# A5360 (MINMON):
# A Single-arm Study to Evaluate the Feasibility and Efficacy of a Minimal Monitoring Strategy to Deliver Pan-genotypic Ribavirin-free HCV Therapy to Populations Living with HCV Who Are HCV Treatment Naïve with Evidence of Active HCV Infection

ACTG
AIDS CLINICAL TRIALS GROUP

# Background & Objectives

**Background:**

- HCV therapy has dramatically evolved over the past decade
- In 2016, WHO announced ambitious targets to eliminate HCV
  - 80% of ~71 million with chronic HCV need to be cured by 2030
  - ~3 million have been treated as of 2020
- "Simple and Safe" models of HCV delivery are needed to address major barriers:
  - Pre-treatment/monitoring tests can cost more than the antiviral therapy
  - Already overburdened health care infrastructure

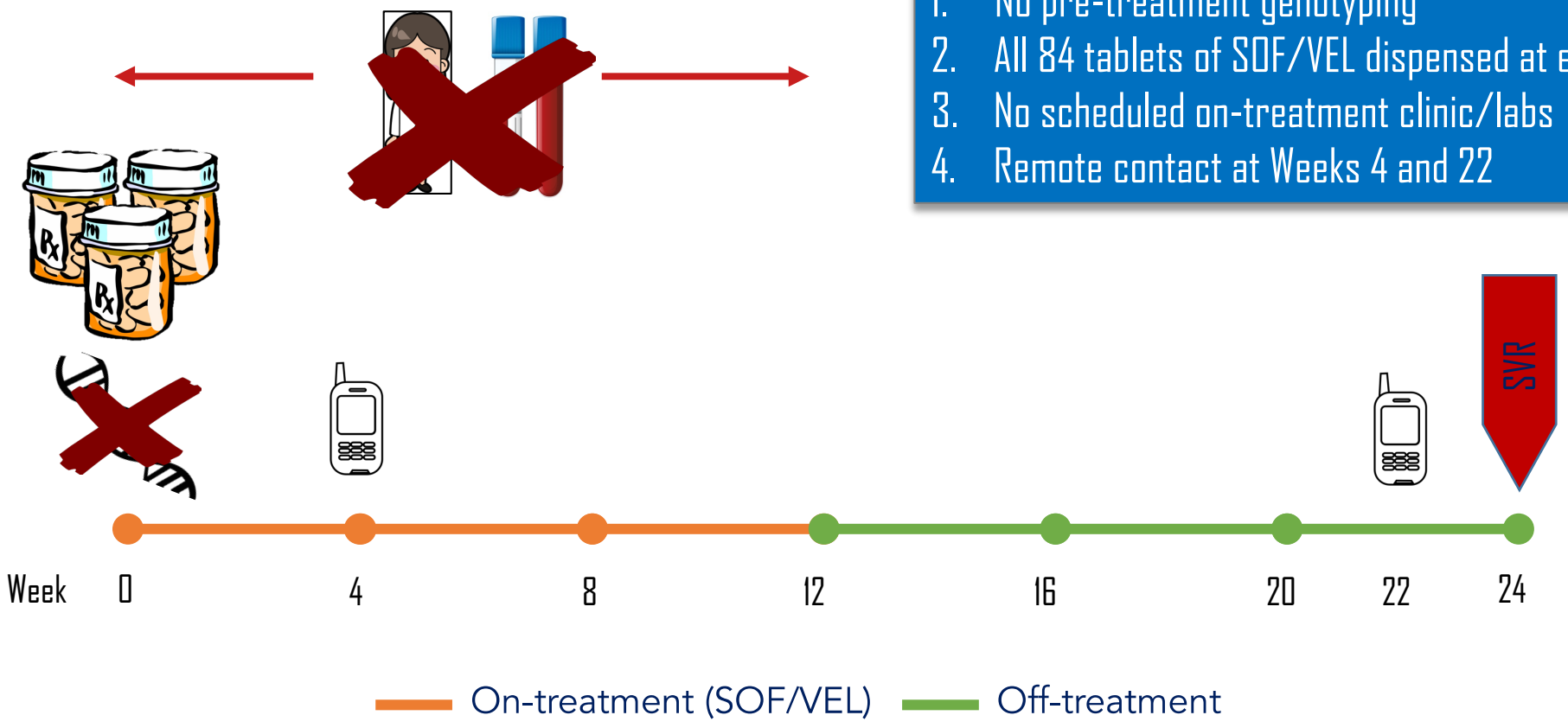
**Study Objective:**

- To evaluate the efficacy and safety of a minimal monitoring (MINMON) approach to deliver HCV therapy globally

Solomon SS for A5360 team; *CROI* 2021, *Abstract 135*

# Design of MINMON Intervention

1. No pre-treatment genotyping
2. All 84 tablets of SOF/VEL dispensed at entry
3. No scheduled on-treatment clinic/labs
4. Remote contact at Weeks 4 and 22




*Solomon SS for A5360 team; CROI 2021, Abstract 135*

# Study Population

| Baseline Characteristic | N=399 |
|---|---|
| Median age in years (Range) | 47 (20 – 82) |
| Female sex at birth, n (%) | 139 (35) |
| Identity across transgender spectrum, n (%) | 22 (6) |
| Race/Ethnicity, n(%)<br>Non-Hispanic White<br>Non-Hispanic Black<br>Non-Hispanic Asian<br>Hispanic, any race | <br>99 (25)<br>57 (14)<br>113 (28)<br>95 (24) |
| History of substance use*, n (%)<br>Current<br>Previous<br>Never | <br>56 (14)<br>170 (43)<br>171 (43) |
| Cirrhosis (FIB-4 ≥ 3.25), n (%) | 34 (9) |
| HIV co-infection, n(%)<br>On cART, HIV RNA<400 copies/ml, n (%)** | 166 (42)<br>164 (99) |
| Median HCV RNA in $\log_{10}$ IU/ml (IQR) | 6.1 (5.6 – 6.6) |
| HCV Genotype***, n(%)<br>Genotype 1<br>Genotype 2<br>Genotype 3<br>Genotypes 4, 5, 6, 7 | <br>249 (62)<br>26 (7)<br>80 (20)<br>41 (10) |

*cART: combination antiretroviral therapy; *current substance use defined as self-report of amphetamines, cocaine, opioids or sedatives in the prior 3 months using ASSIST; **restricted to HIV/HCV co-infected participants; ***genotype data missing on 3 participants*


*Recruitment at US sites limited to 132 participants

Great job specifying female sex at birth and enrolling transgender participants. Consider adding "assigned at birth"

*Solomon SS for A5360 team; CROI 2021, Abstract 135*

# Key Findings

- 95% of participants (379/399) who initiated treatment achieved sustained virologic response (cure) (95% CI: 92.4, 96.7)
- 3.5% of participants (14/397) with follow-up reported at least one SAE between treatment initiation and Week 28 (95% CI: 2.8, 5.8%)
  - None were treatment-related or led to treatment discontinuation or death

**Unplanned Visits:**

- 3.5% of participants (15/399) reported at least one unplanned visit
- Most common reasons for unplanned visits included lab abnormalities detected at baseline and non-adverse clinical events

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# Importance & Next Steps

- MINMON approach to HCV treatment delivery is simple, safe, and efficacious and achieved SVR comparable to standard monitoring guidelines currently in use today
- These findings have the potential to impact HCV treatment delivery guidelines globally
- Coupled with innovative case-findings strategies, the MINMON approach could play a pivotal role in achieving WHO HCV elimination targets

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