

SITE INVESTIGATOR PERCEPTIONS OF MOBILE CLINICAL TRIALS: SUMMARY OF INTERVIEW FINDINGS

We appreciate your input on investigator perceptions of similarities and differences in conducting traditional clinical research as compared to mobile clinical trials. This letter shares the main findings from the interviews.

The purpose of the interviews was to explore site investigators' 1) perceptions on the advantages and disadvantages of mobile clinical trials (MCTs); 2) insights on the site-level budgetary, training, and other support needs necessary to adequately prepare for and implement mobile clinical trials; and 3) guidance for other site investigators who are interested in participating in mobile clinical trials.

In total, we interviewed 12 investigators that had been involved in any kind of clinical research conducted in the U.S. that used mobile devices to collect data, and had been involved previously as an investigator in traditional clinical research with a clinical outcome. The data are summarized below. Informed by these data, as well as data from the larger MCT Program (including legal/regulatory, novel endpoints, and mobile devices), CTTI will produce guidance on incorporating mobile technologies into clinical trials.

SUMMARY OF FINDINGS:

All investigators stated their willingness to participate in another MCT as an investigator because they believed mobile clinical trials to be the future of clinical trials, and/or due to the perceived benefits of such trials over traditional clinical trials.

Investigators identified overall advantages to the conduct of MCTs, such as remote data capture, the improvement in the quality of studies and collected data, and more streamlined study operations.

- Advantages specific to study investigators and staff included the ability to capture data remotely, having access to real-time data for the purposes of monitoring compliance and adverse events and intervening as needed, and the collection of continuous, high frequency data from a real world setting.
- Investigators described advantages specific to MCT participants such as access to real-time data for the purposes of health management and increased participant engagement, and a reduction in patient burden due to fewer in-person visits.

Investigators also provided commentary on factors that made MCTs more challenging to conduct than traditional trials, such as increased resources for learning to use and managing the devices, more complex analyses given the increased volume of data, and difficulty in building rapport due to fewer direct interactions with patients.

- Disadvantages specific to study investigators and staff included the difficulty of reviewing and responding (when necessary) to the amount of real-time data gathered. Furthermore, some investigators cited that the real world setting within which data were collected was compromised due to the amount of intervention from study staff. Device-related challenges were also frequently mentioned, such as difficulty setting up devices, time spent troubleshooting, and barriers with staff adopting new technologies.
- Investigators also acknowledged the impact on research endeavors when study participants are asked to bear more burden with incorporating data capture and device management into their routines, along with overcoming unfamiliarity or concern with using mobile devices. Investigators also acknowledged further challenges when participants had access to real-time data such as unintended behavior change or misinterpretation of data.

More than half of investigators mentioned various support needs for participation in MCTs, such as more time required of investigators given the novelty of technology and related software, as well as the robust amount of data to review.

- Half of investigators mentioned that more staff time was also needed with MCTs due to the learning curve associated with the technologies and software, as well as associated trainings. The abundance of data to monitor was also a reason given that necessitated greater levels of staff time.
- The most frequently cited type of support needed for the conduct of MCTs was in the form of tech support and assistance troubleshooting with devices.
- Investigators mentioned that budgetary support was needed in the form of increased funding for certain elements of MCTs, such as time spent managing the devices (i.e., troubleshooting, interfacing with tech support, device failures, storing and charging devices) and training participants on the use and management of devices.

Guidance for site investigators that are considering involvement in MCTs:

- Numerous investigators noted that their IRBs did not raise any concerns regarding the use of mobile technology in the research as long as the devices met data security and safety requirements.
- Several investigators recognized ways to enhance the effectiveness of device-specific training, such as having in-person, hands-on trainings with supplemental materials provided for future reference.
- The investigators interviewed recommended that other investigators should have sponsors provide specific information regarding devices such as type of device to be used, device capabilities, storage requirements, safety information, intended level of data access for participants, and also seek investigator input about device selection. Investigators also requested that sponsors be sensitive to the level of site burden, including compensation for additional demands posed by MCTs.
- Investigators provided a host of recommendations to address site burden, participant burden, budgetary challenges, training needs, device challenges, data integrity, and contract challenges. Themes that emerged throughout these recommendations were a thorough understanding of devices by sponsors and investigators alike *prior* to trial initiation, sponsor-initiated effort to minimize burden on sites to the extent possible, and adequate support for the use of devices throughout the life of a trial.

The MCT-Stakeholder team will utilize the data collected for this study and the larger MCT Program to propose recommendations to overcome barriers to the use of mobile technology in clinical trials.

Final recommendations will be posted at:
<https://www.ctti-clinicaltrials.org/projects/stakeholder-perceptions>.

Thank you for sharing your perspective with us!

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