

Statistical Analyses for Part 1: Absolute Change From Baseline in CFQ-R Respiratory Domain Score Through Week 8

Statistical analysis title	Statistical Analyses for Part 1: Absolute Change From Baseline in CFQ-R Respiratory Domain Score Through Week 8		Analysis Type	Superiority				
Statistical analysis description	Estimates were obtained from MMRM with dependent variable absolute change from baseline, with treatment, sequence, period and visit within period (Weeks 2, 4, 8) as fixed effects, subject nested within sequence as random effect, and with adjustment for the continuous baseline values of age, ppFEV1 and CFQ-R Respiratory Domain score, using a compound symmetry covariance matrix.							
Comparison groups or subject analysis sets	Part 1: Ivacaftor versus Part 1: Placebo							
Number of subjects in this analysis	38							
Analysis specification	Pre-Specified							
Statistical hypothesis test								
P-value	=0.0004		Comment					
Method [Required if P-value provided]	Mixed Effects Model for Repeated Measures (MMRM)							
Parameter Estimate								
Parameter type	LS mean difference (Standard Error)							
Point estimate	9.6105 (2.5561)							
Confidence interval	Level	95%	Sides	2-sided	Lower limit	4.4874	Upper limit	14.7336
Variability estimate (if applicable)	NA		Dispersion Value	NA				