	21	6	(28.6)	15	(71.4)	4.5	*	*			
ADALIMUMAB	19	2	(10.5)	17	(89.5)	*	*	*			
TOTAL	40	8	(20.0)	32	(80.0)	10.9	*	*	0.34	(0.07, 1.68)	0.164

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.6.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	37	18	(48.6)	19	(51.4)	1.4	3.7	*			
ADALIMUMAB	45	19	(42.2)	26	(57.8)	2.7	11.2	15.9			
TOTAL	82	37	(45.1)	45	(54.9)	1.4	9.0	15.9	0.66	(0.34, 1.27)	0.207

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.6.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=WHITE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	56	11	(19.6)	45	(80.4)	5.0	*	*			
ADALIMUMAB	58	6	(10.3)	52	(89.7)	*	*	*			
TOTAL	114	17	(14.9)	97	(85.1)	10.9	*	*	0.38	(0.14, 1.05)	0.054

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.1.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	10	5	(50.0)	5	(50.0)	1.1	2.8	*
ADALIMUMAB	12	6	(50.0)	6	(50.0)	2.6	5.6	6.2
TOTAL	22	11	(50.0)	11	(50.0)	1.9	5.6	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.1.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NON-WHITE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	18	2	(11.1)	16	(88.9)	*	*	*
ADALIMUMAB	16	1	(6.3)	15	(93.8)	*	*	*
TOTAL	34	3	(8.8)	31	(91.2)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.2.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	3	2	(66.7)	1	(33.3)	0.3	0.3	*
ADALIMUMAB	4	2	(50.0)	2	(50.0)	2.6	6.2	6.2
TOTAL	7	4	(57.1)	3	(42.9)	0.3	6.2	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.2.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=BLACK)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	7	1	(14.3)	6	(85.7)	*	*	*
ADALIMUMAB	6	0		6	(100)	*	*	*
TOTAL	13	1	(7.7)	12	(92.3)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.3.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	2	2	(100)	0		1.9	2.3	2.8
ADALIMUMAB	5	4	(80.0)	1	(20.0)	0.9	2.8	5.6
TOTAL	7	6	(85.7)	1	(14.3)	0.9	2.8	2.8

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.3.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=ASIAN)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	5	1	(20.0)	4	(80.0)	2.8	*	*
ADALIMUMAB	5	1	(20.0)	4	(80.0)	4.8	*	*
TOTAL	10	2	(20.0)	8	(80.0)	4.8	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.4.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	1	(100)	0		1.1	1.1	1.1
ADALIMUMAB	0							
TOTAL	1	1	(100)	0		1.1	1.1	1.1

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.4.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=AMERICAN INDIAN/ALASKA NATIVE)

TREATMENT	N	EVIDENCE OF EDEMA N (%)	CENSORED N (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	0	1 (100)	*	*	*
ADALIMUMAB	0					
TOTAL	1	0	1 (100)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.5.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

TREATMENT	N	EVIDENCE OF EDEMA N (%)	CENSORED N (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	0					
ADALIMUMAB	0					
TOTAL	0					

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.5.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)

TREATMENT	N	EVIDENCE OF EDEMA N (%)	CENSORED N (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	0					
ADALIMUMAB	0					
TOTAL	0					

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.6.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	3	0		3	(100)	*	*	*
ADALIMUMAB	3	0		3	(100)	*	*	*
TOTAL	6	0		6	(100)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.6.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=OTHER)

TREATMENT	N	EVIDENCE OF EDEMA N (%)	CENSORED N (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	4	0	4 (100)	*	*	*
ADALIMUMAB	4	0	4 (100)	*	*	*
TOTAL	8	0	8 (100)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.7.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

TREATMENT	N	EVIDENCE OF EDEMA N	EVIDENCE OF EDEMA (%)	CENSORED N	CENSORED (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	0		1	(100)	*	*	*
ADALIMUMAB	0							
TOTAL	1	0		1	(100)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.7.7.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: RACE=MULTI RACE)

TREATMENT	N	EVIDENCE OF EDEMA N (%)	CENSORED N (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	0	1 (100)	*	*	*
ADALIMUMAB	1	0	1 (100)	*	*	*
TOTAL	2	0	2 (100)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.8.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	15	7	(46.7)	8	(53.3)	1.1	9.0	9.0
ADALIMUMAB	22	6	(27.3)	16	(72.7)	2.8	*	*
TOTAL	37	13	(35.1)	24	(64.9)	2.7	9.0	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.8.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS < 1 YEAR)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	23	4	(17.4)	19	(82.6)	10.9	*	*			
ADALIMUMAB	31	4	(12.9)	27	(87.1)	10.4	*	*			
TOTAL	54	8	(14.8)	46	(85.2)	10.9	*	*	0.72	(0.18, 2.89)	0.642

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.9.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	32	16	(50.0)	16	(50.0)	1.4	3.7	*			
ADALIMUMAB	35	19	(54.3)	16	(45.7)	1.4	8.8	15.7			
TOTAL	67	35	(52.2)	32	(47.8)	1.4	5.6	15.7	0.88	(0.45, 1.73)	0.716

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.9.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF UVEITIS >= 1 YEAR)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	51	9	(17.6)	42	(82.4)	5.0	*	*			
ADALIMUMAB	43	3	(7.0)	40	(93.0)	*	*	*			
TOTAL	94	12	(12.8)	82	(87.2)	*	*	*	0.21	(0.05, 0.82)	0.016

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.10.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	8	2	(25.0)	6	(75.0)	2.1	*	*
ADALIMUMAB	12	2	(16.7)	10	(83.3)	8.3	11.1	*
TOTAL	20	4	(20.0)	16	(80.0)	5.6	11.1	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.10.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=INTERMEDIATE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	15	2	(13.3)	13	(86.7)	*	*	*
ADALIMUMAB	14	0		14	(100)	*	*	*
TOTAL	29	2	(6.9)	27	(93.1)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.11.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	16	7	(43.8)	9	(56.3)	1.3	9.0	*
ADALIMUMAB	23	12	(52.2)	11	(47.8)	1.4	15.7	15.9
TOTAL	39	19	(48.7)	20	(51.3)	1.4	9.2	15.9

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.11.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=POSTERIOR)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	25	6	(24.0)	19	(76.0)	3.7	*	*				
ADALIMUMAB	28	0		28	(100)	*	*	*				
TOTAL	53	6	(11.3)	47	(88.7)	*	*	*	*	(0.00,	)	0.002

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.12.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	23	14	(60.9)	9	(39.1)	1.1	1.9	*			
ADALIMUMAB	22	11	(50.0)	11	(50.0)	1.9	2.8	11.2			
TOTAL	45	25	(55.6)	20	(44.4)	1.4	2.7	8.8	0.66	(0.29, 1.52)	0.321

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.12.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TYPE OF UVEITIS=PANUVEITIS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	34	5	(14.7)	29	(85.3)	5.0	5.6	*				
ADALIMUMAB	32	7	(21.9)	25	(78.1)	9.5	*	*				
TOTAL	66	12	(18.2)	54	(81.8)	5.0	10.4	*	0.82	(0.23,	2.96)	0.767

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.13.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	25	13	(52.0)	12	(48.0)	1.4	2.8	*				
ADALIMUMAB	23	9	(39.1)	14	(60.9)	2.8	8.8	*				
TOTAL	48	22	(45.8)	26	(54.2)	1.9	4.6	11.1	0.46	(0.18,	1.16)	0.091

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.13.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=IDIOPATHIC/OTHER)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	37	6	(16.2)	31	(83.8)	5.6	*	*			
ADALIMUMAB	30	3	(10.0)	27	(90.0)	*	*	*			
TOTAL	67	9	(13.4)	58	(86.6)	5.6	*	*	0.33	(0.07, 1.62)	0.150

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.14.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	8	4	(50.0)	4	(50.0)	0.9	9.0	*
ADALIMUMAB	13	7	(53.8)	6	(46.2)	1.9	9.2	15.9
TOTAL	21	11	(52.4)	10	(47.6)	1.4	9.2	15.9

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.14.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BIRDSHOT CHOROIDOPATHY)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	13	3	(23.1)	10	(76.9)	10.9	*	*
ADALIMUMAB	15	1	(6.7)	14	(93.3)	*	*	*
TOTAL	28	4	(14.3)	24	(85.7)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.15.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

TREATMENT	N	EVIDENCE OF EDEMA N	EVIDENCE OF EDEMA (%)	CENSORED N	CENSORED (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	1	(100)	0		1.4	1.4	1.4
ADALIMUMAB	2	1	(50.0)	1	(50.0)	1.0	*	*
TOTAL	3	2	(66.7)	1	(33.3)	1.0	1.4	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.15.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=MULTIFOCAL CHOROIDITIS AND PANUVEITIS)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	3	1	(33.3)	2	(66.7)	1.8	*	*
ADALIMUMAB	4	1	(25.0)	3	(75.0)	*	*	*
TOTAL	7	2	(28.6)	5	(71.4)	1.8	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.16.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	8	3	(37.5)	5	(62.5)	3.5	6.2	6.2
ADALIMUMAB	5	2	(40.0)	3	(60.0)	6.3	11.2	11.2
TOTAL	13	5	(38.5)	8	(61.5)	6.2	6.2	11.2

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.16.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=VOGT KOYANAGI HARADA)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	10	0		10	(100)	*	*	*
ADALIMUMAB	7	0		7	(100)	*	*	*
TOTAL	17	0		17	(100)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.17.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	3	2	(66.7)	1	(33.3)	1.9	2.8	3.7
ADALIMUMAB	7	2	(28.6)	5	(71.4)	6.2	6.2	*
TOTAL	10	4	(40.0)	6	(60.0)	3.7	6.2	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.17.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=SARCOID)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	7	1	(14.3)	6	(85.7)	4.5	*	*
ADALIMUMAB	9	1	(11.1)	8	(88.9)	*	*	*
TOTAL	16	2	(12.5)	14	(87.5)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.18.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	2	0		2	(100)	*	*	*
ADALIMUMAB	7	4	(57.1)	3	(42.9)	1.4	15.7	*
TOTAL	9	4	(44.4)	5	(55.6)	2.6	15.7	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.18.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DIAGNOSIS=BEHCET'S)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	4	2	(50.0)	2	(50.0)	2.0	3.7	*
ADALIMUMAB	9	1	(11.1)	8	(88.9)	*	*	*
TOTAL	13	3	(23.1)	10	(76.9)	3.7	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.19.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)

TREATMENT	N	EVIDENCE OF EDEMA N	EVIDENCE OF EDEMA (%)	CENSORED N	CENSORED (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	11	5	(45.5)	6	(54.5)	1.0	6.2	*
ADALIMUMAB	12	9	(75.0)	3	(25.0)	1.4	2.8	9.2
TOTAL	23	14	(60.9)	9	(39.1)	1.4	6.2	15.9

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.19.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=1)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	16	0		16	(100)	*	*	*
ADALIMUMAB	11	2	(18.2)	9	(81.8)	9.5	*	*
TOTAL	27	2	(7.4)	25	(92.6)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.20.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	20	11	(55.0)	9	(45.0)	1.2	2.8	9.0			
ADALIMUMAB	27	9	(33.3)	18	(66.7)	5.6	15.7	*			
TOTAL	47	20	(42.6)	27	(57.4)	1.4	9.0	15.7	0.38	(0.15, 0.97)	0.036

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.20.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS=2)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	32	9	(28.1)	23	(71.9)	3.7	5.6	*				
ADALIMUMAB	33	3	(9.1)	30	(90.9)	*	*	*				
TOTAL	65	12	(18.5)	53	(81.5)	5.6	*	*	0.19	(0.05,	0.73)	0.008

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.21.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	16	7	(43.8)	9	(56.3)	1.4	2.9	*
ADALIMUMAB	18	7	(38.9)	11	(61.1)	2.7	11.1	*
TOTAL	34	14	(41.2)	20	(58.8)	2.6	11.1	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.21.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: NUMBER OF UVEITIS FLARES IN THE PAST 12 MONTHS>=3)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	26	4	(15.4)	22	(84.6)	10.9	*	*			
ADALIMUMAB	30	2	(6.7)	28	(93.3)	*	*	*			
TOTAL	56	6	(10.7)	50	(89.3)	*	*	*	0.40	(0.07, 2.19)	0.271

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.22.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	23	9	(39.1)	14	(60.9)	1.4	*	*			
ADALIMUMAB	32	11	(34.4)	21	(65.6)	2.8	11.2	*			
TOTAL	55	20	(36.4)	35	(63.6)	2.6	11.1	*	0.62	(0.25, 1.54)	0.297

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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 14.2__1000.3.1.1.22.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE < 6 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	35	5	(14.3)	30	(85.7)	5.6	10.9	*				
ADALIMUMAB	42	2	(4.8)	40	(95.2)	*	*	*				
TOTAL	77	7	(9.1)	70	(90.9)	*	*	*	0.19	(0.04,	1.02)	0.033

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.23.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	23	14	(60.9)	9	(39.1)	1.0	2.9	9.0			
ADALIMUMAB	25	14	(56.0)	11	(44.0)	1.4	8.8	15.7			
TOTAL	48	28	(58.3)	20	(41.7)	1.4	4.6	15.7	0.76	(0.36, 1.61)	0.471

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.23.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TIME SINCE LAST FLARE >= 6 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	38	8	(21.1)	30	(78.9)	3.7	*	*			
ADALIMUMAB	32	5	(15.6)	27	(84.4)	10.4	*	*			
TOTAL	70	13	(18.6)	57	(81.4)	9.5	*	*	0.55	(0.18, 1.71)	0.295

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.24.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	35	17	(48.6)	18	(51.4)	1.4	3.7	*			
ADALIMUMAB	41	18	(43.9)	23	(56.1)	2.8	9.2	15.7			
TOTAL	76	35	(46.1)	41	(53.9)	1.9	8.8	15.7	0.65	(0.33, 1.27)	0.202

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.24.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE < 15 MG/DAY)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	57	7	(12.3)	50	(87.7)	*	*	*			
ADALIMUMAB	56	6	(10.7)	50	(89.3)	*	*	*			
TOTAL	113	13	(11.5)	100	(88.5)	*	*	*	0.55	(0.18, 1.72)	0.302

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.25.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	3	2	(66.7)	1	(33.3)	1.9	2.8	*
ADALIMUMAB	9	4	(44.4)	5	(55.6)	1.4	2.7	*
TOTAL	12	6	(50.0)	6	(50.0)	1.4	2.8	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.25.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 15 to < 30 MG/DAY)

TREATMENT	N	EVIDENCE OF EDEMA N	EVIDENCE OF EDEMA (%)	CENSORED N	CENSORED (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	4	3	(75.0)	1	(25.0)	3.3	4.6	*
ADALIMUMAB	9	1	(11.1)	8	(88.9)	*	*	*
TOTAL	13	4	(30.8)	9	(69.2)	3.7	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.26.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	8	4	(50.0)	4	(50.0)	0.8	2.7	*
ADALIMUMAB	7	3	(42.9)	4	(57.1)	2.6	15.9	*
TOTAL	15	7	(46.7)	8	(53.3)	0.9	15.9	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.26.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PREDNISONE DOSE AT LAST FLARE >= 30 MG/DAY)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	12	3	(25.0)	9	(75.0)	5.0	10.9	*
ADALIMUMAB	9	0		9	(100)	*	*	*
TOTAL	21	3	(14.3)	18	(85.7)	10.9	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.27.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	29	13	(44.8)	16	(55.2)	1.4	6.2	*				
ADALIMUMAB	38	18	(47.4)	20	(52.6)	2.7	9.2	15.7				
TOTAL	67	31	(46.3)	36	(53.7)	1.9	6.2	15.7	0.66	(0.32,	1.38)	0.264

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.27.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 60 DAYS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	44	5	(11.4)	39	(88.6)	5.6	*	*			
ADALIMUMAB	49	5	(10.2)	44	(89.8)	*	*	*			
TOTAL	93	10	(10.8)	83	(89.2)	*	*	*	0.43	(0.12, 1.63)	0.206

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.28.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	18	10	(55.6)	8	(44.4)	1.1	3.7	*
ADALIMUMAB	19	7	(36.8)	12	(63.2)	1.4	15.9	15.9
TOTAL	37	17	(45.9)	20	(54.1)	1.4	9.0	15.9

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.28.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >= 60 DAYS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	30	8	(26.7)	22	(73.3)	3.7	*	*			
ADALIMUMAB	25	2	(8.0)	23	(92.0)	*	*	*			
TOTAL	55	10	(18.2)	45	(81.8)	10.9	*	*	0.27	(0.06, 1.29)	0.080

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.29.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	16	6	(37.5)	10	(62.5)	2.1	6.2	*
ADALIMUMAB	21	9	(42.9)	12	(57.1)	6.2	9.2	15.7
TOTAL	37	15	(40.5)	22	(59.5)	2.7	8.8	11.1

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.29.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE < 1 MONTH AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	22	3	(13.6)	19	(86.4)	5.0	*	*			
ADALIMUMAB	27	2	(7.4)	25	(92.6)	*	*	*			
TOTAL	49	5	(10.2)	44	(89.8)	9.5	*	*	0.28	(0.04, 1.82)	0.161

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.30.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	14	7	(50.0)	7	(50.0)	1.4	*	*
ADALIMUMAB	17	9	(52.9)	8	(47.1)	1.9	5.6	*
TOTAL	31	16	(51.6)	15	(48.4)	1.4	5.6	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.30.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=1 to < 2 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	23	2	(8.7)	21	(91.3)	5.6	*	*			
ADALIMUMAB	22	3	(13.6)	19	(86.4)	*	*	*			
TOTAL	45	5	(11.1)	40	(88.9)	*	*	*	0.84	(0.12, 5.88)	0.864

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.31.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	9	5	(55.6)	4	(44.4)	1.1	6.4	*
ADALIMUMAB	9	3	(33.3)	6	(66.7)	1.4	*	*
TOTAL	18	8	(44.4)	10	(55.6)	1.1	9.0	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.31.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=2 to < 3 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	12	2	(16.7)	10	(83.3)	10.9	*	*
ADALIMUMAB	12	1	(8.3)	11	(91.7)	*	*	*
TOTAL	24	3	(12.5)	21	(87.5)	*	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.32.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	8	5	(62.5)	3	(37.5)	1.1	2.8	*
ADALIMUMAB	10	4	(40.0)	6	(60.0)	4.6	15.9	15.9
TOTAL	18	9	(50.0)	9	(50.0)	1.9	4.6	15.9

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.32.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: DURATION OF CURRENT FLARE >=3 MONTHS AT BASELINE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	17	6	(35.3)	11	(64.7)	3.3	5.6	*
ADALIMUMAB	13	1	(7.7)	12	(92.3)	*	*	*
TOTAL	30	7	(23.3)	23	(76.7)	3.7	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.33.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=YES)

TREATMENT	N	EVIDENCE OF EDEMA N (%)	CENSORED N (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	0					
ADALIMUMAB	0					
TOTAL	0					

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.33.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=YES)

TREATMENT	N	EVIDENCE OF EDEMA N (%)	CENSORED N (%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	0					
ADALIMUMAB	0					
TOTAL	0					

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.34.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA AT BASELINE=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	47	23	(48.9)	24	(51.1)	1.4	3.7	*				
ADALIMUMAB	57	25	(43.9)	32	(56.1)	2.7	9.2	15.9				
TOTAL	104	48	(46.2)	56	(53.8)	1.9	8.8	15.9	0.67	(0.38,	1.19)	0.169

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.34.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: OCT EVIDENCE OF MACULAR EDEMA BASED ON CRT AT BASELINE=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	74	13	(17.6)	61	(82.4)	5.6	*	*				
ADALIMUMAB	74	7	(9.5)	67	(90.5)	*	*	*				
TOTAL	148	20	(13.5)	128	(86.5)	10.9	*	*	0.35	(0.14,	0.91)	0.025

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.35.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	12	5	(41.7)	7	(58.3)	1.1	*	*
ADALIMUMAB	14	8	(57.1)	6	(42.9)	1.4	11.2	15.7
TOTAL	26	13	(50.0)	13	(50.0)	1.3	11.2	15.7

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.35.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=YES)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	23	4	(17.4)	19	(82.6)	7.3	*	*			
ADALIMUMAB	19	1	(5.3)	18	(94.7)	*	*	*			
TOTAL	42	5	(11.9)	37	(88.1)	*	*	*	0.20	(0.02, 1.87)	0.123

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.36.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	35	18	(51.4)	17	(48.6)	1.4	2.9	9.0				
ADALIMUMAB	43	17	(39.5)	26	(60.5)	2.8	9.2	*				
TOTAL	78	35	(44.9)	43	(55.1)	2.6	6.2	15.9	0.46	(0.23,	0.92)	0.025

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.36.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: IMM USAGE AT BASELINE=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	51	9	(17.6)	42	(82.4)	5.6	*	*			
ADALIMUMAB	55	6	(10.9)	49	(89.1)	*	*	*			
TOTAL	106	15	(14.2)	91	(85.8)	10.4	*	*	0.43	(0.15, 1.23)	0.106

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.37.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	19	10	(52.6)	9	(47.4)	1.1	1.9	*
ADALIMUMAB	14	5	(35.7)	9	(64.3)	2.6	5.6	*
TOTAL	33	15	(45.5)	18	(54.5)	1.4	2.8	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.37.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=YES)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	28	2	(7.1)	26	(92.9)	*	*	*			
ADALIMUMAB	23	2	(8.7)	21	(91.3)	*	*	*			
TOTAL	51	4	(7.8)	47	(92.2)	*	*	*	0.93	(0.13, 6.69)	0.942

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.38.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	28	13	(46.4)	15	(53.6)	2.1	6.2	*			
ADALIMUMAB	43	20	(46.5)	23	(53.5)	2.7	11.1	15.9			
TOTAL	71	33	(46.5)	38	(53.5)	2.7	9.0	15.9	0.79	(0.39, 1.60)	0.509

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.38.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: TOPICAL STEROIDS AT BASELINE=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	46	11	(23.9)	35	(76.1)	4.5	*	*				
ADALIMUMAB	51	5	(9.8)	46	(90.2)	*	*	*				
TOTAL	97	16	(16.5)	81	(83.5)	10.9	*	*	0.28	(0.10,	0.82)	0.014

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.39.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	1	1	(100)	0		1.4	1.4	1.4
ADALIMUMAB	1	0		1	(100)	*	*	*
TOTAL	2	1	(50.0)	1	(50.0)	1.4	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.39.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=YES)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH
PLACEBO	2	1	(50.0)	1	(50.0)	1.9	1.9	1.9
ADALIMUMAB	1	0		1	(100)	*	*	*
TOTAL	3	1	(33.3)	2	(66.7)	1.9	*	*

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.40.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	46	22	(47.8)	24	(52.2)	1.4	3.7	*			
ADALIMUMAB	56	25	(44.6)	31	(55.4)	2.6	9.2	15.9			
TOTAL	102	47	(46.1)	55	(53.9)	1.9	8.8	15.9	0.72	(0.41, 1.29)	0.267

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.40.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: PROTOCOL DEVIATION 'WRONG TREATMENT/INCORRECT DOSE REGARDING PREDNISONE'=NO)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	72	12	(16.7)	60	(83.3)	5.6	*	*			
ADALIMUMAB	73	7	(9.6)	66	(90.4)	*	*	*			
TOTAL	145	19	(13.1)	126	(86.9)	10.9	*	*	0.38	(0.15, 1.00)	0.042

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.41.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	20	12	(60.0)	8	(40.0)	1.1	2.7	6.2				
ADALIMUMAB	20	10	(50.0)	10	(50.0)	4.6	8.8	15.9				
TOTAL	40	22	(55.0)	18	(45.0)	1.4	5.6	9.2	0.40	(0.15,	1.03)	0.049

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.41.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=NORTH AMERICA)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#		P-VALUE@
PLACEBO	35	10	(28.6)	25	(71.4)	4.5	10.9	*				
ADALIMUMAB	28	1	(3.6)	27	(96.4)	*	*	*				
TOTAL	63	11	(17.5)	52	(82.5)	9.5	*	*	0.07	(0.01,	0.54)	0.001

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.42.I

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	19	6	(31.6)	13	(68.4)	3.7	9.0	*			
ADALIMUMAB	28	11	(39.3)	17	(60.7)	1.9	11.2	*			
TOTAL	47	17	(36.2)	30	(63.8)	1.9	11.2	*	1.06	(0.39, 2.87)	0.910

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.3.1.1.42.I.PH

TIME TO OCT EVIDENCE OF MACULAR EDEMA AT OR AFTER WEEK 6 - BASED ON CRT (WITHOUT MACULAR HOLE AND/OR RETINAL DETACHMENT)
ALL SUBJECTS INCLUDING JAPAN (STUDY M10-877, ONLY IN SUBJECTS WITHOUT MACULAR EDEMA BASED ON CRT AT BASELINE)
(INTENT-TO-TREAT ANALYSIS SET, SUBGROUP: GEOGRAPHIC REGION=WESTERN AND EASTERN EUROPE)

TREATMENT	N	EVIDENCE OF EDEMA N	(%)	CENSORED N	(%)	TIME TO MACULAR EDEMA (MONTHS) 25TH	MEDIAN	75TH	HAZARD RATIO$	CI 95%#	P-VALUE@
PLACEBO	28	2	(7.1)	26	(92.9)	*	*	*			
ADALIMUMAB	33	4	(12.1)	29	(87.9)	*	*	*			
TOTAL	61	6	(9.8)	55	(90.2)	*	*	*	1.38	(0.25, 7.72)	0.714

NOTE: OCCURENCE OF MACULA EDEMA AT OR AFTER WEEK 6 WAS COUNTED AS EVENT. DROP OUTS DUE TO REASONS OTHER THAN MACULA EDEMA AT OR AFTER WEEK 6 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	44	69.89	20.587	25.0	50.00	75.00	75.00	100.0			
	ADA	48	66.15	22.767	25.0	50.00	75.00	75.00	100.0			
	TOT	92	67.93	21.714	25.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	44	53.98	24.674	0.0	37.50	50.00	75.00	100.0			
	ADA	48	59.90	22.913	0.0	50.00	50.00	75.00	100.0			
	TOT	92	57.07	23.826	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	44	-15.91	18.748	-50.0	-25.00	-25.00	0.00	25.0			
	ADA	48	-6.25	26.042	-100.0	-25.00	0.00	0.00	50.0			
	TOT	92	-10.87	23.236	-100.0	-25.00	0.00	0.00	50.0			
										9.66	(0.18, 19.13)	0.046A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	44	73.18	16.106	40.0	60.00	80.00	80.00	100.0			
	ADA	47	71.91	13.616	40.0	60.00	80.00	80.00	100.0			
	TOT	91	72.53	14.802	40.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	44	64.55	19.702	20.0	40.00	60.00	80.00	100.0			
	ADA	47	70.43	17.315	20.0	60.00	80.00	80.00	100.0			
	TOT	91	67.58	18.639	20.0	60.00	80.00	80.00	100.0			
CHG FROM BEST*	PLO	44	-8.64	18.997	-60.0	-20.00	0.00	0.00	20.0			
	ADA	47	-1.49	15.877	-40.0	-20.00	0.00	0.00	30.0			
	TOT	91	-4.95	17.725	-60.0	-20.00	0.00	0.00	30.0			
										7.15	(-0.13, 14.42)	0.054A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	44	90.06	13.091	50.0	81.25	100.00	100.00	100.0			
	ADA	48	87.50	14.357	50.0	75.00	87.50	100.00	100.0			
	TOT	92	88.72	13.751	50.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	44	77.56	21.326	25.0	62.50	75.00	100.00	100.0			
	ADA	48	83.33	17.927	50.0	75.00	87.50	100.00	100.0			
	TOT	92	80.57	19.731	25.0	62.50	87.50	100.00	100.0			
CHG FROM BEST*	PLO	44	-12.50	14.265	-50.0	-25.00	-12.50	0.00	0.0			
	ADA	48	-4.17	12.720	-37.5	-12.50	0.00	0.00	25.0			
	TOT	92	-8.15	14.044	-50.0	-12.50	0.00	0.00	25.0			
										8.33	(2.74, 13.92)	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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	44	79.17	19.892	25.0	66.67	83.33	100.00	100.0			
	ADA	48	80.56	21.970	25.0	70.83	83.33	100.00	100.0			
	TOT	92	79.89	20.898	25.0	66.67	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	44	74.53	21.794	25.0	58.33	79.17	91.67	100.0			
	ADA	48	77.52	22.044	25.0	58.33	83.33	100.00	100.0			
	TOT	92	76.09	21.856	25.0	58.33	83.33	100.00	100.0			
CHG FROM BEST*	PLO	44	-4.64	18.044	-58.3	-14.58	0.00	0.00	41.7			
	ADA	48	-3.04	12.799	-33.3	-8.33	0.00	0.00	25.0			
	TOT	92	-3.80	15.463	-58.3	-10.42	0.00	0.00	41.7			
										1.60	(-4.84, 8.04)	0.622A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	44	83.52	17.190	33.3	75.00	91.67	100.00	100.0			
	ADA	48	81.25	20.736	33.3	66.67	91.67	100.00	100.0			
	TOT	92	82.34	19.053	33.3	70.83	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	44	79.92	21.515	25.0	70.83	87.50	100.00	100.0			
	ADA	48	79.69	21.602	25.0	66.67	83.33	100.00	100.0			
	TOT	92	79.80	21.442	25.0	66.67	83.33	100.00	100.0			
CHG FROM BEST*	PLO	44	-3.60	14.534	-50.0	-8.33	0.00	0.00	41.7			
	ADA	48	-1.56	9.824	-25.0	-8.33	0.00	0.00	25.0			
	TOT	92	-2.54	12.276	-50.0	-8.33	0.00	0.00	41.7			
										2.04	(-3.06, 7.14)	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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	44	90.34	17.443	37.5	87.50	100.00	100.00	100.0			
	ADA	48	92.97	14.565	37.5	93.75	100.00	100.00	100.0			
	TOT	92	91.71	15.971	37.5	87.50	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	44	85.23	21.946	12.5	75.00	100.00	100.00	100.0			
	ADA	48	90.36	16.559	37.5	87.50	100.00	100.00	100.0			
	TOT	92	87.91	19.387	12.5	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	44	-5.11	15.561	-62.5	-12.50	0.00	0.00	37.5			
	ADA	48	-2.60	9.282	-50.0	0.00	0.00	0.00	12.5			
	TOT	92	-3.80	12.669	-62.5	0.00	0.00	0.00	37.5			
										2.51	(-2.75, 7.77)	0.345A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	44	75.14	22.775	6.3	68.75	78.13	93.75	100.0			
	ADA	48	72.79	20.118	25.0	56.25	81.25	87.50	100.0			
	TOT	92	73.91	21.343	6.3	62.50	81.25	87.50	100.0			
FINAL/ET VALUE	PLO	44	69.32	26.545	0.0	56.25	75.00	93.75	100.0			
	ADA	48	73.18	22.142	25.0	56.25	75.00	93.75	100.0			
	TOT	92	71.33	24.289	0.0	56.25	75.00	93.75	100.0			
CHG FROM BEST*	PLO	44	-5.82	18.842	-75.0	-9.38	-3.13	6.25	31.3			
	ADA	48	0.39	15.600	-62.5	-6.25	0.00	9.38	43.8			
	TOT	92	-2.58	17.412	-75.0	-6.25	0.00	6.25	43.8			
										6.21	(-0.93, 13.36)	0.087A

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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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	44	78.98	22.193	25.0	62.50	87.50	100.00	100.0			
	ADA	48	78.65	23.057	12.5	62.50	87.50	100.00	100.0			
	TOT	92	78.80	22.524	12.5	62.50	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	44	72.44	28.220	0.0	50.00	75.00	100.00	100.0			
	ADA	48	78.13	25.461	0.0	62.50	87.50	100.00	100.0			
	TOT	92	75.41	26.819	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	44	-6.53	19.900	-62.5	-12.50	0.00	0.00	50.0			
	ADA	48	-0.52	18.765	-50.0	-6.25	0.00	0.00	37.5			
	TOT	92	-3.40	19.445	-62.5	-12.50	0.00	0.00	50.0			
										6.01	(-2.00, 14.02)	0.139A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	44	86.93	23.460	0.0	83.33	100.00	100.00	100.0			
	ADA	48	89.41	17.843	25.0	83.33	100.00	100.00	100.0			
	TOT	92	88.22	20.641	0.0	83.33	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	44	81.25	26.906	0.0	66.67	91.67	100.00	100.0			
	ADA	48	88.02	18.666	41.7	79.17	100.00	100.00	100.0			
	TOT	92	84.78	23.100	0.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	44	-5.68	14.352	-66.7	-8.33	0.00	0.00	16.7			
	ADA	48	-1.39	13.241	-50.0	0.00	0.00	0.00	33.3			
	TOT	92	-3.44	13.876	-66.7	-4.17	0.00	0.00	33.3			
										4.29	(-1.42, 10.01)	0.139A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	43	78.49	28.593	0.0	75.00	83.33	100.00	100.0			
	ADA	48	75.69	28.641	0.0	62.50	83.33	100.00	100.0			
	TOT	91	77.01	28.493	0.0	75.00	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	43	71.51	27.291	0.0	58.33	83.33	91.67	100.0			
	ADA	48	71.27	27.467	0.0	58.33	75.00	91.67	100.0			
	TOT	91	71.38	27.232	0.0	58.33	75.00	91.67	100.0			
CHG FROM BEST*	PLO	43	-6.98	22.925	-75.0	-16.67	0.00	0.00	50.0			
	ADA	48	-4.43	13.271	-41.7	-10.42	0.00	0.00	50.0			
	TOT	91	-5.63	18.409	-75.0	-16.67	0.00	0.00	50.0			
										2.55	(-5.16, 10.25)	0.513A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	44	92.61	14.844	50.0	100.00	100.00	100.00	100.0			
	ADA	48	95.83	9.416	75.0	100.00	100.00	100.00	100.0			
	TOT	92	94.29	12.350	50.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	44	90.34	16.368	50.0	75.00	100.00	100.00	100.0			
	ADA	48	90.63	17.583	25.0	75.00	100.00	100.00	100.0			
	TOT	92	90.49	16.920	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	44	-2.27	11.835	-50.0	0.00	0.00	0.00	25.0			
	ADA	48	-5.21	16.274	-75.0	0.00	0.00	0.00	25.0			
	TOT	92	-3.80	14.323	-75.0	0.00	0.00	0.00	25.0			
										-2.94	(-8.88, 3.00)	0.329A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	44	83.52	22.839	25.0	75.00	100.00	100.00	100.0			
	ADA	47	84.04	22.975	25.0	75.00	100.00	100.00	100.0			
	TOT	91	83.79	22.783	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	44	77.27	25.184	0.0	75.00	75.00	100.00	100.0			
	ADA	47	81.38	25.786	25.0	75.00	100.00	100.00	100.0			
	TOT	91	79.40	25.439	0.0	75.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	44	-6.25	18.774	-75.0	-12.50	0.00	0.00	50.0			
	ADA	47	-2.66	14.021	-50.0	0.00	0.00	0.00	25.0			
	TOT	91	-4.40	16.496	-75.0	0.00	0.00	0.00	50.0			
										3.59	(-3.28, 10.46)	0.302A

* 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__1000.4.1.1.1.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: GENDER=MALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	44	81.51	15.931	39.2	73.64	86.33	94.20	98.7			
	ADA	48	80.94	16.732	35.6	70.23	86.38	93.92	100.0			
	TOT	92	81.21	16.266	35.6	70.61	86.33	94.20	100.0			
FINAL/ET VALUE	PLO	44	76.57	18.635	30.5	63.86	82.54	91.93	100.0			
	ADA	48	80.23	17.398	40.6	65.68	85.28	94.66	99.4			
	TOT	92	78.48	17.995	30.5	64.41	84.20	93.92	100.0			
CHG FROM BEST*	PLO	44	-4.94	12.625	-44.4	-8.50	-1.61	1.76	20.6			
	ADA	48	-0.71	8.298	-26.4	-4.13	-0.72	2.39	25.8			
	TOT	92	-2.73	10.743	-44.4	-5.08	-1.23	1.95	25.8			
										4.23	(-0.16, 8.62)	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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	66	60.61	24.043	0.0	50.00	50.00	75.00	100.0			
	ADA	61	61.07	17.984	25.0	50.00	50.00	75.00	100.0			
	TOT	127	60.83	21.267	0.0	50.00	50.00	75.00	100.0			
FINAL/ET VALUE	PLO	66	46.21	28.502	0.0	25.00	50.00	75.00	100.0			
	ADA	61	50.00	22.822	0.0	50.00	50.00	75.00	100.0			
	TOT	127	48.03	25.898	0.0	25.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	66	-14.39	23.230	-100.0	-25.00	0.00	0.00	25.0			
	ADA	61	-11.07	21.662	-75.0	-25.00	0.00	0.00	25.0			
	TOT	127	-12.80	22.464	-100.0	-25.00	0.00	0.00	25.0			
										3.33	(-4.58, 11.23)	0.406A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	66	70.61	14.975	40.0	60.00	80.00	80.00	100.0			
	ADA	61	67.38	15.265	20.0	60.00	60.00	80.00	100.0			
	TOT	127	69.06	15.141	20.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	66	60.00	21.626	20.0	40.00	60.00	80.00	100.0			
	ADA	61	60.66	19.653	20.0	40.00	60.00	80.00	100.0			
	TOT	127	60.31	20.623	20.0	40.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	66	-10.61	17.964	-60.0	-20.00	0.00	0.00	20.0			
	ADA	61	-6.72	17.197	-60.0	-20.00	0.00	0.00	40.0			
	TOT	127	-8.74	17.638	-60.0	-20.00	0.00	0.00	40.0			
										3.88	(-2.30, 10.07)	0.216A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	66	81.44	17.299	37.5	75.00	87.50	100.00	100.0			
	ADA	61	81.35	19.846	25.0	62.50	87.50	100.00	100.0			
	TOT	127	81.40	18.491	25.0	62.50	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	66	69.13	25.685	12.5	50.00	75.00	87.50	100.0			
	ADA	61	78.28	21.518	25.0	62.50	75.00	100.00	100.0			
	TOT	127	73.52	24.122	12.5	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	66	-12.31	24.366	-87.5	-25.00	0.00	0.00	25.0			
	ADA	61	-3.07	18.351	-75.0	-12.50	0.00	0.00	37.5			
	TOT	127	-7.87	22.093	-87.5	-12.50	0.00	0.00	37.5			
										9.24	(1.61, 16.86)	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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	66	73.55	21.164	16.7	58.33	75.00	91.67	100.0			
	ADA	61	68.92	23.540	16.7	50.00	75.00	91.67	100.0			
	TOT	127	71.33	22.368	16.7	50.00	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	66	63.89	27.632	8.3	33.33	66.67	91.67	100.0			
	ADA	61	65.03	24.430	16.7	41.67	66.67	83.33	100.0			
	TOT	127	64.44	26.046	8.3	41.67	66.67	83.33	100.0			
CHG FROM BEST*	PLO	66	-9.66	17.498	-66.7	-16.67	-8.33	0.00	33.3			
	ADA	61	-3.89	19.001	-66.7	-8.33	0.00	0.00	50.0			
	TOT	127	-6.89	18.391	-66.7	-8.33	0.00	0.00	50.0			
										5.77	(-0.64, 12.18)	0.077A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	66	71.65	22.111	16.7	58.33	75.00	91.67	100.0			
	ADA	61	70.22	22.046	12.5	58.33	75.00	91.67	100.0			
	TOT	127	70.96	22.004	12.5	58.33	75.00	91.67	100.0			
FINAL/ET VALUE	PLO	66	64.52	27.747	8.3	41.67	68.75	83.33	100.0			
	ADA	61	63.56	26.244	16.7	33.33	66.67	83.33	100.0			
	TOT	127	64.06	26.933	8.3	41.67	66.67	83.33	100.0			
CHG FROM BEST*	PLO	66	-7.13	14.466	-50.0	-16.67	-8.33	0.00	25.0			
	ADA	61	-6.66	16.096	-66.7	-8.33	0.00	0.00	16.7			
	TOT	127	-6.91	15.212	-66.7	-16.67	-8.33	0.00	25.0			
										0.47	(-4.89, 5.84)	0.862A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	66	87.31	18.409	25.0	75.00	100.00	100.00	100.0			
	ADA	61	84.02	20.933	25.0	75.00	100.00	100.00	100.0			
	TOT	127	85.73	19.653	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	66	79.73	25.073	12.5	75.00	87.50	100.00	100.0			
	ADA	61	76.95	24.301	12.5	62.50	87.50	100.00	100.0			
	TOT	127	78.40	24.647	12.5	62.50	87.50	100.00	100.0			
CHG FROM BEST*	PLO	66	-7.58	15.793	-50.0	-12.50	0.00	0.00	25.0			
	ADA	61	-7.07	15.029	-50.0	-12.50	0.00	0.00	37.5			
	TOT	127	-7.33	15.372	-50.0	-12.50	0.00	0.00	37.5			
										0.51	(-4.92, 5.93)	0.854A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	66	64.77	24.603	0.0	50.00	68.75	87.50	100.0			
	ADA	61	62.74	25.362	0.0	43.75	62.50	83.33	100.0			
	TOT	127	63.80	24.892	0.0	43.75	68.75	87.50	100.0			
FINAL/ET VALUE	PLO	66	59.85	30.174	0.0	31.25	62.50	87.50	100.0			
	ADA	61	61.85	28.238	0.0	37.50	68.75	81.25	100.0			
	TOT	127	60.81	29.162	0.0	37.50	66.67	87.50	100.0			
CHG FROM BEST*	PLO	66	-4.92	17.868	-58.3	-12.50	0.00	6.25	25.0			
	ADA	61	-0.89	17.449	-43.8	-6.25	0.00	6.25	31.3			
	TOT	127	-2.99	17.714	-58.3	-12.50	0.00	6.25	31.3			
										4.04	(-2.17, 10.25)	0.201A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	66	67.99	28.005	12.5	50.00	75.00	100.00	100.0			
	ADA	61	64.55	26.238	0.0	50.00	62.50	87.50	100.0			
	TOT	127	66.34	27.118	0.0	50.00	62.50	100.00	100.0			
FINAL/ET VALUE	PLO	66	58.52	30.631	0.0	37.50	62.50	75.00	100.0			
	ADA	61	59.02	32.205	0.0	37.50	62.50	87.50	100.0			
	TOT	127	58.76	31.272	0.0	37.50	62.50	87.50	100.0			
CHG FROM BEST*	PLO	66	-9.47	19.372	-75.0	-25.00	0.00	0.00	37.5			
	ADA	61	-5.53	26.957	-87.5	-12.50	0.00	12.50	50.0			
	TOT	127	-7.58	23.314	-87.5	-25.00	0.00	0.00	50.0			
										3.94	(-4.26, 12.14)	0.344A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	66	79.17	25.747	0.0	58.33	91.67	100.00	100.0			
	ADA	61	76.64	28.047	0.0	58.33	83.33	100.00	100.0			
	TOT	127	77.95	26.799	0.0	58.33	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	66	69.89	32.578	0.0	50.00	83.33	100.00	100.0			
	ADA	61	72.27	31.940	0.0	50.00	83.33	100.00	100.0			
	TOT	127	71.03	32.167	0.0	50.00	83.33	100.00	100.0			
CHG FROM BEST*	PLO	66	-9.28	21.960	-75.0	-25.00	0.00	0.00	50.0			
	ADA	61	-4.37	21.279	-75.0	-16.67	0.00	0.00	58.3			
	TOT	127	-6.92	21.690	-75.0	-16.67	0.00	0.00	58.3			
										4.91	(-2.70, 12.51)	0.204A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	56	58.85	30.506	0.0	41.67	64.58	83.33	100.0			
	ADA	51	58.33	28.529	0.0	41.67	58.33	83.33	100.0			
	TOT	107	58.61	29.442	0.0	41.67	62.50	83.33	100.0			
FINAL/ET VALUE	PLO	56	47.99	34.433	0.0	16.67	50.00	79.17	100.0			
	ADA	51	53.43	33.960	0.0	25.00	58.33	83.33	100.0			
	TOT	107	50.58	34.156	0.0	16.67	58.33	83.33	100.0			
CHG FROM BEST*	PLO	56	-10.86	18.373	-58.3	-20.83	-8.33	0.00	33.3			
	ADA	51	-4.90	17.887	-66.7	-8.33	0.00	8.33	33.3			
	TOT	107	-8.02	18.303	-66.7	-16.67	0.00	0.00	33.3			
										5.96	(-1.00, 12.92)	0.093A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	66	95.45	10.660	50.0	100.00	100.00	100.00	100.0			
	ADA	61	91.39	15.059	25.0	75.00	100.00	100.00	100.0			
	TOT	127	93.50	13.068	25.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	66	92.23	16.374	25.0	100.00	100.00	100.00	100.0			
	ADA	61	88.52	17.425	50.0	75.00	100.00	100.00	100.0			
	TOT	127	90.45	16.922	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	66	-3.22	12.072	-50.0	0.00	0.00	0.00	25.0			
	ADA	61	-2.87	15.206	-50.0	0.00	0.00	0.00	25.0			
	TOT	127	-3.05	13.613	-50.0	0.00	0.00	0.00	25.0			
										0.35	(-4.45, 5.15)	0.885A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	66	78.22	22.394	25.0	62.50	75.00	100.00	100.0			
	ADA	61	77.05	23.846	25.0	75.00	75.00	100.00	100.0			
	TOT	127	77.66	23.018	25.0	62.50	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	66	73.11	24.927	25.0	50.00	75.00	100.00	100.0			
	ADA	61	68.85	24.856	25.0	50.00	75.00	100.00	100.0			
	TOT	127	71.06	24.886	25.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	66	-5.11	15.028	-50.0	-25.00	0.00	0.00	50.0			
	ADA	61	-8.20	20.270	-50.0	-25.00	0.00	0.00	25.0			
	TOT	127	-6.59	17.736	-50.0	-25.00	0.00	0.00	50.0			
										-3.08	(-9.32, 3.15)	0.330A

* 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__1000.4.1.1.2.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: GENDER=FEMALE)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	66	73.22	17.882	25.7	58.94	73.09	88.71	98.3			
	ADA	61	70.51	18.071	14.7	58.67	71.17	87.20	99.4			
	TOT	127	71.92	17.953	14.7	58.67	72.33	88.42	99.4			
FINAL/ET VALUE	PLO	66	67.61	21.919	21.1	50.61	70.66	87.79	100.0			
	ADA	61	68.06	20.797	18.5	50.91	69.47	87.16	99.4			
	TOT	127	67.82	21.304	18.5	50.61	70.61	87.79	100.0			
CHG FROM BEST*	PLO	66	-5.61	11.480	-48.0	-12.01	-2.84	2.92	11.7			
	ADA	61	-2.44	12.630	-39.0	-7.08	0.00	4.17	16.5			
	TOT	127	-4.09	12.102	-48.0	-9.02	-1.14	3.48	16.5			
										3.17	(-1.06, 7.40)	0.141A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	22	75.00	25.588	25.0	50.00	75.00	100.00	100.0			
	ADA	20	61.25	20.639	25.0	50.00	50.00	75.00	100.0			
	TOT	42	68.45	24.106	25.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	22	64.77	26.344	25.0	50.00	75.00	75.00	100.0			
	ADA	20	62.50	17.206	25.0	50.00	62.50	75.00	100.0			
	TOT	42	63.69	22.226	25.0	50.00	75.00	75.00	100.0			
CHG FROM BEST*	PLO	22	-10.23	19.909	-50.0	-25.00	0.00	0.00	25.0			
	ADA	20	1.25	18.979	-50.0	0.00	0.00	0.00	50.0			
	TOT	42	-4.76	20.090	-50.0	-25.00	0.00	0.00	50.0			
										11.48	(-0.68, 23.64)	0.064A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	22	75.45	18.446	40.0	60.00	80.00	80.00	100.0			
	ADA	20	73.00	13.416	40.0	60.00	80.00	80.00	100.0			
	TOT	42	74.29	16.101	40.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	22	72.73	23.540	20.0	60.00	80.00	100.00	100.0			
	ADA	20	71.00	17.741	20.0	60.00	80.00	80.00	100.0			
	TOT	42	71.90	20.747	20.0	60.00	80.00	80.00	100.0			
CHG FROM BEST*	PLO	22	-2.73	17.777	-40.0	-20.00	0.00	0.00	20.0			
	ADA	20	-2.00	18.238	-60.0	0.00	0.00	0.00	40.0			
	TOT	42	-2.38	17.780	-60.0	0.00	0.00	0.00	40.0			
										0.73	(-10.51, 11.97)	0.897A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	22	90.34	14.399	62.5	75.00	100.00	100.00	100.0			
	ADA	20	81.25	21.267	25.0	62.50	87.50	100.00	100.0			
	TOT	42	86.01	18.355	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	22	77.27	25.482	12.5	62.50	87.50	100.00	100.0			
	ADA	20	78.75	21.877	25.0	62.50	81.25	100.00	100.0			
	TOT	42	77.98	23.557	12.5	62.50	87.50	100.00	100.0			
CHG FROM BEST*	PLO	22	-13.07	14.678	-50.0	-25.00	-12.50	0.00	12.5			
	ADA	20	-2.50	21.306	-75.0	0.00	0.00	0.00	37.5			
	TOT	42	-8.04	18.688	-75.0	-25.00	0.00	0.00	37.5			
										10.57	(-0.75, 21.89)	0.066A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	22	85.23	20.723	16.7	75.00	91.67	100.00	100.0			
	ADA	20	83.75	23.017	16.7	75.00	91.67	100.00	100.0			
	TOT	42	84.52	21.588	16.7	75.00	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	22	80.68	21.729	33.3	66.67	83.33	100.00	100.0			
	ADA	20	80.83	17.955	41.7	75.00	83.33	95.83	100.0			
	TOT	42	80.75	19.779	33.3	75.00	83.33	100.00	100.0			
CHG FROM BEST*	PLO	22	-4.55	13.044	-41.7	-8.33	0.00	0.00	16.7			
	ADA	20	-2.92	18.192	-50.0	-8.33	0.00	0.00	50.0			
	TOT	42	-3.77	15.531	-50.0	-8.33	0.00	0.00	50.0			
										1.63	(-8.18, 11.43)	0.739A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	22	89.39	15.036	41.7	83.33	91.67	100.00	100.0			
	ADA	20	79.58	21.025	33.3	58.33	87.50	100.00	100.0			
	TOT	42	84.72	18.581	33.3	75.00	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	22	84.85	20.835	33.3	75.00	95.83	100.00	100.0			
	ADA	20	78.75	22.044	25.0	70.83	83.33	100.00	100.0			
	TOT	42	81.94	21.378	25.0	75.00	91.67	100.00	100.0			
CHG FROM BEST*	PLO	22	-4.55	13.295	-50.0	-8.33	0.00	0.00	8.3			
	ADA	20	-0.83	10.781	-25.0	-8.33	0.00	0.00	25.0			
	TOT	42	-2.78	12.162	-50.0	-8.33	0.00	0.00	25.0			
										3.71	(-3.88, 11.31)	0.329A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	22	93.75	18.800	25.0	100.00	100.00	100.00	100.0			
	ADA	20	92.50	15.915	50.0	93.75	100.00	100.00	100.0			
	TOT	42	93.15	17.286	25.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	22	88.64	22.463	12.5	87.50	100.00	100.00	100.0			
	ADA	20	87.50	19.868	25.0	75.00	100.00	100.00	100.0			
	TOT	42	88.10	21.017	12.5	87.50	100.00	100.00	100.0			
CHG FROM BEST*	PLO	22	-5.11	15.265	-62.5	-12.50	0.00	0.00	25.0			
	ADA	20	-5.00	10.260	-25.0	-12.50	0.00	0.00	12.5			
	TOT	42	-5.06	12.967	-62.5	-12.50	0.00	0.00	25.0			
										0.11	(-8.08, 8.31)	0.978A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	22	75.57	26.014	0.0	75.00	81.25	93.75	100.0			
	ADA	20	71.25	22.434	25.0	56.25	81.25	87.50	93.8			
	TOT	42	73.51	24.179	0.0	68.75	81.25	87.50	100.0			
FINAL/ET VALUE	PLO	22	69.98	30.023	0.0	56.25	79.17	93.75	100.0			
	ADA	20	74.38	21.924	18.8	65.63	78.13	90.63	100.0			
	TOT	42	72.07	26.256	0.0	56.25	78.13	93.75	100.0			
CHG FROM BEST*	PLO	22	-5.59	17.172	-56.3	-18.75	0.00	6.25	18.8			
	ADA	20	3.13	9.830	-12.5	-3.13	0.00	9.38	25.0			
	TOT	42	-1.44	14.670	-56.3	-6.25	0.00	6.25	25.0			
										8.71	(-0.13, 17.56)	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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	22	82.95	24.258	12.5	75.00	100.00	100.00	100.0			
	ADA	20	72.50	30.779	0.0	50.00	87.50	100.00	100.0			
	TOT	42	77.98	27.719	0.0	50.00	93.75	100.00	100.0			
FINAL/ET VALUE	PLO	22	73.86	30.106	0.0	50.00	81.25	100.00	100.0			
	ADA	20	71.88	33.165	0.0	50.00	87.50	100.00	100.0			
	TOT	42	72.92	31.225	0.0	50.00	87.50	100.00	100.0			
CHG FROM BEST*	PLO	22	-9.09	15.031	-50.0	-12.50	0.00	0.00	12.5			
	ADA	20	-0.63	24.155	-87.5	0.00	0.00	0.00	37.5			
	TOT	42	-5.06	20.110	-87.5	-12.50	0.00	0.00	37.5			
										8.47	(-3.96, 20.89)	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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DEPENDENCY												
BEST VALUE*	PLO	22	86.74	27.658	0.0	91.67	100.00	100.00	100.0			
	ADA	20	78.75	29.676	0.0	62.50	100.00	100.00	100.0			
	TOT	42	82.94	28.570	0.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	22	80.30	30.488	0.0	66.67	100.00	100.00	100.0			
	ADA	20	78.33	31.807	0.0	62.50	95.83	100.00	100.0			
	TOT	42	79.37	30.756	0.0	66.67	100.00	100.00	100.0			
CHG FROM BEST*	PLO	22	-6.44	17.805	-66.7	0.00	0.00	0.00	8.3			
	ADA	20	-0.42	19.771	-33.3	-12.50	0.00	0.00	58.3			
	TOT	42	-3.57	18.783	-66.7	-8.33	0.00	0.00	58.3			
										6.02	(-5.69, 17.74)	0.305A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DRIVING												
BEST VALUE*	PLO	20	85.00	23.970	0.0	83.33	91.67	100.00	100.0			
	ADA	15	78.89	26.138	0.0	75.00	83.33	100.00	100.0			
	TOT	35	82.38	24.735	0.0	75.00	91.67	100.00	100.0			
FINAL/ET VALUE	PLO	20	77.50	28.498	0.0	66.67	83.33	100.00	100.0			
	ADA	15	73.06	28.819	0.0	58.33	83.33	100.00	100.0			
	TOT	35	75.60	28.298	0.0	58.33	83.33	100.00	100.0			
CHG FROM BEST*	PLO	20	-7.50	21.781	-58.3	-12.50	0.00	0.00	16.7			
	ADA	15	-5.83	15.574	-50.0	-8.33	0.00	0.00	12.5			
	TOT	35	-6.79	19.123	-58.3	-8.33	0.00	0.00	16.7			
										1.67	(-11.81, 15.14)	0.803A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
COLOR VISION												
BEST VALUE*	PLO	22	97.73	7.356	75.0	100.00	100.00	100.00	100.0			
	ADA	20	96.25	12.234	50.0	100.00	100.00	100.00	100.0			
	TOT	42	97.02	9.881	50.0	100.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	22	95.45	12.527	50.0	100.00	100.00	100.00	100.0			
	ADA	20	92.50	14.281	50.0	87.50	100.00	100.00	100.0			
	TOT	42	94.05	13.309	50.0	100.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	22	-2.27	7.356	-25.0	0.00	0.00	0.00	0.0			
	ADA	20	-3.75	12.234	-25.0	0.00	0.00	0.00	25.0			
	TOT	42	-2.98	9.881	-25.0	0.00	0.00	0.00	25.0			
										-1.48	(-7.71, 4.75)	0.634A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
PERIPHERAL VISION												
BEST VALUE*	PLO	22	89.77	19.909	25.0	75.00	100.00	100.00	100.0			
	ADA	20	81.25	21.267	25.0	75.00	75.00	100.00	100.0			
	TOT	42	85.71	20.765	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	22	85.23	23.978	25.0	75.00	100.00	100.00	100.0			
	ADA	20	83.75	23.333	25.0	75.00	100.00	100.00	100.0			
	TOT	42	84.52	23.395	25.0	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	22	-4.55	18.317	-75.0	0.00	0.00	0.00	25.0			
	ADA	20	2.50	13.813	-25.0	0.00	0.00	0.00	25.0			
	TOT	42	-1.19	16.521	-75.0	0.00	0.00	0.00	25.0			
										7.05	(-3.15, 17.24)	0.170A

* 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__1000.4.1.1.3.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: AGE < 30 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
TOTAL SCORE												
BEST VALUE*	PLO	22	85.40	17.890	25.7	84.05	91.72	95.61	98.7			
	ADA	20	78.90	18.848	31.5	69.65	84.92	94.39	99.4			
	TOT	42	82.31	18.422	25.7	72.05	90.02	95.23	99.4			
FINAL/ET VALUE	PLO	22	80.30	21.692	21.1	73.71	88.56	95.34	100.0			
	ADA	20	78.90	20.054	31.2	67.68	86.19	94.02	99.4			
	TOT	42	79.63	20.685	21.1	69.88	87.05	94.66	100.0			
CHG FROM BEST*	PLO	22	-5.11	11.401	-44.4	-9.58	-2.46	2.54	5.0			
	ADA	20	0.00	11.176	-39.0	-1.99	0.00	2.84	17.9			
	TOT	42	-2.67	11.451	-44.4	-6.33	-0.57	2.84	17.9			
										5.11	(-1.94, 12.16)	0.151A

* 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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL HEALTH												
BEST VALUE*	PLO	48	60.94	21.205	0.0	50.00	50.00	75.00	100.0			
	ADA	57	64.47	18.266	25.0	50.00	75.00	75.00	100.0			
	TOT	105	62.86	19.647	0.0	50.00	75.00	75.00	100.0			
FINAL/ET VALUE	PLO	48	45.83	24.372	0.0	25.00	50.00	62.50	100.0			
	ADA	57	56.14	23.755	0.0	50.00	50.00	75.00	100.0			
	TOT	105	51.43	24.472	0.0	50.00	50.00	75.00	100.0			
CHG FROM BEST*	PLO	48	-15.10	17.670	-50.0	-25.00	-25.00	0.00	25.0			
	ADA	57	-8.33	21.304	-75.0	-25.00	0.00	0.00	25.0			
	TOT	105	-11.43	19.924	-75.0	-25.00	0.00	0.00	25.0			
										6.77	(-0.89, 14.44)	0.083A

* 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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
GENERAL VISION												
BEST VALUE*	PLO	48	72.50	13.448	40.0	60.00	80.00	80.00	100.0			
	ADA	56	71.43	15.659	20.0	60.00	80.00	80.00	100.0			
	TOT	104	71.92	14.620	20.0	60.00	80.00	80.00	100.0			
FINAL/ET VALUE	PLO	48	59.58	18.214	20.0	40.00	60.00	80.00	80.0			
	ADA	56	66.43	19.857	20.0	60.00	70.00	80.00	100.0			
	TOT	104	63.27	19.331	20.0	60.00	60.00	80.00	100.0			
CHG FROM BEST*	PLO	48	-12.92	17.740	-60.0	-20.00	0.00	0.00	20.0			
	ADA	56	-5.00	16.733	-60.0	-20.00	0.00	0.00	20.0			
	TOT	104	-8.65	17.574	-60.0	-20.00	0.00	0.00	20.0			
										7.92	(1.20, 14.63)	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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
OCULAR PAIN												
BEST VALUE*	PLO	48	81.51	16.101	37.5	75.00	87.50	100.00	100.0			
	ADA	57	82.68	17.952	25.0	75.00	87.50	100.00	100.0			
	TOT	105	82.14	17.060	25.0	75.00	87.50	100.00	100.0			
FINAL/ET VALUE	PLO	48	71.35	20.622	25.0	62.50	75.00	87.50	100.0			
	ADA	57	80.04	19.744	25.0	75.00	87.50	100.00	100.0			
	TOT	105	76.07	20.519	25.0	62.50	75.00	100.00	100.0			
CHG FROM BEST*	PLO	48	-10.16	19.063	-75.0	-25.00	0.00	0.00	25.0			
	ADA	57	-2.63	14.318	-37.5	-12.50	0.00	0.00	25.0			
	TOT	105	-6.07	16.994	-75.0	-12.50	0.00	0.00	25.0			
										7.52	(1.06, 13.99)	0.023A

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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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
NEAR VISION												
BEST VALUE*	PLO	48	78.39	18.367	33.3	66.67	75.00	100.00	100.0			
	ADA	57	75.00	24.039	16.7	50.00	75.00	100.00	100.0			
	TOT	105	76.55	21.599	16.7	58.33	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	48	70.57	25.314	8.3	50.00	75.00	91.67	100.0			
	ADA	57	72.44	24.698	16.7	50.00	75.00	100.00	100.0			
	TOT	105	71.59	24.878	8.3	50.00	75.00	91.67	100.0			
CHG FROM BEST*	PLO	48	-7.81	17.375	-66.7	-14.58	-8.33	0.00	33.3			
	ADA	57	-2.56	14.599	-58.3	-8.33	0.00	0.00	25.0			
	TOT	105	-4.96	16.066	-66.7	-8.33	0.00	0.00	33.3			
										5.25	(-0.93, 11.44)	0.095A

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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.
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$ 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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
DISTANCE VISION												
BEST VALUE*	PLO	48	76.39	19.625	33.3	66.67	75.00	91.67	100.0			
	ADA	57	76.24	23.051	12.5	58.33	83.33	100.00	100.0			
	TOT	105	76.31	21.452	12.5	62.50	83.33	100.00	100.0			
FINAL/ET VALUE	PLO	48	71.61	23.954	16.7	58.33	75.00	91.67	100.0			
	ADA	57	72.95	25.939	16.7	58.33	75.00	100.00	100.0			
	TOT	105	72.34	24.941	16.7	58.33	75.00	91.67	100.0			
CHG FROM BEST*	PLO	48	-4.77	11.627	-33.3	-8.33	0.00	0.00	25.0			
	ADA	57	-3.29	12.243	-50.0	-8.33	0.00	0.00	16.7			
	TOT	105	-3.97	11.931	-50.0	-8.33	0.00	0.00	25.0			
										1.48	(-3.16, 6.13)	0.528A

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SUBJECTS WHO DO NOT HAVE VALUES AT/AFTER WEEK 6 (E.G. DUE TO PREMATURE DISCONTINUATION 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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
SOCIAL FUNCTIONING												
BEST VALUE*	PLO	48	88.28	18.125	37.5	75.00	100.00	100.00	100.0			
	ADA	57	88.82	18.402	25.0	75.00	100.00	100.00	100.0			
	TOT	105	88.57	18.190	25.0	75.00	100.00	100.00	100.0			
FINAL/ET VALUE	PLO	48	82.81	23.439	12.5	75.00	93.75	100.00	100.0			
	ADA	57	83.77	22.156	12.5	75.00	100.00	100.00	100.0			
	TOT	105	83.33	22.646	12.5	75.00	100.00	100.00	100.0			
CHG FROM BEST*	PLO	48	-5.47	11.790	-37.5	-12.50	0.00	0.00	25.0			
	ADA	57	-5.04	12.690	-50.0	-12.50	0.00	0.00	25.0			
	TOT	105	-5.24	12.230	-50.0	-12.50	0.00	0.00	25.0			
										0.42	(-4.35, 5.20)	0.860A

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$ 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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
MENTAL HEALTH												
BEST VALUE*	PLO	48	67.84	23.207	6.3	59.38	71.88	84.38	100.0			
	ADA	57	64.91	24.199	0.0	50.00	68.75	87.50	100.0			
	TOT	105	66.25	23.682	0.0	50.00	68.75	87.50	100.0			
FINAL/ET VALUE	PLO	48	64.19	29.702	0.0	53.13	71.88	87.50	100.0			
	ADA	57	67.11	27.308	0.0	56.25	75.00	93.75	100.0			
	TOT	105	65.77	28.326	0.0	56.25	75.00	87.50	100.0			
CHG FROM BEST*	PLO	48	-3.65	15.887	-50.0	-12.50	0.00	6.25	25.0			
	ADA	57	2.19	16.724	-43.8	-6.25	0.00	12.50	43.8			
	TOT	105	-0.48	16.529	-50.0	-6.25	0.00	6.25	43.8			
										5.84	(-0.51, 12.19)	0.071A

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# 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__1000.4.1.1.4.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: AGE >= 30 TO < 50 YEARS)

VISIT	TREATMENT	N	MEAN	SD	MIN	Q1	MEDIAN	Q3	MAX	DIFF.$	95% CI#	P-VALUE@
ROLE DIFFICULTIES												
BEST VALUE*	PLO	48	71.88	26.233	12.5	50.00	75.00	100.00	100.0			
	ADA	57	70.18	24.861	0.0	50.00	75.00	100.00	100.0			
	TOT	105	70.95	25.387	0.0	50.00	75.00	100.00	100.0			
FINAL/ET VALUE	PLO	48	66.15	29.168	0.0	50.00	75.00	87.50	100.0			
	ADA	57	71.05	29.708	0.0	50.00	75.00	100.00	100.0			
	TOT	105	68.81	29.424	0.0	50.00	75.00	100.00	100.0			
CHG FROM BEST*	PLO	48	-5.73	18.587	-50.0	-25.00	0.00	0.00	50.0			
	ADA	57	0.88	20.439	-50.0	0.00	0.00	12.50	50.0			
	TOT	105	-2.14	19.799	-50.0	-12.50	0.00	12.50	50.0			
										6.61	(-1.01, 14.23)	0.089A

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# 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]