

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