



THE FORUM
For Collaborative ResearchSM

HBV Forum 6

Jessica Weber, MSc, BSN

Forum for Collaborative Research

Berkeley Public
Health

Agenda

12:30 PM Registration & Lunch Reception		
1:30 PM	Welcome and Housekeeping	<i>Jessica Weber, Forum for Collaborative Research</i>
1:35 PM	Introductory Remarks	<i>Veronica Miller, Forum for Collaborative Research</i>
1:40 PM Session I: Field Updates (a)		
Moderators: <i>Veronica Miller, Forum for Collaborative Research & Robert Gish, Robert G. Gish Consultants LLC</i>		
1:40 PM	What's Hot at The Liver Meeting?	<i>Edward Gane, University of Auckland</i>
1:50 PM	Member Updates	
	- FDA Draft Guidance: Chronic Hepatitis D Virus Infection	<i>Aimee Hodowanec, U.S. Food & Drug Administration</i>
	- Patient Focused Drug Development Meeting	<i>Chari Cohen, Hepatitis B Foundation</i>
	- Hepatitis B Study Update	<i>Scott Harris, Altimmune, Inc.</i>
2:05 PM	Discussion	<i>All</i>
2:15 PM Session II: Regulatory Consideration Panel Topics		
Moderators: <i>Veronica Miller, Forum for Collaborative Research & Marion Peters, ACTG Chicago</i>		
		<i>Stephanie Buchholz, Federal Institute for Drugs & Medical Devices</i>
		<i>Jordan Feld, University Health Network</i>
		<i>Douglas Mayers, Antios Therapeutics</i>
2:15 PM	Panel 1: Potential Intermediate Stages on the Way to "Cure"	<i>Poonam Mishra, U.S. Food & Drug Administration</i>
		<i>Su Wang, Saint Barnabas Medical Center & World Hepatitis Alliance</i>
		<i>Cynthia Wat, Roche Products Ltd</i>
		<i>Gabriel Westman, Swedish Medical Products Agency</i>

Agenda

2:55 PM	Panel 2: Stopping Treatment <ul style="list-style-type: none">- When and How Long?- What to Monitor?- mRNA & Other Markers- Length of Follow-up- Monitoring for Resistance	<i>Mark Avigan, U.S. Food & Drug Administration</i> <i>Stephanie Buchholz, Federal Institute for Drugs & Medical Devices</i> <i>Eric Donaldson, U.S. Food & Drug Administration</i> <i>Pietro Lampertico, University of Milan</i> <i>Ed Marins, Roche</i> <i>Michael Ninburg, Hepatitis Education Project</i>
3:40 PM	Break	
4:10 PM	Panel 3: Core Inhibitor Sub-Classes and Mechanisms of Action	<i>Eric Donaldson, U.S. Food & Drug Administration</i> <i>John Fry, Aligos Therapeutics</i> <i>Lu Gao, Roche</i> <i>Oliver Lenz, Janssen</i>
4:25 PM	Session III: HBV Forum Updates	
	Moderator: <i>Veronica Miller, Forum for Collaborative Research</i>	
4:25 PM	Immune Monitoring Working Group	<i>Sara Ferrando-Martinez, AstraZeneca</i> <i>Adam Gehring, Toronto Centre for Liver Disease</i>
4:35 PM	Liver Safety Monitoring Manuscript (JVH)	<i>Robert Fontana, University of Michigan</i>
4:40 PM	HBsAg Loss Meta-Analysis	<i>Hannah Choi, Toronto Centre for Liver Disease</i>
4:50 PM	Planned Collaboration: Stop Nuc Studies	<i>Harry Janssen, Toronto Centre for Liver Disease,</i> <i>University Health Network</i> <i>Hannah Choi, Toronto Centre for Liver Disease</i>
5:05 PM	Discussion	<i>All</i>

Agenda

5:15 PM Session IV: How Important is Viral and Patient Heterogeneity?

Moderator: *Anuj Gaggar, Gilead Sciences*

Gavin Cloherty, Abbott Labs

Eric Donaldson, U.S. Food & Drug Administration

5:15 PM Panel 4: Implications for Clinical Trial Design

Saeed Hamid, Aga Khan University

Mala Maini, University College London

Leen-Jan van Doorn, DDL Diagnostic Laboratory

5:35 PM Session V: Field Updates (b) and Special Debate

Moderators: *Harry Janssen, Toronto Centre for Liver Disease, University Health Network & Timothy Block, Baruch S. Blumberg Institute and Hepatitis B Foundation*

5:35 PM ICE-HBV:
Global Fund & Messaging Briefing

Veronica Miller, Forum for Collaborative Research

Massimo Levrero, ICE-HBV Board

5:50 PM Special Debate:
HBV Treatment Guidelines
vs. Test-Treat All

Homie Razavi, Center for Disease Analysis Foundation

Brian McMahon, Alaska Native Tribal Health Consortium

6:10 PM Discussion

All

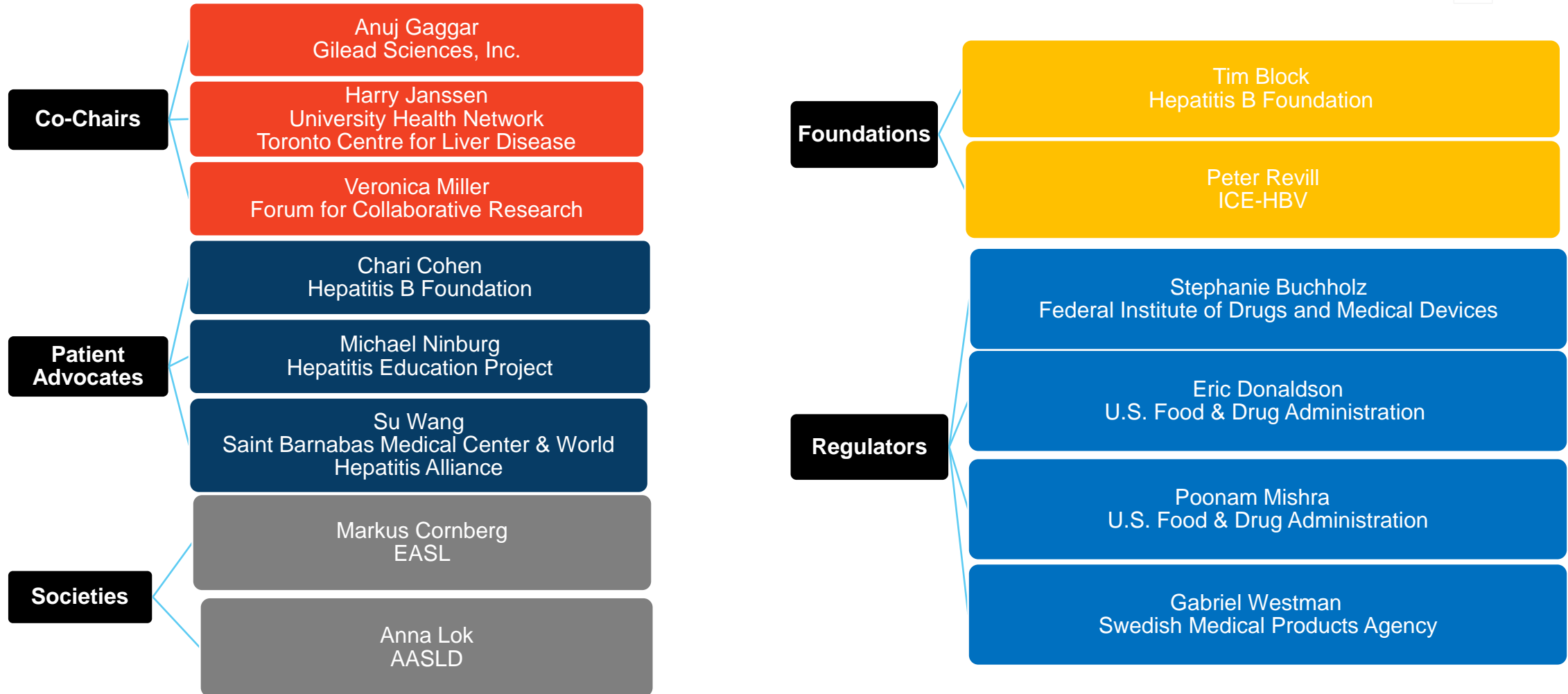
6:20 PM Wrap Up and Next Steps

6:30 PM Evening Networking Reception

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



HBV Forum Steering Committee

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

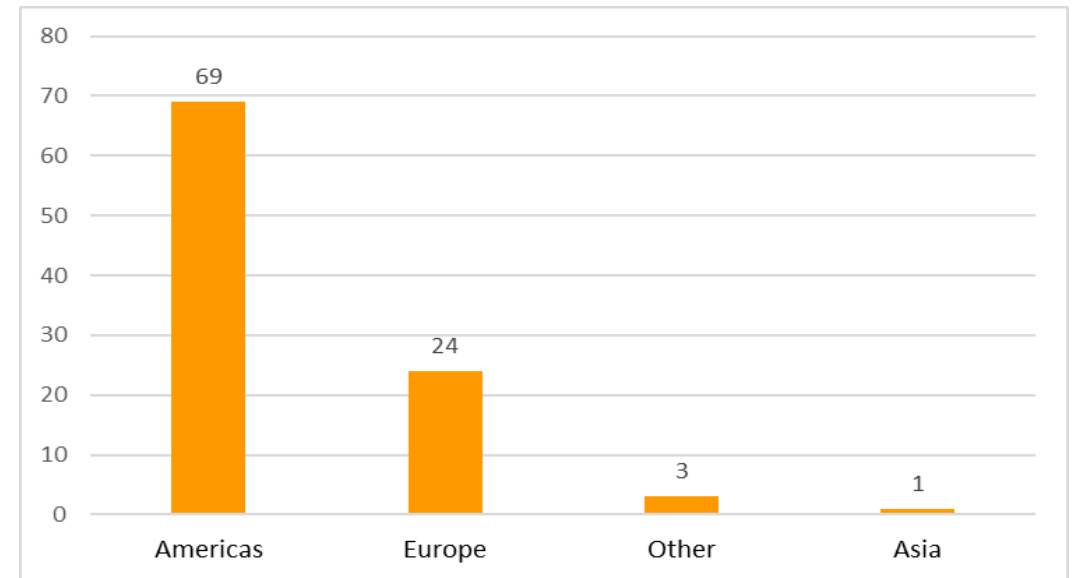
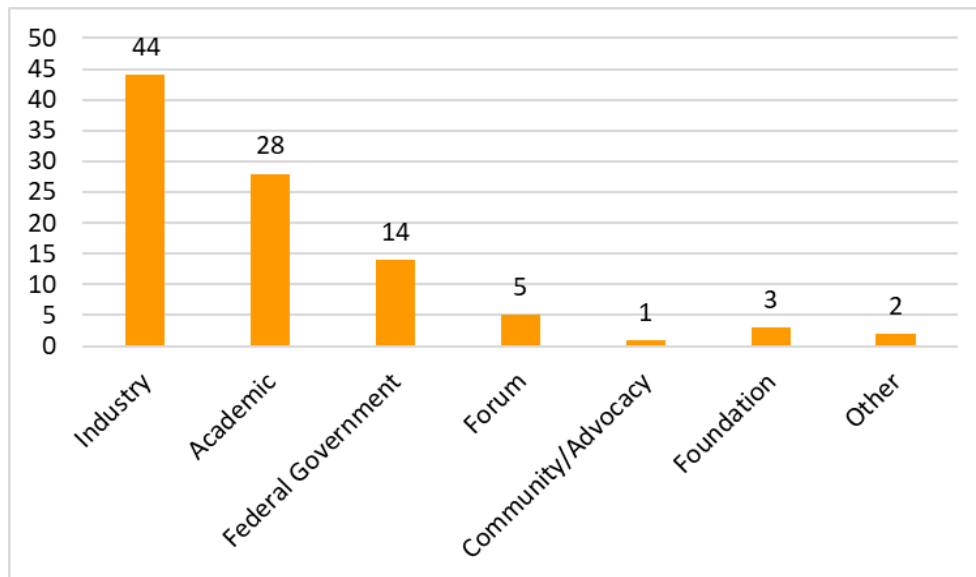
- Maria Beumont-Mauviel**
Janssen
- Gavin Cloherty**
Abbott Diagnostics
- Sara Ferrando-Martinez**
AstraZeneca
- Robert Gish**
Robert G. Gish Consultants LLC
- Wolfgang Jessner**
F. Hoffmann-La Roche AG
- Hema Kapoor**
Quest Diagnostics
- Oliver Lenz**
Janssen Pharmaceuticals ID&V
- Ed Marins**
Roche Molecular Systems
- Christos Petropoulos**
Monogram Biosciences

HBV Forum Working Groups

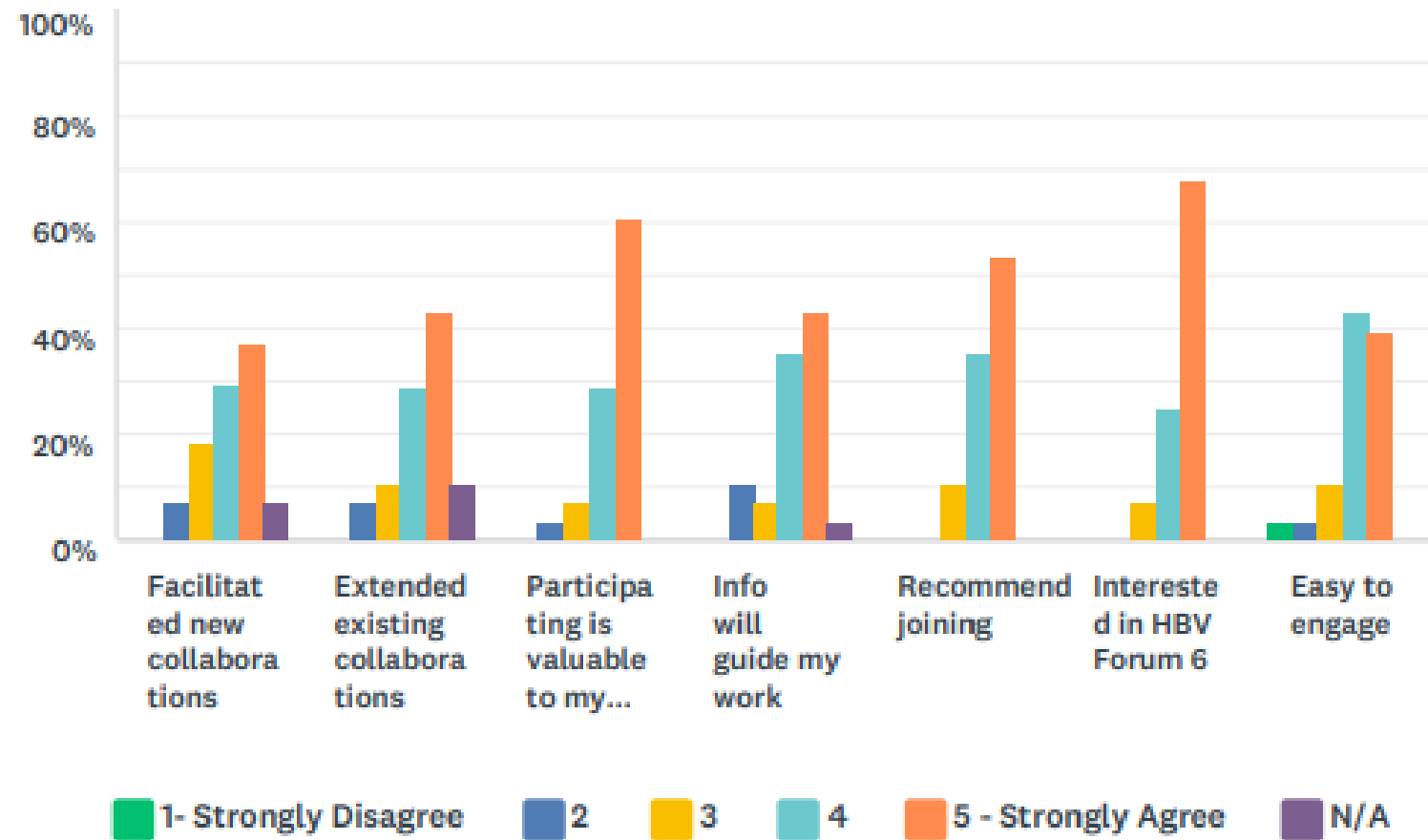
- **Immune Monitoring Working Group** Co-chairs: Adam Gehring, PhD and Sara Ferrando-Martinez, PhD
 - Aim: Identify immune biomarker(s) that predict I) effective viral control and/or II) toxicity in therapies including immune-based interventions.
- **Surrogate Endpoints Working Group** Co-chairs: Marion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

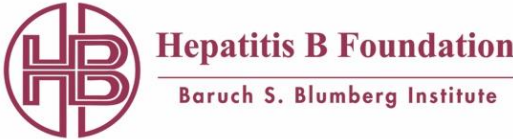


Partner in advanced diagnostic testing



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The following sponsors contribute at their assigned membership levels



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