



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

# Project Updates

**Katherine Barradas, MPH**

Forum for Collaborative Research

# Agenda

## 8:30 AM Registration & Light Breakfast

- 9:00 AM Welcome and Housekeeping *Katherine Barradas, Forum for Collaborative Research*  
Introductory Remarks: Liver Forum Co-Chairs *Veronica Miller, Arun Sanyal, Laurent Fischer*

## 9:15 AM Session I: NASH Clinical Trials Part I - Deep Dive into Recent Trials

**Moderator: Arun Sanyal, Virginia Commonwealth University**

- 9:15 AM Lessons Learned from Trials to Date *Mary Rinella, Northwestern University*  
9:35 AM Transitioning from Pre- to Post-Accelerated Approval *Vlad Ratziu, Hôpital Pitié Salpêtrière*  
9:55 AM Panel Discussion *Panelists & Audience*

## 11:00 AM Break

## 11:30 AM Session II: NASH Clinical Trials Part II - Future Directions

**Moderator: Vlad Ratziu, Hôpital Pitié Salpêtrière**

- 11:30 AM Future of Trial Design and Endpoints for NASH *Arun Sanyal, Virginia Commonwealth University*  
11:55 AM Estimands in NASH Clinical Trials *Peter Mesenbrink, Novartis Pharmaceuticals*  
12:15 PM Panel Discussion *Panelists & Audience*

## 1:00 PM Lunch

# Agenda, Continued

## 2:00 PM **Session III: European Regulatory Updates and Perspective**

**Moderator: Veronica Miller, Forum for Collaborative Research**

2:00 PM Review of EMA Reflection Paper and Stakeholder Meeting *Mark Ainsworth, Danish Medicines Agency*

2:30 PM Panel Discussion *Panelists & Audience*

## 3:30 PM **Break**

## 4:00 PM **Session IV: Working Group Updates**

**Moderator: Laurent Fischer, Allergan**

4:00 PM NASH Cirrhosis *Arun Sanyal, Virginia Commonwealth University*

4:10 PM Standard of Care: Comorbidity MGMT  
*Raluca Pais, Hôpital Pitié Salpêtrière*  
*Vlad Ratziu, Hôpital Pitié Salpêtrière*

4:20 PM Standard of Care: Lifestlye MGMT  
*Sven Francque, Antwerp University Hospital*

4:30 PM Pediatric Issues  
*Joel Lavine, Columbia University*

4:40 PM Discussion  
*All*

## 5:30 PM **Adjourn and Evening Reception**

# Options for Discussion

## ■ Microphones

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- Signal moderator
- Introduce self



## ■ Submit Questions

- <https://www.sli.do/>
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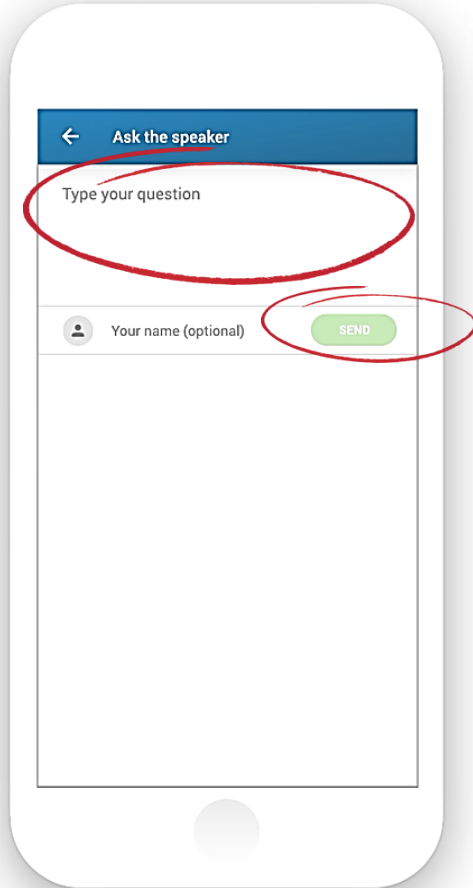


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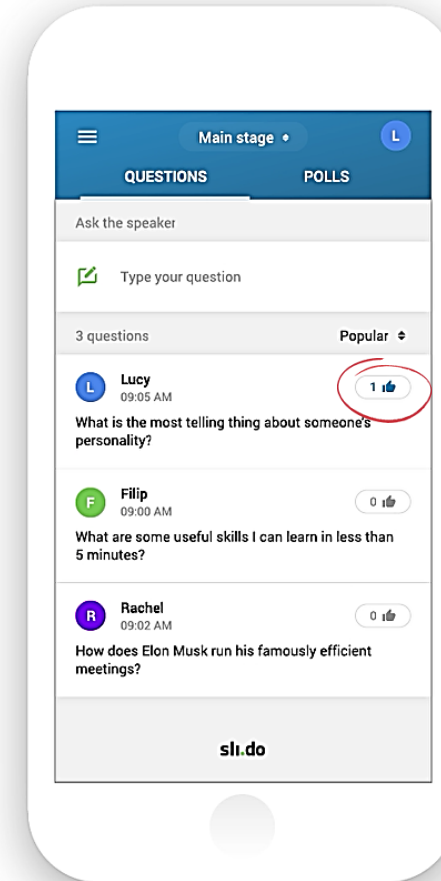
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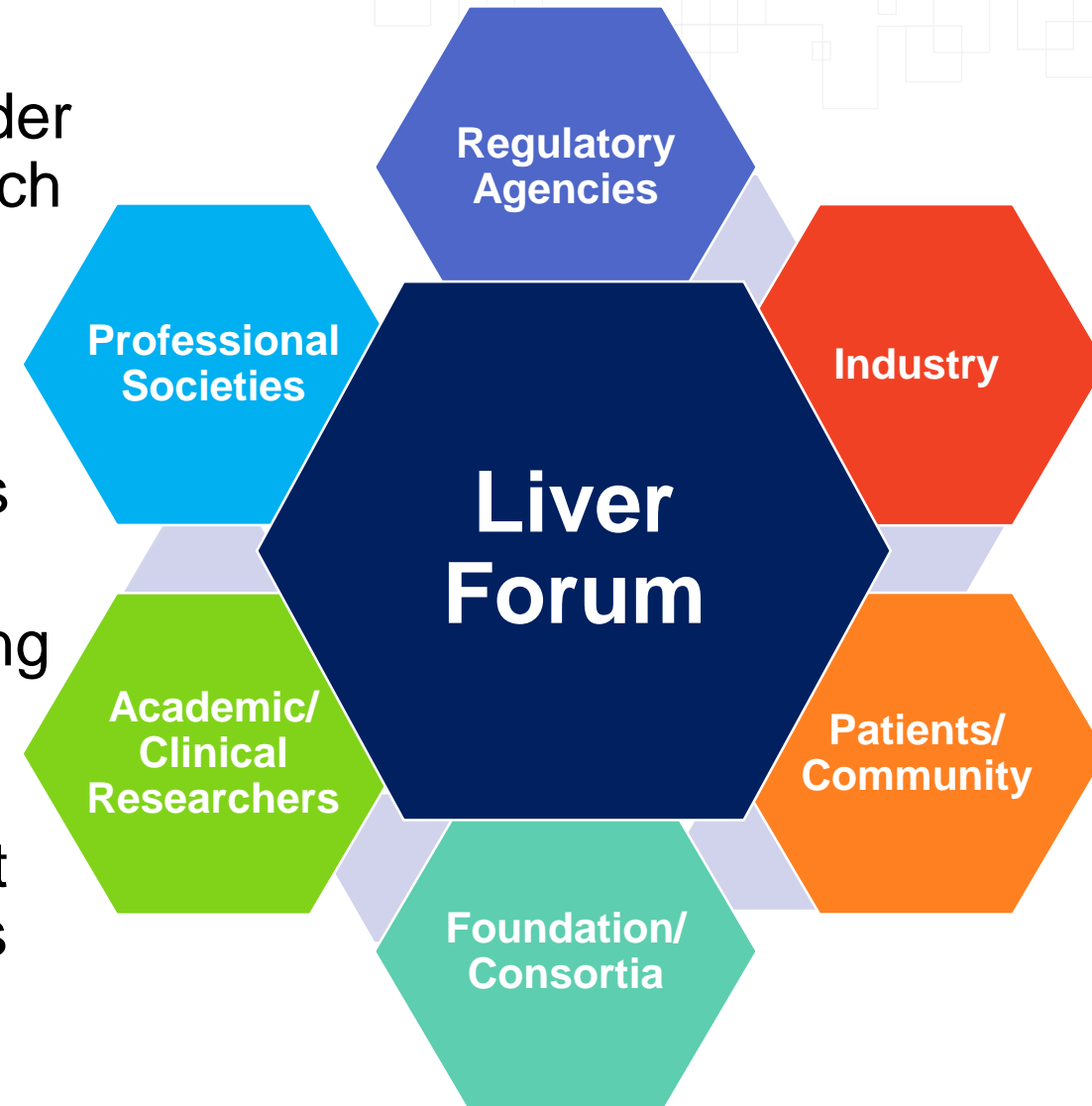
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# Overview of the Liver Forum

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for NAFLD/NASH
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
  - Focus on developing consensus, increasing synergy and collaboration, and reducing duplication and uncertainty
  - Ongoing working group activity throughout the year anchored by larger project events
  - Active & engaged participation



# Rules of the Room

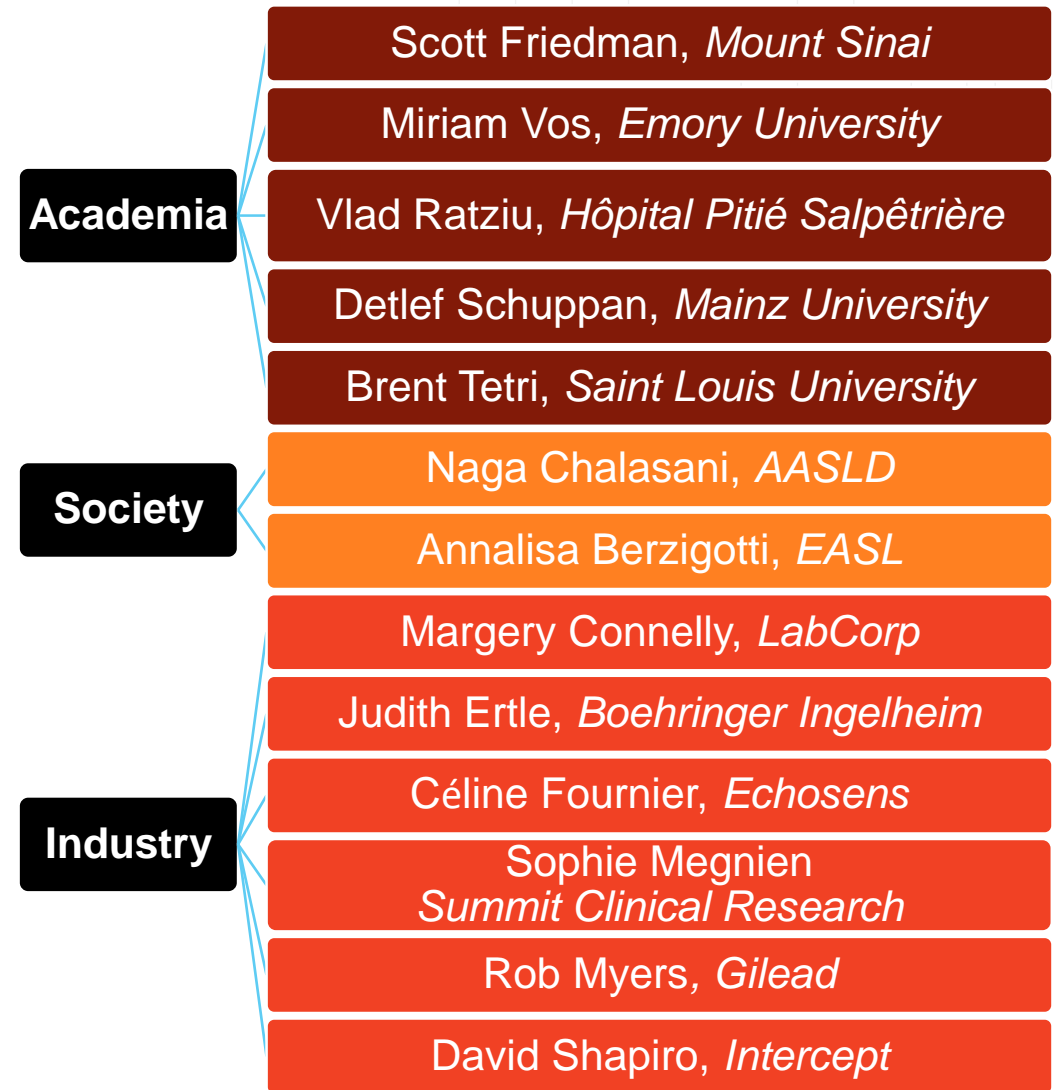
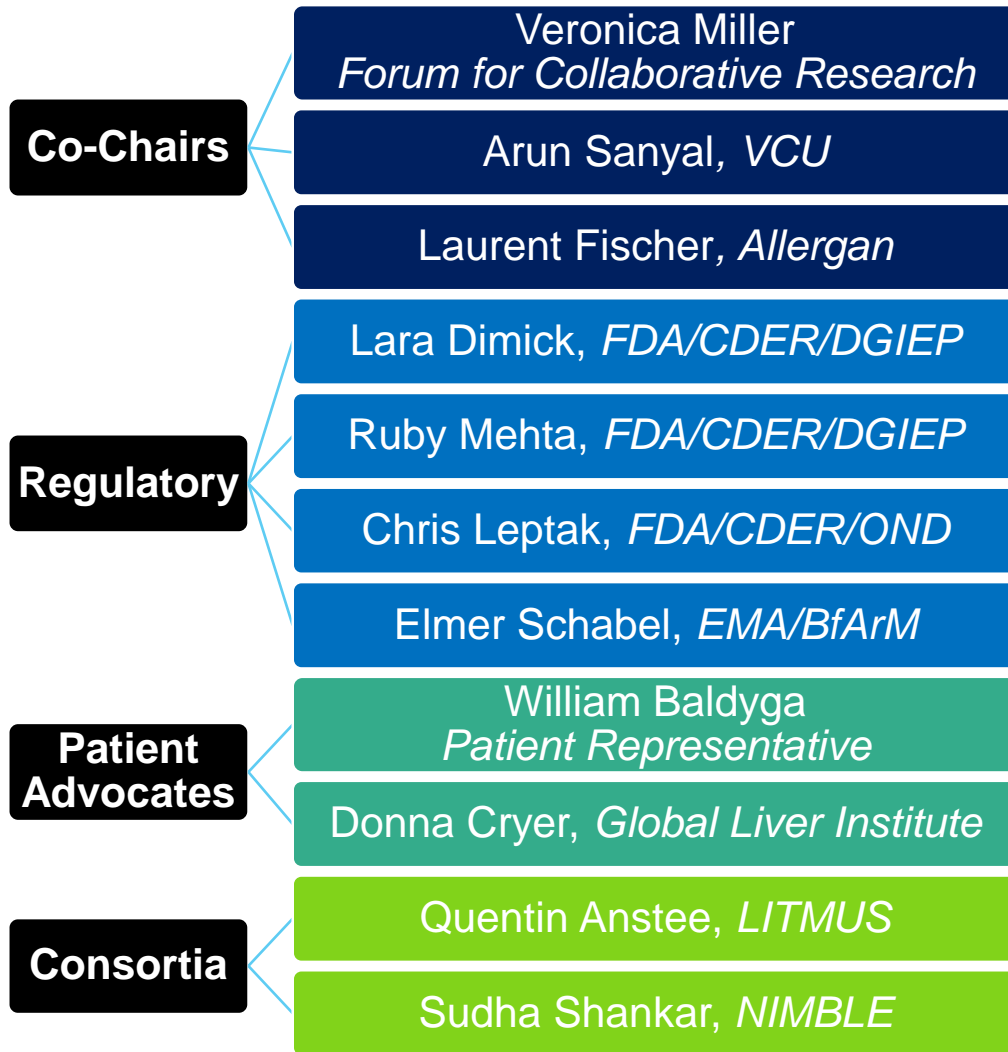
- Presentations, discussions, comments, and questions are not for attribution
  - Participants speak as individuals and express views that may not represent those of their organizations
  - Social Media:
    - ❌ Quotes of speakers/panelists/audience
    - ❌ Detailing meeting proceedings
    - ✅ Photos during receptions
    - ✅ Referencing attendance
    - ✅ Interactions during breaks



**@LIVERFORUM**

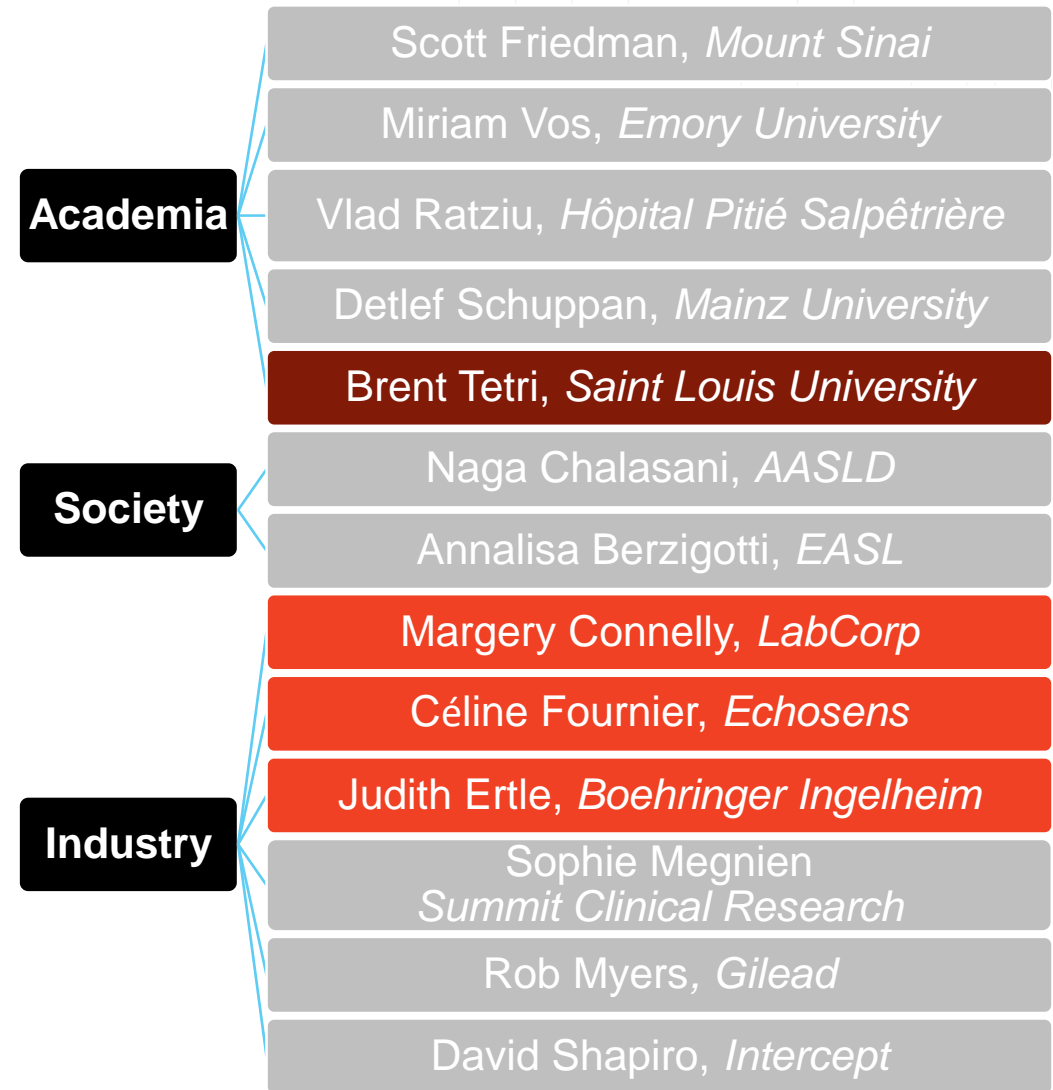
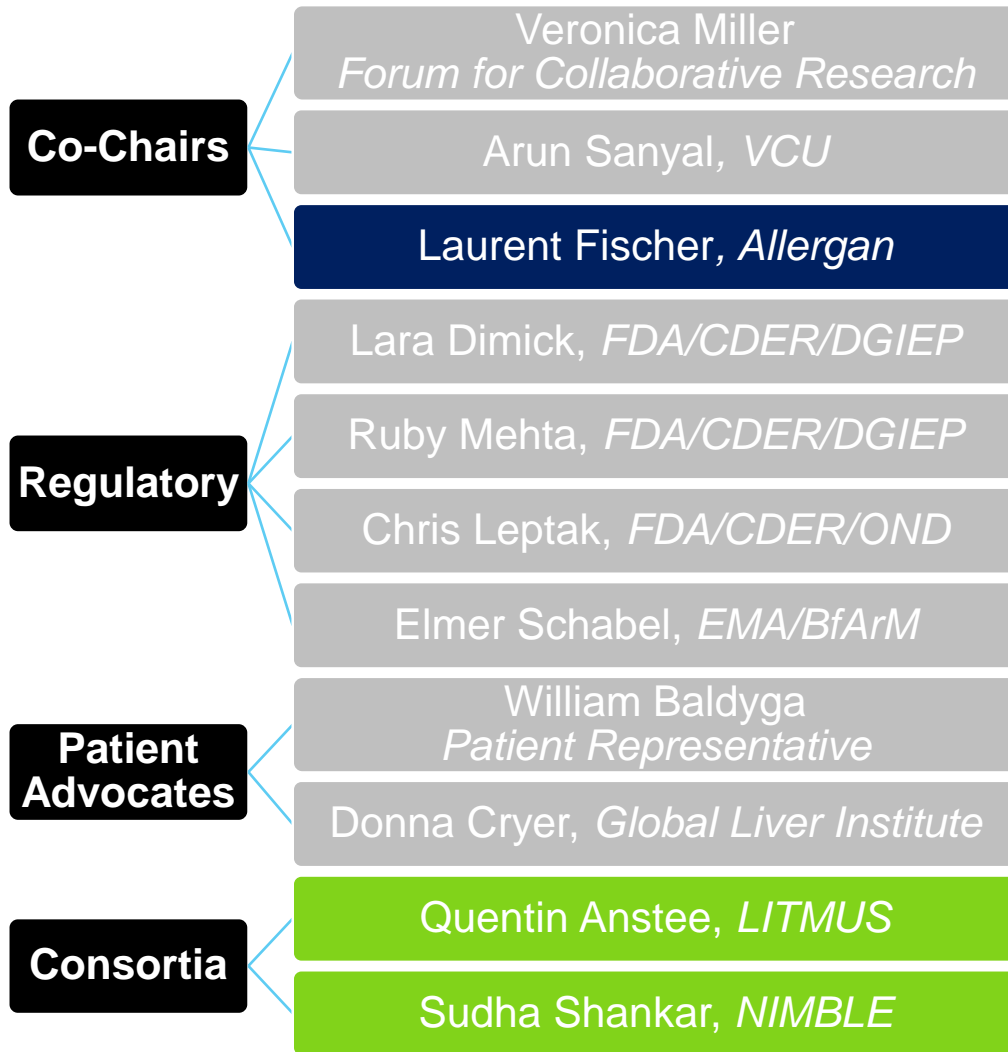


# Steering Committee





# Steering Committee



# Outgoing Steering Committee

- Gary Burgess, Vectura Pharmaceuticals
- Sophie Megnien, Summit Clinical Research
- Richard Torstenson, Allergan

**thank  
you!**

# Recent Accomplishments

- **Case Definitions Working Group Manuscript #2**  
Accepted at Hepatology  
<https://doi.org/10.1002/hep.30672>

**HEPATOLOGY**



Original Article |  Full Access |

Defining Improvement in Nonalcoholic Steatohepatitis for Treatment Trial Endpoints: Recommendations from the Liver Forum

*Amanda Cheung, Brent Neuschwander-Tetri, David Kleiner, Elmer Schabel, Mary Rinella, Stephen Harrison, Vlad Ratziu, Arun Sanyal, Rohit Loomba, Sophie Jeannin Megnien, Richard Torstenson, Veronica Miller, The Liver Forum Case Definitions Working Group*

- **Estimands in Clinical Trials: An Illustration based on NASH**  
Webinar, January 2019, <https://bit.ly/2KKRIBu>

*Presenters: Mouna Akacha, Jürgen Löffler*

*Panelists: James Bell, Santos Carvajal-Gonzalez, Bettina Hansen, Elmer Schabel, Peter Mesenbrink, Veronica Miller*

# Working Group Details

## ■ Case Definitions

- Chairs: Stephen Harrison & Sophie Megnien
  - Manuscripts 1 & 2 published/accepted
- Status: **Complete/ Group Closed**

## ■ Standard of Care: Lifestyle

- Chairs: Manal Abdelmalek, Sven Francque & Oliver Glass
  - Manuscript 1 complete and preparing submission
- Status: **To be assessed**

## ■ Standard of Care: Comorbidities

- Chairs: Raluca Pais & Vlad Ratziu
  - Manuscript 1 under development
- Status: **Active/ Open**



# Working Group Details

## ■ Pediatric Issues

- Chairs: Joel Lavine & Miriam Vos
  - Manuscript 1 submitted to Journal of Hepatology
  - Next focus will be Pediatric Endpoints

- Status: **Active/ Open**

## ■ NASH Cirrhosis

- Chairs: Naga Chalasani, Jean Chan, & Arun Sanyal
- Two subgroups: Compensated and Decompensated
  - Separate workstreams within subgroups: Case Definitions, Stratification, Endpoints

- Status: **Active/ Open**

## ■ Estimands in NASH

- Chairs: Peter Mesenbrink & Veronica Miller
- Status: **Active/ Closed**

All **ACTIVE/ OPEN** working groups welcome additional members!

To join, email me at  
[kgreene@forumresearch.org](mailto:kgreene@forumresearch.org)

# Liver Forum Manuscript Status

Working Group	Title	Status
Data Standardization	Baseline Parameters in Clinical Trials for Nonalcoholic Steatohepatitis: Recommendations From the Liver Forum	Published
Case Definitions	Case Definitions for Inclusion and Analysis of Endpoints in Clinical Trials for Nonalcoholic Steatohepatitis Through the Lens of Regulatory Science	Published
Case Definitions	Defining Improvement in Nonalcoholic Steatohepatitis for Treatment Trial Endpoints: Recommendations from the Liver Forum	Accepted
Pediatric Issues	Considerations for Clinical Drug Development in Pediatric Nonalcoholic Fatty Liver Disease	Revise & Resubmit
Standard of Care	Standardization of Diet and Exercise in Clinical Trials of NAFLD-NASH: Recommendations from the Liver Forum	Preparing Submission
Standard of Care	Management of Comorbidities in NAFLD Clinical Trials	Under Development
NASH Cirrhosis	NASH Cirrhosis Definitions and Recommendations for Clinical Trial Design: Discussions from the Liver Forum	Under Development

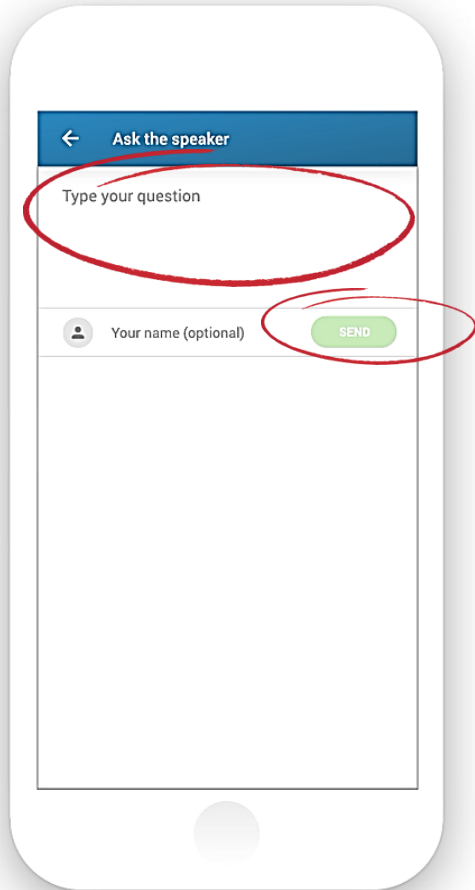
# Liver Forum 10 & PSC Forum 3

- **Logistics**  
September 19-20, 2019  
Bethesda, Maryland
- **Agenda**  
2 full days:
  - ½ day of PSC (Sept. 19, morning)
  - 1 ½ day of NASH
- **Registration to open next week**



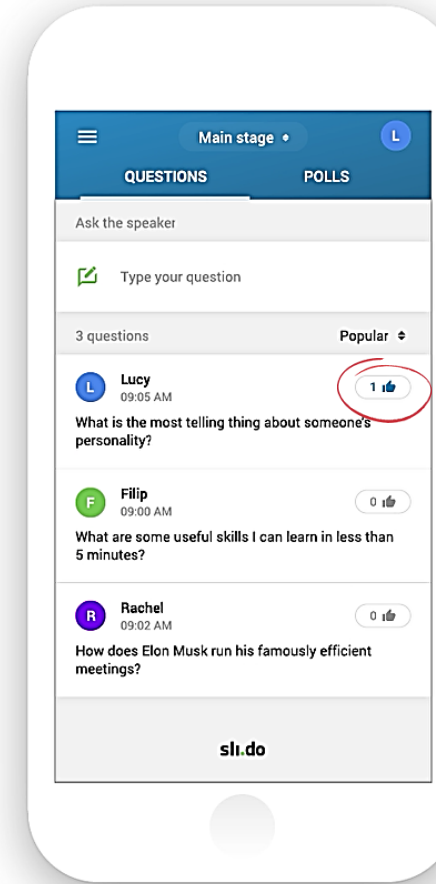
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# THANK YOU!

## ■ Forum Staff

- Ryan Anderson
- Terry Daniels
- Luis Javier Hernandez
- Vin Keane
- Veronica Miller
- Brenda Rodriguez
- Jessica Weber

## ■ Event Coordination

- Taming Healthcare
- Prism Event Management
- Institut Pasteur