13.1 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.

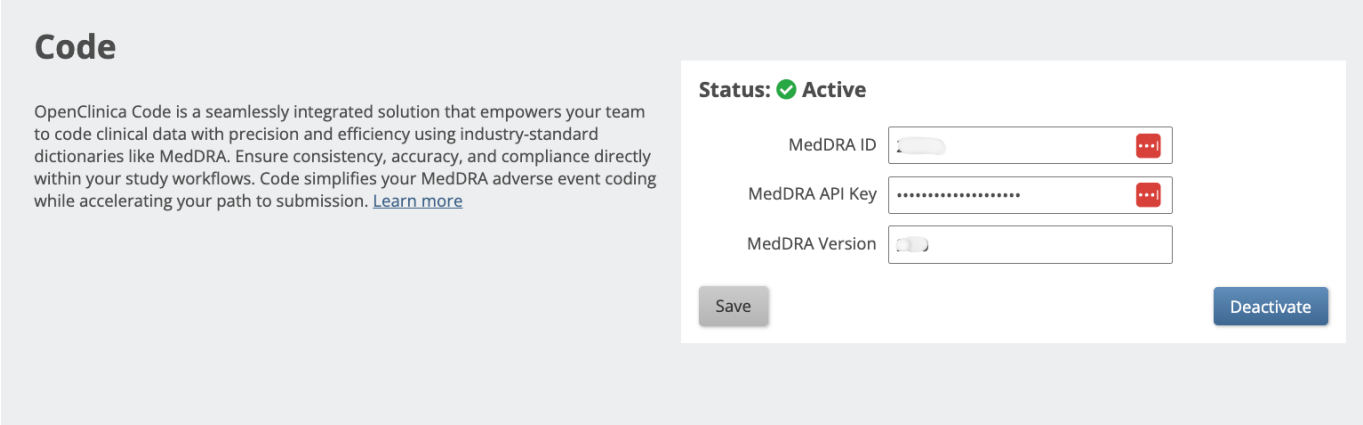
MedDRA Module Access and Entering Credentials

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

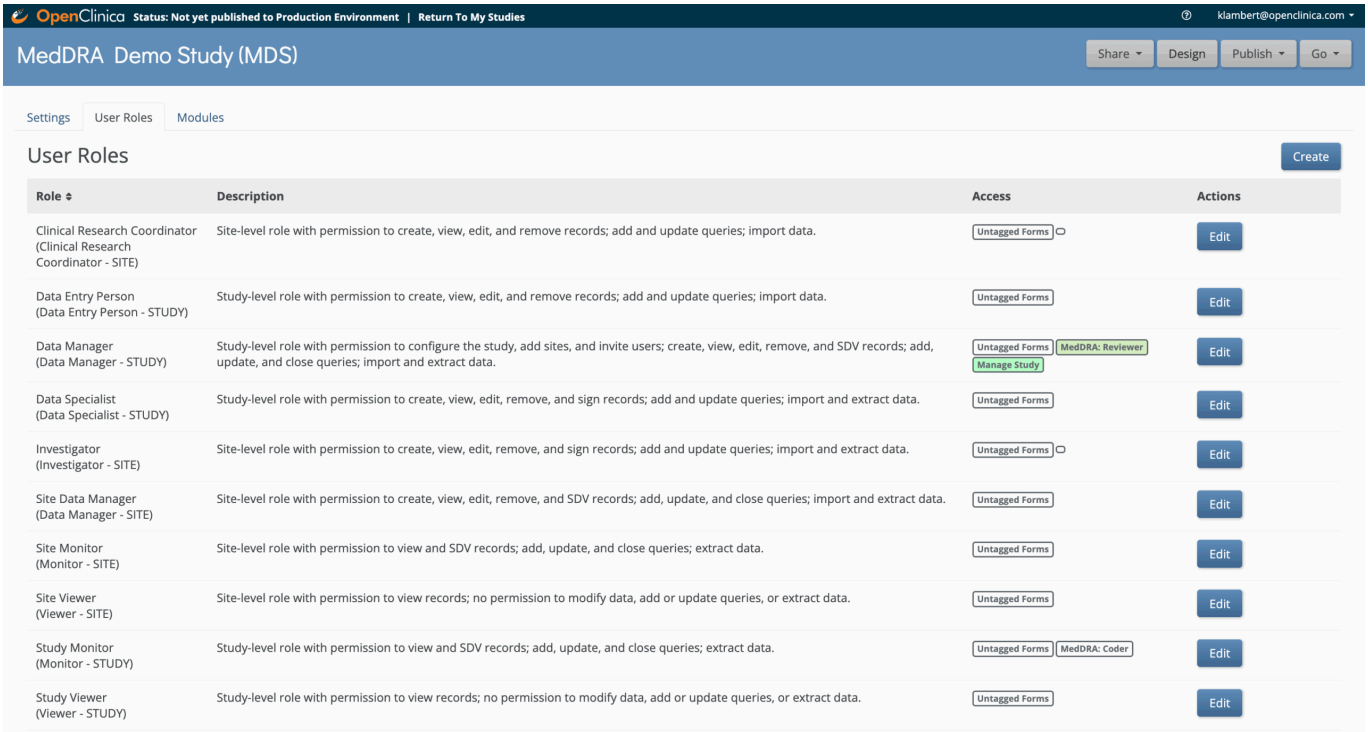
Field	Description
MedDRA ID	A five-digit ID issued by MedDRA to your organization.
MedDRA API Key	Generated from your organization's MedDRA account—distinct from a password. Your organization’s MedDRA API Key must be obtained by logging into the MedDRA self-service portal with a MedDRA ID and password, 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.

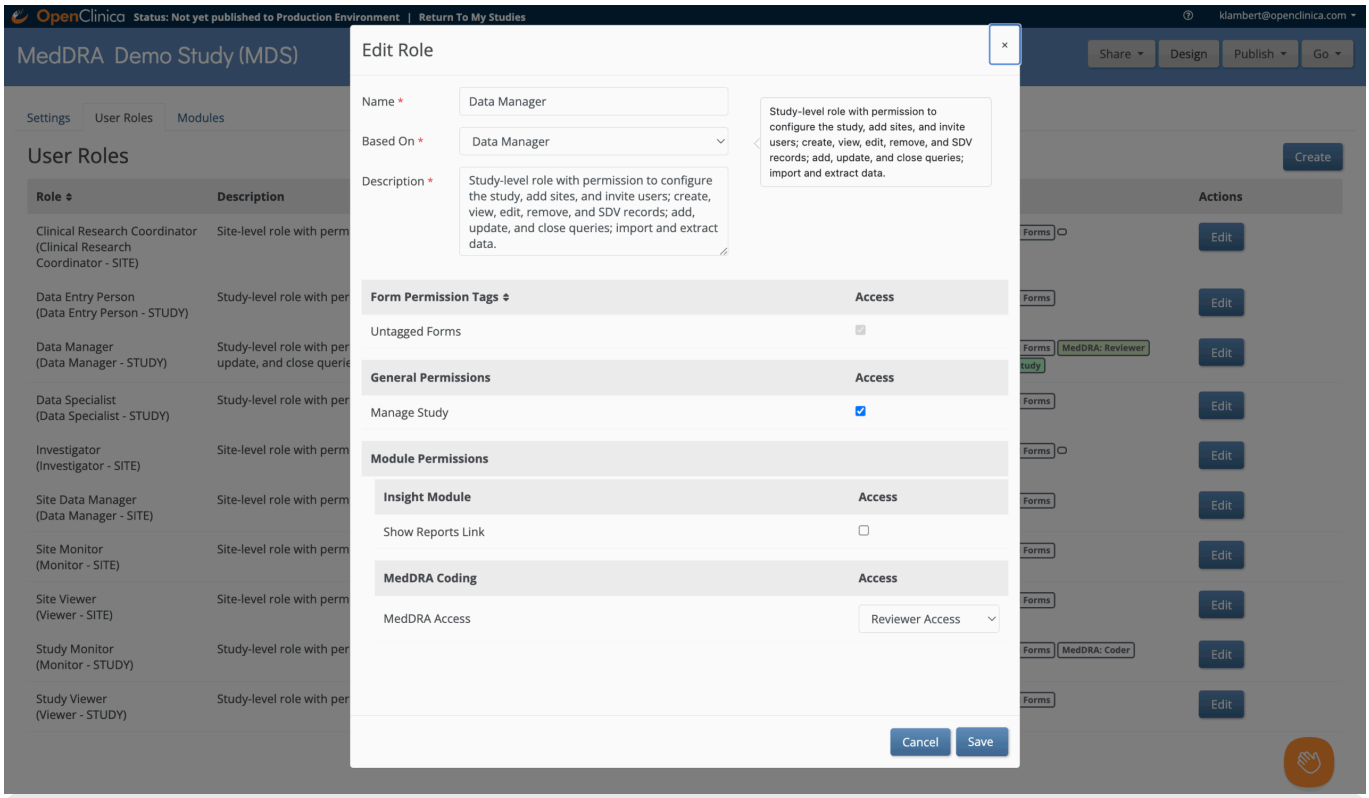


Assigning Permissions Permissions are assigned during role configuration in the study setup:

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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