CTTI

OPTIMIZING MOBILE CLINICAL TRIALS BY ENGAGING PATIENTS AND SITES:

Questions to Support the Implementation of Recommendations

The questions below are designed to support the process of implementing CTTI's Recommendations for Optimizing Mobile Clinical Trials by Engaging Patients and Sites. These questions should be used in conjunction with review of the full set of recommendations; they are intended to help ensure relevant issues are being considered and addressed. Note that not all questions will be applicable to every study.

ENGAGING PATIENTS AND SITES IN PLANNING TRIALS USING MOBILE TECHNOLOGIES

Engage patients and investigative site personnel early and often in planning clinical trials using mobile technologies.

▶ Are relevant patient perspectives being sought from the earliest stages of trial planning?

▶ Does the protocol development process include incorporating patient and site perspectives on the ability of all relevant patient populations to participate in the trial?

▶ Are the perspectives of site personnel being sought on pilot testing, training, infrastructure, and similar issues, particularly as these relate to mobile technologies?

Select mobile technologies based on requirements of the study and needs of the intended user population, starting with the aspect or experience that the assessment is intended to measure.

▶ Have patients and sites been involved in technology selection?

▶ Have the acceptability, usability, and tolerability of the technology for potential trial participants been evaluated?

▶ Have protocol elements been weighed against the potential added burden on participants and sites?

▶ Has due diligence been conducted to ensure the reliability and stability of the mobile technologies throughout the lifespan of the trial?

Identify and conduct necessary feasibility and/or pilot studies with sites and a representative patient population.

▶ Are prior feasibility studies with mobile technologies sufficiently similar and relevant to the trial, or are additional studies needed?

▶ Is a protocol simulation planned to detect potential issues with technologies and study design prior to trial launch?

MAXIMIZING VALUE AND MINIMIZING BURDEN FOR STUDY PARTICIPANTS

Informed consent process should involve an ongoing, interactive conversation with participants.

▶ Does the informed consent process describe the mobile technology, including risks and benefits?

▶ Does the informed consent process set clear expectations related to interaction between participants and investigative site personnel?

▶ Does the informed consent document clearly explain other information that participants need to know about mobile technologies used in the trial?

Account for patients' health literacy and technical literacy in all communications.

▶ Are all patient-facing materials as simple as possible and designed to meet the needs of study participants, including those with low health and/or technical literacy?

Be prepared to collaboratively identify and evaluate privacy risks.

▶ Does the IRB include members with sufficient technological expertise, or otherwise engage such experts, to evaluate the unique privacy risks posed by trials using mobile technologies?

▶ Can IRB findings on privacy risks be shared more broadly in order to establish best practices?

Ensure participants understand the implications for their privacy and confidentiality of the mobile technologies used.

▶ To the extent possible, have measures been taken to protect participant data?

▶ Are participants aware that confidentiality cannot be guaranteed?

▶ For IT service providers that will have access to participant data, have clear guidelines been provided for protecting patient privacy and confidentiality?

▶ Can IT service providers support the sponsor in conveying privacy and confidentiality information to participants in plain language?

▶ Is all privacy and confidentiality information clear to potential participants (even if consumer technologies are used in the trial)?

▶ Does the informed consent document clearly explain which parties will have access to participant data?

Set clear expectations with participants about safety monitoring during the trial.

▶ Do participants know that in the event of a medical emergency they should directly contact emergency services?

▶ Are participants reminded throughout the study of the steps they should take in the event of an emergency?

Provide participants with easy access to technical support.

- ▶ Are all individuals who will be providing technical support familiar with the study and prepared to address participant queries?

- ▶ Have plans for technical support and issue escalation been communicated to all involved parties?

- ▶ Is the contact information for technical support easy to find?

- ▶ Is technical support available to participants outside normal business hours?

- ▶ Is support provided in all needed languages?

- ▶ Is there an automated process in place to detect technology malfunction?

Be mindful that mobile technologies can change the way sites and participants interact during a trial.

- ▶ Will participants remain appropriately engaged throughout the trial, as determined with patient input during trial planning?

- ▶ Have clear expectations been set with participants about communication with relevant study personnel during the trial?

- ▶ Have the benefits and drawbacks of in-person visits vs. remote communication methods been considered?

Identify ways to return value to participants throughout the trial.

- ▶ Has a plan been developed for how, when, and what types of health-related information will be returned to participants?

- ▶ Can real-time access to individual results be provided in a way that maintains study integrity and participant safety?

- ▶ Is the return of data personalized and understandable?

- ▶ Has the plan for sharing data been clearly communicated to potential participants during the informed consent process?

- ▶ Have other ways to return value to participants been identified?

ADDRESSING CHALLENGES FOR INVESTIGATIVE SITES

Clearly delineate responsibilities and consider alternate payment structures in contracts.

- ▶ Does the contract clearly define the responsibilities of all parties?
- ▶ Should contracts include additional budget for feasibility studies, collection of endpoints relevant to future implementation considerations, and/or IT support for sites?
- ▶ Should alternate payment structures, such as lump sum budgets, be considered?

Be prepared for additional time and cost required to incorporate mobile technology into clinical trials.

- ▶ Have sites been provided with information from pilot and similar studies to facilitate accurate budget preparation?
- ▶ Is the budget set up with flexibility to account for unknowns?

Ensure sites have appropriate infrastructure to conduct mobile clinical trials.

- ▶ Are sites recruiting appropriately experienced staff?
- ▶ Are sites that are historically adept at enrolling participants being provided with more devices?

Develop effective training modules for site staff around selected mobile technologies.

- ▶ Does the training offer hands-on practice with technologies used and allow sufficient time to establish familiarity?
- ▶ Are multiple training methods provided to account for diverse learning styles?
- ▶ Will trainings reach all site staff who will be working with the technologies on a day-to-day basis?
- ▶ Has a playbook or series of screenshots been developed to familiarize site staff with how participants will interact with the technologies during the trial?

Streamline and standardize training across sponsors.

- ▶ Does training assess what site staff know and focus on study-specific and other new elements?

Put plans and policies in place to handle technology issues, malfunctions, and loss.

- ▶ Do sites have access to the IT service provider to enable more efficient issue escalation and resolution?
- ▶ Have plans for technology loss and/or malfunction been put in place prior to providing the technology to study participants?