



# **CTTI Considerations for Optimizing Digital Clinical Trials by Engaging Patients and Sites**

**February 21, 2019**

## **CTTI MISSION:**

To develop and drive adoption of practices  
that will increase the quality and efficiency of clinical trials

## OVERVIEW: ENGAGING PATIENTS AND SITES TO DRIVE ADOPTION OF DIGITAL HEALTH TECHNOLOGY IN CLINICAL TRIALS

The use of digital technology holds promise for improving the quality and efficiency of clinical trials, increasing scale and reach, reducing participant burden and increasing engagement, streamlining study operations, and creating opportunities for collecting data that was previously unattainable. Digital technologies can also play a critical role in accelerating the discovery, development, and approval of new medical treatments.

However, to maximize opportunities and minimize challenges associated with digital technology, it is critical to understand the perspectives of patients and investigative site personnel and incorporate those perspectives into trial design and execution. The considerations in this document emphasize considerations that are unique to or particularly important for trials that incorporate digital technologies. They are designed to assist research sponsors in:

- ▶ **Engaging patients and sites in planning** clinical trials using digital technology, including protocol design, technology selection, and pilot testing.
- ▶ **Maximizing value and minimizing burden for study participants**, including considerations for setting participant expectations, protecting privacy, returning individual data, enhancing participant-site interactions, and providing technical support.
- ▶ **Addressing challenges for investigative sites**, from contracting and budgeting considerations, to evaluating site readiness for digital clinical trials and implementing effective and streamlined training.

These evidence-based considerations were developed by experts and leaders across the clinical trials enterprise, including patients and other stakeholders. The considerations are intended to complement CTTI recommendations in the [Digital Health Trials \(DHT\) Hub](#), which also includes projects focused on [Developing Novel Endpoints](#), [Selecting & Testing Digital Technologies](#), [Preparing a Site](#), [Interacting with Regulators](#), [Managing Data](#), and [Planning Decentralized Clinical Trials](#). The patient-focused considerations in this document apply to all trials using digital technologies, from traditional to fully decentralized.

While aimed most directly at sponsors, these considerations will be valuable for all stakeholders, and ultimately will help the research enterprise maximize the opportunities of digital technologies to advance the development of new medical products.

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CTTI's [Digital Health Trials \(DHT\) Program](#), including the considerations in this document, focuses on the use of digital technologies for the collection of objective data (measured directly by the digital technology) in FDA-regulated clinical trials after the time of participant consent. This project did not directly consider the use of digital technologies to collect other types of data, though many of the considerations may apply to other types of data collection via digital technologies.

For the purposes of these considerations and resources, **digital technologies** are defined as digital applications and other wearables, ingestibles, implantables, and portable technologies containing sensors for the remote capture of outcomes data.

## I. Engaging Patients and Sites in Planning Trials Using Mobile Technologies

To successfully use digital technology during the trial, it is critical that sponsors fully incorporate patient and site perspectives during the study planning process. Prior CTTI work<sup>1,2</sup> indicates that engaging patients and sites during the planning and conduct of trials can:

- ▶ Enhance satisfaction and engagement, recruitment and trial feasibility;
- ▶ Ensure research goals are aligned with the needs of the patient community; and
- ▶ Provide a substantial return on investment to the sponsor.

### 1. Engage patients and investigative site personnel early and often in planning clinical trials using digital technologies.

#### Patient vs. Study Participant

In these considerations, we use the term “**patient**” to refer to individuals who have personal experience with a disease or condition, in the present or past. Though not explicitly stated, where this document suggests incorporating patient perspectives, it will also often be appropriate to include the perspectives of caregivers.

We use the term “**study participant**” to indicate patients and healthy volunteers who are actively participating in (i.e., enrolled in) a clinical trial.

<sup>1</sup> See CTTI recommendations on [Quality by Design](#), [Patient Groups & Clinical Trials](#), [Recruitment](#), [Digital Health Trials: Novel Endpoints](#).

<sup>2</sup> Levitan, et al. Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project. *Ther Innov Regul Sci*. doi:10.1177/2168479017716715.

Engaging all stakeholders in study planning is an important aspect of building quality into the scientific and operational design and conduct of clinical trials.

- ▶ Just as for traditional trials, seek out patient perspectives—through advisory panels, surveys, focus groups, simulation exercises, and other methods—from the earliest stages of planning a clinical trial using digital technologies. Ensure that a range of relevant perspectives are represented, including appropriate and diverse racial and cultural backgrounds, ages, income levels, disease states, technical experience/literacy, and levels of functional limitations.
- ▶ At the time of protocol design, engage patients and sites in developing plans for participant inclusion. Consider the implications of trial design, connectivity demands, and technical literacy requirements on the ability of all relevant patient populations to participate; and consider that while digital technologies have potential to help engage traditionally underrepresented populations, they can also introduce unintended biases (e.g., study inclusion criteria requiring home broadband access and smartphone ownership can in some cases limit the ability of traditionally underrepresented populations to participate). For specific areas where patient input is required to ensure high-quality data collection, see CTTI's Digital Technologies table, Promoting and Protecting Data Integrity.
- ▶ Seek out and take into consideration perspectives from site personnel related to expectations or requirements for pilot testing, training, infrastructure, and similar issues, particularly as these relate to digital technologies.
- ▶ For an overview of areas for patient and site input that are unique to trials that use digital technologies, see the [Planning Trials Using Digital Health Technologies resource](#).

## **2. Select digital health technologies based on requirements of the study and needs of the intended user population, starting with the aspect or experience that the assessment is intended to measure.**

Specific considerations related to patient and site needs and expectations include the following:

- ▶ Engage patients and sites in technology selection, and conduct feasibility studies as needed (see Section I, Item 3 below) to ensure that study participants will find the technologies acceptably easy to learn, simple and convenient to use, and physically comfortable. Acceptability, usability and tolerability can be formally evaluated and should be considered alongside other specifications (see CTTI's DHT Digital Technologies [Framework of Specifications to Consider During Digital Health Technology Selection](#) and [Recommendations for Selecting & Testing a Digital Health Technology](#)).
- ▶ Acknowledge and plan for expectations that participants may have for usability and design of digital technologies based on their experiences with consumer products. This may include, for example, addressing expectations for being able to see their data in

real-time via a well-designed and intuitive interface, and associated expectations that data will be available to and monitored by clinical teams during the study.

- ▶ Carefully weigh the value of protocol elements against potential added burden on participants, and ensure that planning includes an assessment of how technologies may affect patients with the conditions being studied.
- ▶ The added burden of digital technologies on site personnel, as well as impact on clinical workflow, should also be carefully considered, especially when numerous or complex digital technologies are selected that may take up clinic space or time; however, this burden may be acceptable if it is anticipated and addressed in advance through appropriate testing, training, budgeting, and support.
- ▶ To minimize undue burden, conduct due diligence to ensure the reliability and stability of the digital technologies throughout the lifespan of the trial.

### **3. When planning a trial using digital technologies, identify and conduct necessary feasibility and/or pilot studies with sites and a representative patient population.**

Trial planning should incorporate findings from feasibility studies conducted among both patients and sites (see CTTI's [DHT Digital Technologies considerations, Section I, Item 5](#) and [Recommendations for Selecting & Testing Digital Health Technology](#)). Testing should collect the information needed to conduct a successful trial and should emphasize information not available from prior feasibility studies. As a rule, the more elements of technology that are new to the sponsor, the more intensive the testing should be.

- ▶ Start by considering whether prior feasibility studies have been completed and whether they are sufficiently similar and relevant to the trial in question. Conduct additional feasibility studies only as needed to ensure the technology meets patient needs (tolerability, acceptability, and usability), fulfills study requirements, and will be used as intended. Even for technologies that require little to no patient interaction, it is important to ensure appropriate testing has been conducted with respect to factors such as charging, syncing, storage, and distribution.
- ▶ Conduct a protocol simulation (i.e., dry run) before trial launch to detect potential issues with technologies and study design. As in traditional trials, protocol simulation typically involves testing key elements of the study protocol (including digital technologies for digital trials) among people who are as representative as possible of the intended participant population. Forgo protocol simulation only when sufficient and recent feasibility data exists with the same technology.
- ▶ Especially for large multi-site studies incorporating digital technologies that are new to the sponsor, sponsors should pilot the trial and related technologies first with center-of-

excellence sites. As in all trials, pilot studies can help to identify and plan for potential issues.

## Section I: Related CTTI Considerations, Resources, and Recommendations

For more information on:

- ▶ Engaging patients and sites in trials, see CTTI's [Patient Groups & Clinical Trials](#) and [Quality by Design recommendations and resources](#).
- ▶ Supporting the selection, development, and inclusion of technology-derived endpoints, see CTTI's [DHT Novel Endpoints considerations](#), resources, and [Recommendations](#).
- ▶ Scientific and technologic issues surrounding the selection and use of digital technologies in clinical trials, see CTTI's [DHT Digital Technologies considerations](#), resources, and [Recommendations for Selecting & Testing Digital Health Technologies](#)).

## II. Maximizing Value and Minimizing Burden for Study Participants

Clinical trials using digital technologies may appeal to study participants for their potential to reduce barriers to participation, make trials less burdensome, and provide access to real-time data that was previously inaccessible. However, the use of digital technologies may actually increase participant burden if risks, needs, and expectations are not considered and addressed during the study planning process. Steps should be taken to ensure that digital technologies used in clinical trials do not add undue burden, that anticipated burdens are offset with corresponding benefits, and that value is provided to participants as well as researchers.

### 1. The informed consent process should involve an ongoing, interactive conversation with participants.

The informed consent process (see also CTTI's [Informed Consent Recommendations](#)) should begin at initial consideration of study participation and continue until study completion. For trials that incorporate digital technologies, it is important to do the following:

- ▶ Include a description of the selected digital technologies in the informed consent process, including benefits and risks associated with their use, as well as participant responsibilities and requirements with respect to the digital technologies (e.g., charging, syncing, completing assessments).
- ▶ Recognize that participants have varied needs and expectations related to interactions with investigative site personnel (e.g., frequency of in-person visits). Set clear expectations at the outset of participation.

- ▶ Just as in traditional trials, ensure that the informed consent document is clear and understandable, conveying required information via simple language and/or images. Careful attention should be given to clearly explaining what potential participants need to know about digital technologies used in the trial, as summarized below and expounded upon in the remainder of this section.

### **Informed Consent: What Participants Need to Know about Digital Technology**

The informed consent process should convey the following to potential clinical trial participants:

- ▶ Description of the technology, including benefits and risks associated with collection, monitoring, and sharing of data
- ▶ How their data will be protected, and that confidentiality cannot be guaranteed
- ▶ Who will have access to their data, including whether and how their data may be commercialized
- ▶ Whether and how participants will be able to access their own health data generated during the trial, and share with other relevant parties such as primary providers
- ▶ Whether and how participant safety is being monitored, addressing potential assumptions of real time monitoring
- ▶ How technical support will be provided and who will provide it

In conveying this information, it is important to consider that long and complex informed consent documents can obscure the information that is most relevant to potential trial participants. A tiered approach (see CTTI's [Informed Consent Recommendations](#)) may often be most appropriate.

## **2. Account for patients' health literacy and technical literacy in all communications.**

Potential participants have varying levels of knowledge related to health and technologies. Participants with high health literacy may have low technical literacy (and vice versa), and even individuals with high health and technical literacy can have challenges using digital technologies (e.g., due to being time limited or distracted). The informed consent process, patient-facing training materials and other communication throughout the trial, as well as the technology itself, should be as simple as possible and designed to meet the needs of the study participants.



### 3. Be prepared to collaboratively identify and evaluate privacy risks.

Researchers and IRBs should be willing to work collaboratively to identify and assess the unique privacy risks posed by trials using digital technologies. These include not only risks to participants, but also risks to non-participants whose images, voices, or other information may be inadvertently collected by digital technologies used or worn by participants.

- ▶ IRBs should either include members with sufficient technological expertise, or be willing to engage with experts who are equipped to evaluate the risks involved.
- ▶ Researchers and IRBs should share their findings in order to establish best practices around identifying, mitigating, and addressing risk. See the [Connected and Open Research Ethics \(CORE\) platform](#) for an approach to sharing best practices related to ethics and regulatory review of research involving digital imaging, sensing, social media, and location tracking technologies.

### 4. Ensure participants understand the implications for their privacy and confidentiality of the digital technologies used.

Ongoing education and communication are critical to ensuring participants understand the benefits and risks regarding the collection, monitoring, and sharing of their data.

- ▶ Researchers should ensure that, to the extent possible, measures have been taken to protect participant data (see CTTI's DHT Digital Technologies considerations, [Appendix 2: Approaches to Securing Data Generated by Digital Technologies](#)).
- ▶ Clearly communicate to participants that, despite these efforts, confidentiality cannot be guaranteed.
- ▶ When IT service providers will have access to participant data, provide them with clear guidelines around protecting patient privacy and confidentiality.
- ▶ While ultimate responsibility for providing privacy and confidentiality information rests with the sponsor, IT service providers should be able to provide this information in plain language for sponsors to use in developing materials for potential research participants.
- ▶ Ideally, patients will not have to understand and accept the often complex terms and conditions associated with consumer technologies in order to participate in a clinical trial. While this may not always be feasible in studies that use consumer technologies, it is essential to be clear and transparent with potential participants about what they are agreeing to, including who will have access to data generated by the technologies, as well as whether and how their data may be commercialized. It is also important to acknowledge that assumptions related to privacy protection may be different as clinical trial participants than as general consumers.

- ▶ The informed consent document should clearly explain which parties will have access to each level of data. During the study planning process, sponsors should engage patients in discussions regarding access to and use of data by external entities to reach a decision that ultimately meets potential participants' levels of comfort and expectations of privacy (see CTTI's [DHT Digital Technologies considerations, Section III, Item 3a](#)). Patients should also be engaged to ensure that explanations of data access and use in the informed consent document will be easily understood.

### Discussing and Communicating Privacy Policies

One tool that can be used to help structure, discuss, and communicate privacy and security approaches for health technologies is the [Model Privacy Notice \(MPN\)](#) developed by the Office of the National Coordinator for Health Information Technology (ONC). The MPN identifies a range of topics, in checklist format, that are valuable to consider for digital technology used in clinical trials. This information should be conveyed in a way that is easy to understand and informative for patients.

## 5. Set clear expectations with participants about safety monitoring during the trial.

Participants using digital technology in a trial may assume that their health is being monitored in real time. To protect participant safety and ensure participants respond appropriately in the event of a medical emergency, it is important to:

- ▶ Clearly instruct participants during the initial consenting process that they should directly contact appropriate emergency services if needed. While the site is responsible for the informed consent discussion, sponsors should provide materials to support the site in discussing data and health monitoring, and appropriate responses to medical emergencies.
- ▶ Remind participants at regular intervals of the steps they should take in the event of an emergency, accounting for the duration of the study and the risk of serious adverse events. An oncology study, for example, might include a monthly reminder during a six-month treatment period. If the participant is still wearing the device during long-term follow-up, reminders might slow to once every three months. It may also be valuable to include a physical communication to participants that accompanies the digital device (e.g., attached to the packaging).

## 6. Provide participants with easy access to technical support.

Site staff, and in particular study coordinators, have established relationships with the participants, are knowledgeable about specific disease characteristics, and can understand the

technical issue in the context of the study. CTTI thus suggests that sites be the initial point of contact for technical support whenever feasible.

In all cases, including fully virtual trials, CTTI suggests considering the following:

- ▶ It is critical that all individuals providing technical support are familiar with the study, trained on handling inappropriate data disclosures, and prepared to address participant queries (identified, for example, through patient engagement and pilot testing strategies recommended in [Section I](#), above).
- ▶ Establish and communicate plans for technical support and issue escalation to all involved parties, including participants and investigative sites (if any). For example, the study coordinator may act as the initial point of contact and would connect participants to appropriate technical support rather than providing support directly.
- ▶ The contact information for front-line technical support (e.g., the study coordinator) should be easy for participants to find even when Internet connectivity is limited. For some digital technologies, contact information could be located directly on the device itself.
- ▶ Ensure technical support will be available to participants outside normal business hours.
- ▶ Technical support should be provided in the same participant languages (at minimum) as informed consent materials.
- ▶ CTTI also suggests putting an automated process in place to detect technology malfunction (see CTTI's [DHT Digital Technologies considerations, Section IV, Item 4](#)), facilitating proactive outreach to participants.

## **7. Be mindful that digital technologies can change the way sites and participants interact during a trial.**

Communication, while important in traditional clinical research, should be an even greater priority in the planning of clinical trials using digital technology. Digital technology can facilitate new forms of communication, reducing the need for in-person visits and facilitating participation in the trial. In planning the trial, however, it is important to:

- ▶ 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 specific direction to participants, including what to expect during a digital clinical 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 when each may be most appropriate.

## 8. Identify ways to return value to participants throughout the trial, including return of outcomes data collected by digital technologies.

Participants may assume that having access to the health information collected about them will be a benefit of clinical trials using digital technologies. In addition, they may bring heightened expectations from their experience with digital technologies in the consumer space. As a result, many participants may expect to have near-real time access to their own health data generated during the trial, as well as comparisons of their data to that of other participants.

- ▶ During the trial planning process, carefully review the outcomes and other health-related information that will be generated during the trial, and develop a plan for returning data to participants, including when and how it will be returned. Planning should incorporate patient and site perspectives, and should provide for appropriate participant access to their individual data as well as aggregate trial results. For example considerations related to returning clinical trial data to participants, see the [MRCT Center's Return of Individual Results to Participants Recommendations Document](#).
- ▶ Provide participants with real-time access to their individual outcomes or other data only if it can be done in a way that maintains study integrity and participant safety. See [Decision Support Resource: Real Time Data Sharing with Study Participants](#), from CTTI's DHT Digital Technologies considerations).
- ▶ When returning data to participants, do so in a way that is both personalized and understandable (e.g., patients should not be expected to distinguish data that is important for clinical treatment from data that is only relevant to the trial.)
- ▶ Clearly communicate plans for sharing data/results with potential participants during the informed consent process.
- ▶ Identify other ways to return value to participants during and after the trial, beyond sharing outcomes data. For example, digital technologies can facilitate better information sharing between participants and their primary care doctors, as well as updates on trial progress. See [Case Study: Returning Value to Participants without Compromising Study Integrity](#) for examples of other ways to return value.

### Section II: Related CTTI Considerations, Resources, and Recommendations

For more information on:

- ▶ Communication and transparency with participants regarding safety monitoring, see CTTI's [DHT Digital Technologies considerations, Section IV, Item 2](#) and [Recommendations for Preparing a Site](#).
- ▶ Risk-based approaches to protecting privacy, see CTTI's [DHT Digital Technologies considerations, Section III, Item 4](#) and [Recommendations for Managing Data](#).

### III. Addressing Challenges for Investigative Sites

Investigators see digital technology as bringing substantial value to research—such as the potential for continuous, high-frequency collection of previously inaccessible real-world data—that makes the use of digital technology exciting and worthwhile. At the same time, the use of digital technology can increase the logistical burden on investigative sites by requiring more time and effort to learn, manage, and maintain technologies. It is important to recognize and plan for these burdens during the budgeting and contracting process and throughout trial execution. In addition to the considerations below, two complementary checklists are provided to assist [research sponsors](#) and [investigative sites](#) in budget and contract planning and evaluating site readiness.

#### 1. Clearly delineate responsibilities and consider alternate payment structures in contracts.

- ▶ Ensure that contracts clearly define the responsibilities of all parties, including details on who will be responsible for providing technical support to participants, replacing malfunctioning technologies, and monitoring real-time data.
- ▶ Where applicable, ensure contracts include budget for feasibility study of technology acceptability and usability, collection of endpoints relevant to future implementation considerations, and IT support for sites.
- ▶ Paying sites on a per-visit basis will not be feasible in trials that replace most visits with mobile data collection. Consider alternate payment structures, such as lump sum budgets.
- ▶ For general recommendations for site budget and contract negotiations, see CTTI's [Investigator Community Recommendations, Section III](#).

#### 2. Be prepared for the additional time and cost required to incorporate mobile technology into clinical trials.

Additional time and costs may be associated with training, purchasing and maintaining digital technologies, communicating with participants, and providing technical support.

- ▶ Sponsors should provide sites with any information gathered during pilot studies or similar studies that would help facilitate accurate budget preparation. Time and cost estimates should be provided well in advance of trial launch to allow sites to budget appropriately.
- ▶ In many cases, trials involving digital technologies incur additional costs that are difficult or impossible to anticipate. Set up budgets with the flexibility to account for unknowns while the trial is under way.

### 3. Ensure sites have appropriate infrastructure to conduct digital clinical trials.

Sponsors should confirm that sites are equipped with the resources necessary to conduct clinical trials using digital technology, such as sufficient Internet speed and Wi-Fi coverage, video and live-streaming capabilities, and hardware and software required for data collection and visits. Site evaluations should also consider relevant experience related to digital technology and associated clinical trials.

- ▶ Sponsors should ensure that sites recruit appropriately experienced staff by listing necessary requirements in job descriptions and considering candidates' technical expertise during the hiring process.
- ▶ Sponsors should also provide more devices to sites that are historically adept at enrolling participants to safeguard against the possibility that having an inadequate number of devices will hamper enrollment.

### 4. Develop effective training modules for site staff around selected digital technologies.

Evidence suggests that some participants will prefer contacting sites with technical support issues. It is critical that site staff who will be interacting with participants are conversant in the technologies participants will be using.

- ▶ Training modules should offer hands-on practice with the digital technologies and allow for sufficient time to establish familiarity.
- ▶ A variety of training methods should be provided to account for diverse learning styles, including in-person sessions, webinars, and video tutorials.
- ▶ Investigator meetings can be an ideal time for training site staff, provided that the staff who will be working with the technologies on a day-to-day basis will be in attendance and will have access to the technologies. If possible, the technologies should be provided to site staff in advance.
- ▶ It may also be helpful to provide a playbook or series of screenshots to enable site personnel to familiarize themselves with how participants will interact with the technologies during the trial. This would also be valuable to site staff when answering participant questions and providing technical support.
- ▶ See also CTTI's [DHT Digital Technologies considerations, Section IV, Item 3](#) for more information on developing effective approaches for preparing investigators and site staff to use digital technologies in clinical trials.

### 5. Streamline and standardize training across sponsors.

When trials incorporate digital technologies, there are often substantial additional training requirements for investigative site personnel. It is thus important to consider when and whether

some technical training will be duplicative of training site staff may have completed for other trials using the same device/technology. Sponsors should assess what sites already know, accept training already completed for other sponsors, and focus training on new or unique elements for the trial.

## 6. Put plans and policies in place to handle technology issues, malfunctions, and loss.

- ▶ Sites should have access to the IT service provider to enable more efficient issue escalation and resolution in the event of technical challenges.
- ▶ Plans for monitoring and responding to technology loss or malfunction should be in place before providing the technology to study participants, as stated in CTTI's [DHT Digital Technologies considerations, Section IV, Item 4](#). Roles, responsibilities, and expected actions around technology failure and loss should be clearly articulated in policies developed during the pre-trial phase. Designated parties assigned these tasks will likely vary depending on the protocol, selected technology, participant population, and in-house capabilities of the sponsor and study sites.

### Section III: Related CTTI Considerations, Resources, and Recommendations

For more information on:

- ▶ Site budget and contract negotiations, see CTTI's [Investigator Community Recommendations, Section III](#).
- ▶ Developing effective approaches for preparing investigators and site staff to use digital technologies in clinical trials, see CTTI's [DHT Digital Technologies considerations, Section IV, Item 3](#) and [Recommendations for Preparing a Site](#).
- ▶ Plans for monitoring and responding to technology loss or malfunction, see CTTI's [DHT Digital Technologies considerations, Section IV, Item 4](#) and [Recommendations for Managing Data](#).

## REFERENCES

1. Levitan B, Getz K, Eisenstein E, Goldberg M, Harker M, Hesterlee S, Patrick-Lake B, Roberts J, DiMasi J. Assessing the financial value of patient engagement: A quantitative approach from CTTI's Patient Groups and Clinical Trials Project. *Therapeutic Innovation & Regulatory Science*. 2017;52(2):220-229. doi: 10.1177/2168479017716715. Available from: <http://journals.sagepub.com/doi/pdf/10.1177/2168479017716715>



## ABOUT THE CONSIDERATIONS:

- ▶ These considerations are based on results from CTTI's DHT Engaging Patients and Sites Project, part of the [Digital Health Trials Program](#).
- ▶ CTTI's [Executive Committee](#) approved on Nov. 30, 2018.
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- ▶ All of [CTTI's official recommendations](#) are publicly available. Use of the recommendations is encouraged with [appropriate citation](#).

## ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations—representing academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups—CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Many regulatory agencies and organizations have applied CTTI's more than 20 existing recommendations, and associated resources, to make better clinical trials a reality. Learn more about CTTI projects, recommendations, and resources at [www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org).