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) 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. Discussions at this part of the workshop will**

    - **Discuss practical short-term and long-term goals for improving the resilience, sustainability, and transparency of the clinical trials enterprise; and**
    - **Consider specific action steps that stakeholders could individually take to support an envisioned change in the next 10 years (by 2025).**

- 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 3: March 24, 2021

Building a More Resilient, Sustainable, and Transparent Clinical Trials Enterprise

11:00a.m. – 3:00p.m. Eastern Time

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

SESSION I THE ROAD TO 2030: AN ATLAS FOR CHANGE

Moderator: CHRISTOPHER AUSTIN
Director
National Center for Translational Sciences
National Institutes of Health

11:10 a.m. **Keynote address**
MARTIN LANDRAY
Professor of Medicine and Epidemiology
Nuffield Department of Population Health
University of Oxford

11:25 a.m. **Frontline Experience: A Panel Discussion**

Physician's perspective on a true "Learning Healthcare System"
ELIZABETH OFILI
Director and Senior Associate Dean
Clinical Research Center & Clinical and Translational Research
Morehouse School of Medicine

Patient's perspective on sustainability
BARBARA SEGARRA-VAZQUEZ
Dean
School of Health Professions, Medical Sciences Campus
University of Puerto Rico

Industry perspective on building community-based research infrastructure
FREDA LEWIS-HALL
Retired Senior Medical Advisor
Pfizer, Inc.

12:00 p.m. **Charge to the Breakout Groups**

12:05 p.m. **"Lightning Round" Breakout Discussion Groups** *(40 min)*

Discussion Questions:

- *What are 1-2 short-term, tangible and measurable goals to ensure a more resilient, sustainable, and transparent clinical trials enterprise that should be met within the next 5 years – by 2025?*
- *What technologies, tools, or techniques could be transformational to improving resilience, sustainability, and transparency in the clinical trials enterprise over the next 5 years?*
- *What are specific models of sustainability, resilience, or transparency that participants have encountered in the past year that might be informative for the clinical trials enterprise, and could they be scaled (in part or in whole)?*

12:45 p.m. **Breakout group wrap up**

12:55 p.m. **BREAK** *(30 min)*

SESSION II THE ROAD TO 2030: A CALL TO ACTION

Moderator: KHAIR ELZARRAD
Deputy Director
Office of Medical Policy
U.S. Food and Drug Administration

1:30 p.m. **"North-Star" Vision of What Is Possible**
BRIAN SOUTHWELL
Senior Director, Science in the Public Sphere Program
RTI International

1:45 p.m. **Frontline Experience: A Road Already Travelled**
DYAN BRYSON
Founder, Patient Engagement Strategist
Inspired Health Strategies

PAMELA TENAERTS
Executive Director
Clinical Trials Transformation Initiative

2:10 p.m. **Charge to the Breakout Groups**

2:15 p.m. **"Lightning Round" Breakout Discussion Groups** *(30 min)*

Discussion Questions:

- *What are 1-2 long-term, tangible and measurable goals to ensure a more resilient, sustainable, and transparent clinical trials enterprise that should be met within the next 10 years – by 2030?*

- *What technologies, tools, or techniques could be transformational to improving resilience, sustainability, and transparency in the clinical trials enterprise over the next 10 years?*

- *What are specific models of sustainability, resilience, or transparency that participants have encountered in the past year that might be informative for the clinical trials enterprise, and could they be scaled (in part or in whole)?*

2:45 p.m. **Breakout group wrap up and Closing Remarks**

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

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3:00 p.m. **Adjourn**