

THE FORUM
For Collaborative ResearchSM

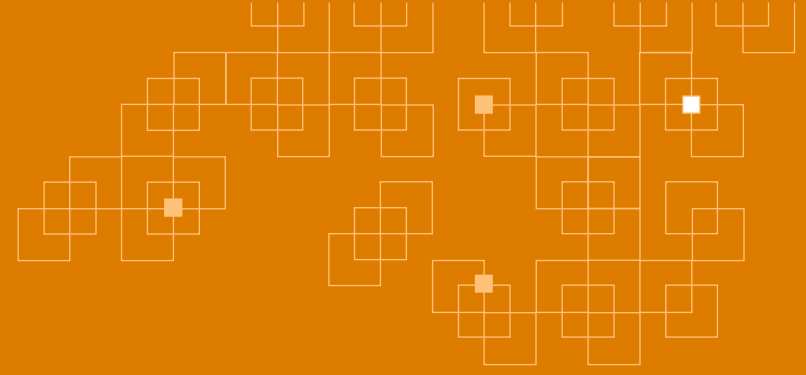
Liver Forum 13

Paris, France

September 7, 2022

Veronica Miller, PhD
Director

Berkeley Public
Health



Welcome & Introduction

Veronica Miller

Arun Sanyal

Judith Ertle

Goals for Today



- Update LF community on activities
- Pick-up on NIT-Clinical Outcomes from LF 13
 - How far have we come since then?
- Trial design issues/analytic methods
 - Competing risks
- Anticipating new science
 - Fibrosis from biochemical and histological perspective
- Working Group proposals

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



Forum Operating Principles

- Independent and neutral venue
 - Ongoing multi-stakeholder dialogue
 - Each stakeholder group has an equal voice
- Facilitate best science-based decisions, in real time
 - Break down inefficiencies and redundancy
 - Increase clarity, collaboration and innovation
 - Benefit to whole field, especially patients

Forum = Safe Space

- Closed meeting
 - No marketing
 - No press
- Bring your expertise
 - Leave your “hat” at the door

Rules of the Room and Zoom



What's said in the room, stays in the room

What's said in the room, is not for attribution

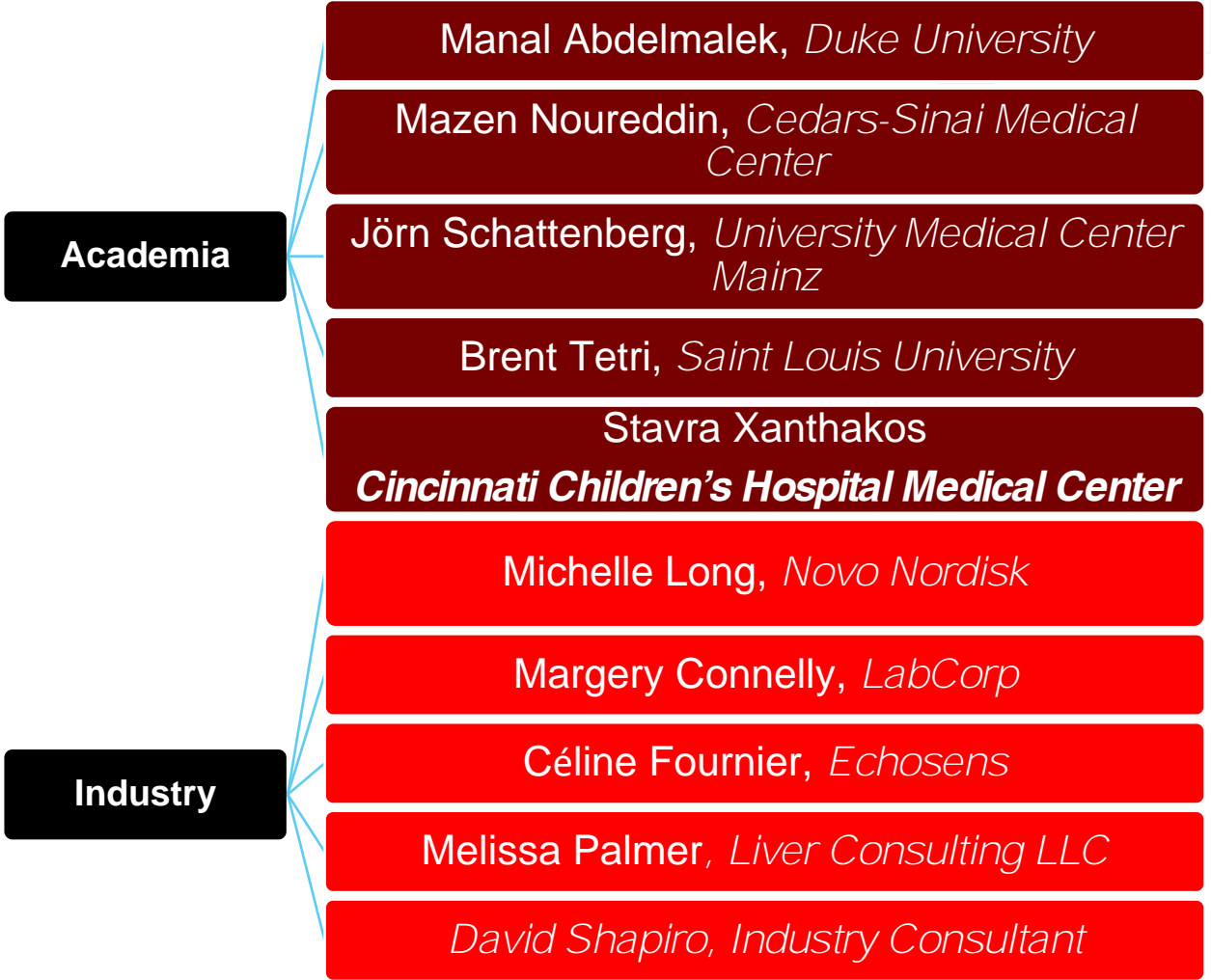
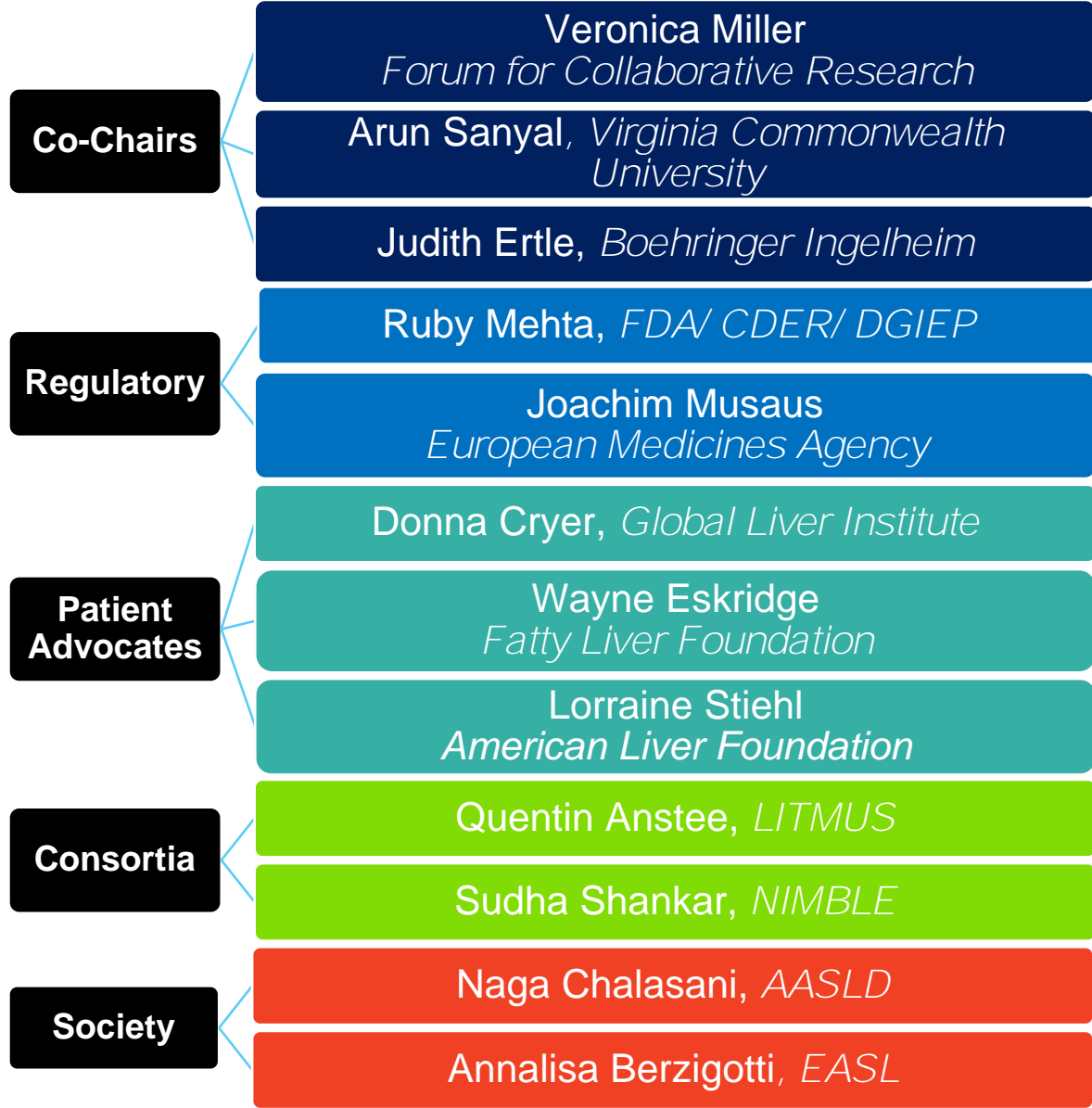
Let the science speak

Active participation

Steering Committee



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Liver Forum Sponsors



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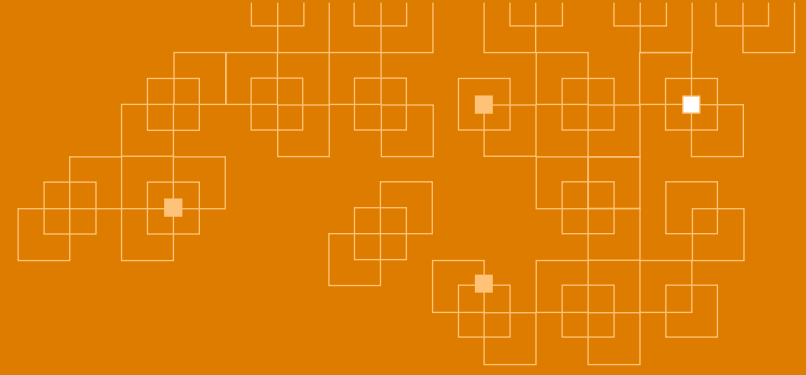
Liver Forum Sponsors



Forum Team



- Veronica Miller – Director
- Brenda Rodriguez – Deputy Director
- Nicholas Murdock – Research Associate
- Joseph Lau – Research Associate
- Mitchell Leus – Research Associate
- Chelsey Campillo – Research Associate
- Zachary Rooney – Research Associate
- Logan Donaldson – Research Associate
- Shilpa Mitra – Research Associate
- Sehyr Khan – Research Associate
- Jeffrey S. Murray – Program Advisor
- John Sninsky – Program Advisor
- Nayri Alajaji, Graduate Student Researcher
- Mayland Treat, Graduate Student Researcher



Liver Forum Updates

The Liver Forum Programs



- Liver Forum
 - NASH
- PSC Forum
- Pediatric Cholestatic Diseases Program

- Materials from April 22-23 LF 12 meeting available
- Submitted manuscript

**A Liver Forum proposal for management of comorbidities in NASH
Clinical Trials**

**Raluca Pais¹, Bertrand Cariou², Mazen Nouredin³, Sven Francque⁴, Jörn Schattenberg⁵,
Manal F. Abdelmalek⁶, Gadi Lalazar⁷, Sharat Varma⁸, Julie Dietrich⁹, Veronica Miller¹⁰,
Arun Sanyal¹¹, Vlad Ratziu¹² on behalf of the Liver Forum**

PSC Forum



- Co-chairs: Kris Kowdley, Adrian Di Bisceglie
- Next PSC Forum meeting: November 8, 2022
- Topics under consideration by SC
 - Discuss possibility of phase 2 and phase 3 endpoints based on MOA
 - Adapt ALP inclusion criteria depending on URSO use

Pediatric Cholestatic Program



- Co-Chairs: Saul Karpen, Henkjan Verkade, Pam Vig
 - Alagille Syndrome
 - Biliary Atresia
 - PFIC
 - Pediatric PSC
 - Transition from peds to adults
- Introductory [webinar- based meeting](#)

RWD-E Program



- [Cross-Forums program](#)
- Collaboration with UC Berkeley Causal Inference Group
 - Co-sponsoring a meeting on statistical methods to combine RW and RCT data for chronic diseases

Placebo Arm Database



- Working Group co-chairs:
 - Manal Abdelmalek
 - Michael Cooreman
- Working group discussion during Session V

Histology Webinar Series Publication Update

Cirrhosis Working Publication Update