



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

# HBV Forum 8

**Veronica Miller**

Forum for Collaborative Research

Tuesday, June 21, 2022

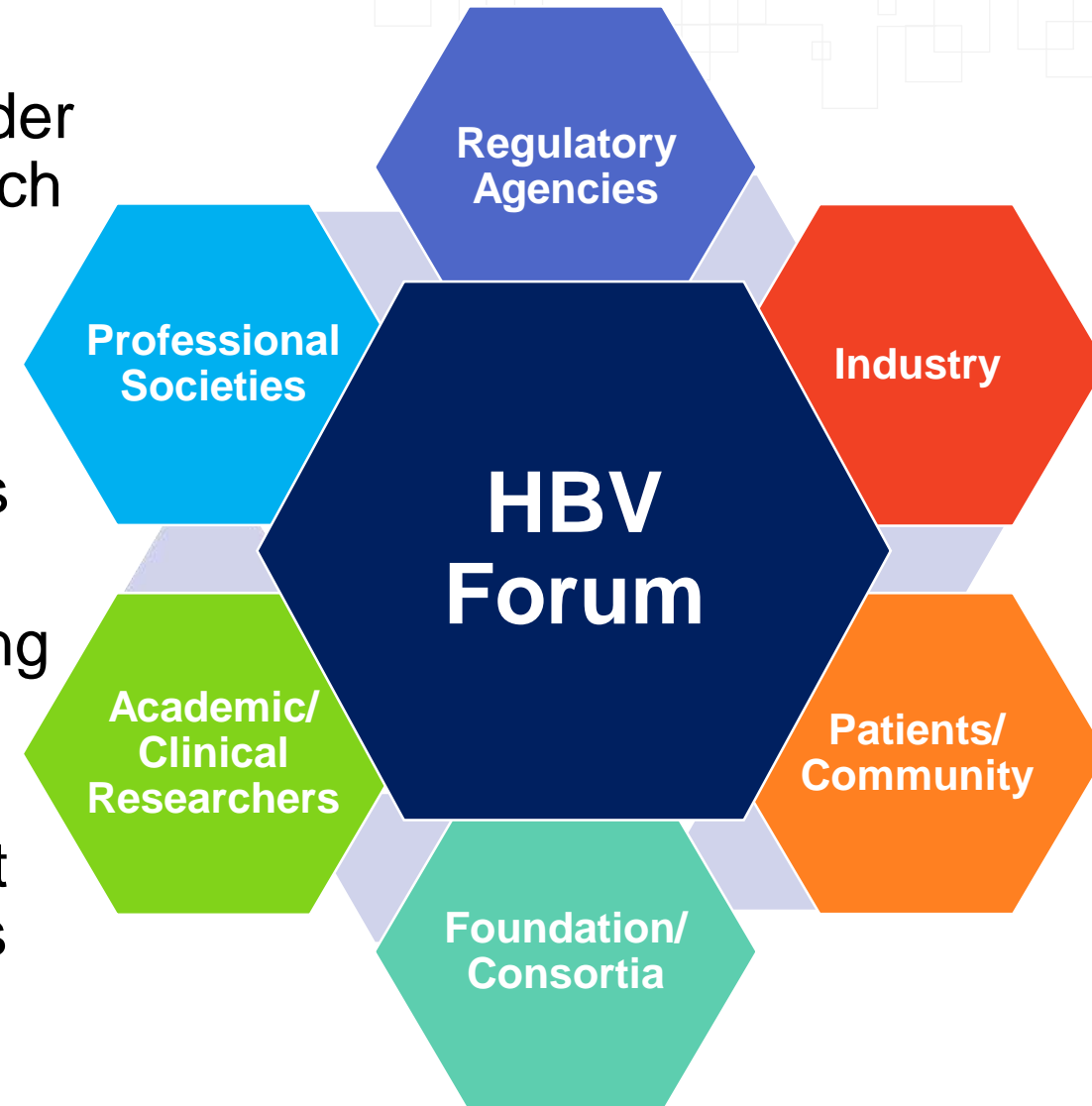
**Berkeley** Public  
Health

# Agenda

<b>12:00 PM</b>	<b>Registration &amp; Lunch</b>
1:00 PM	Session I: Working Group and Regulatory Updates
2:25 PM	Session II: "Stopping Finite Treatment" Paper Presentation
<b>3:30 PM</b>	<b>Break</b>
4:00 PM	Session III: Launch of HDV Co-Infection Working Group
5:00 PM	Session IV: The Role of Biomarkers in Drug Development
<b>6:00 PM</b>	<b>Adjourn and Evening Reception</b>

# Overview of the HBV Forum

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

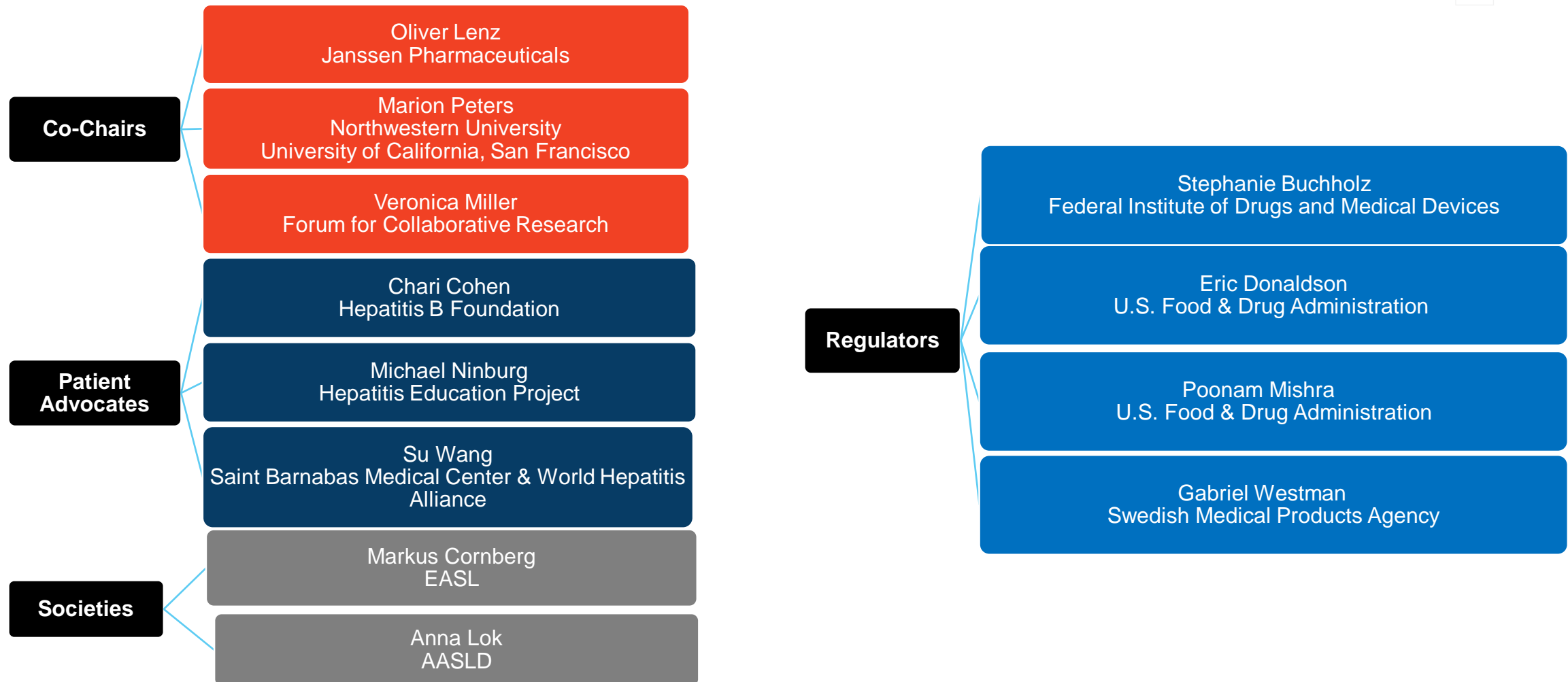
**What's said in the room, stays in the room**

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

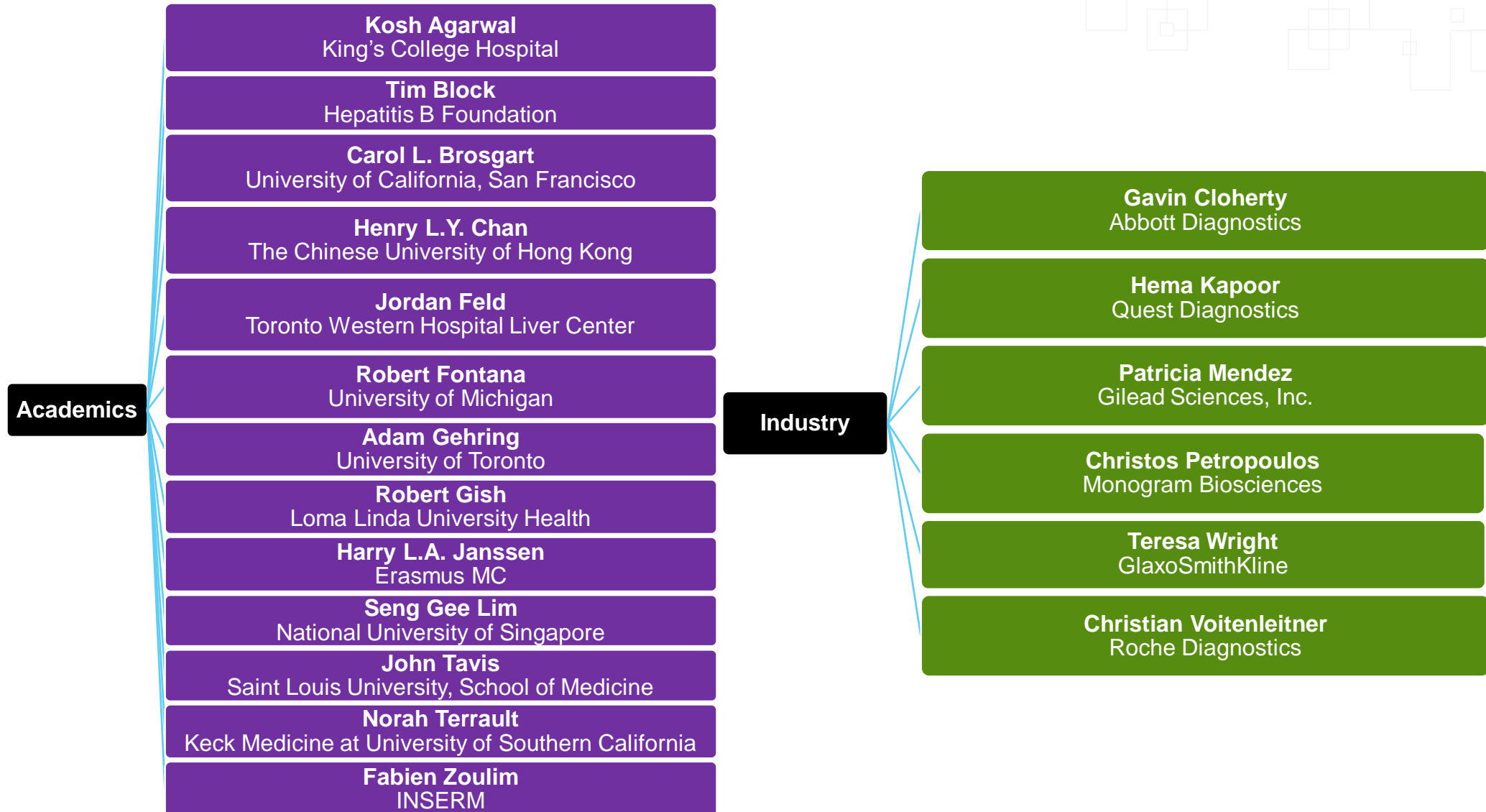
**Let the science speak**

**Active participation**

# HBV Forum Steering Committee



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# HBV Forum Working Groups

- **Immune Monitoring Working Group- Recently Published**
  - Co-chairs: Adam Gehring, PhD and Patricia Mendez
  - Aim: Identify immune biomarker(s) that predict I) effective viral control and/or II) toxicity in therapies including immune-based interventions.
- **CAM Nomenclature Working Group- ACTIVE**
  - Aim: To create a joint statement on behalf of both the HBV Forum and ICE-HBV regarding how to standardize CAM nomenclature and promote consensus within the field.
- **Stopping Finite Treatment Working Group- ACTIVE**
  - Co-chairs: Marion Peters, MD and Kosh Agarwal, MD.
- **Treatment Combination Working Group- Closed**
  - Co-chairs: Prof. Lim Seng Gee, MD and Bruce Given, MD.
  - Aims: I.) Provide clarity on the requirements of novel agents in clinical development, and II.) identify mechanisms to speed up the development of combinations of different promising agents across companies.
- **Liver Safety Monitoring sub Working Group- As needed**
  - Co-chairs: Robert Fontana, MD and Maria Beumont-Mauviel, MD
  - Aim: To Facilitate HBV drug development by developing consensus terminology and definitions for industry, regulators, and investigators to use when testing the safety and efficacy of novel therapeutic agents for chronic HBV when used alone or in combination with other investigational or approved anti-HBV agents

# HBV Forum Working Groups

- **Mechanisms of Action Working Group**- **PLANNING**
  - Co-chairs: Michael Biermer, MD and Jordan Feld, MD.
- **HDV Co-Infection Working Group**- **PLANNING**
  - Co-chairs: Norah Terrault, MD, MPH and Heiner Wedemeyer, MD, PhD
- **Biomarker Working Group** - **PLANNING**

# HBV Forum Working Groups

- **Surrogate Endpoints Working Group- CLOSED**
  - Co-chairs: Marion Peters, MD and Oliver Lenz, PhD.
  - Aim: Strengthen the link of surrogate markers (endpoint in clinical studies) with long term clinical outcomes (e.g., liver disease progression, HCC).
  
- **Diagnostics/Biomarkers Working Group- CLOSED**
  - Co-chairs: Ed Marins, MD and Gavin Cloherty, PhD.
  - Aim: Develop clarity on what is needed for biomarker acceptance and validation for HBV drug/diagnostic development.

# HBV Forum Sponsors



# Special Thanks

Prism Event Management - Paula Blay and her team:

- Jonathan Price
- Edward Sillars
- Penny Jekyll

# Forum Team

- Veronica Miller – Director
- Brenda Rodriguez – Deputy Director
- Jessica Weber – Senior Research Associate
- Nicholas Murdock – Research Associate
- Zachary Rooney – Research Associate
- Joseph Lau – Research Associate
- Chelsey Campillo – Research Associate
- Jeffrey S. Murray – Program Advisor
- John Sninsky – Program Advisor
- Nayri Alajaji, Graduate Student Researcher
- Aliya Mahmoud, Graduate Student Researcher
- Mitchell Leus, Graduate Student Researcher
- Edwin Chojolan, Graduate Student Researcher
- Maggie Kuang, Graduate Student Researcher
- Tyler Mansfield, Graduate Student Researcher