Agenda

Registration and breakfast

Welcome and Introduction to the Center for Regulatory Science (CRS)
Florence Bourgeois and Aaron Kesselheim, Harvard-MIT CRS Co-Directors

Keynote: Richard Platt, Harvard Pilgrim Health Care Institute

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

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

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
Lunch

**Session 3: Repurposing for Unmet Needs**
*Chairred 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**
*Chairred 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**
*Chairred 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

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Submit a poster by **March 18**

For questions, reach out to us at hits_regsci@hms.harvard.edu