1 Overview of OpenClinica

OpenClinica is the worlds most widely-used, open-source software for clinical research. First released in 2005, OpenClinica is designed to meet the diverse needs of modern research environments. It is built as a lightweight, extensible, and modular application. The software is web based and users can access it with a standard web browser and internet connection. For supported web browsers, see System Requirements.

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1.1 Getting Started with OpenClinica

This section shows you how to log in, reset your password, change your user profile, change your current Study or Site, log out, and report issues.

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1.1.1 Log In to OpenClinica

To access OpenClinica, in your web browser go to the OpenClinica login page. If you need the address for the page, see your Business Administrator.

In additional to login functionality, the OpenClinica login page contains a "News" feed or RSS feed section. This section is configurable. Either the standard OpenClinica news or a custom news feed will display. To configure a custom feed contact OpenClinica support.

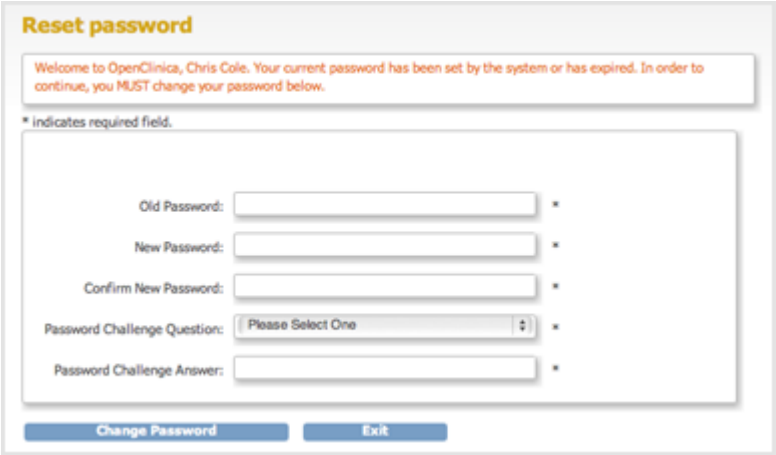
Provide your authorized user name and password, then click Login.

The OpenClinica home page opens.

Reset Password

For security purposes, your system might be configured so that under certain conditions you must reset your password when you try to log in.

When the Reset password page displays, complete the fields in the page. Your password must be at least eight characters long. Then click Change Password.



1.1.2 Get a New Password

If you want to change your password, do that in your User Profile.

If you forgot your password, you can get a new one:

1. Click the Forgot Password link on the Login page.
   The Request Password Form page opens.
2. Complete the fields on the page.
3. Click Submit Password Request.

If you provided the correct information, you will receive an email containing a temporary password, or your Administrator will provide you with a temporary password. Use the temporary password to log in to OpenClinica. You will then be required to reset your temporary password (considered the "old" password) to a new password.

If the information you provided is incorrect, an error message displays. Correct the information and try again or see your Administrator.

1.1.3 Change Current Study or Site

When you use OpenClinica, you work within a specific Study or Study Site (also referred to as a Site and sometimes known as a center in the clinical trial community). In OpenClinica, a Study can have Sites. If a Study has Sites, you can work with the overall Study (working at the Study level), or you can work with just one Site (working at the Site level). Depending on your user Role, you might only have access to your Site and not the Study level; in that event, OpenClinica automatically sets your Site and does not allow you to change it.

The name of the current Study or Site is above the navigation bar and in the Other Info sidebar panel. To view more information about the current Study or Site, click the Study or Site name. The Study Details page opens. For more information, see About Study Details.

If you work with more than one Study or Site, be sure to set the current Study or Site before performing a task.

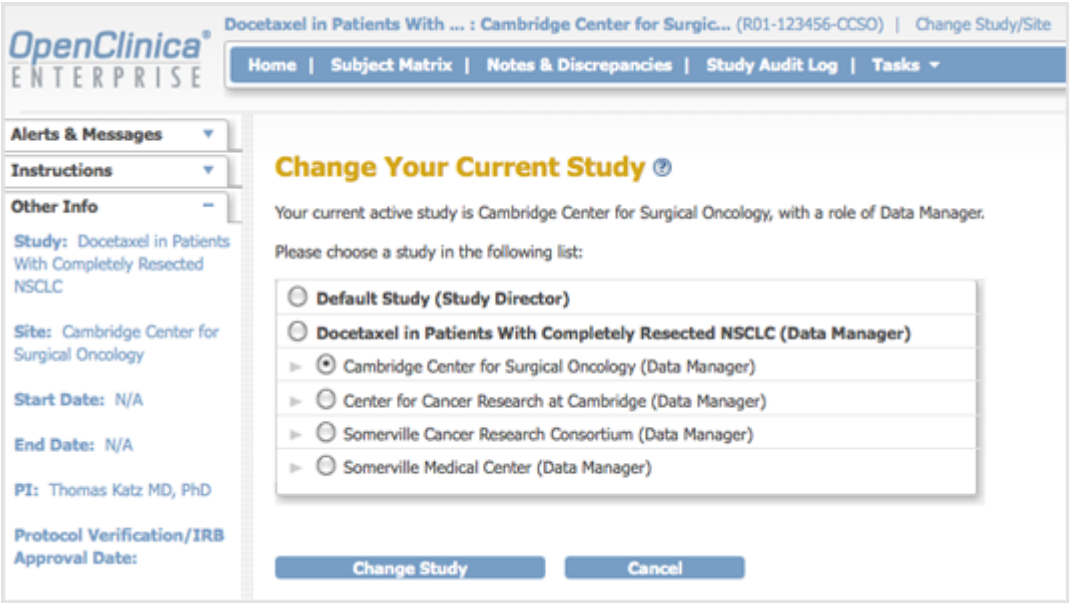
To change the current Study or Site:

1. Click the Change Study/Site link (above the navigation bar).
2. Select the Study or Site you want to work with.
    - Studies are in bold.
    - Sites are listed under a Study and are in a regular font.
3. Click Change Study.
   The Confirm Changing Study page opens.
4. Click Confirm.
5. The new Study or Site name is now in the navigator bar and sidebar.

If you selected a Study that is *frozen* (that is, the Study is no longer accepting data), a pop-up message alerts you. For more information, see Status of Study.

To automatically select a Study as the current Study whenever you log in, specify the Default

Current Study in your User Profile.



1.1.4 Update User Profile

To update your user profile:

1. On the navigation bar, select Tasks > Update Profile.
   The Change User Profile page opens.
2. Update the values you want to change: your name, email address, default active study, password challenge question, password, phone number.
3. Click Confirm Profile Changes.
   The Confirm User Profile Updates page opens.
4. If the information is correct, click Update Profile.
   A message in the Alerts and Messages sidebar notifies you that your profile was updated successfully.

1.1.5 Log Out of OpenClinica

To log out from OpenClinica, click Log Out (above the navigation bar, on the right). To use OpenClinica again, log back in.

For your security, we recommend logging out and completely closing your browser after each session, especially if accessing OpenClinica on a shared computer.

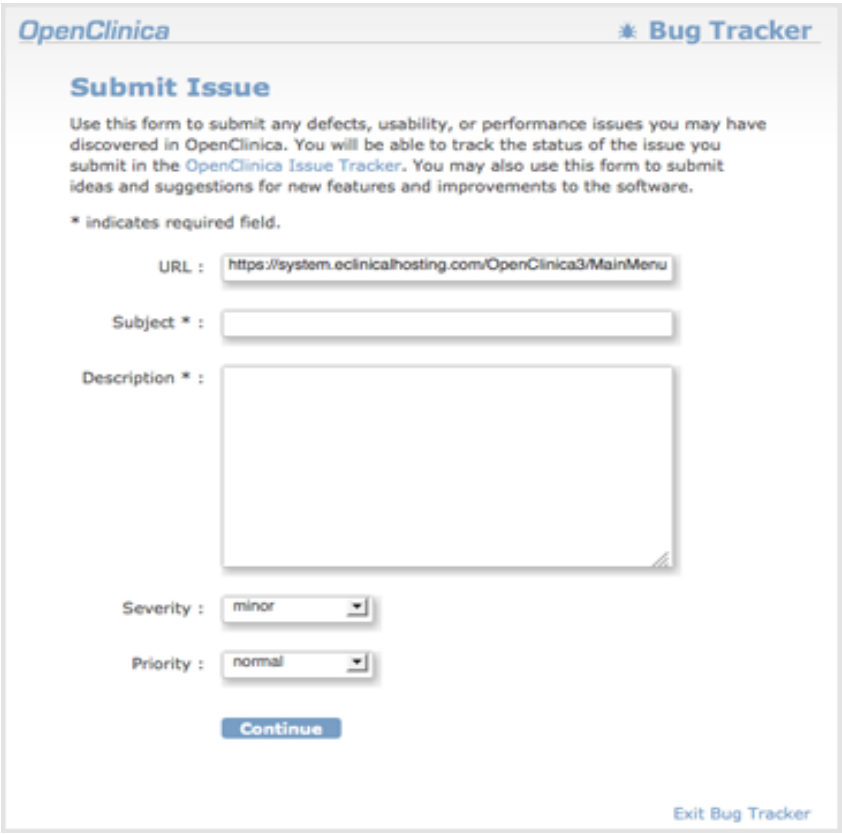
1.1.6 Get Support

Support

For technical information, access to user forums, and issue reporting and tracking, click Support (in the navigation bar). The openclinica.com/support page opens, where you can access the support information.

Report Issue

If you believe you have encountered a problem in the system, report it to OpenClinica. Click Report Issue (in the navigation bar). The Submit Issue page opens. Complete the form, following the instructions on the page. Please be as descriptive and accurate as possible.



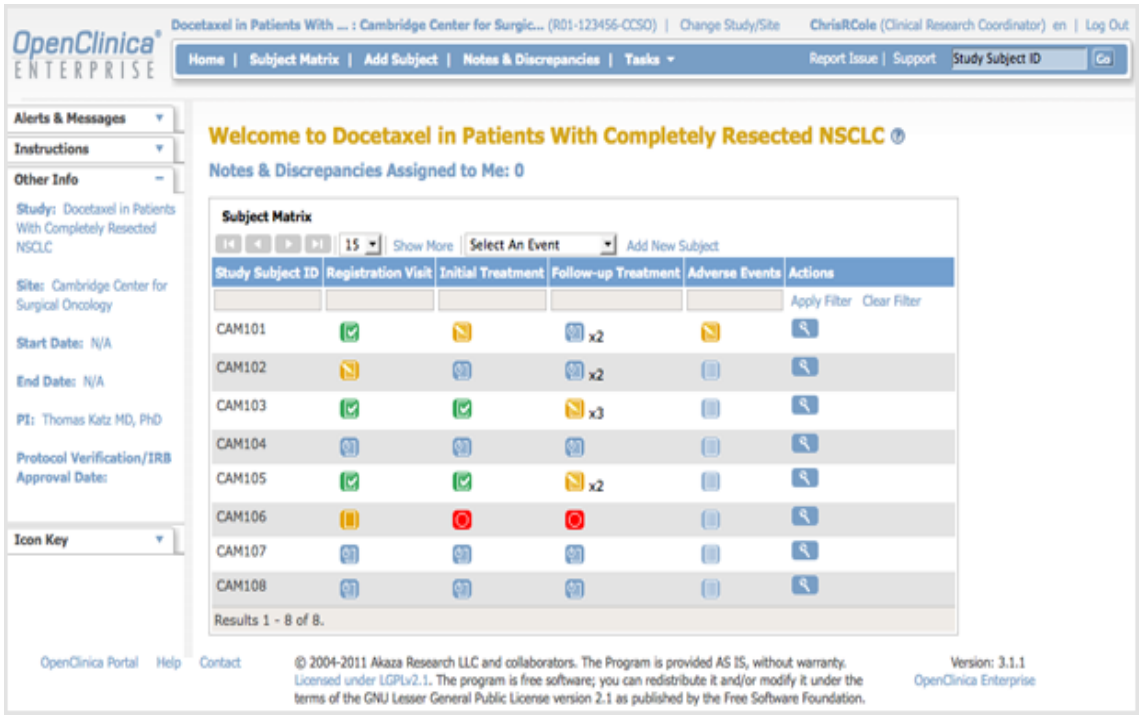
1.2 OpenClinica Home Page

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 User Roles and User Types.

The home page contains the following areas:

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



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1.2.1 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.

1.2.2 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 Study Audit Log.
- **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 getting support.
- **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.

1.2.3 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 About Study Details.

- **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.

1.2.3.1 Status Icons

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

1.2.3.2 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.)

1.2.3.3 Complete Icon List

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

1.2.4 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 body of the home page.

1.2.5 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:

1. The freedom to run the program for any purpose.
2. The freedom to study how the program works and adapt it to your needs.
3. The freedom to redistribute copies so you can help your neighbor.
4. The freedom to improve the program and release your improvements to the public, so that the whole community benefits.

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For details see http://www.gnu.org/licenses/lgpl-2.1.html, or LICENSE.txt provided with the OpenClinica distribution.

- **Version Number:** The version number is for the OpenClinica software you are using.

1.3 Body of OpenClinica Home Page

The body section on the home page always provides a link to the Notes and Discrepancies assigned to you. It also shows one or more tables, which depend on your user Role in OpenClinica. For more information, see User Roles and User Types.

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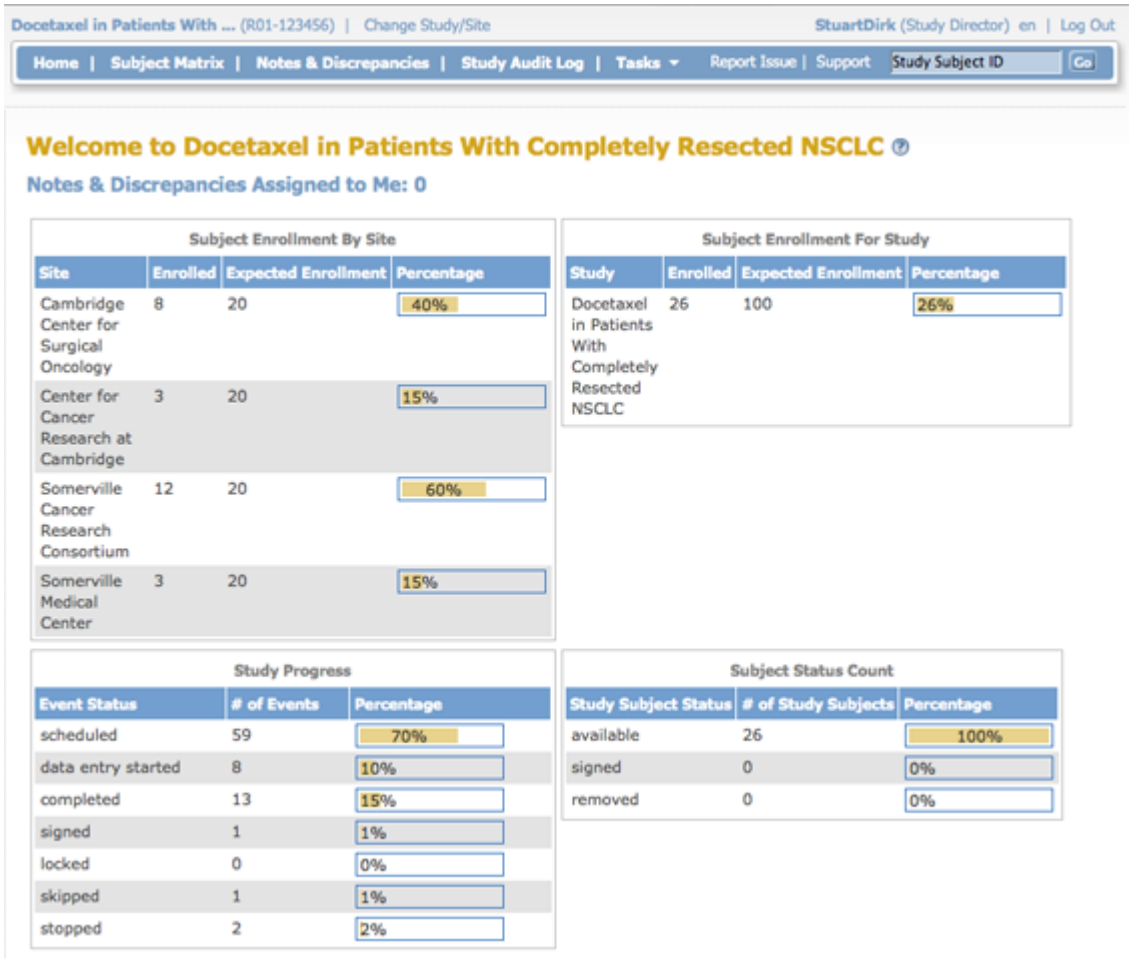
1.3.1 Data Manager and Study Director Home Page

A Data Manager and Study Director see the same information in the home page. It shows summary tables for the current Study or Site: Subject Enrollment By Site, Subject Enrollment For Study, Study Progress, and Subject Status Count.

In the percentage columns, the amount of highlighting represents the percentage number. For example, 0% is not highlighted at all, 50% is half highlighted, and 100% is fully highlighted.

Home Page for Data Manager and Study Director Roles, at the Study Level:



Subject Enrollment by Site

This table is a summary of enrollment at each Site in the Study:

- **Site:** Name of Site.
- **Enrolled:** Number of Subjects who met the criteria for the protocol and have already enrolled at that Site.
- **Expected Enrollment:** Total number of Subjects expected to enroll at that Site, based on preliminary data collected for the Study protocol.
- **Percentage:** The number of Subjects enrolled divided by expected enrollment for that Site.

Subject Enrollment For Study

This table is a summary of enrollment at the Study level (This table is not shown when the Current Study or Site is set to the Site level):

- **Study:** Name of Study.
- **Enrolled:** Number of Subjects who met the criteria for the protocol and have already enrolled in the Study.
- **Expected Enrollment:** Total number of Subjects expected to enroll in the Study, based on preliminary data collected for the Study protocol.
- **Percentage:** The number of Subjects enrolled divided by expected enrollment for the Study.

Study Progress

This table is a summary of Events for the current Study or Site, reporting the progress that has been made within each Event:

- **Event Status:** Values that Event Status can be set to, for all Events in the Study or Site.
- **Number of Events:** The number of Events in the Study or Site having that status.
- **Percentage:** The number of Events having that status divided by the total number of Events in the table.

Subject Status Count

This table is a summary of the status of Subjects in the Study:

- **Study Subject Status:** Values that Subject Status can be set to.
- **Number of Study Subjects:** The number of Study Subjects currently having that status, including any Subjects removed from the Study.
- **Percentage:** The number of Subjects whose Subject Case Books have been signed (after all Events for the Subject were signed) divided by total enrollment for the Study.

Tasks Available to a Data Manager or Study Director

Modules (groups of Tasks) available for the Data Manger and Study Director are:

- Submit Data
- Monitor and Manage Data
- Extract Data
- Study Setup
- Other

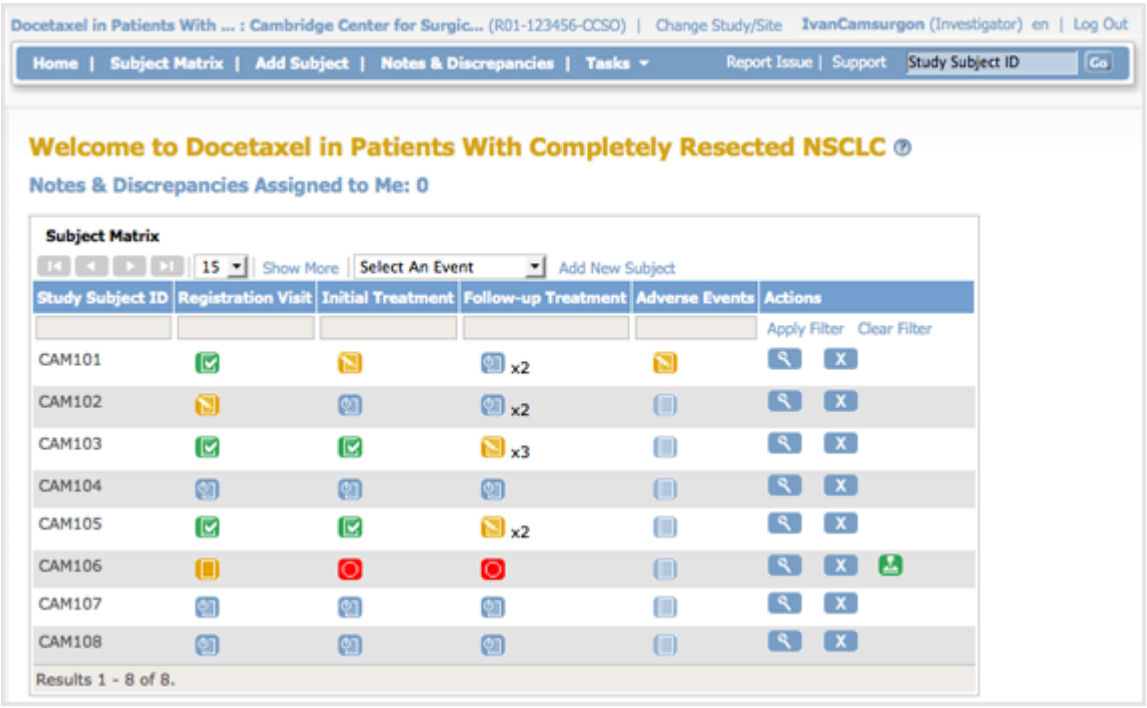
Some of the Tasks a Data Manager or Study Director can perform are:

- Create and Manage CRFs
- Create and Manage Event Definitions

- Create and Manage Rules
- View and Manage Events
- Create and Manage Sites
- Manage Subjects
- Manage Study
- Extract Data

1.3.2 Investigator Home Page

The body of the home page for a user whose role is Investigator for a Site shows the Subject Matrix for the Site.



Tasks Available to an Investigator

Modules (groups of Tasks) available for the Investigator are:

- Submit Data
- Extract Data

Some Tasks an Investigator can perform are:

- View Datasets
- Create Datasets
- Sign Subject Data

1.3.3 Monitor Home Page

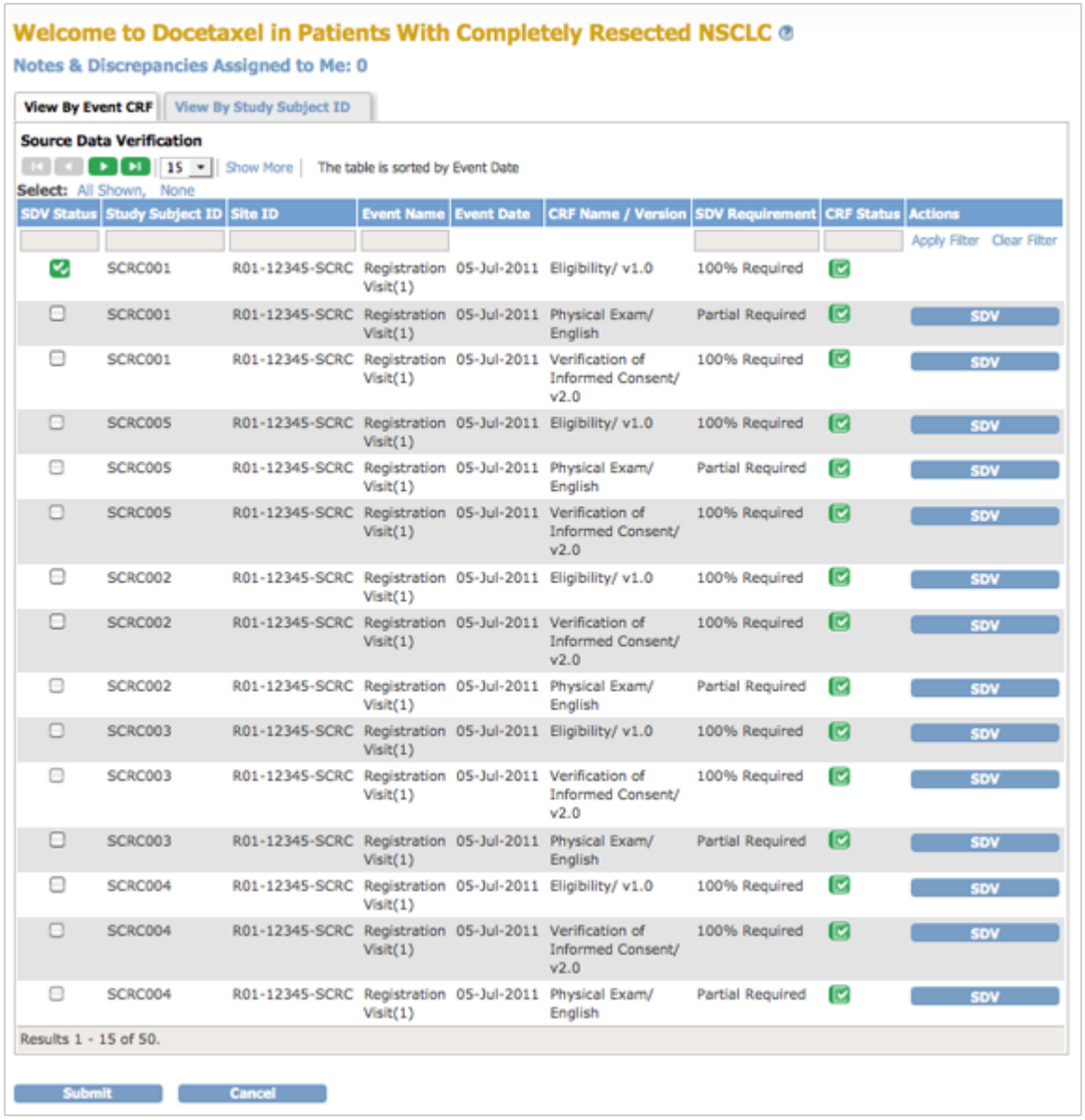
The body of the home page for a user whose Role is Monitor shows the Source Data Verification (SDV) table.

If you are a Monitor for a Site, the SDV table includes only Subjects and data for that Site. If you are a Monitor for a Study, the table includes all Subjects and data for the Study.

The Source Data Verification table provides two views of data, which you access from the tabs at the top of the table:

- **View By Event CRF:** Use this view to evaluate the conformity of the source data in CRFs. The view shows only CRFs that are ready for Source Data Verification, that is, marked complete.
- **View By Study Subject ID:** Use this view for all Subjects, whether or not they are ready for Source Data Verification**.**

For more information, see Source Data Verification.



Tasks Available to a Monitor

Modules (groups of Tasks) available for the Monitor to use are:

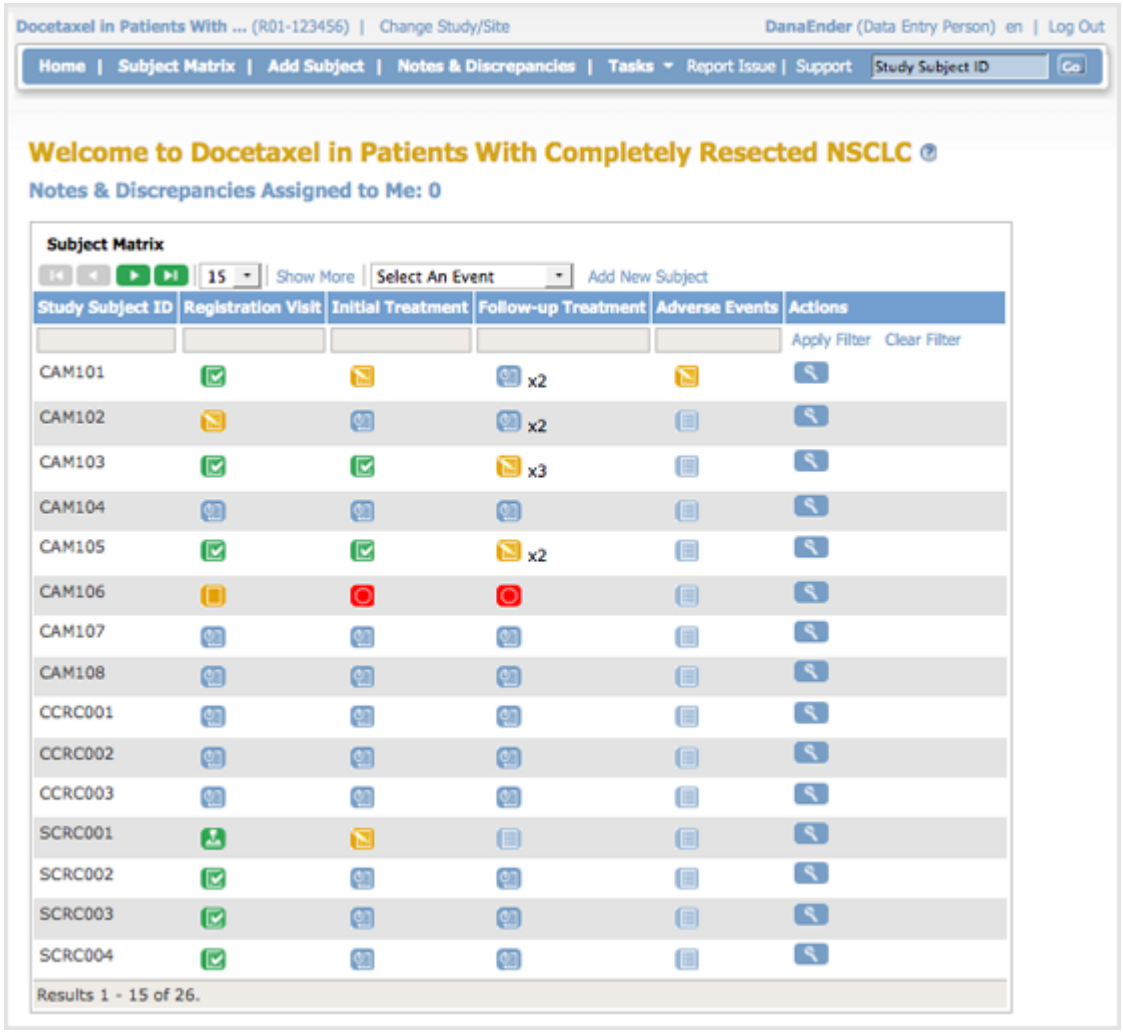
- Monitor and Manage Data
- Extract Data

Some Tasks a Monitor can perform are:

- View All Subjects
- View Events
- Notes & Discrepancies
- Source Data Verification

1.3.4 Data Entry User Home Page

The body of the home page for a user whose Role is Data Entry shows the Subject Matrix. The Subject Matrix is a table with Event information for all Subjects in a Study. 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 in the Study. Each cell contains a colored icon that identifies the status of Event(s) for the Study Subject. See more details about the Subject Matrix.



Tasks Available to a Data Entry User

Modules (groups of Tasks) available for the Data Entry user are:

- Submit Data

Some Tasks a Data Entry user can perform are:

- View All Subjects
- Add Subjects
- Add New Study Events
- View Study Events

1.3.5 Data Specialist Home Page

The body of the home page for a user whose Role is Data Specialist shows the Subject Matrix. The Subject Matrix is a table that has one row of information per Subject in a Study, with the Study Subject ID in the first column. You can view, enter, and change information for Subjects and their Events in the Study. The other columns are for each Event Definition in the Study. In each cell of the matrix, an icon identifies the status of Event(s) for that 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.

Tasks Available to a Data Specialist

Modules (groups of Tasks) available for the Data Specialist to use are:

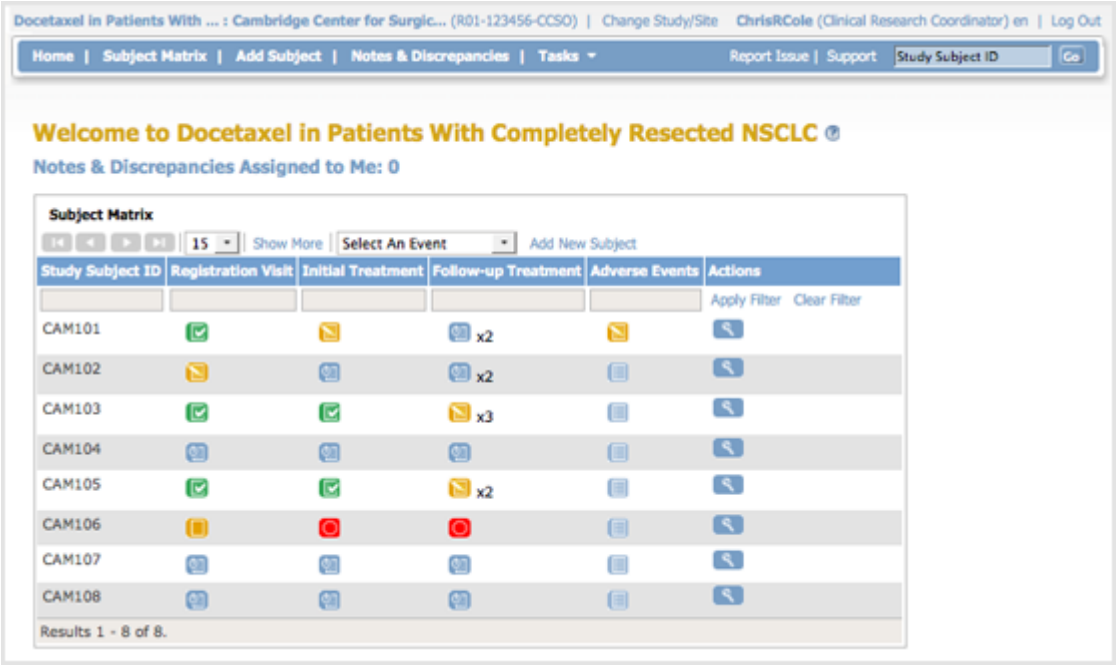
- Submit Data
- Extract Data
- Other

Some Tasks a Data Specialist can perform are:

- View All Subjects
- Add Subjects
- Add New Study Events
- View Study Events
- View Datasets
- Create Datasets

1.3.6 Clinical Research Coordinator Home Page

The body of the home page for a user whose role is Clinical Research Coordinator shows the Subject Matrix for their Site. The Subject Matrix is a table with Event information for all Subjects in a Study. 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 an 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.



Tasks Available to a Clinical Research Coordinator

Modules (groups of Tasks) available for a Clinical Research Coordinator are:

- Submit Data

Some Tasks a Clinical Research Coordinator can perform are:

- View All Subjects
- Add Subjects
- Add New Study Events
- View Study Events
- Enter CRF Data

1.4 Citing OpenClinica

If you use OpenClinica for your research, please reference the platform using the following:

The data collection and management for this paper was performed using the OpenClinica open source software, version 3.1 [or enter appropriate version]. Copyright OpenClinica LLC and collaborators, Waltham, MA, USA, www.OpenClinica.com.

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