

# Regulatory Science to Advance Precision Medicine Forum

Thursday, September 27, 2018

8:30am – 3:30pm

PhRMA Foundation  
950 F Street NW  
Washington, DC 20004

## Agenda

- 8:30 am Continental Breakfast
- 9:10 am Welcome (*Eileen Cannon, PhRMA Foundation and Richard Moscicki, PhRMA*)
- 9:20 am Review of Meeting Objectives (*Joan Adamo and Scott Steele, University of Rochester*)
- 9:30 am Digital Health: Emerging Science and Considerations to Inform Regulatory Decision-Making Presentations
- Rob Califf, Vice Chancellor for Health Data Science, Duke Health; Verily Life Sciences
  - Lara Mangravite, President, Sage Bionetworks
  - James McClain, Program Director, All of Us Research Program, NIH and Praduman Jain, CEO, Vibrent Health
  - Linda Ricci, Associate Director for Digital Health, Office of Device Evaluation, CDRH, FDA
- 11:00 am Discussion
- 11:45 am Charge to the Breakout Groups (*Scott Steele, University of Rochester*)
- 12:00 pm Working Lunch: Breakout Group Sessions (*Information Interface and User Interface*)
- 2:00 pm Break
- 2:15 pm Reports from the Breakout Groups and Discussion
- 3:15 pm Review Progress and Identify Next Steps (*Joan Adamo and Scott Steele, University of Rochester*)
- 3:30 pm Adjourn



## **Regulatory Science to Advance Precision Medicine Forum Participants:**

[Joan Adamo](#), Director, Regulatory Support Services and Assistant Professor, Biomedical Engineering, Clinical and Translational Science Institute, University of Rochester Medical Center

[Adam Berger](#), Director, Clinical and Healthcare Research Policy, Office of Science Policy, Office of the Director, NIH

[Robert Bienvenu II](#), Assistant Research Professor, Department of Anthropology, University of Maryland, College Park

[Khaled Bouri](#), Office of the Chief Scientist, Office of the Commissioner, FDA

[Philip John \(P.J.\) Brooks](#), Program Director, Office of Rare Diseases Research, National Center for Advancing Translational Sciences, NIH

[Jennifer Brown](#), Director, Clinical Research Quality, Spectrum, Stanford Center for Clinical & Translational Research & Education

[Rob Califf](#), Vice Chancellor for Health Data Science, Duke Health; Verily Life Sciences

[Wendy Camelo Castillo](#), Assistant Professor, Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy

[Eileen Cannon](#), President, PhRMA Foundation

[Yvonne Chan](#), Associate Professor, Genetics and Genomic Sciences, and Emergency Medicine; Director, Personalized Medicine and Digital Health, Icahn School of Medicine at Mount Sinai

[Joy Chen](#), Senior Manager, Regulatory Lead, Digital Medicine, Pfizer Innovation Research (PfIRe) Lab, Early Clinical Development, Pfizer

[Silvia Corvera](#), Professor, Program in Molecular Medicine, University of Massachusetts Medical School

[Marisa Cruz](#), Senior Medical Officer, Office of the Center Director, Center for Devices and Radiological Health, FDA

[Felipe Dolz](#), Head, Global Regulatory Science and Policy, Sanofi US

[Katherine Fisher](#), Senior Director, Applied Sciences and Clinical Technologies, Biogen

[H. Timothy Hsiao](#), Program Director, Division of Clinical Innovation, National Center for Advancing Translational Sciences, NIH

[Praduman Jain](#), Founder and CEO, Vibrent Health

[Rasika Kalamegham](#), Group Director, US Regulatory Policy, Genentech, Inc., A Member of the Roche Group

[Karl Kieburtz](#), Professor, Neurology, University of Rochester Medical Center

[Santosh Kumar](#), Director, NIH Center of Excellence for Mobile Sensor Data-to-Knowledge (MD2K), Professor and Lillian & Morrie Moss Chair of Excellence, Department of Computer Science, The University of Memphis

[Michael Liebman](#), Founder, IPQ Analytics, Adjunct Professor of Pharmacology and Physiology, Drexel College of Medicine

[Sheng Lin-Gibson](#), Leader, Biomaterials Group, Biosystems and Biomaterials Division, NIST

[Katherine Luzuriaga](#), PI and Director, UMass Center for Clinical and Translational Science, Vice Provost, Clinical and Translational Research, University of Massachusetts Medical School

[Lara Mangravite](#), President, Sage Bionetworks

[Jomol Mathew](#), ACIO, Data Science and Technology, University of Massachusetts Medical School

[Brian Mayhew](#), Executive Director, Regulatory & Development Policy, Regulatory Affairs – Global Drug Development, Novartis Pharmaceuticals Corporation

[James McClain](#), Program Director, All of Us Research Program, NIH

[Martha J. Morrell](#), Chief Medical Officer, NeuroPace; Clinical Professor of Neurology and, by courtesy, Neurosurgery, Stanford University

[Richard Moscicki](#), Executive Vice President for Science and Regulatory Advocacy, Chief Medical Officer, PhRMA.

[Wendy Nilsen](#), Program Director, Computer & Information Science & Engineering, NSF

[Daryl Pritchard](#), Senior Vice President, Science Policy, Personalized Medicine Coalition

[Debra Rasmussen](#), Global Regulatory Diagnostic Leader, Janssen Pharmaceutical

[Linda Ricci](#), Associate Director for Digital Health, Office of Device Evaluation, Center for Devices and Radiological Health, FDA

[Brad Ringeisen](#), Deputy Director, Biological Technologies Office, DARPA

[Leonard Sacks](#), Associate Director, Clinical Methodology, Center for Drug Evaluation and Research, FDA

[Justin Sanchez](#), Director, Biological Technologies Office, DARPA

[Robert Schuck](#), Clinical Pharmacologist, Genomics and Targeted Therapy, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, FDA

[Joe Selby](#), Executive Director, Patient-Centered Outcomes Research Institute

[Ida Sim](#), Co-Director, Informatics and Research Innovation, UCSF Clinical and Translational Sciences Institute Professor of Medicine, UCSF; Co-Founder, [OpenmHealth.org](#); Co-Founder and Technical Lead, [Vivli](#)

[Scott Steele](#), Director, Regulatory Science Programs and Associate Professor, Public Health Sciences, Clinical and Translational Science Institute, University of Rochester Medical Center

[Zivana Tezak](#), Associate Director, Science and Technology, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, FDA

[Anthony D. Watson](#), Associate Vice President, Regulatory Affairs – Devices, Sanofi US

[Frank F. Weichold](#), Director, Critical Path and Regulatory Science Initiatives, Office of Regulatory Science and Innovation, Office of the Chief Scientist, Office of the Commissioner, FDA

[Amanda Wood](#), IND/IDE Program Coordinator, University of North Carolina, Chapel Hill