DIGITAL HEALTH TRIALS
Recommendations for Managing Data

Digital health technologies have fundamentally changed when, where, and how data can be collected. Yet the critical principle of data collection remains the same: ensuring the authenticity, integrity, and confidentiality of data over time.

You can use CTTI’s recommendations and resources to help understand, plan for, and address the new challenges associated with digital health technologies, including data access, ownership, and storage; data sharing considerations; and communicating trial data with participants.

RECOMMENDATIONS

1. General
   - Collect the minimum data set necessary to address the study endpoints
   - Identify acceptable ranges and mitigate variability in endpoint values collected via mobile technologies
   - Proactively address and map data flow, data storage, and associated procedures

2. Access to Data
   - 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
   - Address data attribution proactively with patient input
   - Ensure that site investigators have access to data generated by their participants
   - Return value to participants throughout the trial, including return of outcomes data collected by digital technologies
   - Let data sharing decisions be driven by safety and trial integrity

3. Security & Confidentiality
   - Apply an end-to-end, risk-based approach to data security
   - Ensure the authenticity, integrity, and confidentiality of data over its entire lifecycle
   - Be prepared to collaboratively identify and evaluate privacy risks
   - Ensure that participants understand the privacy and confidentiality implications of using digital technologies
4. Monitoring for Safety & Quality

- Include appropriate strategies for monitoring and optimizing data quality
- Set clear expectations with participants about safety monitoring during the trial
- Plan appropriately for the statistical analysis of data captured using digital technologies
- Monitor data quality centrally through automated processes
- Minimize missing data

RESOURCES

- Digital Health Technologies Data Flow Diagram
- Decision Support Tool: Real-Time Data Sharing with Study Participants
- Table: Approaches for Safety Monitoring & Managing Safety Signals when using Digital Health Technologies for Data Capture
- Table: Promoting & Protecting Data Integrity
- Table: CTTI Recommended Strategies for Optimizing Data Quality
- Case Study: Returning Value to Participants without Compromising Study Integrity
- Case Study: Sharing Data to Promote Patient Engagement
- Case Study: Using Remote, Smartphone-Based Data Collection to Share Health Insights
- Case Study: Optimizing Data Quality and Participant Privacy
- Glossary: CTTI’s Digital Health Technologies Recommendations