

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

Richard Forshee, 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.

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:

Dena Jaffe, Oracle Health

Stella Chang, OMNY Health

Katy Sadowski, Boehringer-Ingelheim

Nicholaas Honig, Aetion, Inc.

Open Discussion and Q&A

2:15 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

Joe Franklin, Verily Life Sciences

Hussein Ezzeldin, U.S. Food and Drug Administration

Open Discussion and Q&A

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

Moderator: **Nitzan Arad**, 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

Inmaculada Hernandez, University of California San Diego

Rodrigo Refoios Camejo, GSK

Annette James, American Academy of Actuaries

4:30 p.m. Concluding Remarks

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

4:45 p.m. Adjournment

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