



REMOTE DATA COLLECTION

Real-time Data Monitoring in DCTs

Introduction

Once a DCT study is launched, study sponsors and sites must monitor several aspects of the trial on an on-going basis to ensure its proper execution, data integrity, and participant safety. While on-going monitoring is an expectation of all clinical research, in the context of DCTs, it may involve dynamic “real-time” monitoring in addition to new technologies that can be deployed. This document focuses on continuous monitoring of real-time data and the opportunities and potential challenges presented by these digital technologies.

Study elements that can be monitored frequently or in real-time

- Enrollment
- Participants’ completion of required tasks and scheduled activities
- Participant requests to the Helpdesk and the study team
- Notification schedules and responses to those notifications if enabled and required
- Sensor data, e-Patient Reported Outcomes, and other outcome measures
- Safety signals
- Endpoints and outcome measures
- Investigator and sponsor reports
- Overall compliance

Not all of these study elements are unique to DCTs, but some require special considerations. Here we focus on the issues that are either unique or more pronounced in DCTs than in traditional, site-based trials. For example, more frequent (or real-time) monitoring of participants’ compliance with required tasks.

Questions IRBs/ECs to Consider

- What type of study data are available to the investigators and to the participants?
- Are these data unique in some way?
- Will access to data or results impact trial integrity or blinding?
- Are there additional safety concerns?
 - Is there an expectation to respond to real-time reporting of adverse events? Are the mechanisms in place to assure timely response (e.g., 24hr monitoring)
- Are there confidentiality and/or privacy concerns?
- Are staff and systems in place to respond to real-time receipt of participant data, if necessary?



- Does the site/investigator have sufficient resources to support the DCT's requirements for real-time monitoring?

Impact on the Participant

- Dynamic, real-time data or result return:
 - Will the participant and/or treating physician/investigator have access to data or results during the trial?
 - What type of data will participants have access to during the trial?
 - Will this data be understandable and/or actionable by the participant?
 - Will access to the data impact participant behavior, safety or study results?
 - Will participant access to data influence future behavior or impact study blinding?
- Does the ICF clearly explain the extent to which data submitted by participants will be monitored by study staff?
 - Participants may believe that study staff are monitoring their data in real-time, whether or not they are, and fail to alert study staff to possible adverse events or assume staff will respond to possible adverse events.
- Is the quality and burden of participant submission of adverse events considered?
 - Has the protocol anticipated the accuracy, frequency, and burden of participant reporting of adverse events?
 - Will reporting be systematic and comprehensive?
 - Are systems in place to ensure that study staff will review and respond to reports in a timely manner?
 - What procedures are in place for responding to serious or unanticipated adverse event?
- What approaches or mitigation strategies are in place to assure adequate participant compliance for completing questionnaires throughout the study? Participants may attenuate to and tire of completing questionnaires, increasing the potential for missing information.
- What information is communicated to participants about the study staff availability and response time? Are there specific considerations related to data collected through sensors or submitted by participants?
- Has the study team or sponsor minimized the data collection to only that necessary for the study outcomes? Has metadata collection also been minimized?
- What back-up systems are in place should devices, technologies, data transfer, or data storage techniques fail? Are back-up systems proportionally secure?