

Treatment Naïve and Treatment Experienced

# Daclatasvir + Sofosbuvir +/- Ribavirin in Genotypes 1-3 A1444-040 Trial

Sulkowski MS, et al. N Engl J Med. 2014;370:211-21.

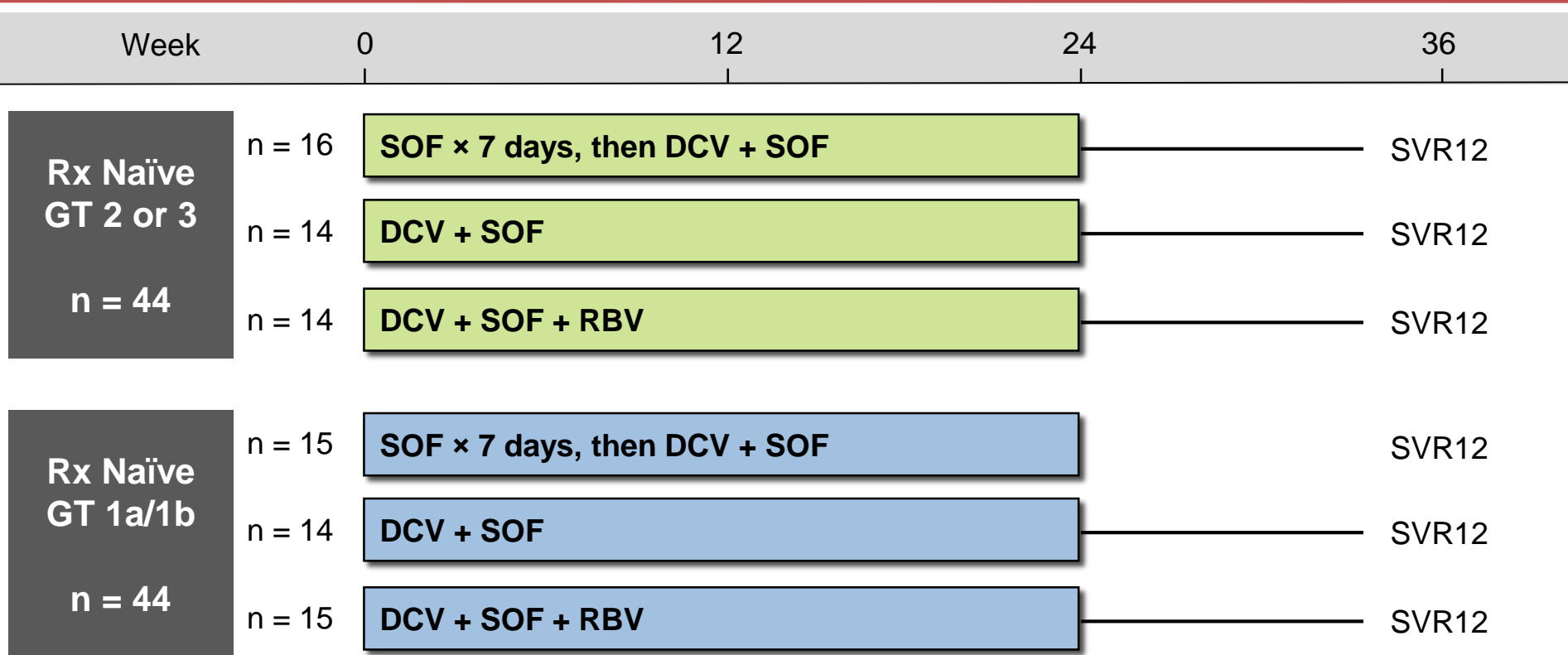
# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 A1444-040 Trial: Features

## Daclatasvir + Sofosbuvir Trial: Features

- **Design:** Randomized, open label, phase 2a, using daclatasvir + sofosbuvir +/- ribavirin in treatment naïve or experienced, chronic HCV GT 1-3
- **Setting:** United States
- **Entry Criteria**
  - Chronic HCV Genotype 1, 2, or 3
  - Treatment naïve or treatment experienced
  - No evidence of cirrhosis
- **Patient Groups**
  - N = 211 total received treatment
  - N = 44 Rx naïve with GT1: DCV+ SOF +/- RBV x 24 weeks
  - N = 44 Rx naïve patients with GT 2 or 3: DCV+ SOF +/- RBV x 24 weeks
  - N = 123 Rx naïve or experienced with GT 1: DCV+ SOF +/- RBV x 12 weeks
- **End-Points:** Primary = SVR12

# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3

## A1444-040 Design: Treatment-Naïve 24 Week Rx



### Drug Dosing

Daclatasvir (DCV): 60 mg once daily

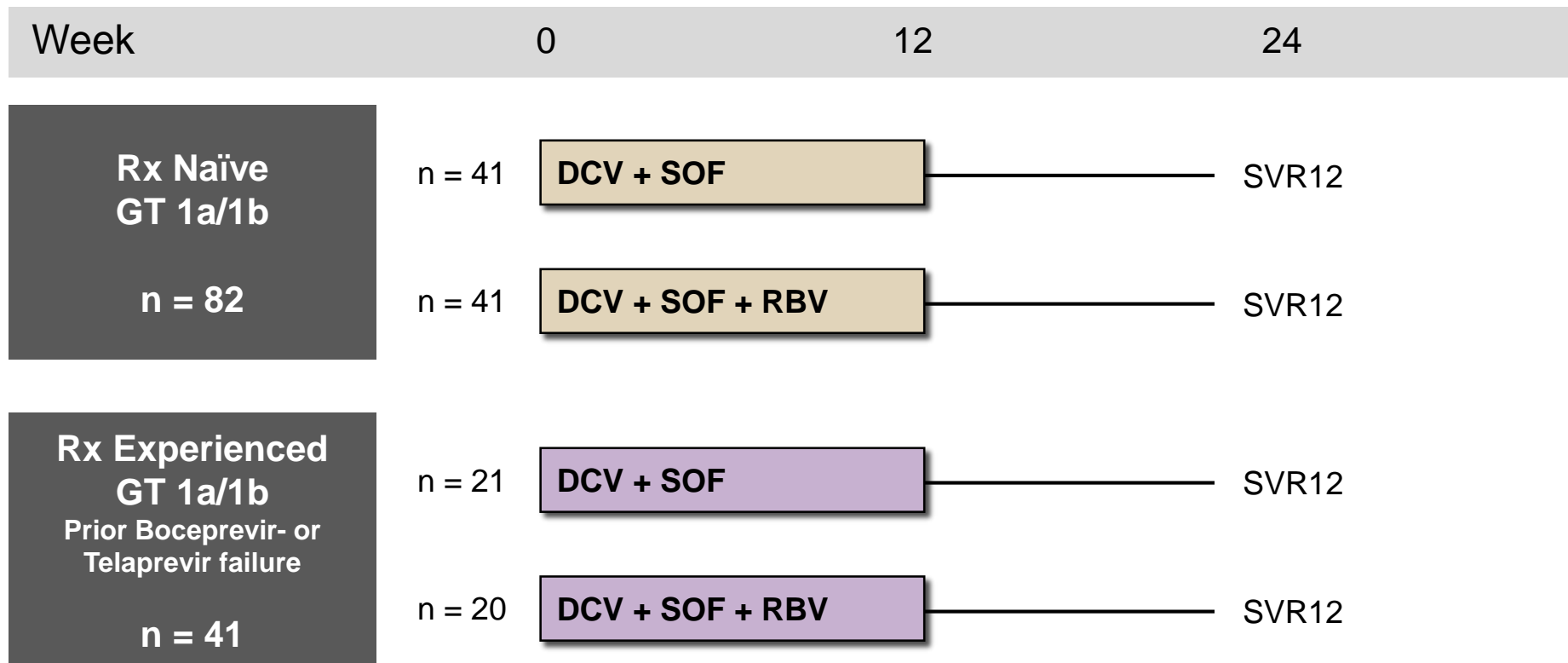
Sofosbuvir (SOF): 400 mg once daily

Ribavirin (RBV): GT1, given weight-based and divided bid (1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg)

Ribavirin (RBV): GT 2,3 (800 mg/day)

# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3

## Design: GT1 Treatment-Naïve & Experienced 12 Week Rx



### Drug Dosing

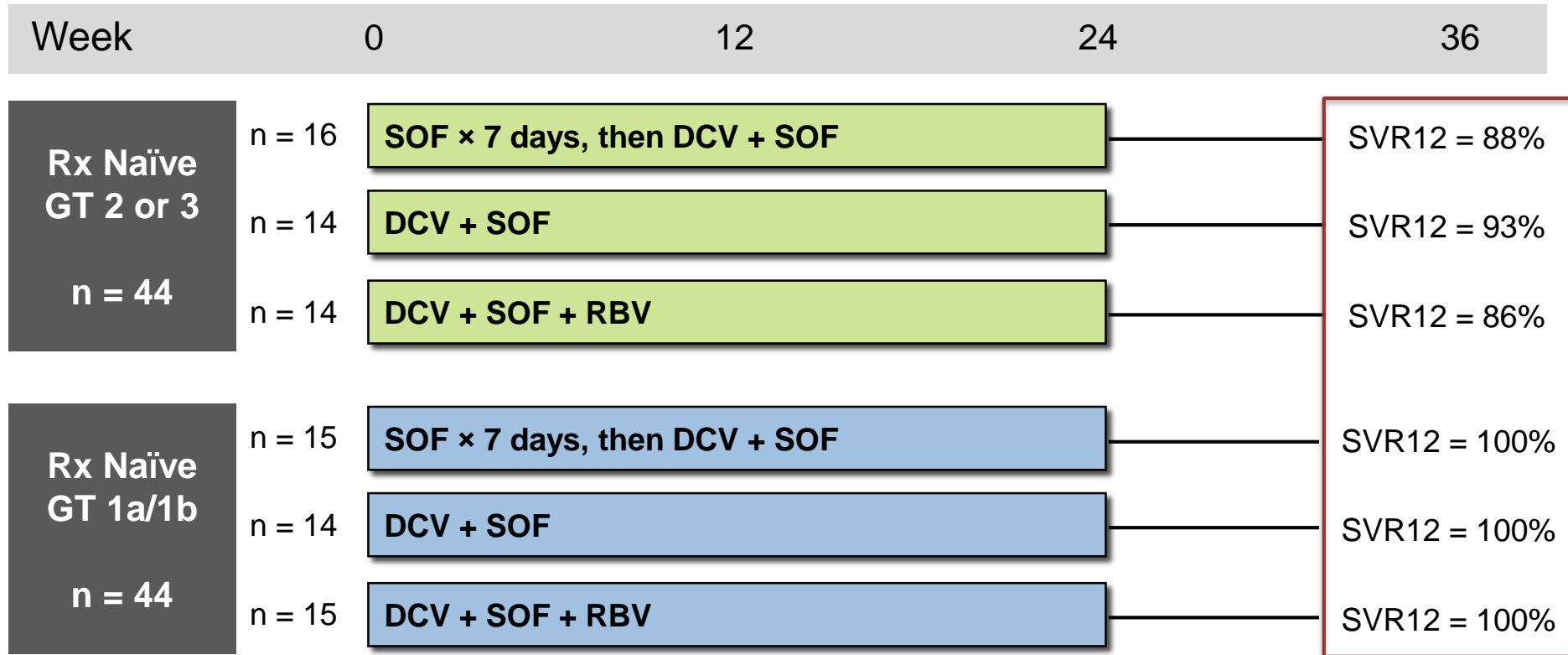
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# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 A1444-040 Treatment-Naïve 24 Week Rx: Results



## Drug Dosing

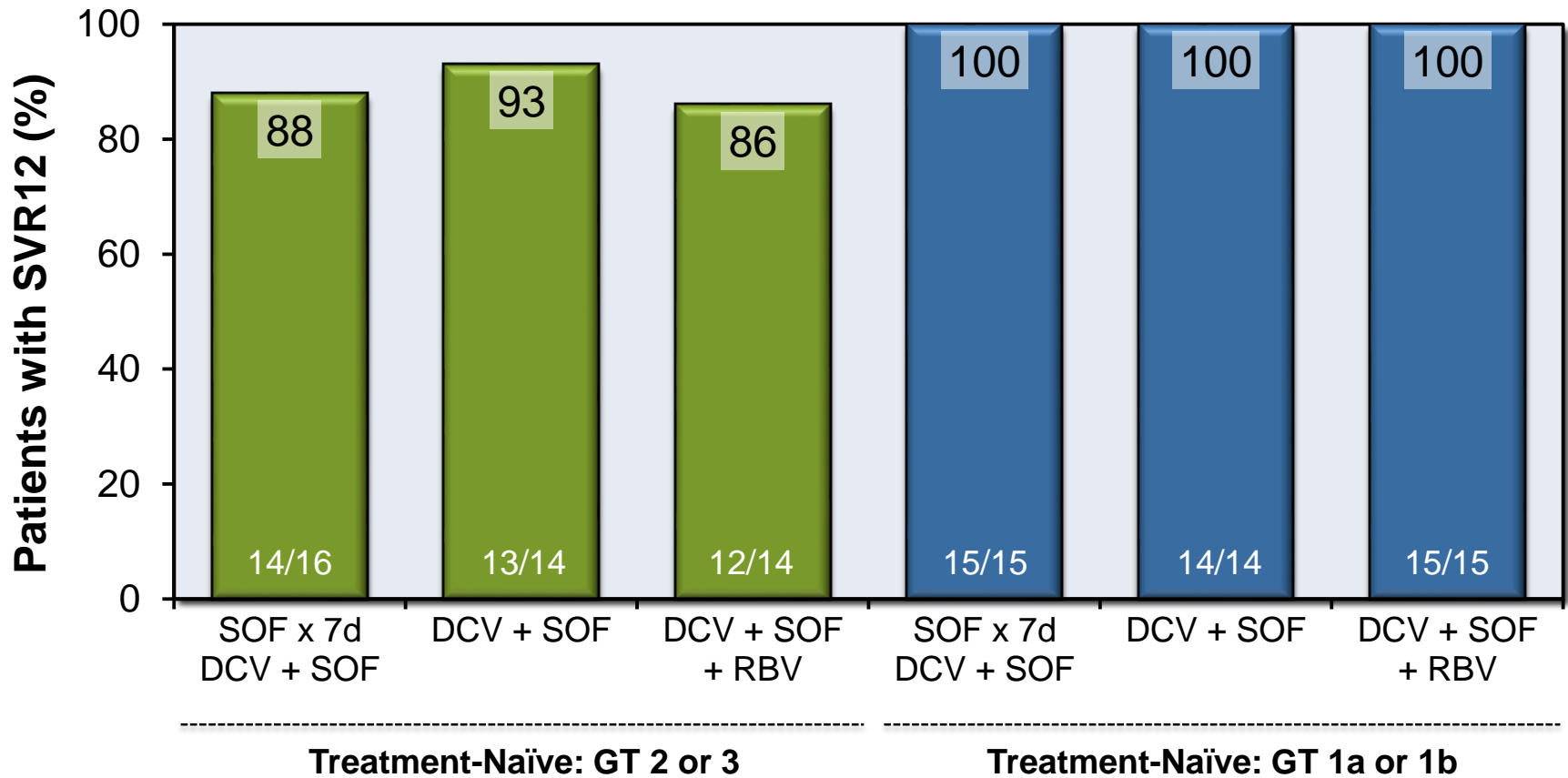
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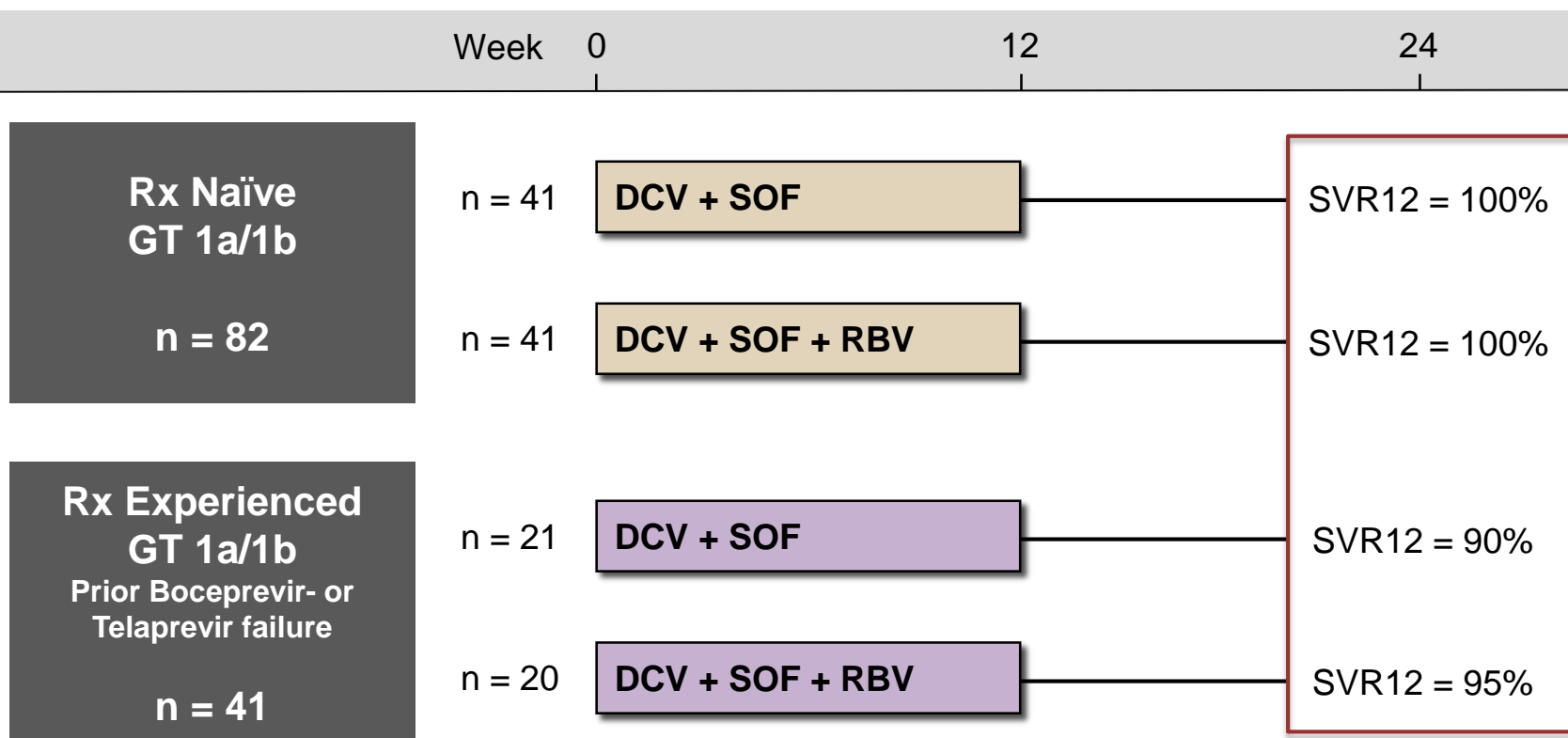
# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 A1444-040 Treatment-Naïve 24 Week Rx: Results



DCV = daclatasvir; SOF = sofosbuvir; RBV = ribavirin

Source: Sulkowski MS, et al. N Engl J Med. 2014;370:211-21.

# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 GT1 Treatment-Naïve & Experienced 12 Week Rx: Results



## Drug Dosing

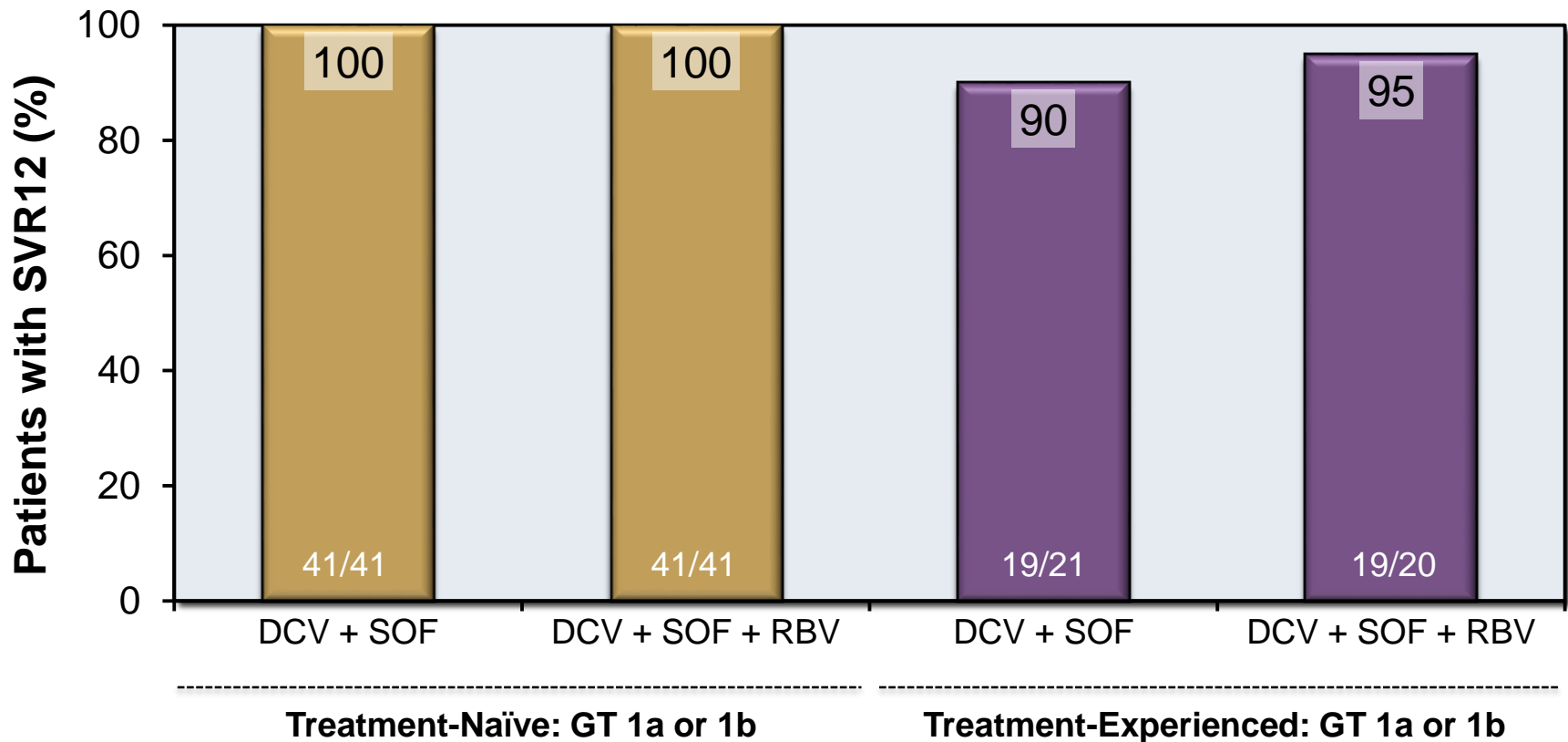
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# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 GT1 Treatment-Naïve & Experienced 12 Week Rx: Results



DCV = daclatasvir; SOF = sofosbuvir; RBV = ribavirin

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# Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 Trial: Conclusions

**Conclusions:** “Once-daily oral daclatasvir plus sofosbuvir was associated with high rates of sustained virologic response among patients infected with HCV genotype 1, 2, or 3, including patients with no response to prior therapy with telaprevir or boceprevir.”

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/>

Funded by a grant from the Centers for Disease Control and Prevention.