

Berkeley

 School of
Public Health



Forum for
Collaborative HIV Research

HBV Forum 1
November 15th 2016
Hyatt Regency Hotel
Boston

www.hivforum.org



Introductions

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Forum for
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Welcoming Remarks

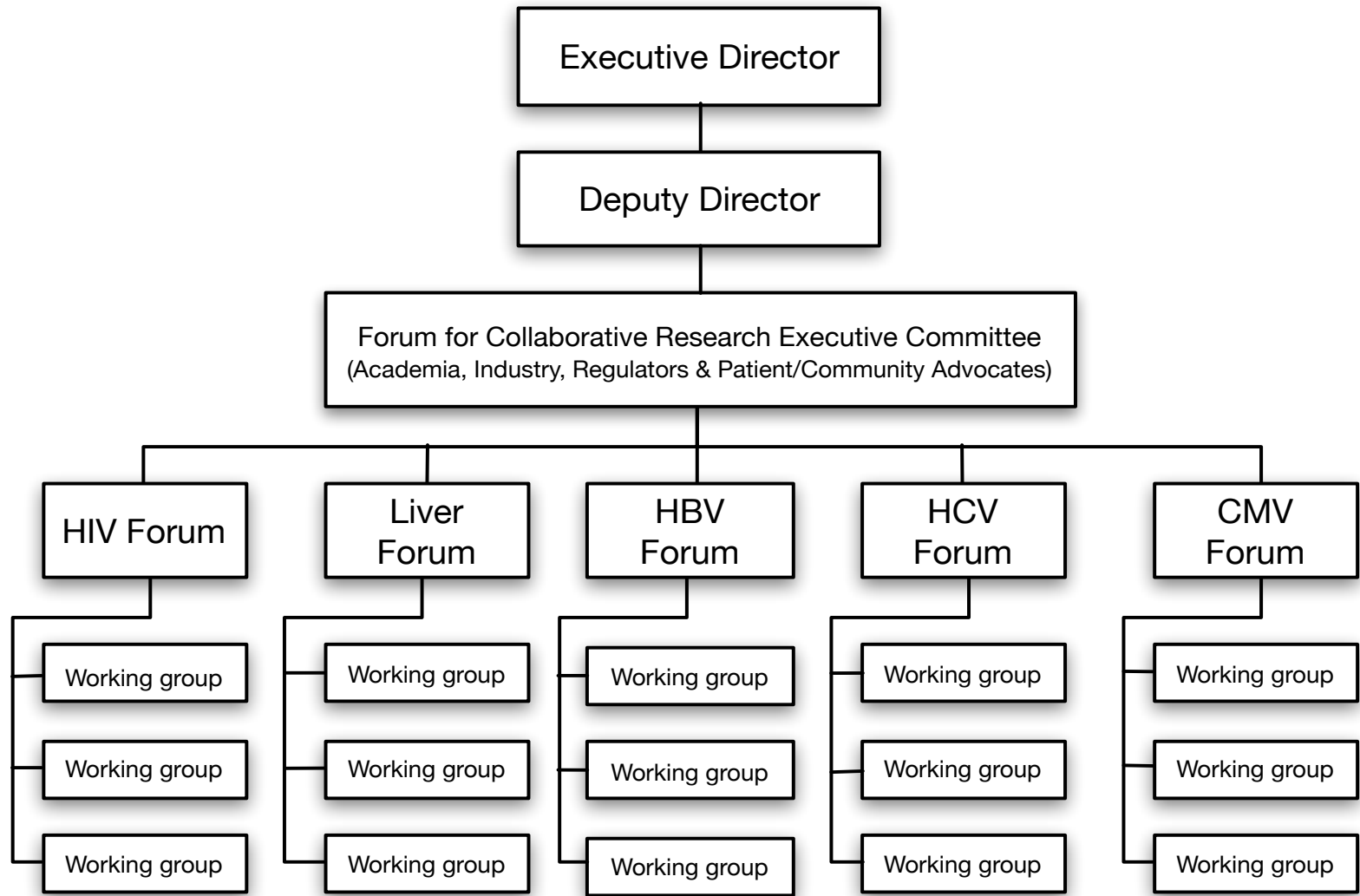
Veronica Miller

William (Bill) Symonds



*Facilitating collaborative research in drug
development and health policy*

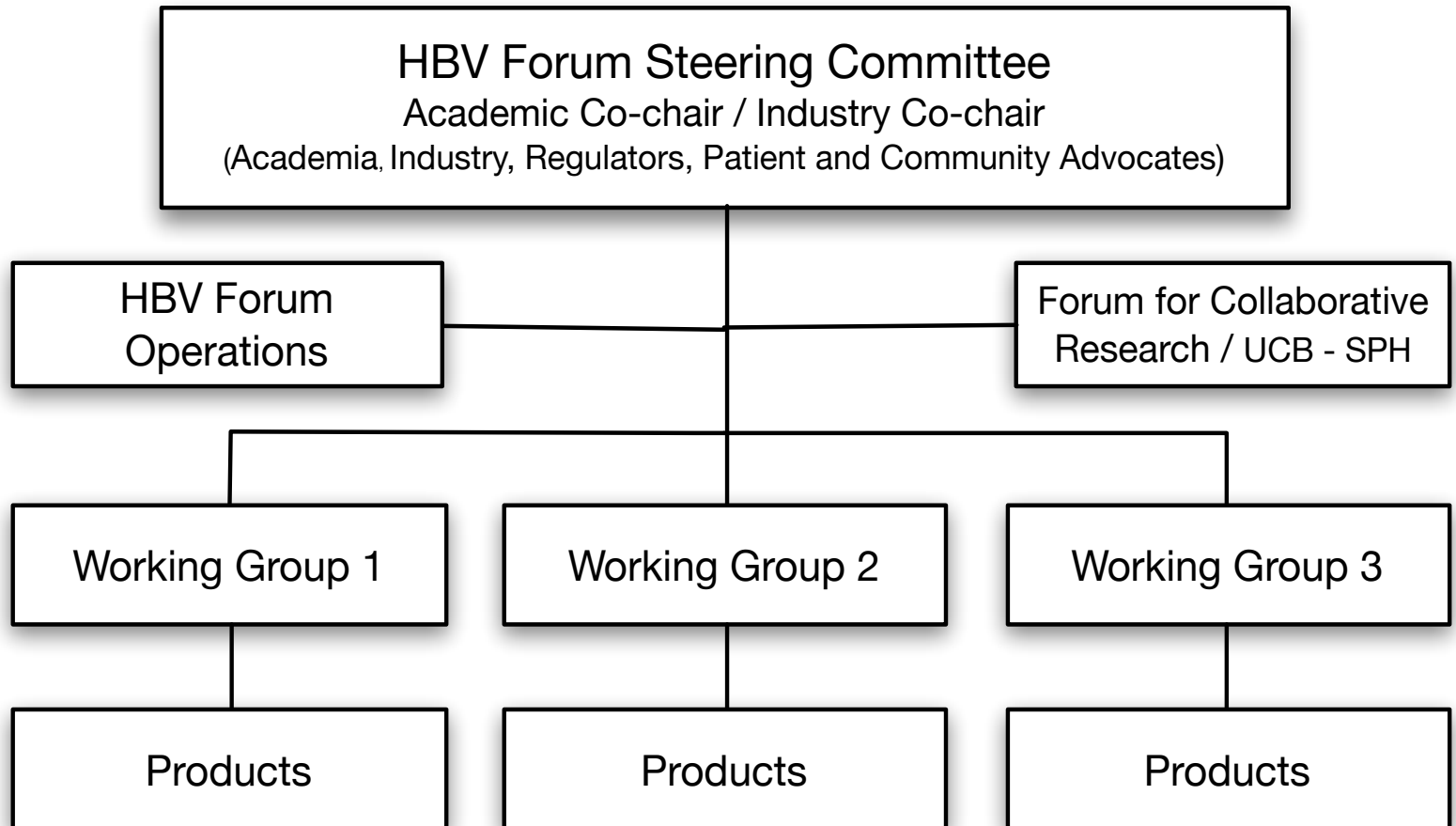
Forum for Collaborative Research
University of California Berkeley School of Public Health





HBV Forum Structure

Facilitating collaborative research in drug development and health policy





Forum's Operating Principle

*Facilitating collaborative research in drug
development and health policy*

“Once new drug candidates and therapeutic strategies are identified, their efficient, safe development is in the best interest of all stakeholders, most of all, the patients”



Impact on Drug Development

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- **Increase**
 - Clarity
 - Efficiency
 - Collaboration
 - Innovation
- **Decrease**
 - Uncertainty
 - Redundancy
 - Development time
 - Risk



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development and health policy*

Win-Win

- Accelerate drug development not by lowering standards, but by increasing efficiency through collaboration



Operating Principles (see handouts)

- Equal voice
- Co-ownership of process
- Open discussion and deliberation
- What's said at the Forum stays at the Forum
- Industry participation:
 - Not contingent on financial support
 - HBV Forum assemblies: 2 max/company
 - More may participate in Working Groups
 - Scientists and clinical researchers
 - Not for marketing and commercial branches

Non-Competitive, Safe Zone



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The screenshot shows the top portion of the AASLD website. At the top left is the AASLD logo with the text "AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES". To the right are links for "Join", "Contact Us", and "Sign In" with a dropdown arrow. Further right are social media icons for Twitter, LinkedIn, YouTube, Facebook, and Instagram, followed by a search bar. Below this is an orange "Donate Now" button with the AASLD Foundation logo. A navigation menu below the header includes "Membership", "Events and Professional Development" (highlighted in red), "Publications", "Liver Research & Awards", and "About AASLD", each with a dropdown arrow. Below the menu is a breadcrumb trail: "Home > Events and Professional Development > AASLD/EASL HBV Treatment Endpoints Workshop". The main heading of the page is "AASLD/EASL HBV Treatment Endpoints Workshop" in white text on a dark green background.

- Anna Lok
- Geoff Dusheiko
- Marc Ghany
- Fabien Zoulim



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Tomorrow's Leadership

- Foster professional development
 - Junior faculty
 - Fellows
 - Interns
- Principles of collaborative drug development and regulatory science
 - Trans-Atlantic
 - Worldwide



HBV Therapeutics and Curative Interventions The HBV Forum

Pedro Goicochea

Boston, Massachusetts
November 15th, 2016



HBV Forum 1

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Registered

84

In-person:

78

Remotely:

6

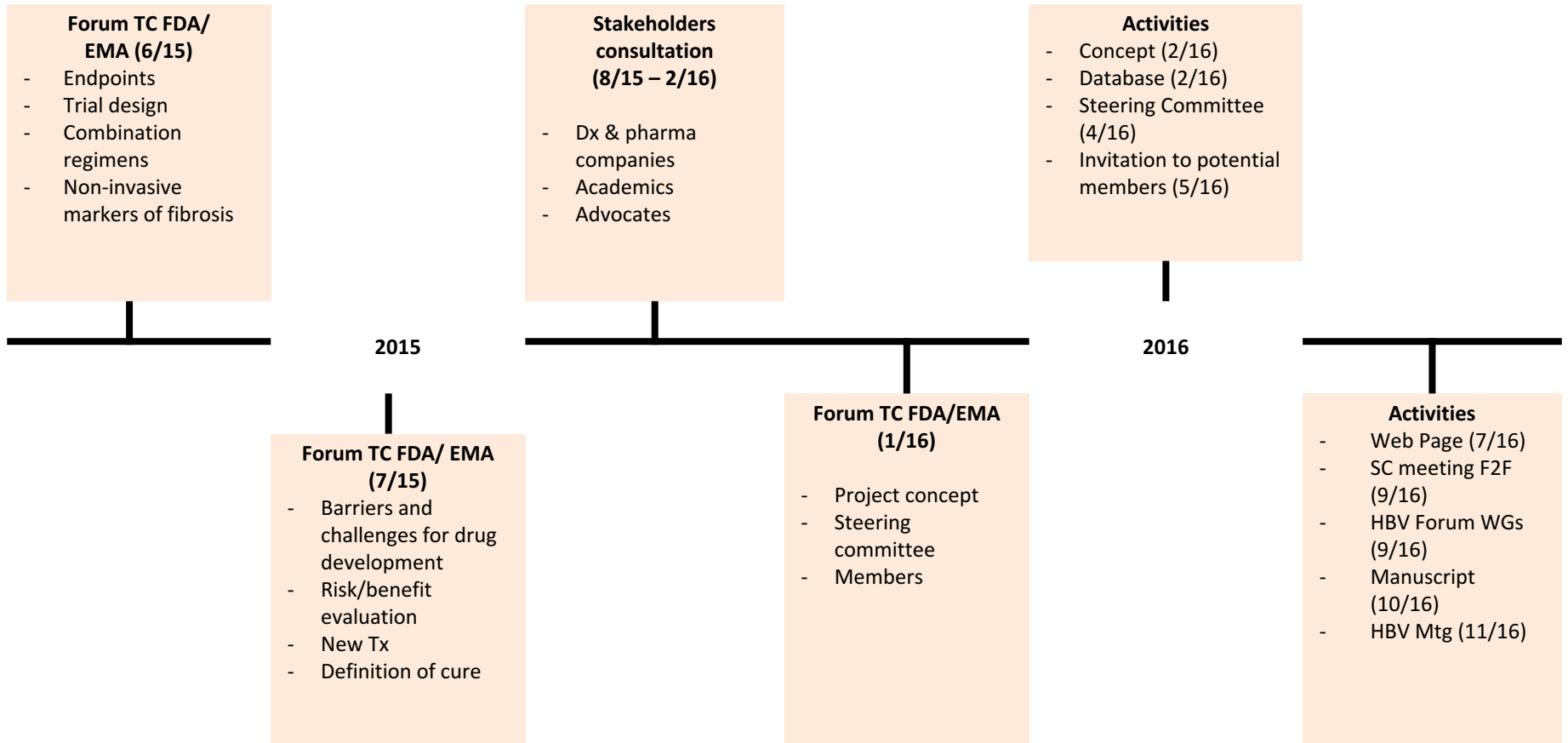


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HBV FORUM 1
November 15th, 2016
Boston, Massachusetts
Draft Agenda

1:00	Light Lunch Reception	
1:30	Welcoming remarks	Veronica Miller & Bill Symonds
1:35	HBV Forum Overview	Pedro Goicochea
1:55	Update on efforts to get quantitative HBsAg Assays	Timothy Block & Robert Gish
2:15	WG update: Diagnostics & Biomarkers	Gavin Cloherty & Ed Marins
2:35	WG update: Treatment combinations	Bruce Given & Seng Gee Lim
2:55	WG update: Surrogate endpoints	Oliver Lenz & Marion Peters
3:15	Natural Disease Progression Definitions...need for a working group?	Panel Discussion
3:45	General Discussion	All
4:15	Break	
4:35	Opportunities for Collaboration: ICE-HBV	Peter Revill
4:50	HBV Cure Project U of Singapore	Seng Gee Lim
5:05	Wrap-up + Next steps	Veronica Miller & Bill Symonds
5:20	Networking Reception	
7:00	Adjourn	

HBV Forum Timeline





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HBV Forum Steering Committee

- **Timothy Block, PhD**
Hepatitis B Foundation
- **Carol L. Brosgart, MD**
University of California, San Francisco
- **Henry LY Chan, MD**
The Chinese University of Hong Kong
- **Gavin Cloherty, PhD**
Abbott Diagnostics
- **Jordan Feld, MD, MPH, FRCP**
Toronto Western Hospital Liver Center
- **Anuj Gaggar, MD, PhD**
Gilead Sciences
- **Robert Gish, MD**
Stanford Robert Gish Consultants LLC
- **Bruce Given, MD**
Arrowhead Research
- **Filip Josephson, MD, PhD**
Swedish Medical Products Agency
- **Oliver Lenz, PhD**
Janssen Pharmaceuticals ID&V
- **Prof. Seng Gee Lim, MD**
National University of Singapore
- **Anna Lok, MD***
University of Michigan
- **Ed Marins, MD**
Roche Molecular Systems
- **Poonam Mishra, MD, MPH**
US Food and Drug Administration
- **Michael Ninburg, MPA**
Hepatitis Education Project
- **Marion Peters, MD**
University of California-San Francisco
- **Prof. Peter Revill, PhD**
University of Melbourne
International Coalition for the Elimination of HBV
- **Bill Symonds, PharmD**
Arbutus Biopharma
- **Fabien Zoulim, MD, PhD**
INSERM - French National Institute of Health

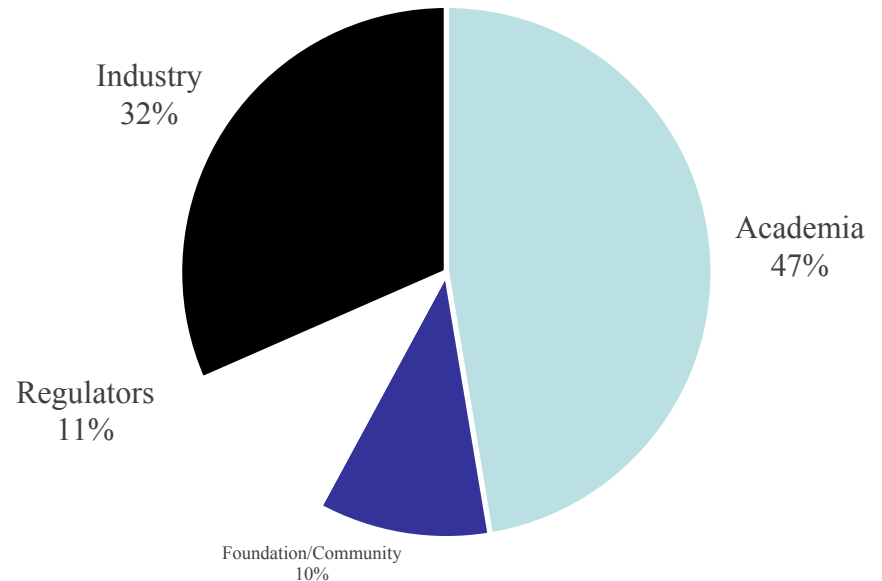


HBV Forum Steering Committee

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- **18 members**
 - Americas = 12
 - Europe = 3
 - Asia = 3
 - Australia = 1
 - Non-US = 8
 - US = 11

HBV Forum SC by Type of Organization





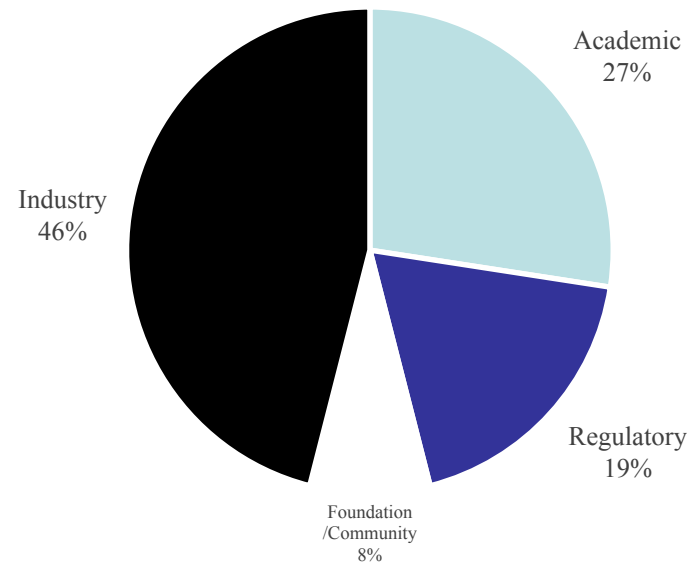
HBV Forum Members

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- **109 members**
 - Americas = 87
 - Europe = 15
 - Asia = 4
 - Australia = 3

 - Non-US = 26
 - US = 83

HBV Forum Members by Type of Organization





Activities

- 6 conference calls
 - April 4th
 - May 17th
 - August 1st
 - September 5th
 - October 6th
 - November 3rd
- Steering committee in-person meeting
 - Alexandria, September 7th, 2016

HBV Forum web page

The screenshot shows the website for the HBV Forum. The main heading is "THE HBV FORUM: HBV THERAPEUTICS AND CURATIVE INTERVENTIONS - ADDRESSING THE REGULATORY PATH" dated July 07, 2016. Below this is a "Background" section with text: "It has been 50 years since the discovery of the Australia antigen conducive to the identification of the hepatitis B virus (HBV) and despite the effective available treatments, no cure for HBV is yet available. Despite the fact that HBV can be efficiently prevented through vaccination, an estimated 240 - 350 million people worldwide are chronically infected with HBV. Current standard of care requires life-long treatment, not optimally accessible in many regions, making the search for a cure to this epidemic an urgent public health priority." A sidebar on the right lists "2015 National Summit" with sub-items: Drug Development, HIV Cure Project, Liver Forum, CMV, and HBV Forum. Other categories include Prevention and Cross-Cutting Topics, with HCV Drug Development listed under the latter.



HBV Forum Operating Principles

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THE HBV FORUM OPERATING PRINCIPLES

Introduction

The HBV Therapeutics and Curative Interventions – **The HBV Forum** – is an independently funded project of the Forum for Collaborative HIV Research (The HIV Forum) and operates in accordance with The HIV Forum’s guiding principles, which include:

- neutrality and independence;
- transparency and accessibility;
- inclusiveness;
- collaboration, and
- efficiency and productivity,



Working Groups

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- 3 working groups
 - Diagnostic & Biomarkers
 - Co-chairs: Gavin Cloherty and Ed Marins
 - 15 members
 - Surrogate Endpoints
 - Co-chairs: Marion Peters and Oliver Lenz
 - 19 members
 - Treatment Combination
 - Co-chairs: Seng Gee Lim and Bruce Given
 - 20 members



Products



HBV Stakeholder Consultation

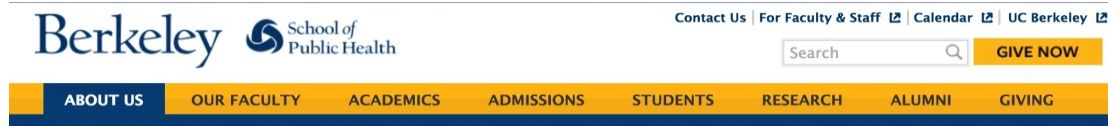
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Curing hepatitis B: The challenges on the path to advance hepatitis B treatment and cure research

Jonathan Liu

University of California, Berkeley School of Public Health
Division of Infectious Diseases and Vaccinology
2016 Master of Public Health Candidate

Sandy Elberg Award for the best Masters' comprehensive paper at the School of Public Health



- NEWS & EVENTS
- School News ▾
- Sanford Samuel (Sandy) Elberg
- In the Media
- Photo Gallery
- Video Room
- Berkeley Wellness
- Dean's Speaker Series ▶
- For Journalists

Sanford Samuel (Sandy) Elberg

Sanford Samuel (Sandy) Elberg PhD died Apr. 8, 2011, in Ukiah, Calif., at age 97. Elberg attended Lowell High School in San Francisco and received his undergraduate and doctoral degrees from UC Berkeley. During World War II he served as an officer at Fort Detrick, Md. Elberg was a professor of immunology and medical microbiology in the School of Public Health from 1938 to 1940. After World War II, he taught in the Department of Bacteriology and served as its chairman from 1952 to 1957. He was appointed Dean of the Graduate Division at Berkeley in 1961, and served in that capacity until his retirement in 1978. Elberg was the recipient of the Berkeley Citation, the Clark Kerr Award, and the Sanford Elberg Lectureship in International Studies. Following retirement, he accepted a position as head of the University of California Overseas Program in Great Britain. Among his research accomplishments was the development of the Rev-1 Brucellosis vaccine. As a member of the World Health Organization, he traveled the world introducing the vaccine, which remains in wide use today.



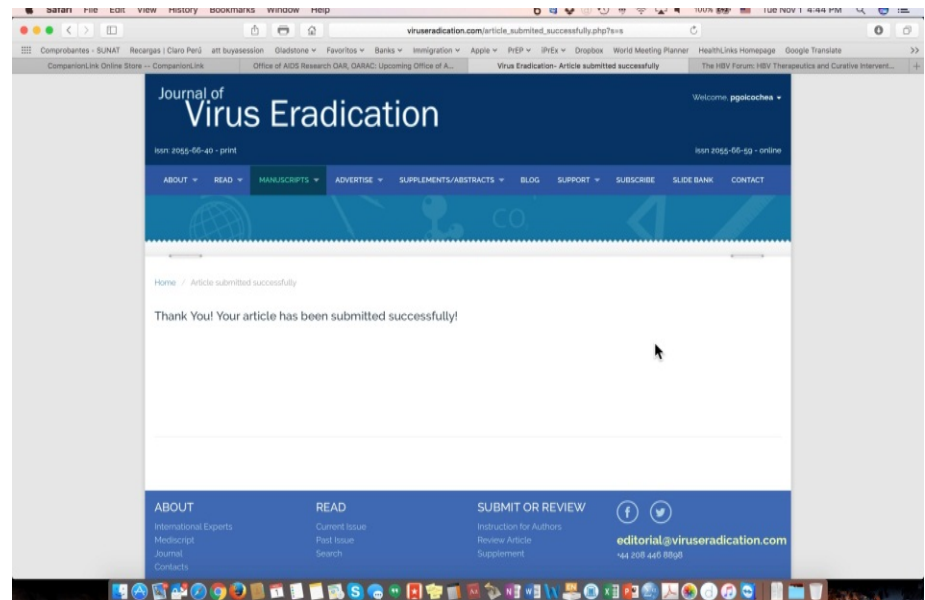
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Manuscript

Advancing the Regulatory Path on Hepatitis B Virus Treatment and Curative Research: A Stakeholders Consultation

Jonathan Liu^{1,2}, Pedro Goicochea¹, Timothy Block³, Carol L. Brosgart⁴, Eric Donaldson⁹, Oliver Lenz⁵, Seng Gee Lim⁶, Ed Marins⁷, Poonam Mishra⁹, Marion Peters⁸, Veronica Miller¹

Submitted to
Journal of Virus
Eradication
on November 1st,
2016





Exciting times!

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GILEAD

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U.S. Food and Drug Administration Approves Gilead's Vemlidy® (Tenofovir Alafenamide) for the Treatment of Chronic Hepatitis B Virus Infection

-- Vemlidy is a Once-Daily Treatment that Demonstrated Similar Efficacy with Improved Renal and Bone Laboratory Safety Parameters Compared to Viread --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 10, 2016-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved Vemlidy® (tenofovir alafenamide, TAF) 25mg, a once-daily treatment for adults with chronic hepatitis B virus (HBV) infection with compensated liver disease.



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DDL DIAGNOSTIC LABORATORY

Partner in advanced diagnostic testing





Thank You!

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Ryan Taylor Anderson
Malene Cobourne
Katie Greene
Ben Hauschild
Jeff Kaminski
Maria Ma
Victoria Mason
Megan McIntosh
Veronica Miller
Brenda Rodriguez
Ken Taymor



Questions

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