TRIALS IN CLINICAL PRACTICE
Expert Meeting

CLINICAL TRIALS TRANSFORMATION INITIATIVE

MEETING SUMMARY | SEPTEMBER 21, 2022

BACKGROUND

When care informs research and research informs care, we enable higher quality, more efficient, and more representative evidence for care. Embedding elements of trials into clinical practice will narrow the gap between clinical research and practice by reducing duplication of trial and care activities, increasing knowledge generation, and promoting the translation of that knowledge into improved patient care. Elements that can be embedded into clinical practice include patient identification, randomization, informed consent, intervention, data acquisition, and/or evidence integration.

To facilitate embedding randomized, interventional clinical trials into clinical practice, **the Clinical Trials Transformation Initiative** (CTTI) created a set of recommendations that provide trial design and operational clarity. As described by meeting panelists, great progress is being made with trials and key initiatives already paving the way, including the ACTIV-6 Study, the RECOVERY Trial, the Coalition for Advancing Clinical Trials at the Point of Care (ACT@POC), and the National Patient-centered Outcomes Research Network (PCORnet). However, challenges remain in driving change and measuring the impact of this change. Thus, a multi-stakeholder expert meeting was conducted to identify pain points of embedding trial elements, determine how CTTI recommendations can overcome those pain points, and ways to measure implementation of the recommendations.

MEETING OBJECTIVES

- Develop strategies for implementing at least 2 of CTTI's new recommendations into the planning of trials intended for regulatory review
- Identify 3 implementation barriers that trial designers and health systems have the power to mitigate
- Brainstorm relevant metrics to monitor and evaluate implementation of the selected recommendations

MEETING THEMES

Throughout the meeting, attendees discussed examples in which elements of a trial could be or have been embedded into care. Although responses varied, key themes emerged:

- Dr. Janet Woodcock, Principal Deputy Commissioner of the U.S. Food and Drug Administration, reiterated the imperatives for conducting trials as part of clinical practice: we have inadequate evidence for care, lack of representativeness of most Americans and health care settings, and an underperforming emergency response mechanism for national health crises.

- The ability to embed aspects of a trial will depend on the ability to align trial design with clinical workflow to minimize provider and patient burden, ensure site readiness with appropriately trained staff and technology resources, define clear channels of accountability, and raise awareness of the value of research and its subsequent impact on care.

- Technology and reusable networks can help overcome some of the barriers, as can changes in culture and policy and good partnerships with patient groups, health system leaders, and IT leaders.

- CTTI recommendations provide design and operational clarity to embed trial elements, but their adoption will require engagement with health care providers, technology support, and ways to measure progress.

NEXT STEPS

Participants discussed how to measure whether adoption of the Trials in Clinical Practice recommendations is improving the quality and efficiency of clinical trials. Initial themes fell into two camps:

1. Measures of progress in clinical trial quality
2. Measures of progress towards a learning health care system.

To assess progress of clinical trial quality, measures might include:
- improved enrollment/retention rate
- whether trials have enrolled reflective and representative populations that align with those being cared for
- participant and health care provider satisfaction/experience with research.

To assess progress at the learning health system level, measures might include:
- whether embedded trials are producing impactful, reliable results that are integrated into clinical decision making
- the proportion of practices in the health care ecosystem that are involved in research
- changes in reimbursement policies
- involvement of medical journals that report on elements embedded into care.

ADDITIONAL RESOURCES

- **Meeting materials,** including agenda, participant list, and presentations
- Read more about CTTI's **Trials in Clinical Practice 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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