

Table 15.9.1.1: SVR12
Full Analysis Set Treatment Group 1

	SOF/VEL/VOX 12 Weeks (N=263)
SVR12	253/263 (96.2%)
95% CI	93.1% to 98.2%
p-value (Compared to 85%)	<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 85%. Source: Listing 16.2.6.1.

Data Extracted: 20Jul2017

Source: .../svr24/version2/prog/t-rna-svr.sas v9.4 Output file: t-rna-svr12-group1.out 21JUL2017:09:11

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