

Table 15.9.1: SVR12
Full Analysis Set

	SOF/VEL/VOX 12 Weeks (N=182)	SOF/VEL 12 Weeks (N=151)
SVR12	178/182 (97.8%)	136/151 (90.1%)
95% CI	94.5% to 99.4%	84.1% to 94.3%
p-value (Compared to 85%)	<0.001	0.092

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 85%.
Source: Listing 16.2.6.1.

Data Extracted: 01Feb2017

Source: .../svr24/version1/prog/t-rna-svr.sas v9.4 Output file: t-rna-svr12.out 06FEB2017:14:10