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

March 24 Breakout Discussion Guide – Session 1

Overview
On January 26, February 9, March 24, and May 11, 2021 the National Academies Forum on Drug Discovery, Development, and Translation will host a 4-part virtual workshop on *Envisioning a Transformed Clinical Trials Enterprise for* 2030. Workshop participants will consider lessons learned from progress and setbacks over the past 10 years, 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. The workshop planning committee has identified three topic-specific priorities for framing the workshop discussions: 1) Enhancing Outcomes in a More Person-Centered and Inclusive Clinical Trials Enterprise; 2) Building a More Resilient, Sustainable, and Transparent Clinical Trials Enterprise; and 3) Practical Applications for Technology to Enhance the Clinical Trials Enterprise.

Breakout group participants will discuss each of the topic-specific priorities listed above.

Discussion Questions for Session 1 of Building a More Resilient, Sustainable, and Transparent Clinical Trials Enterprise

1. **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?**

   Goals to consider:
   - *Strengthen collaboration and coordination*
     - *Increase collaboration to leverage the unique strengths of a broad array of diverse actors across the clinical trials ecosystem.*
     - *Expand collaboration between regulators and industry/academia to consider acceptable innovative methodologies, and ensure that regulators have the expertise to evaluate trials using these methodologies.*
   - *Improve community outreach and engagement with patients and clinicians.*
   - *Other short-term goals to ensure a more resilient, sustainable, and transparent clinical trials enterprise?*

2. **What technologies, tools, or techniques could be transformational to improving resilience, sustainability, and transparency in the clinical trials enterprise over the next 5 years?**

   Ideas to consider:
   - *Improve the usability and interoperability of data*
     - *Define a clear, standardized set of social determinants and clinical metrics to be collected in clinical trials and electronic health records to facilitate collaboration and aggregation of data.*
     - *Expand the use of common trial protocols.*
     - *Update the format and required variables for ClinicalTrials.gov to improve the usability of the data and its transparency.*
   - *Prioritize the experience of patients*
     - *Improve the collection of real-world evidence, while minimizing patient burden.*
     - *Improve current patient recruitment methodologies to increase the likelihood that trials are completed and informative.*
     - *Design clinical trials with the early input of patients, to increase engagement and transparency of the clinical trial enterprise.*

3. **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)?**