

Table 15.9.1: SVR12
 Full Analysis Set

	12 to < 18 Years Old SOF(400mg)+RBV			3 to < 12 Years Old SOF(200mg or 150mg)+RBV		
	Total (N=52)	GT-2 12 Weeks (N=13)	GT-3 24 Weeks (N=39)	Total (N=54)	GT-2 12 Weeks (N=18)	GT-3 24 Weeks (N=36)
SVR12	51/52 (98.1%)	13/13 (100.0%)	38/39 (97.4%)	53/54 (98.1%)	17/18 (94.4%)	36/36 (100.0%)
95% CI	89.7% to 100.0%	75.3% to 100.0%	86.5% to 99.9%	90.1% to 100.0%	72.7% to 99.9%	90.3% to 100.0%
p-value (Compared to 80%)	<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 80%.
 Source: Listing 16.2.6.1.

Data Extracted: 04Oct2018

Source: .../svr24_final/version1/prog/t-rna-svr12.sas v9.4 Output file: t-rna-svr12.out 10OCT2018:10:53