

## **Learning from Patient and Site Perspectives to Develop Better Mobile Clinical Trials: Recommendations from the Clinical Trials Transformation Initiative**

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### **Abbreviations**

MCT – Mobile Clinical Trials

### **Short title**

Engage patients, sites in mobile trials

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**Abstract**

In order to harness the potential of mobile technologies to enhance the quality of clinical research, it is critical to first understand how to engage patients and research sites when planning and conducting mobile clinical trials. The [Clinical Trials Transformation Initiative](#) has developed the first comprehensive, evidence-based set of recommendations for incorporating patient and site perspectives in mobile clinical trials, which can aid in engaging stakeholders, addressing site challenges, and maximizing value for participants.

**Keywords**

mobile technology; patient engagement; mobile clinical trials; virtual trials; digital trials; hybrid trials; site engagement; site support; mobile devices

## Introduction

The ability of mobile technologies to increase efficiency and capture more meaningful data has the potential to transform the clinical research landscape.<sup>1</sup> The use of these technologies offers opportunities to reduce participant burden, streamline study operations, and collect previously unobtainable data that can help accelerate the discovery, development, and approval of new medical products. At the same time, it is critical to understand how to engage patients and research sites when planning and conducting mobile clinical trials in order to optimize these opportunities of using mobile technologies in clinical research.

To pave the way for the more effective use of mobile technologies in trials, the [Clinical Trials Transformation Initiative](#) (CTTI) is presenting the first comprehensive, evidence-based set of recommendations for incorporating the perspectives of patients and sites in trials in which mobile technologies are used for data capture. These recommendations are designed to assist research sponsors in: (1) engaging patients and sites in planning clinical trials using mobile technology, (2) maximizing value and minimizing burden for study participants, and (3) addressing challenges for investigative sites. The complete set of recommendations and associated resources is available at the CTTI website at [www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites](http://www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites).

## Methods

CTTI's Mobile Clinical Trials (MCT) Program began in 2015 with the purpose of identifying and addressing the challenges of planning for and conducting clinical trials that use mobile technologies. This work focused on the use of mobile technologies for the collection of objective data (measured directly by the mobile technology) in FDA-regulated clinical trials following participant consent. In performing this work, CTTI recognized that, while research had been done on patient preferences around mobile technologies in general,<sup>2,3,4,5</sup> little research had been conducted on their perspectives on the use of mobile technologies in clinical research,

despite the fact that positive reception by these participants is critical to their widespread adoption in clinical research.

To address this gap, CTTI conducted a survey of 193 potential research participants to better understand patients' preferences, their willingness to use, and concerns with using mobile technology in clinical research.<sup>6</sup> It also conducted qualitative telephone interviews with 12 site investigators with experience in using mobile technologies in clinical trials. CTTI then convened a two-day expert meeting with investigators, patient partners, regulators, sponsors, technology experts, and others to present findings and solicit additional input.

The following findings summarize the consensus-driven, multi-stakeholder recommendations that arose from the aforementioned work.

## **Findings**

For mobile clinical trials, patients are uniquely positioned to offer input on topics such as whether participants would find a particular device easy to learn, convenient to operate, and physically comfortable, in addition to providing feedback on other study design elements. Similarly, site personnel can best identify potential technology-related issues related to site infrastructure, training, and technical support.

In order to obtain this valuable input, it is critical to seek diverse perspectives from patients and investigative site personnel early and often in planning trials using mobile technologies. As recommended in CTTI's work on Mobile Technologies,<sup>7</sup> outcome measurements that are meaningful to patients should be identified before deciding which (and whether) mobile technology should be used. If the use of mobile technology is determined to be appropriate for a trial, technology selection should be based on the requirements of the study and the needs of the intended user population. Furthermore, it is important to carefully weigh any impact on site staff and clinical workflow against the potential benefits of mobile

technologies, and recognize that mobile technology cannot “fix” a trial that is fundamentally flawed. See Figure 1 for more considerations for planning trials using mobile technologies.

**Figure 1. Planning Trials Using Mobile Technologies**



Full resource available at [www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites](http://www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites)



Feasibility and/or pilot studies should also be conducted with sites and a representative patient population prior to trial launch. As a rule, the level of testing should be commensurate with the complexity and novelty of the technology to the research team. At the same time, it is important to recognize that even simple technologies present a number of potential problems related to their use, maintenance, and distribution that need to be carefully assessed.

While the use of mobile technologies in clinical trials offers important opportunities to provide value and reduce burden for participants, it may actually increase burden if risks, needs, and expectations are not considered during study planning and clearly communicated to participants during the enrollment process.

One critical point of communication is the informed consent document. This document should provide a thorough description of the selected mobile technology, including the benefits and risks associated with its use. It is important that the document provide clear guidance on what participants can expect—and what will be expected of them—during a mobile trial. Researchers should accommodate varying levels of participants' health and technical literacy in the informed consent process and all subsequent communications.

It is also critical to recognize the potential for mobile technologies to change the way participants and site personnel interact during a trial. While some participants may be willing to primarily use forms of communication other than in-person visits, others may still prefer frequent face-to-face interaction.<sup>6</sup> Appropriate measures should be taken to ensure that all participants remain engaged.

Since site personnel can best understand participants' issues and concerns in the context of the study, they should be the initial point of contact for technical support. If individuals other than site staff will be providing support, they should be made familiar with the study and trained on how to handle inappropriate data disclosures and participant queries.

Researchers should also be mindful of the expectations that participants may bring from their experiences with commercial mobile technologies, and address these expectations up front. Participants may, for example, assume that their health is being monitored in real time and fail to call for help in the event of a medical emergency. Similarly, patients may expect real-time access to the data collected about them by mobile technologies; when sharing individual data would jeopardize trial integrity, expectations for what information will be shared, and when, should be clearly communicated during the informed consent process.

It is crucial for researchers to communicate to potential participants that, while every effort will be made to protect their data, confidentiality cannot be guaranteed. All stakeholders, including participants and institutional review boards (IRBs), have a right to fully understand the risks and implications of sharing data via mobile technologies.

The use of mobile technologies, while offering potential benefits to sites, also presents a number of site-specific challenges. Sponsors and sites should be prepared for the additional time needed to train staff and provide technical support, as well as costs for purchasing, storing, setting up, and handling the loss, malfunction, or return of devices. Sponsors should build flexibility into the study budget to account for unforeseen costs and provide any information gathered from pilot studies in advance to facilitate more accurate budgeting.

Sponsors should also clearly delineate the responsibilities of site personnel and consider alternate payment structures in contracts. In trials that rely on remote data collection, lump sum payments may be more feasible and fair than paying sites on a per-visit basis.

Finally, sponsors should ensure that sites have the appropriate infrastructure and training to conduct successful mobile clinical trials. In addition to confirming that sites have the needed hardware, software, and Internet capabilities, sponsors should ensure they are recruiting staff with necessary technical expertise. Training should be offered in a variety of formats, provide the opportunity for hands-on practice, and allow ample time for establishing familiarity with the technology. To enhance efficiency, sponsors should recognize training already completed for other sponsors and customize training to address only those elements of a trial or technology that are new or unique.

## **Discussion**

Incorporating the insights and preferences of patients and sites is crucial to ensuring that all stakeholders derive benefit from clinical trials using mobile technologies and that costly mistakes are avoided. CTTI's recommendations and resources outline steps sponsors and researchers can take to harness the substantial opportunities offered by mobile technologies to advance clinical research and accelerate the development of new medical products.

### **Data availability**

The complete set of recommendations and resources are made publicly available on the CTTI website at <https://www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites>.

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### **Author Contributions**

All authors provided critical review and approval of the submitted version.

### **Declaration of conflicting interests**



The authors have no conflicting interests to disclose.

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