



CTTI Recommendations: Decentralized Clinical Trials

September 2018

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

Clinical Trials Transformation Initiative. Decentralized Clinical Trials. Published September 2018. <https://ctti-clinicaltrials.org/our-work/digital-health-trials/original-digital-health-trials-projects/>.

To facilitate the adoption and appropriate use of mobile technology in clinical trials, the Clinical Trials Transformation Initiative (CTTI) initiated the Mobile Clinical Trials (MCT) Program, which includes four projects focused on the following topics: Decentralized Clinical Trials (DCTs), Novel Endpoints, Stakeholder Perceptions, and Mobile Technologies. The MCT DCT Project concentrates on the actual and perceived legal, regulatory, and practical challenges with DCT design and conduct in the United States.

For the purposes of these recommendations, DCTs are defined as those executed through telemedicine and mobile/local healthcare providers (HCPs), using procedures that vary from the traditional clinical trial model (e.g., the investigational medical product [IMP] is shipped directly to the trial participant).

OVERVIEW: Expanding the Reach of “Traditional” Clinical Trial Sites

Telemedicine, mobile, and local HCPs (e.g., family physicians, general practitioners) have been involved extensively in healthcare delivery but have yet to be widely incorporated into the design and conduct of clinical trials. This is due in part to legal, regulatory, and practical considerations, which are viewed as potential barriers.

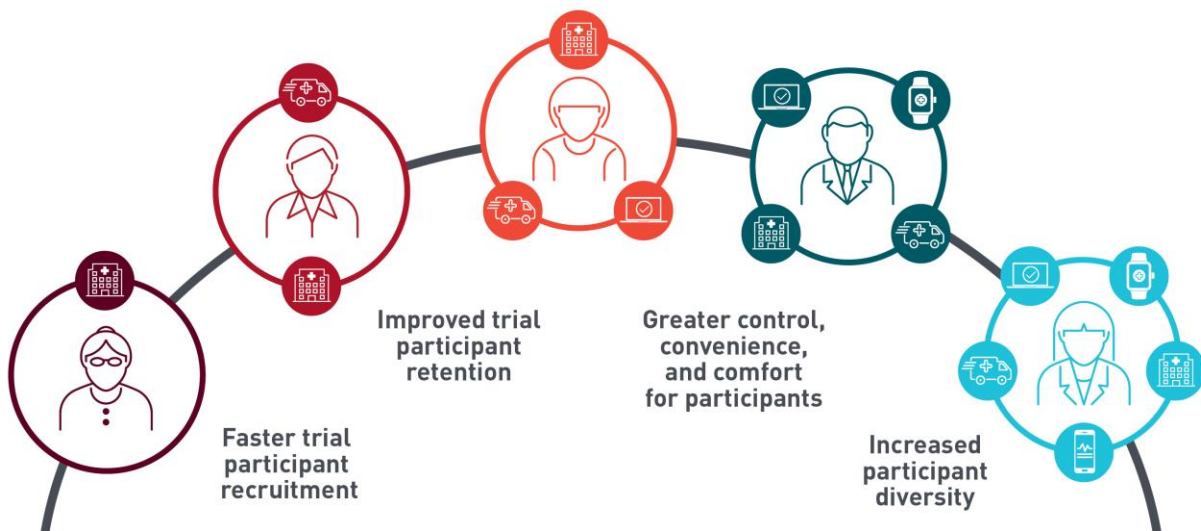
DCTs using telemedicine and other emerging and novel information technology (IT) services offer the potential for local HCPs to participate in clinical trials. This may provide several advantages compared to traditional clinical trials conducted at more centralized clinical trial sites, including the following:

- ▶ Faster trial participant recruitment, which can accelerate trial participant access to important medical interventions and reduce costs for sponsors.
- ▶ Improved trial participant retention, which may reduce missing data, shorten clinical trial timelines, and improve data interpretability.
- ▶ Greater control, convenience, and comfort for trial participants by offering at-home or local patient care.
- ▶ Increased diversity of the population enrolled in clinical trials.
- ▶ An opportunity for home administration or home use of the IMP, which may be more representative of real-world administration/use post-approval.

These potential advantages and benefits apply to all trials in all disease areas but may offer particular advantages in rare diseases, where patients are generally limited in number or are highly geographically dispersed.

The following recommendations focus on legal, regulatory, and practical considerations for planning and conducting DCTs with a focus on the United States. These recommendations are primarily for industry sponsors and clinical research organizations (CROs) but are also valuable to clinical investigators, site personnel, Institutional Review Boards (IRBs), regulators, and state professional licensing boards. By implementing these recommendations, sponsors, CROs, and others can help advance the use of mobile technologies in DCTs, when appropriate, and experience the resulting benefits.

Potential Benefits of Using Decentralized Clinical Trials



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I. DCT Approaches and Protocol Design

DCTs can follow many different approaches, ranging from a fully decentralized approach to varying levels of decentralization. A fully decentralized approach may include any or all of the following elements: no physical trial sites are used for the trial, all visits are performed via telemedicine or mobile/local HCPs, and data are captured remotely through use of mobile technologies (see [CTTI's Mobile Technologies recommendations](#)).

1. A DCT does not have to be an all-or-nothing approach.

Partially decentralized or hybrid approaches to conducting a clinical trial may include some decentralized activities or procedures that require trial participants to travel to a designated trial site location, as they would for a traditional study. Examples include:

- ▶ Mobile HCPs may be sent to the trial participant's home to conduct certain activities (e.g., blood draws, vital sign measurements, trial drug injections), whereas other study activities may be conducted at a clinical trial site.
- ▶ Trial participants and investigative site personnel may use telephone or video conferencing to determine eligibility or discuss the trial's progress and review trial participants' questions.
- ▶ Some visits may require that trial participants travel to a local facility for sample collection or for procedures that require major medical equipment (e.g., x-rays, magnetic resonance imaging, computed tomography scans) or specific medical expertise.
- ▶ A trial may use mobile technologies (e.g., wearables, electronic patient-reported outcome) to capture data outside of a clinical setting or trial site.
- ▶ In a single trial, some participants may be enrolled at traditional clinical trial sites, while others may be enrolled or managed in a decentralized or remote manner.

2. Engage with all stakeholders during the protocol design process.

Early in trial planning and design, engage with the appropriate stakeholders (e.g., patients, U.S. Food and Drug Administration [FDA], IRBs, investigators, CROs, pharmacies, state medical boards, and third-party vendors such as telemedicine or mobile HCPs). CTTI's MCT [Stakeholder Perceptions](#), [Patient Groups & Clinical Trials](#), and [Quality by Design](#) projects provide resources and recommendations for engaging patient groups throughout the research and development process. Suggestions on best practices for engaging stakeholders include the following:

- ▶ **Discuss and incorporate concerns from stakeholder groups.**

This approach may potentially lead to fewer protocol amendments down the line. Additionally, standard operating procedures (SOPs) can be developed to describe processes to reduce operational challenges and to address any process-related concerns.

- ▶ **Meet with regulatory bodies early in the process.**

For clinical trials evaluating drugs regulated by the FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER), sponsors with protocol- or product-specific questions are encouraged to request Type B meetings with the FDA as appropriate. For example, pre-investigational new drug application (pre-IND) meetings; certain end-of-phase I meetings for Subpart E, H, or similar products; end-of-phase 2 meetings; and pre-phase 3 meetings.¹

For meetings that are drug product- or protocol-independent, CROs, IT service providers, technology vendors, and other trial executors are encouraged to request a Critical Path Innovation Meeting² to obtain general advice on elements of a DCT or technology for use in investigational research. Stakeholders can also request a meeting with the Professional Affairs and Stakeholder Engagement staff at the FDA.³

For clinical trials evaluating medical devices that are regulated by the FDA's Center for Devices and Radiological Health (CDRH), sponsors are encouraged to request a Pre-Submission meeting with the FDA to discuss their plans for investigational device exemption (IDE) clinical investigations. The process for requesting a Pre-Submission meeting is described in the appropriate guidance.⁴ Sponsors are also encouraged to contact the Division of Industry and Consumer Education or the relevant pre-market group that would review the IDE application if they have any questions about submitting a request for Pre-Submission feedback.^{5,6}

- ▶ **Meet with experienced vendors (i.e., DCT trial executors with telemedicine and mobile HCPs) to learn from their experience.**

Experienced vendors may provide insight on best practices for incorporating telemedicine in a protocol and streamlining processes.

3. A DCT will require some fit-for-purpose protocol design and conduct considerations, including the following:

- ▶ Requirements for trial-specific procedures: Focus on procedures that are required in the protocol, and determine the following:
 - Activities that must occur at the investigative site (e.g., due to equipment/facility requirements or medical expertise).
 - Activities that can be performed by a local or mobile HCP who can travel to the trial participant.
 - Activities that are amenable to remote performance using mobile technology solutions.
- ▶ Protocol compliance: Consider if additional trial participant safeguards, processes, trial-specific training, and education and procedures are needed to ensure that the protocol is conducted in a compliant manner.
- ▶ Site management: Determine who is responsible for the management of source documents at decentralized sites (i.e., source documents from local physicians, or source documents generated by study participants and collected at home visits by, for example, the clinical investigator, trial personnel, or third-party vendors).
- ▶ Storage of local source documents and electronic information: Indicate where and how local source documents and electronic information will be stored.
- ▶ Technological support: Consider and clearly plan for needed technological support to provide adequate training and troubleshooting for all parties in the trial (i.e., local physician/HCP, trial participant, and/or their caregiver) who will be using the clinical trial technology. Additionally, the sponsor, CRO, telemedicine, mobile, or local HCP should include a plan to ensure that only the study participant or other appropriate study-related personnel enters data when a device is used for data collection.
- ▶ Regional differences: Consider telecommunication availability in the regions in which the DCT will be conducted to ensure consistency with access and performance.

4. Proactively address and map data flow, data storage, and associated procedures.

Data in DCTs may be transferred to and stored among several different parties/locations and systems, including the trial participant, mobile technologies used to capture trial data, third-party vendors, the clinical trial site, a CRO, and the

sponsor. Sponsors/CROs and any other party handling data should take specific actions to control and manage data flow, for example:

- ▶ Map data flow and data storage, starting with clinical trial source data, and consider how data reliability and integrity are assured, including how the data will be controlled and secured (see [CTTI's Mobile Technologies recommendations](#)).
- ▶ Have detailed knowledge of the data flow in the DCT, which should be contained in the protocol or the data management plan referenced in the protocol. Explanation of data flow and data visibility may be achieved through a description or diagram of the electronic data flow and storage of data logistics from trial participants, mobile technology, telemedicine system, and potentially through third-party vendors and IT providers to the investigative site and sponsor.
- ▶ Ensure compliance with applicable data and privacy laws and regulations, taking into account different requirements in different jurisdictions and noting potential differences outside the United States.

5. Streamline telemedicine implementation into clinical trials through the following approaches:

- ▶ **Consider partnering with investigative sites that already use or are familiar with telemedicine in their practice.**
Experienced partners can help streamline trial planning and tasks as well as help ensure that the clinical staff are knowledgeable and trained on telemedicine practices.
- ▶ **Focus on therapeutic areas where telemedicine utilization is most advanced.**
Designing and conducting DCTs in therapeutic areas that have already incorporated telemedicine in their practice (e.g., dermatology, psychiatry, cardiology, and radiology) may streamline processes and increase the likelihood of a successful DCT.
- ▶ **Consult telemedicine providers in protocol development.**
Many telemedicine providers have successfully integrated their technology and services into medical practice and clinical trials, and have insights on the selection of telemedicine modalities in regard to applicability to clinical areas and trial participant usage. Sponsors and stakeholders should engage with telemedicine providers to assist with protocol development, especially the aspects of the protocol that specifically address use of telemedicine.

II. Telemedicine State Licensing

In general, medical practitioners must satisfy the following:

- ▶ Hold a license in the state in which they practice medicine, including any medical activities performed in clinical trials (e.g., ordering laboratory and imaging tests, conducting physical examinations).
- ▶ Be licensed in the state in which the trial participant receives treatment (i.e., the practitioner cannot prescribe drugs or deliver treatments to a trial participant in a state in which the medical practitioner is not licensed).

1. DCTs that operate across multiple states can manage state-by-state medical licensure concerns through the following methods:

- ▶ Maintain an investigator in each state where services are anticipated.
- ▶ Utilize investigators licensed in multiple states.
- ▶ Contract with companies providing licensed mobile HCP research services across all U.S. states (or at least in those states in which the trial will be conducted).

2. For sponsors planning to incorporate telemedicine in clinical research, it is essential that they keep abreast of the complex and varying legal landscape of applicable state laws.

Sponsors should incorporate one or more of the following methods to become informed of the legal landscape:

- ▶ **Use policy organization resource centers.**
Sponsors should consider using online resources of policy organizations that specialize in telemedicine laws. Several state and national telemedicine resource centers^{7,8} exist that publish applicable state telemedicine laws online.
- ▶ **Invest in appropriate legal resources.**
Reliable legal expertise is recommended to track state licensing laws. Due to the many changes occurring regularly in individual states' telemedicine laws, ongoing review of licensing laws is necessary.

To ease the burden on the sponsor's legal staffing, alternative solutions may be necessary, such as seeking external legal consultants and/or partnerships or subscriptions to companies that track and report state-by-state changes in laws and regulations.

III. Drug Supply Chain

Drug supply chain and dispensing laws and regulations vary depending on federal and state statutes and regulations and differ according to the product's registration status with the FDA (investigational or approved). Procedures for IMP delivery directly to the

trial participant may also depend on the nature and stability of the IMP as well as protocol design.

CTTI recommends the following:

1. Review state law requirements for direct-to-trial participant shipping.

Determine whether the states in which the DCT is being conducted have physician-dispensing laws or regulations addressing direct-to-trial participant shipping of IMP. If such laws or regulations exist, sponsors/CROs should develop processes that ensure compliance. Investigative sites should dedicate a point-of-contact for tracking state-specific issues.

If an investigative site is shipping IMP across state lines, the investigative site should dedicate a point-of-contact who is familiar with state pharmacy requirements and track changes to these requirements.

2. Procedures for direct-to-trial participant IMP shipment should be described in the protocol so that the process is clear to the investigator, IRB, and applicable regulatory agencies.

Detailing these procedures increases transparency and assists with development of SOPs.

3. Organizations may choose to engage an IMP management vendor with experience in direct-to-trial participant shipment.

This vendor should have pharmacy licenses in all U.S. states (or in states where services will be utilized). When engagement with this type of IMP management vendor is not feasible, sponsors/CROs should engage a central pharmacy through which shipments can be made directly to trial participants.

4. Formalize SOPs for the IMP accountability chain.

Similar to traditional trials, formal SOPs should outline accountable parties at each step of the IMP supply chain, including the following:

- ▶ IMP administration order
- ▶ IMP storage and inventory
- ▶ IMP dispensing
- ▶ Distribution to the investigator, mobile HCP, pharmacy, or trial participant
- ▶ Documentation of supply chain logistics (e.g., temperature-validated transport containers), including the following:
 - Documentation of relevant temperature tracking and administration within stability parameters
 - Procedures for managing a temperature excursion or product damage once in the trial participant's possession

- ▶ Documentation of the recipient's acknowledgment of receipt
- ▶ Recovery of IMP or the container, both after use (if residual is to be collected and accounted for) and when there is a need for recall such as expiry

Different SOPs may be necessary for different DCT scenarios, and the focus should be on ensuring compliance with applicable federal and state regulations.

IV. Mobile Healthcare Providers

Mobile HCPs (e.g., nurses, physicians, phlebotomists) may be an appropriate substitute for selected visits to investigative sites. Performing selected trial visits at the trial participant's home, workplace, or alternate location may promote participant's compliance and retention, and provide convenience and comfort. Trial responsibilities should be delegated only to personnel who are qualified by training and experience to perform those tasks and allowed by the protocol and applicable state law. Mobile HCPs may offer a way for prospective trial participants to participate in trials regardless of trial duration; frequency of visits; disease state; distance to travel site; school, work, or family obligations; or vacation/travel plans.

To use mobile HCPs effectively, sponsors and trial executors should consider the following:

1. Consult or partner with a mobile HCP vendor with experience conducting clinical trial activities.

Similar to traditional clinical research studies, a different skill set is required for practitioners conducting clinical research versus clinical care. Mobile HCPs should have credentials, qualifications, and experience to conduct clinical trial activities delegated under the applicable protocol and allowed by state law, including the following, as applicable:

- ▶ Good clinical practice training
- ▶ Training on trial-specific requirements
- ▶ Human subject protections
- ▶ Data protection
- ▶ Clinical trial billing

Mobile HCPs may be required under the protocol to perform the following:

- ▶ Blood draws (e.g., safety laboratory samples, pharmacokinetics, genomics)
- ▶ Biological sampling (e.g., pharyngeal and oral mucosal swabs, urine or fecal samples)
- ▶ IMP administration
- ▶ Training and education of the trial participant (e.g., IMP self-administration)

- ▶ Clinical assessments (e.g., vital signs, electrocardiograms, concomitant medications, adverse events)
- ▶ Administration of questionnaires or in-home compliance checks (e.g., timely completion of trial participant diaries, proper storage of IMP)

V. Investigator Delegation and Oversight

DCTs using telemedicine or mobile HCPs should not be held to an alternate standard when it comes to investigator delegation and oversight than with traditional trials, unless required by particular circumstance.

In DCTs, the trial participant may be geographically distant from the investigator and/or the rest of the research team. Certain trial activities may occur remotely or may be performed by the trial participant's individual HCP, local clinical staff, a sub-investigator, remote research staff, or a mobile HCP. Definitions of "routine care" and "practice of medicine" as opposed to "clinical trial-related activities" are generally well understood within the context of traditional trials with pre-specified investigative sites but may not be clear or explicit in DCTs. In remote trials, the separation of routine care/practice of medicine and clinical trial activities should be well-defined in the protocol to minimize ambiguities with the trial team's roles and responsibilities.

When a local HCP performs procedures for a trial participant that would be performed regardless of the patient's participation in the research study, important considerations about the local HCP's role with respect to a clinical trial should be evaluated in relationship to specific FDA regulations and guidances (i.e., 21 CFR 11, 50, 54, 56, 312, and 812).⁹⁻¹⁶

Alternatively, when a local HCP conducts procedures only for the purposes of the clinical trial protocol, this provider would be considered part of the clinical research team with respect to those activities.

1. Delegation of authority and responsibilities in the context of DCTs should not differ from traditional trials. Standard applicable considerations prior to determining delegation possibilities should include the following:

- ▶ Health status, clinical complexity, and vulnerability of the subject population
- ▶ Safety profile of the drug
- ▶ Drug development phase
- ▶ Complexity of the protocol, trial endpoints
- ▶ As described in the protocol, trial-related procedures that can be performed by a local HCP and/or other trial personnel who are sub-investigators
- ▶ Experience, qualification, trial-specific training, education, and necessary licensure of the local HCP/sub-investigator/other trial staff
- ▶ Investigator's plan to supervise trial conduct

2. Determining whether or not to list the HCP as an investigator or sub-investigator on the Form FDA 1572 is dependent on FDA regulations.

The last three bullets above are relevant to determining who and which facilities should be included on the Form FDA 1572^a (“Statement of the Investigator”)⁹ and delegation log. Individual HCPs on the delegation log are included for the specific services they will provide as part of the clinical trial. Signing of Form FDA 1572 occurs only after the HCP’s credentials and qualifications are provided to the investigator. Consult FDA’s guidance⁹ for more information on preparing the form.

VI. Safety Monitoring

Similar to the previous section, DCT safety monitoring plans should not be held to a higher standard than with traditional trials unless merited by particular circumstance. DCT trial designers and executors should demonstrate a working understanding of similarities or differences in safety monitoring efforts in relation to traditional investigative sites.

1. Clearly articulate remote safety monitoring procedures in supporting documentation and train investigative staff on processes that are unique to DCTs.

Elements can include but are not limited to the following:

- ▶ Ensuring that the trial participant at a remote location knows the procedures and ways to obtain information to address possible adverse events (e.g., a list of approved local health care facilities and/or clinicians for emergent issues related to the trial)
- ▶ Pre-coordination between investigators and approved facilities/clinicians near the trial participant’s location on acceptable treatment as well as feedback procedures and reporting requirements.

Establishing a record-keeping protocol can help ensure investigators are current with training requirements and safety monitoring procedures.

^a Note that Form FDA 1572 is required for studies of investigational drugs and biologics conducted under an Investigational New Drug (IND) application, per 21 CFR 312.53. Investigators conducting a study or trial of an investigational device should follow procedures for signing an agreement under 21 CFR 812.43. Clinical trials for drugs and biologics that are not conducted under an IND do not need to file a Form 1572 (see [FDA guidance, Investigational New Drug Applications \(INDs\) — Determining Whether Human Research Studies Can Be Conducted Without an IND](#))

2. Develop protocol-specific safety monitoring and communication escalation plans for trial participants, trial personnel, third-party vendors, and clinical investigators.

Depending on the safety profile of the IMP, one may consider applying a higher standard to patient safety monitoring (i.e., more frequent patient monitoring) and to escalation plans than those used in trials at traditional trial sites.

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ABOUT THE RECOMMENDATIONS

- ▶ These recommendations are based on results from [CTTI's Decentralized Clinical Trials project](#).
- ▶ CTTI's [Executive Committee](#) approved on July 27, 2018.
- ▶ Funding for this work was made possible, in part, by the Food and Drug Administration through grant R18FD005292 and cooperative agreement U19FD003800. Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government. Partial funding was also provided by pooled membership fees from CTTI's member organizations.
- ▶ All of [CTTI's official recommendations](#) are publicly available. Use of the recommendations is encouraged with [appropriate citation](#).

ABOUT CTTI

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 nearly 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.