



Forum for
Collaborative HIV Research

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**



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

Washington, DC 20001

P.O. Box 8

and to potentially control the epidemic itself. In order to take advantage of this

actively use
the medical
health care

CP → SN

TECHN

Groups Unite on New AIDS Drug Therapies

THE WALL STREET JOURNAL MONDAY, AUGUST 5, 1996 B3



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MEMBERS & COLLABORATORS

Government Agencies	Academia / Providers	Industry		Community / Advocacy
USA • CDC • FDA • HHS/OASH • HRSA • NIH - NIAID - NIDA - NIMH - OAR • OGAC • USAID • VA	• ACTG • Epi / Stats • Immunology • Virology • Women's Health	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	HIV • ATAC • CAB-ACTG • CAB-INSIGHT • EATG • NGMAC • TAG
	Foundations • BMGF • amfAR • EGPAF			
	Professional Societies • AAN • AASLD • EASL • HIVMA • IAS • IDSA	Generic • Mylan		HCV • HCAB • NATAP • NVHR • PWB+HCV • TAG
				Insurers • Kaiser Permanente



FDASIA

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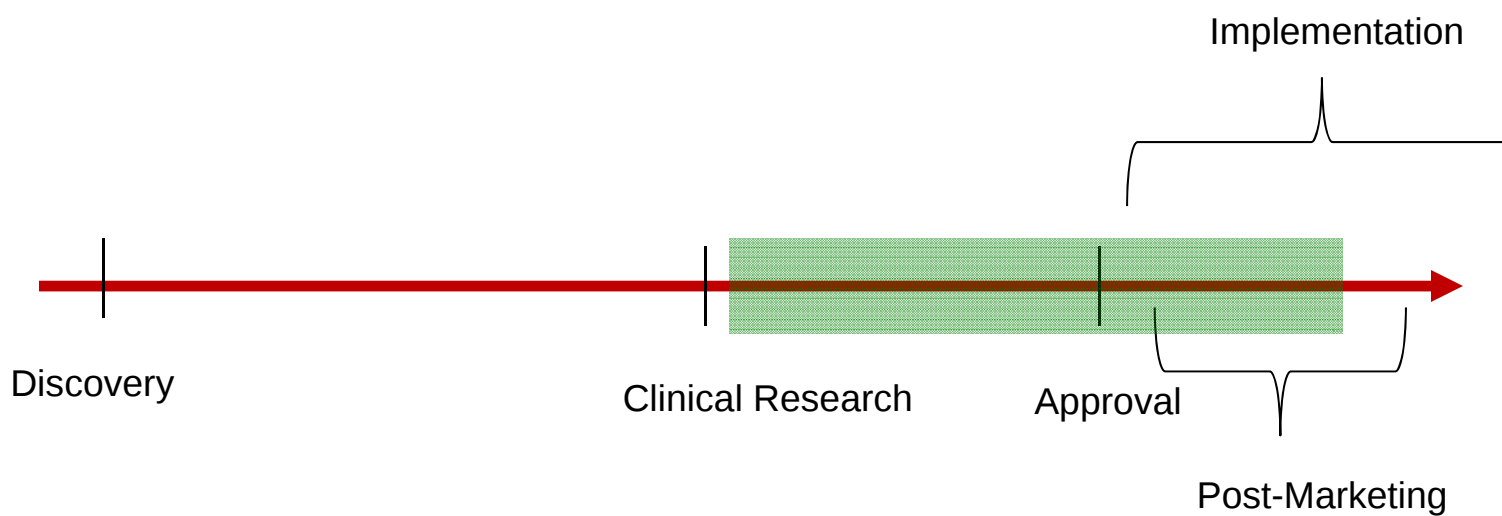
- Food and Drug Administration Safety and Innovation Act
 - Public Law 122-144
 - July 9, 2012
- Section 905 amends Section 505(d) of FD&C Act
 - “implement a structured risk-benefit assessment framework.....”

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.



TRANSLATIONAL MEDICINE

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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



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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

Foundations:

- Stephen Becker, MD
- Rowena Johnston, PhD

Industry:

- Romas Geleziunas, PhD
- George Hanna, MD
- Daria Hazuda, PhD
- Winson Tang, MD, FACP

Academia:

- John Mellors, MD
- Jintanat Ananworanich, MD, PhD



WORKING GROUP MEMBERS

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Jintanat Ananworanich	David Evans	Richard Jefferys	John Mellors	Seema Shah
Rachael Anatol	David Favre	Rowena Johnston	Mike Miller	Matt Sharp
Chuka Anude	Susan Fiscus	Filip Josephson	Veronica Miller	Jeff Sheehy
Jose Arribas	Kevin Fisher	Andy Kaytes	Ron Mitsuyasu	Adam Sherwat
Mark Bagarazzi	Joe Fitzgibbon	Damian Kelly	Paris Mullen	Neil Shortman
Stephen Becker	Charlie Flexner	Hans-Peter Kiem	Rob Murphy	Janet Siliciano
Gwen Binder-Scholl	Yuman Fong	Richard Klein	Jeff Murray	Kim Struble
Jacques Bollekens	Nicole Frahm	Rick Koup	Charles Nicolette	Jeremy Sugarman
Nicolas Chomont	Victor Garcia	Dan Kuritzkes	Una O'Doherty	Geoff Symonds
Mike Cohen	Sam Garner	Diane Lawrence	Lars Ostergaard	Winson Tang
Giulio Maria Corbelli	Romas Geleziunas	Michael Lederman	Cecile Peltekian	Jeff Taylor
Liza Dawson	Sara Goldkind	Sandi Nusinoff Lehrman	Deborah Persaud	Pablo Tebas
Lynda Dee	Cynthia Grossman	Yves Levy	Chris Petropoulos	Randy Tressler
Steve Deeks	George Hanna	Sharon Lewin	Carla Pettinelli	Kati Vandermeulen
Jim Demarest	Patrick Harrington	Jeff Lifson	Sarah Read	Mark Wainberg
Damon Deming	Mark Harrington	Bernard Lo	Harriet Robinson	Chris Ward
Carl Dieffenbach	Daria Hazuda	David Margolis	Anna Laura Ross	Carol Weiss
Tri Do	Gail Henderson	David A Margolis	John Rossi	James Whitney
Karine Dube	Tim Henrich	Javier Martinez-Picado	Asier Saez-Cirion	Celia Witten
Michael Egan	Carey Hwang	Steve Mason	Paul Sato	Brian Woodfall
Joe Eron	Ilan Irony	Julie McElrath	Tim Schacker	Jerry Zack



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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



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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



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POST JUNE 17TH

- Survey
- Publications
- Ongoing working groups
- Intervention specific working groups



ACKNOWLEDGMENTS: FORUM STAFF

Staff

- Rob Besaw
- Ben Hauschild
- Erik Lontok
 - Project Manager
 - WG#2 Manager
- Nivedha Panneer
 - WG#1 Manager

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- Sydney Butler
- Karen Diepstra
- Courtney Hutchison
 - WG#3 Manager
- Sonia Navani
 - WG#3 Manager
- Micha Zheng



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SPECIAL ACKNOWLEDGMENT

- UNC CARE Collaboratory
 - David Margolis
 - Karine Dube



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PANEL DISCUSSION

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