Introduction to CTTI’s Mobile Clinical Trials (MCT) Program

Jennifer Goldsack, CTTI
Why are mobile technologies important in clinical trials?

Watch the Introduction to Mobile Clinical Trials Program from the Mobile Technologies Event

Art credit: Gapingvoid Culture Design Group (www.gapingvoid.com)
Potential Benefits of Using Mobile Technology in Clinical Trials

**PATIENT CENTRIC**
- 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
- Prevention of delays in patient access to meds
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:
Increased number of clinical trials leveraging mobile technology.

4 PROJECTS

- Novel Endpoints
- Mobile Technologies
- Decentralized Clinical Trials
- Stakeholder Perceptions

*Scope: FDA-regulated clinical trials after the time of initial research volunteer consent*
CTTI MCT Novel Endpoints Project
Steps for Novel Endpoint Development

1. Identify an **aspect of health** affected by the disease that the patient cares about
2. Identify the **scope of assessment**: the aspect of an individual’s clinical, biological, physical, or functional state, or experience that the assessment is intended to capture
3. Select the **specific measurement** to report that is a good representation of the aspect of the patient’s medical status
4. Select **suitable mobile device** for data capture
   - YES
   - Are you developing a novel endpoint that is generated using data captured using a mobile device?
   - NO
5. Set or develop standards
6. Describe the study population for whom the endpoint will be targeted
CTTI MCT Decentralized Trials Project

Focus is decentralized trials conducted through telemedicine and mobile healthcare providers in the US.

Federal and local US state laws, regulations, and considerations come into play.

The recommendations will target industry sponsors and CROs, addressing the following topics:

- Protocol Design
- Telemedicine State Licensing Issues
- Drug Supply Chain
- Mobile Practitioners
- Considerations for Investigator Delegation and Oversight
- Safety Monitoring
CTTI MCT Stakeholder Perceptions Project

Project recommendations and resources will address...

- Engaging patient and site perspectives for study planning
- Maximizing value and minimizing burden for study participants
- Addressing barriers for investigative sites
Creating a Comprehensive Toolkit

Developing an integrated, program-level offering

- A “one-stop shop” for mobile clinical trials
- Coming in 2019!
Take Action

- Download published recommendations and resources

- Go to [www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org) to sign up to receive CTTI’s monthly e-newsletter for updates on the rolling release of additional recommendations
  - Decentralized Trials, September 2018
  - Stakeholder Perceptions, January 2019
  - Additional Program level offerings
CTTI’s MCT Mobile Technologies Project
## CTTI MCT Mobile Technologies Project Team

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**Patient** | **Tech** | **Sponsor** | **Academia** | **Government**
Scope and Approach

- Mobile technologies in scope
  - Mobile applications and other wearables, ingestibles, implantables, and portable technologies containing sensors for objective data capture

- Multi-phase approach to evidence gathering
  - Engaged experts beyond the clinical trials enterprise

- Created a comprehensive guide to support the use of mobile technologies for data capture
CTTI MCT Mobile Technologies Project

MOBILE TECHNOLOGY SELECTION

DATA COLLECTION, ANALYSIS, & INTERPRETATION

FDA SUBMISSION & INSPECTION

DATA MANAGEMENT

PROTOCOL DESIGN & EXECUTION

Existing scientific principles

Data quality standards

Participant engagement

REMAIN CRITICAL
I’m optimistic!
THANK YOU.

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www.ctti-clinicaltrials.org