

# 2020 GLOBAL CONFERENCE ON REGULATORY SCIENCE

MACHINE LEARNING AND DATA SCIENCE

Oct 20-21, 2020 | 10am - 3:30pm ET | Virtual Meeting

## DAY 1 AGENDA

Oct 20, 10 am – 3:30 pm Eastern Time

**10:00 AM** **Welcome remarks**

**Peter Sorger**, Professor of Systems Biology, Harvard Medical School, Co-Director, Harvard-MIT Center for Regulatory Science

**10:10 AM** **KEYNOTE Bridging the Data Gap Between the NCI and FDA**

**Ned Sharpless**, Director, National Cancer Institute

**10:40 AM** **TALK Self-Regulation, Research Oversight and Governance by Scientists**

**George Daley**, Dean of Harvard Medical School

**11:00 AM** **PANEL Data Science for Innovative Trial Designs**

*Moderator: Amy Abernethy, Principal Deputy Commissioner, FDA*

*Panelists:*

**Adam Palmer**, Assistant Professor of Pharmacology, UNC Chapel Hill

**Helga Gardarsdottir**, Associate Professor, Utrecht University

**Peter Mol**, Professor of Drug Regulatory Science, University Medical Center Groningen

**Steven Goodman**, Professor of Epidemiology & Population Health, Stanford University

**11:50 AM** **Break**

**12:00 PM** **SESSION 1 Q&A**

*Moderator: Peter Sorger; Ned Sharpless, George Daley, Amy Abernethy, Adam Palmer, Helga Gardarsdottir, Peter Mol, Steven Goodman*

**12:30 PM** **Break**



- 12:40 PM** **LIGHTING TALKS Working Group Activities**  
**Education in Regulatory Science**  
Caleb Alexander, Professor of Epidemiology and Medicine, Johns Hopkins Bloomberg School of Public Health  
Mike Rosenblatt, Chief Medical Officer, Flagship Pioneering
- Digital Pathology, AI and Image-Based Biomarkers in Research and Clinical Practice**  
Sandro Santagata, Associate Professor, Brigham and Women's Hospital
- 1:00 PM** **TALK AI, E-consent and Virtual Clinical Trials: Impact on Health Disparities**  
Fadia Shaya, Professor, University of Maryland (UMB) School of Pharmacy
- 1:20 PM** **Break**
- 1:30 PM** **TALK Data Science in Biomedical Research & Development: Opportunities, Challenges, and Regulatory Considerations**  
Sean Khozin, Global Head of Data Science Innovation, Janssen
- 1:50 PM** **PANEL Advances in Digital Medicine and Patient Care**  
*Moderator:* Ariel Stern, Associate Professor, Harvard Business School  
*Panelists:*  
Andy Coravos, Co-founder and CEO, Elektra Labs  
Ray Dorsey, Director, Center for Health + Technology, University of Rochester  
Luca Foschini, Chief Data Scientist, Evidation Health  
Timo Minssen, Professor & CeBIL Director, University of Copenhagen
- 2:40 PM** **Break**
- 2:50 PM** **SESSION 2 Q&A**  
*Moderator:* Florence Bourgeois; *Fadia Shaya, Sean Khozin, Ariel Stern, Andrea Coravos, Ray Dorsey, Luca Foschini, Timo Minssen*
- 3:20 PM** **Day 1 Recap**  
Florence Bourgeois, Associate Professor of Pediatrics, Harvard Medical School, Co-Director, Harvard-MIT Center for Regulatory Science
- 3:30 PM** **End of Day 1 Plenary Sessions**
- 3:40 PM** **Poster Session: Live Discussions with Authors**
- 5:00 PM** **End of Poster Session**



# DAY 2 AGENDA

Oct 21, 10 am – 3:45 pm Eastern Time

**10:00 AM Welcome Remarks**

**Laura Maliszewski**, Executive Director of the Harvard Program in Therapeutic Science, Harvard Medical School, Co-Director, Harvard-MIT Center for Regulatory Science

**10:10 AM KEYNOTE Reflecting on Regulatory Science in a Complex World**

**Margaret Hamburg**, Former FDA Commissioner, Foreign Secretary, National Academy of Medicine

**10:40 AM TALK Leveraging Patient-Centered Health Data Sharing Platforms for Medical Product Evaluation**

**Nilay Shah**, Professor of Health Services Research, Mayo Clinic

**11:00 AM PANEL The Science and Technology of Patient Input**

*Moderator:* **Annie Saha**, Director of Partnerships to Advance Innovation and Regulatory Science, FDA CDRH

*Panelists:*

**Leslie Wilson**, Professor of Health Policy and Economics, UCSF

**Barry Liden**, Vice President, Patient Engagement, Edwards Lifesciences

**Heidi Dohse**, President & Founder, Tour de Heart

**Joseph Ross**, Professor of Medicine and Public Health, Yale University

**11:50 AM Break**

**12:00 PM SESSION 1 Q&A**

*Moderator:* **Peter Sorger**; *Margaret Hamburg, Nilay Shah, Annie Saha, Leslie Wilson, Barry Liden, Heidi Dohse*

**12:30 PM Break**

**12:40 PM TALK COVID-19 in Iceland: Lessons Learned**

**Kari Stefansson**, Founder and CEO, deCODE genetics

**1:00 PM TALK The Regulatory Response to COVID-19 in APEC: Perspectives from Singapore**

**John Lim**, Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School, Singapore

**1:20 PM Break**

**1:30 PM PANEL Regulatory Response to Emerging Infectious Diseases & Healthcare Crises**

*Moderator:* **Florence Bourgeois**, Associate Professor of Pediatrics, Harvard Medical School, Co-Director, Harvard-MIT Center for Regulatory Science

*Panelists:*



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Steven Galson, Senior Vice President, Amgen  
Meredith Buxton, Chief Executive Officer, Global Coalition for Adaptive Research  
Paul Beninger, Director, MD/MBA Program, Tufts University School of Medicine  
Raffaella Sadun, Professor, Harvard Business School

**2:20 PM** **KEYNOTE “Regulatory Science”: Lessons from the Pandemic**

Janet Woodcock, Director, CDER, FDA (on detail)

**2:50 PM** **Break**

**3:00 PM** **SESSION 2 Q&A**

Moderator: **Mark Namchuk**; *Janet Woodcock, Kari Stefansson, Florence Bourgeois, Steven Galson, Meredith Buxton, Raffaella Sadun*

**3:30 PM** **Day 2 Recap and Conference Closing Remarks**

**Peter Sorger**, Professor of Systems Biology, Harvard Medical School, Co-Director, Harvard-MIT Center for Regulatory Science

**3:45 PM** **End of Day 2**

