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 Building on these discussions, in 2021 the FDA released four draft guidance documents that cover a range of important topics and regulatory considerations for appropriately utilizing real world data and evidence. This session will discuss the published draft guidance, summarize key themes across public comments submitted, and highlight areas of alignment as well as opportunities to further clarify key aspects of regulatory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-Sturrup, 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-Sturrup, Duke-Robert J. Margolis, MD, Center for Health Policy

Presentation: Overview of RWE Collaborative White Papers
  Rachele Hendricks-Sturrup, 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-Sturrup, 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

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