EMBEDDING TRIALS IN HEALTH CARE SETTINGS
Expert Meeting

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

MEETING SUMMARY | MAY 11, 2022

BACKGROUND

Embedding elements of clinical trials, such as randomization, administration of study drug, and data acquisition, into routine care reduces duplication of trial and care activities and promotes the development of a learning health care system, where research will inform practice and practice will inform research. This will naturally lead to better decision making, treatment options, and outcomes for patients. However, integrating interventional clinical trials into health care settings is challenging and complex, and operational direction is needed. Therefore, **the Clinical Trials Transformation Initiative (CTTI)** conducted in-depth interviews with study designers and implementers, gathered case examples, and created a set of draft recommendations to facilitate the fit-for-purpose integration of randomized, interventional trial elements into clinical care; including, but not limited to, trials of drugs, devices, and biologics intended for regulatory review. The multi-stakeholder expert meeting—Embedding Clinical Trials in Health Care Settings— was conducted to review the interview results and case examples, and further refine the recommendations.

MEETING OBJECTIVES

- Present findings from project's evidence generation: in-depth interviews with study designers and implementers
- Refine operational recommendations
- Begin to strategize implementation of operational recommendations

MEETING THEMES

- A paradigm shift is needed so that research is considered part of good clinical care
- Good clinical care and research should align; High quality data collected during routine care should be good enough to support both clinical care and research
- Embedding trial elements is possible and dependent on the needs of the trial
- Operational approaches to incorporating interventional trials into clinical care settings should involve partnerships with patient groups, health system leaders, and IT leaders. Clear roles and responsibilities, and transparency is needed.
- Incentives are needed to enable a sea change, and these may differ by stakeholder group
- If we focus on building a few reusable networks, we can achieve the first stage of a learning health system.

NEXT STEPS

The meeting is one component of the process for finalizing recommendations for embedding trials in health care settings and informing tools that will assist with the implementation of those recommendations.

Project Objectives:

- Identify the barriers and potential solutions to incorporating interventional trials into clinical care settings
- Identify when elements of interventional clinical trial integration into clinical settings would be feasible and the associated benefits and risks
- Describe the operational approaches to incorporating interventional trials into clinical care settings

Because the best big idea is only as good as its implementation, at a future meeting, CTTI will discuss implementation strategies.

ADDITIONAL RESOURCES

- **Meeting materials**, including agenda, participant list, and presentations
- Read more about CTTI's **Trials in Health Care Settings 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.

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