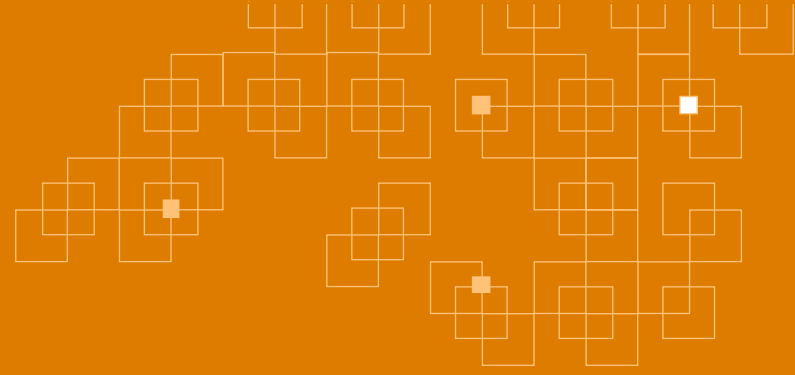




THE FORUM
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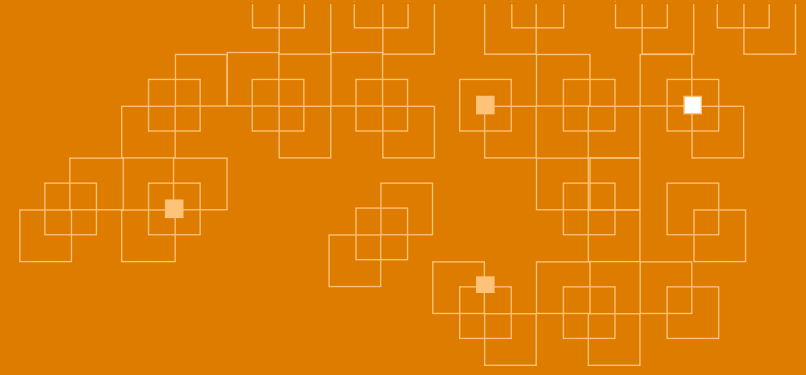
HBV Forum 16

Barcelona, Spain

Tuesday, May 26, 2026

Veronica Miller, PhD

Director, Forum for Collaborative Research



Welcome, Program Overview, and Acknowledgements



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Welcome, Forum Updates, Program Overview, and Acknowledgments



Ekene Osakwe*

*Forum for
Collaborative Research*

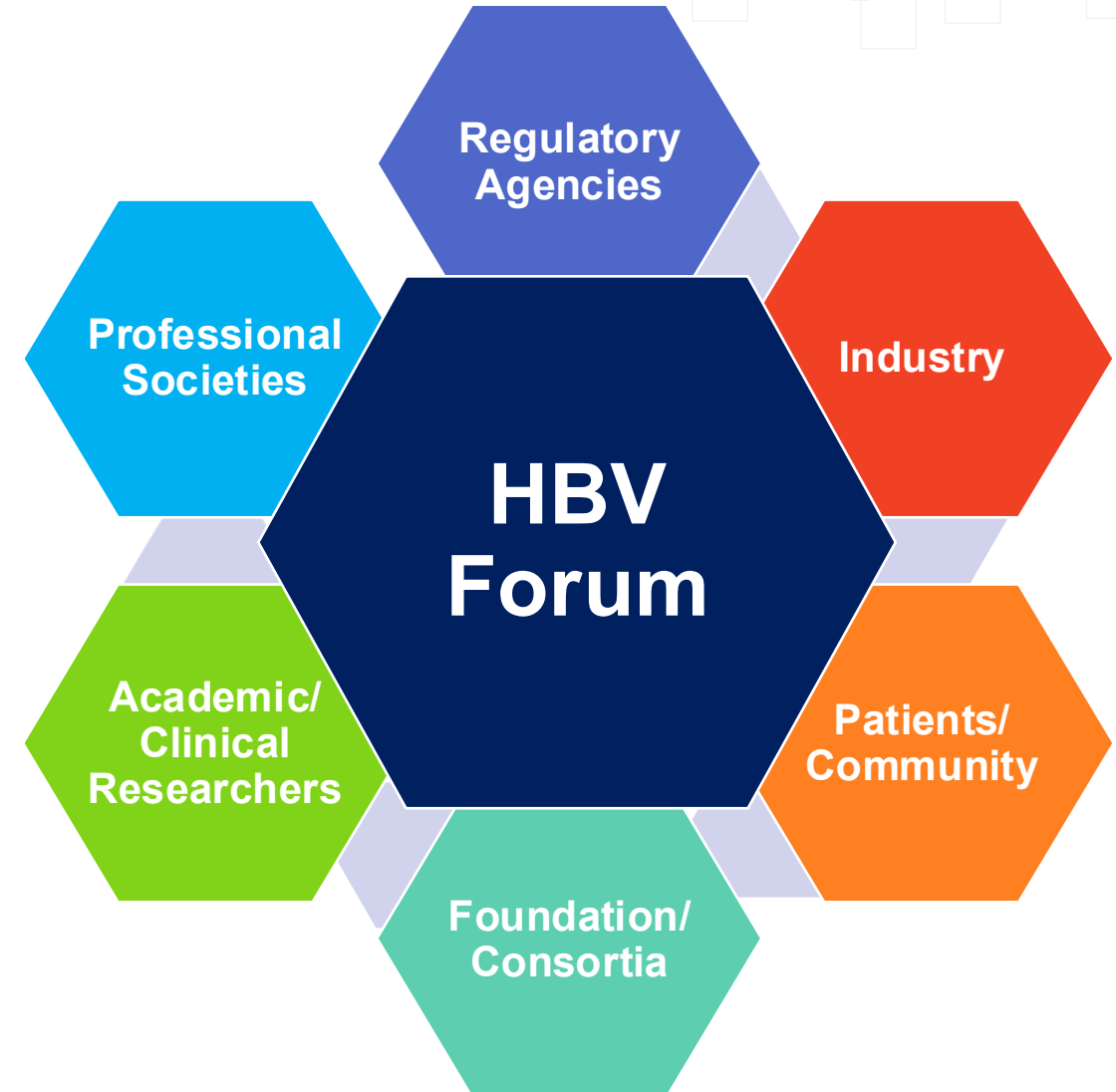
Overview of the HBV Forum



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- **What:** a platform for ongoing multi-stakeholder dialogue to advance the regulatory sciences for diagnosis and treatment of HBV and HDV co-infection, focusing on finite curative treatment
- **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



THE FORUM

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- 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 Updates



Date of submission: 31 March

Submission of comments on

(EMA/283093/2016 rev. 1)

Guideline on the clinical evaluation of medicinal products
intended for the treatment of chronic hepatitis B (CHB)

Newly established working group

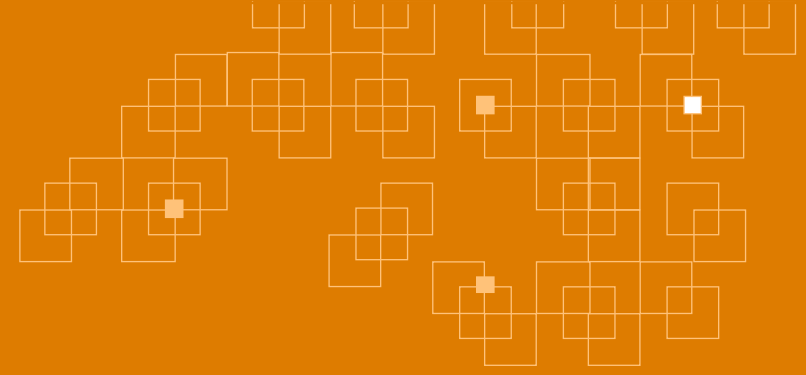
- HDV clinical trials endpoints

Working group updates

- HBV-MASLD working group
 - Draft paper on emerging issues and recommendations from the working group.
- HDV Clinical Trial Endpoints working group
 - Revaluating Endpoints in HDV Clinical Trials: Chronic vs. Finite Therapies
 - Ongoing discussions....preliminary stage of paper development...**in progress**
- HCC working group
 - A position paper assessing gaps in HBV-related HCC research and management, and potential strategies
 - Ongoing discussions...**in progress**

Agenda Overview

CEST		
1:10PM	Session I: Updates	• Rapid Fire Industry Updates • EMA Guideline Review Update • World Hepatitis Summit Feedback • Standardizing HBV Nomenclature
2:05PM	Session II: HBV and MASLD	• HBV/MASLD Draft Paper Overview
3:00PM	Break	
3:15PM	Session III: HDV: Clinical Trial Endpoints	• HDV Working Group: Summary of Key Discussions in Endpoint Design for HDV clinical trials
4:15PM	Session IV: Advancing HBV Treatment Access in Sub-Saharan Africa	• 2for1: Integrate to Eliminate Project Overview • Long-acting HIV Injectables & HBV
5:00PM	Session V: HCC: Gaps and Opportunities for Early Detection	• Hep B Foundation Workshop on Gaps and Opportunities for Early HCC Detection • Perspectives from Asia, Africa, and the Americas
6:35PM	Networking Reception	



Housekeeping

Forum = Safe Space



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

Rules of the Room and Zoom



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- 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

Wi-Fi Access

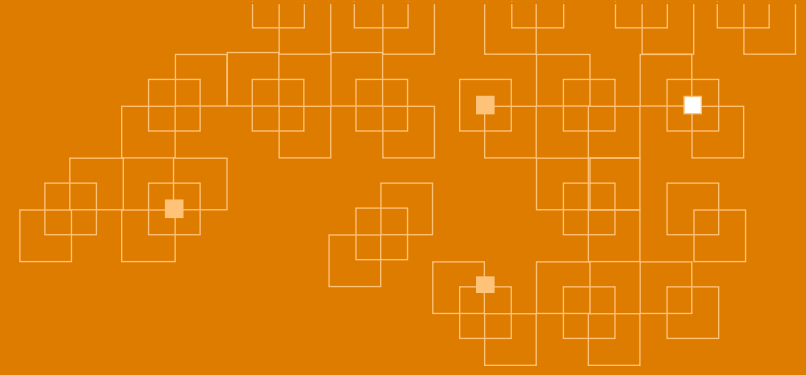
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Passcode: HYATT



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turned to Silent or Vibrate Mode**





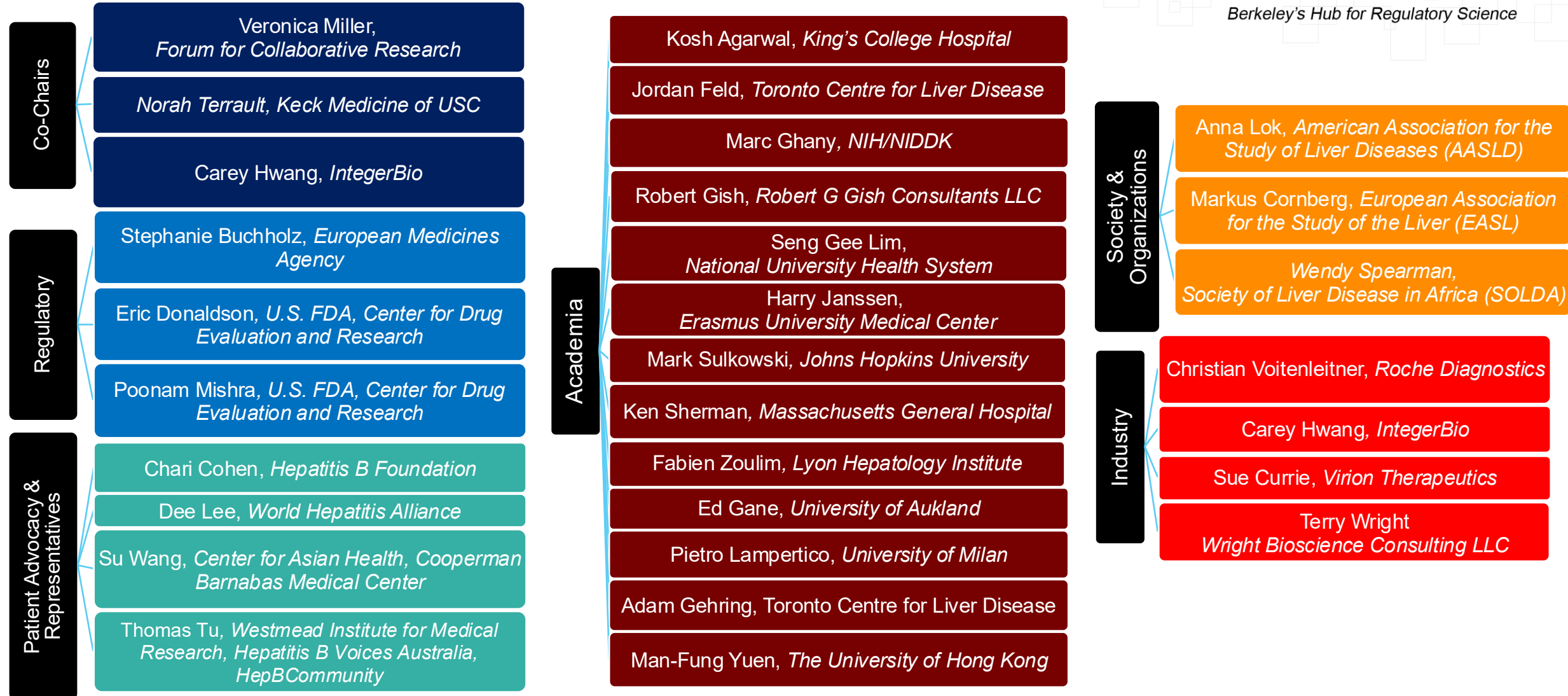
Acknowledgements

HBV Forum Steering Committee Members



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The Forum Team



- Veronica Miller – Executive Director
- Haely Jardas – Executive Assistant

Program Managers

- Shilpa Mitra – Senior Research Associate
- Logan Donaldson – Research Associate
- Ekene Osakwe – Research Associate
- Edyth Dwyer – Research Associate
- Meghan Rakowski – Research Associate
- Seema Desai – Research Associate
- Kathy An – Assistant Research Associate

Administration

- Jordan Cathey – Director Business Operations & Development
- Christopher Berry – Senior Events and Operations Manager
- Alicia Jellinek – Program Financial Analyst

Data & Analysis Center

- Margot Yann – Director, DAC; Principal Data Scientist
- Zachary Rooney – IT Systems Analyst
- Alice Kang – Senior Project Manager
- Debajyoti Debnath – Research Associate
- Sunil Gupta – SAS & CDISC Consultant
- Gitanjali Madan – Senior Clinical SAS Programmer

Program Advisors

- Jeffrey S. Murray – Program Advisor
- Mike Robertson – Program Advisor
- John Sninsky – Program Advisor
- Mark Hartman – Volunteer Advisor

Student Assistants

- Alessi Ayvaz – Graduate Student Researcher

Welcome, Haely!

- **Haely Jardas, MA**
- Executive Assistant
- Assists with logistics, operations, and project management.



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