

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
- 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

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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

- Matthew Roe, Verana Health, Inc
- Leslie Harrold, Corrona, LLC

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, 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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