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 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

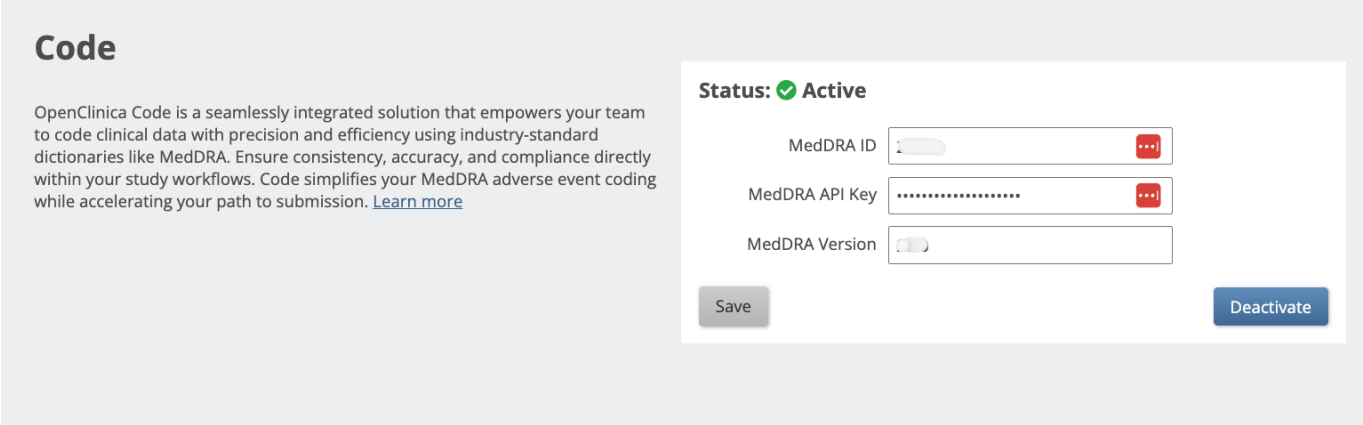
To activate the MedDRA module for your study, follow these steps:

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

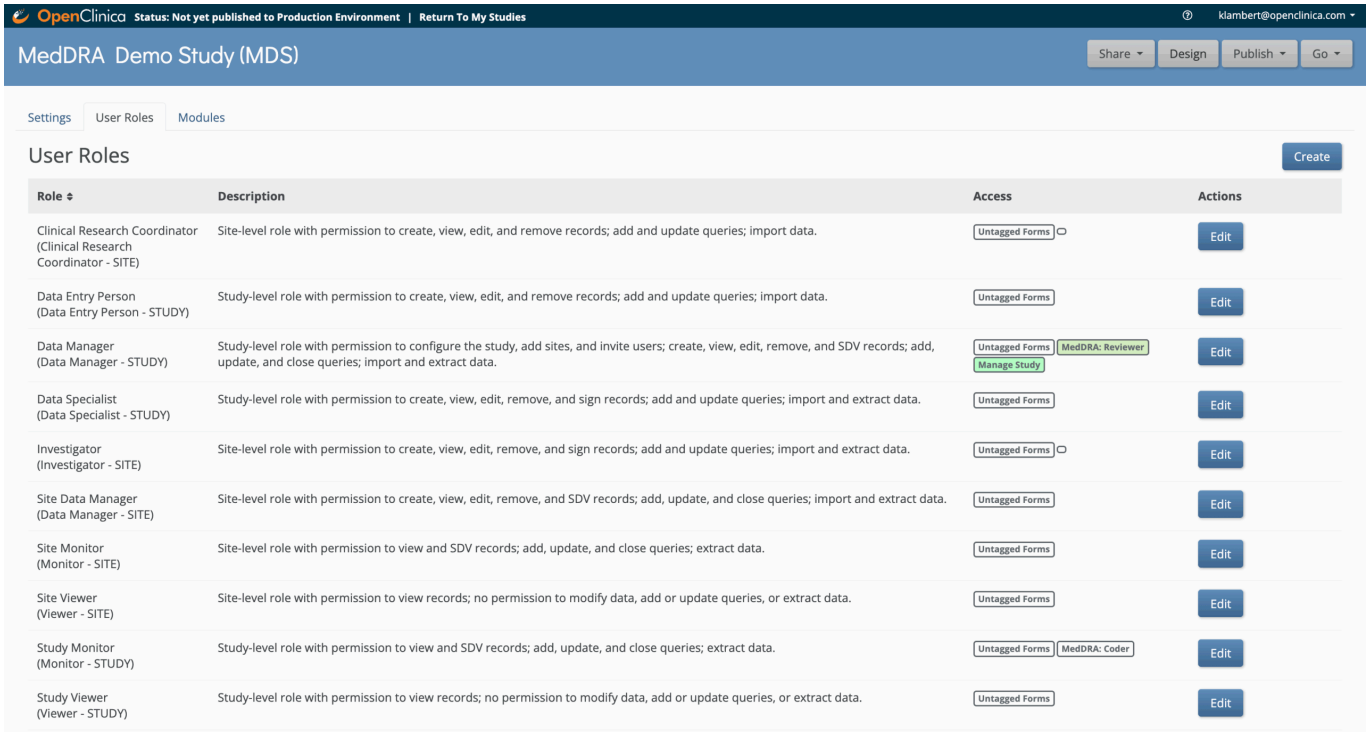
Field	Description
MedDRA ID	A five-digit ID issued by MedDRA to your organization.
MedDRA API Key	Generated from your organization's MedDRA account—distinct from a password. Your organization's MedDRA API Key must be obtained by logging into the MedDRA self-service portal with a MedDRA ID and password,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

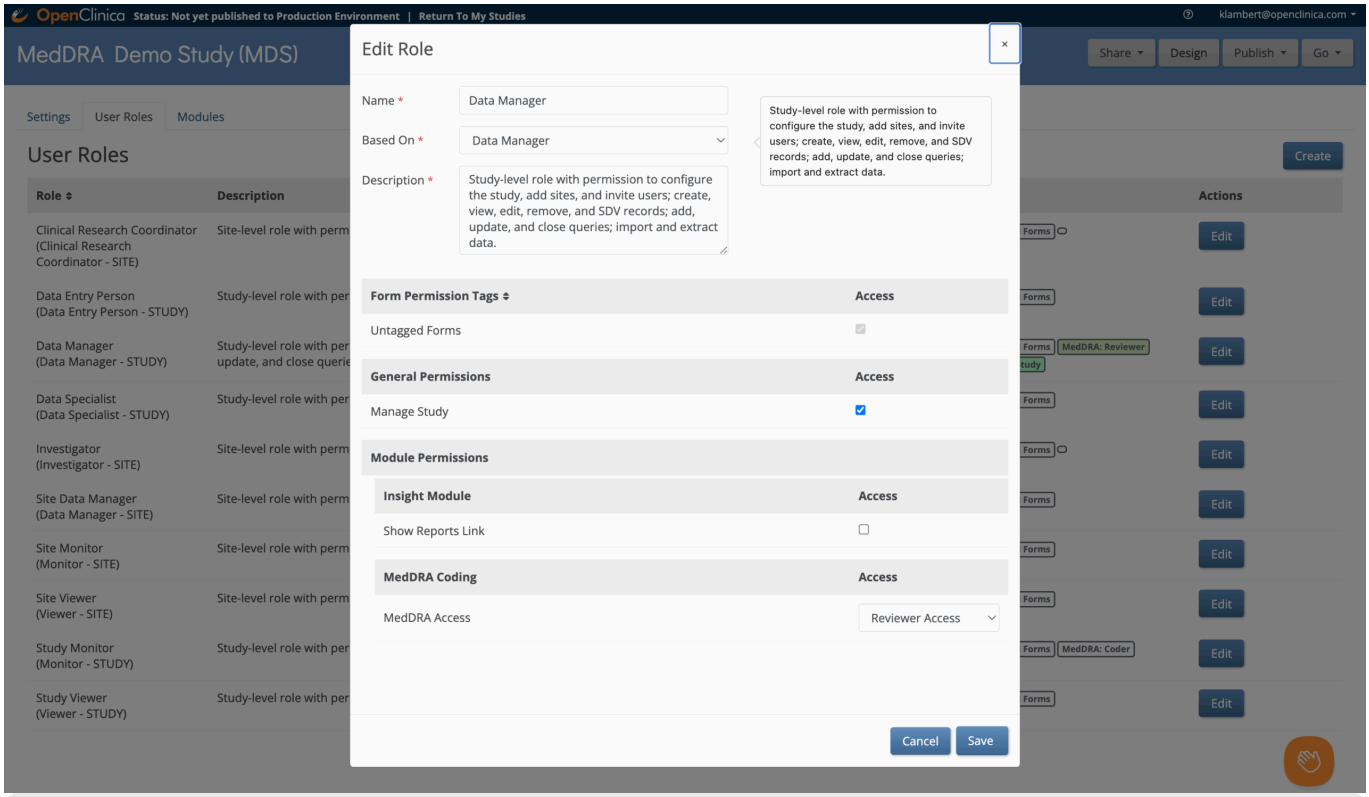


Assigning Permissions Permissions are assigned during role configuration in the study setup:

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.



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Not valid unless obtained from the OpenClinica document management system on the day of use.

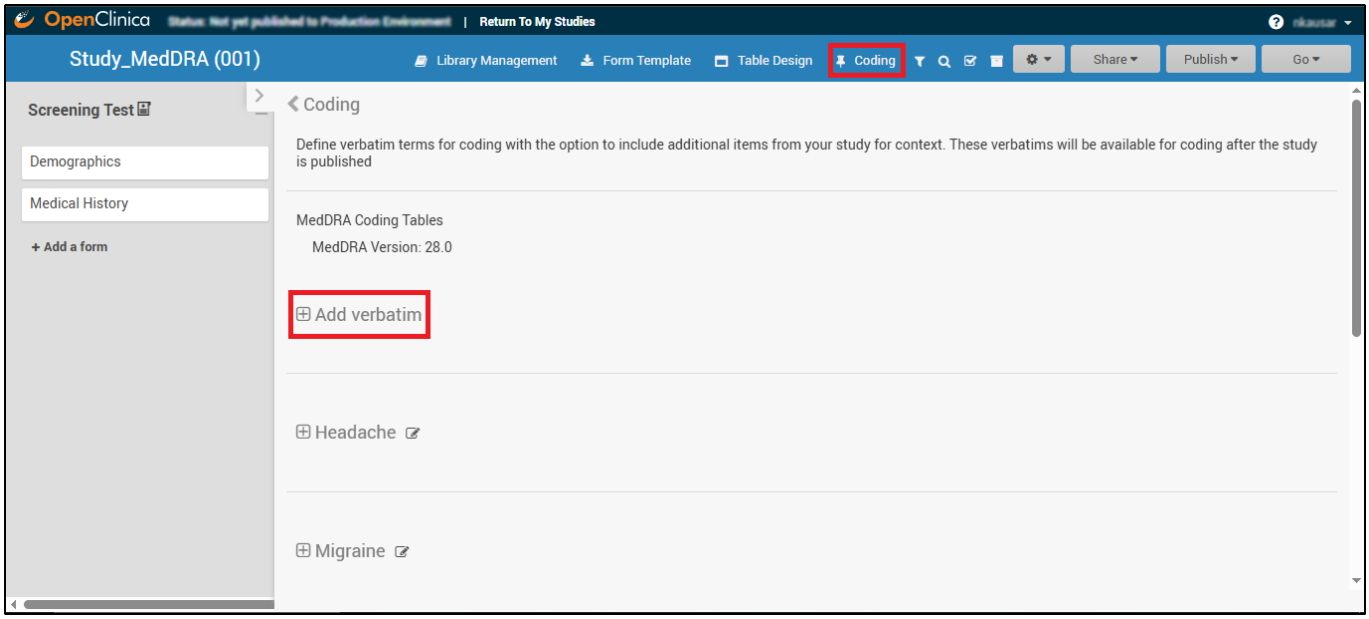
13.2 Code Study Design Configuration

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.

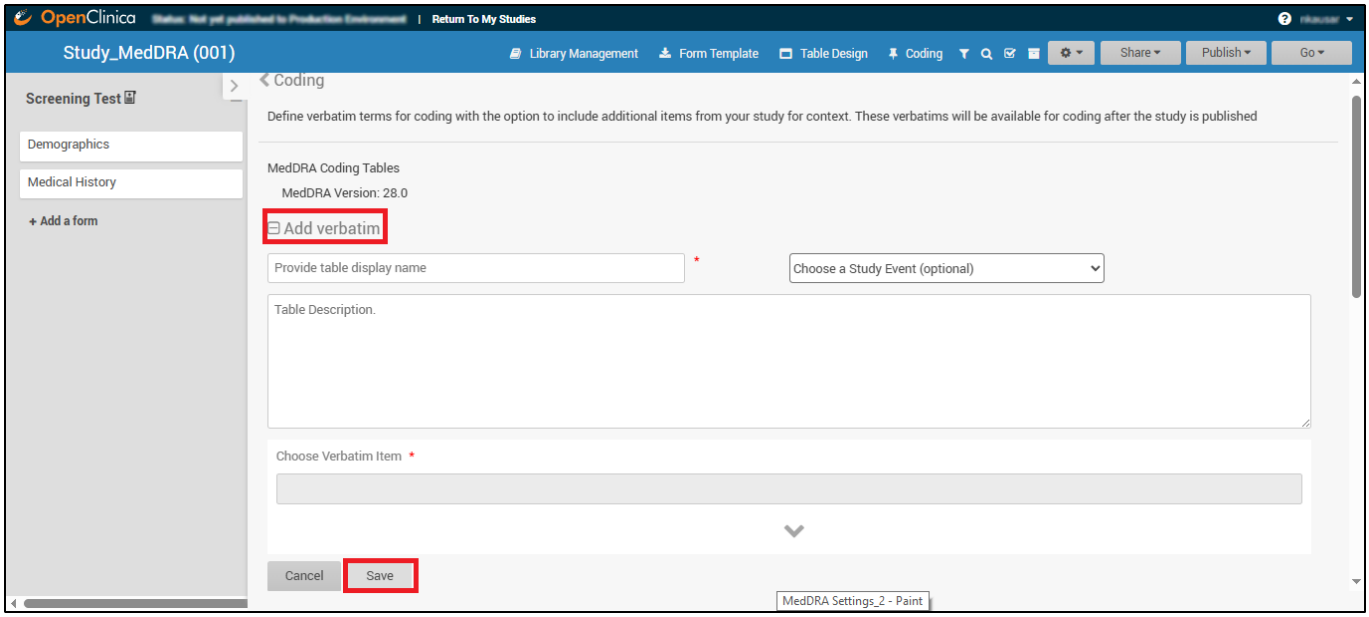
 Note: Table descriptions are only visible in **Study Designer** and do not appear in **Study Runner.**

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.

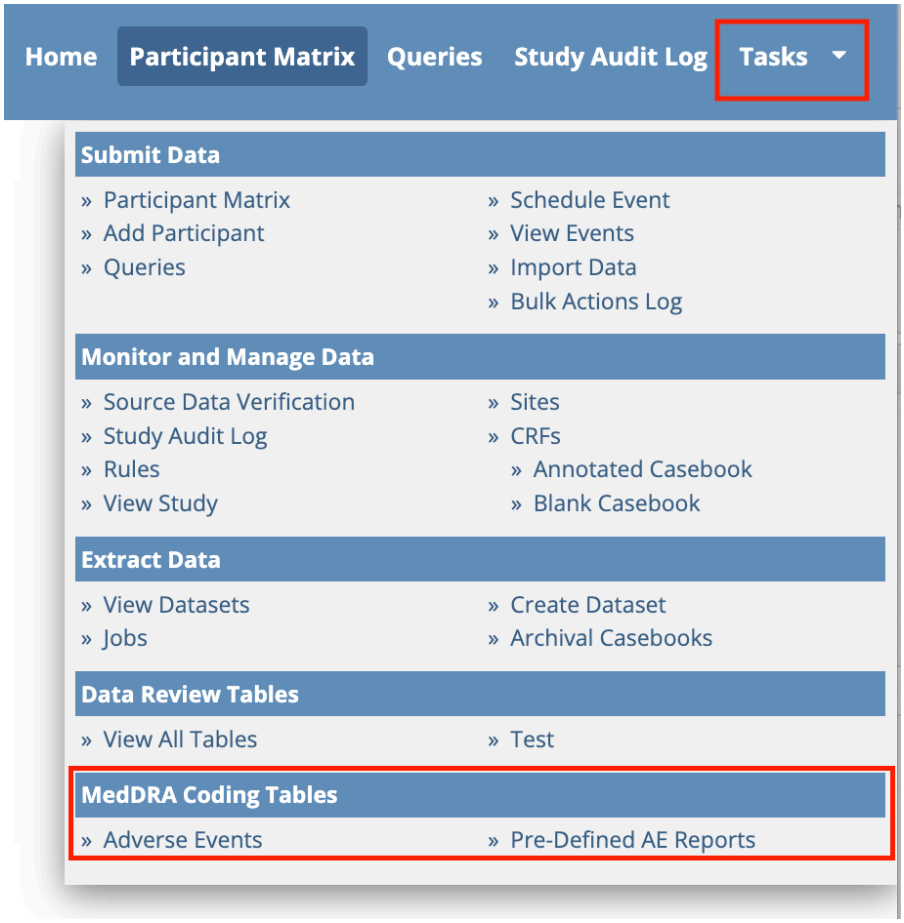
Archiving

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.

13.3 Code in Study Runner

Once coding tables have been configured in **Study Designer** and published, authorized users can begin coding verbatim entries through the **Study Runner** interface. **Note:** Access to coding tables is governed by each user's form access level. Only users with Edit or Review access to a form can view and code verbatims. If a form is restricted by a manual permission tag, only roles explicitly granted that tag can access it in Study Runner. Users with Coder or Reviewer permissions who also have the appropriate form access (Edit or Review) will see a Coding Tables section in the Tasks menu. Forms for which a user has *No Access* or *Read-only* access are not listed. Users with **Coder** or **Reviewer** permissions will see a Coding Tables section in the **Tasks** menu.

- The coding tables listed in this section will match the titles (**Table Display Name**) defined during study design.
- Clicking on a table name opens the live coding interface for that specific verbatim source.



Understanding the Coding Table Layout

The **OpenClinica Code** module screen provides a two-pane interface for reviewing coded results and assigning standardized MedDRA codes.

- The **top section** lists all entered **Verbatims** for review and filtering.
- The **bottom section** allows the user to search MedDRA and apply codes to the selected event.

Top Section – Verbatims

The top section is designed to manage and review all reported records. It allows you to see which events have been entered, check their coding status, and select events for coding. Each row corresponds to one record and includes the following columns:

- **Verbatim:** The free-text term entered by the site user (e.g., "Extreme fatigue"). This acts as a link to open the form in Review mode focused on the item when clicked.
- **Status:** Indicates the current stage of coding:
  - **Verbatim Entered:** A verbatim term has been entered but has not yet undergone any coding attempt. Typically verbatims will be checked by the autocoding feature and transitioned to the appropriate next step (see below) very quickly.
  - **Needs Code:** The system attempted to auto-code the verbatim, but no matching MedDRA term was found. Manual coding is required.
  - **Needs Review – Autocoded:** The system successfully applied an automatic code to the

verbatim during the autocoding process, but the code has not yet been reviewed or confirmed by a user.
    - **Needs Review – Manually Coded:** A user has manually assigned a MedDRA code to the verbatim, but it has not yet been reviewed or approved. Verbatims in this status are excluded from future autocoding attempts.
    - **Approved:** A user with the appropriate coding review privileges has reviewed and confirmed the assigned code—whether applied manually or through autocoding. No further action is required.
- **Code (LLT):** Displays the **Lowest Level Term (LLT)** code once a term is coded. Mouse over this column to see the full MedDRA hierarchy coded.
- **Context Columns:** Configured in Study Designer, provides extra data to the coders about the verbatim being coded.
- **Participant:** Shows the participant ID for traceability. This acts as a link to the Participant Details Page.

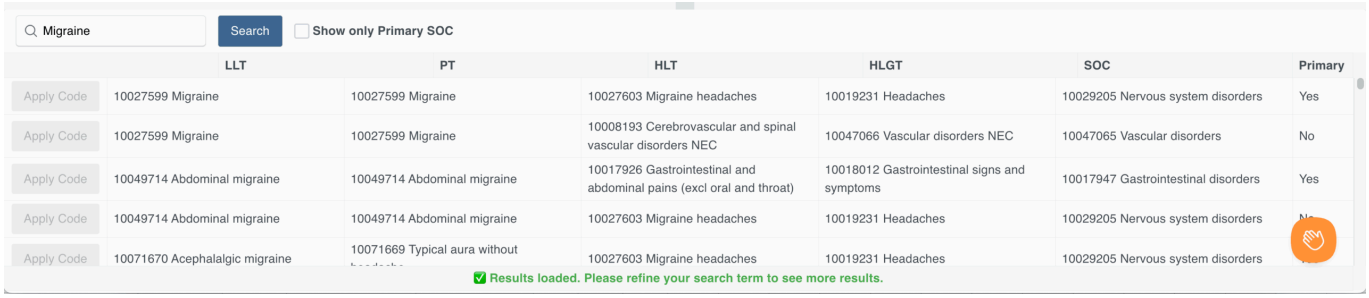
A **checkbox** at the left of each row allows the user to select one or more verbatims for coding or management. A **magnifying glass** next to the checkbox allows the user to search MedDRA for that row's verbatim. A **query** icon appears next to the verbatim name. Click the icon to view queries in the form record. Query actions depend on your form access level: users with *Review* access can add or update queries, while only Monitors and Data Managers can close them. Users with *Read-only* access cannot create or update queries. Above the table are action buttons (e.g., **Approve, Reject, Clear, Add Query**) and a drop-down (e.g., **Active Records**) to manage coding decisions and filter which records are displayed. Each column header includes a **sort arrow** and a **filter icon**. The user can click these to sort entries or filter the list by that column’s values/data.

Bottom Section – MedDRA Term Search and Selection

The bottom section is designed to search for and apply the appropriate code to the selected verbatim(s). By entering a search in the bottom panel, you retrieve all matching MedDRA LLTs and can choose the most precise term. This ensures that the selected verbatim(s) is/are coded using standardized MedDRA terminology. **Key Features**

- **Search Field:** At the top of this section is a text box labeled **Search**. You can type a keyword or phrase into this field and click **Search** (or press **Enter**). The system will then display matching MedDRA terms.
- **Show only Primary SOC:** A checkbox option allows you to restrict results to terms whose **System Organ Class (SOC)** is the term’s primary SOC.
- **Results Table:** Under the search box is a table of MedDRA term options. Each row shows one candidate term with the following columns:
    - **LLT (Lowest Level Term):** The MedDRA **Lowest Level Term** and its code. This is the most specific term that can be applied.
    - **PT (Preferred Term):** The MedDRA **Preferred Term** that the LLT maps to.

    - **HLT (High Level Term), HLGT (High Level Group Term), SOC (System Organ Class):** Higher levels of the MedDRA hierarchy for the selected term. These columns provide context so you can see how the term fits in the overall MedDRA structure.
    - **Primary:** Indicates whether the listed SOC is the term's primary SOC (**Yes** or **No**).
- **Apply Code Button:** On the left of each results row is an **Apply Code** button. Clicking **Apply Code** assigns that LLT to the selected verbatim(s). When a code is applied, the term's code and LLT text will automatically populate the **Code (LLT)** column of the top section for the selected verbatim(s). If a code is applied with multiple verbatims selected, the code will be applied to all of them.



Using the MedDRA Coding Screen

Once data is entered into the Adverse Events form, the MedDRA Coding screen is used to assign standardized MedDRA codes. This process may happen automatically (autocoding) or require manual coding. Both workflows are supported through the two-panel interface described above.

Coding Process Overview

1. **Autocoding:** OpenClinica automatically attempts to code entries when the verbatim term exactly matches a **MedDRA Lowest Level Term (LLT)**. Autocoding is run on every new verbatim value as soon as it is entered into the form.
    - If a match is found, the corresponding LLT is automatically assigned.
    - The Code (LLT) column in the top panel is populated with the term and code.
    - The Status updates to **Needs Review – Autocoded**.
2. **Manual Review / Approval After Autocoding** A **reviewer** must:
    - Confirm the match is accurate by comparing the LLT with the verbatim term.
    - If the code is appropriate, select the checkbox and click **Approve** to confirm the assignment.
    - If the code is not appropriate, proceed with manual coding (see below).
      This review step ensures quality control and allows intervention when the verbatim matches the dictionary term technically but not clinically.
3. **Manual Coding:** When no exact match is found during the autocoding process the user must assign a code manually.
    1. **Locate and select the event**
        - In the top panel, find the row with status **Needs Code** or **Needs Review – Manually Coded / Autocoded**.
        - Click the **magnifying glass** icon to initiate a search for the verbatim term.
    2. **Search for a MedDRA term**
        - In the bottom panel, verify the results obtained or if it shows **No results found**, enter the term from the event description into the **Search for LLT** field.
        - Click Search to display matching LLTs. The results table will list all possible matches.

    - Use the **Show only Primary SOC** option to narrow results if needed. **Notes:**
        i. If no results are returned, try using a more general search term (e.g., "knee" instead of "knee trouble").
        ii. If too many results are returned, refine the search by using a more specific term (e.g., "chest pain" instead of "pain")
3. **Review search results**
    - Carefully evaluate each result's LLT, PT, HLT, HLGT, SOC, and Primary classification.
    - Select the MedDRA term that most accurately reflects the reported event based on your study's coding standards.
4. **Apply the MedDRA code**
    - Select the event row in the top panel if not already selected.
    - The **Apply Code** button for the desired LLT will become active.
    - Click **Apply Code** to assign it to the event.
5. **Finalize or edit**
    - The Status will update to **Needs Review – Manually Coded**.
    - If the code is appropriate, select the checkbox and click **Approve** to confirm the assignment.
    - If incorrect, click **Clear** to remove the code and re-enter the search process.
    - Use **Add Query** to raise a data clarification query if the verbatim is unclear or incomplete.

Access Control Note:

- Users cannot code verbatims from forms they do not have access to.
- If a form is manually tagged with a restricted permission tag, only roles explicitly granted access to that tag can view or code those verbatims.
- Contact data fields within forms are not available for coding and remain masked in all exports and audit logs.

Result Loading Behavior

Search results are loaded dynamically. The first entries appear within a few seconds, but complete results may take 30–45 seconds if many matches exist.

Additional Actions

Use the buttons at the top of the coding interface for the following actions:

Action	Description
Approve	Confirm and finalize a coded term.
Reject	Reject the selected code and return to **Needs Code**.
Clear	Remove the assigned code from the verbatim.
Add Query	Opens a query window to raise a data clarification.

Each action applies to one or more selected rows. Use the checkboxes to select the relevant records.
Access Control Summary: Coding visibility and query permissions follow each user's form access level. Manual tags take precedence over contact tags. Contact data items are not coded and remain masked in all exports and audit logs.

use.