

## 2024 Duke-Margolis Convening on the State of Real-World Evidence Policy

**Thursday, July 25, 2024**

**12 – 4:30 p.m. ET**

Virtual Public Convening

### **Meeting Objective:**

Convened with the Duke-Margolis Real-World Evidence Collaborative, this public convening will provide a venue to review recent RWE Collaborative activities, strategic real-world data and real-world evidence (RWD/E) policy developments, and promising future applications of RWD/E.

### **Convening Agenda**

**12:00 p.m. Welcome and Keynote**

**Mark McClellan**, Duke-Margolis Institute for Health Policy

**12:15 p.m. FDA Remarks**

U.S. Food and Drug Administration

**12:35 p.m. Session 1: Duke-Margolis RWE Collaborative Updates**

Moderator: **Rachele Hendricks-Sturup**, Duke-Margolis Institute for Health Policy

Objective: This session will provide a summary of RWE Collaborative activities over the past year. It will highlight 2024 white paper publications and discuss how this work informs the Duke-Margolis Institute for Health Policy's broader goals. A fireside chat with media members will examine noticeable trends in, and corresponding next steps for, RWD/E.

Presentation: Overview of 2024 Duke-Margolis White Papers and International Harmonization

**Rachele Hendricks-Sturup**, Duke-Margolis Institute for Health Policy

Fireside Chat with Regulatory Intelligence Professionals

**Joanne Walker**, The Evidence Base

**Laura DiAngelo**, AgencyIQ

Open Discussion and Q&A

**1:15 p.m. Session 2: Source Data Access for Decision-Makers**

Moderator: **Trevan Locke**, Duke-Margolis Institute for Health Policy

Objective: This session aims to identify common challenges in access to high quality, reliable, and relevant real-world health care data sufficient for regulatory review and strategies to overcome them. Participants will discuss barriers to providing regulators with source data at the patient-level and opportunities to address those barriers. Discussion will include data standardization efforts that could improve the collection of real-world data and its transformation into research ready, analytic datasets.

Panel Discussion:

**Nicholaas Honig**, Aetion, Inc.

**Stella Chang**, OMNY Health

**Katy Sadowski**, Boehringer-Ingelheim

**Dena Jaffe**, Oracle Health

Open Discussion and Q&A

**2:10 p.m. Break**

**2:30 p.m. Session 3: Applications of Artificial Intelligence in RWE Studies**

Moderator: **Christina Silcox**, Duke-Margolis Institute for Health Policy

Objective: This session aims to provide a policy overview of the intersection between RWE and artificial intelligence (AI) while fostering meaningful discussions and collaboration among session participants. Panelists will discuss exemplary use cases that highlight integration of AI and RWD in regulatory science.

Panel Discussion:

**David Rhew**, Microsoft

**Jaime Smith**, Parexel

**Hussein Ezzeldin**, U.S. Food and Drug Administration

**Joe Franklin**, Verily Life Sciences

Open Discussion and Q&A

**3:30 p.m. Session 4: Leveraging RWD for Pricing, Coverage, and Payment**

Moderator: **Beena Bhuiyan Khan**, Duke-Margolis Institute for Health Policy

Objective: This session will provide an overview of the current RWE policy landscape with a focus on emerging opportunities for the use of RWD/E to inform payment and coverage decisions for novel technologies. Panelists will discuss how different stakeholders are using RWD/E to inform payment and coverage policies. Stakeholders will also discuss the impact of the IRA's drug pricing provisions on the

use of RWE. Additionally, participants will discuss strategic plans for stakeholders to engage on what types of RWE and what sources of RWD may be most useful to inform such policy decisions.

Panel Discussion:

**Lee Fleisher**, Rubrum Advising

**Rodrigo Refoios Camejo**, GSK

**Annette James**, American Academy of Actuaries

**Inmaculada Hernandez**, University of California San Diego

**4:30 p.m.**      **Concluding Remarks**  
**Rachele Hendricks-Sturup**, Duke-Margolis Institute for Health Policy

**4:45 p.m.**      **Adjournment**

This meeting is made possible through the generosity of the Margolis Family Foundation, which provides core resources for the Institute, as well as a combination of financial and in-kind contributions from RWE Collaborative members.