

2022 Duke-Margolis Convening on the State of Real-World Evidence Policy

Virtual Public Workshop Agenda
May 12, 2022

12:00 pm – 5:00 pm ET

Meeting Objective: Convened by the Duke-Margolis Real-World Evidence Collaborative, this public conference will provide stakeholders a venue for reviewing progress to-date on strategic RWD and RWE policy development activities and on promising future applications of these data and evidence.

12:00 pm **Welcome and Overview**

Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

12:15 pm **Keynote**

Jacqueline Corrigan-Curay, U.S. Food and Drug Administration

12:35 pm **Session 1: Advancing Regulatory Acceptability of RWE**

Objective: Since the release of CDER’s RWE Framework in 2018, multi-stakeholder collaborations have explored the opportunities for and challenges to the use of RWE in regulatory decision making. Building on these discussions, in 2021 the FDA released four draft guidance documents that cover a range of important topics and regulatory considerations for appropriately utilizing real world data and evidence. This session will discuss the published draft guidance, summarize key themes across public comments submitted, and highlight areas of alignment as well as opportunities to further clarify key aspects of regulatory use of RWE moving forward.

Moderator: Rachele Hendricks-Sturupp, Duke-Robert J. Margolis, MD, Center for Health Policy

Presentation: Guidance document and public comment overview

Adam Aten and Trevan Locke, Duke-Robert J. Margolis, MD, Center for Health Policy

Panel Discussion:

Angela Dobes, Crohn’s & Colitis Foundation

Nancy Dreyer, IQVIA and ISPE

Jeremy Rassen, Aetion

Nicole Mahoney, Novartis

Richard Willke, ISPOR

Open Discussion and Q&A

1:55 pm **Break**

2:10 pm

Session 2: Re-imagining Evidence Generation: Opportunities for Developing Shared Evidence and Point of Care Clinical Trials

Objective: This session will provide an overview of the RWE Collaborative's latest white papers that re-imagine how RWE can be generated from across the health system to inform a range of evidentiary needs. The white papers center on emerging opportunities for addressing shared evidence needs across stakeholders and improving the development of RWE as part of Point-of-Care Trials.

Moderator: Rachele Hendricks-Sturupp, Duke-Robert J. Margolis, MD, Center for Health Policy

Presentation: Overview of RWE Collaborative White Papers

Rachele Hendricks-Sturupp, Duke-Robert J. Margolis, MD, Center for Health Policy

Panel Discussion:

Marc Berger, ISPOR

Gracie Lieberman, Formerly Genentech

Sally Okun, Clinical Trials Transformation Initiative

Open Discussion and Q&A

3:00 pm

Session 3: What's Next for the Use of RWE?

Objective: In this session, discussants will explore potential strategies or opportunities moving forward to advance the use of real-world evidence in various settings. A lead-off presentation will cover draft legislative proposals including Cures 2.0 and PREVENT Pandemics Act and the PDUFA VII commitments related to RWE. Two separate panels will follow the presentation. The first panel will focus on data considerations including data infrastructure, data quality, and privacy considerations, and the second panel will discuss a range of RWE use cases that could inform its further application.

Presentation: Overview of draft legislative proposals and RWE commitments

Dure Kim, Duke-Robert J. Margolis, MD, Center for Health Policy

Panel Discussion 1: Data Considerations

Moderator: Rachele Hendricks-Sturupp, Duke-Robert J. Margolis, MD, Center for Health Policy

Jeff Brown, TriNetX

Elise Berliner, Cerner Enviza

Luca Foschini, Evidation

Lauren Silvis, Tempus

Open Discussion and Q&A

Panel Discussion 2: Learning from RWE Pilot Projects

Moderator: Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

Stephanie Reisinger, Flatiron Health

Shirley Wang, Brigham and Women's Hospital/ISPOR and ISPE

Laura Roe, Verily

Solomon Iyasu, Merck

Open Discussion and Q&A

4:45 pm **Closing Remarks and Adjournment**

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

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