



**HIV/AIDS Clinical Research in the Resource  
Limited Setting  
Roundtable 1: Accessing Drugs for Clinical  
Research**

**The Forum for Collaborative HIV Research**

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Director

[www.hivforum.org](http://www.hivforum.org)

**Forum for Collaborative  
HIV Research**

**School of Public Health &  
Health Services**

**The George Washington  
University**



The Forum for Collaborative HIV Research is a public/private partnership including government agencies, industry, HIV researchers and clinicians, payors, and the HIV patient advocacy community.

Our mission is to facilitate and enhance HIV research.

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# Forum History



- Established in 1997, following  
**Keystone Center Dialogue Group on Establishment of Studies  
to Optimize Medical Management of HIV Infection**  
**May - August 1996**
- Recommendations presented to and endorsed by Vice  
President Gore
- GOAL: “To facilitate information exchange and actively  
catalyze appropriate stakeholders to develop and  
implement new studies to address critical unanswered  
questions regarding optimal medical management of HIV  
disease.”

# Forum Characteristics



- Collaboration
- Ownership (by each stakeholder)
- Independence (not run by any ONE stakeholder)
- Credibility
- Productivity (no duplication of other work)
- Accountability (to stakeholders)
- Accessibility

# The Forum Executive Committee



- Government Agencies
  - US DHHS (NIH, CDC, FDA, HRSA), State Department (OGAC)
  - European Regulatory: EMEA
- Industries
  - Abbott, Bayer Diagnostic, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Roche Laboratories, Roche Molecular Systems, Pfizer, Schering-Plough, Tibotec, Virologic
- Payors: Kaiser Permanente
- Academia
  - US and Europe
- Providers
- Patient Advocacy
  - US and Europe
- Foundations & Organizations (Gates, amFAR, IAS)

# Mechanisms & Outcomes



- Workshops
- Roundtable Discussions
- On-Going Working Groups
- Conference Activities
  - Satellite Symposia
  - Feedback of projects and reports
- Identification of gaps, recommendations, collaborations between programs, constituencies, etc; dissemination of information, publication and position papers, streamlined funding, etc

# The Global HIV/AIDS Research Agenda Roundtable Series



- Roundtable 1: Accessing drugs for clinical research in government funded research
- Roundtable 2: The role and perspective of innovator and generic/copy product industry in supporting the clinical research agenda
- Roundtable 3: Ethics and responsibilities for all stakeholders

# Rules of the game.....



- Open, honest, constructive, collaborative discussion
  - Leave your “hat” at the door, bring your expertise to the roundtable
- Moderators role in guiding the discussion
- Refreshments available throughout
- Working lunch



# Steering Committee for Roundtable 1



Ben Cheng	Forum for Collaborative HIV Research
Mark Dybul	Office of the Global AIDS Coordinator
Gregg Gonsalves	Gay Mens' Health Crisis
Roy Gulick	Cornell University
Sally Hodder	University of Medicine and Dentistry New Jersey,
King Holmes	Center for AIDS & STD, University of Washington
Michel Kazatchkine	Ambassador, Struggle against HIV/AIDS, France
Dan Kuritzkes	Harvard Medical School
Sandra Lehrman	Division of AIDS, NIH
Veronica Miller	Forum for Collaborative HIV Research
Paolo Miotti	Office of AIDS Research, NIH
James Rooney	Gilead Sciences
Paul Volberding	University of California, San Francisco

# Special acknowledgments



- Roundtable 1 supported in part by IDSA
- Special thanks to
  - Ipsita Das – project coordinator
  - Ben Cheng and Becky Griesse



# Introduction of Participants

- Roundtable Chairs:
  - King Holmes
  - Michel Kazatchkine
- Researchers
- Industry
- Agency & Sponsors
- Foundations
- NGOs
- Community advocates
- Legislative staffers

# Today's Roundtable



- Goals and Objectives
- Presenting the problem
  - researcher's perspective
  - public sector perspective
  - private sector perspective
  - ethicists perspective
- Restating the problem
- Developing guiding principles

# The Global HIV/AIDS Research Agenda



- Other 1
- Other 2
- Other 3
- Procuring Drugs
- Other 4
- Other 5
- Other 6

