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 Breakout Discussion Guide – Session 2

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) Ensuring More Appropriate Use of Technologies to Optimize the Clinical Trials Enterprise.

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

Discussion Questions for Session 2: Building a More Resilient, Sustainable, and Transparent Clinical Trials Enterprise

1. The following are potential goals related to building more resilience, sustainability, and transparency into the clinical trials enterprise identified by the workshop planning committee. Please briefly comment on these potential goals before moving to the discussion questions:

    - 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

    Do you agree with these goals? If not, what would you change and how? *(10mins)*

    -
    -
    -

2. **What are some interim actions to be taken and/or milestones to be met that will be critical for achieving these goals?**

   Identify 1-2 short-term actions and/or milestones that should be addressed within the next five years (by 2025). Which stakeholders are needed to effectively carry out these activities? *(10 mins)*

   -
   -

   Identify 1-2 long-term actions and/or milestones that should be addressed within the next decade (by 2030). Which stakeholders are needed to effectively carry out these activities? *(10 mins)*

   -
   -