



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

DRAFT AGENDA

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- 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**
- 8:35 – 9:05 am** **Keynote Address**
Janet Woodcock, MD - Director of Center for Drug Evaluation and Research at FDA
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- 9:05 – 9:15 am** **Lightning Talk**
- 9:15 – 10:15 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: Steven Goodman, MD, MHS, PhD - Associate Dean of Clinical and Translational Research at Stanford
Carl Peck, MD - Chairman of NDA Partners
Alfred Sandrock, MD, PhD - Chief Medical Officer at Biogen
- 10:15 – 10:30 am** **Break**
- 10:30 – 10:40 am** **Lightning Talk - Patient Preferences in Upper Limb Prostheses**
Leslie Wilson, PhD – Professor of Clinical Pharmacy at UCSF
- 10:40 – 11:40 am** **Panel Discussion - Academia, Government and Industry in Regulatory Science: Cross-Sector Collaboration and Avoiding Conflicts of Interest**

Moderators: Robert Califf, MD - Professor of Medicine at Duke University
Howard Bauchner, MD - Editor-In-Chief of the Journal of the American Medical Association

Panelists: Mildred Cho, PhD - Professor of Pediatrics 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 of the Office of Regulatory Science and Innovation at FDA
Andrew Weber, MS – Accelerating Therapeutics for Opportunities in Medicine (ATOM), GlaxoSmithKline

11:40 – 12:40 pm Lunch

12:40 – 12:50 pm Lightning Talk

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

2:15 – 3:15 pm Panel Discussion - Advancing Discovery to First-In-Human Clinical Trials for New Medical Products

Moderators: Joseph Wu, MD, PhD - Director of the Stanford Cardiovascular Institute
Jay Bradner, MD - President of Novartis Institutes for Biomedical Research

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 of Center for Biologics Evaluation and Research at FDA

3:15 – 3:45 pm Closing Keynote
Peter Marks, MD, PhD - Director of Center for Biologics Evaluation and Research at FDA

3:45 – 4:00 pm Final Remarks
George Scangos, PhD - CEO of Vir Biotechnology

4:00 – 5:00 pm Reception and Poster Session