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

# May 11 Breakout Discussion Guide

**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**.

Below are several problem statements, or goals that could be achieved through the application of technology, which have been discussed throughout the previous sessions of this workshop. Following each goal is a non-exhaustive list of potential approaches to achieve the particular goal. Considering these approaches and any additional approaches that you deem relevant to the goal, we ask you to discuss within the breakout groups 1) how is a ***particular technology*** uniquely suited to address this approach? 2) what are the ***barriers*** (real or perceived) to implementing effective use of this technology? and 3) which ***actors*** are uniquely positioned to help implement use of the technology?

At the beginning of the breakout session, the breakout room moderator will assign your group one of the goals below.

## Session 1

**GOAL 1**: Enable a more person-centered and easily accessible clinical trials enterprise[1].

*Achieving this goal could help build trust, meet the needs of patients and communities, and improve patient outcomes.*

Potential approaches:

1. Enhance community engagement, "user-friendliness", and relevance of trials among patients, clinicians, and community-based organizations throughout the development lifecycle of medical products—from early target identification through clinical trial conduct to increase research discoveries.
2. Extend the reach, reliability, and reportability of clinical trials for relevant stakeholders, including patients, clinicians, and community-based organizations.
3. Develop processes and/or decision-making tools for patients and clinicians to better assess opportunities to participate in clinical trials.
4. Bridge the technical divide between populations (e.g., could be defined by age, geography, socioeconomic factors, able-bodiedness or tech-comfort).

| Approach | How is a particular technology uniquely suited to address this approach? | What are the barriers (real or perceived) to implementing effective use of this technology? | Which actors are uniquely positioned to help implement use of the technology? |
|---|---|---|---|
| **1** | | | |
| **2** | | | |
| **3** | | | |
| **4** | | | |
| **5** | | | |
| **6** | | | |

[1] Related to the Clinical Trial Transformation Initiative's Vision for 2030. For more information, see https://www.ctti-clinicaltrials.org/transforming-trials-2030

**GOAL 2:** Simplify trials (less data collection, fewer site visits) and lower costs while still generating high-quality data and robust answers to relevant research questions.

*Achieving this goal could help make high-quality trials easier to conduct; involve a broader range of patients, communities, and investigators in research; and guide responsibly using/re-using data.*

Potential approaches:

1. Streamline trial startup and enrollment processes.
2. Simplify or standardize data collection from multiple sources (e.g. smartphone apps, wearable sensors, and other remote, sensor-based tools that combine hardware and software[2]) to enable broader data sharing and data use/reuse.
3. Enhance the role of routine data capture to minimize patient and clinician burden.
4. Enable data, information, and knowledge exchange among key stakeholders (e.g., federated networks of real-world data to optimize clinical trial operations[3]).

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[2] https://www.nationalacademies.org/event/03-24-2020/the-role-of-digital-health-technologies-in-drug-development-a-workshop

[3] https://www.nap.edu/catalog/18998/sharing-clinical-trial-data-maximizing-benefits-minimizing-risk

## Session 2

**GOAL 3:** Establish a clinical trials enterprise that is diverse, equitable, and inclusive.

*Achieving this goal could help improve patient outcomes and overall health, meet the needs of patients and communities, and improve the overall relevance of clinical research. It could also make high-quality trials easier to conduct; involve a broader range of patients, communities, and investigators in research; and guide responsibly using/re-using data.*

Potential approaches:

1. Improve the engagement of underrepresented patient populations in clinical trials throughout the development lifecycle of medical products—from early target identification through clinical trial conduct to increase research discoveries.
2. Lower barriers to recruitment so that participating in clinical trials is a straightforward option for patients and their providers.
3. Enable community-based providers in rural or underserved areas to participate in clinical research and clinical trials.
4. Engage a more diverse clinical trials clinical trials enterprise workforce.

| Approach | How is a particular technology uniquely suited to address this approach? | What are the barriers (real or perceived) to implementing effective use of this technology? | Which actors are uniquely positioned to help implement use of the technology? |
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**GOAL 4:** Establish a national network of community-based clinical trial sites.

*Achieving this goal could help integrate clinical research and practice, improve overall research relevance and preparedness by involving a greater range of participants, and ultimately minimize need for additional staff or resources to conduct new trials.*

Potential approaches:

1. Create a mechanism to enable more efficient information sharing, which includes community-based stakeholders involved in trial design, conduct, and analyses.
2. Develop a process or decision-making tool to assist in resource prioritization and allocation toward trials with more robust trial designs and/or public health needs.
3. Enable sustained multi-stakeholder community-based partnerships and communities of research that are reciprocal, and support cooperation and mutual learning throughout the drug research and development lifecycle.
4. Establish infrastructure and training opportunities to support an effective clinical trials workforce in rural and/or community locations.

| Approach | How is a particular technology uniquely suited to address this approach? | What are the barriers (real or perceived) to implementing effective use of this technology? | Which actors are uniquely positioned to help implement use of the technology? |
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