

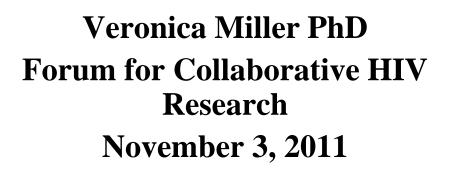
Located in Washington DC, part of the School of Public Health





Forum for Gollaborative HIV Research

HCV DRUG DEVELOPMENT Advisory Group # 7 MEETING



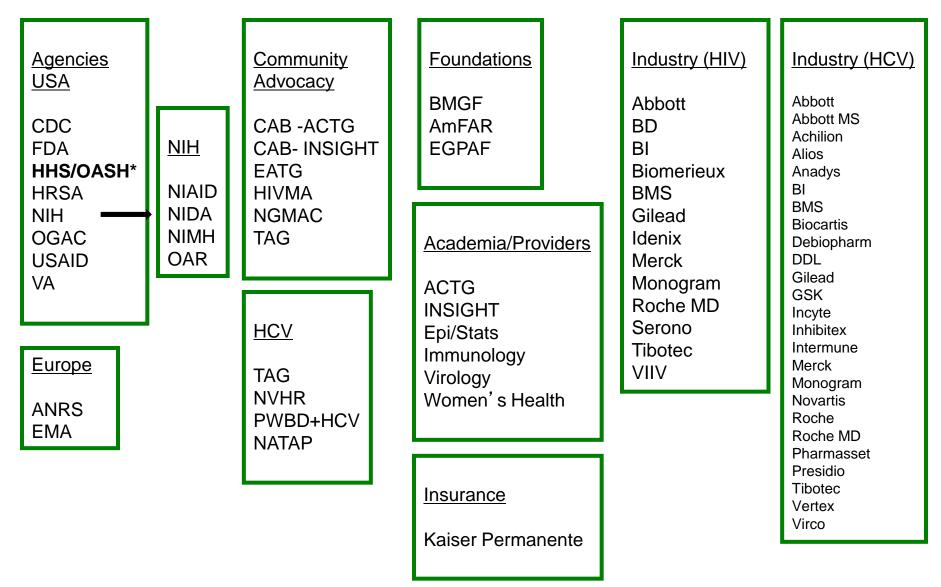


FORUM MISSION

• 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



V Miller Nov 3, 2011



HCV DRUG DEVELOPMENT ADVISORY GROUP (HCV DRAG)

- **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

- Michelle Berrey, MD
- Patrick Harrington, PhD
- Ira Jacobson, MD
- Filip Josephson, MD, PhD
- **Dale Kempf, PhD
- *Ann Kwong, PhD
- Nina Mani, PhD MPH
 - * Co-Chairs** Past Co-Chair

- Veronica Miller, PhD
- Isabel Najera, PhD
- *Jean-Michel Pawlotsky, MD, PhD
- Stuart Ray, MD
- Kimberly Struble, PharmD
- Tracy Swan

enhancing & facilitating HIV research



FORUM RULES

- 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



SUPPORT ACKNOWLEDGMENT

• The Forum receives funding from member pharmaceutical and diagnostic companies



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