

Advancing Representative Enrollment in Clinical Trials

Virtual Public Webinar

July 18, 2023

12:00-4:00 Eastern

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

12:10 p.m. **Introduction: Key Terminology, Meeting Goals, Level Setting**
Trevan Locke, Duke-Robert J. Margolis, MD, Center for Health Policy

12:25 p.m. **Session 1: Defining the Current Clinical Trial Landscape**
Objective: This session will describe current challenges to achieving representative trial enrollment from the perspective of various stakeholders. Panelists will discuss the best ways to measure success in achieving representation goals, the impact of the current policy and regulatory landscape, and progress made in recent years to advance representative trial enrollment.

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

Presentation: Measuring Clinical Trial Representativeness
Jen Miller, Yale School of Medicine

Panel Discussion

- Jen Miller, Yale School of Medicine
- Lola Fashoyin-Aje, Oncology Center of Excellence, FDA
- Sneha Dave, Generation Patient

1:25 p.m. **Break**

1:35 p.m. **Session 2: Building Capacity for Representative Trials in Community Settings**
Objective: This session will discuss broad strategies and areas of opportunity for improving representative trial enrollment through community engagement and capacity building. Panelists will discuss alternative approaches to conducting clinical trials, explore the role of education and community partnerships in promoting representative enrollment, and consider current financial, technological, and cultural barriers to trial implementation in community settings.

Moderator: Andrea Thoumi, Duke-Robert J. Margolis, MD, Center for Health Policy

Opening Remarks: Sandra Yankah, Duke-Robert J. Margolis, MD, Center for Health Policy

Panel Discussion

- **Nadine Barrett**, Duke CTSI Center for Equity in Research
- **Perla Nunes**, Julius L. Chambers Biomedical Biotechnology Research Institute
- **Yasmeen Long**, FasterCures
- **Jennifer Byrne**, Javara

2:35 p.m.

Fireside Chat

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

Kirsten Bibbins-Domingo, JAMA; University of California, San Francisco

2:55 p.m.

Session 3: Defining the Role of Various Stakeholders in Improving Trial Representation

Objective: This session will discuss actionable next steps for various stakeholders and relevant accountability measures for ensuring progress on trial representation efforts. Discussion will include strategies for fostering a culture of representative and trustworthy research, the potential role of point-of-care trial and other innovative trial approaches, avenues for introducing or refining policies to encourage representative enrollment, and strategies for addressing remaining gaps to operationalizing representative enrollment.

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

Presentation: Overview of Duke-Margolis preliminary recommendations

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

Panel Remarks:

- **Sara Calvert**, Clinical Trials Transformation Initiative
- **Carla Rodriguez-Watson**, Reagan Udall Foundation for the FDA
- **Salina Waddy**, National Center for Advancing Translational Sciences
- **Megan McKenzie**, Genentech
- **Silas Buchanan**, Institute for eHealth Equity

3:55 p.m.

Closing Remarks

4:00 p.m.

Adjournment

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