# Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speakers</th>
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<tbody>
<tr>
<td>12:30 PM</td>
<td>Registration &amp; Lunch Reception</td>
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<tr>
<td>1:30 PM</td>
<td>Welcome and Housekeeping</td>
<td>Jessica Weber, Forum for Collaborative Research</td>
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<tr>
<td>1:35 PM</td>
<td>Introductory Remarks</td>
<td>Veronica Miller, Forum for Collaborative Research</td>
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<tr>
<td>1:40 PM</td>
<td>Session I: Field Updates (a)</td>
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<tr>
<td></td>
<td>Moderators: Veronica Miller, Forum for Collaborative Research &amp; Robert Gish, Robert G. Gish Consultants LLC</td>
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<tr>
<td>1:40 PM</td>
<td>What's Hot at The Liver Meeting?</td>
<td>Edward Gane, University of Auckland</td>
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<td>1:50 PM</td>
<td>Member Updates</td>
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<td></td>
<td>FDA Draft Guidance: Chronic Hepatitis D Virus Infection</td>
<td>Aimee Hodowanec, U.S. Food &amp; Drug Administration</td>
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<td></td>
<td>Patient Focused Drug Development Meeting</td>
<td>Chari Cohen, Hepatitis B Foundation</td>
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<td>Hepatitis B Study Update</td>
<td>Scott Harris, Alimmune, Inc.</td>
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<tr>
<td>2:05 PM</td>
<td>Discussion</td>
<td>All</td>
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<td>2:15 PM</td>
<td>Session II: Regulatory Consideration Panel Topics</td>
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<td></td>
<td>Moderators: Veronica Miller, Forum for Collaborative Research &amp; Marion Peters, ACTG Chicago</td>
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<td>2:15 PM</td>
<td>Panel 1: Potential Intermediate Stages on the Way to &quot;Cure&quot;</td>
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<td>Stephenie Buchholz, Federal Institute for Drugs &amp; Medical Devices &amp; Poonam Mishra, U.S. Food &amp; Drug Administration</td>
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<td>Jordan Feld, University Health Network</td>
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<td>Douglas Mayers, Antios Therapeutics</td>
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<td>Su Wang, Saint Barnabas Medical Center &amp; World Hepatitis Alliance</td>
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<td>Cynthia Wat, Roche Products Ltd</td>
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<td>Gabriel Westman, Swedish Medical Products Agency</td>
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<th>Time</th>
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<tr>
<td>2:55 PM</td>
<td>Panel 2: Stopping Treatment</td>
<td>Mark Avigan, U.S. Food &amp; Drug Administration</td>
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<td></td>
<td>- When and How Long?</td>
<td>Stephanie Buchholz, Federal Institute for Drugs &amp; Medical Devices</td>
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<td></td>
<td>- mRNA &amp; Other Markers</td>
<td>Pietro Lampertico, University of Milan</td>
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<td></td>
<td>- Length of Follow-up</td>
<td>Ed Marins, Roche</td>
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<td></td>
<td>- Monitoring for Resistance</td>
<td>Michael Ninburg, Hepatitis Education Project</td>
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<td></td>
<td><strong>3:40 PM</strong> Break</td>
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<tr>
<td>4:10 PM</td>
<td>Panel 3: Core Inhibitor Sub-Classes and Mechanisms of Action</td>
<td>Eric Donaldson, U.S. Food &amp; Drug Administration</td>
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<td>John Fry, Aligos Therapeutics</td>
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<td>Lu Gao, Roche</td>
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<td>Oliver Lenz, Janssen</td>
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### 4:25 PM Session III: HBV Forum Updates

**Moderator:** Veronica Miller, Forum for Collaborative Research

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<th>Time</th>
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<tr>
<td>4:25 PM</td>
<td>Immune Monitoring Working Group</td>
<td>Sara Ferrando-Martinez, AstraZeneca</td>
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<td>Adam Gehring, Toronto Centre for Liver Disease</td>
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<td>4:35 PM</td>
<td>Liver Safety Monitoring Manuscript (JVH)</td>
<td>Robert Fontana, University of Michigan</td>
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<td>4:40 PM</td>
<td>HBsAg Loss Meta-Analysis</td>
<td>Hannah Choi, Toronto Centre for Liver Disease</td>
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<td>4:50 PM</td>
<td>Planned Collaboration: Stop Nuc Studies</td>
<td>Harry Janssen, Toronto Centre for Liver Disease, University Health Network</td>
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<tr>
<td>5:05 PM</td>
<td>Discussion</td>
<td>All</td>
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<td>Moderator</td>
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<tr>
<td>5:15 PM</td>
<td><strong>Session IV: How Important is Viral and Patient Heterogeneity?</strong></td>
<td><strong>Moderator:</strong> Anuj Gaggar, Gilead Sciences</td>
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<td><strong>Panel 4: Implications for Clinical Trial Design</strong></td>
<td>Gavin Cloherty, Abbott Labs Eric Donaldson, U.S. Food &amp; Drug Administration</td>
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<td><strong>Moderators:</strong> Harry Janssen, Toronto Centre for Liver Disease, University Health Network &amp; Timothy Block, Baruch S. Blumberg Institute and Hepatitis B Foundation</td>
<td>Saeed Hamid, Aga Khan University Mala Maini, University College London Leen-Jan van Doorn, DDL Diagnostic Laboratory</td>
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<tr>
<td>5:35 PM</td>
<td><strong>Session V: Field Updates (b) and Special Debate</strong></td>
<td><strong>Moderators:</strong> Harry Janssen, Toronto Centre for Liver Disease, University Health Network &amp; Timothy Block, Baruch S. Blumberg Institute and Hepatitis B Foundation</td>
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<td><strong>ICE-HBV:</strong> Global Fund &amp; Messaging Briefing</td>
<td>Veronica Miller, Forum for Collaborative Research Massimo Levrero, ICE-HBV Board</td>
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<td><strong>Special Debate:</strong> HBV Treatment Guidelines vs. Test-Treat All</td>
<td>Homie Razavi, Center for Disease Analysis Foundation Brian McMahon, Alaska Native Tribal Health Consortium</td>
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<td>6:10 PM</td>
<td><strong>Discussion</strong></td>
<td>All</td>
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<tr>
<td>6:20 PM</td>
<td><strong>Wrap Up and Next Steps</strong></td>
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<tr>
<td>6:30 PM</td>
<td><strong>Evening Networking Reception</strong></td>
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*Panel 4: Implications for Clinical Trial Design*  
Gavin Cloherty, Abbott Labs  
Eric Donaldson, U.S. Food & Drug Administration  
Saeed Hamid, Aga Khan University  
Mala Maini, University College London  
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*Session V: Field Updates (b) and Special Debate*  
Harry Janssen, Toronto Centre for Liver Disease, University Health Network & Timothy Block, Baruch S. Blumberg Institute and Hepatitis B Foundation

*ICE-HBV: Global Fund & Messaging Briefing*  
Veronica Miller, Forum for Collaborative Research  
Massimo Levrero, ICE-HBV Board

*Special Debate: HBV Treatment Guidelines vs. Test-Treat All*  
Homie Razavi, Center for Disease Analysis Foundation  
Brian McMahon, Alaska Native Tribal Health Consortium
Reminders

- We restrict participation to experts with the necessary scientific knowledge from organizations or entities with a clear commitment to advancing the therapeutic field related to HBV.

- We recruit project members meeting the scientific expertise criteria from the various stakeholder groups.

- Presentations, discussions, comments, and questions are not for attribution. Participants speak as individuals and express views that may not represent those of their organizations.

- We expect all meeting participants to behave professionally, engage in discussion, and discourage the presence of passive observers.
HBV Forum Steering Committee

Co-Chairs
- Anuj Gaggar
  Gilead Sciences, Inc.
- Harry Janssen
  University Health Network
  Toronto Centre for Liver Disease
- Veronica Miller
  Forum for Collaborative Research

Patient Advocates
- Chari Cohen
  Hepatitis B Foundation
- Michael Ninburg
  Hepatitis Education Project
- Su Wang
  Saint Barnabas Medical Center & World
  Hepatitis Alliance

Societies
- Markus Cornberg
  EASL
- Anna Lok
  AASLD

Foundations
- Tim Block
  Hepatitis B Foundation
- Peter Revill
  ICE-HBV

Regulators
- Stephanie Buchholz
  Federal Institute of Drugs and Medical Devices
- Eric Donaldson
  U.S. Food & Drug Administration
- Poonam Mishra
  U.S. Food & Drug Administration
- Gabriel Westman
  Swedish Medical Products Agency
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Academics

Carol L. Brosgart
University of California, San Francisco

Henry L.Y. Chan
The Chinese University of Hong Kong

Jordan Feld
University Health Network

Robert Fontana
University of Michigan

Adam Gehring
University of Toronto

Seng Gee Lim
National University of Singapore

Marion Peters
University of California, San Francisco

Teresa Wright
Veterans Administration Medical Center

Fabien Zoulim
INSERM

Industries

Maria Beumont-Mauviel
Janssen

Gavin Cloherty
Abbott Diagnostics

Sara Ferrando-Martinez
AstraZeneca

Robert Gish
Robert G. Gish Consultants LLC

Wolfgang Jessner
F. Hoffmann-La Roche AG

Hema Kapoor
Quest Diagnostics

Oliver Lenz
Janssen Pharmaceuticals ID&V

Ed Marins
Roche Molecular Systems

Christos Petropoulos
Monogram Biosciences
HBV Forum Working Groups

- **Immune Monitoring Working Group** Co-chairs: Adam Gehring, PhD and Sara Ferrando-Martinez, PhD
  - Aim: Identify immune biomarker(s) that predict I) effective viral control and/or II) toxicity in therapies including immune-based interventions.

- **Surrogate Endpoints Working Group** 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).

- **Treatment Combination Working Group** Co-chairs: Seng Gee Lim, 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** 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

- **Diagnostics/Biomarkers Working Group** 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 5

- Vienna, Austria
  - 97 attendees: 78 in person, 19 remote
HBV Forum 5: Evaluation Results
Sponsors

The following sponsors contribute at their assigned membership levels

[Logos of Abbott, ALIGOS Therapeutics, altimmune, ANTIOS Therapeutics, Arbutus Biopharma, assemblybio, DDL Diagnostic Laboratory, Enanta Pharmaceuticals, Enyo Pharma]

*Partner in advanced diagnostic testing*
Sponsors

The following sponsors contribute at their assigned membership levels:

- Gilead
- Hepatitis B Foundation
- Janssen
- MedImmune
- Monogram Biosciences
- Quest Diagnostics
- Roche
- Springbank Pharmaceuticals
- VIR
THANK YOU!

- **The Forum for Collaborative Research**
  - Executive Director: Veronica Miller
    - Katherine Barradas
    - Terry Daniels
    - Dario Dieguez
    - Luis Javier Hernandez
    - Vin Keane
    - Angela Monahan
    - Brenda Rodriguez
    - Jessica Weber

- **Prism Event Management**
  - Paula Blay
  - Mairead O’Reilly
  - Sarah Matthews
Thank you!

Contact Information:
Jessica Weber
jweber@forumresearch.org