

THE FORUM
For Collaborative ResearchSM

HBV Forum: Stopping NUCs in Drug Development Webinar

Wednesday, July 14, 2021



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Introduction & HBV Forum Update

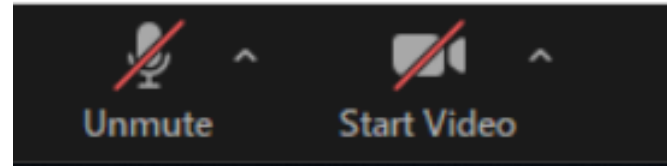
Jessica Weber

Forum for Collaborative Research

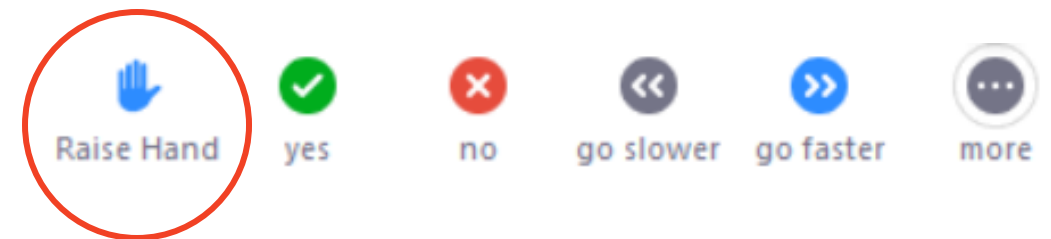
Agenda

HBV Forum - Stopping NUCs in Drug Development webinar		
Wednesday, July 14 12:00-2:00pm ET		
12:00 PM Meeting Open		
Moderators: Harry Janssen, University of Toronto & Nezam Afdhal, Beth Israel Deaconess Medical Center		
12:00 PM	Introduction	
12:10 PM	Overview of Stopping NUCs in Current Clinical Practice	Grishma Hirode, University of Toronto
12:25 PM	Overview of Recommendations and Current Industry Strategies for Stopping NUCs: Lessons Learned	Maria Beumont-Mauviel, Janssen Luisa Stamm, Assembly Biosciences Anna Maria Geretti, Roche Susanna Tan, Gilead Sciences, Inc.
12:45 PM	Trial Design (flares and mitigating risk)	Poonam Mishra, U.S. Food and Drug Administration (FDA) Stephanie Buchholz, Federal Institute for Drugs and Medical Devices (BfArM)
1:05 PM	How to move forward? -When to stop? -When to retreat?	Kosh Agarwal, King's College London Marion Peters, Northwestern University
1:25 PM	Overall Discussion and Audience Q&A	Moderated by: Harry Janssen, University of Toronto & Nezam Afdhal, Beth Israel Deaconess Medical Center
2:00 PM Meeting Close		

HBV Forum- Stopping NUCs Webinar



- You will be muted on entry
- Clarifying questions may be answered by the presenter
- Discussion will take place after the presentations
- To ask questions or make a comment:
 - If generally applicable to the session, please use the Zoom chat function and send to **everyone**
 - Or use the **raise your hand** function



Rules of the [Zoom] Room

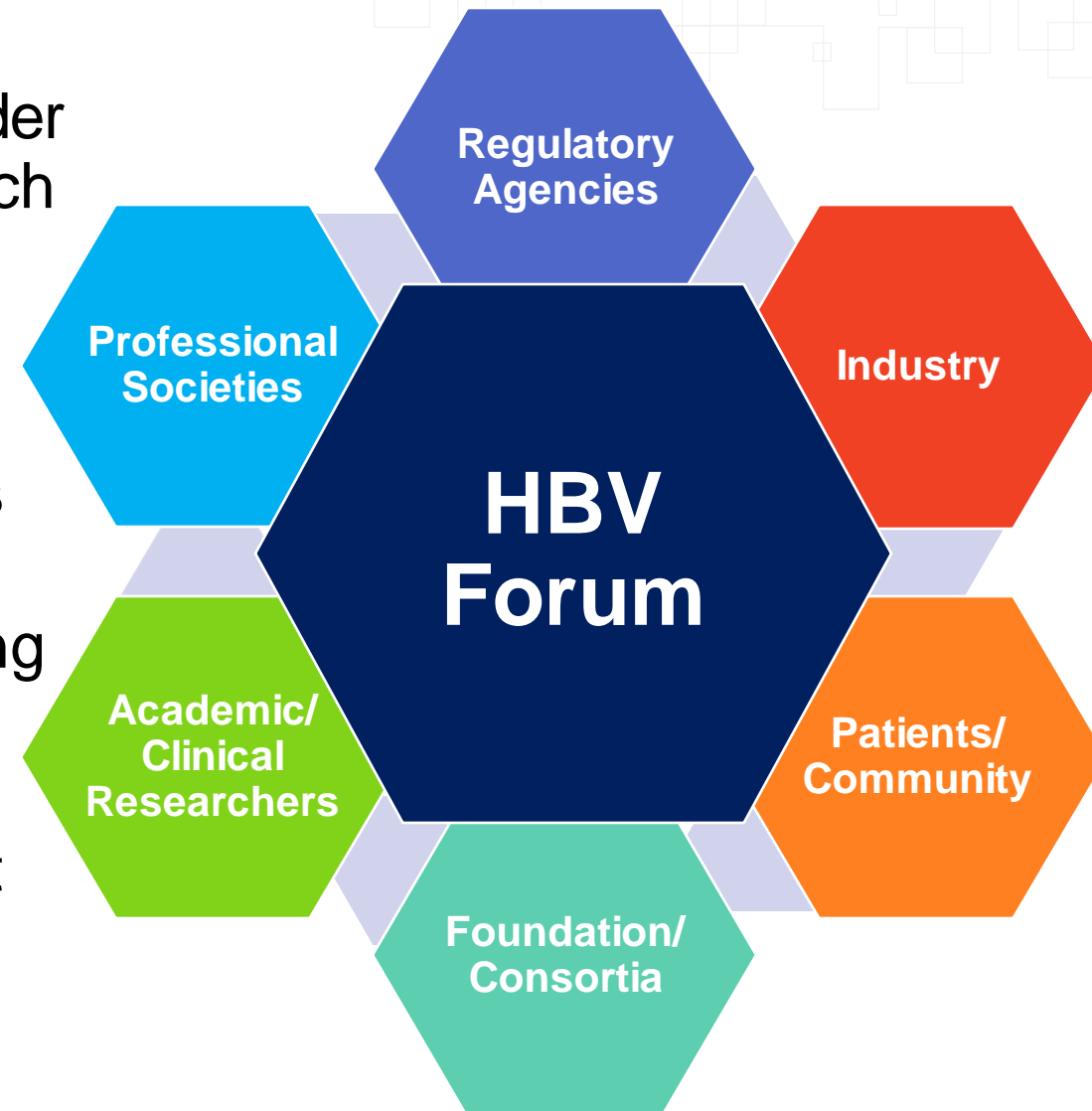
- **Presentations, discussions, comments, and questions are not for attribution**
 - Participants speak as individuals and express views that may not represent those of their organizations
 - Recording by participants is not permitted. Slides will be available on our website pending speaker permission.
- **Participation Reminder (Forum Operating Principles)**
 - We restrict participation to experts with the necessary scientific knowledge from organizations or entities with a clear commitment to advancing the diagnostic and therapeutic field of the disease area of the project they participate in, whether they be from government, academia, industry or community. Only in this way can we achieve the effectiveness and productivity needed to add value to the field. The Forum is not a venue for marketing and/or investment experts.

HBV Forum- Stopping NUCs in Drug Development Webinar

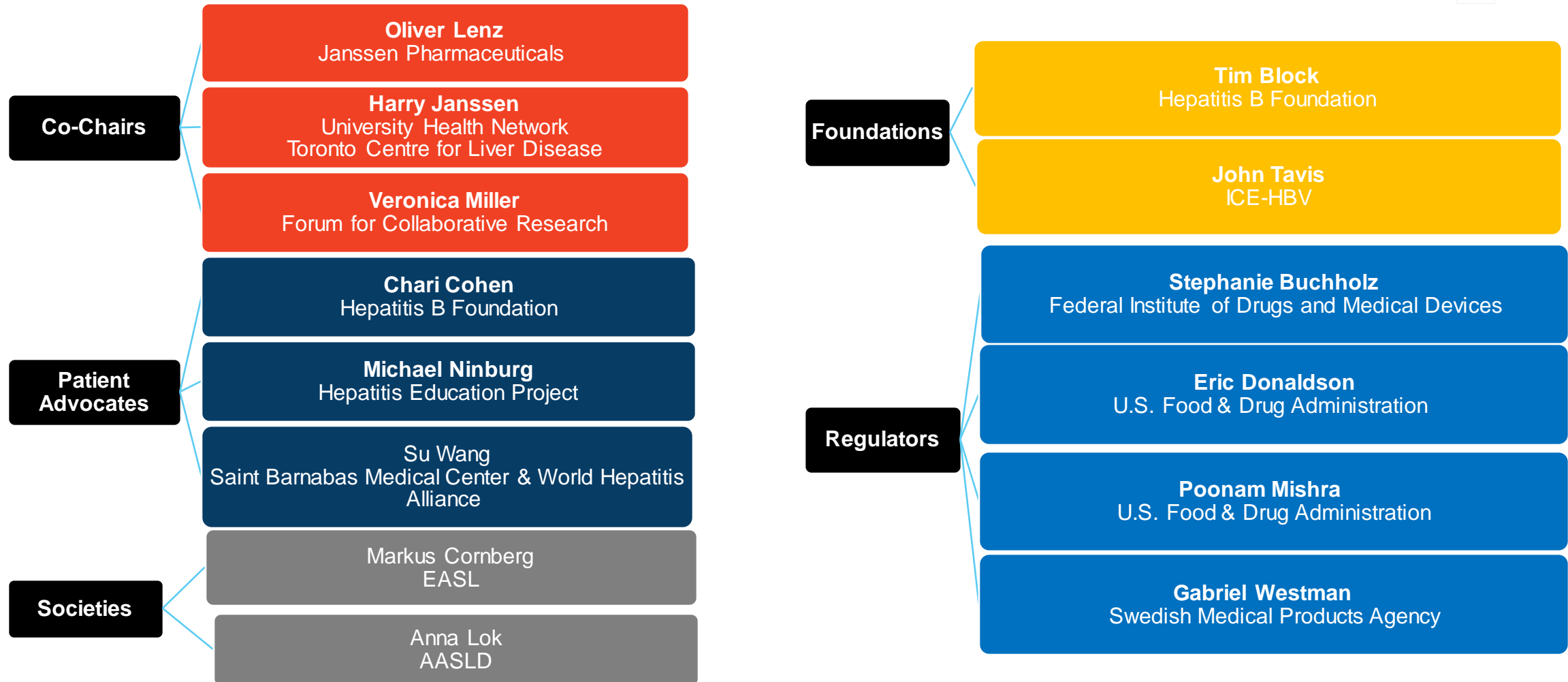
- This webinar will feature an overview of stopping NUCs in current clinical practice, presentations on industry strategies, regulatory perspectives on trial design, a discussion of how to move forward and an audience q&a.
- This is the first in a series of three HBV Forum webinars in 2021. We will also have webinars focused on therapeutic vaccines and treatment indications based on the science.
- The Forum will also be hosting a webinar on Translating Real World Data into Real World Evidence.

Overview of the HBV Forum

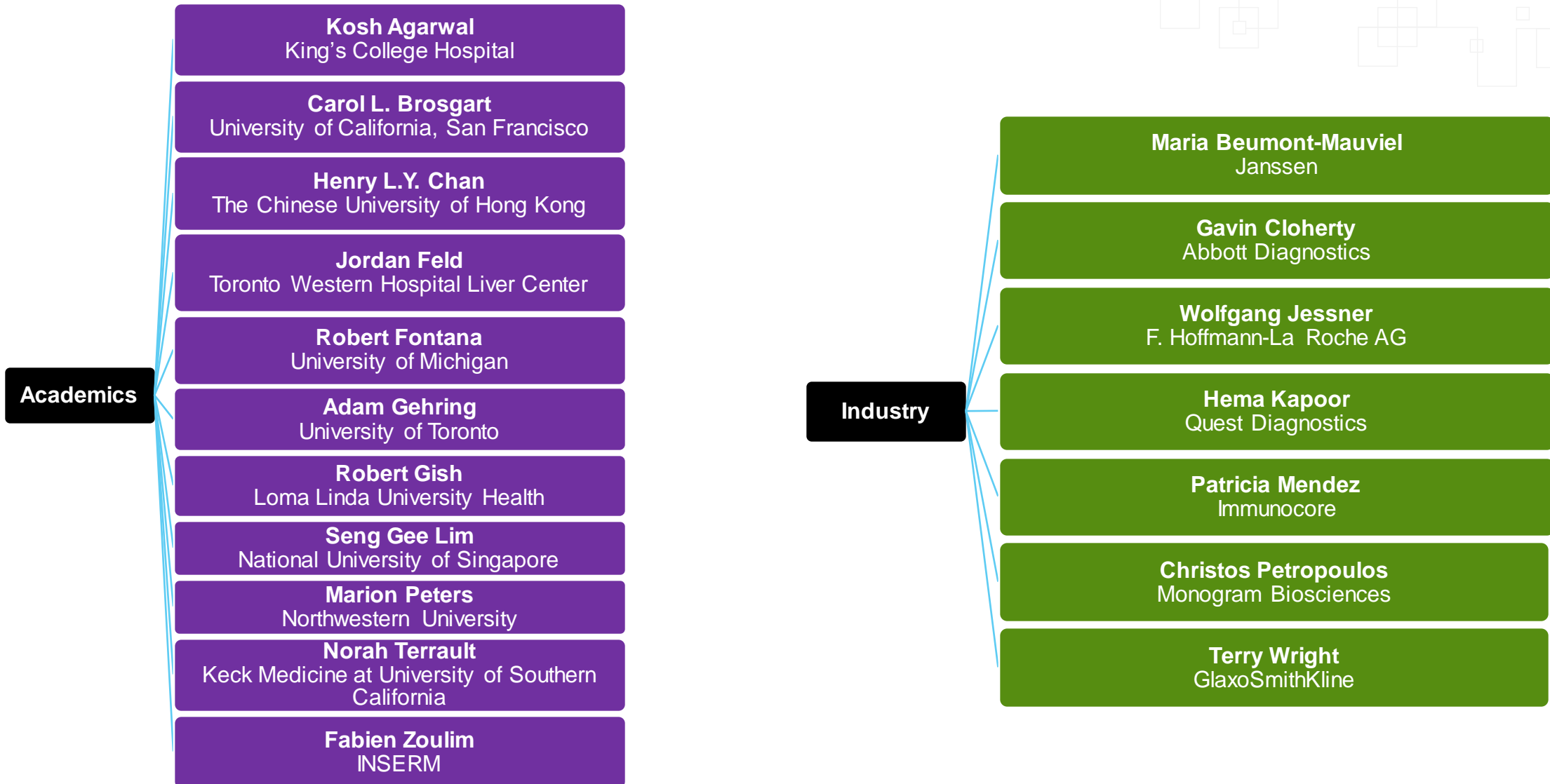
- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for HBV
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
 - Focus on developing 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



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HBV Forum- Stopping NUCs in Drug Development Webinar

- Today we will focus on how “stopping NUCs” fits into the drug development path for curative HBV treatments.
 - Stopping treatment is a necessary step in assessing efficacy of finite HBV treatments
 - Safety concerns
 - Need for some standardization for interpretation and cross-trial comparisons
- We bring the perspectives of multiple stakeholders to the discussion of *When to stop NUCs?* and *When to retreat?*
 - The idea is to learn together, facilitate evolving consensus and encourage standardization where possible
- We look forward to active participation from all during today’s session and ongoing discussion of this important topic