

16.2 OpenClinica Home Page

The OpenClinica home page is the main page for the current Study or Site. It displays after you log in, after you change a Study or Site, or when you click Home in the navigation bar. The home page provides tools and links to features in OpenClinica.

What you see on the home page and the tasks available to you depend on your user Role and Type in OpenClinica. For a list of allowable tasks, see <u>User Roles and User Types</u>.

The home page contains the following areas:

- Top of page
- Navigation bar
- Sidebar
- · Body of page
- · Bottom of page



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

16.2.1 Top of Page

The top of the page is the area above the navigation bar. It contains:

- Name of Current Study: The name of the current Study, and the current Site if one is selected. To view more information about the Study or Site, click the name. For more information, see About Study Details.
- **Change Study/Site:** Allows you to change the current Study or Site. See more details about changing the Study or Site.
- **User Name and Role:** Name of the user who is currently logged in to OpenClinica and the user Role they are assigned to in OpenClinica, such as Data Manger.
- Log Out: Ends your OpenClinica session. See more about logging out.

16.2.2 Navigation Bar

The navigation bar, which is near the top of the page, provides access to the main features in OpenClinica. The features available depend on your user role.

- **Home:** Wherever you are in OpenClinica, click Home to go to the home page for the current Study or Site.
- Subject Matrix: The Subject Matrix is a table with Event information for all Subjects in the current Study or Site. You can view, enter, and change information for Subjects and their Events in the Study. There is one Subject per row, with the Study Subject ID in the first column. The other columns are for each Event Definition in the Study. Each cell contains a colored icon that identifies the status of Event(s) for the Study Subject. Move the cursor over an icon in the matrix to view and access a Subject's data and actions for that Event. Refer to the Icon Key in the sidebar for icon descriptions. See more details about the Subject Matrix.
- Add Subject: Allows you to add a new Subject to the Current Study or Site.
- Notes & Discrepancies: Notes and Discrepancies provide query and discrepancy management capabilities to help you verify the accuracy and completeness of data in a clinical trial. Use this set of tools to flag and track issues that arise when capturing, monitoring, and managing data in a Study (such as incomplete or inaccurate data), and to facilitate communication between users (such as Clinical Research Coordinators and Monitors) to resolve these issues. See more details about Notes and Discrepancies.
- **Study Audit Log:** The Study Audit Log provides a history of actions for subjects in the Study. See more details about the <u>Study Audit Log</u>.
- **Tasks:** Click Tasks for a menu of actions you can perform in OpenClinica. The actions are grouped into modules in the Tasks menu. Modules and items included in the Tasks menu depend on permissions for your user Role.
- **Report Issue:** Click the Report Issue link when you experience what you believe is a problem with OpenClinica. See more details about reporting issues.
- **Support:** Click Support to access support information. See more details about <u>getting support</u>.
- **Search Box and Go Button:** To view a history of Events for a Subject and access other information about the Subject, enter the Study Subject ID in the search box; then click Go or press Enter.

16.2.3 Sidebar

The sidebar is a set of panels along the left edge of the page. To expand a panel (show information in it), click the down arrow in the panel. To collapse a panel (hide information in it), click the minus sign.

• Alerts and Messages: These alerts and messages display when you perform actions in

OpenClinica. For example, after you log in, a message reports the date you last logged in. Look here for confirmation that an action you performed was successful, or to see if there were any errors.

- **Instructions**: The Instructions panel provides brief directions or a summary of what you can do at that point in OpenClinica. For more information, click the Help button (question mark) in the body of the page.
- **Other Information**: This shows the name of the current Study or Site, start and end date of the Study, the name of the Principal Investigator, and the Protocol Verification/IRB Approval Date, if it applies. To see details for the Study or Site, click the name. For more information, see <u>About Study Details</u>.
- **Icon Key**: The panel is available when icons are used in the body of the page, such as for the Subject Matrix. It shows each icon relevant to that page and describes what the icon means.

16.2.3.1 Status Icons

- Not started
- Scheduled
- Data entry started
- Stopped
- Skipped
- Completed
- Signed
- Locked
- Invalid

16.2.3.2 Action Icons

The icons available and exactly what they do when you click them are based on your user Role.

- View: Click to see details for the object the icon is associated with
- Edit: Click to change details for the object.
- Set Role: Click to assign a Role for the user within the Study.
- Remove: Click to remove the object.
- Restore: Click the Restore icon to restore an object that was previously removed. (The icon appears only after object has been removed.)

16.2.3.3 Complete Icon List

- Administrative editing
- Archive
- Calendar
- Completed
- Create new
- Delete
- Discrepancy Note: add
- Discrepancy Note: closed

- 凡 Discrepancy Note: new
- Discrepancy Note: not applicable
- Discrepancy Note: resolution proposed
- Discrepancy Note: updated
- Double data entry
- Download
- Edit
- Enter data
- Export
- Form contains changed/unsaved data
- Form has unchanged data
- Help
- Initial data entry completed
- Invalid
- Locked
- New version
- Not started
- 📳 Print
- Reassign
- Remove
- **Remove role**
- Restore
- Scheduled
- SDV complete
- Set role
- Sign
- Skipped
- Started
- Stopped
- Un-archive
- **View**

16.2.4 Body of Home Page

What you see in the body of the home page is based on your user Role and the action you just performed. See more details about the <u>body of the home page</u>.

16.2.5 Bottom of Page

The bottom of the page contains:

OpenClinica Portal: Click OpenClinica Portal to go to https://community.openclinica.com/.
The portal provides valuable information and links to the developers workspace, getting started with OpenClinica, forums, news and upcoming events, a CRF library, and much more.

- **Help**: Click the Help link at the bottom of the page to open the OpenClinica User Documentation.
- **Contact**: If you want to send feedback or questions to the OpenClinica Business Administrator for your organization, click Contact, then complete and submit the form.
- **Software License:** OpenClinica is distributed under the GNU Lesser General Public License (GNU LGPL). The GNU Lesser General Public License is a free software license, and as such, grants to you the four following freedoms:
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• Version Number: The version number is for the OpenClinica software you are using.