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 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) will provide an overview discussion on how an envisioned 2030 clinical trials enterprise may differ from the current system. It will discuss key challenges and opportunities in improving person-centeredness and inclusivity, building resilience and transparency, and integrating new technologies. Specifically, workshop discussions will
    - Highlight lessons learned from progress and setbacks over the past 10 years
        - Consider components of the clinical trials enterprise that have been modified or abandoned in response to COVID-19 that establish positive and sustainable examples of change
    - Consider how an envisioned 2030 clinical trials enterprise might differ from the current system

- 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.

- 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 webinar sessions.

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

Workshop Part 1: January 26, 2021

11:00a.m. – 3:30p.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: A MORE PERSON-CENTERED AND INCLUSIVE CLINICAL TRIALS ENTERPRISE

Session Objectives:

- Discuss key priority challenges and opportunities when it comes to person-centeredness and inclusivity in the 2030 clinical trials enterprise

11:10 a.m. **A Story in Action: Person-Centeredness and Inclusivity**

TERRIS KING
Former Director, Office of Minority Health
Centers for Medicare and Medicaid Services

11:25 a.m. **Facilitated Breakout Groups** *(30mins)*

Discussion Questions:

- *Do you agree with the proposed goals listed below for enhancing person-centeredness and inclusivity?*
- *What would you change, and how?*
- *What are potential interim actions or milestones that might be key to achieving these goals?*

Goals to consider for enhancing person-centeredness and inclusivity

- Improve representation and relevance
- Improve community engagement, transparency, and "user-friendliness" to foster trust, counter misinformation, and meet the needs of patients
- Demonstrate trustworthiness to the general public of clinical trials
- Engage and prepare a diverse clinical research workforce

11:55 a.m. **Breakout Group Report-outs** *(10mins)*

12:10 p.m. **BREAK** *(30mins)*

SESSION II A MORE RESILIENT, SUSTAINABLE, AND TRANSPARENT CLINICAL TRIALS ENTERPRISE

Session Objectives

- Discuss key priority challenges and opportunities when it comes to building a more resilient, sustainable, and transparent clinical trials enterprise

12:45 p.m. **The State of Clinical Trials in 2021: A Perspective from Industry**
ELLIOTT LEVY
Sr. Vice President, R&D Strategy and Operations
Amgen, Inc.

1:00 p.m. **A Story in Action: Building a More Resilient, Sustainable, and Transparent Clinical Trials Enterprise**
JANET WOODCOCK
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration

1:15 p.m. **Facilitated Breakout Groups** *(30mins)*

Discussion Questions:

- *Do you agree with the straw vision statement for building a more resilient, sustainable, and transparent clinical trials enterprise (below)?*
- *What would you change, and how?*
- *What are some potential interim actions or milestones that might be key to achieving these goals?*

Goals to consider for building a more resilient, sustainable, and transparent clinical trials enterprise

- Improve community engagement, transparency, and "user-friendliness" to foster trust, counter misinformation, and meet the needs of patients
- Reduce complexity and streamline trials and trial start-up, and standardize key data elements
- Support regulatory robustness, flexibility, and built-in ability to adjust (e.g., in times of stress, to handle new tech robustly)
- Reduce conduction of "uninformative" clinical trials and prioritize resources to robustly-designed trials
- Generate a larger amount of high-quality evidence at lower cost
- Reduce risk aversion to improve research questions and trial design innovation
- Embrace novel statistical techniques to power trials
- Connect and embed clinical care and clinical research

1:45 p.m. **Breakout Group Report-outs** *(10mins)*

2:00 p.m. **BREAK** *(30mins)*

SESSION III MORE APPROPRIATE USE OF TECHNOLOGIES TO OPTIMIZE THE CLINICAL TRIALS ENTERPRISE

Session Objectives

- Discuss key priority challenges and opportunities when it comes to appropriately using new technologies to optimize the 2030 clinical trials enterprise

2:30 p.m. **A Story in Action: Optimizing with New Technologies**
ROBERT CALIFF
Head of Clinical Policy and Strategy
Verily Life Sciences and Google Health

2:45 p.m. **Facilitated Breakout Groups** *(30mins)*

Discussion Questions:

- *Do you agree with the proposed goals listed below for more appropriately using new technologies to optimize the clinical trials enterprise?*
- *What would you change, and how?*
- *What are some potential interim actions or milestones that might be key to achieving these goals?*

Goals to consider for more appropriately using technology to optimize the clinical trials enterprise

- Decentralize clinical trials
- Use digital tools for clinical trials management
  - Develop resources to help institutions that need more support
- Increase local capacity for research innovation
- Collate efforts to frame new technologies as part of an ecosystem rather than a series of unrelated one-off tech solutions
- Develop and deploy systems and tools to combine many sources of data
- Incorporate patient input into research
- Advance analytics for recruitment and analysis

3:15 p.m. **Breakout Group Report-outs** *(10mins)*

WRAP UP

3:30 p.m. **Wrap Up Discussion and Closing 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

3:35 p.m. **Adjourn**