

UNDERSTANDING PATIENT & INVESTIGATORS' PERCEPTIONS OF MOBILE CLINICAL TRIALS

Expert Meeting



MEETING DETAILS | JAN. 9-10, 2018



BACKGROUND

The use of mobile technology holds the promise and potential for higher quality, more efficient clinical trials. It allows remote participation in some or all study activities, and may facilitate longstanding goals of the research enterprise such as reducing the burden of participation, increasing participant satisfaction, increasing protocol adherence, and facilitating participation by a more diverse population.

Critical to the widespread adoption of mobile technology in clinical trials is positive reception by key stakeholders. However, until recently, very little was known about the possible benefits and barriers perceived by clinical investigators and trial participants. As such, the Clinical Trials Transformation Initiative (CTTI)—as part of its Stakeholder Perceptions Project within CTTI's Mobile Clinical Trials (MCT) Program—conducted qualitative and quantitative research to better understand their perceptions, and reviewed the findings in a multi-stakeholder expert meeting in January 2018.



MEETING OBJECTIVES

During this meeting, CTTI and relevant stakeholders—including investigators, patient partners, regulators, technology experts, sponsor representatives, and others—achieved the following:

- Presented findings from CTTI evidence-gathering activities examining the perspectives of investigators and potential research participants on the use of mobile technology for collection of objective data in clinical trials.
- Discussed how this and additional evidence presented may be used to provide direction to the research enterprise for the appropriate utilization of mobile technology in clinical trials.
- Started to identify products that CTTI should develop to equip the clinical trials enterprise to address the barriers, preferences, and needs of investigative site personnel and potential research participants in regulatory submission trials using mobile technology.



MEETING THEMES

- **Mobile Could Transform Clinical Trials:** The successful adoption of mobile technology requires rethinking how trials are designed and conducted. At the same time, many of the factors that define high-quality trial design remain the same, whether or not mobile technology is used.
- **Patient Voice is Key:** All stakeholders agreed that patient input is critical in the planning of mobile clinical trials (just as for traditional trials), as well as in the design and/or selection of mobile devices used.
- **Start with the Problem, not the Device:** Devices should be selected and tailored to the study, not vice versa. Device selection needs to be driven by a well-designed study protocol, with input from patients and investigators, and based on the needs of the intended user population.
- **Communicate, Communicate, Communicate:** Mobile technology can change the ways site staff and study participants interact during a trial. Steps should be taken to ensure that participants fully understand the study, feel valued throughout the trial, and are able to easily communicate with site staff and access technical support.
- **Support—in All Forms—is Needed:** From new processes and standards around mobile trial-related concerns (i.e. patient confidentiality, missing or inaccurate data, etc.), to budgets for training, device purchases, and technical support, new resources are required to help researchers incorporate mobile technology in clinical trials.



NEXT STEPS

As a next step, the CTTI MCT Stakeholder Perceptions Project Team will use the findings from this meeting to inform general recommendations to address barriers to, and incorporate preferences for, the use of mobile technology in clinical trials, as perceived by potential research participants and investigative site personnel. The scope of the program includes use of mobile technology in FDA-regulated clinical trials after the time of participant consent.



ADDITIONAL RESOURCES

- **Meeting materials**, including agenda, participant list, and presentations
- Read more about CTTI's **MCT Stakeholder Perceptions Program**
- Read more about CTTI's **MCT Program**
- For more information, please contact Zach Hallinan at zachary.hallinan@duke.edu



ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations, CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Learn more about CTTI at www.ctti-clinicaltrials.org.



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