



**THE FORUM**  
For Collaborative Research<sup>SM</sup>



PROMOTING GLOBAL COLLABORATION IN HBV CURE RESEARCH

# HBV Forum: Therapeutic Vaccines Webinar

**Tuesday, January 18th, 2022**

**Berkeley** Public  
Health



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# Introduction

**Emily Gainor**

Forum for Collaborative Research

**Berkeley** Public  
Health

# Agenda



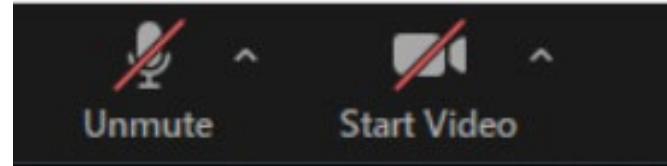
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Meeting Open		
Moderator: Adam Gehring, University of Toronto		
		<i>Veronica Miller, Forum for Collaborative Research</i> <i>John Tavis, Saint Louis University</i>
10:30am ET	Welcoming Remarks	
	Overview of Therapeutic Vaccines for HBV	
	a. Overview of Therapeutic Vaccines for HBV: Goals of Therapeutic Vaccines Moving Forward (including a brief discussion on previous strategies)	<i>Ulla Protzer, Technical University of Munich</i>
	Company Presentations:	
	a. Vir (Michael Schmid)	
	b. Virion (Hildegund Ertl)	
	c. VBI (Francisco Diaz-Mitoma)	
	d. GSK (Ventzi Vassilev)	
	e. Altimune (Sarah Browne)	
	Discussion & Audience Questions:	
	Potential Topics:	<i>Previous Presenters</i>
	a. Optimal combinations	<i>Regulators</i>
	b. Monitoring response [peripheral, intrahepatic, etc]	<i>Patient Representatives</i>
	c. Stratification/ patient groups	
	d. Endpoints	
12:15pm ET		
		<i>Veronica Miller, Forum for Collaborative Research</i>
12:55pm ET	Conclusions/ Next Steps	

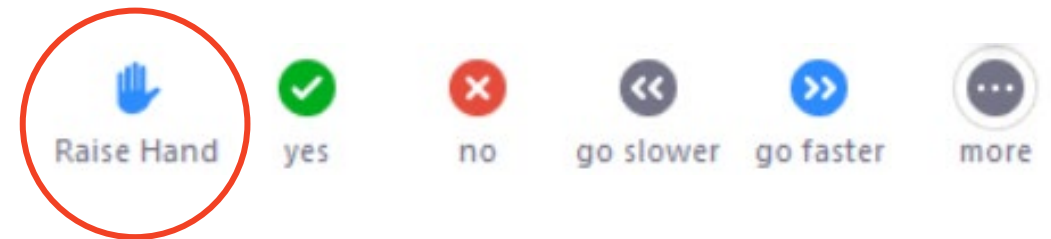
Adjourn Webinar

Berkeley Public Health

# HBV Forum- Therapeutic Vaccines 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.



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# Introduction and HBV Forum Updates

**Veronica Miller**

Forum for Collaborative Research

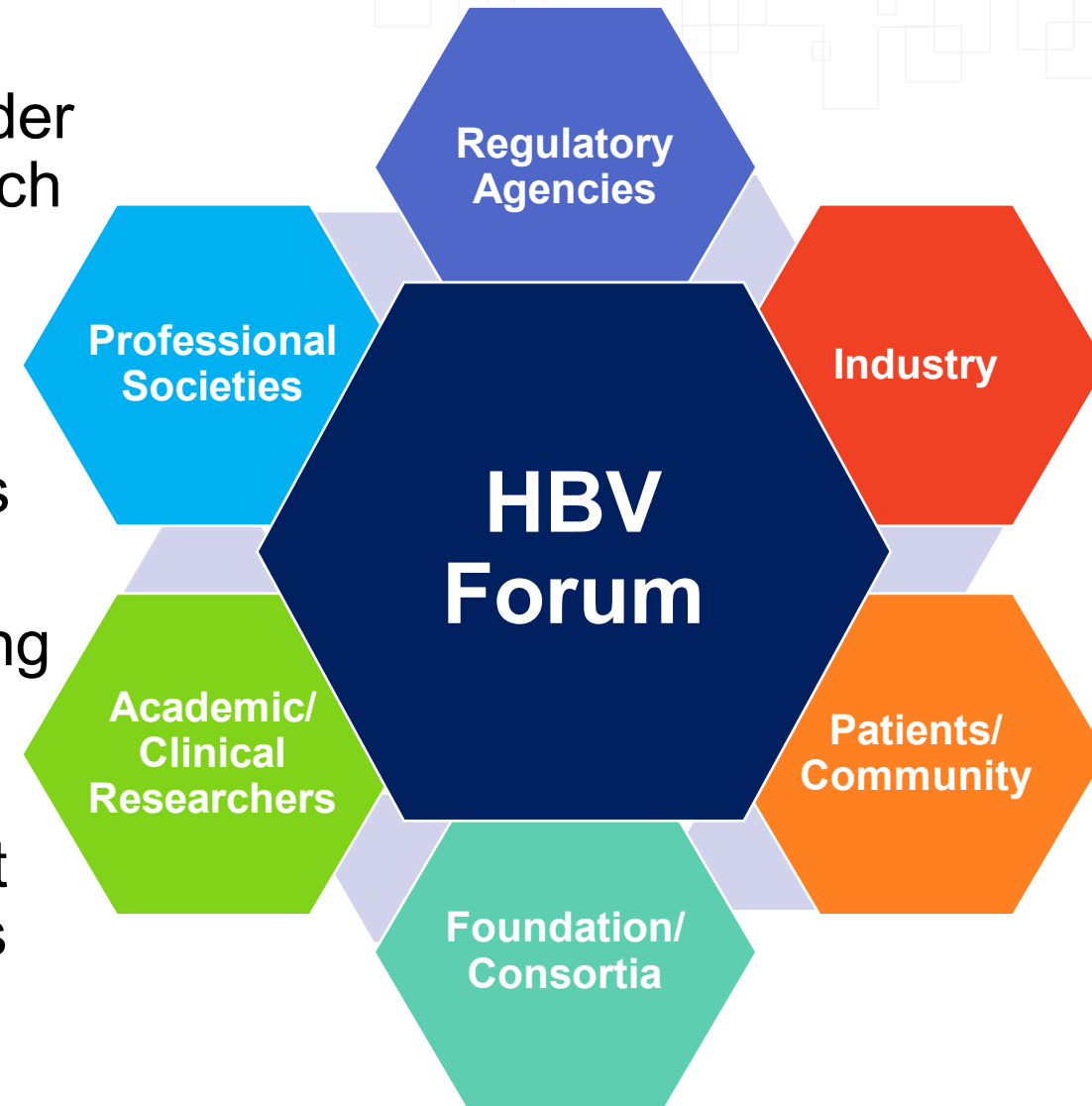
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# HBV Forum- Therapeutic Vaccines Webinar

- This webinar will feature an overview of therapeutic vaccines for HBV, presentations on industry strategies, and an audience q&a with a panel representing academia, industry, regulators, and patient advocates.

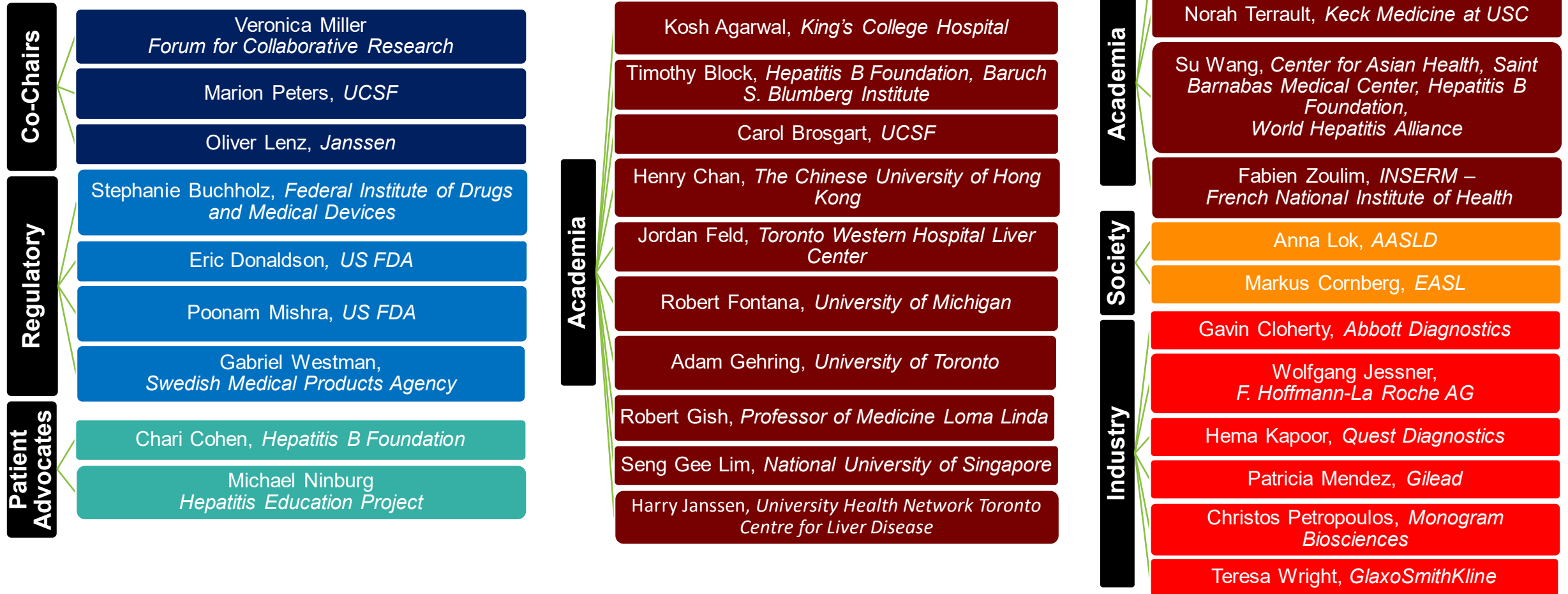
# Overview of the HBV Forum

- **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 Members



# HBV Forum Sponsors



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IMMUNOCORE



# Last but not least!



- Forum Staff
  - Emily Gainor – Research Associate
  - Brenda Rodriguez – Deputy Director
  - Jessica Weber – Senior Research Associate
  - Joseph Lau – Research Associate
  - Victoria Mason – Research Associate
  - Nicholas Murdock – Research Associate

# HBV Forum Updates

- **Steering Committee Leadership Update**
  - Steering Committee Co-Leads: Oliver Lenz and Marion Peters
    - Thank you to Harry Janssen and Anuj Gaggar
- **Recent Past Webinars**
  - [Stopping NUCs in Drug Development](#)
  - [Intrahepatic Panel Webinar](#)
  - [Webinar Series Safety Panel](#)
- **Upcoming Webinars**
  - Liver Forum: Histology Webinar Series (January 28th)

# HBV Forum Updates

- Immune Monitoring Working Group: manuscript accepted to the *Journal of Hepatology*
- New working group on treatment discontinuation to evaluate finite treatment
- Additional new working groups to be announced shortly!

## Immunological Biomarker Discovery in Cure Regimens for Chronic Hepatitis B Virus Infection

### Key Points:

- Current evidence suggests that some level of immune reconstitution will be required for functional cure of chronic hepatitis B with both novel immune-targeting and direct acting antiviral therapies.
- Phenotypic and functional assays to characterize changes in the HBV-specific immune responses during and off treatment will be necessary to understand the relationship between viral antigen reduction and immune responses, predict clinical outcomes after discontinuation of therapy, inform combination strategies and improve our understanding of liver damage.
- The extent of immunological analyses should be carefully assessed with new experimental therapies that may not have logically predicted impacts on HBV-directed immunity and tested in ancillary studies in late Phase 1 or early Phase 2 clinical studies.
- In addition to validating the mechanism of action (MoA) for immunotherapies, the behavior of the immune response and immunological biomarkers during and off treatment will provide meaningful information to inform patient selection for clinical trials and safety monitoring related to combination therapy and liver inflammation.
- Standardization of assays across diverse laboratories is a challenge and subsequent validation for their use in clinical research will require collaboration among laboratory experts, immunologists, drug developers, regulators and the HBV research community.