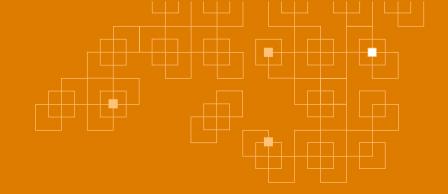




TAVI Forum 8 Copenhagen, DK Tuesday, April 18, 2023

Veronica Miller, PhD Director





Welcome & Introductory Remarks

Veronica Miller

Camille Kotton

Per Ljungman

Meeting Agenda



- Session I: CMV Definitions Working Group
 - Update on CMV Definitions and Lessons learned
 - Introduction to the Swiss Transplant Cohort Study
- Session II: Adenovirus Working Group
 - Update on Working Group Discussions
 - Launch of the AdV Diagnostics Working Group
- Session III: CMV Immune Diagnostics Update
 - CMV-CMI Project Update
- Session IV: Concluding Remarks
 - Next Steps



Overview of the TAVI Forum

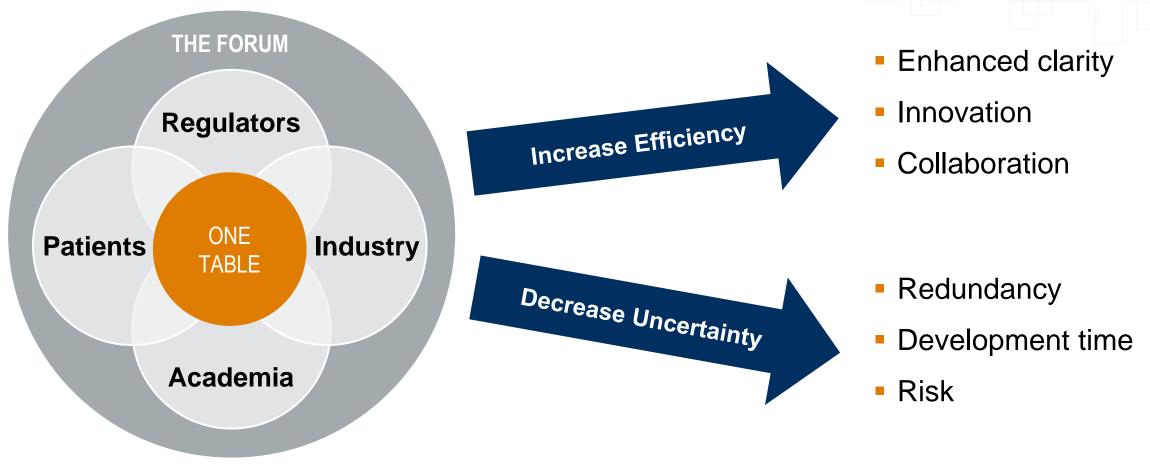
- What: a platform for <u>ongoing</u> multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for TAVI
- How: provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
 - Focus on developing 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





The Forum's Concept







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



Veronica Miller, Forum for Collaborative Research

Per Ljungman, Karolinska University Hospital

Camille Kotton, Mass. General Hospital

Stephanie Buchholz, *European Medicines Agency*

Takashi Komatsu, FDA/CDER

Aimee Hodowanec, FDA/CDER

Jules O'Rear, FDA/CDER

Gabriel Westman, Swedish Medical Products
Agency

Michael Boeckh, *University of Washington*

Roy F. Chemaly, *University of Texas MD*Anderson Cancer Center

Paul Griffiths, *University College London*

Atul Humar, *University of Toronto*

Ajit Limaye, University of Washington

Paul Baum, Roche Molecular Systems

Barbara Anne Haber, Merck Research Labs

Celia Lin, Vera Therapeutics

Richard Riese, AlloVir

Industry

Academia



Co-Chairs

Regulatory

TAVI Forum Sponsors



















Eurofins Clinical Diagnostics

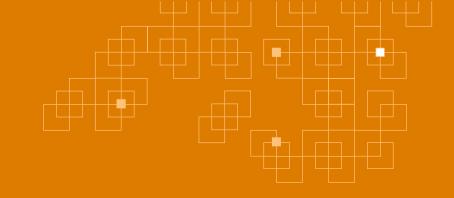


Forum Team Updates



- New Team Members
 - Chris Hoffman, IT and Operational Director
 - Azza Karrar, Senior Research Associate, Liver Forum
 - Margot Yann, Lead Data Scientist
 - Sammy Berman, Research Data Analyst

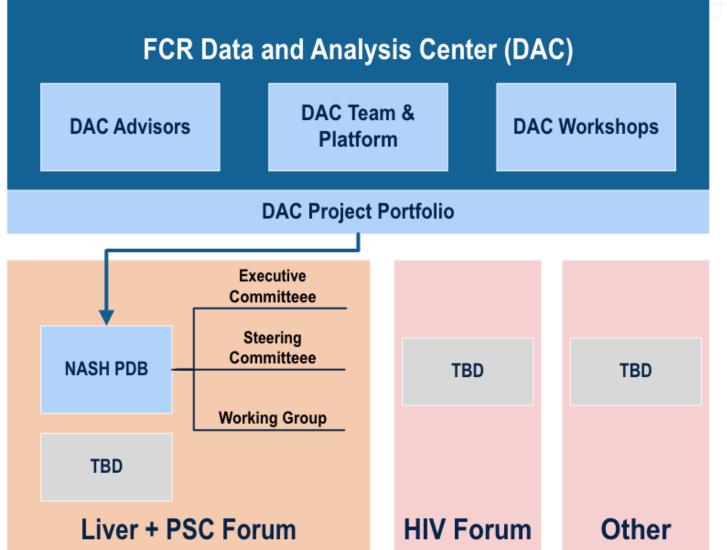




Data and Analysis Center (DAC) Overview

DAC Organization Model







Chris Hoffman, PhD

IT & Operational Director



- Experience leading a set of research computing services and projects designed to facilitate research across the Berkeley campus.
- Expertise with complex challenges related to research involving highly sensitive data; campus-wide Research Data Management Programs; IRB; and Information Systems.



Zachary Rooney, MSCS

Research Associate



- Experience in Java, Python, C, Swift, MIPS, and in programming biomedical devices and in storing health data for patient and health care providers' use.
- Knowledge of programming languages, computer systems, and computer networking building a diverse portfolio with data structures, algorithms, and computer systems examples.



Margot Yann, PhD, M.Eng

FOR COLLABORATIVE RESEARCH

Senior Computational and Data Science Research Specialist



- Experience in research and applications using Deep Neural Networks, Bayesian Networks, Multiagent Learning, and Game Theory—and processes at the forefront of artificial intelligence.
- Hands-on big-data experience in Natural Language Processing (NLP), Computer Vision, and Electronic Health Records (EHR) both in industry and academia.
- Wide background and expertise in AI & ML in healthcare.





Samantha Berman, MSc, BSc

Research Data Analyst



- Expertise in mathematical modeling and longitudinal public health studies.
- Experience integrating national health datasets, dozens of longitudinal health-related studies, and other social and environmental dataset.

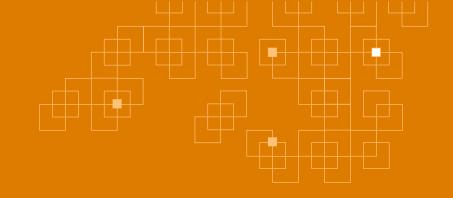
Forum Team



- Veronica Miller Director
- Brenda Rodriguez Deputy Director
- Nicholas Murdock Research Associate
- Mitchell Leus Research Associate
- Shilpa Mitra Research Associate
- Logan Donaldson Research Associate
- Sehyr Khan Research Associate
- Azza Karrar Senior Research Associate
- Alicia Jellinek Program Financial Analyst

- Chris Hoffman IT and Operational Director
- Margot Yann Lead Data Scientist
- Zachary Rooney Research Associate
- Sammy Berman Research Data Analyst
- Jeffrey S. Murray Program Advisor
- John Sninsky Program Advisor
- Nayri Alajaji, Graduate Student Researcher
- Mayland Treat, Graduate Student Researcher





BKV Working Group Update

BKPyV Assay VL Threshold Study



- Co-Pls: Ajit P. Limaye & Hannah Imlay
- Multicenter cross-sectional study Prospective & Retrospective patient cohorts
 - Determine plasma BKPyV load threshold that optimizes sensitivity and specificity for the diagnosis of biopsy-confirmed BKPyVAN
 - Determine positive predictive value (PPV) and negative predictive value (NPV) of BKPyV plasma load thresholds among kidney transplant recipients who undergo "for-cause" renal allograft biopsy



The Forum's Scientific Advisory Support Collaborative Research



- Forum/Berkeley provides neutral home
 - Fundraising/fund distribution
 - Data management and analysis (if needed)
- Scientific Advisory Committee provides guidance on study design and analysis
 - Academic experts (including statistics), study investigators, industry sponsors, and regulators

