



THE FORUM
For Collaborative ResearchSM

Introduction & Liver Forum Update

Katherine Barradas

Forum for Collaborative Research

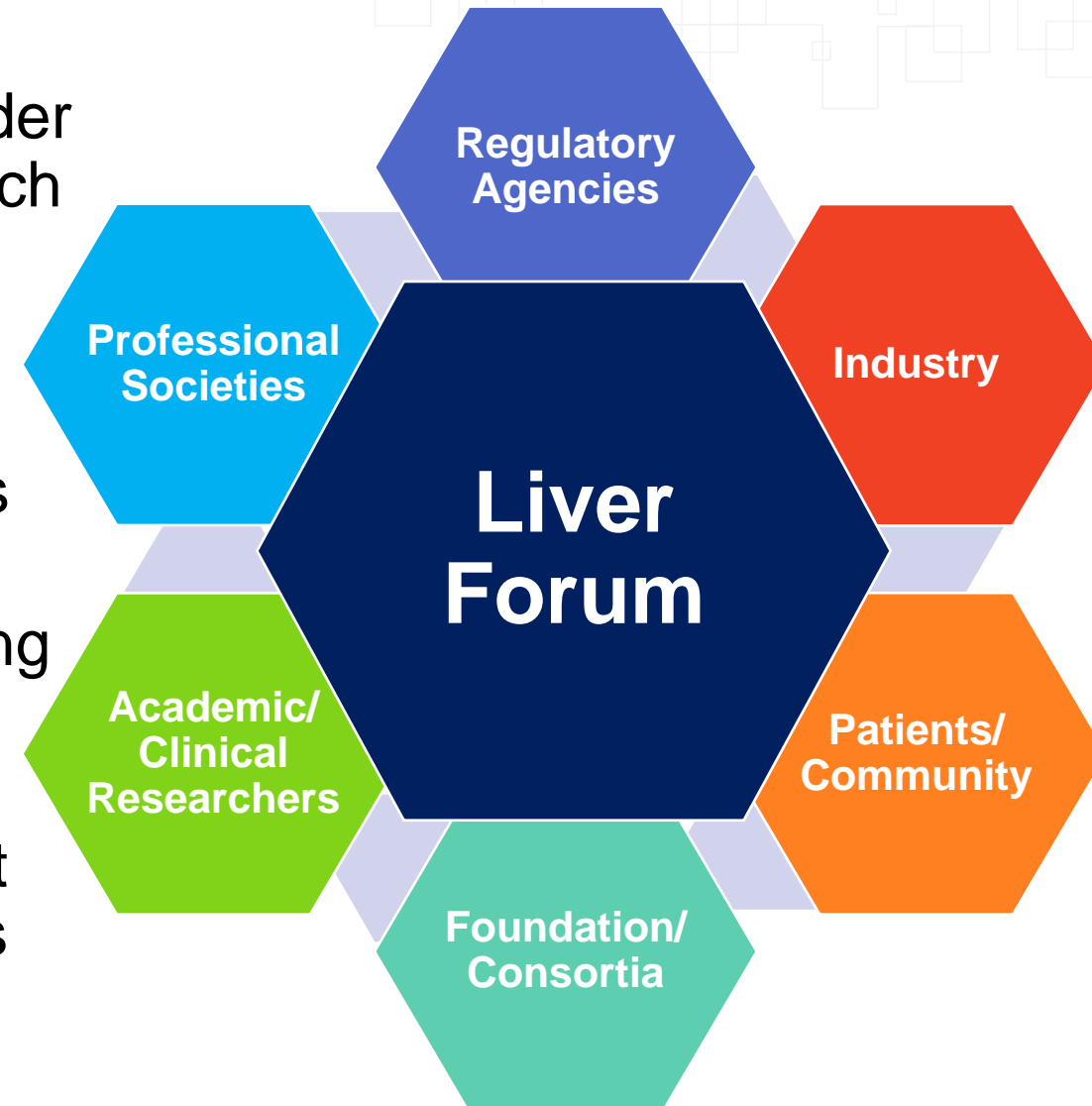
Agenda

Moderator: *Veronica Miller, Forum for Collaborative Research*

11:00 AM	Liver Forum Updates	<i>Katherine Barradas, Forum for Collaborative Research</i>
11:10 AM	NIMBLE Update	<i>Tania Kamphaus, Foundation for the National Institutes of Health</i>
11:20 AM	LITMUS Update	<i>Richard Torstenson, AbbVie</i>
11:30 AM	Recent NASH Clinical Trial Results & Implications	<i>Mazen Nouredin, Cedars-Sinai Medical Center</i>
11:55 AM	FDA Update	<i>Ruby Mehta, U.S. Food and Drug Administration</i>
12:00 PM	EMA Reflection Paper Update	<i>Katherine Barradas, Forum for Collaborative Research***</i>
12:05 PM	Global Liver Institute Updates	<i>Donna Cryer, Global Liver Institute</i>
12:15 PM	Group Discussion	<i>All</i>
12:55 PM	Future Directions & Next Steps	<i>Veronica Miller, Forum for Collaborative Research</i>
1:00 PM	Adjourn Webinar	

Overview of the Liver Forum

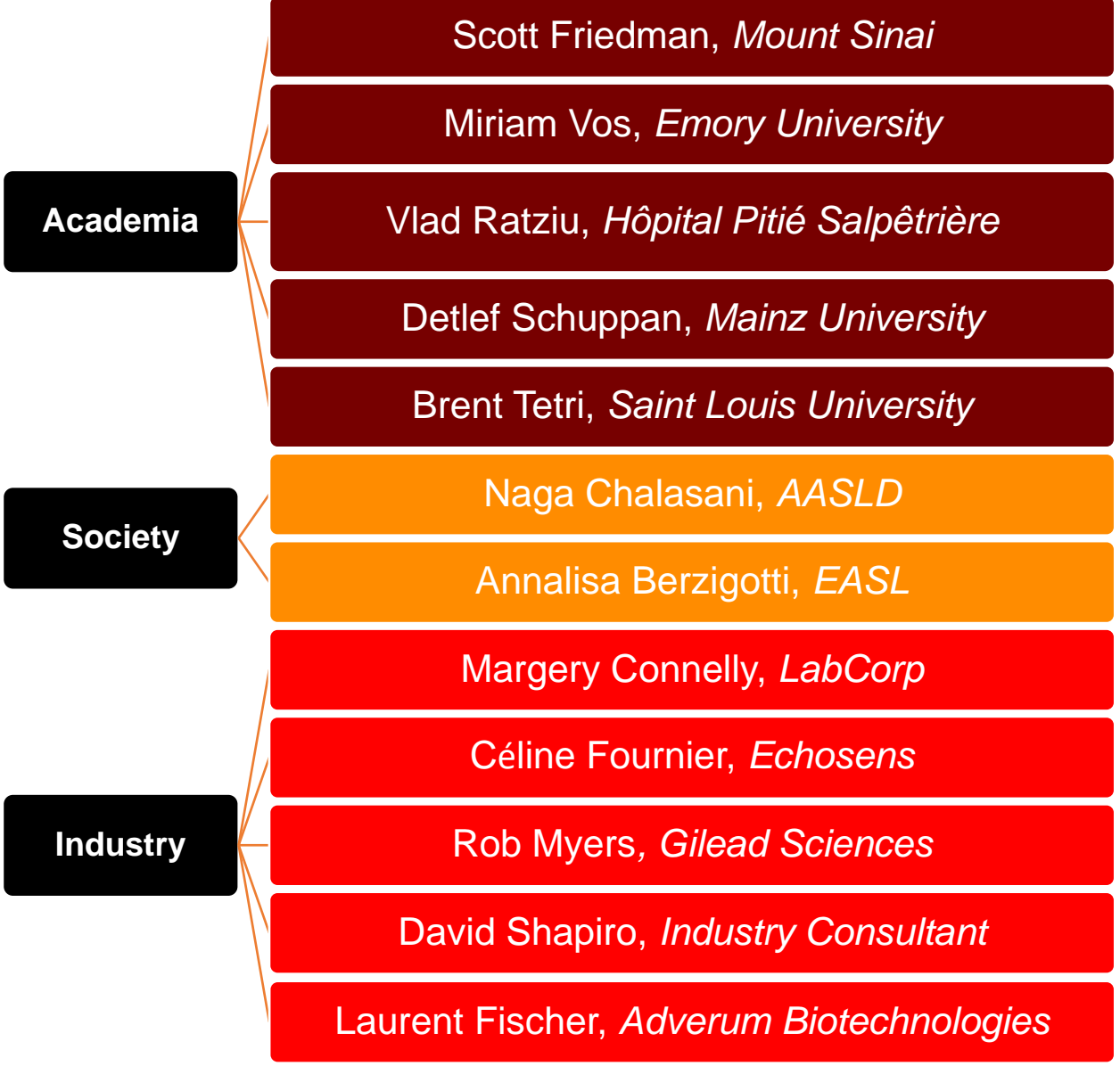
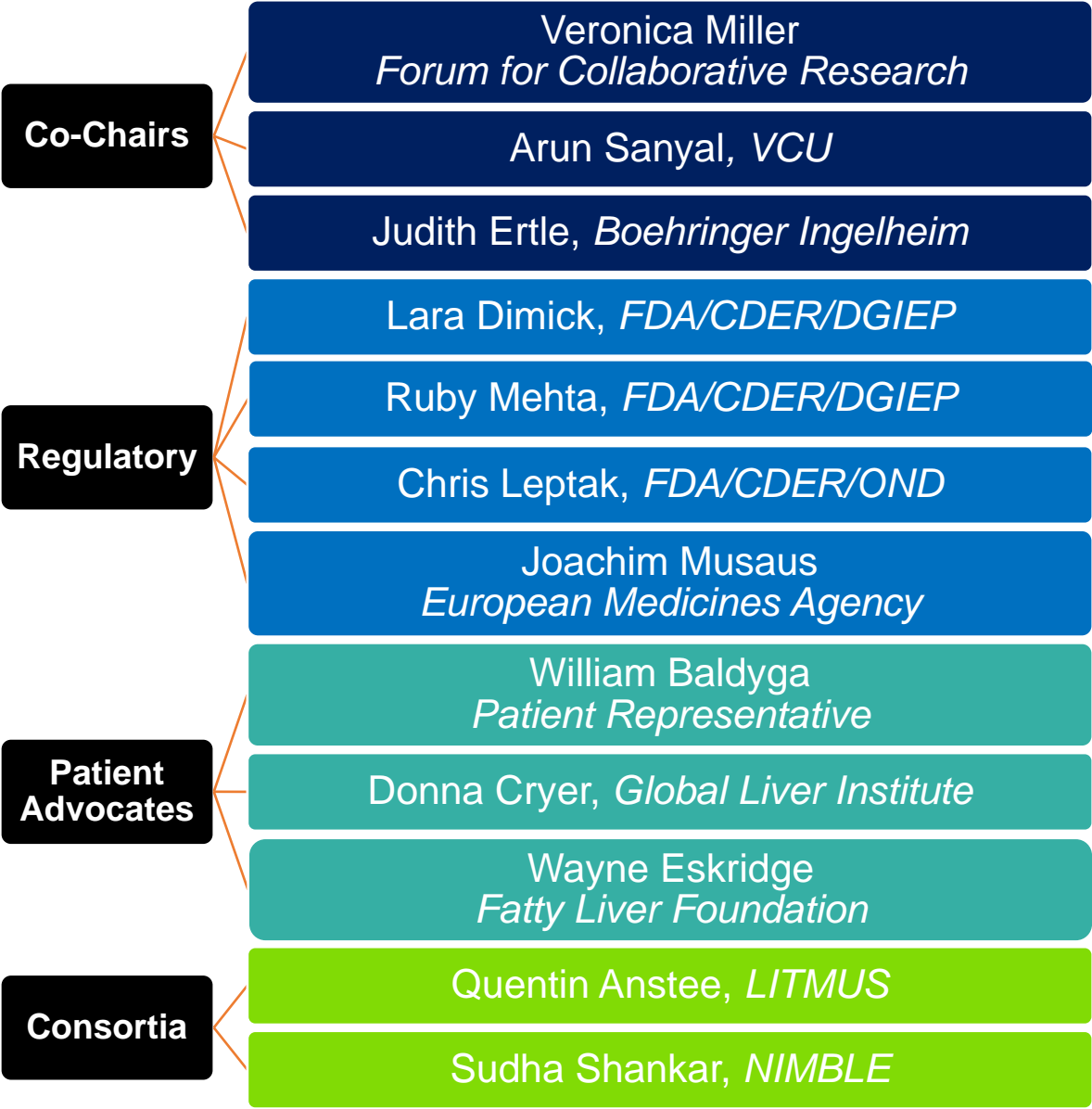
- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for NAFLD/NASH
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
 - Focus 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 [Zoom] 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
 - Recording by participants is not permitted. Slides will be available on our website pending speaker permission.
- **Participation Reminder (Forum Operating Principles)**
 - We restrict participation to experts with the necessary scientific knowledge from organizations or entities with a clear commitment to advancing the diagnostic and therapeutic field of the disease area of the project they participate in, whether they be from government, academia, industry or community. Only in this way can we achieve the effectiveness and productivity needed to add value to the field. The Forum is not a venue for marketing and/or investment experts.

Steering Committee



Recent Activities & Accomplishments

- **Accepted: NASH Cirrhosis Manuscript #1**

Attribution of Nonalcoholic Steatohepatitis as an Etiology of Cirrhosis for Clinical Trials Eligibility: Recommendations From the Multi-stakeholder Liver Forum

Mazen Nouredin, Jean Chan, Katherine Barradas, Lara Dimick-Santos, Elmer Schabel, Stephanie Omokaro, Frank Anania, Robert Myers, Veronica Miller, Arun Sanyal, Naga Chalasani, for the Liver Forum NASH Cirrhosis Working Group

In Press, Gastroenterology, <https://doi.org/10.1053/j.gastro.2020.04.039>

- **Accepted: Standard of Care Lifestyle Manuscript**

Standardization of Diet and Exercise in Clinical Trials of NAFLD-NASH: Recommendations from the Liver Forum

Oliver Glass, Claudia Filozof, Mazen Nouredin, Mark Berner-Hansen, Elmer Schabel, Katherine Barradas, Jörn M. Schattenberg, Veronica Miller, Sven Francque, Manal F. Abdelmalek, for the Liver Forum Standard of Care Working Group

In Press, Journal of Hepatology, <https://doi.org/10.1016/j.jhep.2020.04.030>

Working Group Details

Working Group	Chairs	Status
Data Standardization	Joanne Imperial & Andrew Muir	Completed
Case Definitions	Stephen Harrison & Sophie Megnien	Completed
Standard of Care: Lifestyle	Manal Abdelmalek & Sven Francque	To be Assessed
Estimands in NASH	Peter Mesenbrink & Veronica Miller	Active/ Closed
Standard of Care: Comorbidities	Raluca Pais & Vlad Ratziu	Active/ Open
Pediatric Issues	Joel Lavine & Miriam Vos	Active/ Open
NASH Cirrhosis	Naga Chalasani & Arun Sanyal	Active/ Open

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

To join, email me at kbarradas@forumresearch.org

Upcoming Webinars

■ Liver Forum Histology Series

- **Session 1:** Best Practices for Increasing Reliability of Liver Biopsies in NASH Clinical Trials

Tuesday, September 1, 2020; 12:00pm – 2:00pm ET

- **Session 2:** Innovations in Liver Biopsy Assessment- Utilizing Digital Methods and AI Technology

Date TBD (October 2020)

- **Session 3:** Causality Assessment for Suspected DILI in NASH Clinical Trials- Determining When to Biopsy

Date TBD (November or December 2020)

- Additional sessions being considered for development

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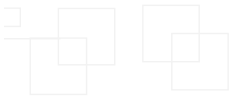
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Thank You!