13 OpenClinica Code

This guide explains how to use the **OpenClinica Code** module within OpenClinica 4 for collecting and coding adverse event (AE) and medical event data.

MedDRA (Medical Dictionary for Regulatory Activities) is a standardized, hierarchical medical terminology used globally in clinical trials and pharmacovigilance. It standardizes terminology and enables consistent analysis and monitoring of medical events.

 For more information on MedDRA, refer to the **Official MedDRA website.**

OpenClinica 4 supports the integrated medical coding of adverse events (AEs). This module enables both manual and automated coding of AEs. To use this feature, you must activate and configure it with valid MedDRA credentials. This functionality streamlines the coding process, ensuring faster, more accurate data entry and regulatory compliance.

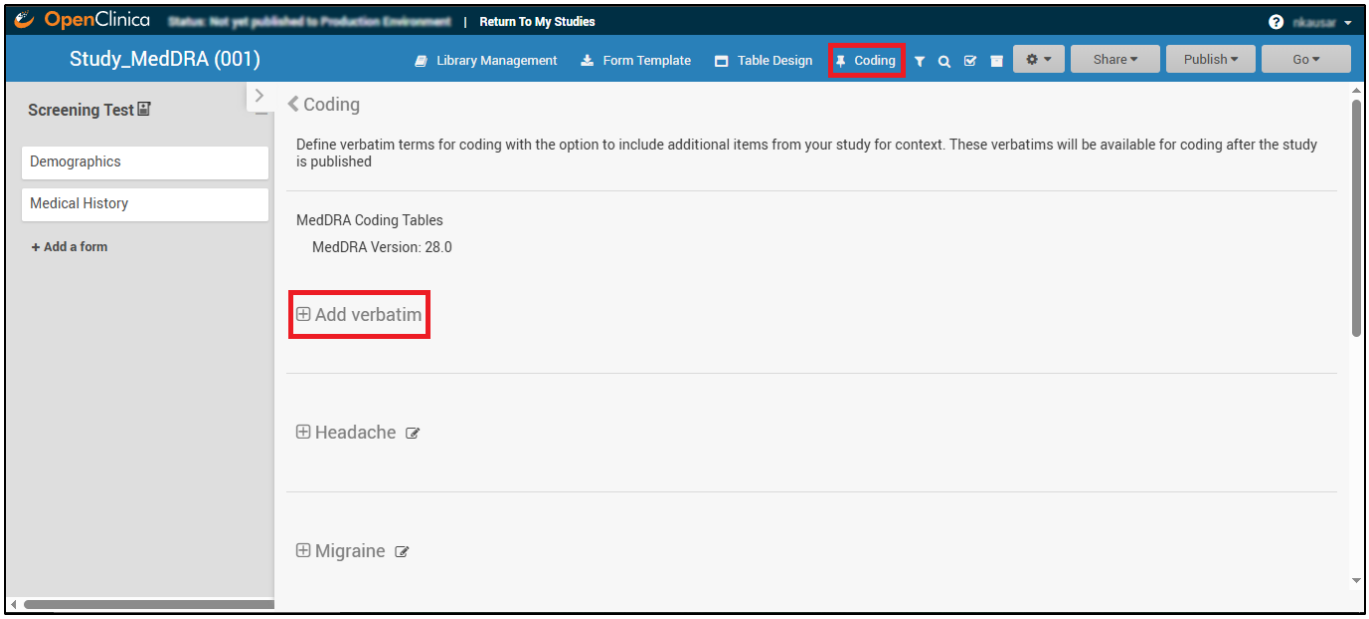
13.1 Code Study Design Configuration

Once the **Code module** has been activated, you must configure it in **Study Designer** to indicate which items should be coded. This setup informs the coding module about which verbatim fields in your study should be coded using MedDRA terminology. **Note:** The coding table setup in **Study Designer** is only available if the **Code module** has been configured.

Navigating to the Coding Tab

1. **Go to Study Designer:** At the top of the screen, click the **Design** button.
2. **Navigate to the Coding Design Interface:** In the **Study Designer** workspace, click on the **Coding** option in the top menu bar.

The **Coding** tab opens, where you can manage coding settings. Here, you will see the **MedDRA Coding Tables** section and the option to **Add verbatim** terms for coding.



Adding and Configuring a Verbatim Table

The following instructions outline the process for setting up a **MedDRA Coding Table**:

1. Click **Add Verbatim** in the **Coding** section.
2. **Provide Table Display Name:** This becomes the header title and **Tasks Menu** label (e.g., "Adverse Event Coding") within **Study Runner**.
3. **Choose a Study Event** (Required only if the form is used in multiple events): If the form containing the verbatim field is used in multiple events, the user must select which event to associate with the coding table. If the form is used in only one event, this selection step is not required.
    - The verbatim can originate from any form within the study, whether used in visit-based or common events, and from either repeating or non-repeating forms.
4. **Enter Table Description** (Optional): Add notes or internal guidance for the coding team.

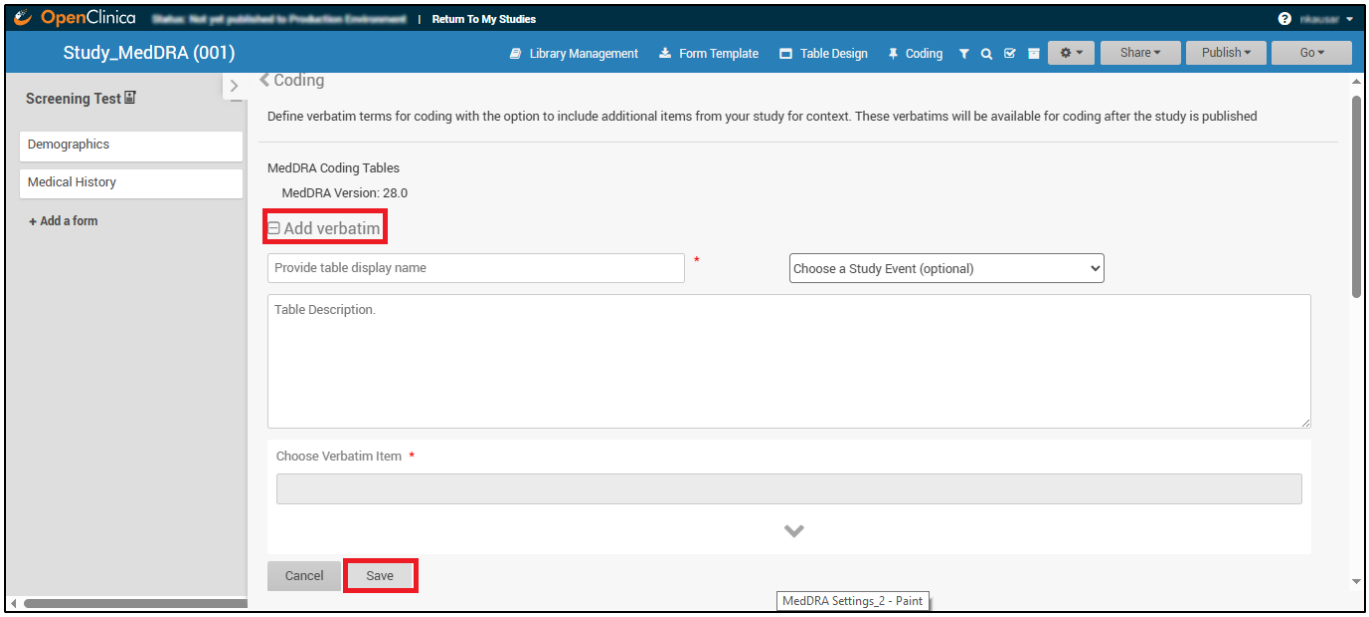
 Note: Table descriptions are only visible in **Study Designer** and do not appear in **Study Runner.**

5. **Choose Verbatim Item:** Select the free-text field (e.g., "AE Description") from your forms that will be coded.

 Note: The item selected as the verbatim cannot be part of a repeating item group; the system prevents such selection. In addition to **Adverse Events**, coding may also be used for other data types, such as **Medical History**. If used for this purpose, the **Medical History form** must be designed without placing the relevant items in repeating item groups.

6. Click **Save** to create the table. After saving, you can edit:
    - Table name
    - Table description
    - Context items: These context columns provide extra data to the coders but are not the verbatim being coded (e.g., patient date of birth, age, weight, or any data that can be used as a reference for the verbatim).

 The verbatim itself cannot be edited after saving, as it defines the entire table.



Publishing Coding Tables to Study Environments

Tables and changes only appear in **Study Runner** once published. Unpublished coding tables will not be available to users entering or reviewing data. To Publish:

1. Click the **Publish** button at the top right of **Study Designer**.
2. Choose your target environment (**Production** or **Test**).
3. Click **Publish** to confirm the changes and make your coding table live.

 Note: You cannot change the selected verbatim item after publishing (**Production** or **Test**) the study. If the verbatim field needs to be changed, **Archive** the existing table and create a new one.

Archiving

Once a table is archived, it becomes read-only and remains available for export. Archived tables can no longer be modified, regardless of whether they contain coded data or are empty.

13.2 Code Activation and User Permissions

In this section, **Administrators** will learn how to request and activate the **Code** module in **OpenClinica 4**, as well as how to assign user roles to ensure that only authorized individuals can perform medical coding. You can begin study and form design activities immediately—such as creating CRFs, defining events, and building the study—without MedDRA credentials. However, configuring coding workflows and the ability to code adverse event data is unavailable until valid MedDRA credentials are entered and the module is enabled.

Licensing and Activation Requirements

Using the MedDRA module requires two separate licenses:

1. An OpenClinica subscription that includes the **Code** Module.
2. An active MedDRA license.

 If you are unsure whether your organization has an active MedDRA license, contact the administrator within your organization.

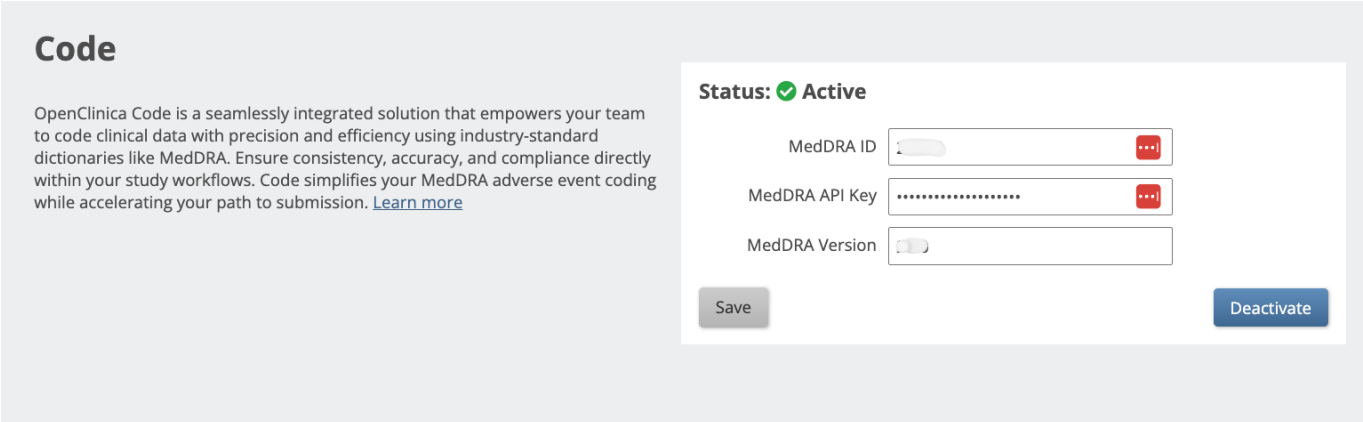
MedDRA Module Access and Entering Credentials

To activate the MedDRA module for your study, follow these steps:

1. Navigate to the **Modules** page in OpenClinica.
2. Request **Access** for activation of the **Code** Module.
3. Enter your organization's MedDRA credentials and click **Save**. The system will automatically confirm:
    1. MedDRA ID, MedDRA API Key, and MedDRA Version.
    2. Whether your MedDRA license is active.
4. After successful validation, the MedDRA Coding section displays: **MedDRA ID**, **MedDRA API Key** (masked), and **MedDRA Version**.
5. Once the request is approved by the OpenClinica team, the status will change to **Active.** At that time, you will be able to configure the MedDRA Coding table, publish the study including MedDRA settings, and code data.

MedDRA Credentials Fields

Field	Description
MedDRA ID	A five-digit ID issued by MedDRA to your organization.
MedDRA API Key	Generated from your organization's MedDRA account—distinct from a password. Your organization’s MedDRA API Key must be obtained by logging into the MedDRA self-service portal with a MedDRA ID and password, and then generating a key according to MedDRA’s instructions. This only needs to be done once for your organization. The same key can be used in multiple studies. **How to obtain the API Key:** Log in to the MedDRA website and generate the API key (distinct from MedDRA login credentials).**mid.meddra.org/account/register**
MedDRA Version	The MedDRA dictionary version number to be used in your study.

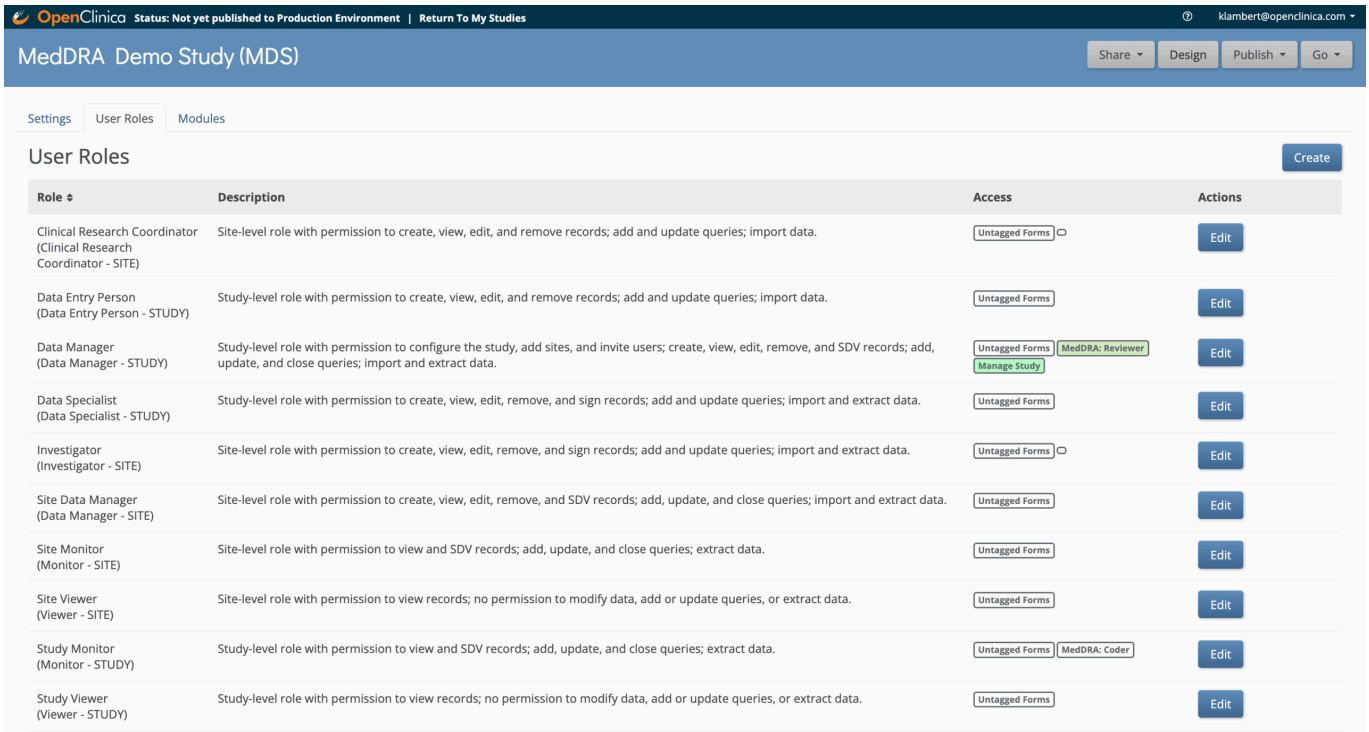


 Once credentials are valid and saved, no further changes are typically needed during the study, unless you need to update the **MedDRA Version**. This will only impact which MedDRA version is

queried to code new verbatims going forward. If you change your MedDRA dictionary version mid-study, any re-coding must be done manually. If you deactivate the **Code** Module, you will lose access to download coded terms. Please ensure you have downloaded each MedDRA Coding Table from Study Runner prior to deactivating **Code**.

MedDRA User Role Permissions in OpenClinica

Access to **Code** functionality in **OpenClinica 4** is determined by specific MedDRA module permissions assigned to each role. This allows for fine-tuning responsibilities based on your team's structure and regulatory requirements. User role permission configuration for MedDRA will be available once the MedDRA module has been activated.



Assigning Permissions Permissions are assigned during role configuration in the study setup:

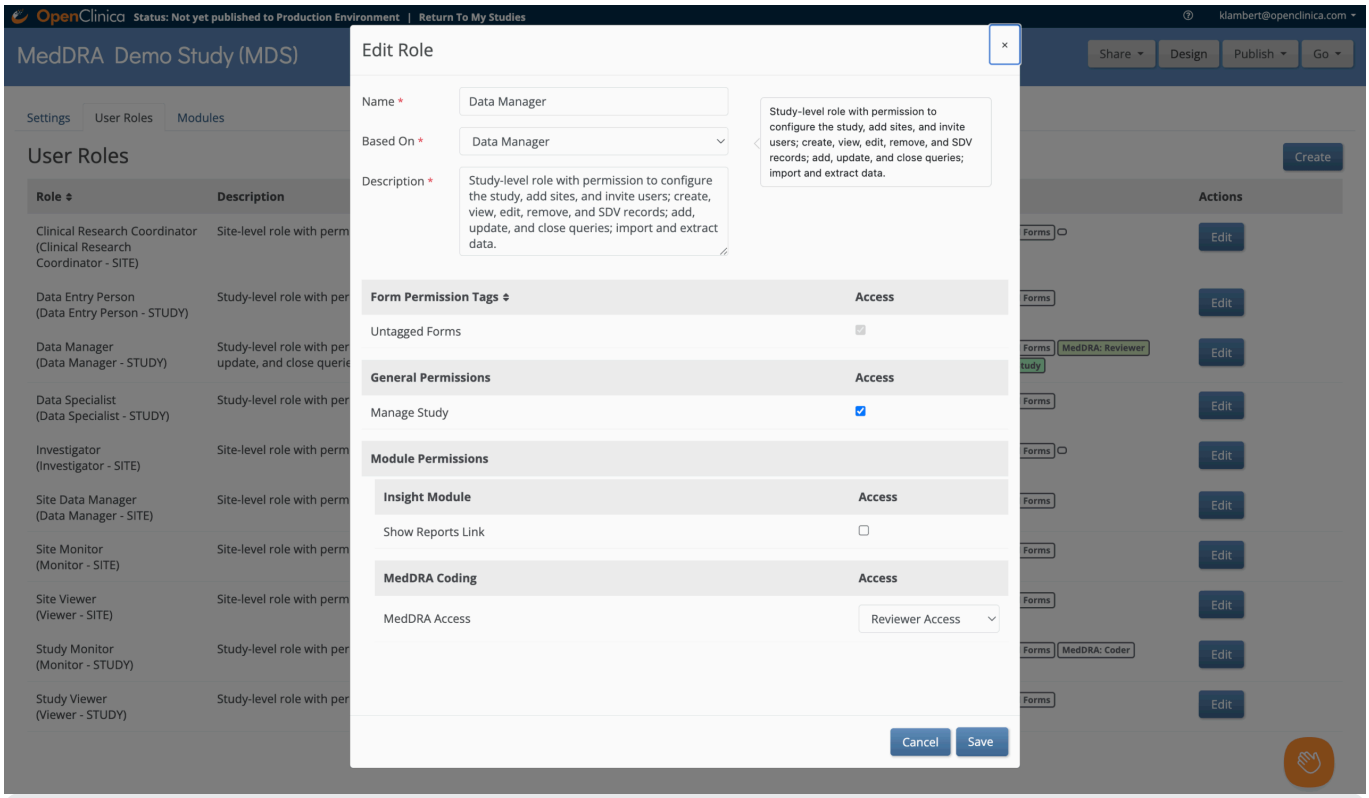
1. Navigate to **Settings > User Roles**.
2. Edit an existing role or create a new one.
3. In the permissions list, locate **MedDRA Coding**.
4. Select the desired MedDRA Access level from the dropdown selector.
5. Click the Save button.

There are two main levels of access permissions for MedDRA coding in OpenClinica:

1. **Coder Access:**
    - **Capabilities:** Manually assign codes to uncoded terms, add queries, and export coding data.
    - **Limitations:** No access to the review workflow. Cannot clear or overwrite autocoded values.
    - **Intended users:** Medical Coders or Data Managers responsible for assigning and validating coded data, but not for managing approvals.
2. **Reviewer Access:**
    - **Capabilities:** Perform all coding activities in Study Runner, including coding tasks, overriding automatic and manual codes, reviewing codes through approval or rejection, adding queries, and exporting data.

- **Intended users:** Senior Medical Coders, Data Managers, or other roles that require full authority to assign, validate, and review codes within a study

3. **No Access:** Users who have neither Coder nor Reviewer access cannot access the MedDRA coding table at all.



Approved for publication by Paul Bowen. Signed on 2025-09-05 5:38PM

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