



THE FORUM
For Collaborative ResearchSM

HBV Forum: Intrahepatic Panel Webinar

Thursday, September 24, 2020

Berkeley Public
Health



THE FORUM
For Collaborative ResearchSM

Introduction & HBV Forum Update

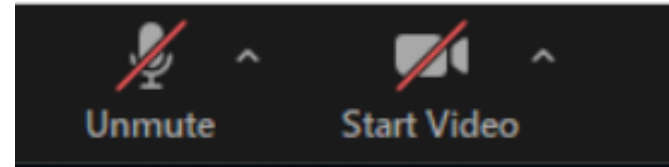
Jessica Weber

Forum for Collaborative Research

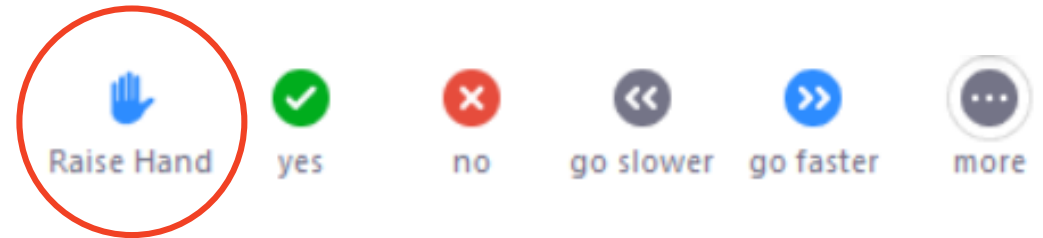
Agenda

11:00 AM ET	Begin	
	Moderators:	Anuj Gaggar, <i>Gilead Sciences</i> Adam Gehring, <i>Toronto General Hospital Research Institute</i>
11:00 AM	Welcome and Introduction	Jessica Weber, <i>Forum for Collaborative Research</i>
11:05 AM	Presentations:	
	<ul style="list-style-type: none">• Clinical perspectives on conducting biopsies and FNAs	Ray Chung, <i>Harvard Medical School</i>
	<ul style="list-style-type: none">• Should more biopsies be conducted at study enrollment?	Joe Balestreri
	<ul style="list-style-type: none">• Intrahepatic virology for which you need core biopsies	Ashwin Balagopal, <i>Johns Hopkins University School of Medicine</i>
	<ul style="list-style-type: none">• Update on FNAs	Mala Maini, <i>University College London</i>
	<ul style="list-style-type: none">• PathAI Technology	Oscar Carrasco-Zevallos, <i>PathAI</i> Stephanie Buchholz, <i>Federal Institute of Drugs and Medical Devices</i>
	<ul style="list-style-type: none">• Regulatory Perspectives	Kathleen Whitaker, <i>U.S. Food and Drug Administration (TBC)</i>
12:20 PM	Discussion	All
1:00 PM ET	Adjourn	

HBV Forum 7- Intrahepatic Panel Webinar



- You will be muted on entry
- 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
- For specific issues or technical questions:
 - Zoom Chat ****Technical Assistance****



Rules of the [Zoom] Room

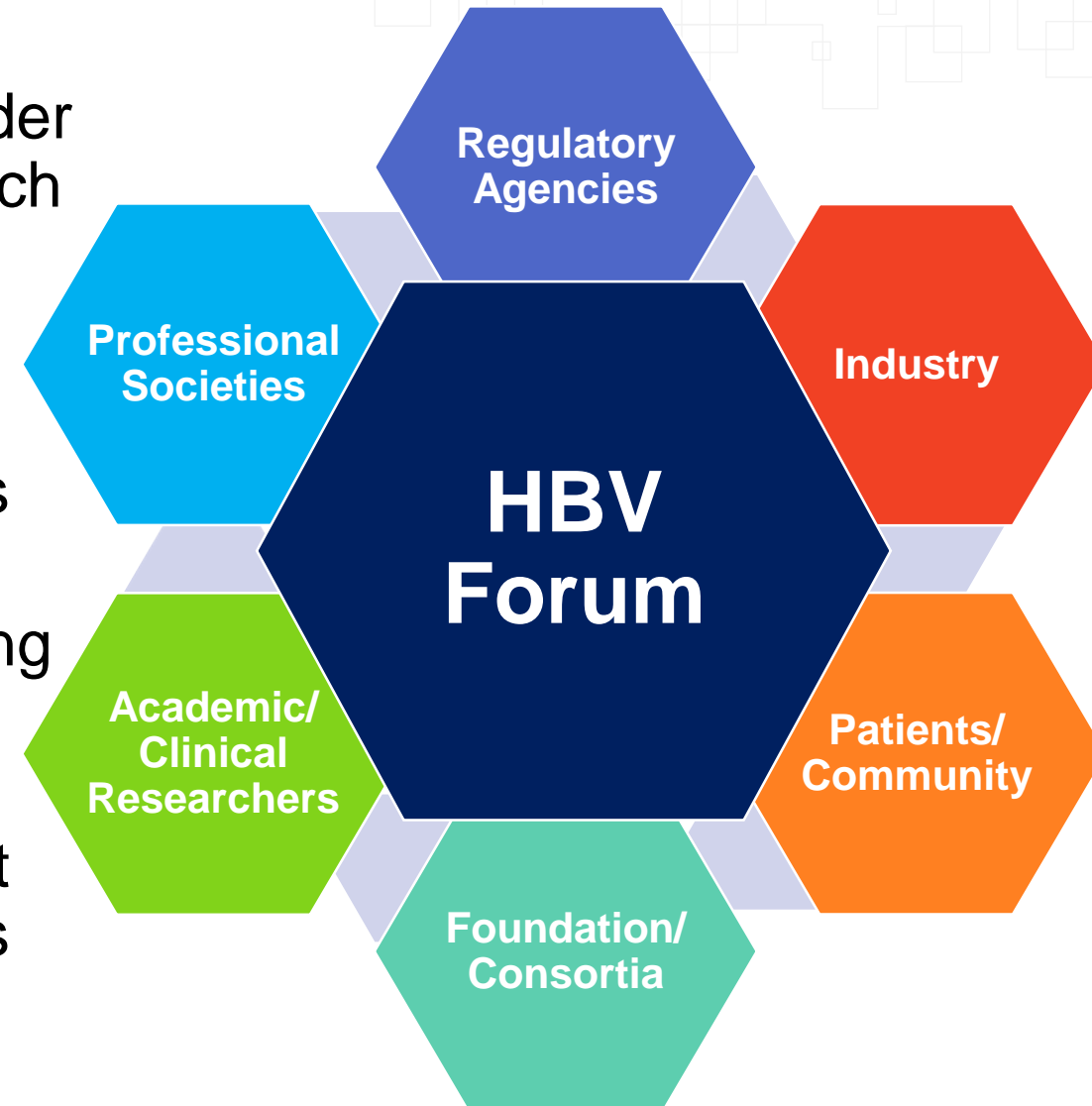
- **Presentations, discussions, comments, and questions are not for attribution**
 - Participants speak as individuals and express views that may not represent those of their organizations
 - Recording by participants is not permitted. Slides will be available on our website pending speaker permission.
- **Participation Reminder (Forum Operating Principles)**
 - We restrict industry 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. 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 7- Intrahepatic Panel Webinar

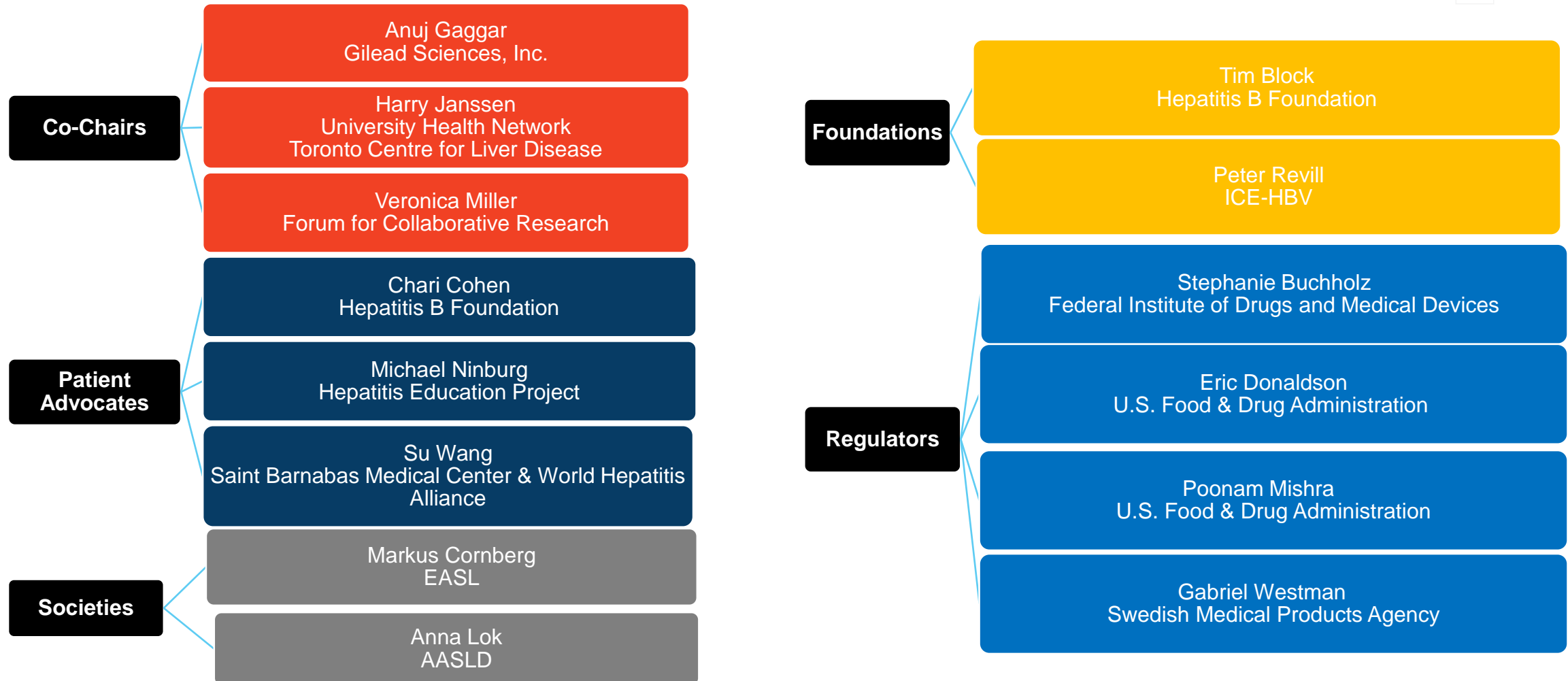
- The Intrahepatic Panel Webinar will include presentations from various stakeholder perspectives related to digital technology, biopsies and FNAs.
- This is the second in a series of three webinars designed to replace the in-person HBV Forum 7 meeting.
- The final HBV Forum 7 webinar will feature follow-up from several HBV Forum 6 sessions and we will keep you updated as we organize ongoing HBV Forum web meetings.

Overview of the HBV Forum

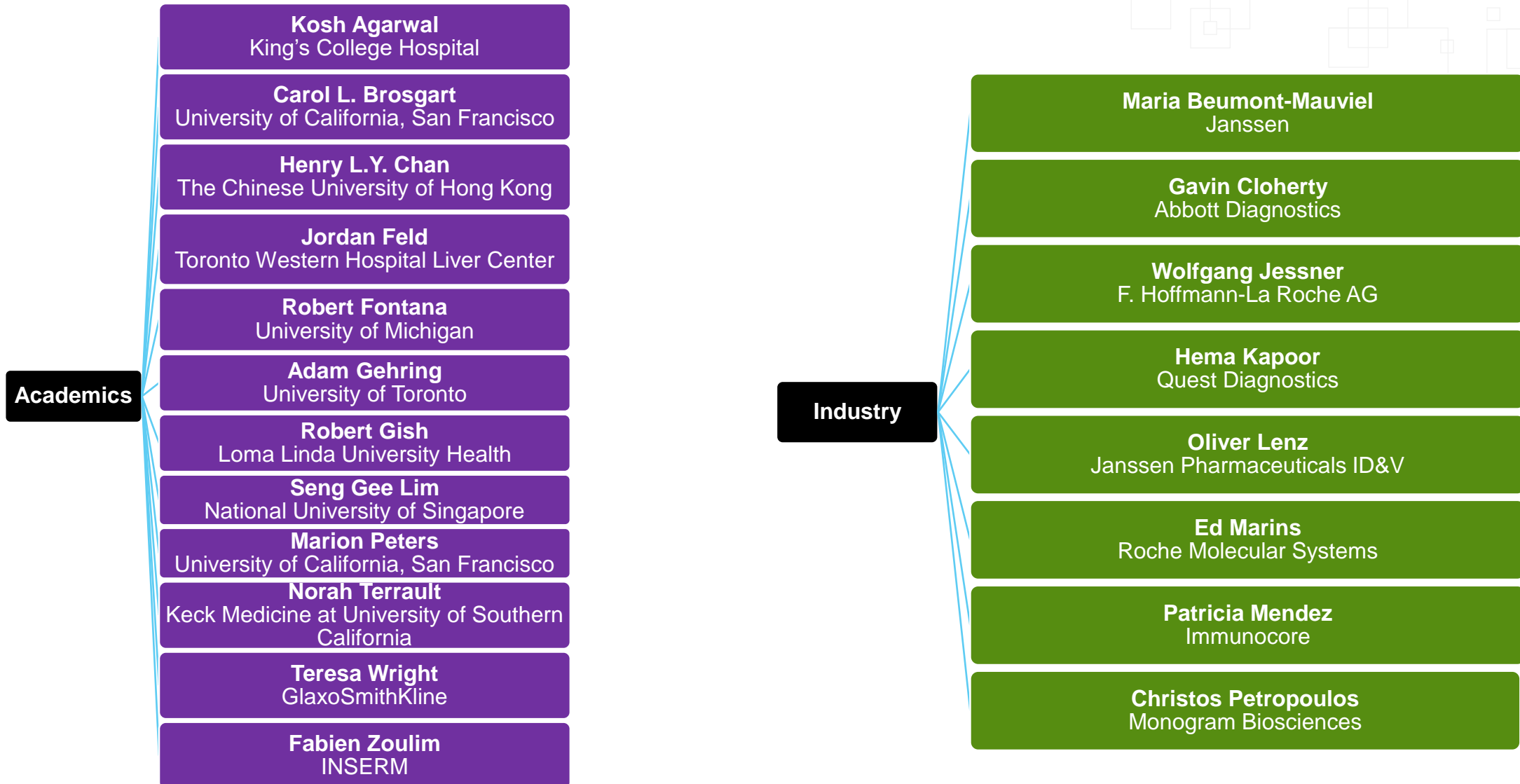
- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for HBV
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
 - Focus on developing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



HBV Forum Steering Committee



HBV Forum Steering Committee



HBV Forum Working Groups

- **Immune Monitoring Working Group- ACTIVE**
 - 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.

- **Treatment Combination Working Group- ONGOING**
 - 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- ONGOING**
 - 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

- **Surrogate Endpoints Working Group- COMPLETED**
 - 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- COMPLETED**
 - 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.

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