

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

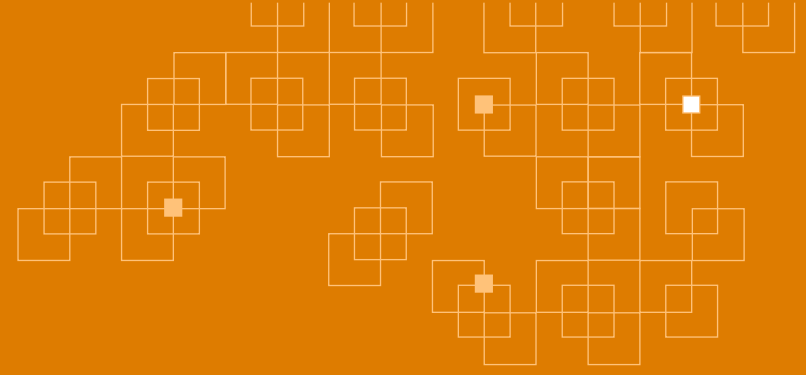
# Liver Forum 14

Bethesda, MD

March 31-April 1, 2023

Veronica Miller, PhD  
Director

**Berkeley** Public  
Health



# Welcome & Introduction

Veronica Miller

Arun Sanyal

Judith Ertle

# 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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## Co-Chairs

Veronica Miller  
*Forum for Collaborative Research*

Arun Sanyal, *Virginia Commonwealth University*

Judith Ertle, *Boehringer Ingelheim*

## Regulatory

Ruby Mehta, *FDA/CDER/DHN*

Joachim Musaus  
*European Medicines Agency*

Charmaine Stewart, *FDA/CDER/DHN*

## Patient Advocates

Donna Cryer, *Global Liver Institute*

Wayne Eskridge  
*Fatty Liver Foundation*

Lorraine Stiehl  
*American Liver Foundation*

## Consortia

Quentin Anstee, *LITMUS*

Sudha Shankar, *NIMBLE*

## Society

Naga Chalasani, *AASLD*

Annalisa Berzigotti, *EASL*

## Academia

Manal Abdelmalek, *Mayo Clinic*

Mazen Nouredin, *Houston Research Institute*

Jörn Schattenberg, *University Medical Center Mainz*

Brent Tetri, *Saint Louis University*

Stavra Xanthakos  
*Cincinnati Children's Hospital Medical Center*

## Industry

Michelle Long, *Novo Nordisk*

Margery Connelly, *LabCorp*

Céline Fournier, *Echosens*

Melissa Palmer, *Liver Consulting LLC*

David Shapiro, *Industry Consultant*

# Liver Forum Sponsors





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# Forum Team Updates



- **New Staff**
  - Chris Hoffman, IT and Operational Director
  - Azza Karrar, Senior Research Associate
  - Margot Yann, Lead Data Scientist
  - Sammy Berman, Research Data Analyst
- **Since LF13**
  - Sehry Khan, BA

# The Liver Forum Welcomes:



**Azza Karrar, MSc, PhD**

**Senior Research Associate**



- Extensive experience working on immunopathology of liver disease.
- Has led translational efforts focusing on immunopathogenesis, biomarkers and therapeutic targets of NASH related-liver fibrosis.
- Served as Biologist with the FDA, CDRH to provide regulatory consultation on premarket approval application, product development protocols and post market applications.

# The Liver Forum Welcomes:

## Sehyr Khan, BA

### Research Associate



- Sehyr has a bachelor's in Neuroscience from Wellesley College.
- She gained her experience during her undergraduate career at the MIT McGovern Institute for Brain Research and the Center for Addiction Medicine at Massachusetts General Hospital.



# The Data & Analysis Center Team



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Chris Hoffman, PhD  
IT & Operational  
Director



Margot Yann, PhD,  
MEng, Lead Data  
Scientist



Zach Rooney, MSCS  
Research Associate



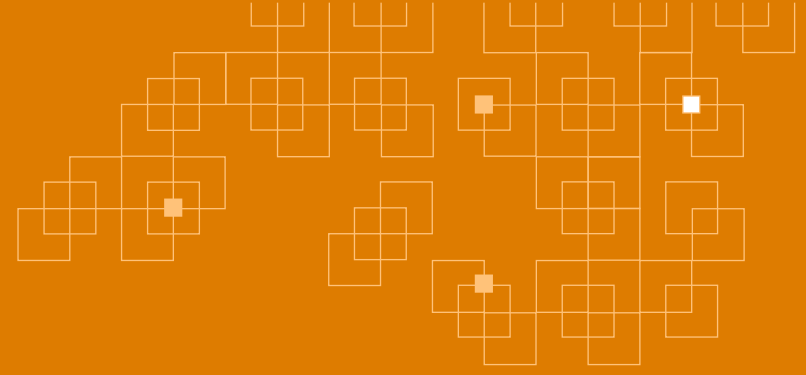
Sammy Berman, MSc  
Research Data Analyst



# Forum Team



- Veronica Miller – Director
- Brenda Rodriguez – Deputy Director
- Nicholas Murdock – Research Associate
- Mitchell Leus – Research Associate
- Logan Donaldson – Research Associate
- Shilpa Mitra – Research Associate
- **Sehyr Khan – Research Associate**
- **Azza Karrar – Senior Research Associate**
- Alicia Jellinek – Program Financial Analyst
- **Chris Hoffman – IT and Operational Director**
- **Margot Yann – Lead Data Scientist**
- Zachary Rooney – Research Associate
- Sammy Berman – Research Data Analyst
- 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



# New Publication



**A proposal from the Liver Forum for the management of comorbidities in nonalcoholic steatohepatitis therapeutic trials**

**Raluca Pais<sup>1,2</sup>, Bertrand Cariou<sup>3</sup>, Mazen Nouredin<sup>4</sup>, Sven Francque<sup>5</sup>, Jörn M. Schattenberg<sup>6</sup>, Manal F. Abdelmalek<sup>7</sup>, Gadi Lalazar<sup>8</sup>, Sharat Varma<sup>9</sup>, Julie Dietrich<sup>10</sup>, Veronica Miller<sup>11</sup>, Arun Sanyal<sup>12</sup>, Vlad Ratziu<sup>1,13\*</sup>**

- J Hep – in press

# Liver Forum



- 4 active working groups:
  - Combination Therapy Working Group
  - Digital and AI/ML Histology Working Group
  - Placebo Arm Database Working Group
  - Pooling of Endpoints Working Group
- Topics under consideration by SC include:
  - Clinical trial design following drug approval
  - Use of biomarkers and non-Invasive tools to measure treatment response
  - Assessing and refining NASH trial endpoints

# Liver Forum Events



- **Liver & PSC Forum EASL Evening Reception-** June 20, 2023, in Vienna, Austria
- **Liver Forum 15-** September 6, 2023, in Paris, France
- **Liver Forum 16-** March 29-30, 2024, in Washington, DC