

Statistical Analyses for Absolute Change From Baseline in Lung Clearance Index (LCI) Through Day 29

Statistical analysis title	Statistical Analyses for Absolute Change From Baseline in LCI Through Day 29		Analysis Type	Superiority				
Statistical analysis description	The primary analysis for the primary efficacy variable was based on a mixed effect model. The model included the absolute change from the baseline in each period as the dependent variable, sequence, treatment, and period as fixed effects, study baseline LCI as the covariate, and subject nested within sequence as the random effect.							
Comparison groups or subject analysis sets	Ivacaftor versus Placebo							
Number of subjects in this analysis	18							
Analysis specification	Pre-Specified							
Statistical hypothesis test								
P-value	=0.0004		Comment					
Method [Required if P-value provided]	Mixed-Effect Model							
Parameter Estimate								
Parameter type	Least Squares (LS) Mean Difference							
Point estimate	-2.069							
Confidence interval	Level	95%	Sides	2-sided	Lower limit	-2.98	Upper limit	-1.15
Variability estimate (if applicable)	NA		Dispersion Value	NA				