DIGITAL HEALTH TRIALS

Recommendations for Selecting and Testing a Digital Health Technology

There are many digital health technologies in the marketplace—how do you choose thebest one for your trial? And after you've selected the candidate technology for your trial, how do you prepare it for use in the field?

CTTI's recommendations and resources will help you understand what needs to be considered before selecting a digital health technology and walk you through the feasibility testing, verification, and validation processes.

This document provides a set of high level recommendations. A detailed considerations document is available under the Resource section of this document and at https://ctti-clinicaltrials.org/our-work/digital-health-trials/selecting-and-testing-dht/

RECOMMENDATIONS

1. **Know what you want to measure† before selecting the digital health technology**

   ► The decision to use a digital health technology for data capture should be driven by the following motivations:

      1. Unmet patient or scientific need for a better assessment, and/or

      2. The promise of more efficient, less burdensome trials through digital data capture approaches.

2. **Digital health technology selection should be specification-driven and collaborative**

   ► The selection of the digital health technology is a multi-factorial decision that should be tailored to each trial and driven by specific requirements, such as:

      o The technical performance specifications and functional requirements for measuring the outcome assessment of interest;

      o The study needs (i.e., constraints and nuances of the central scientific question); and

      o The needs and preferences of study participants.

> ▶ A framework of specifications to consider, designed to facilitate collaboration between sponsors and digital health technology manufacturers, is available [here](#).

3. A digital health technology's regulatory status should not be the sole driver in sponsors' decisions about which technology to use

> ▶ CTTI recommends that a specification-driven approach be used to optimize digital health technology selection.

4. The appropriateness of the selected digital health technology should be justified through verification and validation processes

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VERIFICATION VS VALIDATION

Verification assures that the digital health technology reliably measures what it claims to measure, and it is usually performed by the technology manufacturer using a series of engineering bench tests.

Validation ensures that the data generated by the digital health technology accurately represents the outcome assessment it purports to be measuring.

> ▶ A digital health technology manufacturer should provide the sponsor with documentation of performance characteristics along with their limitations.

> ▶ Data monitoring should occur in an automated, centralized fashion so that irregular data—which may indicate the presence of calibration errors—can be immediately flagged and investigated.

> ▶ Validation should test the digital health technology in both a controlled environment (i.e., the laboratory or clinic) and a real-world environment.

> ▶ Validation should occur in the participant population of interest, and it is likely that the validation process will be optimized through collaboration between digital health technology manufacturers, sponsors, and other technical and clinical experts.

> ▶ Ultimately, sponsors are responsible for determining whether the endpoints in question have been adequately validated for their trial; however, CTTI recommends that digital health technology manufacturers support this decision-making process by being as transparent as possible.

5. Be mindful that digital health technologies can change the way sites and participants interact during a trial

▶ In planning the trial, it is important to do the following:

    ○ Recognize that many participants may value a human connection. Based on discussions with patients about the level of interaction that they want, take steps to ensure participants will remain appropriately engaged.

    ○ Set clear expectations and provide participants with specific directions, informing them about what to expect during a digital health trial and how to easily communicate with relevant study personnel.

    ○ Carefully weigh the benefits and drawbacks of both in-person visits and remote communication methods, and consider when each may be the most appropriate.

6. Feasibility studies conducted before full implementation in a large study reduce risk

▶ Prior to the trial launch, sponsors should consider conducting feasibility (or pilot) studies of their chosen technology(ies) to assess their tolerability, acceptability, and usability and identify other, unanticipated issues with their proposed use—such as poor wear-time compliance—within the specific context of the trial.

7. Define and test processes for the implementation, operation, and maintenance of digital health technologies in the field prior to launching the trial

▶ All users of digital health technologies for data capture, including those with digital health technology management responsibilities, should have the appropriate education, training, and experience to perform their assigned tasks.

▶ A robust digital health technology management plan should be developed during the pre-trial phase, with feasibility assessments conducted where appropriate.

▶ While sponsors are ultimately responsible for digital health technology management in the field, it should be clear who is assigned the task of ensuring different aspects of digital health technology management.

▶ Standard operating procedures (SOPs) should be developed and followed for any operational and user issues that may arise.

8. Have a plan in place for digital health technology failure

▶ Take steps in advance of trial initiation to mitigate the risk of digital health technology malfunction.

▶ Clearly articulate the roles, responsibilities, and expected actions using SOPs developed during the pre-trial phase.

▶ Put in place automated processes for detecting technology malfunctions.

▶ Ensure that technologies can be quickly replaced whenever they cannot be easily fixed in the field.

▶ Develop strategies for managing technology failure that include processes for determining whether it is appropriate to merge data from two different digital health technologies for a single trial study participant, if needed.

RESOURCES

▶ [Considerations for Advancing the Use of Digital Technologies for Data Capture & Improved Clinical Trials Document](#)

▶ [Framework: Specifications to Consider During Digital Health Technology Selection](#)

▶ [Case Study: Feasibility Testing to Promote Successful Inclusion of Digital Health Technologies for Data Capture](#)

▶ [Case Study: Verification & Validation Processes in Practice](#)

▶ [Feasibility Studies Database](#)

▶ [Glossary: CTTI's Digital Health Technologies Recommendations](#)

†For recommendations to support the selection, development, and inclusion of digitally-derived endpoints, see CTTI's [Novel Endpoints recommendations and resources.](#)

For more information on CTTI's Digital Health Trials work, please visit http://www.ctti-clinicaltrials.org/our-work/digital-health-trials