Recommendations Executive Summary: Advancing the Use of Mobile Technologies for Data Capture & Improved Clinical Trials

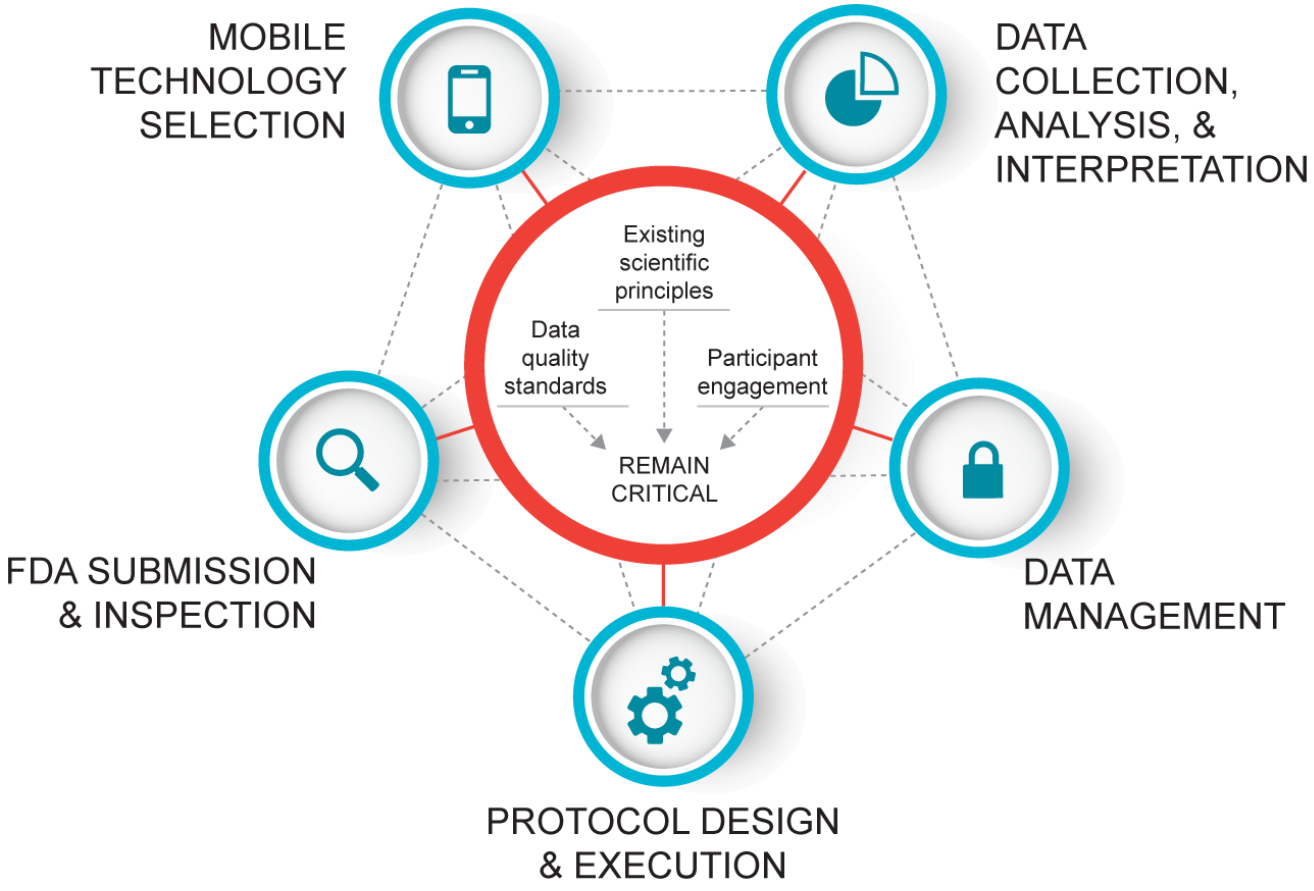
Mobile technology offers a powerful tool to improve the quality and efficiency of clinical trials.

Potential benefits include:

- Capturing previously unavailable, objective, “real world” data from patients during their daily lives,
- Reduced barriers to participation, and
- Lower costs associated with conducting clinical trials.

Mobile technologies for data collection should be considered in all future trials to improve the quality and efficiency of clinical trials and the value of the data they collect. However, despite the significant promise of using mobile technologies—including mobile applications and other wearables, ingestibles, implantables and portable technologies containing sensors—for data capture, they have yet to be widely incorporated into regulated clinical trials.

To promote increased use, the Clinical Trials Transformation Initiative (CTTI) has developed a comprehensive guide to the many considerations that accompany the decision to use a mobile technology for data capture. By bringing together regulatory, technical, clinical, operational, and patient experts, CTTI has created a resource to guide both newcomers to using mobile technologies in clinical trials and experienced trialists seeking specific information.



These recommendations highlight much commonality with "traditional" trial best practices, and show a low barrier of entry for sponsors of studies evaluating new drugs, biologics, and medical devices. These resources are primarily intended for sponsors, recognizing their role as "first in line" to decide whether to include mobile technologies for data capture for a clinical trial. Contract research organizations (CROs) and outsourced electronic service vendors, such as mobile technology manufacturers, will also find this information valuable in understanding how to optimize the use of mobile technologies in clinical trials.

Contents At-A-Glance

Access more detailed information and guidance by clicking on the summary statements or resources below or visiting www.ctti-clinicaltrials.org/projects/mobile-technologies.

Recommendations

Mobile Technology Selection

- Know what you want to measure before selecting the mobile technology
- Mobile technology selection should be specification-driven and collaborative
- CTTI recommends that a technology's regulatory status not be the sole driver in sponsors' decisions about which mobile technology to use
- The appropriateness of the selected mobile technology should be justified through verification and validation processes
- Feasibility studies conducted before full implementation in a large study reduce risk

Data Collection, Analysis, and Interpretation

- Biostatisticians and data scientists, as appropriate, should be involved in all decisions regarding protocol design, data collection, analysis, and interpretation.
- Collect the minimum data set necessary to address the study endpoints
- Include appropriate strategies for monitoring and optimizing data quality
- Address data attribution proactively with patient input
- Identify acceptable ranges and mitigate variability in endpoint values collected via mobile technologies
- Minimize missing data
- Plan appropriately for the statistical analysis of data captured using mobile technologies
- Establish industry-wide standards to drive the successful scaling and more rapid acceptance of clinical trials using mobile technologies for data capture.

Data Management

- Ensure the authenticity, integrity and confidentiality of data over its entire lifecycle
- Optimize data accessibility while preventing data access from unauthorized users.
- Ensure that access to data meets your needs prior to contracting an electronic service vendor
- Apply an end-to-end, risk-based approach to data security
- Monitor the quality of data captured by mobile technologies centrally through automated processes
- Ensure that site investigators have access to data generated by their participants.

Protocol Design and Execution

- Data sharing decisions should be driven by safety and trial integrity
- Communication and transparency with participants regarding safety monitoring is critical
- Define and test processes for the implementation, operation, and maintenance of mobile technologies in the field prior to launching the trial

- Have a plan in place for mobile technology failure
- The considerations that inform adaptive designs in a trial using mobile technologies are the same as for traditional studies.

FDA Submission and Inspection

- Ensure that trials conducted using mobile technologies for data capture may be readily reconstructed (i.e., end-to-end traceability)
- Source data should be the primary data resource provided to FDA during inspection
- Be prepared to provide supporting material for mobile technology-based claims to FDA as part of any marketing application

Additional Guidance

Resources

- Mobile technology selection framework
- Strategies for optimizing data quality
- Data flow diagram
- Strategies for promoting and protecting data integrity
- Decision Support Tool: Real Time Data Sharing with Study Participants
- Framework of Approaches for Safety Monitoring and Managing Safety Signals
- Data and supportive information to provide FDA inspectors
- What sponsors should include in their submissions to FDA

Case Examples

- Verification and Validation Processes in Practice
- Feasibility Testing to Promote Successful Inclusion of Mobile Technologies for Data Capture
- Optimizing Data Quality and Participant Privacy
- Using Remote, Smartphone-Based Data Collection to Broadly Share Health Insights
- Sharing Data to Promote Patient Engagement

Appendices

- Technical approaches to promoting correct data attribution
- Approaches to securing data generated by mobile technologies

Glossary

- Definition of all technical and regulatory terms used