

Table 15.9.1: SVR12
Full Analysis Set

	SOF/VEL/VOX 8 Weeks (N=110)	SOF/VEL 12 Weeks (N=109)
SVR12	106/110 (96.4%)	105/109 (96.3%)
95% CI	91.0% to 99.0%	90.9% to 99.0%
p-value (Compared to 83%)	<0.001	<0.001

HCV RNA was analyzed using COBAS AmpliPrep/COBAS TaqMan HCV Quantitative Test v2.0 with limit of quantitation 15 IU/mL. SVR12 is sustained virologic response (HCV RNA < LLOQ) 12 weeks after stopping study treatment. A missing SVR12 value is imputed as a success if it is bracketed by values that are termed successes (ie, '<LLOQ TND' or '<LLOQ detected'); otherwise, the missing SVR12 value is imputed as a failure. TND = target not detected. The exact 95% CI for the proportion within treatment group is based on the Clopper-Pearson method. The p-value is obtained from the 2-sided exact 1-sample binomial test for the superiority over the performance goal of 83%. The SVR12 rate in SOF/VEL will be tested at the 0.05 significance level if and only if the SVR12 rate in SOF/VEL/VOX is significant at 0.05.

Source: Listing 16.2.6.1.

Data Extracted: 26Jan2017

Source: .../svr24/version1/prog/t-rna-svr.sas v9.4 Output file: t-rna-svr12.out 26JAN2017:15:39