

Statistical Analyses for Change From Baseline in CFQ-R Score (Respiratory Domain Score, Pooled) Through Day 29

Statistical analysis title	Statistical Analyses for Change From Baseline in CFQ-R Score (Respiratory Domain Score, Pooled) Through Day 29		Analysis Type	Superiority				
Statistical analysis description	The raw scores in CFQ-R were summarized into different domains of health (12 domains for adolescents and adults 14 years of age and older, 8 domains for children ages 12 and 13 years, 8 domains for children ages 6 to 11 years, and 11 domains for parents/caregivers). Each domain was analyzed in a similar way as for the primary efficacy variable. The primary analytical focus was the respiratory health domain which was analyzed by combining all self-response questionnaire versions.							
Comparison groups or subject analysis sets	Ivacaftor versus Placebo							
Number of subjects in this analysis	19							
Analysis specification	Pre-Specified							
Statistical hypothesis test								
P-value	=0.3796		Comment	P-value was not adjusted for multiple comparisons.				
Method [Required if P-value provided]	Mixed-Effect Model							
Parameter Estimate								
Parameter type	LS Mean Difference							
Point estimate	3.991							
Confidence interval	Level	95%	Sides	2-sided	Lower limit	-5.40	Upper limit	13.39
Variability estimate (if applicable)	NA		Dispersion Value	NA				