



# Study Closeout

## Introduction

Study or trial closeout is the process by which all activities related to the clinical trial are reconciled, recorded, reported, and stored at the end of the trial. Study closeout is an important component of quality; properly executed, it will also simplify access to study documentation and data access in the future or if the study undergoes post-closure audit or inspection.

The responsibilities of investigators and their study teams, and of the IRB/EC in its oversight role, are similar in DCTs and traditional trials. The major focus of the IRB/EC should be on aspects that differ between the two types of trials, including the disposition of the device (if not provided by the participant) and research data, and reconciliation and disposition of any investigational product, particularly if the product has been delivered to a home or local sites.

Given the nature of participant engagement in decentralized clinical trials, some investigators prefer to manage the closeout process with each participant as they complete their study participation, and then later closeout the overall study itself. We first consider activities related to the participant, and second, related to the entire study, with an emphasis on those activities relevant DCTs. There are different processes for the collection, transfer, and storage of data from DCTs than traditional trials.

## Study Closeout Activities Related to Individual Participants

The following end-of-study considerations should be reviewed:

- The participant has completed their role in study, including all study procedures and data collection.
- Participant data have been captured and source documentation is available and verified.
- Data is complete, clean, and the database is locked.
- All study data have been transferred from devices.
- Participant has returned devices and sensors, or instructions for destruction provided if required.
- If participant used their own device (phone or tablet), provisions for deletion of study data (i.e., cookies and sensitive personal data) and apps have been communicated and/or verified.
- Only necessary personal identifying data have been retained in the study data
- Investigational product, if shipped to participant, has been accounted for, and any residual product has been returned and/or destroyed, as applicable.



## Study Close-out

1. Data
  - Only necessary personal identifying data have been retained in the study data
  - All eCRF/EDCs have been completed and submitted as applicable
  - All queries have been resolved
  - Participant access has been removed or deactivated from the connected device or other eCOA data capture/patient engagement platforms
  - Quality Control database
  - Database lock
  - Data storage arranged, retrieval and backup recorded
2. Investigational product or study drug and pharmacy:
  - Site/Local/home investigational product or study drug accounted for
  - Accountability logs and forms reviewed and filed
  - Shipping logs documentation is reviewed and filed
  - Any discrepancy documented, investigated, and resolved
  - Pharmacy documentation is in order
  - Remaining investigational product or study drug, materials, and compounds are returned or destroyed as outlined in the protocol or agreement with the sponsor
3. Documentation and Closeout
  - All unanticipated problems, adverse events, and serious adverse events have been documented, resolved, and reported as required
  - All study documentation available and securely retained
  - eConsents or ICFs on file
  - Study files reconciled with Trial Master File
  - Study closure forms submitted to IRB/EC
  - IRB/EC closure confirmed
  - Any discrepancy documented, investigated, and resolved
  - Final inventory/reconciliation of remaining or unused trial supplies, including devices loaned to participant and equipment loaned to the local site, completed
  - Trial supplies returned to the sponsor or destroyed, as applicable
  - Biospecimens recorded, stored for future use (where permitted), and documented
    - Note: Do not close out the study if biological specimens containing individually identifiable information are maintained in the approved study-specific repository or upon which analysis or research continues. The study may be closed if biospecimens are transferred to a different repository that has separate IRB/EC approval.