



**Forum for  
Collaborative HIV Research**

# **HCV DRUG DEVELOPMENT ADVISORY GROUP MEETING #8**

**FORUM FOR  
COLLABORATIVE HIV  
RESEARCH  
APRIL 17, 2012**



*enhancing & facilitating HIV research*

# FORUM MISSION

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- 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.
- Our mission is to facilitate and enhance HIV research.
- HIV collaborative model applied to HCV



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# SUPPORT ACKNOWLEDGMENT

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- The Forum receives funding from member pharmaceutical and diagnostic companies



# HCV DRUG DEVELOPMENT ADVISORY GROUP (HCV DRAG)

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- **Purpose:** bring together parties interested in and working in HCV drug development
  - Composition: representatives from industry, academics and regulatory agencies, community advocates
- **Objectives:**
  - Provide scientific guidance to facilitate discussion between regulatory agencies, academia, community and industry on:
    - ⊙ Clinical trial design for HCV DAA's in diverse populations
    - ⊙ Consensus on appropriate methodology for HCV resistance testing in drug development
      - Sequence analysis and phenotype analysis
    - ⊙ Standardization of nomenclature and definitions (with AASLD and EASL and IDSA)
      - Consensus on LOD/LLOQ cutoffs for HCV viral assays for key points in therapeutic timeline
    - ⊙ Educational slide deck for public use



# HCV DRAG WORKING GROUPS

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- **Purpose:** Carry out the work of the DrAG
- **WGs:** Available at [www.hivforum.org](http://www.hivforum.org)
  - Sequence Analysis Working Group (SAWG)
  - Phenotype Analysis Working Group (PAWG)
  - Clinical Trials Working Group (CTWG)
  - Definitions/Nomenclature Working Group (DNWG)
  - Educational Slide Set Working Group (EdWG)
  - Database Working Group (DbWG)
- WG affiliation is important!
- Contact us with your choice of group(s) membership



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# HCV DRAG: STEERING COMMITTEE

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- **\*Robert Kaufmann, MD, PhD**
- **Patrick Harrington, PhD**
- **Daria Hazuda, PhD**
- **Ira Jacobson, MD**
- **Donald Jensen, MD**
- **Filip Josephson, MD, PhD**
- **Ann Kwong, PhD**
- **\*Jean-Michel Pawlotsky, MD, PhD**
- **Nina Mani, PhD, MPH**
- **Veronica Miller, PhD**
- **Isabel Najera, PhD**
- **Stuart Ray, MD**
- **Kimberly Struble, PharmD**
- **Tracy Swan**

**\*Co-Chairs**



# DRAG POSTER: EASL 2012

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- Presentation Date: Friday, 20 April
- Session Title: Category 08b: Viral Hepatitis C: Clinical Except Therapy)  
Poster Board Number: 897
- “Consensus recommendations for virologic nomenclature in DAA clinical trials”



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