



**Forum for
Collaborative HIV Research**

CMV IN TRANSPLANTATION ENDPOINTS & CLINICAL TRIAL DESIGN

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5 September 2014

Washington, DC



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
- 2007: Apply HIV collaborative model to HCV
- **2014: New Opportunities**
 - **CMV in transplantation**
 - **Anti-fibrotics for NASH and liver fibrosis/cirrhosis**

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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

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

P.O. Box 8

actively use
the medical
health care

CP → SN

TECHN

Groups Unite on New AIDS Drug Therapies

facilitat

THE WALL STREET JOURNAL MONDAY, AUGUST 5, 1996 **B3**



MEMBERS & COLLABORATORS

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Government Agencies	Academia / Providers	Industry		Community / Advocacy
USA <ul style="list-style-type: none"> • CDC • FDA • HHS/OASH • HRSA • NIH <ul style="list-style-type: none"> - NIAID - NIDA - NIMH - OAR • OGAC • USAID • VA 	<ul style="list-style-type: none"> • ACTG • Epi / Stats • Immunology • Virology • Women's Health 	HIV <ul style="list-style-type: none"> • Abbvie • Abbott Mol. • Alere • BI • Bio-Rad • BMS • Genentech • Gilead • Illumina • Janssen • Merck • Monogram • Orasure • PacBio • Quest • Quintiles • Roche MS • Tobira • ViiV 	HCV (cont.) <ul style="list-style-type: none"> • Abbvie • Abbott Mol. • Achillion • BI • BMS • DDL • Genentech • Gilead • GSK • Idenix • Janssen • Medivir • Merck • Monogram • Novartis • PPD • Quest • Quintiles • Roche MS • Vertex • Virco 	HIV <ul style="list-style-type: none"> • ATAC • CAB-ACTG • CAB-INSIGHT • EATG • NGMAC • TAG
	Foundations <ul style="list-style-type: none"> • BMGF • amfAR • EGPAF • Schinazi FF 			HCV <ul style="list-style-type: none"> • HCAB • NATAP • NVHR • PWB+HCV • TAG
Europe <ul style="list-style-type: none"> • ANRS • EMA 	Professional Societies <ul style="list-style-type: none"> • AAN • AASLD • EASL • HIVMA • IAS • IDSA 	Generic <ul style="list-style-type: none"> • Mylan 		Insurers <ul style="list-style-type: none"> • Kaiser Permanente



MEMBERS & COLLABORATORS -2

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Regulatory Agencies

FDA-CDER

- DAVP
- DGIEP

FDA-CBER

- Vaccines
- Cell/Tissue + Gene Therapy

FDA-CDRH

EMA

- Virology
- Gastroenterology

Industry

CMV

- Abbott
- Astellas
- Chimerix
- Microbiotix
- Novartis
- Oxford Immunotec
- Qiagen
- Roche MS
- + more

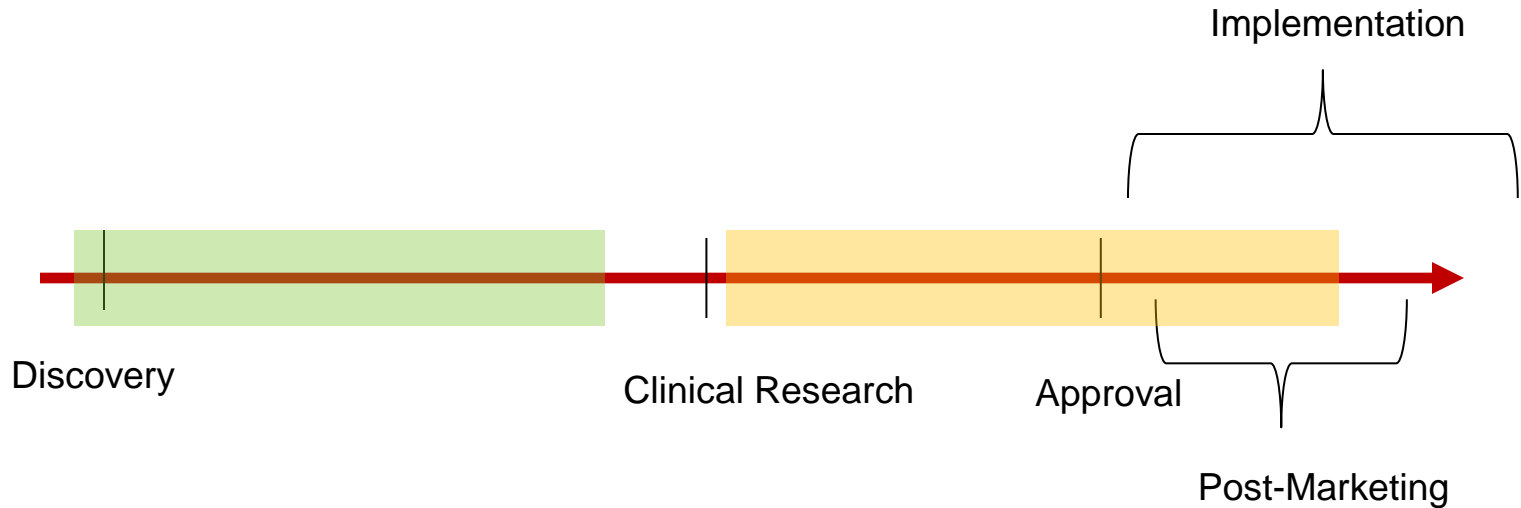
NASH/Fibrosis

- Abbvie
- Biogen
- BMS
- Boehringer Ingelheim
- Fibrogen
- Galactin
- Genfit
- Gilead
- GSK
- Intercept
- Intermune
- Kadmon
- Takeda
- Tobira
- Valor
- + more



TRANSLATIONAL MEDICINE

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CMV + TRANSPLANTATION

Why this project?



CMV + TRANSPLANTATION

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- **Advances**
 - Clinical practice
 - Diagnostic technologies
 - Drug & vaccine development
- **Lack**
 - Standardization
 - Consensus on surrogacy
 - Consensus on clinical trial design
- **Need**
 - Trans-Atlantic collaborative approach to inform/accelerate drug development



GOALS & OBJECTIVES

- Overarching goal
 - Safe/effective drugs (therapeutic strategies) and vaccines for this unmet medical need
 - Increase efficiency/accelerate drug development
- Objectives
 - Review & discuss specific key questions to inform regulatory guidance
 - Identify gaps in knowledge
 - Discover/implement opportunities for collaboration to fill the gaps

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PROCESS

- “Process” vs. “Meeting”
 - Safe space for *ongoing* deliberation
 - Build consensus where & when possible
- Division of labor as needed
 - Topic specific working groups



TODAY'S AGENDA

- Session 1:
 - Set project framework
 - Gather stakeholder perspectives on overall needs/key questions for the project
- Sessions 2+3:
 - Begin focus on specific key questions
- Session 4:
 - Set infrastructure for ongoing discussion



FORUM HOUSE RULES

- Closed meeting
 - Open, constructive dialogue
 - Moderated discussions
 - “What’s said in this room stays in this room”
- Everyone participates
 - No “observers”
 - No press
- Meeting report (and website materials)
 - Vetted by participants
 - Not for attribution

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THANKS & ACKNOWLEDGMENTS



STEERING COMMITTEE

- Michelle Berrey*
- Per Ljungman*
- Paul Baum
- Michael Boeckh
- Gavin Cloherty
- Lesia Dropulic
- Paul Griffiths
- Atul Humar
- Peter Hunt
- Filip Josephson
- Takashi Komatsu
- Philip Krause
- Li Li
- Francisco Martinez-Murillo
- Veronica Miller
- Jeff Murray
- Jules O'Rear
- Michele Trucksis
- Bernhardt Zeiher



FINANCIAL SUPPORTERS

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- IDSA
 - Travel support



FORUM STAFF

- Rob Besaw
- Erik Lontok
- Ben Hauschild
- Nivedha Panneer
- Brenda Rodriguez
- Micha Zheng

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ALL PROJECT MEMBERS!

enhancing & facilitating HIV research