

Elbasvir-Grazoprevir in HCV GT 1,4, or 6 in PWID* on Opiate Agonist Therapy

C-EDGE CO-STAR

*PWID = Persons Who Inject Drugs

Dore GJ, et al. Ann Intern Med. 2016;165:625-34.

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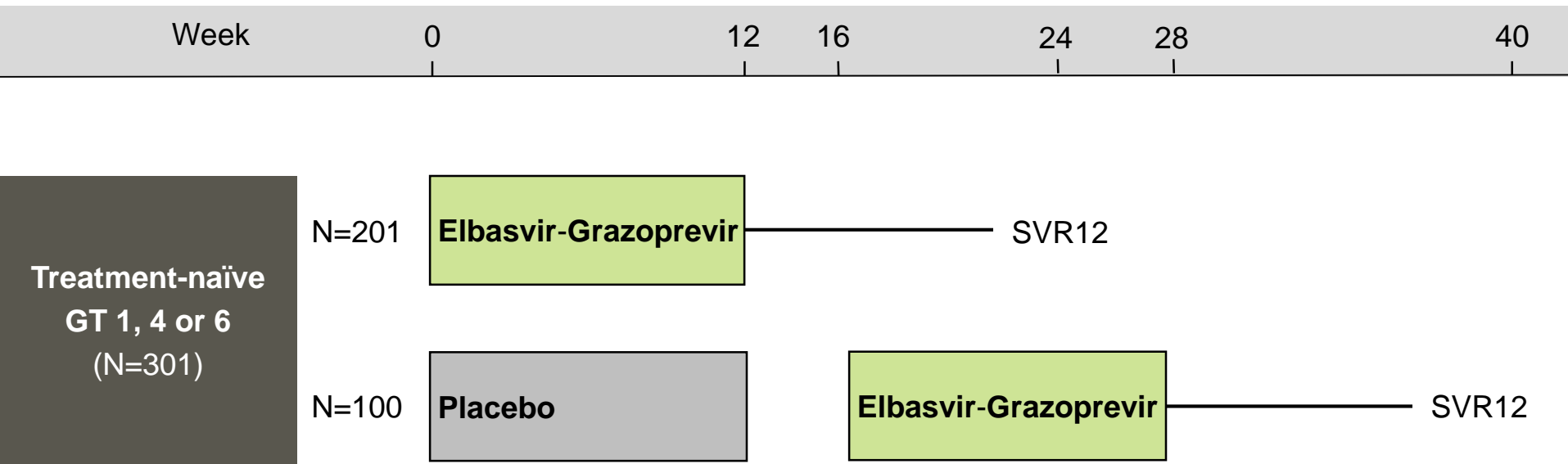
C-EDGE CO-STAR: Study Features

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- **Design:** Randomized, phase 3, placebo-controlled, double-blind, multi-site trial using a fixed-dose combination of elbasvir-grazoprevir in treatment-naïve chronic HCV genotype 1, 4, or 6 in persons who inject drugs who are receiving opiate agonist therapy
- **Entry Criteria**
 - Chronic HCV Genotype 1, 4, or 6
 - No prior treatment
 - 18 years or older
 - Opiate Agonist Therapy for ≥ 3 months and kept $\geq 80\%$ of appointments
 - HCV RNA $\geq 10,000$ IU/mL
 - Cirrhosis allowed with goal 20% of subjects with cirrhosis
 - HIV infection allowed
- **Primary End-Point:** SVR12

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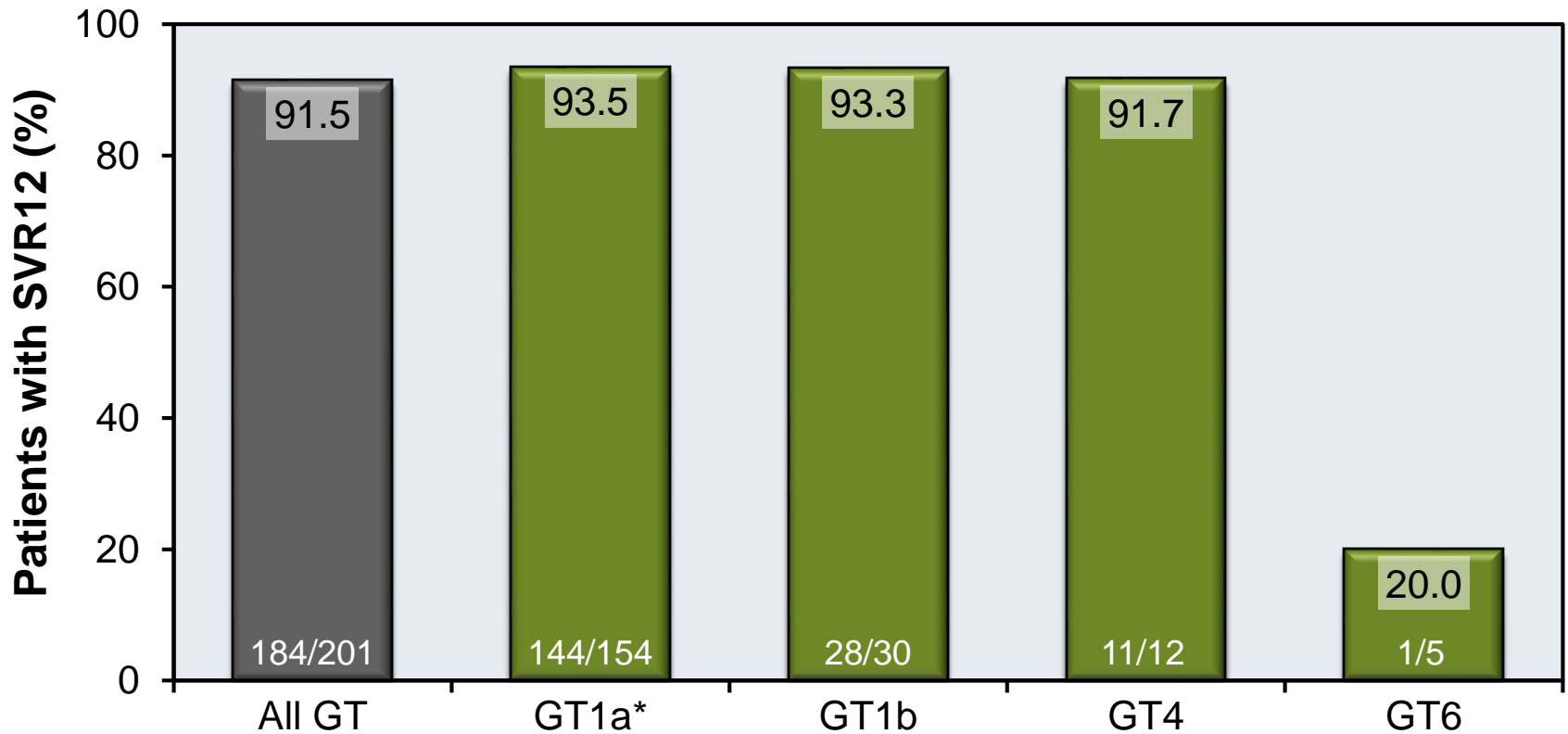


Drug Dosing

Grazoprevir-elbasvir (100/50 mg): fixed dose combination; one pill once daily

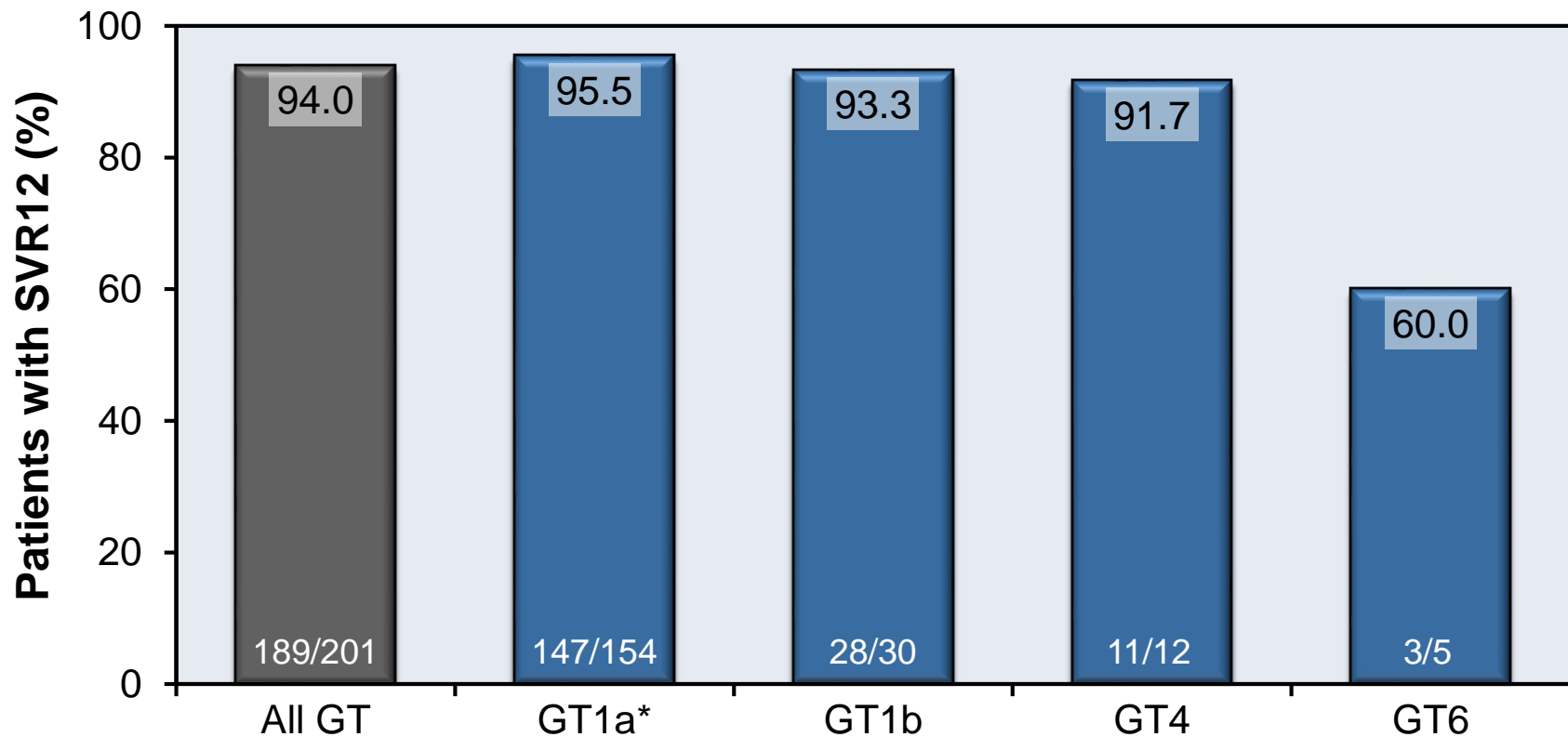
Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR: Results in Immediate Treatment Group

C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Failures)



Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR: Results in Immediate Treatment Group

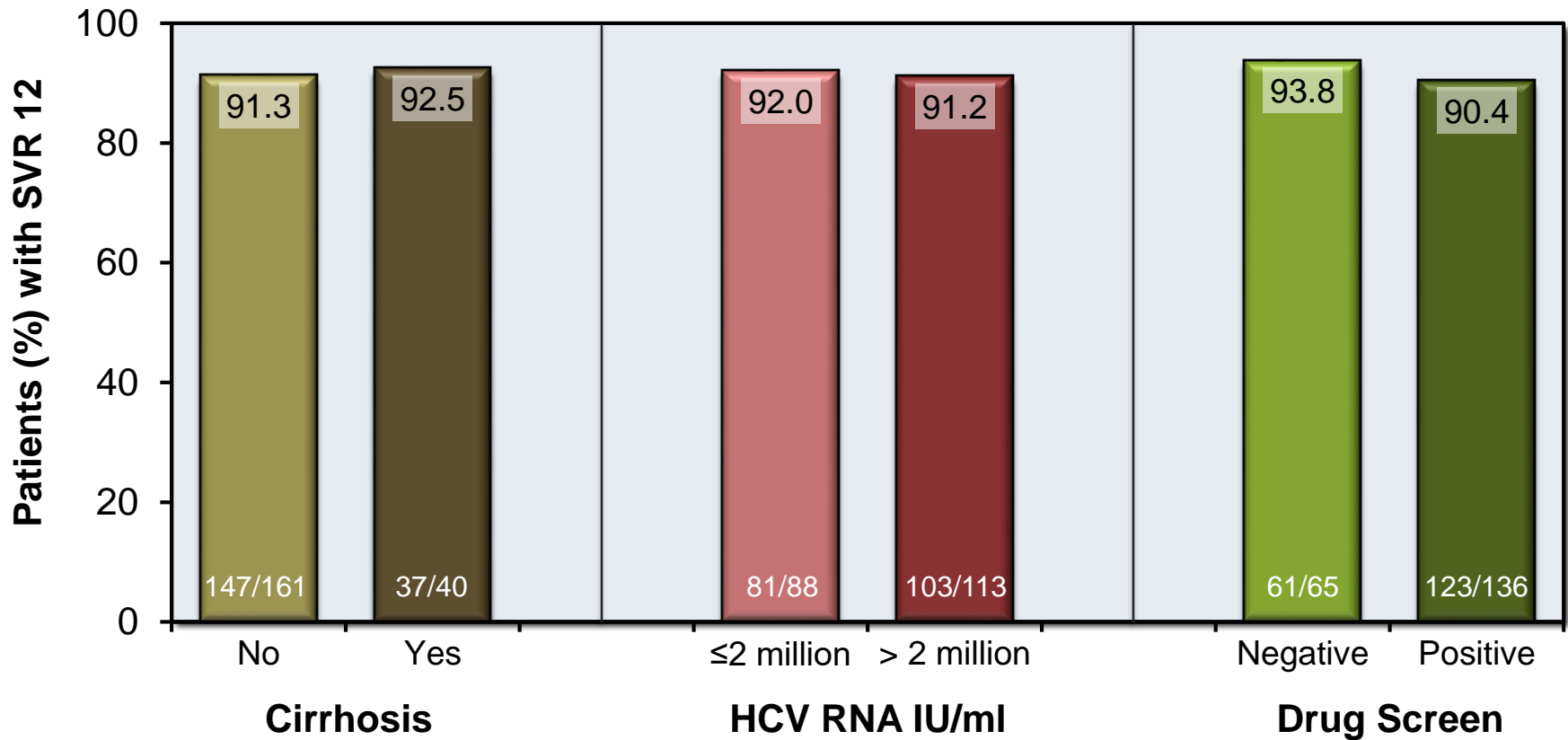
C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Responses)



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C-EDGE CO-STAR: Results

C-EDGE CO-STAR: SVR12 Results Subgroup Analysis



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C-EDGE CO-STAR: Safety

Adverse Event (AE), n (%)	Elbasvir-Grazoprevir	
	Immediate (n=201)	Deferred (Placebo) (n=100)
Discontinuation due to AE	1 (0.5)	1 (1.0)
Serious AEs	7 (3.5)	4 (4.0)
Deaths	0	1 (1.0)
Any AE in ≥10% of patients	166 (82.6)	83 (83.0)
Fatigue	32 (15.9)	20 (20.0)
Headache	25 (12.4)	13 (13.0)
Nausea	22 (10.9)	9 (9.0)
Laboratory AEs		
Hemoglobin <8.5 g/dl	1 (0.5)	1 (1.0)
Bilirubin >2.6 times upper limit of normal	0	0
Creatinine >2.5 times baseline level	0	0

Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR: Conclusions

Conclusions: “Patients with HCV infection who were receiving OAT and treated with elbasvir-grazoprevir had high rates of SVR12, regardless of ongoing drug use. These results support the removal of drug use as a barrier to interferon-free HCV treatment for patients receiving Opiate Agonist Therapy (OAT).”

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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