

enhancing and facilitating HIV research



## Forum for Collaborative HIV Research



Located in Washington DC, part of the School of Public Health



**Forum for  
Collaborative HIV Research**

# **HCV DRUG DEVELOPMENT ADVISORY GROUP # 7 MEETING**

**Veronica Miller PhD  
Forum for Collaborative HIV  
Research  
November 3, 2011**



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# 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

Agencies  
USA

CDC  
FDA  
**HHS/OASH\***  
HRSA  
NIH  
OGAC  
USAID  
VA

NIH

NIAID  
NIDA  
NIMH  
OAR

Community  
Advocacy

CAB -ACTG  
CAB- INSIGHT  
EATG  
HIVMA  
NGMAC  
TAG

Foundations

BMGF  
AmFAR  
EGPAF

Industry (HIV)

Abbott  
BD  
BI  
Biomerieux  
BMS  
Gilead  
Idenix  
Merck  
Monogram  
Roche MD  
Serono  
Tibotec  
VIIV

Industry (HCV)

Abbott  
Abbott MS  
Achillion  
Alios  
Anadys  
BI  
BMS  
Biocartis  
Debiopharm  
DDL  
Gilead  
GSK  
Incyte  
Inhibitex  
Intermune  
Merck  
Monogram  
Novartis  
Roche  
Roche MD  
Pharmasset  
Presidio  
Tibotec  
Vertex  
Virco

Europe

ANRS  
EMA

HCV

TAG  
NVHR  
PWBD+HCV  
NATAP

Academia/Providers

ACTG  
INSIGHT  
Epi/Stats  
Immunology  
Virology  
Women's Health

Insurance

Kaiser Permanente



# 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)
      - Consensus on LOD/LLOQ cutoffs for HCV viral assays for key points in therapeutic timeline
    - ⊙ Educational slide deck for public use



# HCV DRAG: STEERING COMMITTEE

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- Michelle Berrey, MD
- Patrick Harrington, PhD
- Ira Jacobson, MD
- Filip Josephson, MD, PhD
- \*\*Dale Kempf, PhD
- \*Ann Kwong, PhD
- Nina Mani, PhD MPH
- Veronica Miller, PhD
- Isabel Najera, PhD
- \*Jean-Michel Pawlotsky, MD, PhD
- Stuart Ray, MD
- Kimberly Struble, PharmD
- Tracy Swan

\* Co-Chairs

\*\* Past Co-Chair



# FORUM RULES

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- Constructive dialogue between expert stakeholder representatives
  - All stakeholder groups represented
  - Everyone brings their expertise to the table
    - Everyone participates
  - Formal presentations limited to background and/or overview topics
- Closed (by invitation only) meetings
  - Confidentiality -- what's said in this room, stays in this room



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# SUPPORT ACKNOWLEDGMENT

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- The Forum receives funding from member pharmaceutical and diagnostic companies



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