## 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

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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| 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 |
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 --
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

Funding for this workshop was made possible in part by a cooperative agreement from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written workshop materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.