



**THE FORUM**  
For Collaborative Research<sup>SM</sup>

# Welcome and Introduction

**Katherine Greene**

Forum for Collaborative Research

# Agenda

## 12:30 PM Welcome Reception and Registration

## 2:00 PM Session I: Project and Regulatory Updates

2:00 PM	Welcome and Introduction	Katherine Greene, <i>Forum for Collaborative Research</i>
2:15 PM	Champion of Collaboration Award	<b>Awardee:</b> Cheronda Cherry-France, <i>U.S. FDA</i>
2:25 PM	Core Outcomes in NASH Project	Donna Messner, <i>Center for Medical Technology Policy</i>
2:35 PM	Regulatory Update	Lara Dimick-Santos, <i>U.S. FDA</i>
2:45 PM	Regulatory Discussion	Lara Dimick-Santos, <i>U.S. FDA</i> Elmer Schabel, <i>European Medicines Agency</i>

## 3:10 PM Session II: Parallel Breakout Sessions

European Payer Perspective	<i>OPEN SESSION: Plenary Room</i>
NASH Biomarker Overview	<i>OPEN SESSION: Carlades Room</i>
NASH Cirrhosis Working Group	<i>WG MEMBERS: Grand Causses Room</i>

## 4:30 PM Break

# Agenda

4:30 PM **Break**

5:00 PM Breakout Session Report

5:40 PM Working Group Updates

6:00 PM **Session III: Combination Therapy**

6:00 PM EU Requirements for Fixed Dose Combinations and Lessons Learned from Hypertension and Diabetes: Implications for NASH Elmer Schabel, *European Medicines Agency*

6:20 PM FDA Considerations for Fixed-Dose Drug Combinations and Lessons Learned Stephanie Omokaro, *U.S. FDA*

6:35 PM Industry Perspectives on Combination Therapy Laurent Fischer, *Allergan*  
Eric Hughes, *Novartis Pharma AG*  
Rob Myers, *Gilead Sciences*  
Steve Rossi, *NGM Biopharmaceuticals*

7:05 PM Discussion

7:30 PM **Adjourn and Evening Reception**

# LIVER FORUM REVIEW

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for NAFLD/NASH
- **Who:** regulatory agencies, professional societies, patient representatives, academic and clinical researchers, industry organizations (pharmaceutical, device, diagnostic, biotech)
  - Scientific experts with commitment to advancing the field
  - Not a venue for marketing, investors, journalists
  - Participation in the Liver Forum is by invitation

# LIVER FORUM REVIEW

- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups working in NAFLD/NASH field
  - Focus on developing consensus, increasing synergy and collaboration, and reducing duplication and uncertainty
  - Process vs. “Meeting”
    - Ongoing working group activity throughout the year anchored by larger project events
  - Active & engaged participation
    - Entering the room = consent to be called on

# LIVER FORUM REVIEW

- **Why:** “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”



# RULES OF THE ROOM

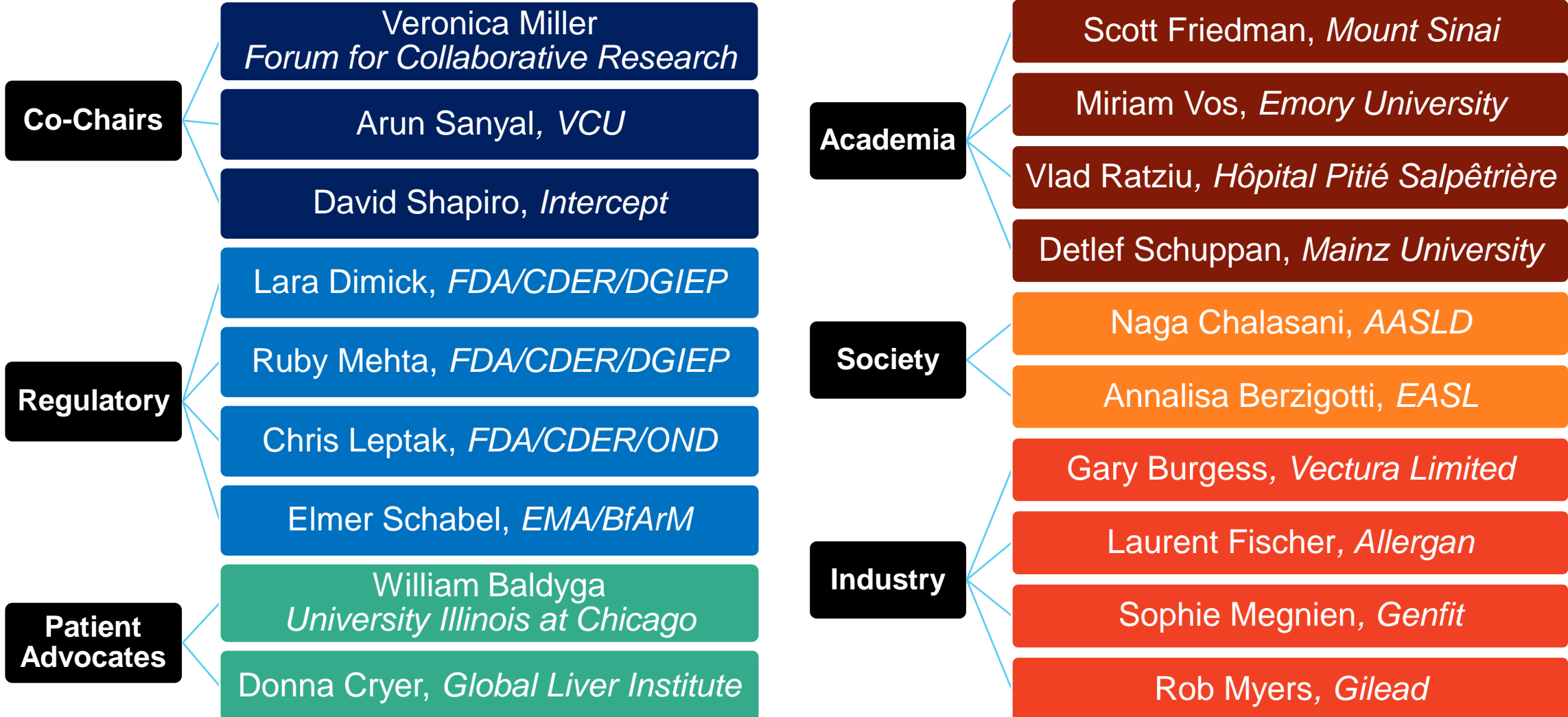
- “What’s said in the room, stays in the room”
  - Comments/questions are not for attribution
  - Social Media:
    - ❌ Meeting
    - ✅ Receptions



**@LIVERFORUM**

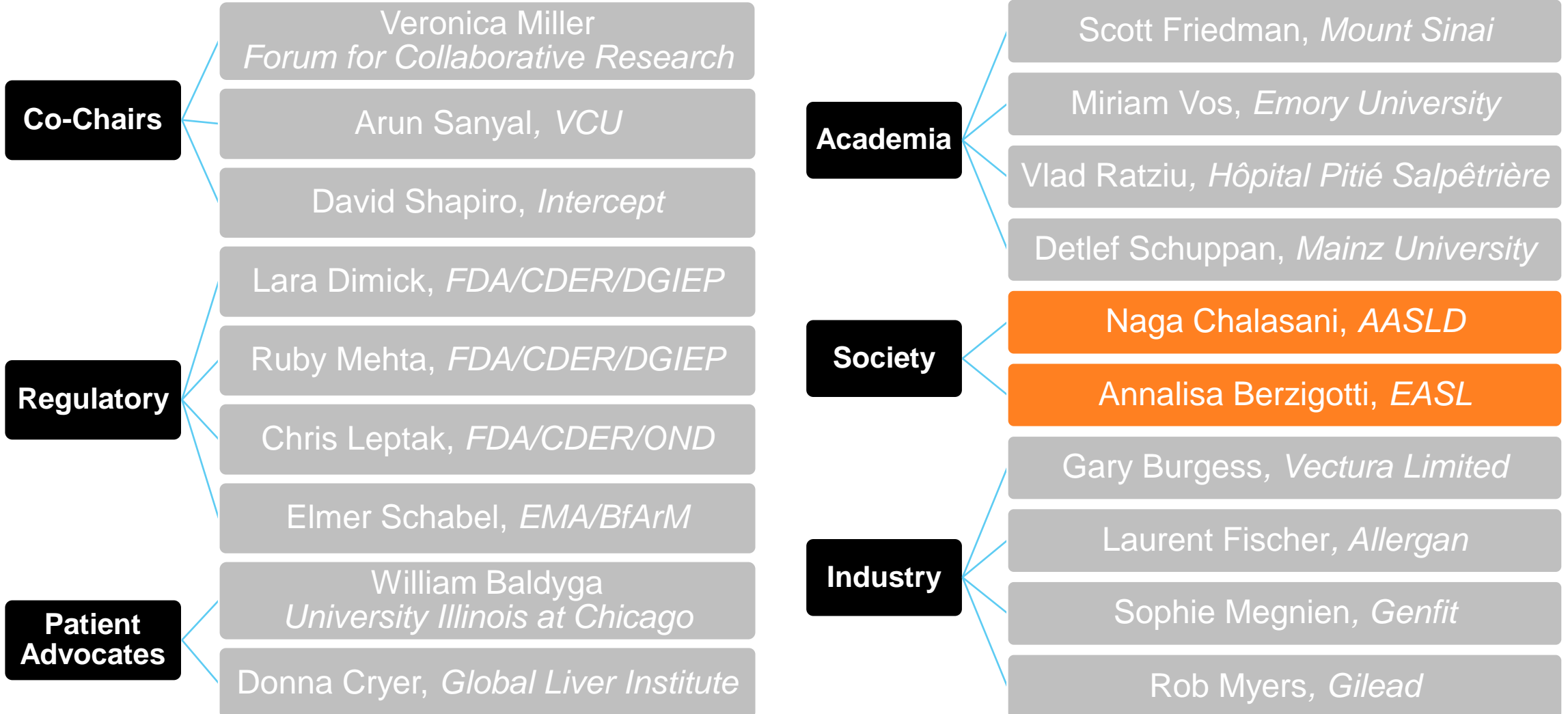


# STEERING COMMITTEE



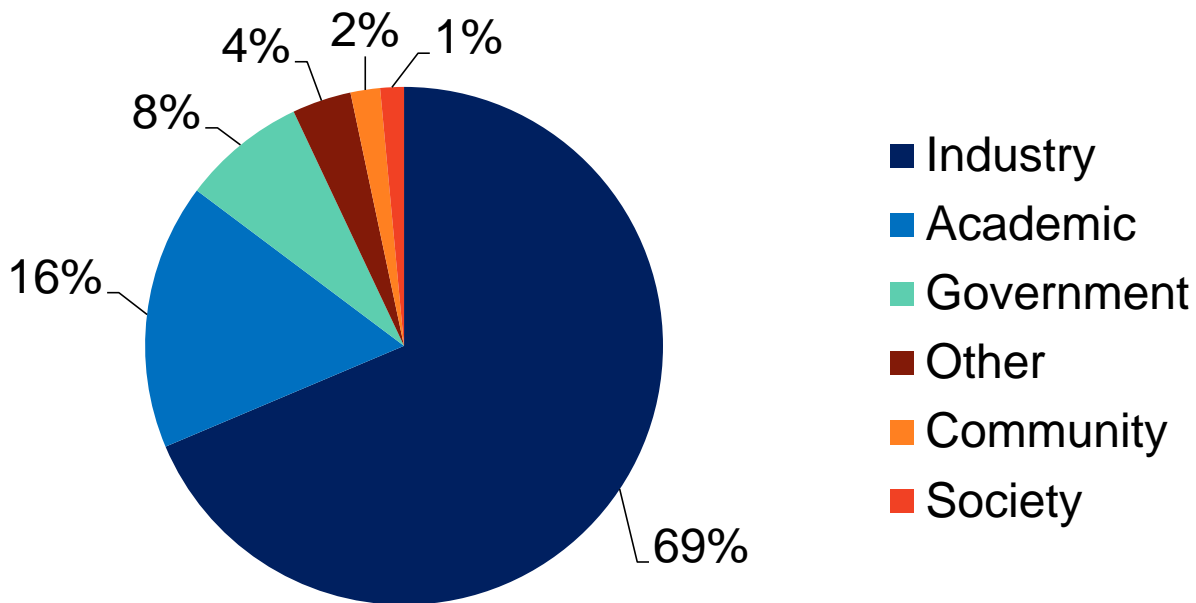


# STEERING COMMITTEE

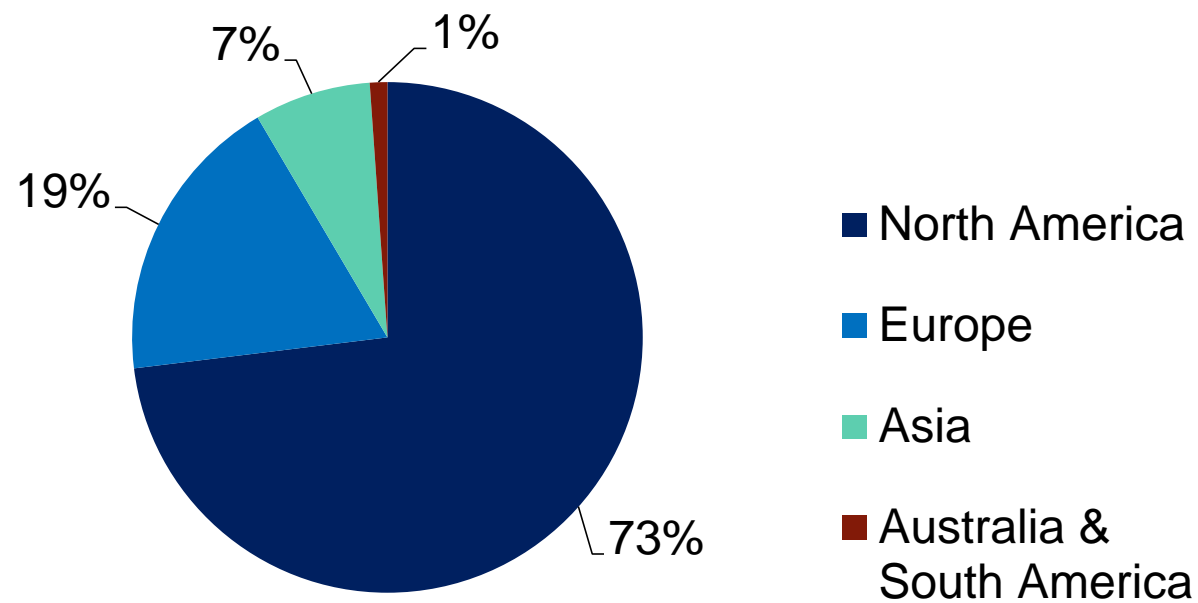


# LIVER FORUM 7 RECAP

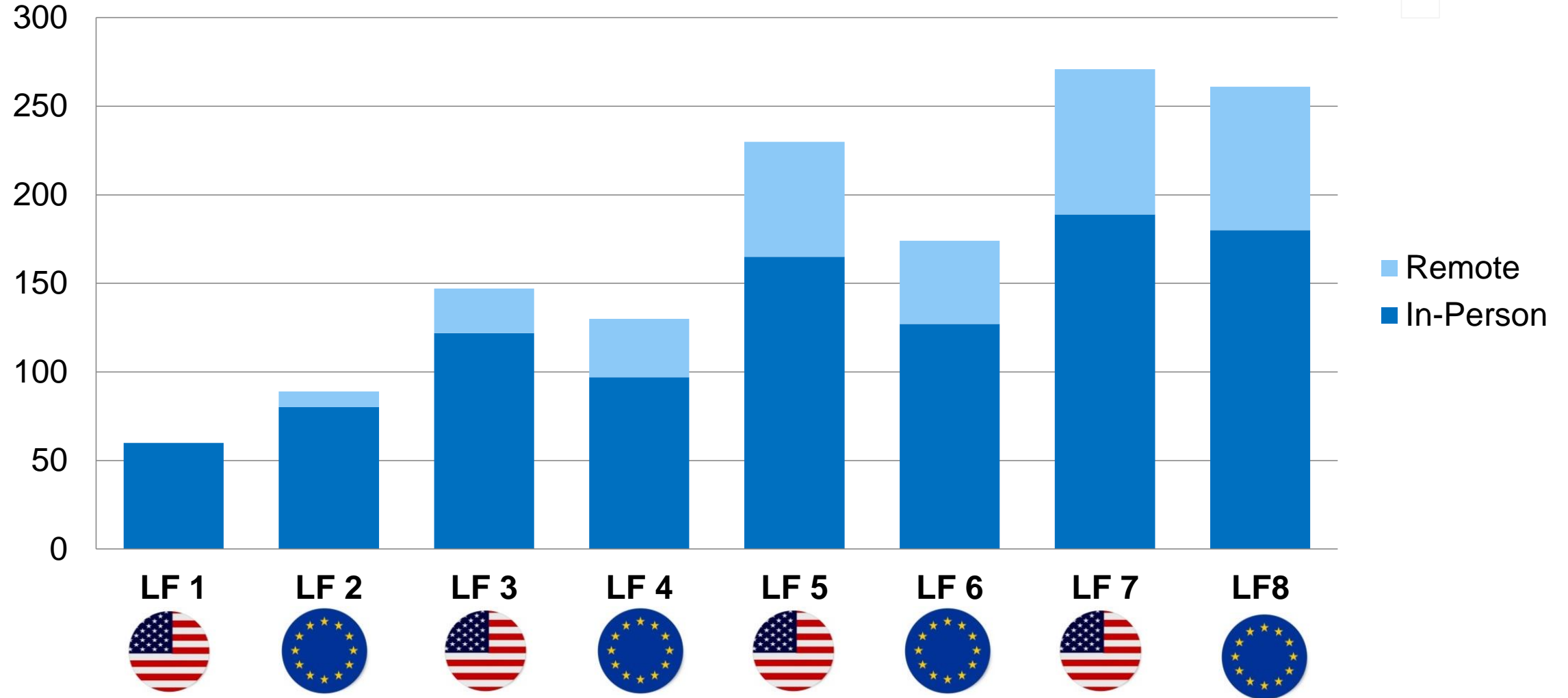
## Attendance by Organization Type



## Attendance by Geographic Location



# PARTICIPATION



# LIVER FORUM 7 RECAP

## ■ **Based on feedback:**

- Eliminated scheduled activities from lunch reception
- Added longer discussion time
- Added new method to ask questions and make comments
- Added breakouts to allow focused discussions
- Preserved networking time
- New working groups

**Complete the evaluation!**

*(constructive feedback)*

# RECENT ACCOMPLISHMENTS

- **Baseline parameters in clinical trials for nonalcoholic steatohepatitis: recommendations from the Liver Forum**

*Yuval A. Patel, Joanne C. Imperial, Andrew J. Muir, Quentin M. Anstee, David DeBroda, Lara Dimick-Santos, Claudia Filozof, Ruby Mehta, Arun J. Sanyal, Elmer Schabel, Brent A. Neuschwander-Tetri, Veronica Miller, on behalf of the Liver Forum Data Standardization Working Group*

2017, Gastroenterology, <https://doi.org/10.1053/j.gastro.2017.07.024>

- **Case definitions for inclusion and analysis of endpoints in clinical trials for nonalcoholic steatohepatitis through the lens of regulatory science**

*Mohammad Shadab Siddiqui Stephen A. Harrison Manal F. Abdelmalek Quentin M. Anstee Pierre Bedossa Laurent Castera Lara Dimick-Santos Scott L. Friedman Katherine Greene David E. Kleiner Sophie Megnien Brent A. Neuschwander-Tetri Vlad Ratziu Elmer Schabel Veronica Miller Arun J. Sanyal on behalf of the Liver Forum Case Definitions Working Group*

2018, Hepatology, <https://doi.org/10.1002/hep.29607>

# WORK IN PROGRESS

## ■ **Case Definitions Working Group**

- Defining improvement in NAFLD for treatment trial endpoints:  
Recommendations from the Liver Forum

## ■ **Pediatric Working Group**

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

## ■ **Standard of Care: Lifestyle Working Group**

- Recommendations on Standardization of Diet and Exercise in Clinical Trials of NAFLD

# ADDITIONAL ACTIVITIES

- **Standard of Care Working Group**
  - Lifestyle Management
  - Comorbidity Management
- **NASH Cirrhosis Working Group**
  - Compensated NASH Cirrhosis
  - Decompensated NASH Cirrhosis
- **Core Outcomes in NASH**
  - Center for Medical Technology Policy

# 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](http://WWW.EXPERTMEDICALEVENTS.COM/NASH)**

JOIN US

**18-19 MAY 2018**

**WASHINGTON, D.C., USA**

## PROGRAM COMMITTEE 2018



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



**Arun Sanyal, MD, MBBS** -  
Virginia Commonwealth  
University, Richmond, VA, USA



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



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

## SELECTED SPEAKERS



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



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



**Detlef Schuppan, MD,  
PhD** - University of Mainz,  
Germany



**Patrick Bossuyt, PhD** -  
AMC-University of Amsterdam,  
The Netherlands

## MEETING ORGANIZERS







# Paris NASH Meeting

July 5 & 6, 2018  
Institut Pasteur

## Organized by

### Veronica Miller

UC Berkeley School  
of Public Health,  
Washington DC, USA

### Arun Sanyal

Virginia Commonwealth  
University School of Medicine,  
Richmond, Virginia, USA

### Lawrence Serfaty

Hôpital Hautepierre  
Hôpitaux Universitaires  
de Strasbourg, France

## Scientific committee

Quentin Anstee  
Pierre Bedossa  
Jean-François Dufour  
Scott Friedman  
Fabio Marra  
Manuel Romero-Gómez  
Frank Tacke  
Michael Trauner

**ONLINE REGISTRATION**  
before June 11, 2018  
[www.paris-nash.org](http://www.paris-nash.org)

**Abstract Submission**  
for poster presentations  
before May 6, 2018

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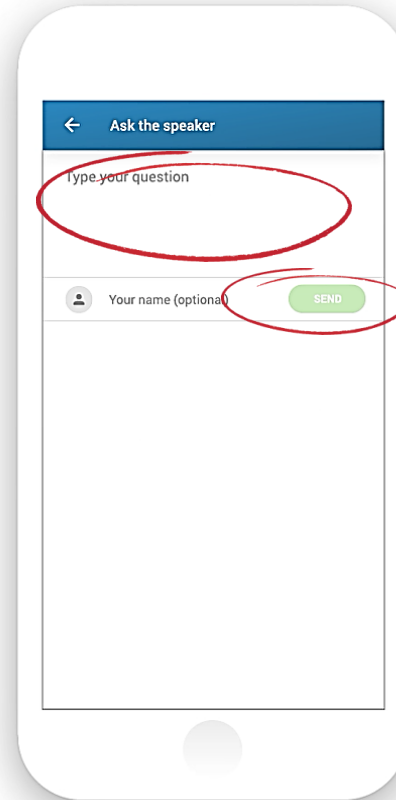
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# PRACTICE USING SLIDO

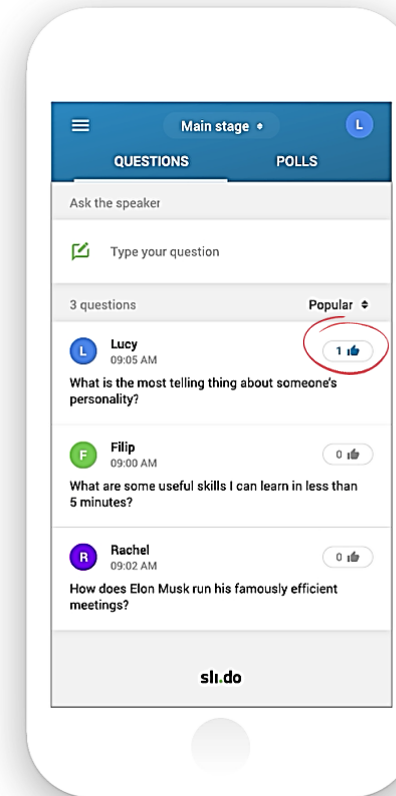
1. Go to [www.slido.com](http://www.slido.com)
2. Enter event #LF8

Type questions  
and submit



“Should we get started?”

“Like” questions



# THANK YOU!

## ■ Forum Staff

- Malene Cobourne
- Terry Daniels
- Katherine Greene
- Pedro Goicochea
- Luis Javier Hernandez
- Victoria Mason
- Veronica Miller
- Brenda Rodriguez
- Ken Taymor
- Jessica Weber

## ■ Prism Event Management

- Paula Blay
- Mairead O'Reilly
- Sarah Matthews
- Graham Hill
- George Seaton
- Jonathan Price
- James Jones
- Peter Ward
- James Lucas