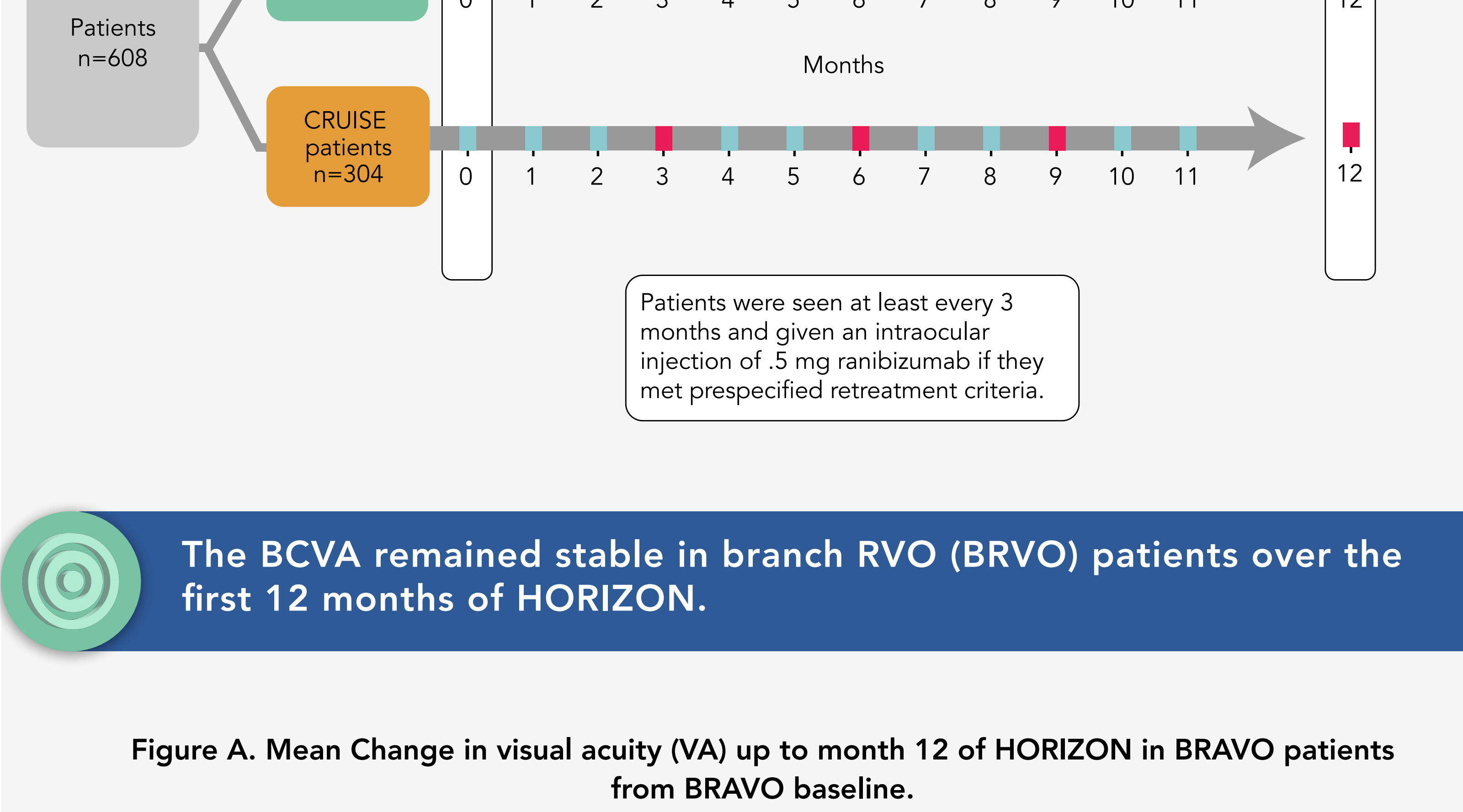


Ranibizumab for Macular Edema Due to Retinal Vein Occlusions: Long-term Follow-up in the HORIZON Trial

Heier JS, Campochiaro PA, Yau LJ, et al. *Ophthalmology*. 2012;119:802-809.
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The objective of this study was to assess long-term safety and efficacy of intraocular ranibizumab injections in patients with macular edema after retinal vein occlusion (RVO). Primary outcome measures included incidence and severity of ocular and nonocular adverse events (AEs), while key efficacy outcomes included mean change from baseline in best-corrected visual acuity (BCVA), Early Treatment of Diabetic Retinopathy Study (EDTRS) letter score, and central foveal thickness.

This study was an open-label extension trial of the 12-month Ranibizumab for the Treatment of Macular Edema following Branch Retinal Vein Occlusion: Evaluation of Efficacy and Safety (BRAVO) and Central Retinal Vein Occlusion Study: Evaluation of Efficacy and Safety (CRUISE) trials.



The BCVA remained stable in branch RVO (BRVO) patients over the first 12 months of HORIZON.

Figure A. Mean Change in visual acuity (VA) up to month 12 of HORIZON in BRAVO patients from BRAVO baseline.

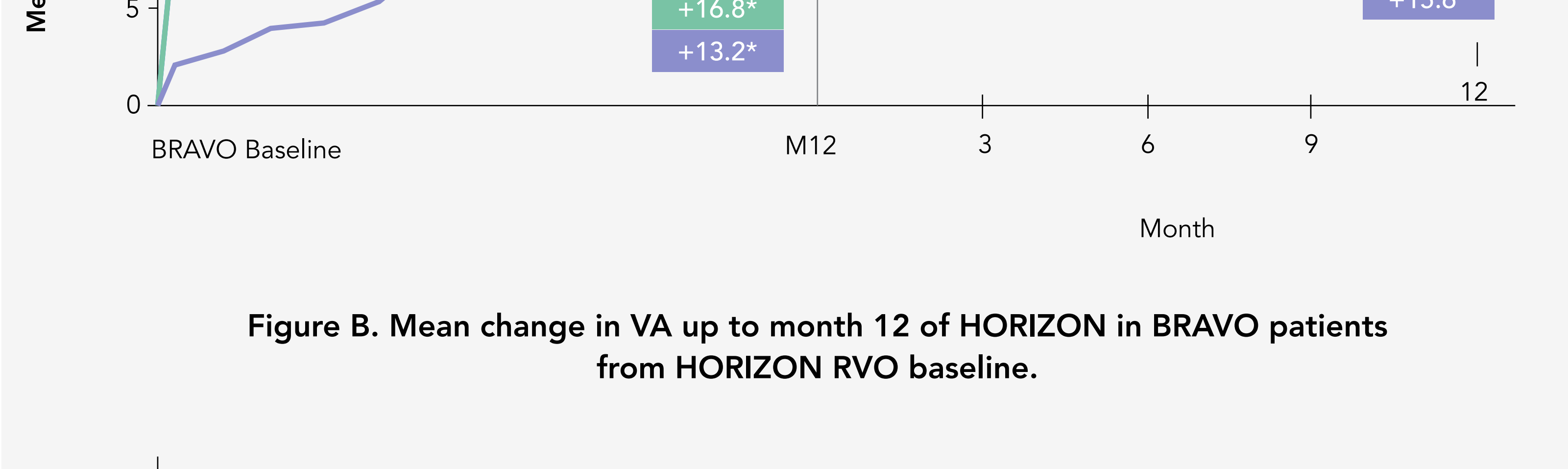


Figure B. Mean change in VA up to month 12 of HORIZON in BRAVO patients from HORIZON RVO baseline.

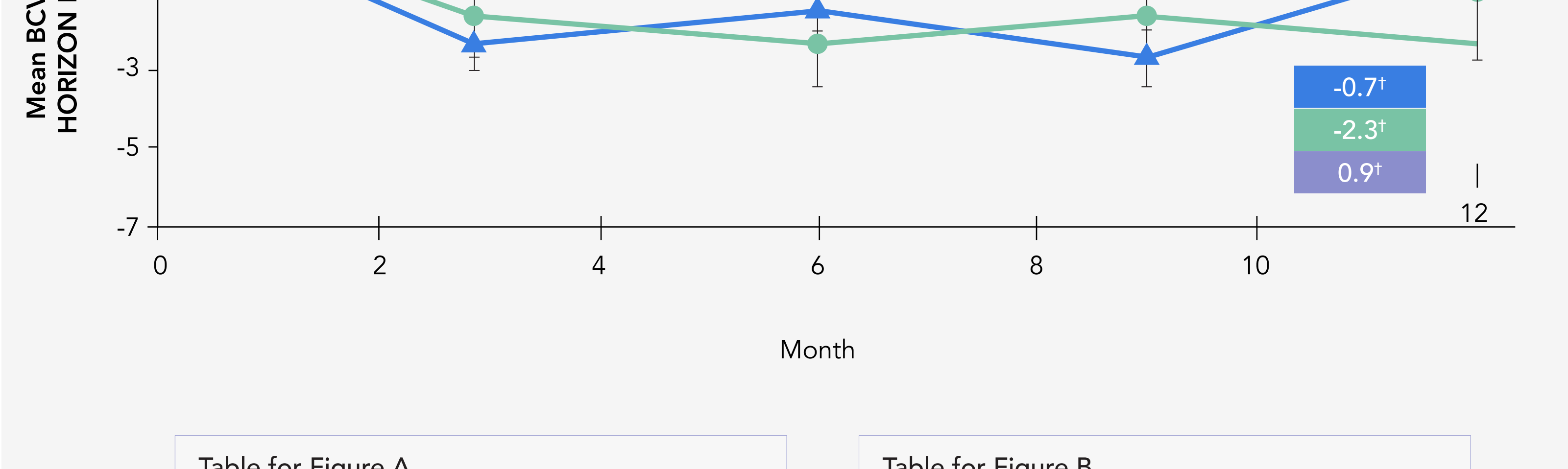


Table for Figure A

	Month				
	M12	3	6	9	12
Patients with VA Score (n)	104	99	98	92	73
	103	98	96	86	66
	97	92	88	84	66

Table for Figure B

	Month				
	0	3	6	9	12
Patients with VA Score (n)	104	99	98	92	66
	103	98	96	86	66
	97	92	88	84	66

Vertical bars are ± 1 SEM. *Includes patients with data available at that time point and BRAVO baseline. †Includes patients with data available at HORIZON baseline and month 12. BCVA = best-corrected visual acuity; BRAVO = Ranibizumab for the Treatment of Macular Edema following Branch Retinal Vein Occlusion: Evaluation of Efficacy and Safety; RVO = retinal vein occlusion; SEM = standard error of the mean.

The BCVA decreased in ranibizumab patients with central RVO (CRVO) over the first 12 months of HORIZON.

Figure C. Mean change in VA up to month 12 of HORIZON in CRUISE patients from CRUISE baseline.

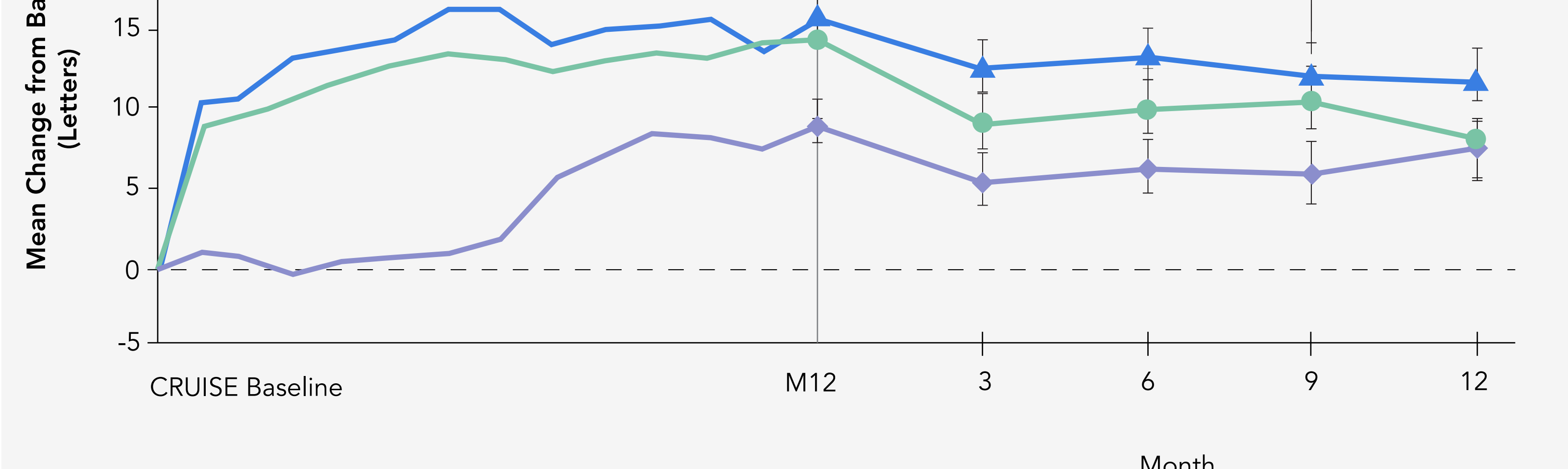


Figure D. Mean change in VA up to month 12 of HORIZON in CRUISE patients from HORIZON RVO baseline.

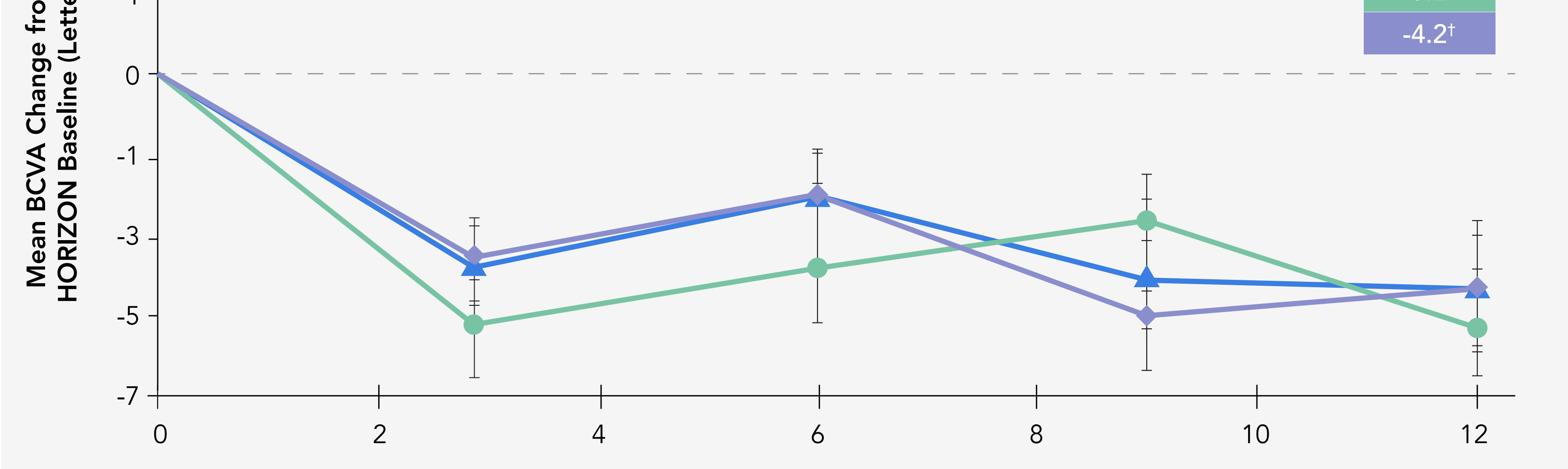


Table for Figure C

	Month				
	M12	3	6	9	12
Patients with VA Score (n)	98	94	92	76	51
	106	106	102	88	70
	96	94	92	78	60

Table for Figure D

	Month				
	0	3	6	9	12
Patients with VA Score (n)	98	93	91	75	50
	106	105	101	87	69
	96	92	90	76	58

Vertical bars are ± 1 SEM. *Includes patients with data available at that time point and CRUISE baseline. †Includes patients with data available at HORIZON baseline and month 12.

Mean CFT increases from HORIZON RVO baseline were minimal in BRVO patients at Month 12.

Figure E. Mean change in central foveal thickness (CFT) up to month 12 of HORIZON in BRAVO patients from BRAVO baseline.

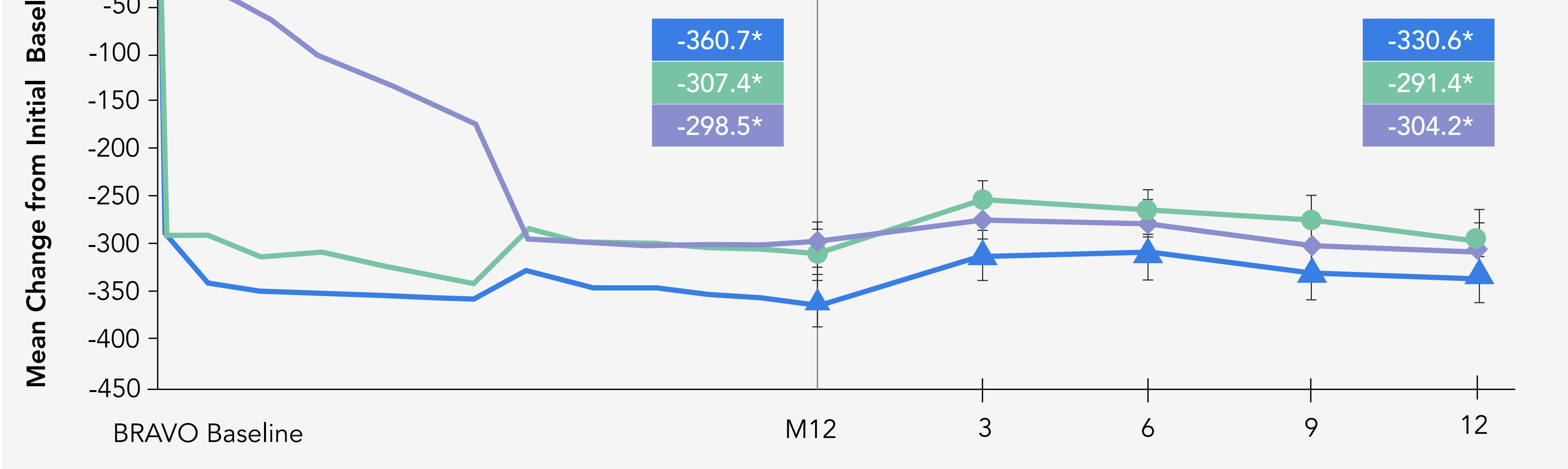


Figure F. Mean change in CFT up to month 12 of HORIZON in BRAVO patients from HORIZON RVO baseline.

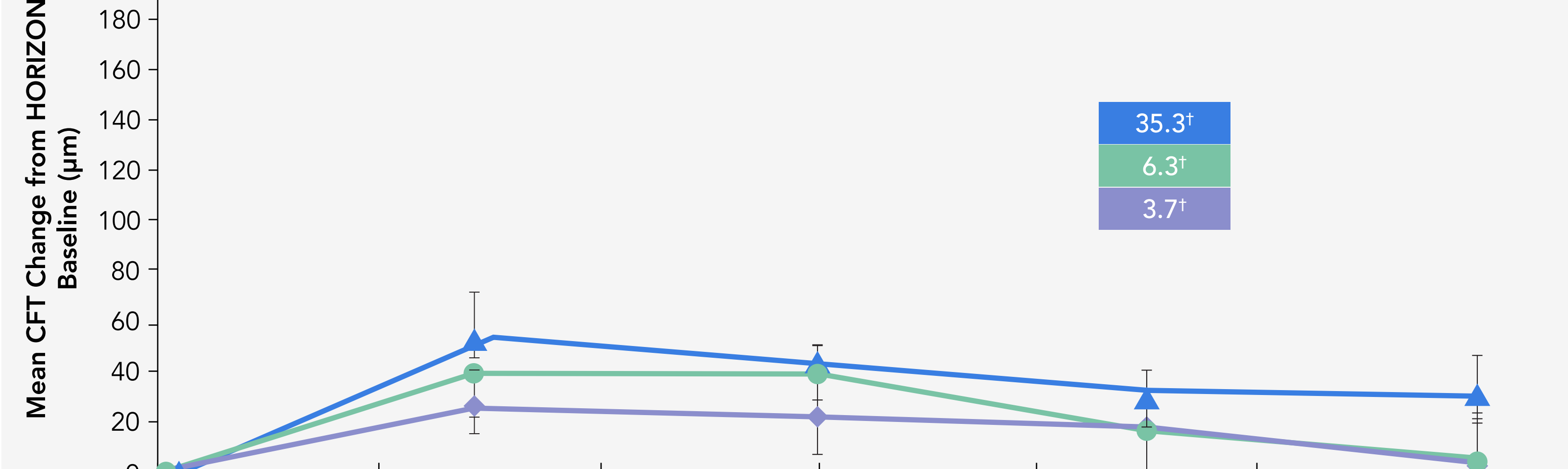


Table for Figure E

	Month				
	M12	3	6	9	12
No. of patients with CFT	104	99	97	89	72
	103	97	96	85	65
	96	91	87	78	63

Table for Figure F

	Month				
	0	3	6	9	12
No. of patients with CFT	104	99	97	89	72
	103	97	101	85	65
	96	90	86	77	62

Vertical bars are ± 1 SEM. *Includes patients with data available at that time point and BRAVO baseline. †Includes patients with data available at HORIZON baseline and month 12.

Mean CFT increases from HORIZON RVO baseline were greater for CRVO patients at Month 12.

Figure G. Mean change in CFT up to month 12 of HORIZON in CRUISE patients from CRUISE baseline.

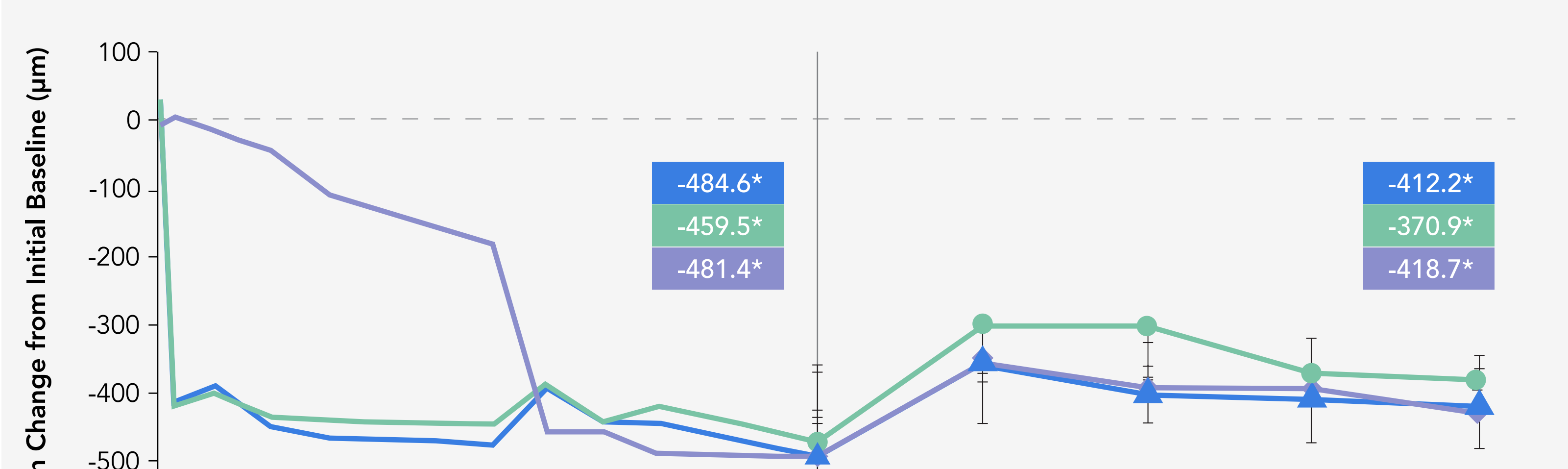


Figure H. Mean change in CFT up to month 12 of HORIZON in CRUISE patients from HORIZON RVO baseline.

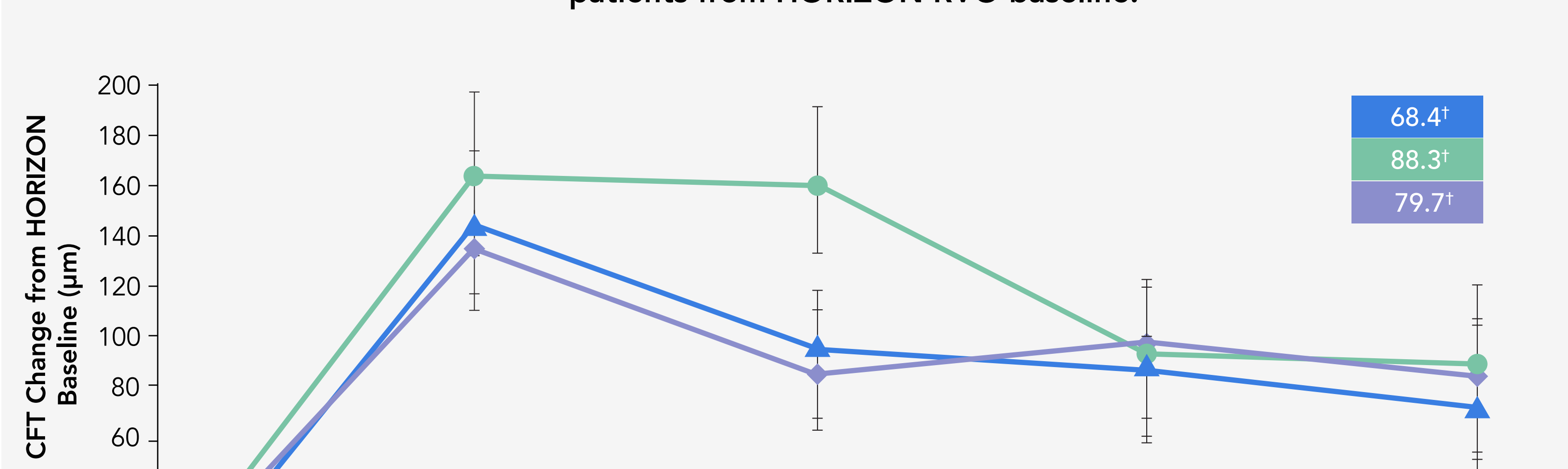


Table for Figure G

	Month				
	M12	3	6	9	12
No. of patients with CFT	98	91	90	75	51
	106	101	100	86	69
	97	95	91	74	57

Table for Figure H

	Month				
	0	3	6	9	12
No. of patients with CFT	98	90	89	75	51
	107	102	101	86	69
	97	94	90	73	56

Vertical bars are ± 1 SEM. *Includes patients with data available at that time point and CRUISE baseline. †Includes patients with data available at HORIZON baseline and month 12.

Conclusions and Relevance

No new safety events were identified with long-term use of ranibizumab; rates of serious adverse events (SAEs) potentially related to treatment were consistent with prior ranibizumab trials. Reduced follow-up and fewer ranibizumab injections in the second year of treatment were associated with a decline in vision in central RVO patients, but vision in branch RVO patients remained stable. Results suggest that during the second year of ranibizumab treatment of RVO patients, follow-up and injections should be individualized and, on average, central RVO patients may require more frequent follow-up than every 3 months.