

Assessing U.S. Clinical Trials Site Capacity and Readiness for Public Health Emergencies

Expert Meeting



MEETING SUMMARY | July 30-31, 2025



BACKGROUND

Ensuring that U.S. clinical trial sites are prepared to respond to public health emergencies is essential for protecting patients and generating timely evidence for vaccines and therapeutics. Recent crises have underscored both the strengths and the limitations of the nation's clinical trial infrastructure. While rapid evaluation and emergency use authorization are possible, challenges remain in enabling sites to activate quickly and adapt to evolving demands.

CTTI's Watchtower Project was created to address these challenges. The project will assess and estimate U.S. clinical trial site capacity and readiness, with particular focus on sites' ability to scale during emergencies. Its goal is to establish a framework that evaluates readiness, identifies gaps, and offers scalable solutions to strengthen national preparedness for future public health threats.

As part of this effort, the Watchtower Expert Meeting convened leaders from across the clinical research community to reflect on lessons learned from past responses, consider evolving site and network models, and discuss what should be included in a comprehensive readiness framework. Insights from these discussions will inform the development of practical tools to support a coordinated and effective clinical trial response in future emergencies.



MEETING OBJECTIVE

- ▶ Gather perspectives on what information should be included in a framework to assess site capacity and capabilities to support a coordinated response to future public health emergencies.



MEETING THEMES

Throughout the two-day meeting, attendees discussed prior experiences, current challenges, and opportunities to strengthen clinical trial infrastructure in the U.S. The following key themes emerged:

- ▶ **Persistent gaps in site readiness remain**, including fragmented guidance, trial design challenges, limited decentralized trial capacity, and barriers to equitable enrollment.
- ▶ Successful mobilization efforts such as the Trial Innovation Network and the VA's COVID-19 research network demonstrate the **value of centralized infrastructure, interagency coordination, and urgency in reducing site activation timelines.**
- ▶ **Clinical trial site models are shifting toward centralized and network-based approaches**, with increased use of embedded staff, remote sites, and mobile health services, alongside declining reliance on part-time research sites. Collaboration across networks and organizations is necessary to maintain readiness.
- ▶ **Development of a site readiness framework for emerging respiratory infectious diseases** is essential to reduce inefficiencies, ensure consistency, and support equitable site selection and startup.
- ▶ **Integration of community engagement strategies and real-world data**, including the use of EHRs for patient identification and site selection, will **strengthen** trial execution.



NEXT STEPS

Solutions for strengthening site readiness and capacity to support a coordinated response during future public health emergencies were discussed, including the need to:

- ▶ Streamline site startup by addressing common barriers such as lengthy contracting, slow IRB review, and overly complex protocols
- ▶ Expand the use of digital tools such as e-consent and remote participation platforms and leverage EHR data to support site selection and patient identification
- ▶ Provide practical resources such as readiness checklists and documentation to help sites maintain preparedness between crises
- ▶ Build workforce flexibility by developing surge staffing plans, cross-training staff to take on multiple roles, and focusing on retention strategies to reduce turnover
- ▶ Create a framework with standardized readiness definitions and processes so assessments are consistent across sites and can be compared nationally

The CTTI Social Science team will review the key themes and insights discussed during this meeting to inform CTTI's next steps.



ADDITIONAL RESOURCES

- ▶ [Meeting materials](#), including agenda, participant list, and presentations
- ▶ Read more about CTTI's [Watchtower Project](#)



ABOUT THE CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI)

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Bringing together organizations and individuals from across the enterprise, CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges.



ctti@mc.duke.edu
ctti-clinicaltrials.org