

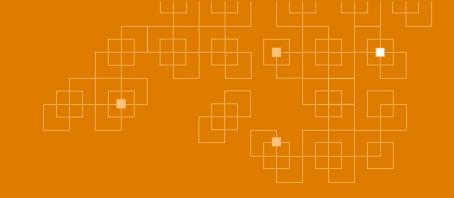


Setting the Stage

Veronica Miller

Forum for Collaborative Research





Disease Assessment Strategies to Accelerate Drug Development

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







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





Upcoming Events

- Liver Forum networking reception June 21
 - ILC/London
- Liver Forum in person pre-Paris NASH Sept 7
 - Paris





Special Event

- MOSAIC
 - Metabolic Multi-Organ Science to Accelerate Innovation in Clinical Trials
- June 30 and July 1
 - Washington DC French Embassy
- Organized by CVDT
 - In Collaboration w Liver Forum

https://mosaic-nash.org/agenda/

https://mosaic-nash.org<https://ic-nash.org/



Steering Committee



Veronica Miller Forum for Collaborative Research Arun Sanyal, Virginia Commonwealth **Co-Chairs** University Judith Ertle, Boehringer Ingelheim Ruby Mehta, FDA/ CDER/ DGIEP Regulatory **Joachim Musaus** European Medicines Agency Donna Cryer, Global Liver Institute **Patient** Advocates Wayne Eskridge Fatty Liver Foundation Quentin Anstee, LITMUS Consortia Sudha Shankar, NIMBLE Naga Chalasani, AASLD Society Annalisa Berzigotti, *EASL*

Manal Abdelmalek, *Duke University* Mazen Noureddin, Cedars-Sinai Medical Center Jörn Schattenberg, *University Medical Center* **Academia** Mainz Brent Tetri, Saint Louis University Stavra Xanthakos Cincinnati Children's Hospital Medical Center Kristine Buchholtz Novo Nordisk Margery Connelly, LabCorp Céline Fournier, *Echosens* **Industry** Melissa Palmer, Liver Consulting LLC David Shapiro, Industry Consultant





























EA Pharma Co., Ltd.



































FORUM FOR COLLABORATIVE RESEARCH



















































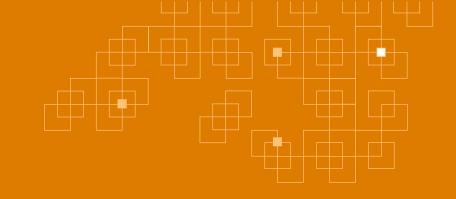












April 22-23 Meeting Theme "Show us the data"



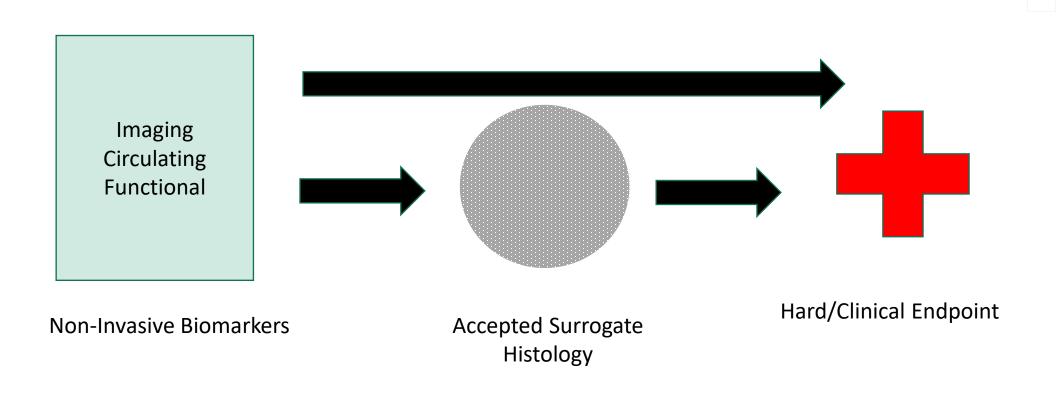
Progress to non-invasive biomarkers

- Ongoing dialogue
 - The first of a series
 - Iterative process
 - Until we get there

"Show us the data"







"Show us the data"





Opportunities for Improved Integration of Biomarker Development Activities within Drug Development





Note: These pathways do not exist in isolation and many times parallel efforts are underway within or between pathways. All share common core concepts, are datadriven, and involve regulatory assessment and outcomes based on the available data.



April 22-23 Meeting Goals

- Review existing data
 - Diagnostic Context of Use
 - Prognostic/Predictive Context of Use
- Assess gaps
- Collaborate to fill gaps
- Repeat as needed

"Show us the data"



Forum Team

THE FORUM
For Collaborative Research®

- Veronica Miller Director
- Brenda Rodriguez Deputy Director
- Jessica Weber Senior Research Associate
- Nicholas Murdock Research Associate
- Joseph Lau Research Associate
- Chelsey Campillo Research Associate

- Jeffrey S. Murray Program Advisor
- John Sninsky Program Advisor
- Nayri Alajaji, Graduate Student Researcher
- Edwin Chojolan, Graduate Student Researcher
- Maggie Kuang, Graduate Student Researcher
- Tyler Mansfield, Graduate Student Researcher

