



THE FORUM
For Collaborative ResearchSM
*Berkeley's Hub for Regulatory
Science*

Welcome, Introduction, Forum Updates, Program Overview & Acknowledgments

Shilpa Mitra, MPH

Forum for Collaborative Research

Overview of the TAVI Forum

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for TAVI
- **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



History of the TAVI Forum

- CMV Forum (2014)
 - Development of standardized definitions
 - Recommendations for clinical trial designs
- TAVI Forum (2019)
 - Adenovirus, BK Virus, HSV, HHV-6, etc.
 - Immunocompromised populations
 - Working group outputs include consensus papers and research projects

Refractory and Resistant Herpes Simplex Virus Mucocutaneous Infections in Immunocompromised Patients: Literature Review and Proposed Definitions for Use in Clinical Trials

Roy F. Chemaly,^{1,Ⓢ} Tali Shafat,^{1,Ⓢ} Anna Wald,^{2,Ⓢ} Camille N. Kotton,^{3,Ⓢ} Genovefa Papanicolaou,^{4,5,Ⓢ} Michelle K. Yong,^{6,7,8} Veronica Miller,^{9,Ⓢ} Takashi E. Komatsu,^{10,a,Ⓢ} Charu Mullick,^{10,a} Aimee C. Hodowanec,^{10,a,Ⓢ} Gabriel Westman,^{11,12,a} Fareed Khawaja,^{1,Ⓢ} Alexander Birkmann,^{13,Ⓢ} and Per Ljungman^{14,15,Ⓢ}; HSV Resistance Working Group of the Transplant Associated Viral Infections Forum

Herpes simplex virus (HSV) infection is one of the most prevalent viral infections worldwide. In general, host immunity is sufficient to clear viral shedding and recurrences, although it is insufficient to prevent subsequent virologic reactivations. In immunocompromised patients, prolonged and difficult-to-treat HSV infections may develop. The diagnosis of refractory HSV infection is based on the lack of clinical response to nucleoside analogs. Antiviral resistance is confirmed via genotypic and/or phenotypic testing. To provide consensus definitions of refractory and/or resistant (R/R) HSV mucocutaneous infections for clinical trial use, the HSV Resistance Working Group of the Transplant Associated Viral Infections Forum, which includes international clinicians, scientists, industry representatives, and regulatory officials, conducted a literature review of previously published data related to R/R HSV infections in immunocompromised patients. We propose definitions of R/R HSV mucocutaneous infections, which will be subject to re-evaluation and revision based on forthcoming data and future studies.

Keywords. herpes simplex virus; resistance; refractory; definitions; immunosuppression.

Forum Operating Principles

- Independent and neutral venue
 - Ongoing multi-stakeholder dialogue
 - Each stakeholder group has an equal voice
- Facilitate best science-based decisions, in real time
 - Break down inefficiencies and redundancy
 - Increase clarity, collaboration and innovation
 - Benefit to whole field, especially patients

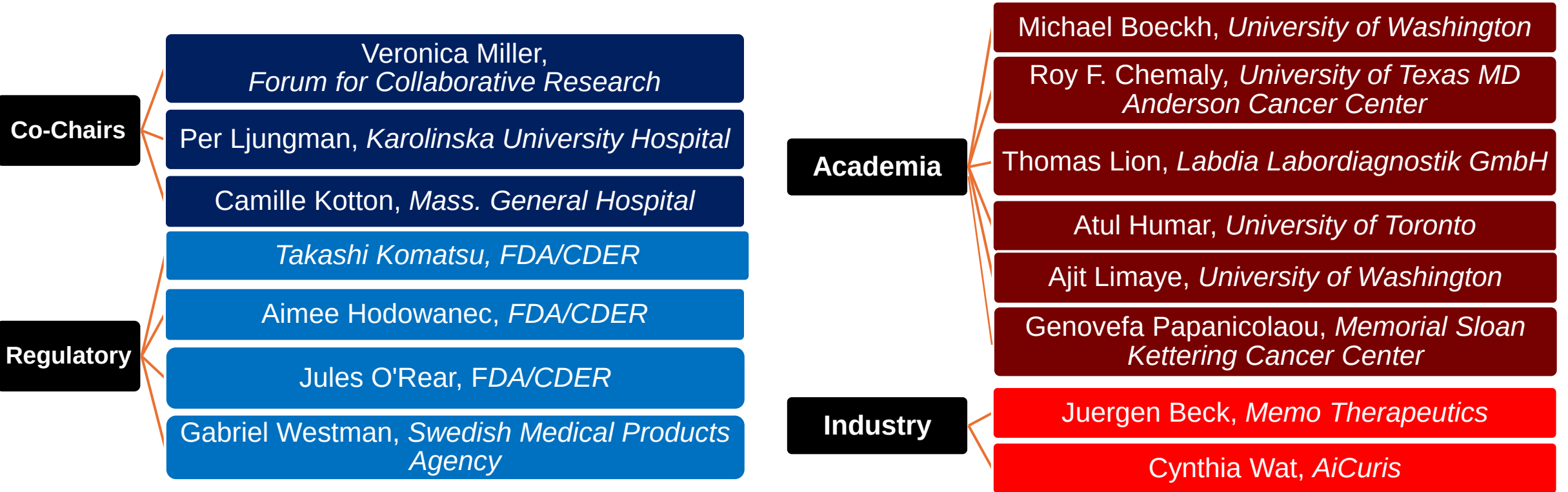
Forum = Safe Space

- Closed meeting
 - No marketing
 - No press
- Bring your expertise
 - Leave your “hat” at the door

Rules of the Room and Zoom

- What's said in the room, stays in the room
- What's said in the room, is not for attribution
- Let the science speak
- Active participation

Steering Committee



TAVI Forum Sponsors



The Forum Team (1)

- Veronica Miller – Director & Faculty Lead

Program Leads and Project Managers

- Robin Schaefer – Postdoctoral Scholar
- Logan Donaldson – Research Associate
- Sehyr Khan – Research Associate
- Mitchell Leus – Research Associate
- Shilpa Mitra – Research Associate
- Ekene Osakwe – Research Associate
- Edyth Dwyer – Research Associate

Data & Analysis Center

- Margot Yann – Lead Data Scientist
- Mengxi Bai – Research Data Analyst
- Zachary Rooney – Technical & Infrastructure Lead

Administration

- Jordan Cathey – Development Consultant
- Donna Dahrouge – Assist. Director, Administration
- Christopher Berry – Sr. Events and Operations Manager
- Alicia Jellinek – Program Financial Analyst

Program Advisors

- Richard Haubrich – Program Advisor
- Jeffrey S. Murray – Program Advisor
- Mike Robertson – Program Advisor
- John Sninsky – Program Advisor

The Forum Team (2)

Student Researchers and Assistants

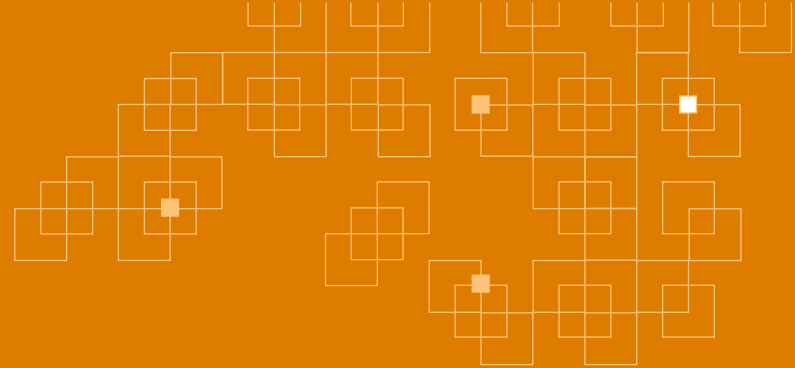
- Roma Ranade – Graduate Student Researcher
- Alessi Ayvaz – Undergraduate Student Assistant
- Allison Li – Undergraduate Student Assistant
- Kathy An – Undergraduate Student Assistant

Meeting Agenda

Time	Agenda
2:00 PM	Welcome and Introductions
2:15 PM	Session I: Industry Roundtable • Herpes Simplex Virus • BK Virus • Adenovirus • CMV • COVID-19 Session II: Measles in Immunocompromised Populations
4:30 PM	Break
4:45 PM	Session II: New Topics in Transplant and Immunocompromised Populations • H5N1 • CMV Combination Therapies • HBsAg+ Donors in Organ Transplantation
6:45 PM	Concluding Remarks and Next Steps
7:00 PM	Adjourn and Evening Reception

Acknowledgements

- East West Audio-Visual Team
- Hilton Vienna Waterfront Hotel Staff



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Thank You