The Forum HIV Cure Project: Focus on Regulatory Issues

A Collaborative Effort to Map the Regulatory Pathway for HIV Cure Strategies

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Forum Mission

- Public/private partnership including government agencies, industry, HIV researchers and clinicians, insurers, foundations and the HIV patient advocacy community
- Mission: to facilitate and enhance HIV research
  - Neutral & independent space
- Apply HIV collaborative model to HCV
  - CMV in transplantation
  - Anti-fibrotics for NASH and liver fibrosis/cirrhosis

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What was the Impetus?

The Keystone National Policy Dialogue on Establishment of Studies to Optimize Medical Management of HIV Infection

Many decision leaders are interested in making progress on these issues. Vice President Al Gore held a meeting with pharmaceutical executives and government officials in February, 1996 to discuss drug development of therapeutics, vaccines, and microbicides to combat HIV. The Keystone Dialogue Group was convened to develop a framework to establish studies to provide information for optimizing the medical management of HIV infection. The...
# Members & Collaborators

## Government Agencies
- **USA**
  - CDC
  - FDA
  - HHS/OASH
  - HRSA
  - NIH
    - NIAID
    - NIDA
    - NIMH
    - OAR
  - OGAC
  - USAID
  - VA
- **Europe**
  - ANRS
  - EMA

## Academia / Providers
- ACTG
- Epi / Stats
- Immunology
- Virology
- Women’s Health

## Industry
### HIV
- Abbvie
- Abbott Mol.
- Alere
- BI
- Bio-Rad
- BMS
- Genentech
- Gilead
- Illumina
- Janssen
- Merck
- Monogram
- Orasure
- PacBio
- Quest
- Quintiles
- Roche MS
- Tobira
- ViiV

### HCV (cont.)
- Abbvie
- Abbott Mol.
- Achillion
- BI
- BMS
- DDL
- Genentech
- Gilead
- GSK
- Idenix
- Janssen
- Medivir
- Merck
- Monogram
- Novartis
- PPD
- Quest
- Quintiles
- Roche MS
- Vertex
- Virco

## Foundations
- BMGF
- amfAR
- EGPAF

## Professional Societies
- AAN
- AASLD
- EASL
- HIVMA
- IAS
- IDSA

## Community / Advocacy
### HIV
- ATAC
- CAB-ACTG
- CAB-INSIGHT
- EATG
- NGMAC
- TAG

### HCV
- HCAB
- NATAP
- NVHR
- PWB+HCV
- TAG

## Insurers
- Kaiser
- Permanente
FDASIA

- Food and Drug Administration Safety and Innovation Act
  - Public Law 122-144
  - July 9, 2012
- Section 905 amends Section 505(d) of FD&C Act
  - “implement a structured risk-benefit assessment framework…….”
In PDUFA V, FDA also committed to a new initiative called Patient-Focused Drug Development with the goal of obtaining the patient perspective on certain disease areas during the five year period of PDUFA V. Assessment of a product’s benefits and risks involves an analysis of the severity of the condition treated and the current treatment options available for the given disease. This information is a critical aspect of FDA’s decision-making as it establishes the context in which the regulatory decision is made. FDA believes that drug development and FDA’s review process could benefit from a more systematic and expansive approach to obtaining the patient perspective on disease severity and current available options in a therapeutic area.
Enhancing & facilitating HIV research

Translational Medicine

Discovery | Clinical Research | Approval | Post-Marketing | Implementation
Lessons Learned

• Neutral, independent setting
• Right stakeholders involved; equal voice
  – FDA & EMA
• Dialogue/discussion to reach consensus where possible
  – Focus on issues & concerns of common interest
• Structure in place for evolving consensus
• Dedicated “safe space” and time for the interaction to take place
Steering Committee

Co-Chairs:
- Daniel Kuritzkes, MD
- Veronica Miller, PhD

Community:
- David Evans
- Mark Harrington

Federal Government:
- Jeffrey Murray, MD, MPH
- Sarah Read, MD MHS PhD
- Paul A. Sato, MD, MPH
- Celia Witten, PhD, MD
- Carol Weiss, MD, PhD

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- Rowena Johnston, PhD

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Academia  Community/Advocacy  Federal Government  Foreign Government  Foundation  Industry

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**Working Groups**

- **Overall membership:**
  - 100+ experts
  - International representation
  - Academics, community, federal agencies (regulators) industry

- **#1: Biomarkers & Endpoints**
  - John Mellors & Michael Miller

- **#2: Clinical Trials – Risk:Benefit**
  - Jintanat Ananworanich & Joe Eron

- **#3: Patient education, recruitment & informed consent**
  - David Evans & Tim Henrich
Today’s Goals

- Regulatory Pathway for HIV Cure Research:
  - Developing consensus Part I
- Establish the baseline
  - Where are we at?
- Presentation and discussion of WGs output
- Feedback from the HIV community
  - Begin the multi-stakeholder dialogue

This is just the beginning – the conversation will continue
Post June 17th

- Survey
- Publications
- Ongoing working groups
- Intervention specific working groups
Acknowledgments: Forum Staff

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- Rob Besaw
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- Erik Lontok
  - Project Manager
  - WG#2 Manager
- Nivedha Panneer
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Panel Discussion

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- Dan Kuritzkes (HMS/BWH), moderator
- Debra Birnkrant (CDER/FDA)
- Sandra Nusinoff Lehrman (Merck)
- Mark Harrington (TAG)
- Sarah Read (DAIDS/NIH)
- Paul Sato (OAR/NIH)