Mobile Clinical Trials: CTTI Recommendations for Engaging Patients as Partners

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School of Medicine & Health Sciences
THE GEORGE WASHINGTON UNIVERSITY

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- The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.

Agenda

- Brief Introduction to CTTI & the Mobile Clinical Trials Program
- Multi-Stakeholder Recommendations for Mobile Clinical Trials:
  - Engaging Patients and Sites
  - Maximizing Value and Minimizing Burden
- Discussion

CTTI Strengths

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Public-Private Partnership
Co-founded by Duke University & FDA
Involves all stakeholders
80+ members

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

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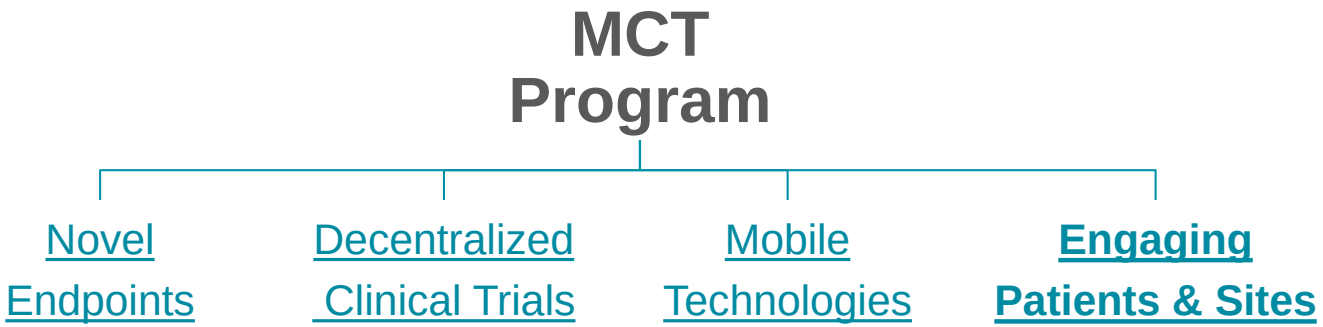
CTTI Mobile Clinical Trials (MCT) Program

- **PURPOSE:** Develop evidence-based recommendations* that affect the widespread adoption and use of mobile technology in clinical trials for regulatory submission.
- **ANTICIPATED IMPACT:** High quality, efficient trials that successfully leverage the use of mobile technology in ways that incorporate the needs and expectations of potential research participants and investigative sites



Scope: FDA-regulated clinical trials after the time of initial research volunteer consent

PATIENT CENTRICITY

- High-quality, patient-centric endpoints
- Endpoints that matter to patients
- Reduced participation burden
- Fewer barriers to participation
- Better, more complete info

EFFICACY

- Improved predictability rates
- Increase in # of potentially successful treatments

EFFICIENCY

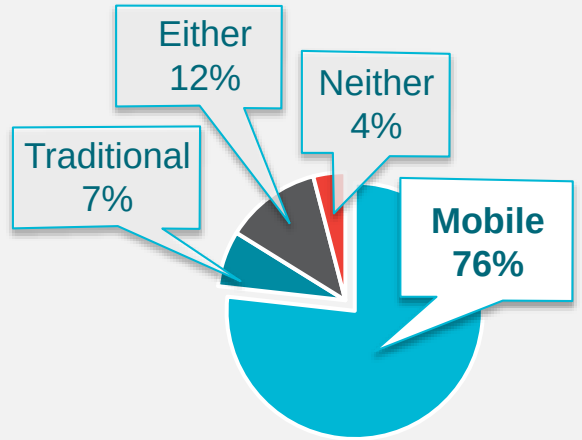
- Generation of data needed by payers to make coverage determinations
- Prevention of delays in coverage, payment, & use decisions
- Patient access to meds

Potential Benefits of Using Mobile Technology in Clinical Trials

Patient Survey: Highlighted Findings

- Most respondents (84%) said they did not need to see trial doctor more often than start and end of study
- A range of devices acceptable but should be:
  - Simple to learn and use
  - Convenient in daily life
  - Frequently show patients the information being collected
  - Half or more of respondents wanted trial staff to provide in-person training and troubleshooting for the device
- Assurances of confidentiality important to patient participation

"If you had the option to take part in either of these trials (traditional or mobile), which would you be more likely to join?"



Multi-Stakeholder Recommendations: Engaging Patient & Site Perspectives In Planning Mobile Trials

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

2. Select mobile technologies based on requirements of the study and **needs of the intended user population**.*

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

See also the previously released Mobile Technology Selection Framework, available at https://www.ctti-clinicaltrials.org/projects/mobile-technologies

Project Resource: **Planning Trials Using Mobile Technologies**

 SELECTING OUTCOME MEASURES	➢ Focus on measures that are meaningful to patients. Select a technology-derived assessment only if better (e.g., more meaningful to patients or more informative) than existing outcome assessments.
 DEFINING STUDY PARTICIPANT CHARACTERISTICS	➢ Develop plans for participant inclusion and diversity, and identification of opportunities and risks related to technology access and literacy.
 SELECTING MOBILE TECHNOLOGIES	➢ Weigh protocol elements against added participant burden; evaluate the acceptability, usability, and tolerability of mobile technologies; and plan for participant expectations. ➢ As necessary, test mobile technologies with sites and a representative patient population.
 PLANNING TRIAL LOGISTICS	➢ Identify and develop plans for addressing technical support needs of participants, as well as facilitating patient-site interactions. ➢ Identify and develop plans to address challenges for investigative sites, including budgets and contracting, infrastructure, training, and technology malfunctions.
 DEVELOPING STUDY MATERIALS & COMMUNICATIONS	➢ Seek input on informed consent materials, including specific considerations related to data and health monitoring, health and technical literacy, and patient privacy and confidentiality ➢ Evaluate opportunities to return outcomes and other data, and determine how best to return value to study participants.

Full resource available at https://www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites

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Conduct Necessary Feasibility Studies

Recommendations include:

- **Focus on information not available from prior feasibility studies.***
- **The more elements of technology that are new to the sponsor, the more intensive the testing should be.**

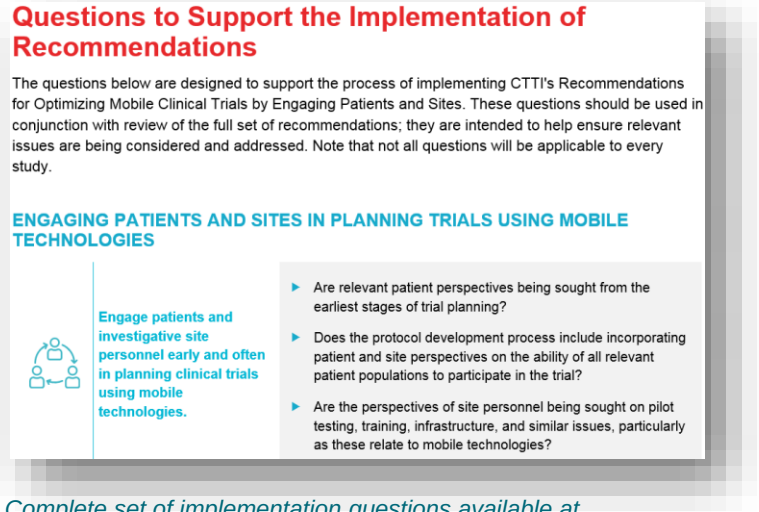
Testing may include:

- **Feasibility studies** to ensure technology meets patient needs (tolerability, acceptability, usability).
- **Protocol simulation** (i.e., dry run) to detect potential issues before trial launch.
- **Piloting** the trial and related technologies with center-of-excellence sites.

**CTTI will soon be launching an interactive database of published feasibility studies*

Example Implementation Questions

- 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?
- Have **protocol elements been weighed against the potential added burden** on participants 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?

Complete set of implementation questions available at https://www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites

Multi-Stakeholder Recommendations: Maximizing Value & Minimizing Burden for Study Participants

1. The informed consent process should involve an ongoing, interactive conversation.
2. Account for **patients' health literacy and technical literacy** in all communications.

3. Be prepared to collaboratively **identify and evaluate privacy risks.**
4. Ensure participants understand the implications for their privacy and **confidentiality of the mobile technologies used.**
5. Set clear expectations with participants about **safety monitoring** during the trial.

6. Provide participants with easy access to **technical support.**
7. Be mindful that mobile technologies can change the way **sites and participants interact** during a trial.
8. Identify ways to **return value to participants** throughout the trial, including return of outcomes data collected by mobile technologies.

Detailed recommendations & implementation questions available at https://www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites

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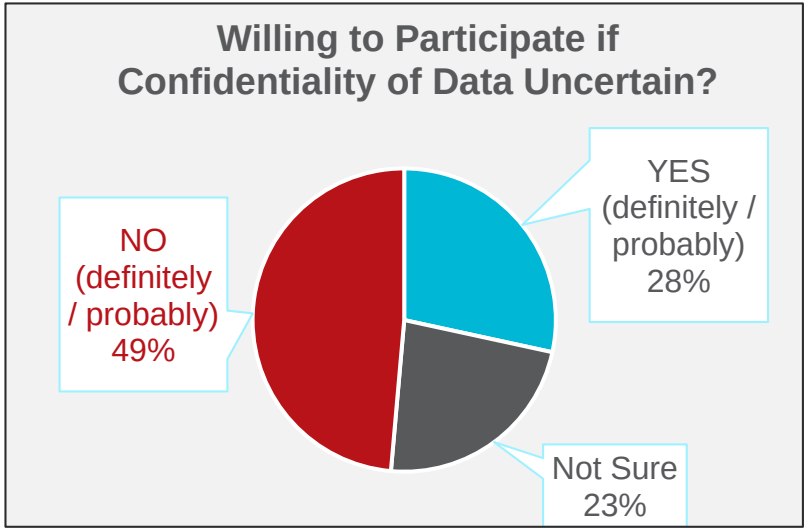
Patient Survey: Confidentiality Important But Few Expressed Concerns

- **49%** (n=91) **reported they would not take part in a mobile trial if** they were uncertain their information would remain confidential

But…

- Over half (55%, n=103) reported that they were **not worried that others, besides the research team, would be able to see their data** collected by the technology

- Over half (62%, n=116) reported that they were **comfortable or very comfortable using mobile technology that tracked their location in a clinical trial**



Informed Consent

What participants need to know about mobile technologies

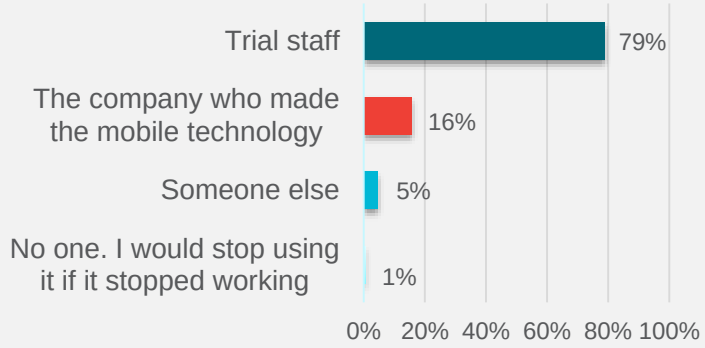
- Description of technologies
- Data access and commercialization
- Data sharing with participants & providers
- Safety monitoring (& whether real time)
- Data privacy & confidentiality
- Technical support access

A tiered consent approach may help convey information clearly. See CTTI's Informed Consent recommendations.

Example Implementation Questions:
Technical Support & Patient/Site Interaction

- Is the contact information for **technical support easy to find?**
- Are all individuals who will be providing technical support familiar with the study & **prepared to address participant queries?**
- Have the benefits & drawbacks of **in-person visits vs. remote communication methods** been considered?

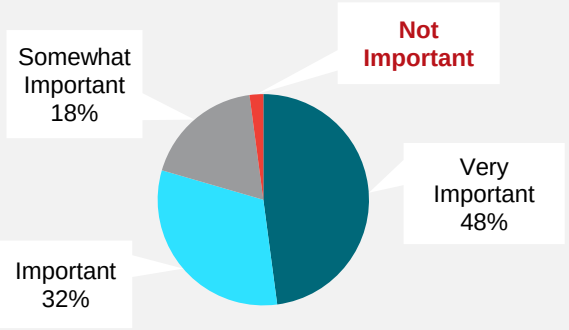
Patient Survey: "Who would you most want to contact to fix the mobile technology if it stopped working?"



Example Implementation Questions:
Returning Value to Participants

- **Has a plan been developed for how, when, & 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?
- Have **other ways to return value** to participants been identified?

Patient Survey: "How important or not important is it that you are shown the information collected about you by the mobile technology?"



Resources to Support Implementation

- Recommendations & Implementation Questions
- Planning Trials Using Mobile Technologies
- Case Study: Returning Value to Participants without Compromising Study Integrity
- Checklist for Sponsors: Considerations in Selecting & Equipping Sites for Clinical Trials with Mobile Technologies
- Checklist for Investigative Sites: Questions to Ask During Budgeting & Contracting

Available at
www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites

Thank You to the MCT Engaging Patients & Sites Project Team

Team Leaders

- Cindy Geoghegan (Individual Patient)
- Steve Morin (FDA/OC)
- Virginia Nido (Genentech, a member of the Roche Group)^
- William Wood (UNC-Chapel Hill)

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- David Brennan (MedStar Health)*
- Kara Dennis (Medidata Solutions)*
- Sue Dubman (Individual Patient)
- Guy Eakin (Arthritis Foundation)*
- Terri Hinkley (ACRP)*
- Les Jordan (Target Health, Inc)
- Hassan Kadhim (Bristol-Myers Squibb)
- Kristine Nelson (EMMES Corporation)*
- Amanda Niskar (Individual Patient)
- Paul O'Donohoe (Medidata Solutions)
- Petros Okubagzi (MedStar Health)
- Ido Paz-Priel (Genentech, a member of the Roche Group)
- Ken Skodacek (FDA/CDRH)
- Junyang Wang (FDA/CDER)
- Immo Zadezensky (FDA/CDER)*

^Executive Committee Champion | *Former Team Member

THANK YOU.

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