

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

The Forum for Collaborative HIV Research

Veronica Miller Director

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.



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."





- 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





- 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

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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

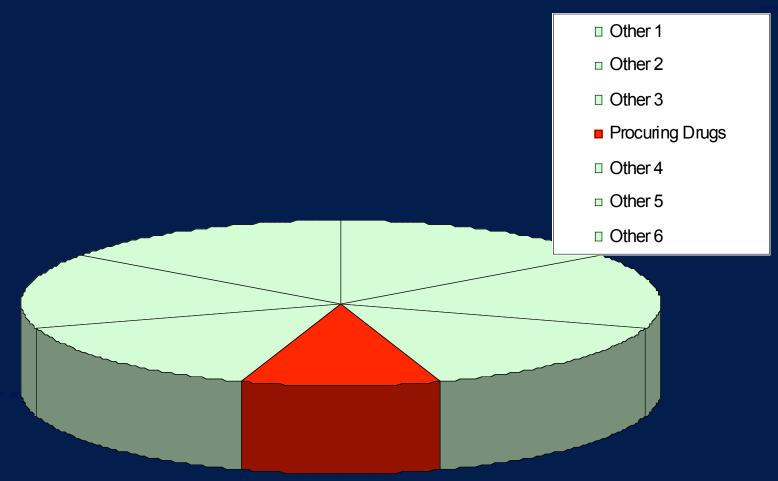


Today's Roundtable

- 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



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