



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. N **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.

The screenshot shows the OpenClinica Study Runner interface. The top navigation bar includes 'Home', 'Participant Matrix', 'Queries', 'Study Audit Log', and 'Tasks'. The 'Tasks' menu is expanded, showing several sections: 'Submit Data', 'Monitor and Manage Data', 'Extract Data', 'Data Review Tables', and 'MedDRA Coding Tables'. The 'MedDRA Coding Tables' section is highlighted with a red box and contains two items: 'Adverse Events' and 'Pre-Defined AE Reports'.

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.

Adverse Events MedDRA version: 28.0 CRF Name: Adverse Event Report

Approve Reject Add Query Active Records

| Verbatim | Status | Code (LLT) | age | serious | Participant |
|---|-------------------------------|------------------------------------|-----|-----------|-------------|
| Migraine | Needs Review - Autocoded | 10027599 Migraine | | | WRH-007 |
| Sore gums | Needs Review - Autocoded | 10041359 Sore gums | 18 | No (no) | WRH-001 |
| Sore gums | Approved | 10041359 Sore gums | 38 | Yes (yes) | WRH-002 |
| Sore gums | Approved | 10041359 Sore gums | | | WRH-006 |
| Floating spots in field of vision | Approved | 10016780 Floaters vitreous | 38 | No (no) | WRH-002 |
| Blindness | Needs Code | | | Yes (yes) | WRH-003 |
| Extra vision | Needs Code | | 90 | Yes (yes) | WRH-004 |
| Three cluster headaches | Needs Code | | | | WRH-006 |
| Cluster headache | Needs Review - Manually Coded | 10086872 Episodic cluster headache | | No (no) | WRH-006 |
| Watery brain | Needs Code | | 18 | Yes (yes) | WRH-001 |
| Patient suffered a broken leg | Needs Code | | 38 | No (no) | WRH-002 |
| Seizure after exposure to bright lights | Needs Code | | 38 | | WRH-002 |

Showing 1 to 20 of 26 entries

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.

Q Migraine Search Show only Primary SOC

| | LLT | PT | HLT | HLGT | SOC | Primary |
|------------|------------------------------|-------------------------------|--|--|-------------------------------------|---------|
| Apply Code | 10027599 Migraine | 10027599 Migraine | 10027603 Migraine headaches | 10019231 Headaches | 10029205 Nervous system disorders | Yes |
| Apply Code | 10027599 Migraine | 10027599 Migraine | 10008193 Cerebrovascular and spinal vascular disorders NEC | 10047066 Vascular disorders NEC | 10047065 Vascular disorders | No |
| Apply Code | 10049714 Abdominal migraine | 10049714 Abdominal migraine | 10017926 Gastrointestinal and abdominal pains (excl oral and throat) | 10018012 Gastrointestinal signs and symptoms | 10017947 Gastrointestinal disorders | Yes |
| Apply Code | 10049714 Abdominal migraine | 10049714 Abdominal migraine | 10027603 Migraine headaches | 10019231 Headaches | 10029205 Nervous system disorders | No |
| Apply Code | 10071670 Acephalgic migraine | 10071669 Typical aura without | 10027603 Migraine headaches | 10019231 Headaches | 10029205 Nervous system disorders | No |

Results loaded. Please refine your search term to see more results.

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.

Approved for publication by Kate Lambert. Signed on 2025-11-18 9:00AM

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