

Berkeley



FORUM
for Collaborative
RESEARCH

Welcome and Introduction

Moderators

Veronica Miller, Forum for Collaborative Research

David Shapiro, Intercept Pharmaceuticals

Arun Sanyal, Virginia Commonwealth University

Presenter

Katherine Greene, Forum for Collaborative Research

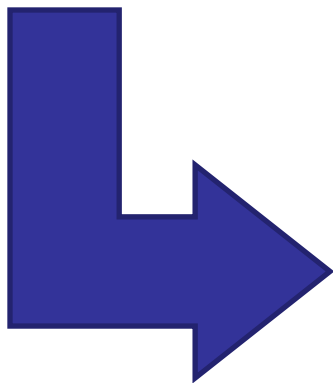


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Forum Evolution



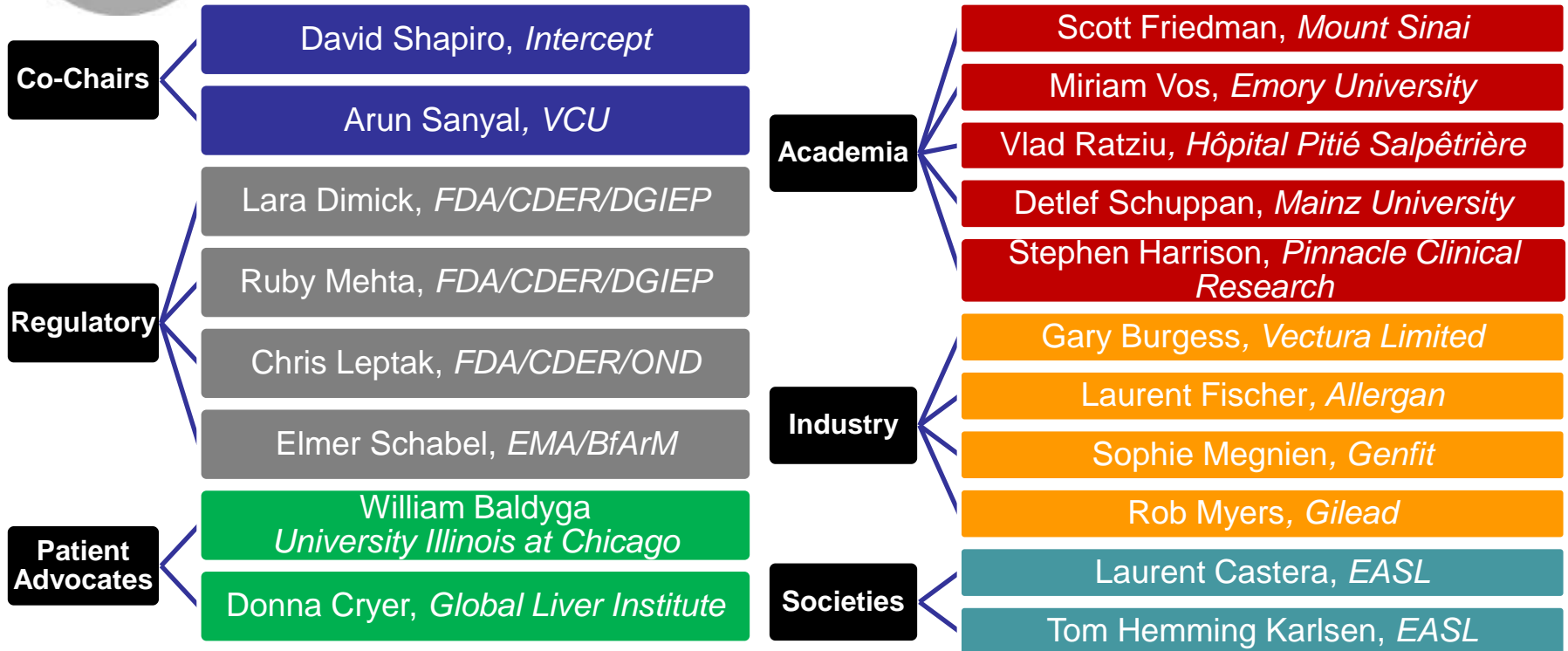
**Forum for
Collaborative HIV Research**



**FORUM
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RESEARCH**



Liver Forum Steering Committee



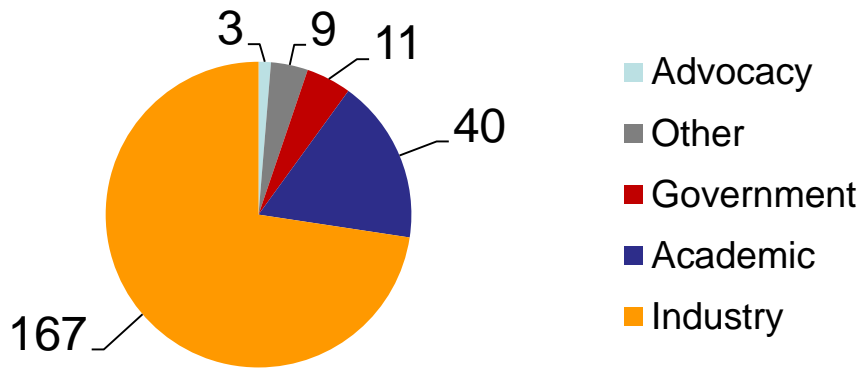


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Liver Forum 5

- Liver Forum 5, Boston MA:
 - 230 attendees: 165 in-person, 65 remote

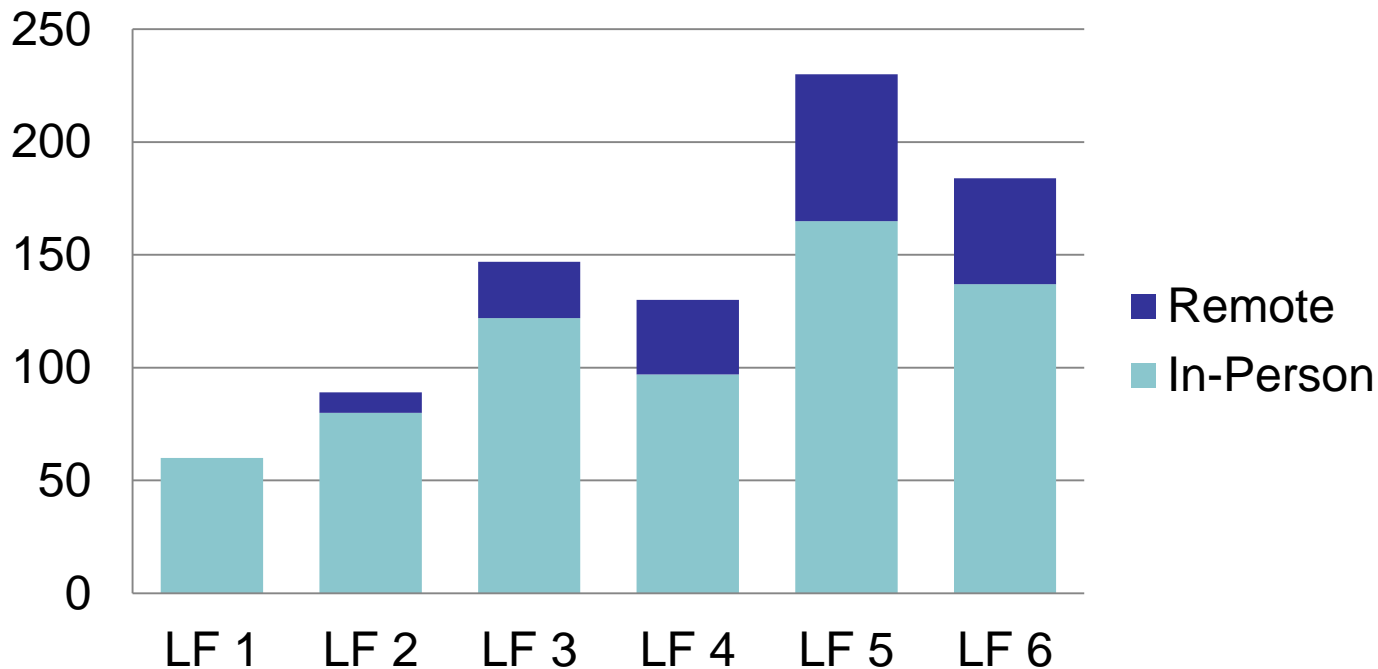
Attendance by Organization





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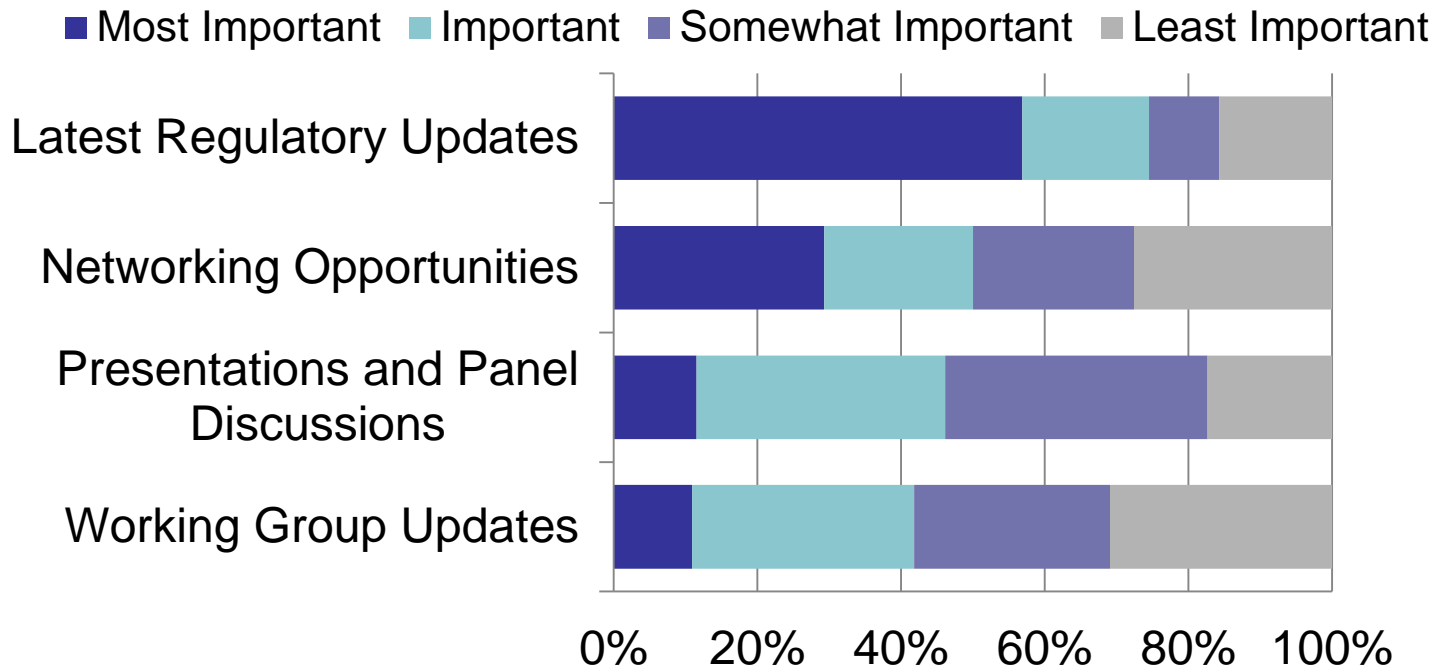
Participation by LF





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Importance of Liver Forum 5 Components





Overall Value of the Liver Forum

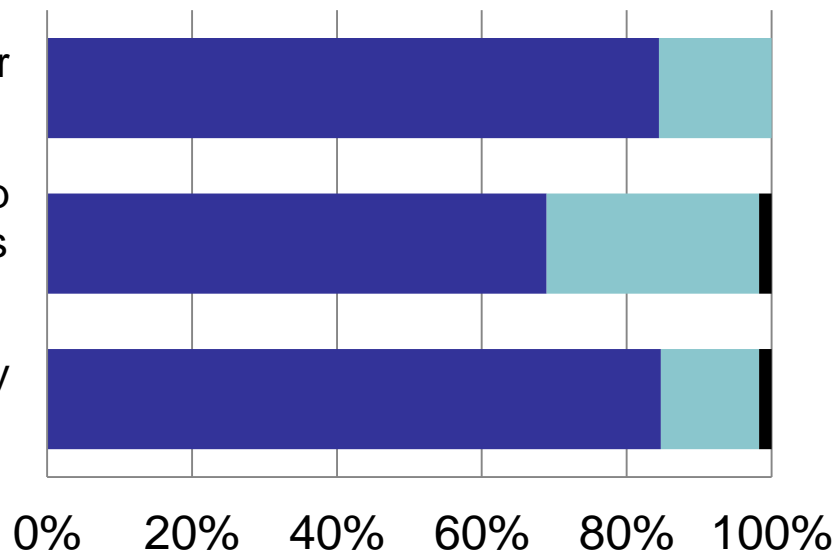
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■ Agree ■ Somewhat Agree ■ Disagree ■ Too soon

I would recommend joining the Liver Forum to a peer/colleague.

The Liver Forum discussions help guide the work my organization is doing right now.

The Liver Forum is valuable to my work





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Liver Forum 5 → 6

- **Pediatric Working Group:**
 - In-Person Meeting, March 20, 2017
- **Placebo Arm Working Group:**
 - Launched, first conference call April
- **New Workshops:**
 - NASH Biomarkers Workshop, May 5-6
 - Causal Inference & Adaptive Design, May 10

International Workshop on NASH BIOMARKERS

An interactive workshop
stimulating international and
cross-disciplinary interchange, in-
depth discussion and debate on
biomarkers for NASH

REGISTER HERE: WWW.EXPERTMEDICALEVENTS.COM/NASH

JOIN US

5-6 MAY 2017

WASHINGTON, D.C., USA



MEETING CHAIRS 2017



Veronica Miller, PhD -
Forum for Collaborative Research,
Washington, DC, USA



Arjun Sanyal, MD, MBBS -
Virginia Commonwealth
University, Richmond, VA, USA

PROGRAM COMMITTEE



Quentin Anstee BSc,
MBBS, PhD - Newcastle
University, Newcastle, UK



Pierre Bedossa, MD, PhD
University of Paris-Diderot,
Paris, France



Charles Boucher, MD,
PhD - Erasmus Medical
Center, The Netherlands



Roberto Calle
MD, FACE, FACP
FNIH, Bethesda, MD, USA



Gregory Everson, MD,
FACP - University of Colorado
Denver, Denver, CO, USA



Chris Leptak MD, PhD -
FDA Office of New Drugs,
Silver Spring, MD, USA



Elmer Schabel, MD
European Medicines Agency,
London, UK & BfArM, Bonn,
Germany



Claude Sirlin, MD
UC San Diego,
San Diego, CA, USA



Causal Inference & Adaptive Design Workshop

Wednesday, May 10 – Washington D.C.

To Register: https://hivforum.formstack.com/forms/adaptive_design

About

- Full-day workshop (8:00am – 5:00pm)
- Presentations on causal inference; group sequential design; regulatory perspective.
- Panel discussion

Audience

- Statisticians & applied researchers
- Those involved in planning/ design of clinical trials

Register

- Free registration
- Maximum 50 participants
- For more info: kgreen@hivforum.org



Mark van der Laan, PhD
Professor, Biostats & Statistics
University of California Berkeley



Maya L. Petersen MD, PhD
Associate Professor, Biostats & Epi
University of California Berkeley



Yeh-Fong Chen, PhD
Mathematical Statistician
U.S. Food and Drug Administration



Veronica Miller, PhD
Executive Director
The Forum for Collaborative Research



Manuscripts

- **Case Definitions:**

- Manuscript 1: Case definitions for inclusion and analysis of endpoints in clinical trials for NASH
- Manuscript 2: Defining improvement in NAFLD for treatment trial endpoints



- **Data Standardization:**

- Manuscript 1: Baseline parameters in clinical trials for nonalcoholic steatohepatitis



- **Pediatric Issues:**

- Manuscript 1: Regulatory considerations for clinical trials in pediatric nonalcoholic fatty liver disease





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Forum “Fellows”

- **Mohammad Shadab Siddiqui**
 - Arun Sanyal, Virginia Commonwealth University
 - Case Definitions
- **Yuval Patel**
 - Andrew Muir, Duke University
 - Baseline Parameters
- **Amanda Cheung**
 - Brent Tetri, Saint Louis University Hospital
 - Defining Improvement in NAFLD



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Member & Sponsor Update

- **Total Industry Members: 110**
- **Total Current Sponsors: 48**
- **New Sponsors Since LF5:**
 - MEDIAN Technologies
 - Cirius Therapeutics, Inc.
 - CTI Clinical Trial and Consulting Services
 - Humedics GmbH



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Member & Sponsor Update

New Industry Members:

1. Anylam
2. Cirius Therapeutics, Inc.
3. Digma Medical
4. Eiger BioPharmaceuticals, Inc.
5. Fibrotouch
6. Glympse Bio
7. HistoIndex Pte Ltd
8. Humedics GmbH
9. Karos Pharmaceuticals
10. MEDIAN Technologies
11. Medimmune
12. Nordic Bioscience
13. PPD
14. Yuhan Corporation



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Financial Sponsors

abbvie



Bristol-Myers Squibb





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Many Thanks

- **Forum Staff**

- Malene Cobourne
- Ben Hauschild
- Pedro Goicochea
- Katherine Greene
- Jeffrey Kaminski
- Veronica Miller
- Brenda Rodriguez
- Ken Taymor
- Jessica Weber

- **Prism Event Management**

- Paula Blay
- Graham Hill
- Ash Lawson
- Mairead O'Reilly
- Sarah Sanderson
- George Seaton