Meeting Objective: Convened by the Duke-Margolis Real-World Evidence Collaborative, this public conference will provide a venue for reviewing recent Collaborative activities, real-world data (RWD) and real-world evidence (RWE) policy developments, and promising future applications of RWD/RWE. Discussion will focus on the role of master protocols for RWE, evaluating real-world efficacy in patient subgroups, and the generation of more practically relevant evidence by leveraging RWD.

12:30 pm Welcome and Overview of RWE Policy Updates
Rachele Hendricks-Sturrup, Duke-Robert J. Margolis, MD, Center for Health Policy

12:50 pm Keynote

1:15 pm Session 1: Role of Master Protocols for RWE
Objective: Discussion will center around how research involving real-world data and real-world evidence can apply lessons learned from traditional clinical trials, which have utilized master and common protocols. Additionally, panelists will share thoughts on how different research contexts can best leverage master protocols to fit with the research question. Finally, data considerations when designing master protocols for both prospective and retrospective studies will be explored.

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

Presentation: Overview of RWE Master Protocols White Paper
Rachele Hendricks-Sturrup, Duke-Robert J. Margolis, MD, Center for Health Policy

Panel Discussion
Open Discussion and Q&A

2:15 pm Break

2:25 pm Session 2: Evaluating Real-World Efficacy in Patient Subgroups
Objective: There is measurable value in understanding the individual and/or combined influence of clinical and demographic characteristics among patient subgroups, especially in cases where such characteristics can be a proxy for observable variations in treatment effects. In this session, we describe opportunities and challenges to identifying, understanding, and leveraging RWD to estimate and measure treatment effects among and across patient subgroups. We will also discuss important terminology considerations that accompany measurements of therapeutic effect in subgroups, supplementing clinical
trials with RWD for subgroup analysis, leveraging RWD as an equitable solution to address data missingness, and leveraging RWD to improve care among patient subgroups.

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

**Presentation:** Overview of Patient Subgroups White Paper

**Nora Emmott,** Duke-Robert J. Margolis, MD, Center for Health Policy

**Panel Discussion**

**Open Discussion and Q&A**

**3:25 pm**  
**Session 3: Generating Practically Relevant Evidence with Real World Data**

**Objective:** This discussion will explore opportunities to leverage advances in real-world data collection and evaluation to integrate clinical research into the point-of-care. Panelists will discuss their future visions for leveraging RWD at the point-of-care to improve our ability to efficiently generate evidence and improve outcomes for patients.

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

**Presentation:** Overview of LHS White Paper and ACT@POC

**Trevan Locke,** Duke-Robert J. Margolis, MD, Center for Health Policy

**Panel Discussion**

**4:25 pm**  
**Closing Remarks and Adjournment**

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

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