The National Academies of SCIENCES ENGINEERING MEDICINE

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

Envisioning a Transformed Clinical Trials Enterprise for 2030 – A 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) considered achievable goals to enhance person-centeredness and inclusivity in the clinical trials enterprise; and discussed ways to improve public engagement and partnership.

- Part Three (March 24, 2021) considered approaches to build resilience, sustainability, and transparency. The discussion included 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 outlined in prior virtual workshop parts. Discussion in this part of the workshop will**

    - **Discuss practical short-term and long-term goals for ensuring thoughtful and deliberate partnership with and use of new technologies to improve 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).**

For additional information on the virtual workshop, please visit the main project page.

Workshop Part 4: May 11, 2021

Practical Applications for Technology to Enhance the 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, Global Regulatory Affairs and Safety
Amgen, Inc.

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

SESSION I THE ROAD TO 2030: AN ATLAS FOR CHANGE

Moderator: JENNIFER GOLDSACK
Executive Director
Digital Medicine Society

11:10 a.m. **Keynote address**
AMY ABERNETHY
Former Principal Deputy Commissioner of Food and Drugs
U.S. Food and Drug Administration

11:25 a.m. **Frontline Experience: A Panel Discussion**
A perspective on patient burden and accessibility
TARA HASTINGS
Senior Associate Director of Patient Engagement
Michael J. Fox Foundation

A perspective on digital law
JAN BENEDIKT BRÖNNEKE
Director Law & Economics Health Technologies
health innovation hub

A perspective on improving software and experience for clinical trial sites
BRADFORD HIRSCH
Chief Executive Officer
SignalPath Research

11:55 a.m. **Charge to the Breakout Groups**

12:00 p.m. **"Lightning Round" Breakout Discussion Groups** *(25 min)*

The breakout groups will be assigned one of the two following goals and asked to discuss practical applications and partnerships with new technologies that can address key priority challenges, opportunities aligned with this goal that will move us towards the clinical trials enterprise envisioned for 2030. See associated breakout discussion guides for more detail.

- **GOAL 1**: **Enable a more person-centered and easily accessible clinical trials enterprise.** This also relates to the vision of the Clinical Trial Transformation Initiative for 2030: https://www.ctti-clinicaltrials.org/transforming-trials-2030
- **GOAL 2: Simplify trials (less data collection, fewer site visits) and lower costs while still generating high-quality data and robust answers to relevant research questions.**

12:25 p.m. **Breakout group wrap up**

FIRESIDE CHAT

12:30 p.m. **Fireside chat**
MARK MCCLELLAN
Director
Duke-Margolis Center for Health Policy

AMY ABERNETHY, *Moderator*
Former Principal Deputy Commissioner of Food and Drugs
U.S. Food and Drug Administration

1:00 p.m. **BREAK** *(30 min)*

SESSION II THE ROAD TO 2030: A CALL TO ACTION

Moderator: ANITA ALLEN
Henry R. Silverman Professor of Law, Professor of Philosophy
University of Pennsylvania Carey Law School

1:30 p.m. **Frontline Experience: A Road Already Travelled**
JANICE CHANG
Chief Operating Officer
TransCelerate BioPharma Inc.

PAM TENAERTS
Chief Scientific Officer
Medable, Inc.

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

2:00 p.m. **"Lightning Round" Breakout Discussion Groups** *(25 min)*

The breakout groups will be assigned one of the two following goals and asked to discuss practical applications and partnerships with new technologies that can address key priority challenges, opportunities aligned with this goal that will move us towards the clinical trials enterprise envisioned for 2030.

- **GOAL 3: Establish a clinical trials enterprise that is diverse, equitable, and inclusive.**
- **GOAL 4: Establish a national network of community-based clinical trial sites.**

2:25 p.m. **Breakout group wrap up**

CLOSING PANEL

2:35 p.m. **A "North-Star" Vision of What Is Possible**
ANDY CORAVOS
Chief Executive Officer and Co-Founder
Elektra Labs

ERIC PERAKSLIS
Chief Science and Digital Officer
Duke Clinical Research Institute

SAM ROOSZ
Co-founder and CEO
Crescendo Health

2:55 p.m. **Workshop wrap-up**
STEVEN GALSON, *Workshop Co-chair*
Senior Vice President, Research & Development
Amgen, Inc.

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

3:00 p.m. **ADJOURN**