



Envisioning a Transformed Clinical Trials Enterprise for 2030 A 4-Part Virtual Workshop

January 26, February 9, March 24, and May 11, 2021

This virtual public workshop will provide a venue for stakeholders to consider a transformed clinical trial enterprise for 2030. Workshop participants will consider lessons learned from progress and setbacks over the past 10 years, since the previous 2011 workshop, *Envisioning a Transformed Clinical Trials Enterprise* in the United States, and, looking forward, discuss goals and key priorities for advancing a clinical trials enterprise that is more efficient, effective, person-centered, inclusive, and integrated into the health delivery system of 2030.

This virtual workshop will be conducted in four parts:

- Part One (January 26, 2021) provided an overview discussion on how an envisioned 2030 clinical trials enterprise may differ from the current system. It discussed key challenges and opportunities in improving person-centeredness and inclusivity, building resilience and transparency, and integrating new technologies.
- Part Two (February 9, 2021) will consider achievable goals to enhance person-centeredness and inclusivity in the clinical trials enterprise; and discuss ways to improve public engagement and partnership. This part of the workshop will:
 - Discuss practical short-term and long-term goals for improving the person-centeredness and inclusivity of the clinical trials enterprise; and
 - Consider specific action steps that stakeholders could individually take to support an envisioned change in the next 5 years (by 2025) and in the next 10 years (by 2030).
- Part Three (March 24, 2021) will consider approaches to build resilience, sustainability, and transparency. The discussion will include the convergence and integration of clinical research and clinical practice; data sharing and management; and efficient, engaging scientific communication.
- Part Four (May 11, 2021) will consider ways the thoughtful and deliberate use of new technologies could improve the clinical trials enterprise and support goals outline in prior virtual workshop parts.

For additional information on the virtual workshop, please visit [the main project page](#).

Workshop Part 2: February 9, 2021

Enhancing Outcomes in a More Person-Centered and Inclusive Clinical Trials Enterprise

11:00a.m. – 3:00p.m. ET

- 11:00 a.m. **Welcome and Opening Remarks**
STEVEN GALSON, *Workshop Co-chair*
Senior Vice President, Research & Development
Amgen, Inc.
- ESTHER KROFAH, *Workshop Co-chair*
Executive Director
FasterCures, Milken Institute
- LUTHER CLARK, *Moderator*
Deputy Chief Patient Officer &
Global Director, Scientific, Medical, and Patient Perspective
Merck & Co., Inc.

SESSION I THE ROAD TO 2030: AN ATLAS FOR CHANGE

- 11:10 a.m. **Frontline Experience: A Fireside Chat**
ESTHER KROFAH, *Moderator*
Executive Director
FasterCures, Milken Institute
- ELISEO PÉREZ-STABLE
Director
National Institute on Minority Health and Health Disparities
National Institutes of Health
- RICHARDAE ARAOJO
Associate Commissioner for Minority Health
Director, Office of Minority Health and Health Equity
U.S. Food and Drug Administration
- MEGAN O'BOYLE
Principal Investigator, Phelan-McDermid Syndrome Data Network
PCORI
- 11:45 a.m. **Charge to the Breakout Groups**
- 11:50 a.m. **“Lightning Round” Breakout Discussion Groups (30 min)**

- *What are 1-2 **short-term**, tangible and measurable goals to ensure a more person-centered and inclusive clinical trials enterprise that should be met within the next 5 years – by 2025?*
- *What technologies, tools, or techniques could be transformational to improving inclusiveness and equity in the clinical trials enterprise over the next 5 years?*

12:30 p.m. **Session I Wrap Up** (10 min)

12:45 p.m. **BREAK** (30 min)

SESSION II THE ROAD TO 2030: A CALL TO ACTION

1:15 p.m. **“North-Star” Visions of What Is Possible** (10 min each)

SILAS BUCHANAN
Chief Executive Officer
Institute for eHealth Equity

MARILYN A. METCALF
Senior Director, Patient Engagement
GlaxoSmithKline

1:40 p.m. **Frontline Experience: A Road Already Travelled**

MARGARET ANDERSON
Consulting Managing Director, Strategy and Analytics
Deloitte

1:50 p.m. **Charge to the Breakout Groups**

2:00 p.m. **“Lightning Round” Breakout Discussion Groups** (30 min)

- *What are 1-2 **long-term**, tangible and measurable goals to ensure a more person-centered and inclusive clinical trials enterprise that should be met within the next 10 years – by 2030?*
- *What technologies, tools, or techniques could be transformational to improving inclusiveness and equity in the clinical trials enterprise over the next 10 years?*

2:30 p.m. **Session II Wrap Up** (10 min)

WRAP UP

2:45 p.m. **Wrap Up Discussion and Closing Remarks**

LUTHER CLARK, *Moderator*
Deputy Chief Patient Officer &
Global Director, Scientific, Medical, and Patient Perspective

Merck & Co., Inc.

ESTHER KROFAH, *Workshop Co-chair*
Executive Director
FasterCures, Milken Institute

STEVEN GALSON, *Workshop Co-chair*
Senior Vice President, Research & Development
Amgen, Inc.

3:00 p.m.

Adjourn