

Developing Study Endpoints in Real-World Settings

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

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Agenda

- 1:30 pm** **Welcome and Overview**
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy
- 1:35 pm** **Session I: A Roadmap for Developing Endpoints in Real-World Settings**
Objective: Given the multi-stakeholder nature of real-world endpoint development, a need exists to standardize key terms and concepts. Using common terminology, this presentation will walk through a new research roadmap for developing effectiveness endpoints in the real-world setting.
Presentation:
- Kerra Mercon, Duke-Robert J. Margolis, MD, Center for Health Policy
- 1:50 pm** **Session II: Selecting and Validating the Assessment Tool**
Objective: Differences in data collection practices, patient populations, and care patterns in the real-world setting may require the selection of different endpoint components than would be chosen for a clinical trial. In this session, panelists will discuss the unique considerations for developing and validating endpoints in the real-world setting, building on the lessons learned from the clinical trial setting.
Moderator: Mark McClellan
- Panelists:*
- Linda Nelsen, GlaxoSmithKline
 - Bryce Reeve, Duke University
 - Vincent Willey, HealthCore
 - Jennifer Goldsack, Digital Medicine Society (DiMe)
- Moderated Q&A*
- 2:25 pm** **Session III: Policy Implications for Advancing the Acceptability of Real-World Endpoints**
Objective: In this session, panelists will explore the opportunities to advance endpoint development and validation through multi-stakeholder collaboration. Discussion will cover the importance of developing endpoints that are meaningful a range of stakeholders and the potential to harmonize endpoints across a therapeutic area.
Moderator: Mark McClellan
- Panelists:*
- Bellinda King-Kallimanis, LUNgevity Foundation
 - Eric Klein, Eli Lilly and Company
 - Elisabeth Oehrlein, National Health Council
- Moderated Q&A*
- 2:55 pm** **Next Steps and Closing Remarks**
Mark McClellan