



# **ADVANCING HCV DRUG DEVELOPMENT: A COLLABORATIVE APPROACH**

**Veronica Miller PhD  
Forum for Collaborative HIV  
Research**



*enhancing & facilitating HIV research*

# FORUM MISSION

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- Our mission is to facilitate and enhance HIV research.
- The Forum for Collaborative HIV Research is a public/private partnership including government agencies, industry, HIV researchers and clinicians, payors, foundations and the HIV patient advocacy community.
- HIV collaborative model applied to HCV



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# SUPPORT ACKNOWLEDGMENT

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- This meeting is supported by HCV DRAG funds.
- The Forum receives funding from member pharmaceutical companies.



# HCV DRUG DEVELOPMENT ADVISORY GROUP (HCV DRAG)

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- **Purpose:** bring together parties interested in and working in HCV drug resistance to discuss issues pertinent to HCV drug development and resistance testing
  - Composition: representatives from industry, academics and regulatory agencies, community advocates
- **Goals:**
  - Provide scientific guidance to facilitate discussion between industry, regulatory agencies, and other parties integral to HCV drug development
    - Produce consensus recommendations of appropriate methodology for HCV resistance testing in drug development
    - Clinical trial design
    - Standardization of nomenclature and definitions (with AASLD and EASL)



# HCV DRAG: STEERING COMMITTEE

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- Ira Jacobson, MD
- Filip Josephson, MD, PhD
- Dale Kempf, PhD
- Ann Kwong, PhD
- Nina Mani, PhD MPH
- Veronica Miller, PhD
- Isabel Najera, PhD
- Jules O'Rear, PhD
- Jean-Michel Pawlotsky, MD, PhD
- Stuart Ray, MD
- Jur Strobos, MD, JD, FACEP
- Kimberly Struble, PharmD
- Tracy Swan



# MEETING GOALS

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- Direct acting antivirals (DAAs) have the potential to change the treatment landscape for chronic HCV infection, similar to ARVs and HIV
- Draft FDA guidance, recent opinions from EMA and new trial information presented at 2010 EASL and AASLD provide the background for today's meeting to discuss:
  - Future trial designs and endpoints, including evaluation of interferon and/or ribavirin sparing regimens
  - Use of two or more DAAs in treatment-naïve, treatment-experienced trials
  - Drug resistance issues and their impact on treatment
  - Need for DAAs and approaches in certain special populations: HIV/HCV co-infected, liver transplant patients, people with bleeding disorders, current drug users and those in opiate substitution therapy, pediatrics and EAP/Treatment INDs



# MEETING FORMAT

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- Formal presentations in Session 1 and moderators of Session 3
- Followed by moderated panel discussions:
  - Introduction of panelists
  - Discussion of questions posed by moderators
  - Questions from public/webcast participants to panelists