



Innovations in Regulatory Science Summit

Sponsored by the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation

Mission Bay Conference Center, 1675 Owens St, San Francisco, CA
Sunday, January 12, 2020

AGENDA

- 8:00 – 8:05 am** **Welcome**
Kuldev Singh, MD, MPH - Professor of Ophthalmology at Stanford University
- 8:05 – 8:25 am** **Overview of UCSF-Stanford CERSI**
Russ Altman, MD, PhD - Co-Director of UCSF-Stanford CERSI
Kathy Giacomini, PhD - Co-Director of UCSF-Stanford CERSI
- 8:25 – 8:35 am** **Opening Remarks from Stanford**
Marc Tessier-Lavigne, PhD - President, Stanford University
- 8:35 – 8:45 am** **Opening Remarks from UCSF**
Sam Hawgood, MD - Chancellor, University of California San Francisco (UCSF)
- 8:45 – 8:55 am** **Lightning Talk - Defining the Strength of Evidence in Therapeutic Development**
Steven Goodman, MD, MHS, PhD - Associate Dean of Clinical and Translational Research at Stanford
- 8:55 – 9:55 am** **Panel Discussion - Accelerating Clinical Trials in the Development and Approval of Innovative Medical Products**
- Moderators: Laura Esserman, MD, MBA - Professor of Surgery at UCSF
Janet Woodcock, MD - Director of Center for Drug Evaluation and Research at FDA
- Panelists: Amy Abernethy, MD, PhD - Principal Deputy Commissioner at FDA
Steven Goodman, MD, MHS, PhD - Associate Dean of Clinical and Translational Research at Stanford
Sandra Horning, MD - Former Chief Medical Officer at Genentech/Roche
Carl Peck, MD - Chairman of NDA Partners
Alfred Sandrock, MD, PhD - Chief Medical Officer at Biogen
- 9:55 – 10:10 am** **Break**
- 10:10 – 10:20 am** **Lightning Talk - Patient Preferences in Upper Limb Prostheses**
Leslie Wilson, PhD - Professor of Clinical Pharmacy at UCSF
- 10:20 – 11:20 am** **Panel Discussion - Academia, Government and Industry in Regulatory Science: Cross-Sector Collaboration and Avoiding Conflicts of Interest**
- Moderators: Howard Bauchner, MD - Editor-In-Chief of the Journal of the American Medical Association
Robert Califf, MD - Former FDA Commissioner, Head of Health Policy and Strategy,

- Panelists:** Google Health and Verily Life Science (Alphabet)
 Mildred Cho, PhD - Professor of Pediatrics (Center for Biomedical Ethics) at Stanford
 Arthur Ciociola, PhD - Vice President, Head Regulatory Affairs, Global Drug Development Ophthalmology at Novartis
 Malvina Eydelman, MD - Director, Division of Ophthalmic and Ear, Nose & Throat Devices (CDRH) at FDA
 Carol Linden, PhD - Director, Office of Regulatory Science and Innovation at FDA
 Andrew Weber, MS - Accelerating Therapeutics for Opportunities in Medicine (ATOM), GlaxoSmithKline
- 11:20 – 11:50 am Keynote Address**
Moderator: Russ Altman, MD, PhD - Professor of Bioengineering at Stanford
Speaker: Janet Woodcock, MD - Director, Center for Drug Evaluation and Research at FDA
- 11:50 – 12:40 pm Lunch**
- 12:40 – 12:50 pm Lightning Talk - Safer Labeling of Pediatric Medications: Reducing Literacy-related Health Disparities among Chronically Ill Adolescents**
 Lee Sanders, MD - Associate Professor of Pediatrics at Stanford
- 12:50 – 1:50 pm Panel Discussion - Real-World Evidence, Artificial Intelligence and Novel Medical Devices**
Moderators: Adam Gazzaley, MD, PhD - Professor of Neurology, Physiology and Psychiatry at UCSF
 Anne Wojcicki - CEO of 23andMe
Panelists: Russ Altman, MD, PhD - Professor of Bioengineering at Stanford
 Edward Chang, MD - Professor of Neurological Surgery at UCSF
 Daphne Koller, PhD - Founder & CEO of Insitro
 Bakul Patel, MSEE, MBA - Associate Director for Digital Health (CDRH) at FDA
- 1:50 – 2:05 pm Break**
- 2:05 – 2:15 pm Lightning Talk - The Activity of Inactive Ingredients**
 Brian Shoichet, PhD - Professor of Pharmaceutical Chemistry at UCSF
- 2:15 – 3:15 pm Panel Discussion - Advancing Discovery to First-In-Human Clinical Trials for New Medical Products**
Moderators: Jay Bradner, MD - President of Novartis Institutes for Biomedical Research
 Joseph Wu, MD, PhD - Director of the Stanford Cardiovascular Institute
Panelists: Hal Barron, MD - Chief Scientific Officer at GlaxoSmithKline
 Mathai Mammen, MD, PhD - Global Head of Research and Development at Janssen
 Peter Marks, MD, PhD – Director, Center for Biologics Evaluation and Research at FDA
- 3:15 – 3:45 pm Closing Keynote**
Moderator: George Scangos, PhD - CEO of Vir Biotechnology
Speaker: Peter Marks, MD, PhD – Director, Center for Biologics Evaluation and Research at FDA
- 3:45 – 4:00 pm Closing Remarks**
 Russ Altman, MD, PhD - Co-Director of UCSF-Stanford CERSI
 Kathy Giacomini, PhD - Co-Director of UCSF-Stanford CERSI
- 4:00 – 5:00 pm Reception and Poster Session (co-sponsored by the UCSF School of Pharmacy)**
 Hosted by B. Joseph Guglielmo, PharmD - Dean, UCSF School of Pharmacy