HOSTED BY
Harvard-MIT Center for Regulatory Science

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**
Harvard-MIT CRS Leadership

10:10 AM KEYNOTE **Bridging the Data Gap Between the NCI and FDA**
Ned Sharpless, Director, National Cancer Institute, former Acting Commissioner of the FDA

10:40 AM TALK **Non-Canonical Trials in Gene Therapy**
George Daley, Dean of Harvard Medical School (HMS)

11:00 AM PANEL **Data Science for Innovative Trial Designs**
Moderator: Amy Abernethy, Principal Deputy Commissioner, Acting Chief Information Officer, FDA

Panelists:
Adam Palmer, Assistant Professor, University of North Carolina
Helga Gardarsdottir, Associate Professor, Utrecht University
Peter Mol, Vice-chair EMA Scientific Advice Working Party, Principal assessor at Medicines Evaluation Board
Steven Goodman, Associate Dean of Clinical and Translational Research and Professor of Epidemiology and Population Health, Stanford

11:50 AM **Break**

12:00 PM SESSION 1 Q&A
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**

1:00 PM TALK **AI, E-consent and Virtual Clinical Trials: Impact on Health Disparities**
Fadia Shaya, Professor & Director, Institute of Clinical and Translational Research, University of Maryland

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 Strategy, Janssen R&D, Johnson & Johnson

1:50 PM PANEL **Advances in Digital Medicine and Patient Care**
Moderator: Ariel Stern, Associate Professor, Harvard Business School
Panelists:
Andy Coravos, CEO, Elektra Labs
Ray Dorsey, Professor, University of Rochester Medical Center
Luca Foschini, Chief Data Scientist & Co-founder Evidation Health, Inc.
Timo Minssen, Professor, University of Copenhagen (UCPH), Founding Director of UCPH's Center for Advanced Studies in Biomedical Innovation

2:40 PM **Break**

2:50 PM SESSION 2 Q&A
Fadia Shaya, Sean Khozin, Ariel Stern, Andrea Coravos, Ray Dorsey, Luca Foschini, Timo Minssen

3:20 PM **Day 1 Recap**

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**
Harvard-MIT CRS Leadership

10:10 AM KEYNOTE
Peggy Hamburg, Chair of the Board AAAS, Foreign Secretary, National Academy of Medicine, former FDA Commissioner

10:40 AM TALK **Leveraging Patient-Centered Health Data Sharing Platforms for Medical Product Evaluation** (TENTATIVE TITLE)
Nilay Shah, Associate Professor, Mayo Clinic

11:00 AM PANEL **The Science and Technology of Patient Input**
Moderator: **Annie Saha**, Director of External Expertise and Partnerships, FDA CDRH
Panelists:
Leslie Wilson, Professor of Clinical Pharmacy, UCSF
Others: *TBA*

11:50 AM **Break**

12:00 PM SESSION 1 Q&A
Peggy Hamburg, Nilay Shah, Annie Saha, Leslie Wilson

12:30 AM **Break**

12:40 PM TALK **COVID-19 Topic** [TITLE TBD]
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 (CoRE), Duke-National University of Singapore (Duke-NUS) Medical School

1:20 PM **Break**

1:30 PM PANEL **Regulatory Response to Emerging Infectious Diseases & Healthcare Crises**
Moderator: **Florence Bourgeois**, Co-Director, Harvard-MIT CRS
Panelists:
Steven Galson, Senior Vice President for Global Regulatory Affairs and Strategy, Amgen
Meredith Buxton, Chief Executive Officer, Global Coalition for Adaptive Research
Paul Beninger, Associate Professor, Tufts University School of Medicine
Raffaella Sadun, Professor, Harvard Business School

2:20 PM	KEYNOTE Janet Woodcock, FDA Office of the Commissioner, former Director, Center for Drug Evaluation and Research
2:50 PM	**Break**
3:00 PM	SESSION 2 Q&A Janet Woodcock, Kari Stefansson, Florence Bourgeois, Steven Galson, Meredith Buxton, Paul Beninger
3:30 PM	**Day 2 Recap and Conference Closing Remarks**
3:45 PM	**End of Day 2**