

Table 14.02.02/3a Summary of BCVA Score by Visit, LOCF [1]
(Full Analysis Set)

Treatment Group	Visit	n	Value at visit							n	Change from baseline						
			Mean	SD	Min	Q1	Median	Q3	Max		Mean	SD	Min	Q1	Median	Q3	Max
Laser + VTE* (N=90)	BASELINE	90	57.7	11.27	25	53	59	66	73								
	WEEK 1	89	59.1	12.35	23	53	60	67	84	89	1.5	7.22	-23	-2	2	5	19
	WEEK 4	90	61.2	12.62	24	55	62	70	86	90	3.5	8.33	-22	0	3	7	34
	WEEK 8	90	61.2	14.68	7	55	64	72	95	90	3.5	11.45	-52	-3	3	9	35
	WEEK 12	90	62.3	14.67	16	55	64	72	91	90	4.6	11.2	-43	-1	4	11	35
	WEEK 16	90	62.9	14.63	15	56	65.5	72	94	90	5.2	11.12	-44	-2	5	12	34
	WEEK 20	90	63.8	14.85	18	56	66	73	95	90	6.1	12.07	-41	0	6	13	36
	WEEK 24	90	64.6	15.79	3	56	68	74	91	90	6.9	12.91	-56	1	6	15	38
	WEEK 28	90	67.5	15.55	18	60	71.5	78	97	90	9.8	11.68	-40	3	9.5	17	39
	WEEK 32	90	68.6	14.17	24	63	70.5	78	90	90	10.9	10.97	-27	5	10	17	44
	WEEK 36	90	69.2	15.01	24	62	72.5	78	98	90	11.5	11.73	-27	4	12	17	44
	WEEK 40	90	68.8	14.95	20	62	72	78	98	90	11.1	11.57	-27	4	11	18	43
	WEEK 44	90	70.2	15.29	21	65	72.5	80	98	90	12.5	11.78	-27	4	12.5	19	43
VTE (N=91)	WEEK 48	90	70.7	15.07	25	64	74	80	94	90	13	12.06	-27	5	13	21	45
	WEEK 52	90	69.9	15.17	20	63	74	80	94	90	12.2	11.94	-27	4	13	20	44
	BASELINE	91	58.6	11.36	27	54	59	68	73								
	WEEK 1	91	67.4	10.71	28	62	69	76	86	91	8.8	8.94	-7	3	7	14	41
	WEEK 4	91	70.9	10.75	34	65	73	78	89	91	12.3	10.31	-10	5	11	19	47
	WEEK 8	91	72	11.29	31	67	75	79	89	91	13.4	10.79	-13	6	12	20	46
	WEEK 12	91	73.4	11.9	22	69	76	80	91	91	14.7	11.25	-14	8	14	20	47
	WEEK 16	91	74.3	11.47	27	69	78	82	91	91	15.6	11.12	-13	9	14	22	49
	WEEK 20	91	74.7	11.13	37	69	77	82	91	91	16.1	11.42	-13	9	15	24	49
	WEEK 24	91	75.6	11.7	34	71	79	83	94	91	17	11.88	-13	9	16	23	59
	WEEK 28	91	75.5	12.07	25	73	79	84	91	91	16.9	11.97	-13	9	16	25	54
	WEEK 32	91	75.3	12.06	31	71	78	84	95	91	16.6	12.13	-13	9	15	24	54
	WEEK 36	91	76.3	12.23	23	72	79	84	94	91	17.6	12	-13	10	17	25	48
	WEEK 40	91	75.6	12.74	17	73	78	84	93	91	17	12.1	-19	10	17	24	51
	WEEK 44	91	76.5	12.3	32	73	79	84	94	91	17.8	12.04	-18	11	17	25	46
	WEEK 48	91	75.9	13.49	10	73	79	84	93	91	17.3	13	-26	10	17	24	50
	WEEK 52	91	75.7	13.08	17	72	78	84	91	91	17.1	13.07	-19	11	17	24	50

Note: - VEGF Trap-Eye (VTE) administered as 2 mg every 4 weeks through week 24, then every 8 weeks through week 48.

*Initial laser group as randomized. 67 patients received VTE rescue treatment from Week 24.

[1]: Last observation carried forward (LOCF) method was used to impute missing data

Source: CRF Pages 276, 277 and 281, 282

Table 14.02.03/3a Summary of Central Retinal Thickness by Visit, LOCF [1]
(Full Analysis Set)

Treatment Group	Visit	Value at visit								Change from baseline							
		n	Mean	SD	Min	Q1	Median	Q3	Max	n	Mean	SD	Min	Q1	Median	Q3	Max
Laser + VTE* (N=90)	BASELINE	90	553.5	188.14	247	401	525	648	1114								
	WEEK 1	89	537.4	159.68	282	410	535	647	976	89	-15.7	88.66	-392	-65	-12	38	207
	WEEK 4	90	507.9	150.1	202	388	490	622	925	90	-45.6	153.36	-674	-105	-20	34	362
	WEEK 8	90	474.2	148.21	182	348	471	559	901	90	-79.2	174.51	-683	-147	-60	32	377
	WEEK 12	90	461.3	150.28	207	340	453	543	901	90	-92.2	177.93	-690	-162	-73	17	279
	WEEK 16	90	447.7	147.73	210	328	440.5	555	901	90	-105.8	186.5	-764	-192	-75	12	271
	WEEK 20	90	426.2	140.19	211	315	423	516	901	90	-127.3	189.65	-722	-225	-93.5	-11	353
	WEEK 24	90	425.5	149.75	197	299	410	523	901	90	-128	195.02	-719	-231	-100	-6	370
	WEEK 28	90	330.9	128.55	173	258	288.5	336	901	90	-222.6	193.39	-854	-310	-191	-89	162
	WEEK 32	90	313.8	123.16	176	247	278	311	901	90	-239.7	203	-893	-326	-197.5	-90	63
	WEEK 36	90	309.7	121.5	165	249	275	316	901	90	-243.8	202.33	-893	-324	-207	-97	63
	WEEK 40	90	318	125.15	165	251	276.5	318	901	90	-235.5	204.91	-907	-337	-185	-84	63
	WEEK 44	90	305.5	120.36	168	248	270	302	901	90	-248	200.36	-907	-332	-205.5	-93	63
VTE (N=91)	BASELINE	91	558.9	185.91	227	440	528	648	1273								
	WEEK 1	91	338.5	80.43	197	294	314	362	766	91	-220.4	169.86	-860	-308	-189	-97	-6
	WEEK 4	91	302.6	74.92	190	270	292	313	809	91	-256.3	186.83	-1017	-361	-236	-121	104
	WEEK 8	91	291.3	72.95	185	262	277	302	687	91	-267.6	191.14	-1078	-373	-239	-125	-7
	WEEK 12	91	281.9	47.81	178	259	277	299	468	91	-277	189.4	-1065	-378	-253	-130	0
	WEEK 16	91	278.5	43.61	177	258	276	297	443	91	-280.4	189.56	-1062	-382	-250	-130	-3
	WEEK 20	91	277.7	41.97	170	257	274	296	431	91	-281.2	189.3	-1061	-380	-253	-136	-2
	WEEK 24	91	278.5	44.49	172	254	273	299	451	91	-280.4	189.72	-1061	-382	-255	-137	-6
	WEEK 28	91	277.4	46.72	174	254	272	295	508	91	-281.5	190.66	-1061	-386	-252	-139	-4
	WEEK 32	91	291.3	69.45	190	255	273	303	655	91	-267.6	194.02	-1061	-380	-245	-138	51
	WEEK 36	91	275.6	42.1	169	255	269	294	467	91	-283.4	189.63	-1058	-386	-252	-142	-5
	WEEK 40	91	295.8	75.2	174	256	277	309	600	91	-263.1	194.23	-1062	-380	-224	-123	81
	WEEK 44	91	274.4	42.78	173	253	272	294	454	91	-284.5	187.8	-1062	-390	-260	-141	-8
	WEEK 48	91	300.1	90.02	179	250	276	305	692	91	-258.8	199.55	-1056	-375	-235	-124	135
	WEEK 52	91	275	42.97	174	250	271	295	470	91	-283.9	189.1	-1066	-385	-257	-133	-10

Note: - VEGF Trap-Eye (VTE) administered as 2 mg every 4 weeks through week 24, then every 8 weeks through week 48.

*Initial laser group as randomized. 67 patients received VTE rescue treatment from Week 24.

[1]: Last observation carried forward (LOCF) method was used to impute missing data

Source: CRF Pages 413