DIGITAL HEALTH TRIALS

Recommendations to Sponsors for Supporting Sites

When planning clinical trials that use DCT elements and/or digital health technologies, use CTTI's recommendations and resources to develop robust plans for testing, documentation, technical support, training, communication, data integrity, and participant safety.

RECOMMENDATIONS

1. Build Awareness and Support

- Educate sites about the anticipated benefits and challenges of DCT elements and digital health technologies, including new processes that will be implemented, the underlying rationale for their inclusion in any planned protocol, and mitigation plans for addressing potential issues.
- Listen carefully to the experiences, perceptions, and recommendations of investigators and site personnel, ensuring effective two-way communication throughout trial planning and execution.

2. Budget

- Carefully assess the additional time and cost that will be required for sites to implement any DCT and digital health elements (e.g., time and cost related to training, monitoring, oversight, technology support) and plan budgets to be able to pay sites appropriately.
- Clearly delineate responsibilities and consider implementing alternative payment structures in contracts.

3. Develop Infrastructure

- Ensure sites have the appropriate infrastructure to support the planned DCT or digital health technology elements.
- Confirm appropriate plans and policies are in place to handle technology issues, malfunctions, and failures that could result in risks to participant safety and/or data loss.
- Agree on expectations and processes for the oversight of any non-site trial personnel, such as mobile nurses.

4. Train

- Develop effective training modules for trial personnel (both site-based and mobile) around planned DCT elements and digital health technologies. Start by assessing what trial personnel already know, accept equivalent training already completed for other sponsors, and focus training on new or unique elements for the trial (e.g., protocol-specific safety monitoring and communication escalation plans and procedures).
- Whenever relevant, support sites in training and educating local health care providers that contribute to patient care and trial data collection (i.e., those who perform trial-related activities that require a detailed knowledge of the protocol, investigational product, and investigator's brochure).

5. Support Effective Site/Patient Communication

- Provide sites with all the materials necessary to effectively educate, train, and support study participants regarding any DCT elements and/or digital health technologies used in the trial.
- Be transparent in communications with participants regarding safety monitoring.
- Account for participants' health literacy and technical literacy in all communications.
- Provide participants with easy access to technical support.
- Ensure that site investigators have timely access to data generated by their participants and DCT service providers.

RESOURCES

- Considerations for Optimizing Digital Clinical Trials by Engaging Patients and Sites
- Planning Trials Using Mobile Technologies: Gathering Patient & Site Input
- Questions to Ask: Engaging Patients & Sites in Digital Health Trials
- Checklist for Sponsors: Considerations in Selecting & Equipping Sites for Clinical Trials with Digital Health Technologies
- Checklist for Investigative Sites: Questions to Ask During Budgeting & Contracting