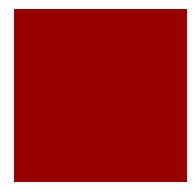


#### HCV Drug Development & People Who Use Drugs

HCV DRAG Meeting # 7 San Francisco, CA San Francisco Marriott Marquis



# WHY?

 Assess risks/benefits of HCV treatment in the context of OST/ongoing drug use

Failure to enroll current and former drug users/people on OST supports justification for withholding treatment

In the context of collapsing public health systems, or urgent and unmet medical need, clinical trials may be the best—or only—option for access to HCV treatment

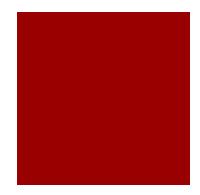
## Current/Former Drug Users: An Implied Population

Special populations listed in regulatory guidance on HCV drug development:

- Decompensated liver disease and/or pre-transplant
- Post-transplant
- Hepatic impairment
- HIV/HCV coinfected patients
- PEG IFN and RBV intolerant patients,
- Patients with prior DAA experience
- Pediatric patients

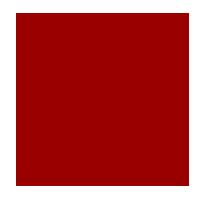
EMA: Guideline on Clinical Evaluation of Medicinal Products for Treatment of Hepatitis C. Draft for Consultation. January 2011. FDA: Guidance for Industry. Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment. Draft Guidance. September 2010.

### Gaps in HCV Drug Development



Population	Boceprevir	Telaprevir
People on OST	0%	0.5% or 11 of 2,290

# Regulatory Guidance on DDIs w/ OST



#### "...priority should be given to studies of coadministration with other drugs used in the management of HCV, HIV, liver transplantation, depression and **substance abuse**, as well as oral contraceptives. Within these areas, essential drugs...that have a foreseen potential for interaction, should be prioritized for study. Such data is expected to be available at the time of the marketing authorisation."

#### **FDA**

**EMA** 

Does not mention methadone or buprenorphine

- Registration trials usually exclude or grudgingly include people who use drugs (although rarely)
  - Lack of clarity around concerns: safety, adherence?
  - Lack of effort to address these, i.e. DDIs, training/ selecting experienced investigators
  - Use of drug testing, which screens out the wrong people
  - Under-utilization of multidisciplinary care
  - No peer involvement
  - Criteria are vague, and subjective (up to the investigator, but no guidance/information provided)

