2025 Duke-Margolis Convening on the State of Real-World Evidence Policy

Virtual Public Convening
Thursday, July 31
12 pm – 4:30 pm ET

Agenda

Meeting Objective:
The Duke-Margolis Real-World Evidence Collaborative's annual convening showcases the latest real-world data and evidence (RWD/E) policy developments.

12:00 pm **Welcome and Opening Remarks**
Rachele Hendricks-Sturrup, Duke-Margolis Institute for Health Policy

12:15 pm **Session 1: Fireside Chat on the State of RWE Policy in the US (35 mins)**
Objective: The convening will open with a conversation about current possibilities—and future visions—for RWD/E. We will hear expert insights and perspectives on how regulators, policymakers, and payers should approach RWE generation and implementation to foster a competitive, harmonized, and efficient landscape that supports robust innovation in patient care.

Moderator: **Mark McClellan,** Duke-Margolis Institute for Health Policy
Discussant: **Robert Califf,** Duke University
Discussant: **Steve Farmer**, ABIG Health
Discussant: **Donna Rivera,** U.S. FDA

12:50 pm **Session 2: Cultivating the Integration of Research into Care (50 mins)**
Objective: This session will explore the opportunities and challenges in scaling point-of-care and pragmatic trials for prospective RWD collection and accrual. The goal of this discussion is to offer valuable and actionable insights advancing pre- and post-market evidence generation to meet the needs of regulators, policymakers, payers, patients, and providers.

Moderator: **Brian Canter,** Duke-Margolis Institute for Health Policy
Panel Discussion:

- **Amy Abernathy***,* Highlander Health
- **Michael Mack,** Baylor Scott & White
- **Ivy Altomore,** Flatiron Health
- **Amanda Borens,** Tesselate Data Consulting
- **Heather Stone,** U.S. FDA

1:40 pm **Session 3: Progress on RWE to Support Reasonable and Necessary Payer Coverage (50 mins)**

Objective: This session will focus on current emerging strategies to ensure RWD/E is capable of generating high-quality and compelling evidence that meets the coverage needs of patients, health systems, payers, and regulators. Panelists will highlight current initiatives underway to develop standardized RWE frameworks intended to guide payer decisions and pricing of medical products and related health care services.

Moderator: **XXXX,** Duke-Margolis Institute for Health Policy
Panel Discussion:

- **Shirley Wang,** Harvard University and Brigham and Women's Hospital
- **Cate Lockhart,** AMCP
- **Ashley Jaska,** Aetion
- **Kate Davidson,** CMMI

2:30 pm **Break (15 mins)**

2:45 pm **Session 4: Shaping the International RWE Regulatory Policy Landscape (50 mins)**
Objective: The session will bring together global stakeholders to discuss the evolving role of RWE in regulatory policy, review key areas of proposed alignment across regions, and share opportunities to address signs of misalignment. Panelists will discuss how they are considering the integration of RWE into decision-making processes and how to strengthen international collaboration in regulatory approaches.

Moderator: **Valerie J. Parker,** Duke-Margolis Institute for Health Policy
Panel Discussion:

- **Gracy Crane,** Roche
- **Julia (Jingyu) Luan,** AstraZeneca
- **Daniel Rosenberg**, J&J and ICH
- **Chiho Suzuki**, PMDA

3:35 pm **Session 5: Sharing Lessons Learned to Date on RWE to Support Regulatory Decision-Making (45 mins)**
Objective: This session will share lessons learned across a breadth of regulatory use cases involving RWD/E. Panelists will discuss present challenges to developing RWD/E to address questions of regulatory concern. Lastly, participants will also discuss key steps to transform those challenges into opportunities to co-create with regulators.

Moderator: **Rachele Hendricks-Sturrup,** Duke-Margolis Institute for Health Policy
Panel Discussion:

- **Anne-Marie Meyer,** Independent Advisor
- **Heather Rubino,** Pfizer

- **Chris Kim,** Amgen

4:20 pm **Closing Remarks and Adjournment**