



# The Harvard-MIT CRS Regulatory Science Symposium

April 2, 2019

8:30am - 7pm | American Academy of Arts and Sciences | Cambridge, MA

## Agenda

Registration and breakfast

**Welcome and Introduction to the Center for Regulatory Science (CRS)**

*Florence Bourgeois and Aaron Kesselheim, Harvard-MIT CRS Co-Directors*

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**Keynote:** Richard Platt, Harvard Pilgrim Health Care Institute

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**Session 1: Digital Health**

*Chaired by Florence Bourgeois, Harvard-MIT CRS*

Andy Coravos, Elektra Labs

Liza Hoffman, Beth Israel Deaconess Medical Center

John Brownstein, Boston Children's Hospital

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Morning Coffee Break

**Session 2: Legal and Ethical Challenges in International Clinical Trials**

*Chaired by Barbara Bierer, Brigham and Women's Hospital*

Stephen Rosenfeld, Quorum Review IRB

David Peloquin, Ropes & Gray LLP

Barbara Bierer, Brigham and Women's Hospital

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**Panel 1: Towards an Agile Regulatory Framework**

*Chaired by Gigi Hirsch, Massachusetts Institute of Technology*

Paul Howard, Food and Drug Administration

Anne-Virginie Eggimann, Bluebird Bio

Ed Pezalla, Enlightenment Bioconsult

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Lunch

**Session 3: Repurposing for Unmet Needs**

*Chaired by Artem Sokolov, Harvard Medical School*

Mark Albers, Massachusetts General Hospital

Joohee Sul, Food and Drug Administration

Sandro Santagata, Brigham and Women's Hospital

**Panel 2: Complex generics**

*Chaired and Moderated by Michael Sinha, Harvard-MIT CRS*

Rena Conti, Boston University

Wenlei Jiang, Food and Drug Administration

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Afternoon Coffee Break

**Session 4: Real World Evidence and Regulatory Decision Making**

*Chaired by Sebastian Schneeweiss, Brigham and Women's Hospital*

Jacqueline Corrigan-Curay, Food and Drug Administration

Jeremy Rassen, Aetion

Jessica Franklin, Brigham and Women's Hospital

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**Closing remarks**

*Florence Bourgeois and Aaron Kesselheim, Harvard-MIT CRS Co-Directors*

**Drinks Reception with Student and Trainee Poster Session**

Register at <https://bit.ly/2NxmN4N>

Submit a poster by **March 18**

For questions, reach out to us at [hits\\_regsci@hms.harvard.edu](mailto:hits_regsci@hms.harvard.edu)