



Innovations in Regulatory Science Summit

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

Fisher Banquet Room - Mission Bay Conference Center
1675 Owens St, San Francisco, CA

Saturday, January 5, 2019

AGENDA

Opening Session

- 8:00 – 8:05 am** **Welcome**
Kathy Giacomini, PhD - Co-Director of UCSF-Stanford CERSI
George Scangos, PhD - CEO of Vir Biotechnology
Kuldev Singh, MD, MPH - Professor of Ophthalmology at Stanford University
- 8:05 – 8:25 am** **Overview of UCSF-Stanford CERSI**
Kathy Giacomini, PhD - Co-Director of UCSF-Stanford CERSI
- 8:25 – 8:35 am** **Opening Remarks**
Sam Hawgood, MD - UCSF Chancellor
- 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 – 9:25 am** **Lightning Talk Presentations**
Overview of OneSource (Laura Esserman)
Defining the Strength of Evidence in Therapeutic Development (Steven Goodman)

Panel Discussion 1

- 9:25 – 10:25 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

10:25 – 10:40 am Break

10:40 – 11:00 am Lightning Talk Presentations

The Accelerated Digital Clinical Ecosystem (Andrew Auerbach)

Intracranial Closed-Loop Stimulation to Impact Depression (Katherine Scangos)

Panel Discussion 2

11:00 – 12:00 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: Robert Califf, MD - Professor of Medicine at Duke University
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

12:00 – 1:00 pm Lunch

1:00 – 1:20 pm Lightning Talk Presentations

Patient Preferences in Upper Limb Protheses (Leslie Wilson)

Patient Reported Outcomes for Minimally Invasive Glaucoma Surgery (Malvina Eydelman)

Panel Discussion 3

1:20 – 2:20 pm 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

2:20 – 2:30 pm Break

2:30 – 2:50 pm Lightning Talk Presentations

Bioequivalence and Excipients in Drug Products (Ling Zou)

Cheminformatic Tools for Generic Drugs (Josh Pottel)

Panel Discussion 4

2:50 – 3:50 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
Brook Byers, MBA - Founding Partner of Kleiner Perkins
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

Closing Session

3:50 – 4:20 pm Closing Keynote
Peter Marks, MD, PhD - Director of Center for Biologics Evaluation and Research at FDA

4:20 – 4:30 pm Final Remarks
George Scangos, PhD - CEO of Vir Biotechnology and Organizers

4:30 – 5:30 pm Reception and Poster Session