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,

Google Health and Verily Life Science (Alphabet)

Panelists: 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, Office of Health Technology 1 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

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