

Treatment Naïve (unfavorable baseline treatment characteristics)

Sofosbuvir + Ribavirin in HCV Genotype 1 NIH SPARE

Osinusi A, et al. JAMA. 2013;310:804-11.

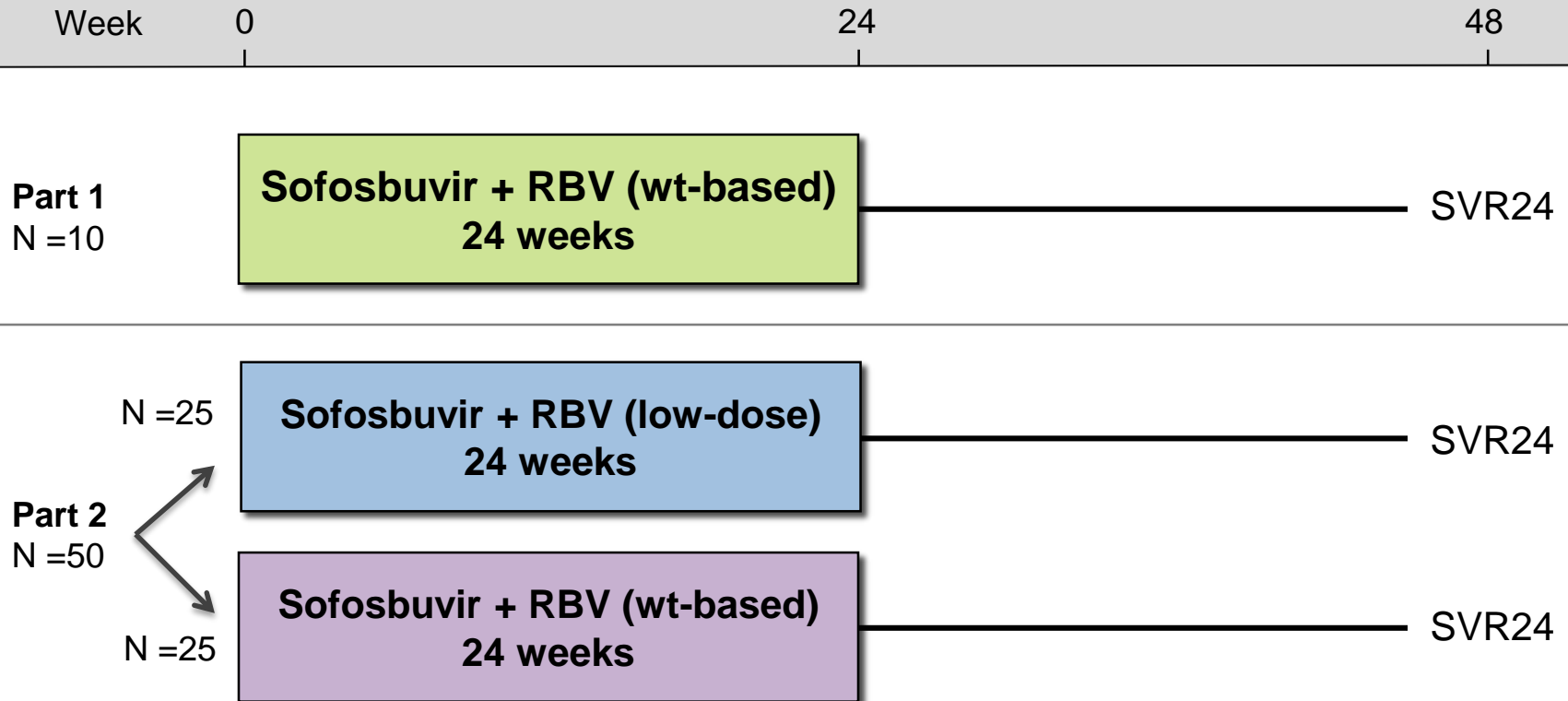
Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1

NIH SPARE Trial: Features

NIAID/NIH Trial: Features

- **Design**
 - Randomized, open-label, 2-part, phase 2 study of sofosbuvir and ribavirin
 - Part 1: “proof of concept”
 - Part 2: low dose versus weight-based dose of ribavirin in GT-1
- **Setting:** Single center: NIAID
- **Entry Criteria:** HCV genotype 1; treatment-naïve
- **Patient Characteristics**
 - N = 60 HCV-monoinfected patients
 - HCV Genotype: 1A (70%), 1B (30%)
 - IL28B Genotype: 81% non-CC
 - Age and Sex: median 54 (range 48-57); 62% male
 - Race: 83% black; 13% white
 - Liver disease: 23% had advanced fibrosis (F3-F4 by Knodell-HAI scoring)
- **Primary end-points:** Efficacy (SVR24) and safety

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIH SPARE Trial: Design



Drug Dosing

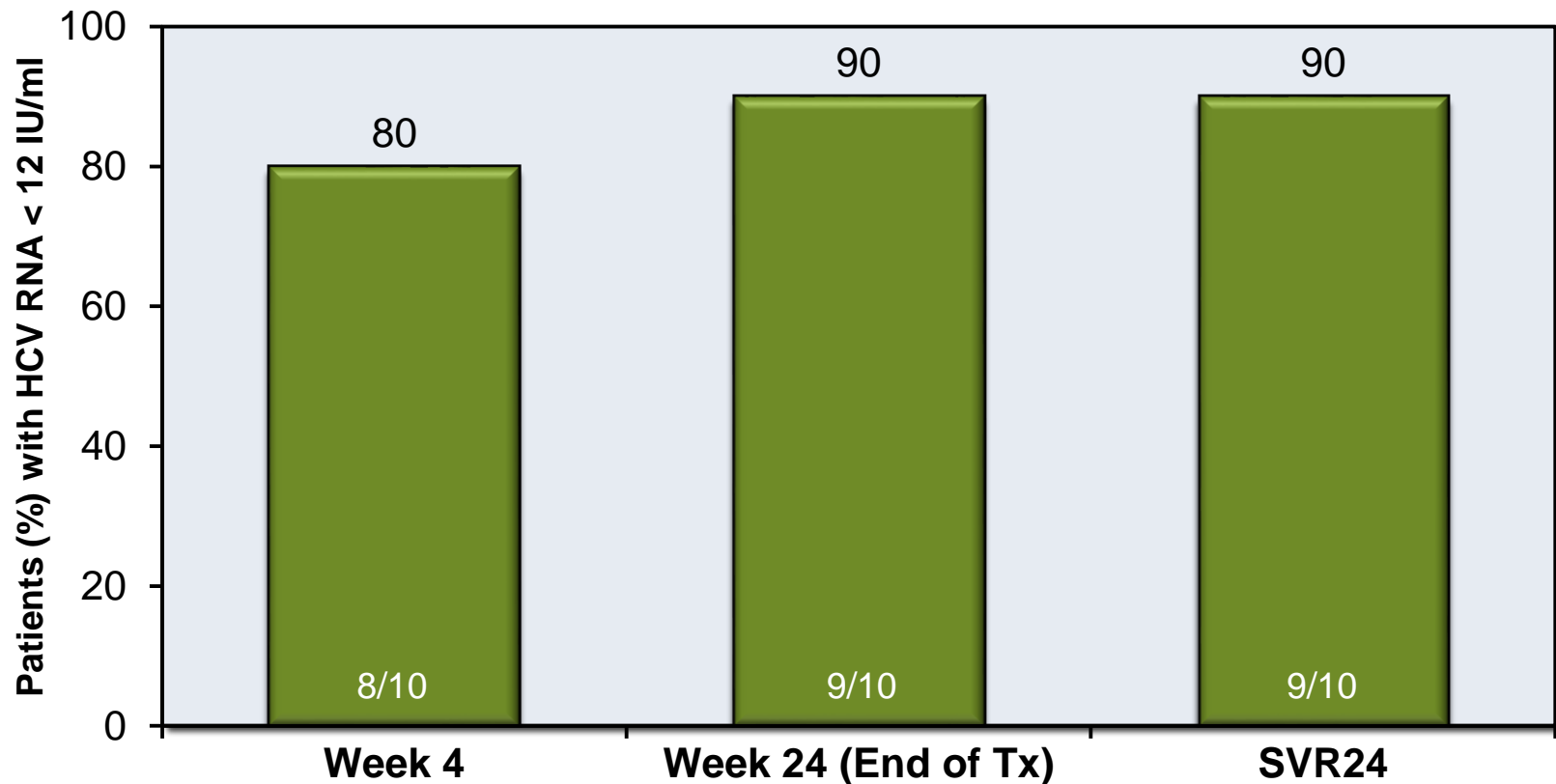
Sofosbuvir: 400 mg once daily

Low-dose Ribavirin (divided bid): 800 mg/day

Weight-based Ribavirin (divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIH SPARE Trial: Part 1 Results

NIH SPARE Part 1: HCV <12 IU/ml by Study Timepoint

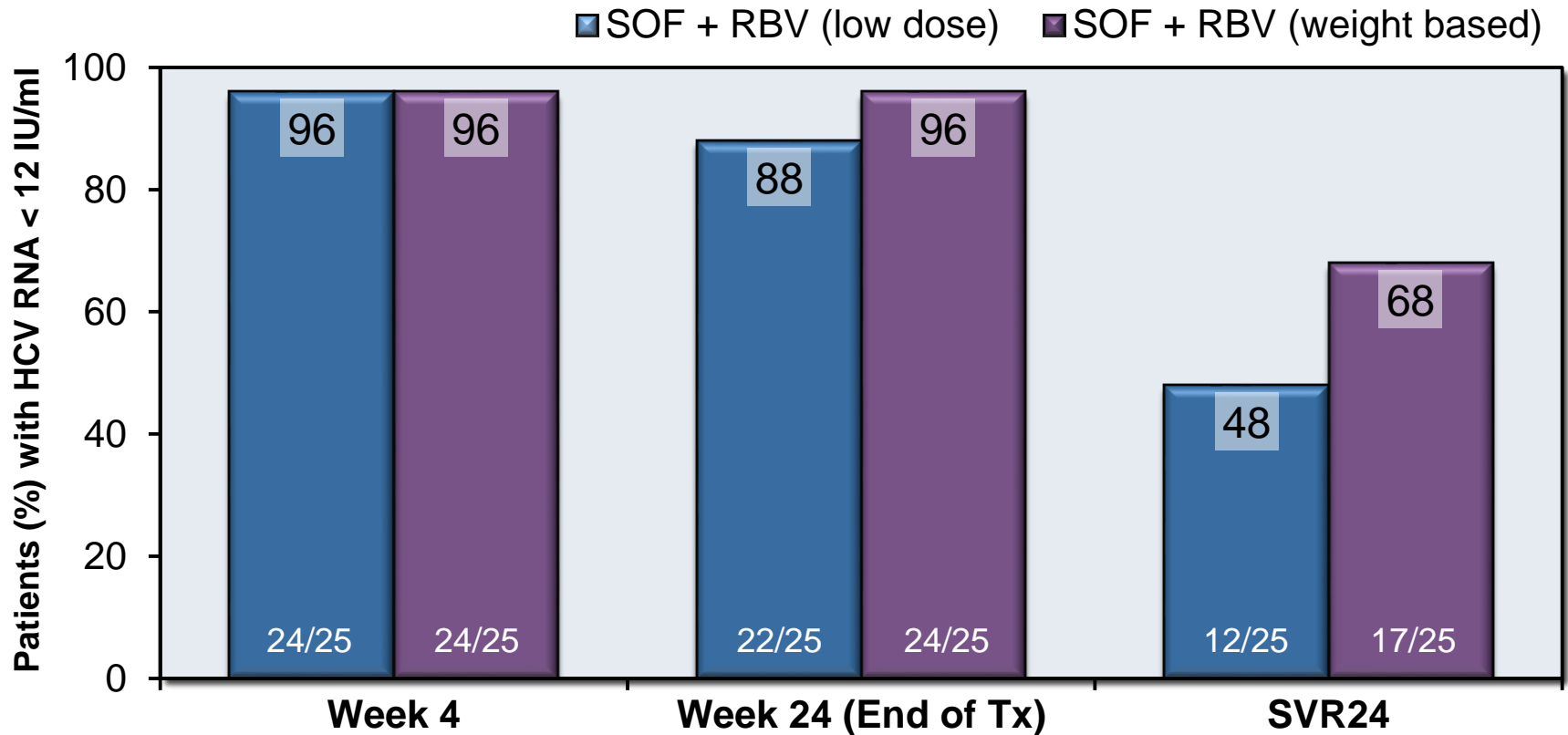


All 10 patients in Part 1 received sofosbuvir plus weight-based ribavirin

Source: Osinusi A, et al. *JAMA*. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIH SPARE Trial: Part 2 Results

NIAID/NIH Part 2: HCV RNA <12 IU/ml by Study Timepoint

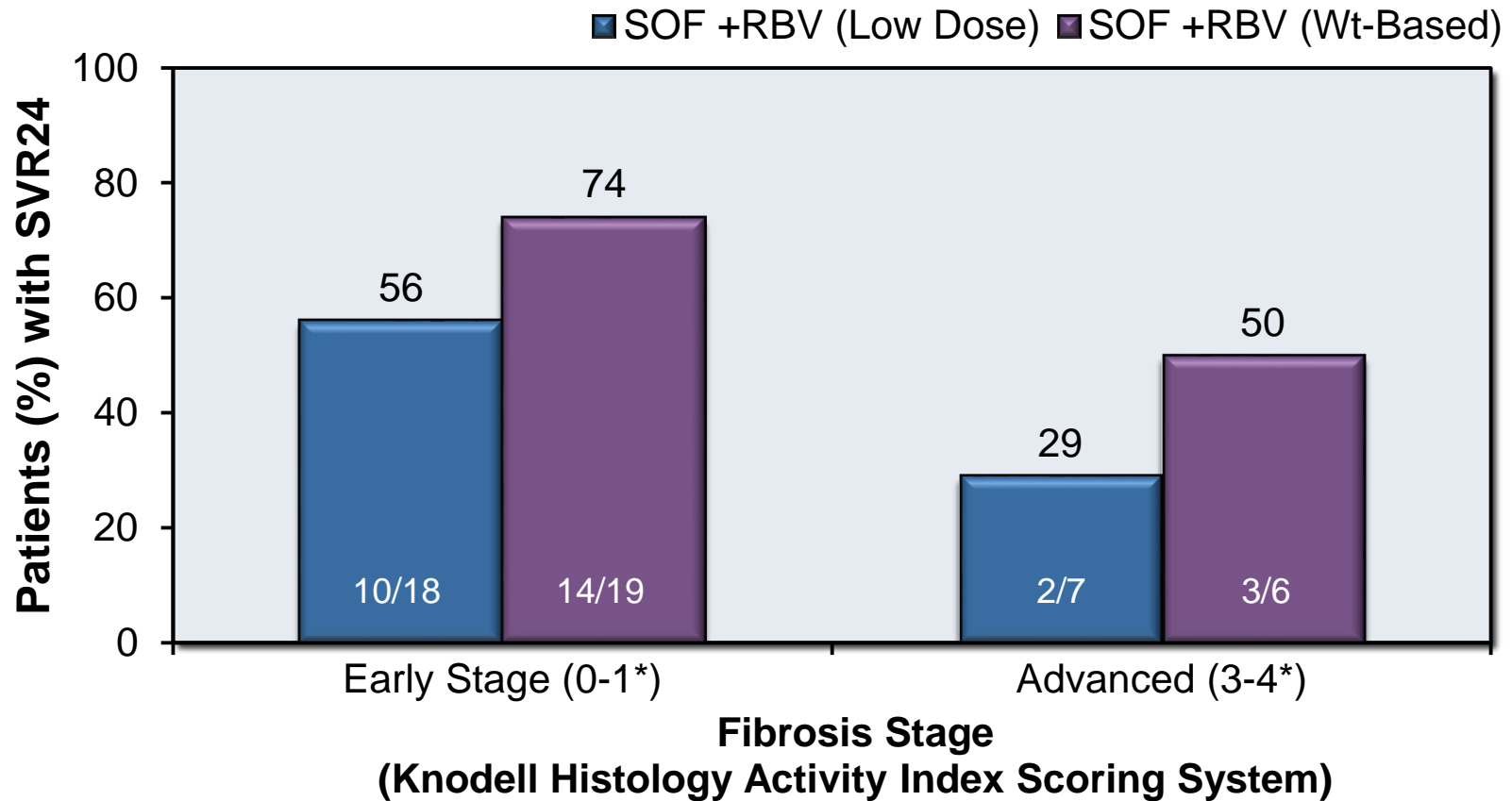


SOF = Sofosbuvir; RBV = Ribavirin

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIH SPARE Trial: Part 2 Results

NIH SPARE Part 2: SVR24 by Fibrosis Stage

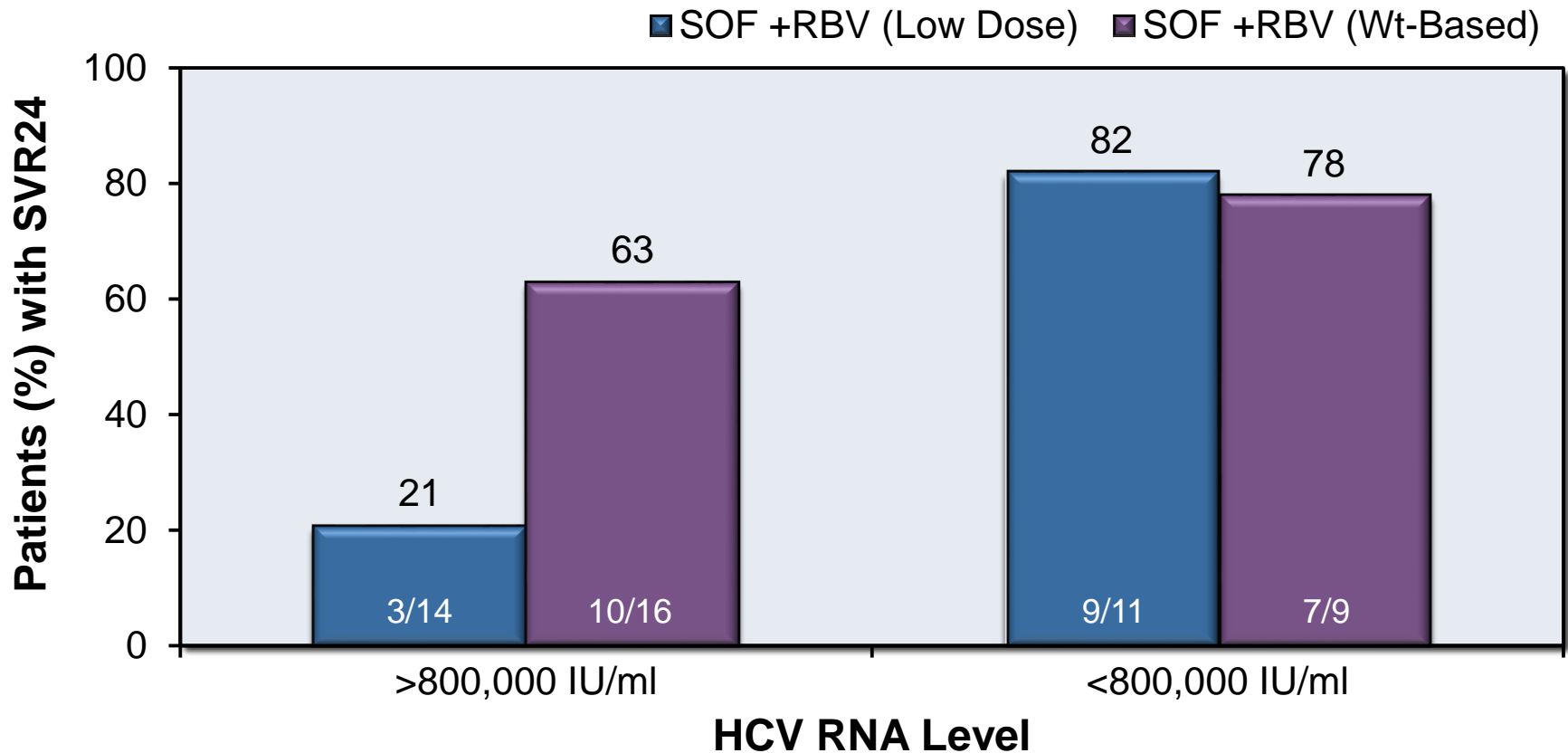


SOF = Sofosbuvir; RBV = Ribavirin

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Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIH SPARE Trial: Part 2 Results

NIH SPARE Part 2: SVR24 by Baseline HCV RNA Level



SOF= Sofosbuvir; RBV = Ribavirin

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIH SPARE Trial: Conclusions

Conclusion: “In conclusion, treatment with a 24-week regimen of sofosbuvir and ribavirin resulted in an SVR rate of 68% in the weight-based ribavirin regimen and 48% in the low-dose ribavirin regimen among patients with chronic HCV and unfavorable traditional predictors of treatment response who are representative of the demographics of the US HCV epidemic.”

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

Hepatitis Web Study

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

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