

Statistical Analyses for Change in BCVA in ETDRS letter score from baseline at Study Week 12

Statistical analysis title	Statistical analysis 1: At Study week 12		Analysis Type	Other
			Comment	
Statistical analysis description	Study analysis is performed for change in BCVA in ETDRS letter score from baseline at week 4. Subjects will be assessed at each clinic visit for best corrected visual acuity using the early treatment diabetic retinopathy study chart. Visual function of the study eye and the fellow eye was assessed using the ETDRS. The subject's ETDRS testing score was recorded in the appropriate eCRF page at each study visit. For subjects who received rescue treatment the last observed value before rescue treatment was used. A 2-sided 90% confidence intervals based on the t-statistic was calculated.			
Comparison groups or subject analysis sets	Study Week 12			
Number of subjects in this analysis	50			
Analysis specification	<i>Pre-specified</i>			
Statistical hypothesis test				
P-value	Choose an item.		Comment	
Method [Required if P-value provided]	90% confidence interval based on t-statistic <i>Other method name: (specify)</i>			
Parameter Estimate				
Parameter type	Mean Difference (Net)			
Point estimate	-2.36			

Confidence interval	Level	90%	Sides	2	Lower limit	-4.18	Upper limit	-0.54
Variability estimate	Standard Deviation			Dispersion Value	7.68			