Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HCV/HIV Coinfection
ACTG A5360 (MINMON)

Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

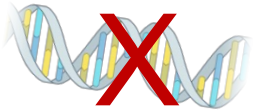
Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Study Overview

- **Design**: Phase 4 open-label single-arm trial to examine the safety and efficacy of a minimal monitoring approach to HCV care delivery using 12 weeks of sofosbuvir-velpatasvir in treatment-naïve patients
- **Setting**: Multiple sites in Brazil, South Africa, Thailand, Uganda & United States
- **Entry criteria**:
  - Chronic HCV infection as determined by HCV RNA >1000 IU/ml
  - Treatment-naïve
  - Age 18 or older
  - HIV coinfection permitted
  - Compensated cirrhosis permitted (FIB-4 ≥3.25, capped at ≤20% participants)
  - Absence of coinfection with HBV
- **Primary End-point**: SVR ≥22 weeks post-treatment initiation

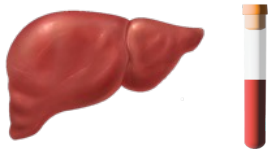
Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON):

No Genotype



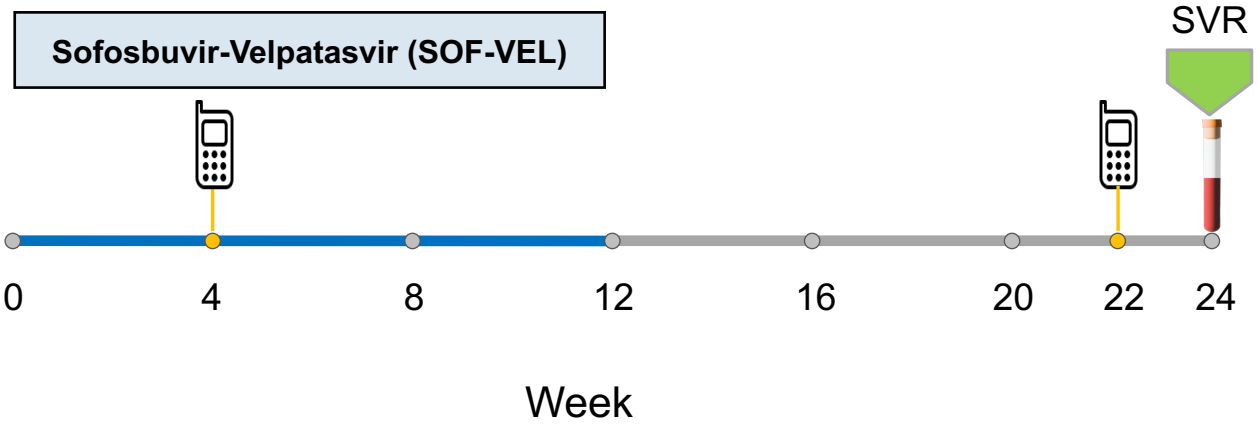
Cirrhosis Status by Fib-4



All pills provided at Entry

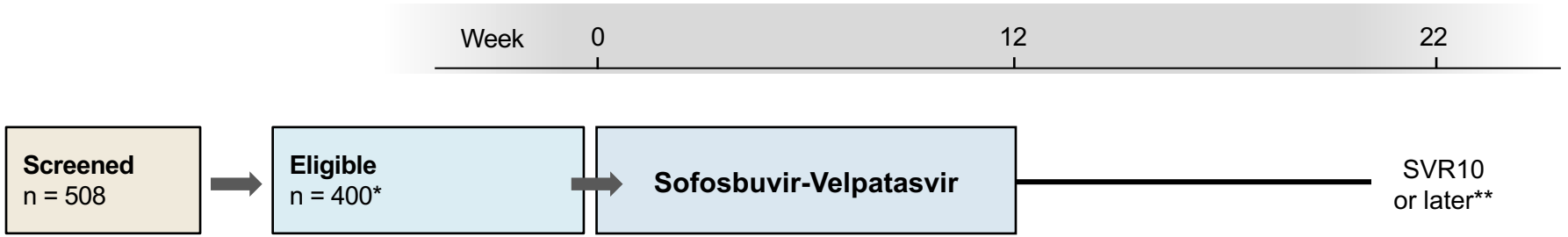
Sofosbuvir-Velpatasvir

- No pre-treatment genotyping
- Cirrhosis determination based on Fib-4
- All treatment medication provided at entry
- No scheduled on treatment visits/labs
- Remote contact at weeks 4 and 22



Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Trial Design



Drug Dosing
Sofosbuvir-velpatasvir: 400/100 mg once daily
*Final analytic set was n = 399 since one study participant never started SOF-VEL
**SVR ascertainment permitted out to week 76 of study

Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

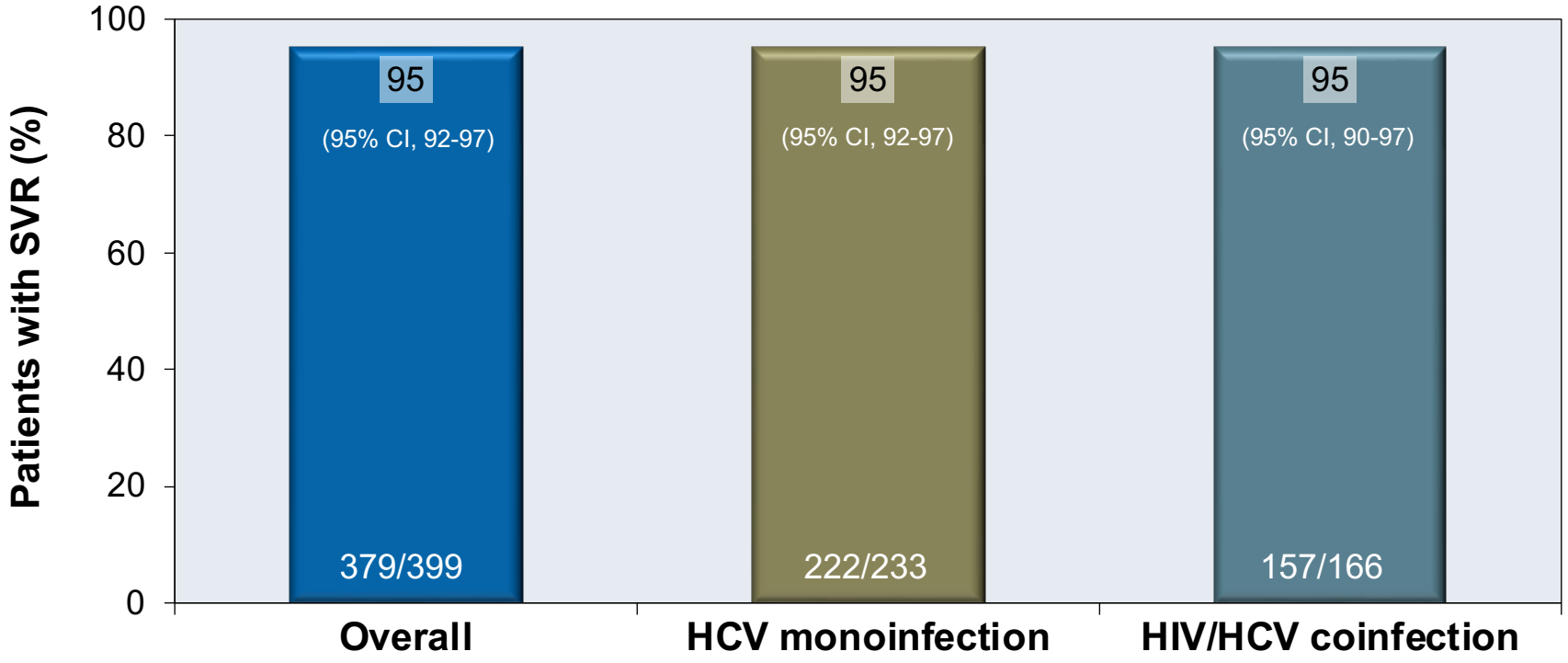
Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Study Population

Baseline Characteristic	Sofosbuvir-Velpatasvir (n = 399)
Age, median (range)	47 (20-82)
Female sex at birth, n (%)	139 (35)
Identity across transgender spectrum, n (%)	22 (6)
Race, n (%) White Black Asian	 166 (42) 72 (18) 113 (28)
HCV RNA $\log_{10}$ IU/mL, median (IQR)	6.1 (5.6 – 6.6)
Current injection drug use, n (%)	12 (3)
Current alcohol use, n (%)	161 (40%)
Cirrhosis (by FIB-4 ≥3.25), n (%)	34 (9)
HIV coinfection, n (%) Suppressed on antiretroviral therapy, n (% of HIV/HCV)	166 (42) 164 (99)

IQR, interquartile range; FIB-4, Fibrosis-4 index

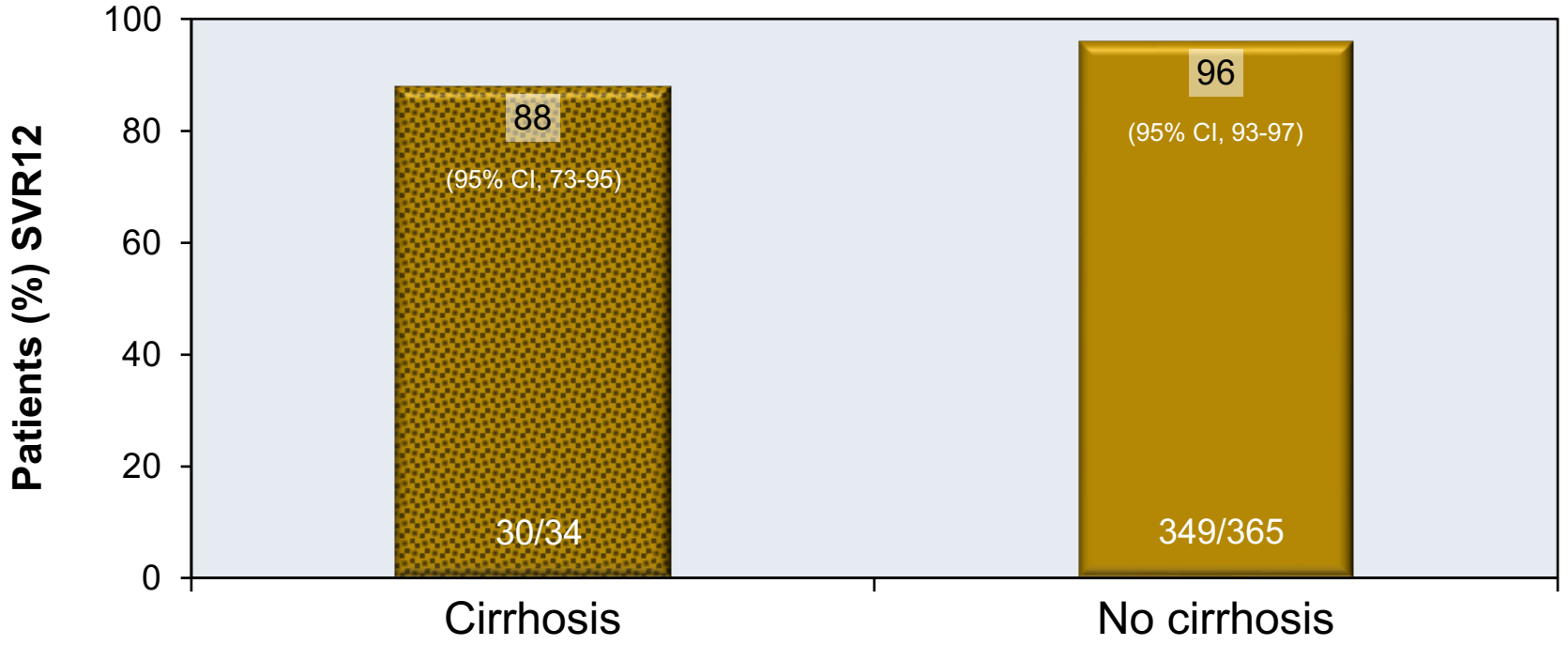
Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Results, Overall and by HIV Status



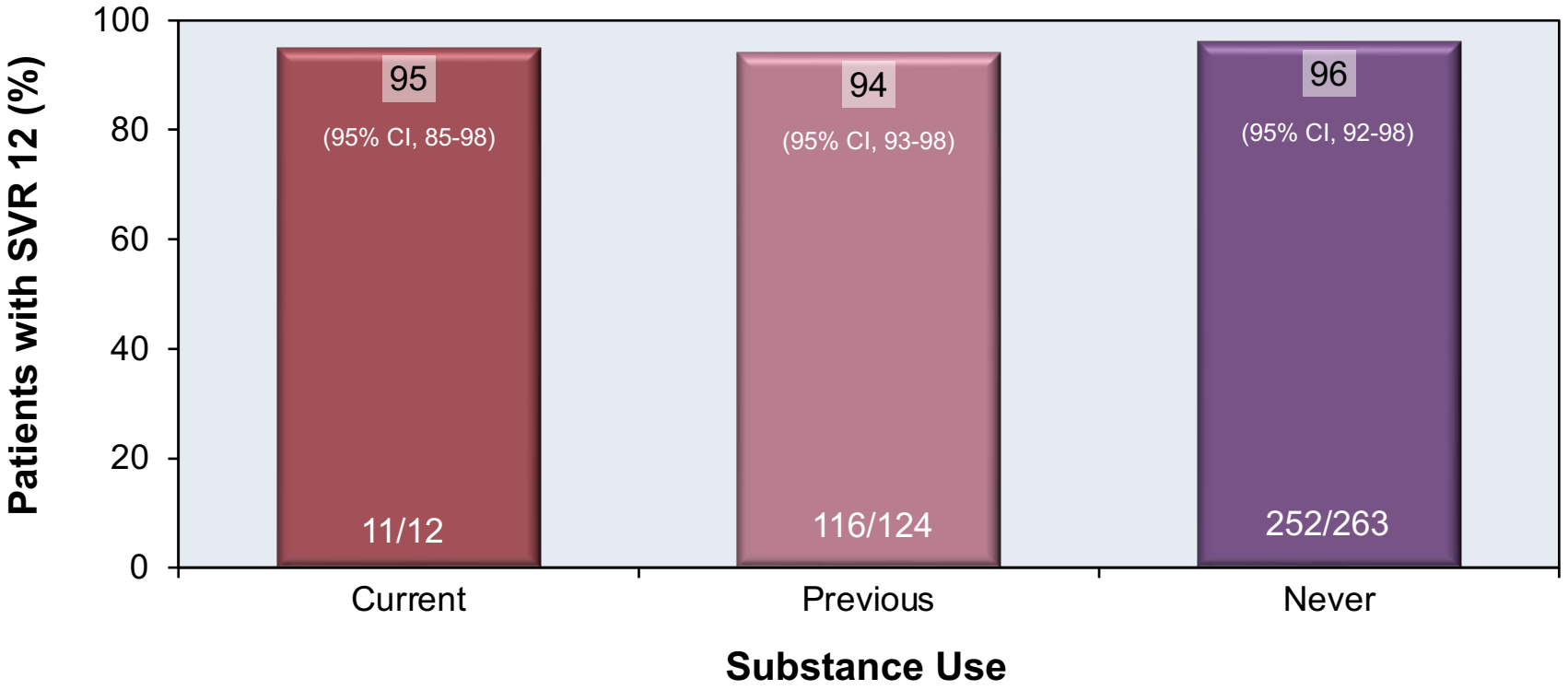
Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Results by Cirrhosis Status



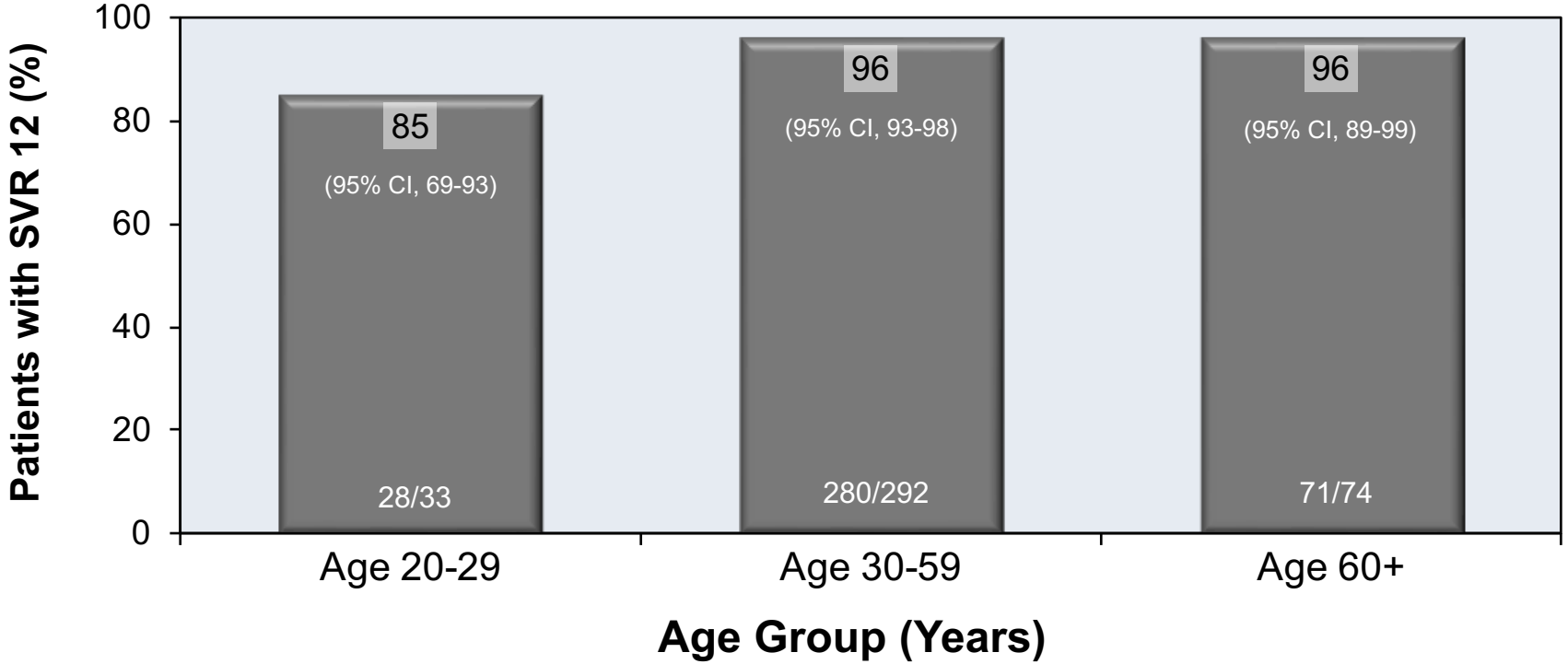
Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Results by Injection Drug Use Status



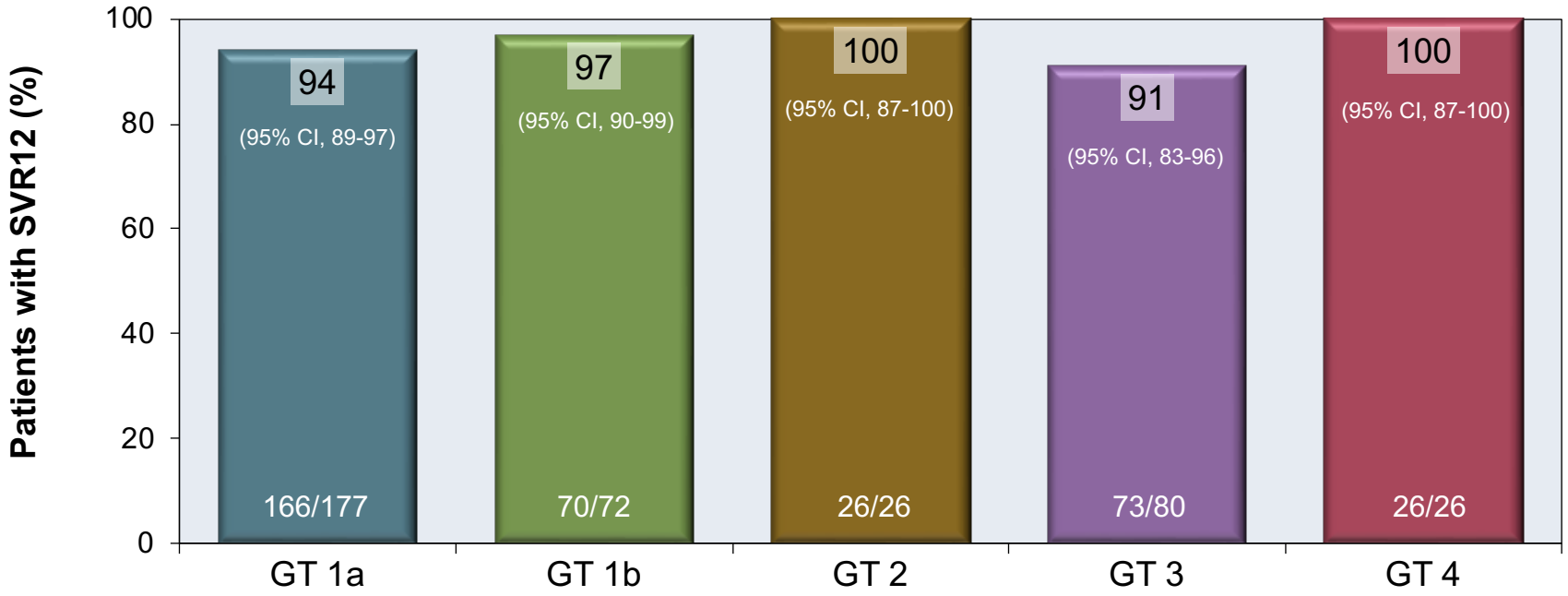
Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Results by Age



Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

MINMON Study: Sofosbuvir-velpatasvir with minimal monitoring Results by HCV Genotype



Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

MINMON Study: Sofosbuvir-velpatasvir with minimal monitoring Study events

- 15 (3.8%) participants with following events:
  - n=3 adverse events (AE)
  - n=8 abnormal lab values at baseline
  - n=6 non-AE clinical events
- 3 participants reported losing medications
  - 1 after 14 days on study
  - 2 received replacement (interruption: 4 and 7 days)
- 2 participants reported premature discontinuation
  - One loss of medications, one due to AE

Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Conclusions

Interpretation: “In this diverse global population of people with HCV, the MINMON approach with sofosbuvir–velpatasvir treatment was safe and achieved SVR comparable to standard monitoring observed in real-world data. Coupled with innovative case finding strategies, this strategy could be crucial to the global HCV elimination agenda.”

Source: Solomon SS, et al. Lancet Gastroenterol Hepatol. 2022;7:307-17.

Acknowledgments

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