Royal Papworth Hospital
NHS Foundation Trust

GD013

Database locking

Database locking is the process whereby a dataset is readied for analysis and then its state is kept constant – i.e. locked so that the data cannot be amended.

There are two types of lock:

1. An **Interim lock** is a process that provides a snapshot of a database at a particular point in time while the study is still in progress. This is only performed if specified in the protocol.
2. A **Hard lock** refers to the process whereby a database has been cleaned and validated and all edit permissions are revoked. Data in a hard locked database is considered clean, complete (as far as is possible) and ready for analysis; no further amendments are expected.

The following steps are part of lock preparation. What is required for a hard lock and an interim lock will be documented in the Data Management Plan (DMP). The items marked with * are always required for a hard lock.

1. Case Report Form (CRF) completion review
    a. The database should be reviewed to ensure the appropriate CRFs have been completed appropriately for each participant.
    b. If the study is using OpenClinica the CRFs should be marked complete.*
2. Data query review*
    a. Final review of data to identify and resolve any remaining queries.
    b. Any unresolved data queries should be documented and signed off by appropriate parties.
    c. Review missing data.
3. Automatic edit check (AEC) review
    a. AECs are usually run via an automated program after the data has been entered, generating a report listing the possible validation issues. All validation issues should be reviewed prior to lock.
    b. Any unresolved validation issues should be documented and signed off by the appropriate parties.
4. Source data verification (SDV) review*
    a. The level of SDV specified in the monitoring plan should be achieved.
5. Serious adverse event (SAE) reconciliation
    a. Reconcile any AE reported as an SAE in clinical database against events reported to pharmacovigilance.
    b. If SAE reconciliation is required by a non-Papworth sponsored study, the Sponsor's SOP and guidelines should be followed.
6. Coding
    a. The DMP will specify whether coding is required.
7. All coding must have been completed prior to a hard lock PI Signature*

    a. CRFs should be signed off by the PI.
    b. If the data changes those CRFs should be re-signed.
    c. If the study is using OpenClinica the CRFs can be marked off as signed within the system.
    d. If the study is not using OpenClinica, and an electronic signing system is not available, the CRFs can be signed off using paper.
8. Authorisation to lock obtained from all parties*
    a. If an interim lock is required the interim lock form (FRM053) must be completed specifying what data, subjects and/or CRFs are to be included. FRM053 should be used to record which steps have been completed prior to interim lock.
    b. If a hard lock is required the Lock Approval Form (FRM017) must be completed. FRM017 should be used to record which steps have been completed prior to hard lock.

Once the steps specified in the DMP have been completed, the database can be locked. The database should have all edit permissions revoked to prevent any amendments to the database.

After a hard lock the dataset should not be amended, but it can be unlocked if necessary. Unlocking a hard locked dataset should be avoided as this can only be approved through a formal process at Sponsor level. The following steps are always required when unlocking and relocking a database:

1. Authorisation to unlock obtained from all parties by means of the Database Unlock Request Form (FRM019) being completed.
2. Prior to re-locking the following steps need to be undertaken:
    a. The audit trail for the database should be reviewed to confirm that only the approved changes were made. Any files, data etc. created to support this process should be retained.
    b. A new Lock Approval Form (FRM017) should be used to authorise the relock.

Signing CRFs

The PI should sign off each patient's dataset at the end of study once all data queries for that patient are resolved and the data provided for that patient is deemed clean and accurate.

For studies using OpenClinica, the preferable option is for PIs to sign off the patient’s dataset using OpenClinica’s built-in function. When a casebook for a Subject is signed, OpenClinica automatically sets the status for all Study Events for that Subject to "signed". After an Event status is "signed", any changes to the CRF automatically change the Event status to "completed". OpenClinica also allows for the signing of individual CRFs if required.

In some cases it may not be applicable or appropriate for the CRFs to be signed off in OpenClinica, in which the subject records can be signed off on paper or using a e-signature system like DocuSign.