



REMOTE DATA COLLECTION

Remote Visits: Including Telemedicine, In-Home Visits, and Local Providers

Introduction

With DCTs, interactions between the participant and study team can be either virtual, using telemedicine or video-enabled visits or conducted by local providers who can accommodate seeing the participant at a nearby clinic or laboratory center or visit the participant in their home. “Bringing the trial to the patient,” when a site or hospital visit is not necessary, decreases the burden and possibly the expense of participation and is generally appreciated by participants. Some participants, however, prefer to visit the trial site for personal reasons (e.g., a reluctance to invite someone into their home, lack of privacy) and, therefore, whenever there is a choice as to the method of visits, the participant should be offered that choice. Here we enumerate considerations for DCT visits enabled through telemedicine (including both tele-visits (e.g., telephone only and video visits)), in-home visits, and local providers.

Telemedicine

Telemedicine involves one or more virtual visits between patient and investigator or research team member up to and including a completely virtual relationship between patient and research study team and/or the use of a digital platform in the absence of a physical (hands-on) exam to maintain notes and progress reports and to record clinical and personal observations. In addition, telemedicine visits may be accompanied by local laboratory or imaging capabilities, if necessary.

The potential benefits of telemedicine include:

- Convenience for both participants and sites because it reduces time, effort, and possibly expense
- Increased geographic reach (e.g., rural settings) and diversity (e.g., race/ethnicity, age) of study populations
- Greater participant flexibility
- Decreased burden on participants and researchers by reducing travel
- Preservation of social distancing with decreased exposure in case of infection, epidemic, or pandemic
- Decreased spread of disease and time research team spends with infected patients
- Potential to increase participant access, enrollment, and retention



Policies, coverage and payment rates, technologies, and familiarity with services provided by telemedicine are continuing to evolve. The same is true with knowledge and experience with telemedicine in clinical research. Telemedicine decreases the time, expense, and inconvenience of the ‘visit’ for participants, while it increases access to medicine in remote and rural areas. Further, the number of physiological sensor technologies (e.g., smartphones, blood pressure cuffs, pulse oximeters, activity trackers, glucometers, and scales) is increasing.

Challenges to the adoption of telemedicine

- Inequality
 - Internet access, connectivity, and access to and comfort with the use of digital technologies varies among different demographic and geographic populations (“digital divide”). The problem may disproportionately affect people of color, Indigenous peoples, people with disabilities, older adults, low-income households, and people who live in rural areas. For example, the cost of data access plans must be considered, may be limiting, and may be a disincentive for participants who have limited cellular plans.
 - Inclusion of people with disabilities in research may be more challenging.
- Translations
 - Software and software platforms may not be available in multiple languages, limiting participation for individuals whose preferred language is other than English.
 - There is limited availability of multiple languages for software and platforms
- Confidentiality
 - Some individuals may not have private or isolated areas in their homes to host a telemedicine visit or may be unable to disable digital monitoring systems such as Alexa or Google Assistant. Disclosure to third parties may occur unintentionally; this risk must be mitigated. For example, participants may be able to conduct a telemedicine visit at a local church or pharmacy that has a private space where a participant may have a remote visit.
- Security
 - Like all remote technologies, security must be addressed for all data, including data collection, transfer, storage, and retrieval related to the video.
- Validation
 - How data will be validated must be addressed before leveraging remote technologies. The sponsor or investigator, for example, might send a participant a fitness tracker to monitor exercise and heart rate or ask a participant to send a picture of their feet on a scale to verify the weight.
 - The identity of participants must be verified and identify clinical site personnel must be confirmed and documented.
- Professional licensing
 - In advance of enabling telemedicine visits, professional licensing for investigators, if needed, must be considered, as well as state and country telemedicine laws.



- In the US, for clinical trials of a drug or device where there is a telehealth or video-conferencing visit, the investigator generally needs to be licensed in the state where the participant is located. Internationally, telemedicine is even more challenging.
- Variable reimbursement for a visit, if allowable and applicable
- Sharing of clinically relevant study data with physicians involved in the care of the patient.
- Costs of implementation
- Lack of clarity in and/or conflicting regulations and applicable laws
- Security and delivery concerns when delivering prescribed medication or devices (see investigational products)
- Providing adequate PI oversight may be challenged if contract (non-study) personnel are engaged.

In telemedicine visits, IRBs/ECs should consider:

- Participant preferences for a method of interaction with the research study team
- The nature of the study interventions, if any, that will be performed during a telehealth or video-conferencing visit and whether there is a need for someone else to be present?
- Privacy considerations for the participant. Is there a private setting for the telemedicine visit?
 - There should be detailed information to the participant that telemedicine visits may expose private information, and that creating a private setting for these 'visits' are preferred.
- The provider and study personnel should ensure they do not have any protected health information visible on the screen if they are in their office.
- Equitable access to the internet, cellular data, devices, software, technical support
- The languages available in software and software platforms
- Modifications and accommodations for the inclusion of people with disabilities
- Data privacy and security in collection, transfer, and storage
- Methods of data validation and remote monitoring
- Shipment, receipt, administration, and disposal of investigational and other research products and their documentation
- The ability of the PI to provide adequate oversight of healthcare providers (HCPs) recruited for study activities.

In-Home Visits

In-home visits involve a research study team member, their designee, or a third-party vendor visit the participant's home, usually because face-to-face interaction is necessary or preferred. Visits can be necessary due to required medication administration; collection of specimens, observational data, or other data; or safety concerns for the participant, including adverse events. An in-home visit is convenient for the participant and decreases their time, effort, and costs of visiting the study site; the research team incurs costs and time investment. Participants



have expressed concerns about personal visits to the home regarding of privacy. For example, there may be neighborhood concern or stigma involved when a gowned and masked person arrives at a home, or the inability to find a private or isolated area in the home away from other people.

Other issues also need to be understood, such as: is the professional visiting considered an “investigator” on the trial? Do they have appropriate credentials, licensure, and training? Are they handling the investigational product(s)? Is adequate emergency care available, if needed? Is the research team member aware of mandatory reporting requirements (e.g., child or elder abuse)? Is there continuity in research staff performing home visits to engender trust and communication between participants and research team members? Will the PI be able to provide adequate oversight of trial conduct?

In summary, with in-home visits:

- The research study team either directly performs in-home visits or contracts with third-party vendors (with sponsors or study team directly) to conduct face-to-face visits and interactions with participants
- IRBs/ECs must consider whether third-party vendors are engaged in the research and whether the training, qualifications, and credentials of the personnel involved must be verified and/or if reliance agreements and/or other contractual agreements to define responsibilities and liability are needed.
- Travel burden is eliminated (e.g., time, expense, inconvenience) for participants when providers visit their home; this must be weighed against potential new burdens (e.g., privacy, safety, scheduling challenges. Options (e.g., for the site or in-home visits) should be provided whenever possible.

Potential benefits

- Convenient for the participant in time, effort, and expense (decreased burden)
- Greater flexibility for participants
- Helpful for studies that require face-to-face contact and when participants prefer not to or cannot enter or travel to a clinical setting/site
- Licensed professionals can administer treatments at and during home visits
- Home-visiting professionals can directly observe and interact, collect specimens, and ascertain patient-reported data
- Allows for a larger and more diverse study population
- Reduced opportunity costs for participants (time, expenses of traveling and/or childcare)

Potential Challenges

- In some particular social circumstances for the participant, in-home visits may not be convenient or appropriate
- Time and expense costs might be greater for the research site
- Potential privacy and confidentiality concerns of participants with home access



- Potential increased burden on patients (perception that house needs to be clean)
- Regulatory and administrative issues with third-party vendor contracting (e.g., credentialing, licensure, accountability, liability)
- Challenges to PI oversight of contracted parties or use of non-study personnel
- Regulatory uncertainties (e.g., who is engaged? In the US, who is an investigator requiring an FDA Form 1572 or Delegation of Authority?)
- Different capacity for and time to emergency care (i.e., call 911 versus crash cart on site)
- Challenges when specialized equipment, significant testing, or procedures are required
- Concerns for maintaining data security and transfer among the study team, participants, and third-party vendors
- Security and accountability concerns when delivering prescribed medication or devices

For in-home visits, IRBs/ECs should consider:

- Participant preferences for the method of interaction with the research study team
- Risks to privacy and confidentiality of participant
- Availability of emergency and other care
- Status of the healthcare provider: competencies, licensure, status as the investigator or engaged research personnel (e.g., on FDA Form 1572)
- Responsibility grid for providers and third-party vendors if engaged
- Mechanisms to ensure adequate PI oversight

Local Visits

For “local visits,” a participant may visit a local provider, laboratory, imaging center, or other site for their required research visit. Laboratory tests and imaging studies can often be performed locally, and the results sent to the responsible investigator. This is convenient, particularly in settings where routine labs or imaging are needed, and if there is equivalence between results obtained at the primary versus the local site. A local visit can also be used when face-to-face evaluation or specialized testing must be conducted in a clinical setting. Unless the services rendered are considered standard of care, the local site or must have appropriate training (e.g., GCP) and instruction.

In summary, with local visits:

- The study requires the participant to have contact with a clinician
- Participants are seen by local providers (possibly their customary providers), laboratories, and imaging centers
- The research study team or sponsor may contract with third-party vendors in local communities for patients to visit
- Data are transferred to the investigator study site



- Decreases, but does not eliminate, travel burden and opportunity costs to patients

Potential benefits

- Permits face-to-face visual and physical assessment of participant
- Less burden (e.g., travel distance)
- Relationship with local provider preserved
- Emergency services available
- More in-depth evaluations of the patient
- Accurate and validated study data

Potential Challenges

- Requires some travel, time, and expense for participants
- Training of local providers must be provided and assured
- Regulatory issues and responsibility for third-party vendors (credentialing, licensure, accountability, status)
- Monitoring/regulation of protocols at third-party local providers
- The local provider may or may not be an investigator

For local visits, IRBs/ECs should consider:

- The need for a face-to-face participant visit, laboratory tests, or imaging study
- Whether the local site or provider is adequately trained, credentialed, licensed, and familiar with the specific research protocol
- Assurance of PI oversight assured
- Data security and privacy for data collection, transfer, and storage
- Responsibility grid for providers and third-party vendors, if engaged