Statistical Analysis 1 for Percentage of Participants With Sustained Virologic Response 12 Weeks After Treatment

Statistical Analysis Overview	Comparison Groups	ABT-450/r/ABT-267 and ABT-333, Plus RBV
	Comments	With a sample size of 300 subjects and assuming that 85% of the subjects in Arm A will achieve sustained virologic response (SVR) 12, this study has greater than 90% power to demonstrate non-inferiority with a 2-sided 95% lower confidence bound greater than 60% and greater than 90% power to demonstrate superiority with a 2-sided 95% lower confidence bound greater than 70% (based on the normal approximation of a single binomial proportion).
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Based on historical SVR rates for noncirrhotic peg-interferon/ribavirin (pegIFN/RBV) treatment-experienced subjects administered telaprevir plus pegIFN/RBV, the lower confidence bound (LCB) of the 95% confidence interval (CI) must have exceeded 60% to achieve noninferiority of the ABT-450/r/ABT-267 and ABT-333, plus RBV treatment group as compared with the historical rate for telaprevir plus pegIFN and RBV, and the LCB of the 95% CI must have exceeded 70% to achieve superiority.

Method of Estimation	Estimation Parameter	Other [Percentage of Participants with SVR12]
	Estimated Value	96.3
	Confidence Interval	(2-Sided) 95% 94.1 to 98.4
	Estimation Comments	95% CI calculated using the normal approximation to the binomial distribution. In order to control the Type I error rate at 0.05, a fixed-sequence testing procedure was used to proceed through the primary and numbered secondary efficacy endpoints.