Accelerating Drug Development through Collaboration

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Forum for Collaborative HIV Research
Washington DC

www.hivforum.org

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

Forum Model & Principles

- 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
  - of products to all members & the public

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

Beginnings

1996
- White House (Al Gore)
  - Keystone Dialogue

1997 (GWU)
- 1 year funding (HHS)
- 5 year multi-stakeholder funding
  - NIH, CDC, HRSA, CMS
  - Non-renewable
- Pharmaceutical companies (4-6)

2001
- International: Europe
  - Pharma, hospitals, diagnostics

2010
- UC Berkeley SPH
- New disease areas
“In non-IDU individuals in the continuous ART control arms ... we identified no evidence for a raised risk of death compared with the general population in HIV-infected individuals on ART, with an undetectable viral load, who maintained or had recovery of CD4 T-cell counts to at least 500 cells/ml.”

There is reason to believe that the gap in non-AIDS mortality between HAART-treated individuals and HIV-uninfected individuals may continue to decrease, that is, that HIV-related non-AIDS death may decline further. Better therapy regimens and improved social support hold the prospect of improving the survival of all HAART initiators nearer to that of HIV-uninfected individuals.
HIV/AIDS Today

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

Facilitating Collaborative Research in Drug Development and Health Policy

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

21st Century Challenge

- 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
Regulatory Process

- 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

Advantages/Contribution
- 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

Lessons Learned/Confirmed
- 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
Rapid Advancement

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

Liver Disease is a Collaborative Process!

Liver Forum Steering Committee

- 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 Castella, 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 Baladya, Patient Representative
- Tracy Swan, Patient Advocate
Revisit Operating Principles

- 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