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

February 9 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) 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 1 of Enhancing Outcomes in a More Person-Centered and Inclusive Clinical Trials Enterprise

1. **What are 1-2 short-term, tangible and measurable goals to ensure a more person-centered and inclusive clinical trials enterprise that should be met within the next 5 years – by 2025?**

   Goals to consider:
   - *Strengthening the workforce*
     - *Engage with and invest in minority-serving institutions, early-career researchers, and medical schools to prepare and mentor a diverse workforce*
     - *Engage with family physicians and other primary care providers working in the community, including them early on in trial design and implementation, to improve recruitment and expand the clinical trials network*
     - *Require diversity, equity, and inclusion education as well as implicit bias training for the clinical trials workforce*
   - *Invest in community-based participatory research*
     - *Establish and nourish patient- and community-based partnerships to support person-centered outreach, including through public-private partnerships (e.g., NIH, pharmaceutical companies, community-based organizations)*
     - *Embed clinical trials and research in the communities in which patients live and work*

- *Engage/support/hire community-based leaders, clinicians, and patients to carryout outreach, advocacy, and build trust within the community*

- *Other short-term goals to ensure a more person-centered and inclusive clinical trials enterprise?*

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

Ideas to consider:

- *Incorporate patient populations early on in the design and implementation of clinical trials*

  - *Define and commit to principles and measurable targets for inclusive and representative research, as well as engagement*

  - *Collect outcomes data that are important to the community, and report outcomes and demographic data with transparency*

  - *Develop metrics, based on outcomes important to the community to evaluate and measure improvement in representation, relevance, and engagement*

- *Employ pragmatic trial designs*

  - *Consider pragmatic effectiveness testing from the early stages of trial design, as a means to inform efficacy testing and recruitment*

  - *Design clinical trials to recruit participants that reflect the demographics that the underlying disease affects*

- *Develop consistent reporting requirements for demographic data that are encouraged/enforced by key stakeholders (e.g., peer-review journals, funders, sponsors, regulatory agencies, NIH)*