

Berkeley School of Public Health

Forum for Collaborative HIV Research

## Accelerating Drug Development through Collaboration

October 7, 2015  
 Veronica Miller, PhD  
 UC Berkeley School of Public Health  
 Forum for Collaborative HIV Research  
 Washington DC

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

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Forum Mission

facilitating collaborative research drug development & health policy

- 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**
- **NASH and liver fibrosis/cirrhosis**
- **HBV Treatment & Cure**

Miller StopNASH 2015 [www.hivforum.org](http://www.hivforum.org)

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Forum Model & Principles

facilitating collaborative research drug development & health policy

The diagram illustrates the Forum Model & Principles. It features a central purple box containing core principles, surrounded by eight stakeholder groups in light blue circles. The stakeholder groups are: Government Agencies, Academia, Foundations, Professional Societies, Industry, Community, Advocacy Organizations, and Health Insurers. The core principles are:

- **Collaboration**
  - achieve optimal resource utilization
- **Ownership**
  - of the process by all stakeholders
- **Independence**
  - from bias
- **Credibility**
  - scientifically & ethically sound principles
- **Productivity**
  - avoid duplication
- **Accountability**
  - to all the stakeholders
- **Accessibility**
  - of products to all members & the public

Miller StopNASH 2015 3

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facilitating collaborative research  
drug development & health policy

## Accelerating Access to Better and Safer Drugs for All (without lowering standards)

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## Beginnings

- ▼ 1996
  - White House (Al Gore)
  - Keystone Dialogue
- ▼ 1997 (GWU)
  - 1 year funding (HHS)
  - 5 year multi-stakeholder fundin
    - o NIH, CDC, HRSA, CMS
    - o Non-renewable
    - o Pharmaceutical companies (4-6)
- ▼ 2001
  - International: Europe
    - o Pharma, biotech, diagnostics
- ▼ 2010
  - UC Berkeley SPH
  - New disease areas



Miller StopNASH 2015

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

\*Forum Annals Vol 1; 1996

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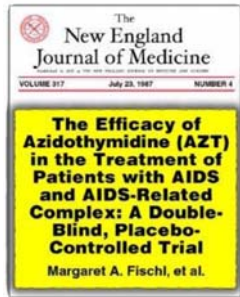
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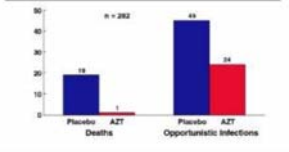
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BW 002: 24-Week Study of AZT vs. Placebo in Patients with AIDS or ARC



Miller StopNASH 2015

Fauci Sept 2011 hivforum.org

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## HIV/AIDS Today

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drug development & health policy

- Treatment is Prevention
  - Reduced transmission
- Pre-Exposure Prophylaxis
  - Reduced acquisition
- Research for HIV cure

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## Facilitating Collaborative Research in Drug Development and Health Policy

facilitating collaborative research  
drug development & health policy

- Stakeholder engagement driven deliberative process
- Co-evolution of science and regulatory guidance

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## 21<sup>st</sup> Century Challenge

facilitating collaborative research  
drug development & health policy

- Maximizing benefit of treatment while decreasing safety risk
- Context:
  - ↑ understanding of biology and disease
  - ↓ development of new therapeutics
  - ↑↑ cost of bringing new therapeutics to market

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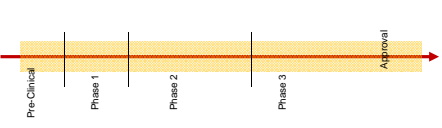
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## Regulatory Process

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drug development & health policy



- Sponsor ↔ Agency
  - Single sponsor
  - Single agency
  - Confidential proceedings
- Advantages of Forum model
  - Involvement of *all* concerned stakeholders
  - Cross-Atlantic regulatory perspectives
  - Cross-Atlantic academic and patient/community perspective

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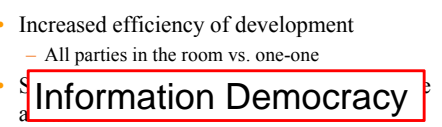
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## Advantages/Contribution

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drug development & health policy



- Increased efficiency of development
  - All parties in the room vs. one-one
- Information Democracy
  - Recruitment of new partners and collaborators
- Support and synergize with other ongoing efforts

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## Lessons Learned/Confirmed

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enhancing & facilitating HIV research



- 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

VM CUNY Mar 5/15 [www.hivforum.org](http://www.hivforum.org)

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## Rapid Advancement

facilitating collaborative research  
drug development & health policy

- Paradigm shift vs. incremental advancement
- Challenge to health care systems around the world
- No medical reason to withhold therapy

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## Liver Disease is a Collaborative Process!

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drug development & health policy

Miller Gotham Forum Apr 14-15

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

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## Liver Forum Steering Committee

facilitating collaborative research  
drug development & health policy

- Co-chairs
  - Gary Burgess, *Conatus*
  - Arun Sanyal, *VCU*
- FDA
  - Lara Dimick, *CDER/DGIEP*
  - Ruby Mehta, *CDER/DGIEP*
- EMA
  - Elmer Schabel, *BfArM*
- Carol Brosgart, *UCSF*
- Laurent Castera, *Hôpital Beaujon*
- Stephen Harrison, *Brooke Army Med Center*
- Markus Peck, *Med Uni Vienna*
- Scott Friedman, *Mount Sinai*
- Veronica Miller, *HIV Forum*
- Massimo Pinzani, *UCL*
- Detlef Schuppan, *Mainz Uni Med Center/BIDMC*
- Jeff Bornstein, *Biogen Idec*
- Eric Hughes, *BMS*
- David Shapiro, *Intercept*
- William Baladyga, Patient Representative
- Tracy Swan, Patient Advocate

Liver Forum 2  
21 April 2015

Joint Leadership




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## Revisit Operating Principles

facilitating collaborative research  
drug development & health policy

- Ownership
  - Co-owned by all stakeholders
  - Neutrality and independence
- Level playing field
  - No “pay to play”
- Equal voice
- Informal, but structured, dialogue
  - Avoid ppt presentations
  - Bring expertise, not dogma

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