



Advancing Representative Enrollment in Clinical Trials

Virtual Public Webinar
July 18, 2023

Draft Agenda

Meeting Objective:

This public meeting will explore challenges to achieving representative enrollment in clinical trials. Topics discussed will include opportunities to synthesize best practices where possible and identify policy levers for achieving measurable change. We will also explore learnings and examples from the current clinical trial landscape with an eye towards improving clinical trial conduct across a broad range of clinical sites and locations by advancing pragmatic trial principles. Panel discussions will focus on critically examining actionable steps various stakeholders can take to advance the mission of representative trial enrollment.

12:00 p.m. Welcome and Opening Remarks

12:10 p.m. Presentation

Overview of Duke-Margolis' work thus far around representation in clinical trials and level setting on key terminology and goals for this meeting

12:25 p.m. Session 1: Defining the Current Clinical Trial Landscape

Moderator: Trevan Locke, Duke-Margolis Center for Health Policy

Presentation

- Brief presentation to provide an overview of the stakeholders involved with this topic and why cooperation and alignment from the various stakeholders is essential for meaningful change in this domain

Objective

- Describe challenges in achieving representative trial enrollment from the perspective of various stakeholders
- Discuss how trial representation goals can be measured
- Discuss the current policy and regulatory landscape surrounding trial representation
- Explore patient and community needs in trial participation

1:25 p.m. Break

1:35 p.m. Session 2: Building Capacity for Representative Trials in Community Settings
Moderator: Andrea Thoumi, Duke-Margolis Center for Health Policy

Presentation: Duke-Margolis Staff

- Overview of key findings thus far and level setting for the discussion

Objective

- Discuss broad strategies and areas of opportunity for improving representative trial enrollment that were outlined in literature and highlighted within interviews with stakeholders
- Discuss how alternative trial methodologies can promote representative enrollment
- Explore the role of education and community partnerships in promoting representative enrollment
- Consider financial, technological, and cultural barriers to trial implementation

2:35 p.m. Fireside Chat
Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

2:55 p.m. Session 3: Defining the Role of Various Stakeholders in Improving Trial Representation
Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Presentation

- Overview of early recommendations to kick off discussion

Objective:

- Discuss areas of opportunity and accountability measures for various stakeholders
- Discuss role of culture change in fostering a culture of research that benefits patients and clinicians (e.g., changing funding structures/ requirements for participants (e.g., SSN requirement that prevents/discourages individuals with immigration concerns from participation, improving representation within research and medical settings), acknowledging historical and current practices within the trial space and medical domains that discourage participation, improving transparency of trial and clinical research findings)

3:55 p.m. Closing Remarks

4:00 p.m. Adjournment