

AMERICAN ASSOCIATION FOR
THE STUDY OF LIVER DISEASES



**Forum for
Collaborative HIV Research**

THE LIVER FORUM

November 6, 2014

Boston, MA

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
- Original Mission: to facilitate and enhance HIV research
 - **Neutral & independent space**
- Apply HIV collaborative model to HCV (2006)
- Apply HIV and HCV model to CMV (transplantation) and liver disease (2014)

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

THE WALL STREET JOURNAL MONDAY, AUGUST 5, 1996 B3

2014 AND BEYOND

facilitating collaborative research
drug development & health policy

“Facilitating Collaborative Research in Drug Development and Health Policy”

- Stakeholder engagement-driven process
 - Equal voice
- Science-based discussion, dialogue, deliberation
 - Focus on issues of common interest
- Consensus when/where possible
 - Structure in place for *evolving* consensus
- Maintain neutrality and independence
- Collective ownership

MEMBERS, SPONSORS & COLLABORATORS

facilitating collaborative research
drug development & health policy

Government Agencies	Foundations	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"> BMGF amfAR EGPAF Schinazi FF 	HIV <ul style="list-style-type: none"> Abbvie Abbott Alere BI Bio-Rad BMS Genentech Gilead Illumina Janssen Merck Monogram Orasure PacBio Quest Quintiles Roche MS Tobira ViiV Mylan 	HCV <ul style="list-style-type: none"> Abbvie Abbott Achillion BI BMS DDL Genentech Gilead GSK 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 Project Inform HCV <ul style="list-style-type: none"> HCAB NATAP NVHR PWB+HCV
Europe <ul style="list-style-type: none"> ANRS EMA 	Professional Societies <ul style="list-style-type: none"> AAN AASLD EASL HIVMA IAS IDSA 			Insurers <ul style="list-style-type: none"> Kaiser Permanente

MEMBERS, SPONSORS & COLLABORATORS -2

*facilitating collaborative research
drug development & health policy*

Government Agencies

FDA-CDER

- DAVP
- DGIEP

FDA-CBER

- Vaccines
- Cell/Tissue +
Genetherapy

FDA-CDRH

Industry

CMV

- Abbott
- Astellas
- Cell Medica
- Chimerix
- Merck
- Microbiotix
- Novartis
- Oxford Immunotec
- Roche MS

NASH/Fibrosis

- AstraZeneca
- Biogen
- BMS
- Boehringer Ingelheim
- Conatus
- diaPharma
- Fibrogen
- Galactin Therapeutics
- Genentech
- Genfit
- Gilead
- GSK
- Health Resonance
- Intercept
- Intermune
- Kadmon
- Lilly
- Madrigal
- Merck
- NGM
- Novartis
- Perspectum Diagnostic
- Resonance Health
- Roivant
- Takeda
- Tobira
- VLVbio

THE LIVER FORUM: BRIEF HISTORY

*facilitating collaborative research
drug development & health policy*

- FDA & AASLD joint meeting
 - Sept 5 and 6, 2013
- Carol Brosgart, Arun Sanyal, Scott Friedman
 - Meeting with V Miller during AASLD 2013
- Leadership commitment from AASLD and EASL Spring 2014
- First public presentation, discussion and invitation for interested parties to join:
 - AASLD ETC in Chicago: June 2014
- Steering Committee confirmed: June 2014
- First project meeting “The Liver Forum 1”:
 - November 6, 2014

Liver Forum 1

Nov 6'14

7



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*
 - Jeff Murray, *CDER/DAVP*
- 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*
- Dennis Grasela, *BMS*
- David Shapiro, *Intercept*
- TBN, Patient Representative

TRANSPARENCY: SPONSORSHIP

*facilitating collaborative research
drug development & health policy*

- Forum receives contributions through UC Berkeley Foundation
 - Gift fund contributions subject to 2.5% indirect fee
- All Forum projects are self-funded
 - No overarching operational funds
 - i.e. “Liver \$\$” for Liver Forum activities
- Funding Strategy
 - Maintain as broad a funding base as possible
 - Explore all possibilities
 - Federal
 - Foundations/Trusts
 - ✓ Societies
 - ✓ Industry

TRANSPARENCY: SPONSORSHIP

INDUSTRY MEMBERSHIP

facilitating collaborative research
drug development & health policy

- Liver Forum membership open to industry scientific experts
 - all companies with a commitment to the field
- Voluntary contributions
 - Amount dependent on ability to pay
 - No amount is too small
 - Current range: \$3,000 to \$40,000
 - Contribution (whatever size) does not translate into enhanced “benefits” to sponsor

BUDGET CONSIDERATIONS

*facilitating collaborative research
drug development & health policy*

- The Liver Forum:
 - Process vs. “Meeting”
 - Ongoing activities through smaller working groups throughout the year, anchored by project meetings in conjunction with AASLD and EASL
 - Resource intensive in terms of staff
- Highest portion of budget for staff and operations
 - Meeting/logistics cost kept to a minimum
- Annual budget 350K – 450K
 - Contingent on intensity of WG activity and output

TRANSPARENCY: GOVERNANCE

*facilitating collaborative research
drug development & health policy*

- Project led by Steering Committee
 - All stakeholder groups represented
- One academic and one industry co-chair
 - Forum tradition
- Industry representation
 - Initial representation based on previous experience working w Forum and distribution among types of companies
 - ◉ Rotation plan – staggered beginning year 2
- Other leadership opportunities
 - Working group co-chairs

RULES OF ENGAGEMENT

*facilitating collaborative research
drug development & health policy*

- Liver Forum open to experts with commitment to the field
- Leave “hat” at the door
 - Participate as individuals rather than representing organization/agency
- Active, engaged participation
 - No observers
 - Signing up = may be called on
- Open, constructive dialogue
- Website and journal publication
 - No press
 - Published material vetted by participants
 - ◉ Not for attribution

ACKNOWLEDGMENTS

*facilitating collaborative research
drug development & health policy*

- Steering Committee/Leadership
- Sponsors
- Forum staff/consultants
 - Rob Besaw
 - Nivedha Panneer
 - Brenda Rodriguez
 - Audrey Jackson
- Informed Horizons, LLC
 - Margie Poole and team

LIVER FORUM FINANCIAL SPONSORS

facilitating collaborative research
drug development & health policy



THE LIVER FORUM: OVERALL GOALS

*facilitating collaborative research
drug development & health policy*

- Pick-up where AASLD/FDA joint meeting left off
- Independent and neutral venue for ongoing multi-stakeholder dialogue
- Facilitate best science-based decisions, in real time, regarding efficacy and safety
 - Break down inefficiencies
 - Increase clarity
 - Benefit to the whole field, especially the patient

TODAY'S OBJECTIVES

*facilitating collaborative research
drug development & health policy*

- Official launch of The Liver Forum!
- Meet and get to know the players
- Understand process and governance
- Understand regulatory perspectives
 - EMA and FDA
- Organize/structure around working groups
- Roll up sleeves and get ready for action