



**THE FORUM**

For Collaborative Research<sup>SM</sup>

*Berkeley's Hub for Regulatory Science*

# Liver Forum 16

## Bethesda, MD

**Friday, March 22 & Saturday, March 23, 2023**

**Veronica Miller, PhD**

*Director, Forum for Collaborative Research*

# Wi-Fi Access

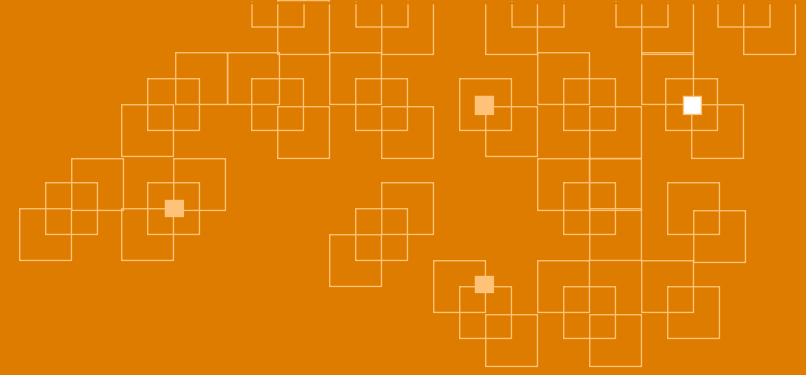
**Network:** MarriottBonvoy\_Conference



**Passcode:** MHQ2024



**Please ensure your phone is  
turned to Silent or Vibrate Mode**



# Welcome, Introduction, Forum Updates, Program Overview, and Acknowledgment

**Veronica Miller, *Forum***

# Overview of the Liver Forum



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- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for MASLD/MASH
- **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

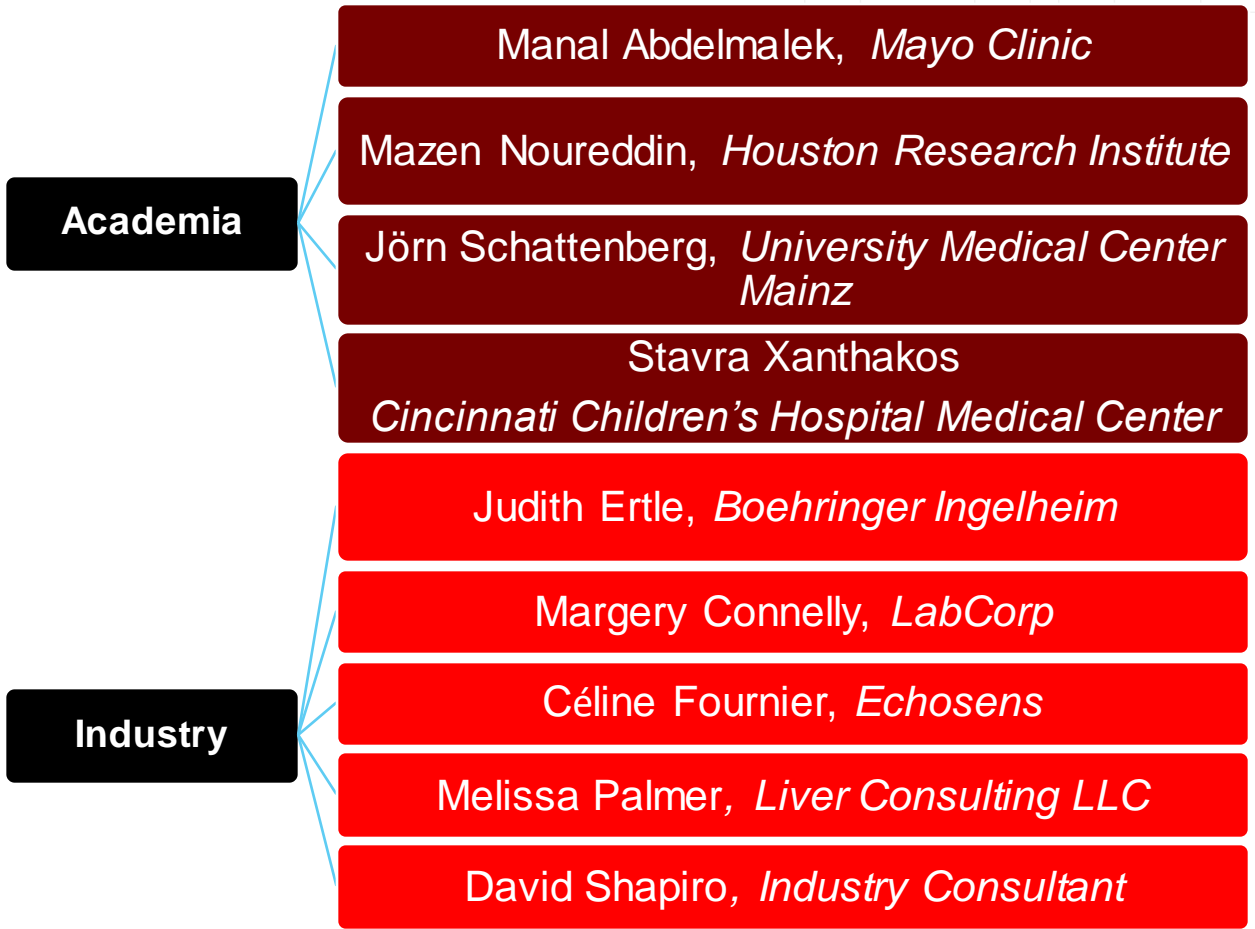
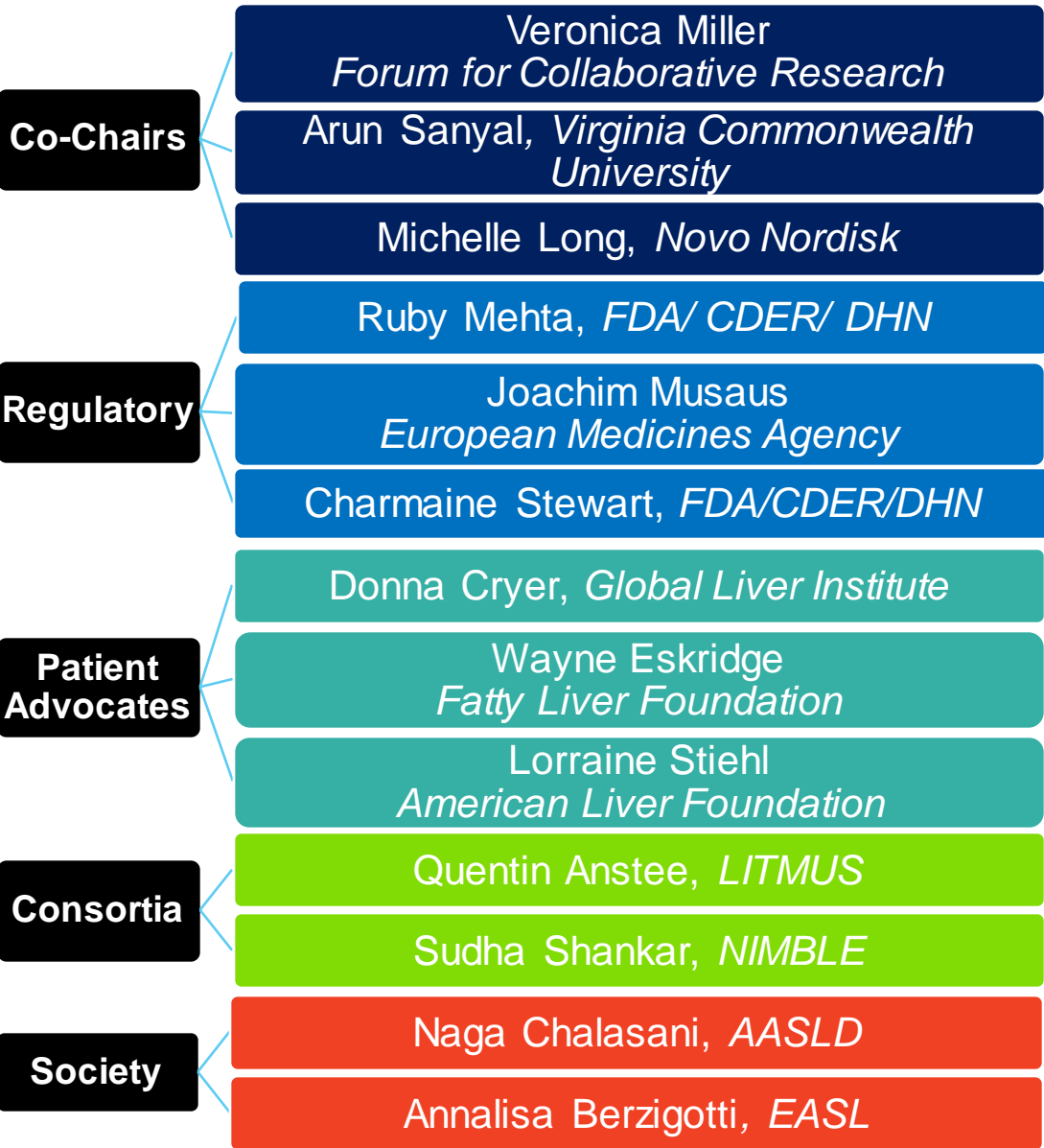
# Rules of the Room and Zoom

- 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



EA Pharma Co., Ltd.



# The Forum Team



- Veronica Miller – Director & Faculty Lead

## Program leads and project managers

- Robin Schaefer – Postdoctoral Scholar
- Azza Karrar – Senior Research Associate
- Logan Donaldson – Research Associate
- Sehyr Khan – Research Associate
- Mitchell Leus – Research Associate
- Shilpa Mitra – Research Associate

## Data & Analysis Center

- Chris Hoffman – IT and Operational Director
- Margot Yann – Lead Data Scientist
- Zachary Rooney – Technical & Infrastructure Lead

## Administration

- Donna Dahrouge – Assist. Director, Administration
- Christopher Berry – Events and Operations Manager
- Donnice Butler – Sr Admin Assistant
- Alicia Jellinek – Program Financial Analyst

## Student Assistants

- Alessi Ayvaz – Undergraduate Student Assistant

## Program Advisors

- Richard Haubrich – Program Advisor
- Jeffrey S. Murray – Program Advisor
- Mike Robertson – Program Advisor
- John Sninsky – Program Advisor



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# Review of Liver Forum 16 Goals and Objectives

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

# Goals for Today

- Discussion Clinical Trials for MASH : Anticipating Marketing Approval(s)
  - Regulatory perspectives
  - Overview of clinical trials once therapeutics are approved for marketing
- Lessons Learned
  - NASH / MASH program- OCA
  - Challenges in continuing long-term randomization with drugs approved for marketing: COBALT
  - Challenges with RWD-RWE in the liver disease space: HEROES STUDY
- Resmetirom Program Updates
- Collaboration for Greater Efficiency
  - PDB, CRSDA, RLD
- Standardizing for Greater Efficiency
  - Standardizing MASH NITs and MASH clinical outcomes assessments