Fostering Collaboration to Advance Representative Enrollment in Clinical Trials

March 28, 2024

Duke | MARGOLIS INSTITUTE *for* Health Policy

Welcome and Opening Remarks

Trevan Locke, Duke-Margolis Institute for Health Policy

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Workshop Agenda

10:00 a.m.	Welcome
10:10 a.m.	Opening Presentation
10:25 a.m.	Session 1: Moving Beyond Targeted Outreach Towards Continual Community Engagement
11:25 a.m.	Break
11:35 a.m.	Session 2: Building and Scaling Innovative Clinical Trial Infrastructure
12:35 p.m.	Break
12:50 p.m.	Session 3: Funding Considerations to Increase Representativeness in Clinical Trials
1:50 p.m.	Session 4: Future Reflections
2:35 p.m.	Closing Remarks
2:45 p.m.	Adjournment

Meeting Notes

- Support for this event was provided by the Robert Wood Johnson Foundation. The views expressed here do not necessarily reflect the views of the Foundation.
- These slides and a recording of this event will be available on the Duke-Margolis website in 3-5 business days

Audience Participation

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What sector best represents you?

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Setting the stage

- Despite a growing body of work to address lack of representation in clinical trials, major gaps remain
- Meanwhile, there is a push to reimagine clinical trial conduct leveraging a modern trial infrastructure
- By integrating leading community engagement practices with robust infrastructure and supportive funding models, we can develop trials that are more inclusive, accessible, and impactful

What do we mean by representation?

- An equitable clinical research infrastructure would be comprised of clinical trials and studies that accurately match the demographics of the disease burden under study
- Such trials would be adequately powered to answer meaningful questions about safety and efficacy in underrepresented subpopulations
- Clinical research should be a two-way street with patients and communities contributing to question identification and prioritization

The Current Landscape

- The federal government is setting standards and requirements for encouraging representativeness in clinical trials. Under FDORA, passed by Congress in 2022, FDA will require drug sponsors to submit diversity action plans for their trials. Updated guidance for these plans is pending.
- In 2020, Congress passed the Clinical Trial Treatment Act, which requires all state Medicaid programs to cover routine costs associated with qualifying clinical trials. This act went into effect in 2022.
- In 2022, the National Academies released a report titled: Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups.
- In 2023, CTTI released recommendations for improving diversity in clinical trials and a corresponding maturity model.
- MRCT has released several interrelated resources to support more diverse and inclusive representation.
- Trial sponsors, payers, academic journals, and other stakeholders have engaged in voluntary efforts to increase trial representation.

Advancing Representative Enrollment in Clinical Trials; July 18, 2023

- How do we define what good looks like?
- How do we build capacity for representative trials in community settings?
- What should expectations for stakeholders be?

https://youtu.be/XP4AiTc73kc

Moving the conversation forward

- What further actions are required?
- How do we measure the success of those actions?
- How do we make sure approaches are sustainable and scalable?
- Who is responsible for investing time and resources to make those actions feasible?

Shared Goals

- Move Beyond Targeted Outreach Towards Continual Community Engagement
- Build and Scale Innovative Clinical Trial Infrastructure
- Explore Funding Strategies to Increase Representativeness in Clinical Trials

Moving Beyond Targeted Outreach Towards Continual Community Engagement

- The role of community outreach in driving improved health outcomes is widely acknowledged, however, there is still a lack of sustained community engagement.
- Community engagement involves building relationships within a community to foster trust, community building, and investment in local initiatives.
- There is a need to identify and adopt standards for community engagement that promote sustainability and scalability.
- With this as a foundation, providing support for other aspects of representative clinical trials will be more impactful.

Building and Scaling Innovative Clinical Trial Infrastructure

- Traditional clinical trials, while a gold standard for evidence generation, are also often exclusive in several ways.
- As more pragmatic trial approaches proliferate, there are opportunities to make clinical research more accessible to more people while still generating relevant evidence about populations in the real-world.
- However, the infrastructure to power these trials is still fragmented and in development
- Sustained investment is needed to create robust innovative trial infrastructure that can make clinical research more accessible.

Funding Considerations to Increase Representativeness in Clinical Trials

- True success in achieving representative trials will require sustained investment in community engagement, trial infrastructure, workforce development, among other areas.
- Government and industry funding will likely make up the bulk of this investment
- To drive that investment, business models and business cases that showcase the potential value of investing in representative clinical research should be explored.
- For example, some evidence suggests that prioritizing representative enrollment is not any slower than nonrepresentative enrollment.

Acknowledging and addressing systemic issues

- Today, we'll discuss many of the most important topics around more representative clinical trials.
- However, there are additional systemic issues such as lack of insurance, language barriers, lack of time/resources, and other barriers that will continue to be a concern for trial participation.
- Furthermore, this issue is not a checklist or numbers game. Truly representative trials require addressing concerns of potential participants, involving a diverse enough population that trials are powered to make informed decisions, and fostering bidirectional relationships between sponsors and participants.

Session 1: *Moving Beyond Targeted Outreach Towards Continual Community Engagement*

Moderator: **Sandra E. Yankah**, Duke-Margolis Institute for Health Policy

Speakers

Andrea Thoumi, Duke-Margolis Institute for Health Policy

Nadine Barrett, Wake Forest University School of Medicine

Bridgette McCullough, ACIRAH Health

Perla Nunes, Perla Nunes Consulting

Silas Buchanan, Institute for eHealth Equity

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What is one word that comes to mind when you think of meaningful and lasting community engagement?

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Session 2: *Building and Scaling Innovative Clinical Trial Infrastructure*

Moderator: **Trevan Locke**, Duke-Margolis Institute for Health Policy

Speakers

Pamela Tenaerts, Medable, Inc.

Meghan McKenzie, Genentech

Amanda Wagner Gee, Milken Institute

Martin Mendoza, National Institutes of Health

Grail Sipes, Office of Science and Technology Policy

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Are pragmatic/point-of-care trials a viable means of improving evidence generation in non-academic research settings?

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In one or two words describe the most pressing infrastructure change needed to support community hospitals engaging in clinical research.

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Session 3: *Funding Considerations to Increase Representativeness in Clinical Trials*

Moderator: **Marianne Hamilton Lopez**, Duke-Margolis Institute for Health Policy

Speakers

Donna O'Brien, Manatt Health

Jennifer Gibson Levy, Henry Ford Health System

Jennifer Byrne, Javara

Priscilla Pemu, Morehouse School of Medicine

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Who is most responsible for investing to drive better representation?

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Session 4: *Future Reflections*

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Moderator: **Salimah El-Amin**, Duke University

Speakers

Mimi Fenton, Walmart Healthcare Research Institute

Adrienne Martinez-Hollingsworth, AltaMed Health Services

Michel Reid, GSK

Barbara Bierer, Brigham and Women's Hospital & Harvard Medical School

Carolyn Shore, National Academies of Sciences, Engineering, and Medicine

Closing Remarks

Trevan Locke, Duke-Margolis Institute for Health Policy

Thank You!

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