

Berkeley



**FORUM**  
for Collaborative  
**RESEARCH**

# The HBV Forum

**Presenter**

Pedro Goicochea

**HBV Forum 3**

October 24<sup>th</sup>, 2017

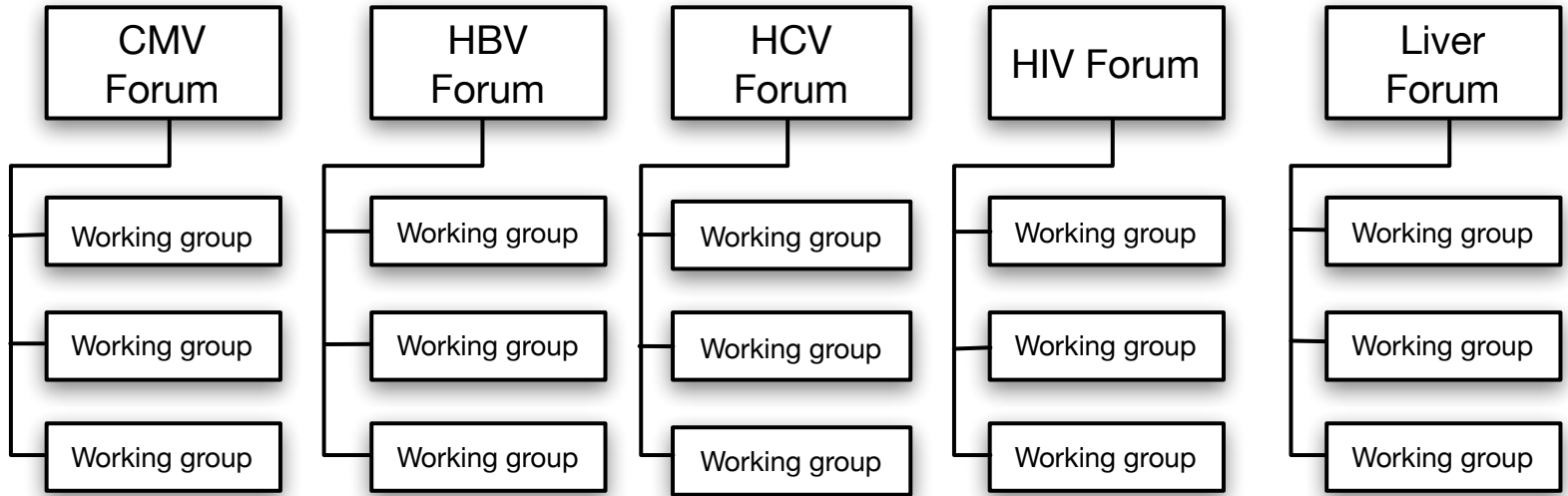
Marriott Marquis, Washington DC

[www.forumresearch.org](http://www.forumresearch.org)



# Forum for Collaborative Research

University of California Berkeley School of Public Health





# Forum Operating Principles

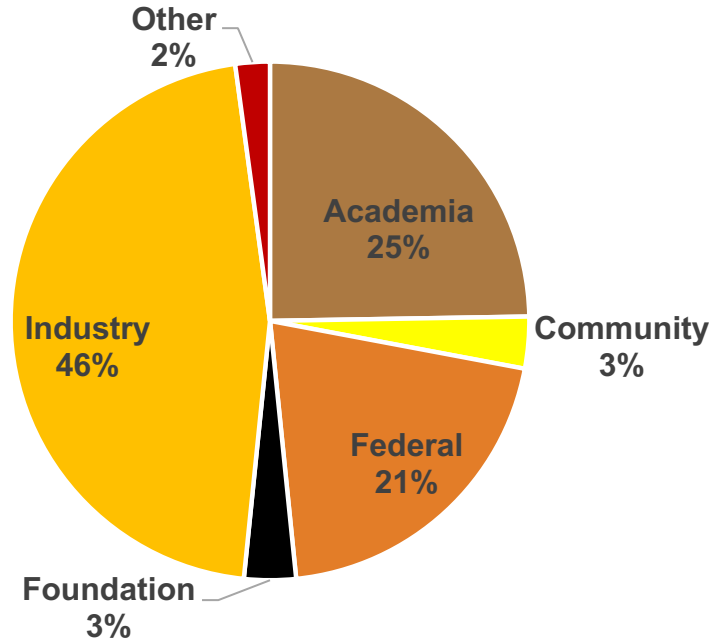
---

- 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



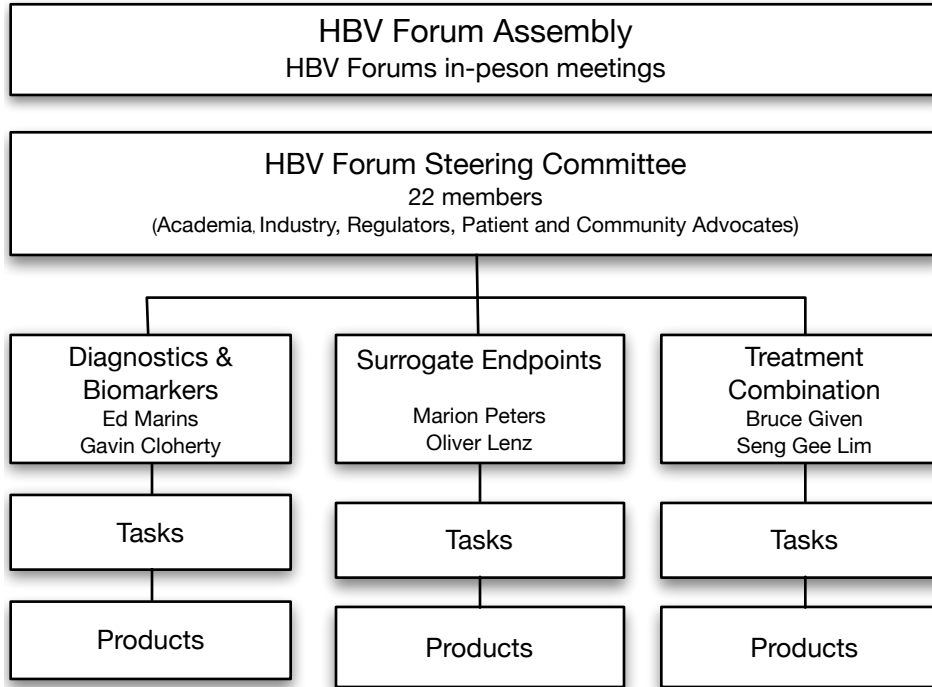
# HBV Forum 3

**99**  
**Participants**





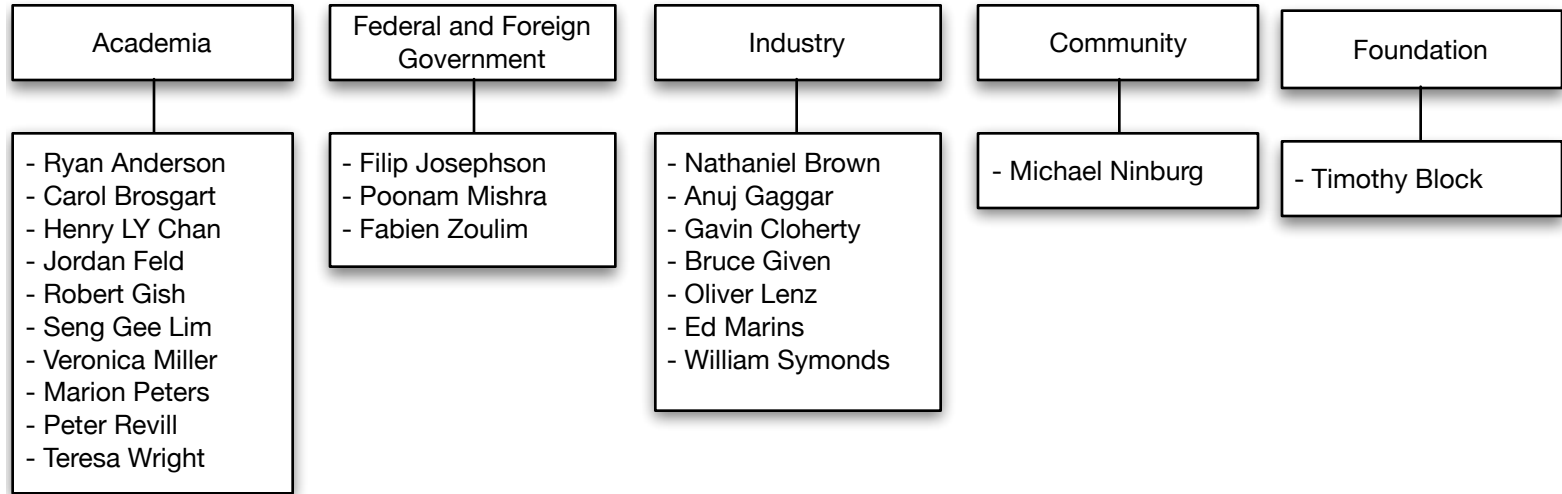
# HBV Forum Overview





# Steering Committee

---





# Working Groups Achievements

---

- Diagnostic & Biomarkers
- Surrogate Endpoints
- Treatment Combination



# Diagnostics & Biomarkers Working Group

---

- Gavin Cloherty
- Jordan Feld
- Maria Garcia
- Robert Gish
- Radhakrishnan (Kris) Iyer
- Oliver Lenz
- Stephen Locarnini
- Maria Ma
- Ed Marins
- Patricia Mendez
- Veronica Miller
- Jean-Michel Pawlotsky
- Christos Petropoulos
- Andrew Vaillant
- Sophie Wang
- Su Wang
- Heiner Wedemeyer
- Kathleen Whitaker
- Joseph Yao





# Activities

---

- Matrix of the regulatory status of HBV Markers
- Commentary on the status of HBV biomarkers



# Surrogate Endpoints Working Group

---

- Ibironke Addy
- Ryan Anderson
- Nathaniel Brown
- Henry LY Chan
- Gavin Cloherty
- Eric Donaldson
- Geoffrey Dusheiko
- Robert Gish
- Bettina Hansen
- Michael Hombach
- Maureen Kamishke
- Pietro Lampertico
- Oliver Lenz
- Uri Lopatin
- Eduardo Martins
- Biran McMahon
- Veronica Miller
- Charu Mullick
- Jeffrey Murray
- Michael Ninburg
- Sandra Palleja
- Daniela Paulsen
- Jean-Michel Pawlosky
- Marion Peters
- Ross Leland Pierce
- Sybil Tasker
- Andrew Vaillant
- Hugh Watson
- Hwai I Yang



# Activities

---

- Literature review on sAg loss and long term clinical outcomes
- Collaborate with other stakeholders on a meta-analysis on sAg loss an long term clinical outcomes



# Treatment Combination Working Group

---

- Addy Ibrinke
- Nezam Afdhal
- Ryan Anderson
- Tanvir Bell
- Carol Brosgart
- Nataniel Brown
- Jordan Feld
- Anuj Gaggar
- Ed Gane
- Bruce Given
- Radhakrishnan (Kris) Iyer
- Chris Kukka
- Pietro Lampertico
- Seng Gee Lim
- Stephen Locarnini
- Uri Lopatin
- Mala Maini
- Eduardo Martins
- Patricia Mendez
- Veronica Miller
- Jules O'Rear
- Sandra Palleja
- Daniela Paulsen
- Jean-Michel Pawlotsky
- Kimberly Struble
- David Suhy
- Jon Sullivan-Bolyai
- Andrew Vaillant
- Cythia Wat
- Kelly Wong
- Teresa Wright



# Activities

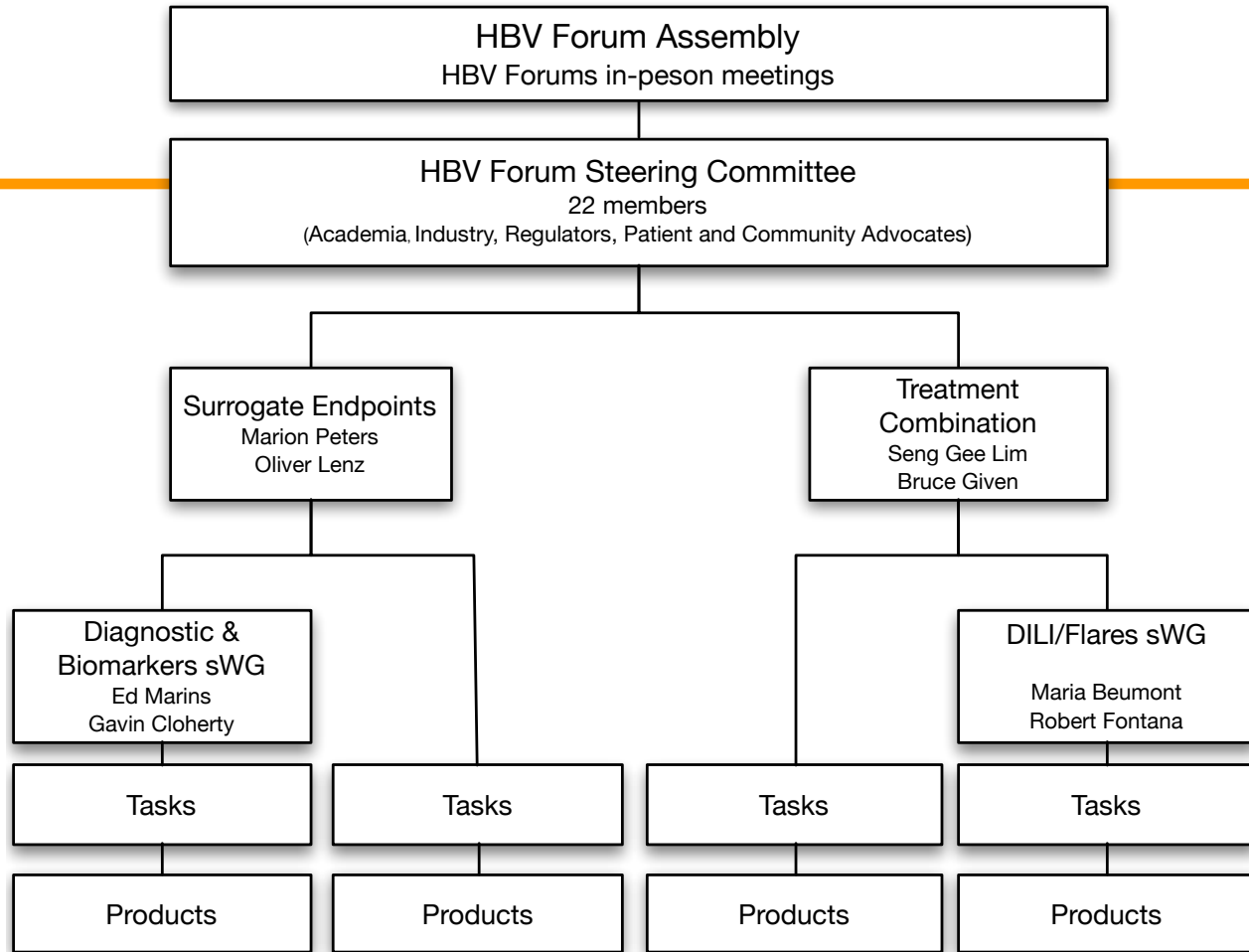
---

- Flare protocols and references
- Combination treatment matrix
- Manuscript under internal review



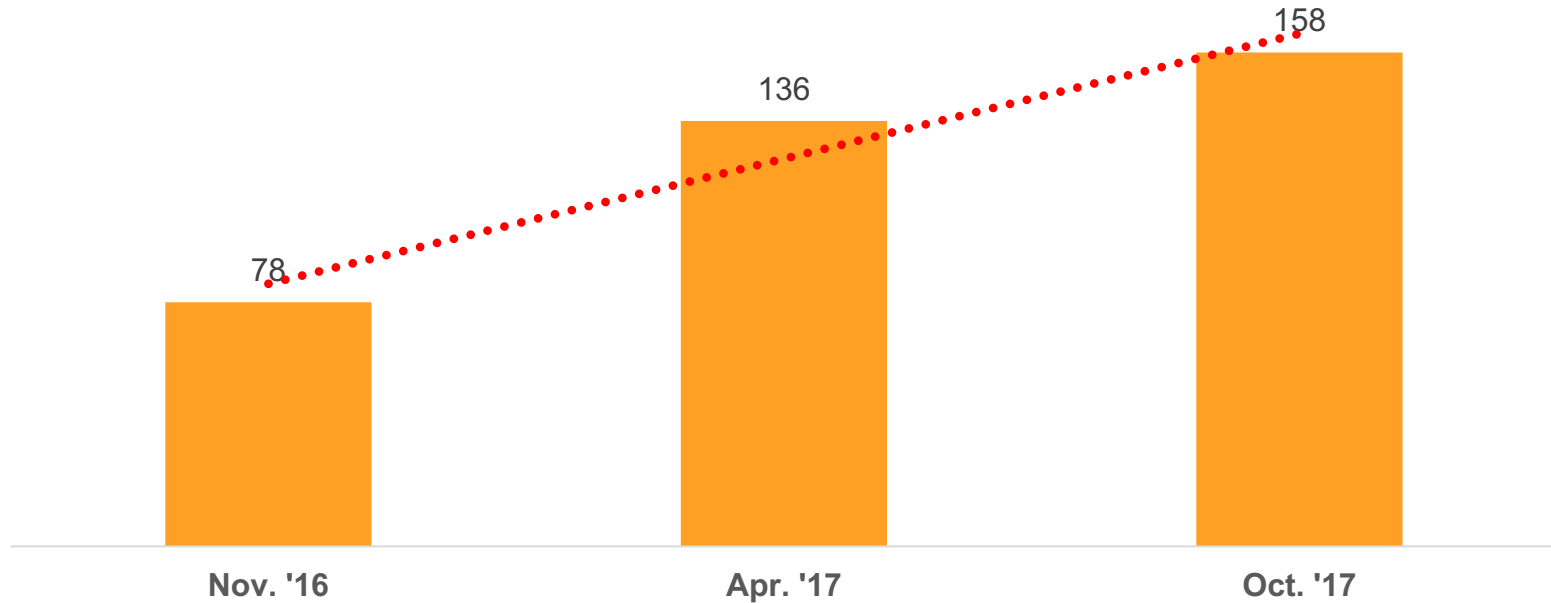
---

# Evolution of the HBV Forum





# HBV Forum Members







# Member & Sponsor Update

---

- **Total Industry Members: 35**
- **Total Current Sponsors: 14**
- **New Sponsors Since Since HBV Forum 2:**
  - **Altimune**
  - **Assembly Biosciences**
  - **MedImmune**



# Financial Sponsors

---





# Financial Sponsors

---





12:30

Light Lunch Reception

1:30 Welcoming Remarks

Veronica Miller  
Pedro Goicochea

1:45 Current FDA Perspective on HBV Drug Development

Poonam Mishra

2:00 FDA Perspective on HBV Diagnostic Devices

Kathleen Whitaker

2:15 Quantitative Serum HBsAg Assay Validation for U.S. Patient Testing

Robert Gish

2:30 Implications of HBsAg from Integrated DNA for Clinical Trial Design

Bruce Given

2:45 HBV Next Generation Sequencing

Leen-Jan van Doorn

3:00 Panel discussion

Timothy Block  
Carol Brosgart  
Anuj Gaggar  
Edward Gane  
Maureen Kamischke



3:40	Break	
4:00	Diagnostics and Biomarkers Working Group Updates - Achievements	Ed Marins Gavin Cloherty
4:10	Discussion	All
4:20	Surrogate Endpoints Working Group Updates - Achievements - Updates on Collaboration with Other Stakeholders - Next Steps	Oliver Lenz
4:40	Discussion	All
4:50	Treatment Combination Working Group Updates - Achievements - Recommendations: Position Paper - Next Steps	Bruce Given Seng Gee Lim
5:10	Discussion	All
5:20	Road Map of Research Priorities for HBV Cure	Tim Block
5:30	Discussion	All
5:40	International Coalition to Eliminate HBV	Peter Revill
6:10	Discussion	All
6:20	Wrap up	Veronica Miller
6:30	Networking Reception	
7:30	Adjourn	



# Thank You!

---

- **Forum Staff**

- Ryan Anderson
- Malene Cobourne
- Terry Daniels
- Katherine Greene
- Luis Javier Hernandez
- Jeffrey Kaminiski
- Maria Ma
- Victoria Mason
- Veronica Miller
- Brenda Rodriguez

- Ken Taymor
- Jessica Weber

- **Prism Event Management**

- Paula Blay
- Rachel Heitkamp
- Graham Hill
- Ash Lawson
- Mairead O'Reilly
- Sarah Sanderson
- George Seaton