

Berkeley



Forum for
Collaborative HIV Research

Liver Forum #4
April 12th 2016
Fira Congress Hotel, Barcelona

www.hivforum.org

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Forum for
Collaborative HIV Research

Wi-Fi Access Instructions

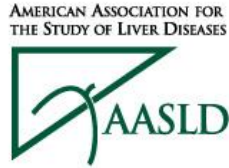
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Welcome and Project Overview

www.hivforum.org



Forum's Operating Principle

*Facilitating collaborative research in drug
development and health policy*

“Once new drug candidates and therapeutic strategies are identified, their efficient, safe development is in the best interest of all stakeholders, most of all, the patients”



*Facilitating collaborative research in drug
development and health policy*

Impact on Drug Development

- **Increase**
 - Clarity
 - Efficiency
 - Collaboration
 - Innovation
- **Decrease**
 - Uncertainty
 - Redundancy
 - Development time
 - Risk



*Facilitating collaborative research in drug
development and health policy*

Win-Win

- Accelerate drug development not by lowering standards, but by increasing efficiency through collaboration



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development and health policy*

Liver Forum Members

- Regulators
 - FDA
 - DGIEP
 - OND
 - CDrh
 - EMA
- Societies
 - AASLD
 - EMA
- Industry
- Academic
 - US
 - Europe
- Patient
- Informal yet structured
- “Non-player ecosystem orchestrator”
- “Multi-stakeholder partnerships that enables adaptive management”



*Facilitating collaborative research in drug
development and health policy*

Key Characteristics

- “Information Democracy”
- Non-competitive, safe environment
- Independent
- Co-ownership
- Synergy vs. duplication
- Transparency



*Facilitating collaborative research in drug
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Tomorrow's Leadership

- Foster professional development
 - Junior faculty
 - Fellows
 - Interns
- Principles of collaborative drug development and regulatory science
 - Trans-Atlantic
 - World wide



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Forum “Fellows”

- Yuval Patel MD
 - Duke University/Andrew Muir
- Mohammad Shadab Siddiqui
 - VCU/Arun Sanyal
- Lauren Smith
 - UC Berkeley MPH/Veronica Miller
- Shruti Tibrewala
 - UC Berkeley MBA/Veronica Miller



Opportunity Open!

*Facilitating collaborative research in drug
development and health policy*



Liver Forum History

Facilitating collaborative research in drug development and health policy

- Precipitating event:
 - Sept 2013 AASLD-FDA September joint workshop
- Recruit AASLD and EASL leadership
 - Q4 2013/Q1 2014
- Recruit FDA and EMA participation
 - Q4 2013/Q1 2014
- Develop concept note
 - Q1 2014
- Establish Steering Committee
 - Q1/Q2 2014
- LF #1: AASLD/ Boston, 2014
- LF#2: EASL/Vienna, 2015
- LF#3: AASLD/San Francisco, 2015



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development and health policy*

Achievements

- Space for informal exchange of regulatory perspectives
 - EU, US
- New collaborations among LF members



Achievements: Increase Clarity

- WGs output: Manuscripts ready for publication
 - Disease definition
 - Standardization of baseline parameters
 - Pediatric NASH – regulatory considerations
 - Review of current NASH trials landscape



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Industry Members

- Total 69
 - 23 pharma
 - 17 biopharmaceuticals
 - 14 biotech
 - 8 start-ups
 - 12 diagnostic
 - 3 CRO



Financial Sponsors

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DS Biopharma 

 **EASL**
European Association
for the Study of the Liver


echosens

 **avalenz**
Breathtaking Solutions


FRACTYL[®]

 **GENFIT**
TOWARDS BETTER MEDICINE

 **GILEAD**

 **gsk** do more
feel better
live longer

 **ICON**
A Symbol of Excellence

immuron

Intercept  pharmaceuticals


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?? John Joseph Sninsky & ???



?? Susan Bardsley Sninsky ?



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Liver Forum Steering Committee

Facilitating collaborative research in drug
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- Co-chairs
 - Gary Burgess, *Vectura*
 - Arun Sanyal, *VCU*
- FDA
 - Lara Dimick, *CDER/DGIEP*
 - Ruby Mehta, *CDER/DGIEP*
 - Chris Leptak, *CDER/OND*
- EMA
 - Elmer Schabel, *BfArM*
- William Baldyga, *Patient Rep*
- Carol Brosgart, *UCSF*
- Laurent Castera, *Hôpital Beaujon*
- Stephen Harrison, *Brooke Army Med Center*
- Tom Karlsen, *Norway/EASL*
- Scott Friedman, *Mount Sinai*
- Joel Lavine, *Columbia*
- Veronica Miller, *HIV Forum*
- Massimo Pinzani, *UCL*
- Detlef Schuppan, *Mainz Uni Med Center/BIDMC*
- Jeff Bornstein, *Biogen Idec*
- Helena Brett-Smith, *BMS*
- David Shapiro, *Intercept*
- Donna Cryer, *Global Liver Institute/Patient Rep*



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Many Thanks

- **Forum Staff**
 - Malene Cobourne
 - Jeff Kaminski
 - Brenda Rodriguez
 - Lauren Smith (MPH Intern)
 - Myrna Cozen
- **Prism Event Management**
 - Paula Blay
 - Graham Hill
 - Ash Lawson
 - Mairead O'Reilly
 - George Seaton



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Today's Program

- Part 1: Updates & Next Steps
 - Working Group Updates
- Part 2: Innovation and Opportunities for Collaboration
 - Making the most of data: Target Learning
 - Gathering the best of data: MyOwnMed