



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 coinfecting 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 Draft Guidance.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

EMA

“..priority should be given to studies of co-administration 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

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)

