INNOVATING CLINICAL TRIALS WITH MOBILE TECHNOLOGY

You have questions. We're finding the answers.

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

To pave the way for advances in FDA-regulated clinical trials, we are exploring the practical implications of integrating mobile devices after the point of informed consent. We are developing strategies for dealing with large volumes of data, as well as tips for engaging with FDA during trial design, execution, and monitoring.

Bottom line: We hope to bring about improvements in trial quality and efficiency through use of mobile technology.

WILL WORKLOAD INCREASE FOR SITE STAFF?

Our evidence shows that device failure and management should not fall on site staff. Plus, current trials using mobile devices are not monitoring data in real-time; patients should be told not to expect emergency care or treatment adjustments based on data recorded using the trial devices.

Bottom line: Many trial processes will remain the same.

WHAT ABOUT THE LEGAL ISSUES?

We are collecting others' experiences and addressing legal and regulatory issues, such as investigator licensing. Specifically, we are:

- Clarifying who qualifies as an investigator per FDA regulations
- Detangling telemedicine laws across 50 states
- Clarifying the supply chain for investigational drug shipments

WILL THE DATA HAVE INTEGRITY?

Mobile devices offer the opportunity to collect more complete and informative data than ever before. Our evidence suggests randomization will help offset errors from device misuse.

Bottom line: Data standards should not be higher for trials using mobile devices.

WHAT ARE BENEFITS OF NOVEL ENDPOINTS GENERATED USING MOBILE TECHNOLOGY?

Our evidence suggests several potential benefits:

- Data capture during activities of daily living
- Better insight into the true burden of a disease
- Improved ability to distinguish which drugs may help patients before phase 3 trials

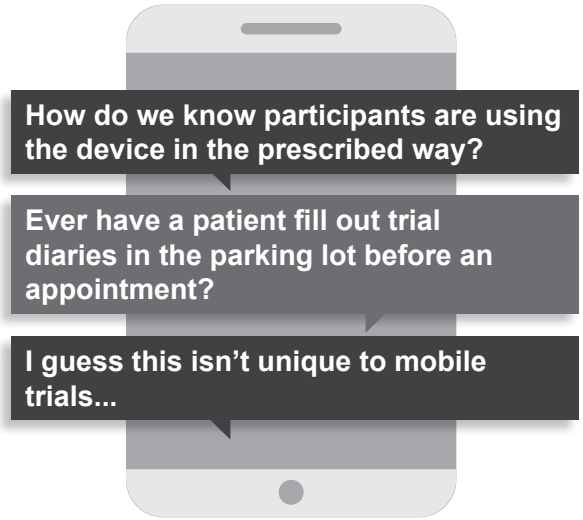
Bottom line: Better measures are possible with mobile technology.

WILL TRIAL PARTICIPATION BE IMPACTED?

Initial evidence suggests several potential benefits:

- Reduced burden of participation
- Increasing participant satisfaction
- Increased protocol adherence
- Participation by a more diverse population

Bottom line: Patients have a lot to gain from integrating mobile technology into trials.



COMING SOON! Best practices for developing novel endpoints and tools to implement these practices, including:

- Required steps and recommended approaches for developing a novel endpoint
- Strategies to reduce friction and optimize this process
- Four use cases demonstrating how this process works

Each of CTTI's 4 MCT Projects will be issuing recommendations and tools over the next year.

THE 4 PROJECTS OF CTTI'S MOBILE CLINICAL TRIALS (MCT) PROGRAM*

- LEGAL & REGULATORY ISSUES
- NOVEL ENDPOINTS
- MOBILE DEVICES
- STAKEHOLDER PERCEPTIONS

WANT MORE INFO?

Learn more about CTTI's MCT Program:
http://bit.ly/CTTI-MCT

Stay informed with CTTI's monthly e-newsletter:
http://bit.ly/CTTI-Newsletter