



3.3.2 LMS Integration

OpenClinica enforces role-based training to ensure users are prepared before accessing study data in production. This page explains how training enforcement works, what users and administrators can expect, and how to configure training requirements for user roles.

Overview

OpenClinica training has two components:

Training Type	Description
Required training	Role-based training configured by a Study Administrator. Users must complete this before accessing the Production environment in Study Runner.
Optional training	Self-service resources, including Resources beacon content and tooltips, available at any time for onboarding and reference. Completion is not tracked.

How Training Enforcement Works

When you log in to Study Runner, OpenClinica checks whether you have completed any required training for your assigned role. If training is incomplete, you are redirected to the **Training Page** before you can access the Production environment. Each training module includes a quiz. To be marked complete, you must score **80% or higher** on the accompanying quiz. Once you complete all required training, access is granted automatically and you are redirected to the Study Runner homepage. Training status updates in real time — no manual refresh is needed. If your role does not require training, or if training is already complete, the Study Runner homepage opens normally. □

Note: Training enforcement applies to both new and existing users. If your role requires training, the Training Page appears at login regardless of when your account was created.

Training Completion and Role Assignments

Training completion is tracked at the user account level within a customer domain. This means:

- If you are assigned the same role across multiple studies in the same domain, you only need to complete training once.
- If you are assigned a different role, you must complete the training required for that role.

Environment and Study Behavior

Training enforcement depends on which environment and study you select:

- **Production:** Required training is enforced.
- **Test:** Training is not required, allowing you to practice workflows and explore functionality without completing training first.

For users assigned to multiple studies, enforcement depends on the study selected. If a study does not require training, the study homepage opens normally. If it does require training and you have not completed it, you are redirected to the Training Page. □ **Note:** On the Change Study page, both Production and Test studies appear. Training requirements apply only to Production studies. For more information, refer to [Change Study](#).

Training Completion Records and Audit Logging

OpenClinica records and retains completion data for the five core LMS-based trainings, regardless of whether they are configured as required for a given role.

After a core training is completed, OpenClinica stores the completion record internally to support long-term retention, protect records from alteration or deletion, and provide audit evidence for inspections.

Training Module Completion

When the LMS confirms completion of an individual training module, OpenClinica creates a **Training_Module_Complete** audit log entry. Each entry includes:

- Audit event name (Training_Module_Complete)
- System date and time when completion is recorded
- Target object (the user the training data is associated with)
- The user associated with the completion
- Training name
- Value ({blank} / Yes)

All Required Training Complete for User Role

After you complete all required training for a user role, OpenClinica creates an **All_Required_Training_Complete** audit event. This event is logged in each study where you are assigned the applicable role to support traceability across study contexts. This event is created in the following situations:

- A user newly completes all required training for their role.
- A user who has already completed required training is assigned to a new study with the same training requirement.
- Core Training Required is enabled for a role whose currently assigned users have already completed the required training.

These audit events ensure consistent documentation of training compliance across studies and role assignments.

View Training Status for Your Study

To see which users have completed or not yet completed required training, use the **People Table** on the **Share Page**. The People Table displays a **Training Status** column for each user assigned to the study, allowing you to quickly identify who has and has not completed required training.

- Navigate to the **Share Page** for your study.
- Review the **People Table** and check the **Training Status** column for each user.

Training Status	Meaning
Complete	All required training for the user's role has been completed.
Not Complete	Required training for the user's role has not been completed. The user cannot access the Production environment for this study until training is completed.
Not Applicable	No training is required for the user's role.

□ **Note:** The **Training Status** column only appears in the People Table when at least one user role in the study has training required. If no roles require training, the column is hidden.

Export Training Completion Records

If you need a record of training completion for audit or compliance purposes, download the User and Role Audit Log. This log includes the **Training_Module_Complete** and **All_Required_Training_Complete** audit events described above and can be used to verify completion outside of the application. **Note:** For more information on accessing the User and Role Audit Log, refer to [Using OpenClinica as an Administrator](#).

Configure Training Requirements

This section is for Administrators responsible for configuring user roles. Training requirements can be configured for each user role. If Core training is required, the specific course is automatically chosen for each of the five core base roles:

- Clinical Research Coordinator (CRC) / Data Entry Person
- Investigator / Data Specialist
- Data Manager
- Monitor
- Viewer

Enable Core Training for a Role

To require Core training for a role, enable the **Core Training Required** option in the role settings. Once enabled, all users assigned to the role must complete the designated training before accessing the Production environment for the study.

1. Navigate to **Settings** → **User Roles**.
2. Select the role you want to configure and click **Edit**.
3. In the Edit Role window, scroll down to the **Training Requirements**
4. Enable **Core Training Required**.
5. Click **Save**.

Tip: You can also set the training requirement when creating a new user role. **Tip:** If you have tight timelines between a study being published to Production and first patient in (FPI), consider assigning users to the Test environment first before granting Production access. Users can complete training through the **Resource Center** and complete it at their own pace. Because training completion is tracked at the user account level, their completed training will already be on record when you are ready to grant Production access.

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