

Treatment Naïve and Treatment Experienced

HIV Coinfection

# Simeprevir in HIV Coinfection, GT-1 C212 Trial

Dieterich D, et al. Clin Infect Dis. 2014;59:1579-87.

# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

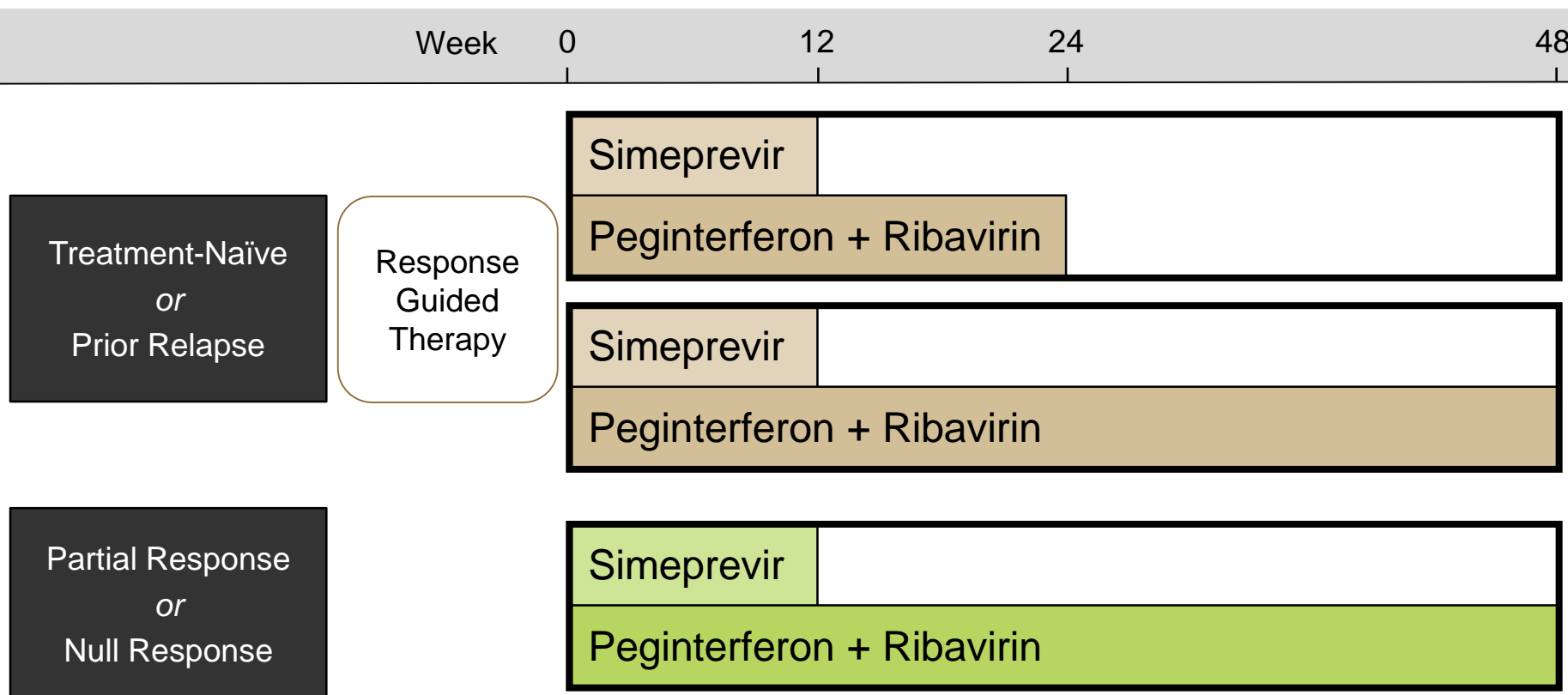
## Study C212: Study Features

### C212 Trial: Features

- **Design:** Open-label, phase 3, trial evaluating simeprevir + PEG + RBV in HCV-HIV and GT 1 (treatment naïve and experienced)
- **Setting:** 39 sites in 7 countries
- **Entry Criteria**
  - HIV coinfection; HCV genotype 1
  - Treatment naïve or treatment experienced
  - Group 1: HCV treatment-naïve or prior relapse
  - Group 2: Prior partial or null response or cirrhosis
  - CD4  $\geq$  200 if on stable ARV therapy; CD4  $\geq$  500 if no ARV therapy
  - Stable antiretroviral therapy = HIV RNA < 50 copies/ml > 8 weeks
- **Patient Characteristics**
  - N = 106 HCV-HIV coinfecting patients
  - Race: white (82%); black (14%)
  - Baseline Median CD4 (cells/mm<sup>3</sup>): 629 cells/mm<sup>3</sup>
- **Primary End-Points:** Efficacy (SVR12), safety, and impact on HIV

# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

## Study C212: Design



### Drug Dosing

Simeprevir: 150 mg once daily

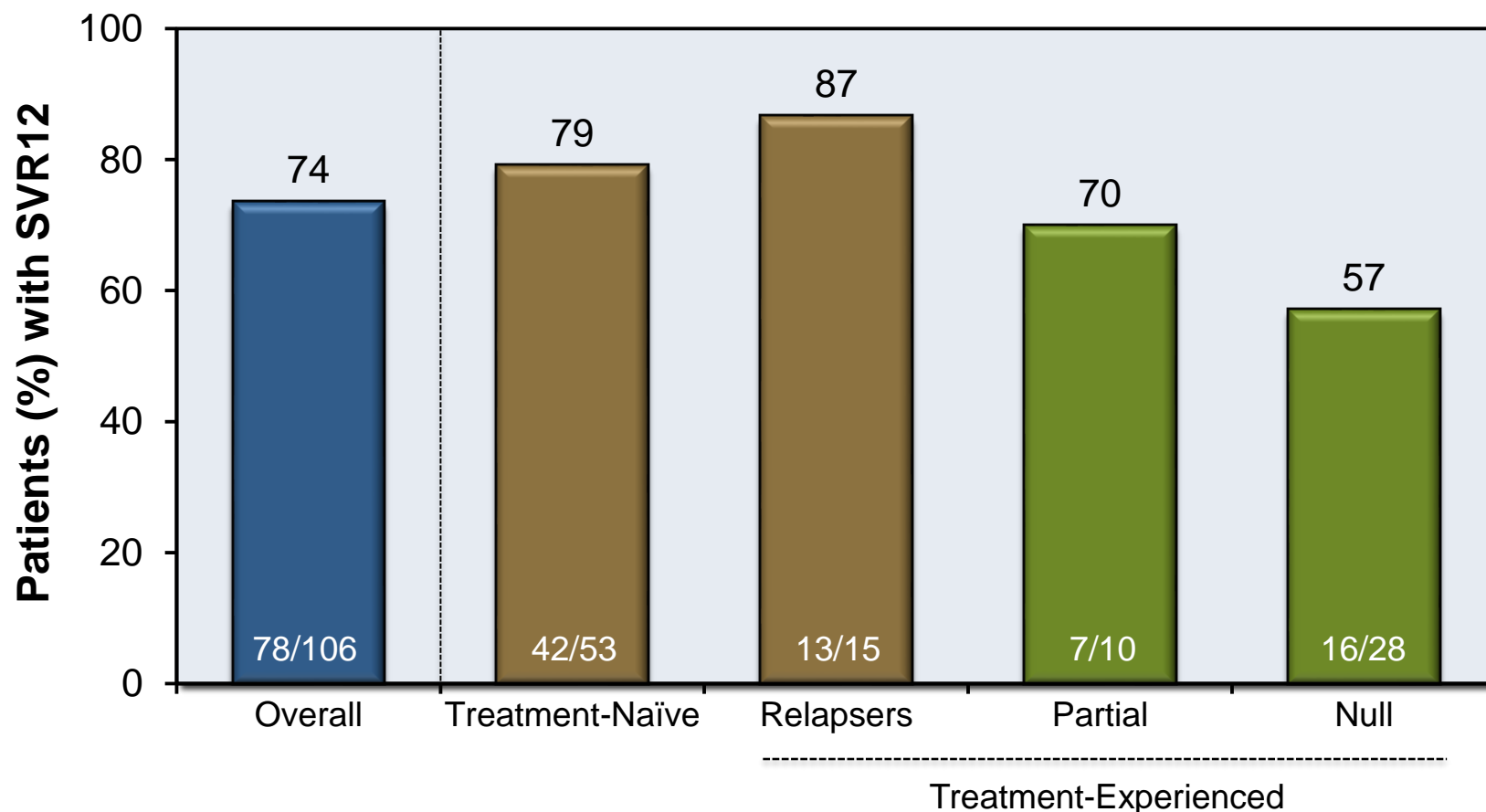
Peginterferon alfa-2a (PEG): 180 mcg/week

Ribavirin (RBV) weight-based (in 2 divided doses): 1000 mg if < 75kg or 1200 mg/day if ≥ 75kg

# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

## Study C212: Results

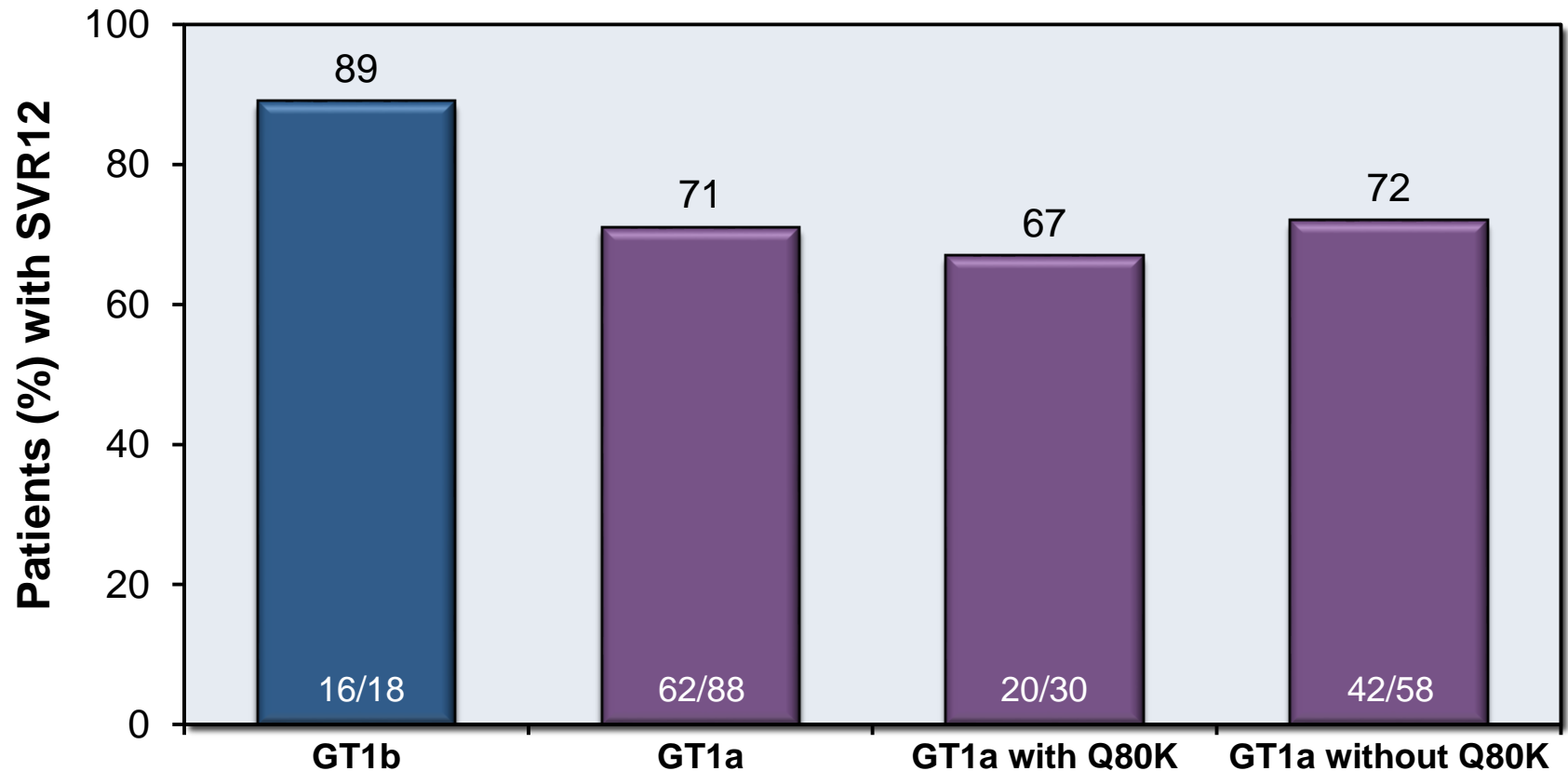
### C212: SVR12 by Prior Treatment Status



# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

## Study C212: Results

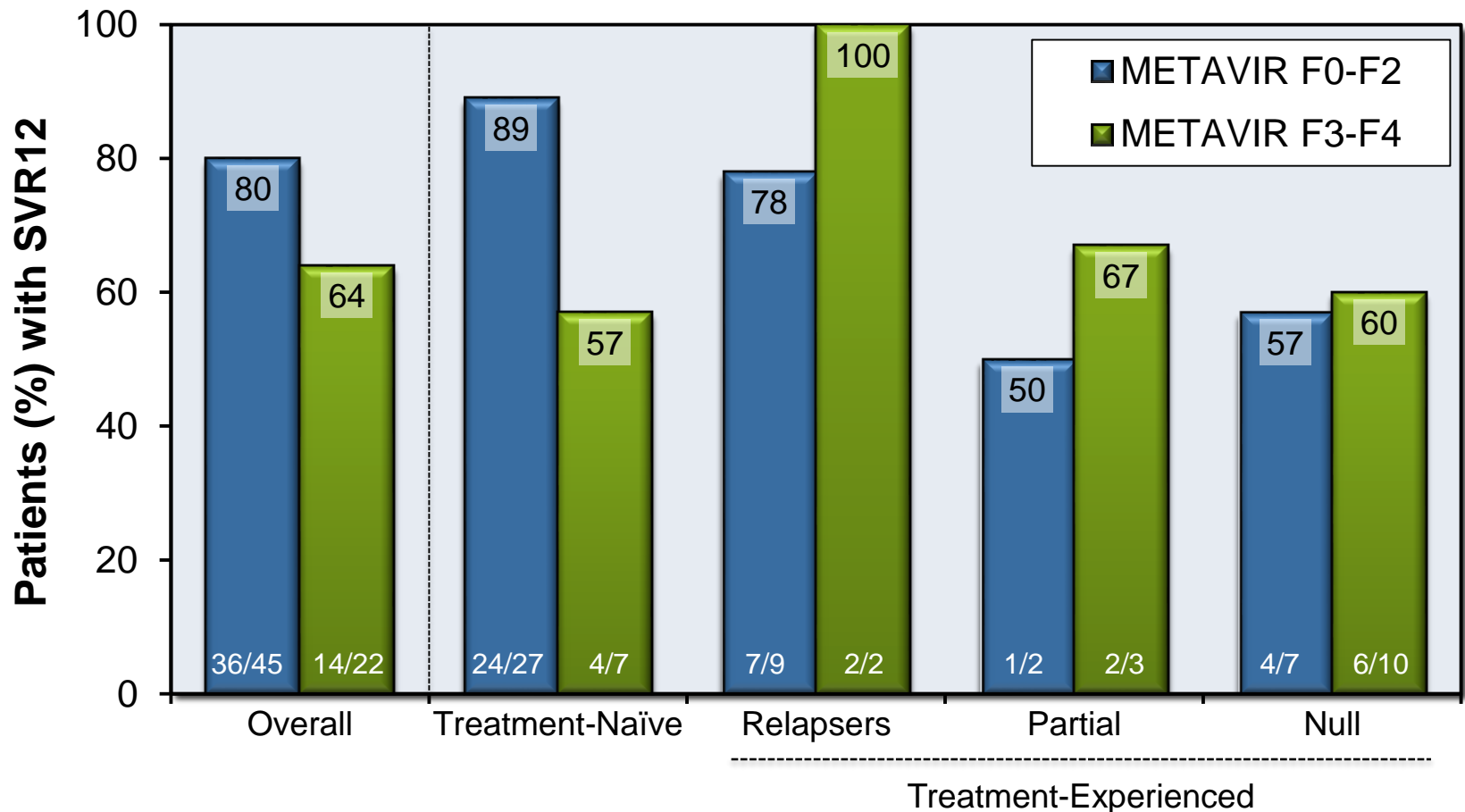
C212: SVR12 by GT1 Subtype and Baseline NS3 Q80K Polymorphism



# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

## Study C212: Results

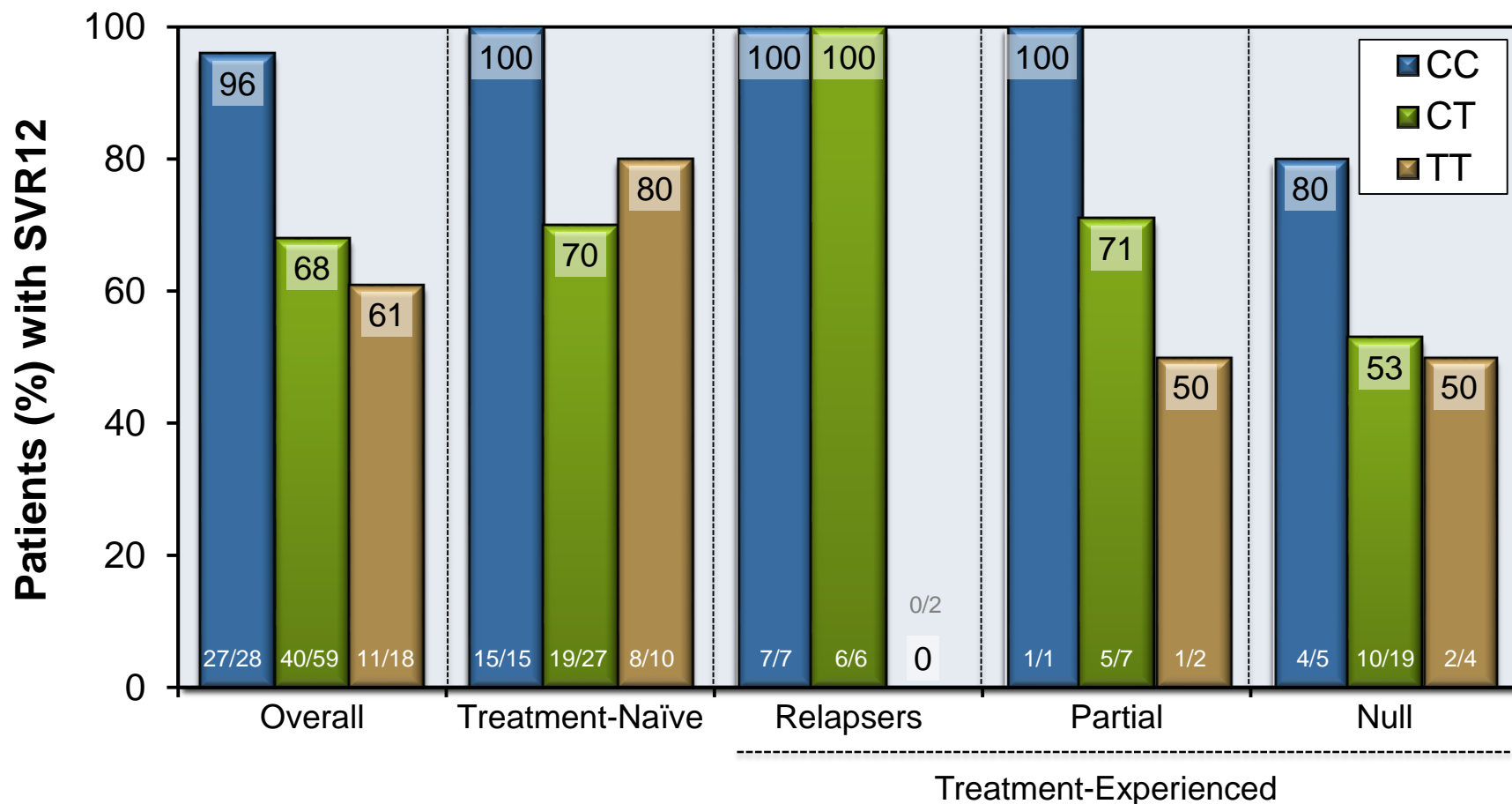
### C212: SVR12 by Fibrosis Stage and Prior History



# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

## Study C212: Results

### C212: SVR12 by IL28B Genotype



# Simeprevir + PEG + Ribavirin for HCV-HIV Coinfection

## Study C212: Conclusions

**Conclusions:** “Simeprevir was generally well tolerated with safety similar to that observed in HCV-monoinfected patients and high SVR12 rates in HCV treatment-naïve patients, prior relapsers, prior partial responders, and prior null responders with HIV-1 coinfection.”



This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

[www.hepatitisc.uw.edu](http://www.hepatitisc.uw.edu)

Hepatitis Web Study

<http://depts.washington.edu/hepstudy/>

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