

Establishing a High-Quality Real-World Data Ecosystem

Duke-Margolis Center for Health Policy | 2-Day Online Workshop

Monday, July 13 | 1:00 – 4:00 pm ET

Tuesday, July 14 | 1:00 – 4:30 pm ET

Day 1 Agenda | Monday, July 13

- 1:00 pm** **Welcome and Overview**
- **Marta Wosińska**, Duke-Robert J. Margolis, MD, Center for Health Policy
- 1:10 pm** **Introduction: Establishing a High-Quality Real-World Data Ecosystem**
- Presentation: What is a High-Quality Data Ecosystem and Why is it Needed?*
- **Jacqueline Corrigan-Curay**, U.S. Food & Drug Administration
- Presentation: Cultural and Institutional Considerations to Align Stakeholders Around a High-Quality RWD Ecosystem*
- **Lesley Curtis**, Duke University
- 1:30 pm** **Session 1: Identifying Data Capture Challenges and Understanding Stakeholder Needs**
Moderator: Lesley Curtis, Duke University
- Panel Perspectives and Moderated Discussion*
- **Richard Moldwin**, College of American Pathologists
 - **Zach Hettinger**, MedStar Health Research Institute
 - **Andy Coravas**, Elektra Labs, Inc.
 - **Ernesto Ramirez**, Evidation Health, Inc.
- Audience Q&A*
- 2:10 pm** **Break**
- 2:20 pm** **Session 2: Emerging Insights and Lessons Learned from Initiatives to Optimize Data Capture at the Point of Care**
Moderator: Lesley Curtis
- Presenters*
- **Monica Bertagnolli**, Harvard Medical School and Brigham and Women's Hospital
 - **Laura Esserman**, The University of California, San Francisco

Panel Perspectives and Moderated Discussion

- **Eric Perakslis**, Duke University
- **Teresa Zayas Cabán**, Office of the National Coordinator for Health Information Technology
- **Peter Margolis**, Cincinnati Children's Hospital

Audience Q&A

3:30 pm **Spotlight: RWE Evidence Accelerator**

Presentation: Lessons Learned from COVID-19

- **Amy Abernethy**, U.S. Food & Drug Administration

Audience Q&A

4:00 pm **Day 1 Closing Remarks**

- **Lesley Curtis**, Duke University
- **Marta Wosińska**, Duke-Margolis Center for Health Policy

-- Day 2 Agenda on next page --

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Day 2 Agenda | Tuesday, July 14

- 1:00 pm** **Welcome and Opening Comments**
- **Mark McClellan**, Duke-Margolis Center for Health Policy
- 1:10 pm** **Session 3: Translating Early Successes of Core Data Element Programs to Therapeutic Areas beyond Oncology**
Moderator: Mark McClellan, Duke-Margolis Center for Health Policy
- Presenters*
- **Leslie Harrold**, Corrona, LLC
 - **Chhaya Shadra**, Verana Health, Inc
- Panel Perspectives and Moderated Discussion*
- **Patrick Ryan**, Janssen Research and Development
 - **Paul Friedman**, Mayo Clinic
 - **Peter DeVault**, Epic Systems Corporation
- Audience Q&A*
- 2:20 pm** **Break**
- 2:30 pm** **Session 4: Emerging Tools & Technologies to Support High-Quality Data Capture**
Moderator: Mark McClellan
- Panel Perspectives and Moderated Discussion*
- **Sam Roosz**, Datavant
 - **Ryan Moog**, Cerner Corporation
 - **Ian Shakil**, Augmedix, Inc.
 - **Stephanie Reisinger**, Veradigm Life Sciences, Allscripts Healthcare LLC
 - **Brian Anderson**, The MITRE Corporation
- Audience Q&A*
- 3:40 pm** **Session 5: Next Steps Toward Establishing a High-Quality RWD Ecosystem**
Moderator: Mark McClellan
- Panel Perspectives and Moderated Discussion*
- **Michael Vasconcelles**, Flatiron Health, Inc.
 - **Zubin Eapen**, HealthCore Inc.
 - **John Halamka**, Mayo Clinic
- Audience Q&A*
- 4:30 pm** **Day 2 Closing Remarks and Adjournment**

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