17 Completing Your Study

The following workflow outlines the recommended steps for closing out a study (that is, preparing for database lock) and archiving it.

 Note: The Production and Test environments for each study are managed independently.

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1. Sign Records

Investigators and designated users can electronically sign records to confirm data accuracy and completeness.

Who Can Sign

- **Investigator** role at the site level
- **Data Specialist** role at the study level (if configured)

For details, see **Signing Participant Records**.

Prerequisites

- Events must have a status of **Completed** before they can be signed.

Where to Sign

- **Casebook level:** The casebook can be signed if all scheduled events for a participant are **Completed**, **Stopped**, or **Skipped**.
- **Event level:** The event can be signed if all required forms are **Complete** and all non-required forms are not *In Progress*.
    - In some cases, you may need to manually mark the event **Complete** on the **Edit Event** screen before signing.

 Tip: Use **OpenClinica Insight** reports to track signed versus unsigned data and configure **Pulses** to automatically send signature reminders to Investigators.

2. Freeze the Study

Freezing a study prevents data entry or modification while allowing queries to continue.

How to Freeze

Data Managers can freeze individual sites or the entire study environment by editing the **Site Settings** or **Study Settings**.

How to Unfreeze

Data can be unfrozen at any time using the same settings.

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3. Lock the Study

Locking a study prevents any data changes while maintaining full visibility for review and reporting.

Locking Options

- Lock at the **Event**, **Site**, or **Study Environment** level.
- Once an event has been scheduled, a Data Manager can lock it.

Notes

- Data does **not** need to be signed before it can be locked.
    - If your SOPs require data to be signed before locking, you must verify this manually, as the system does not enforce it.
- The **Participant Matrix** shows which data are locked or unlocked.
- Use **Insight** reports for additional detail.

To unlock data, use the same settings used to apply the lock.

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4. Archive Data

After locking the study environment, archive your study data for long-term retention and audit readiness.

 Note: OpenClinica retains your data for as long as your subscription is active.

When a study environment is in **Archived** status, its data becomes read-only and cannot be accessed without reactivation. Archiving may therefore be optional or can be performed later, depending on your study's requirements.

Extract Study Data

Export all study data using the **CDISC ODM XML (Full with OpenClinica Extensions)** format. This extract includes:

- Study metadata
- Query-related data
- Audit log data

Print or Generate Archival Casebooks

Archival casebooks include all participant data, queries, and audit trail information—providing a complete, audit-ready record of your study.

You can create casebooks in two ways:

- **PDF Archival Casebooks** — Available to **Admin Data Managers** from the **Tasks** menu. To generate these, follow the steps in **Generating Participant Casebooks**.
- **JSON or XML Casebooks** — Available to all Data Managers from the **Participant Details** page.
  These formats allow you to generate casebooks for all participants within a site or across the entire study.

To generate multiple JSON or XML casebooks:

1. Select **JSON** or **XML** as the format.
2. Click **Get Link** to generate a modifiable URL for the casebook export.
   - For example, the following URL would show the casebook for one participant: *https://acme.openclinica.io/OpenClinica/rest/clinicaldata/xml/view/S_DF/**SS_DF001**/*/*?includeDNs=y&includeAudits=y&includeMetadata=n&showArchived=y*
   - Replacing the SS_DF001 with an asterisk (*) will give you casebooks for all the subjects for this site in a single file. (*https://acme.openclinica.io/OpenClinica/rest/clinicaldata/xml/view/S_DF/*/*/*?includeDNs=y&includeAudits=y&includeMetadata=n&showArchived=y*)

 Tip: JSON and XML casebooks are best for bulk exports, automation, or long-term archival. PDF casebooks are optimized for regulatory submission or human-readable records.

Archive the Study Environment

Change the **Production** study environment status to **Archived** to remove it from your active subscription count.

Once a study is archived:

- The environment immediately stops refreshing in **Insight**.
- A support ticket is automatically created to document the archiving, and **OpenClinica Support** will deactivate the environment.
- You can reactivate the study environment at any time by updating its status.

If both the **Production** and **Test** environments are archived, the study will appear on the **Retired Studies** page within **My Studies** instead of the **Active Studies** page.

 Note:
When a study is unarchived, **Insight** refreshes resume automatically if the data mart was not fully deactivated.
If the data mart was deactivated, you must re-request activation.
This process does not affect existing **Questions** or **Dashboards** at any time.

 Note:
If the study is only paused temporarily or was published to Production prematurely, change the study status to **Design** instead of **Archived**.
Studies in **Design** status continue to count toward your subscription limit.