



**Forum for
Collaborative HIV Research**

HCV TRIALS IN THE POST- APPROVAL ERA OF TELAPREVIR AND BOCEPREVIR – THE WAY FORWARD

**Veronica Miller PhD
Forum for Collaborative HIV
Research
October 18, 2011**



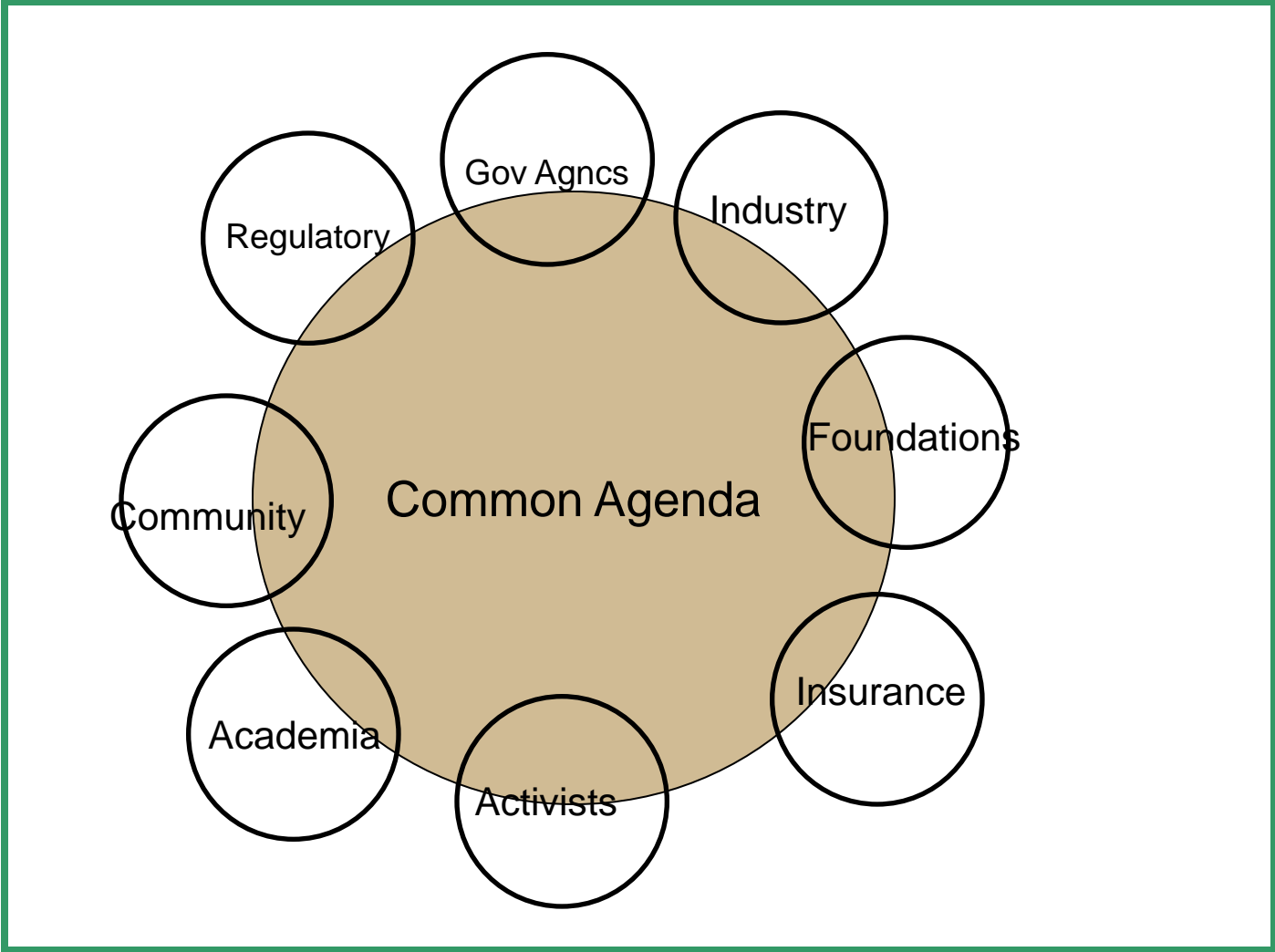
enhancing & facilitating HIV research

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



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)

- **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

enhancing & facilitating HIV research

- Michelle Berrey, MD
- Ira Jacobson, MD
- Filip Josephson, MD, PhD
- *Dale Kempf
- *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
- Kimberly Struble, PharmD
- Tracy Swan

* Co-Chairs



enhancing & facilitating HIV research

SUPPORT ACKNOWLEDGMENT

- This meeting is supported by HCV DrAG funds
- The Forum receives funding from member pharmaceutical and diagnostic companies