

8 Using OpenClinica as an Administrator

Administrators have access to manage settings, users, roles, sites, modules, and publishing for all studies in your OpenClinica domain. Additionally, administrators can assign Study Designer and/or Study Runner access to themselves (as well as other users) for any study in the domain. The **User Type** of **Administrator** should be assigned to a limited number of users in your organization. (More information on User Types and Roles can be found here: **User Access and Sharing**).

Administrators are the Only User Type with Access to:

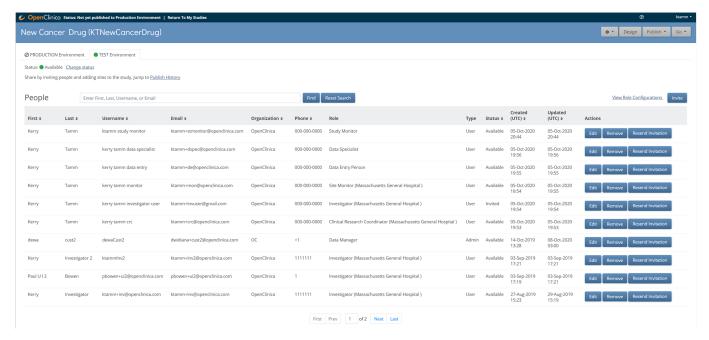
- · Create a study
- Perform central user administration
- Access user roles and audit logs
- Access the web services Swagger interface

Study-Specific User Administration

Users with a **User Role** of **Data Manager** in the Test and/or Production environments can manage user accounts for studies in those environments.

To Manage Users for a Study:

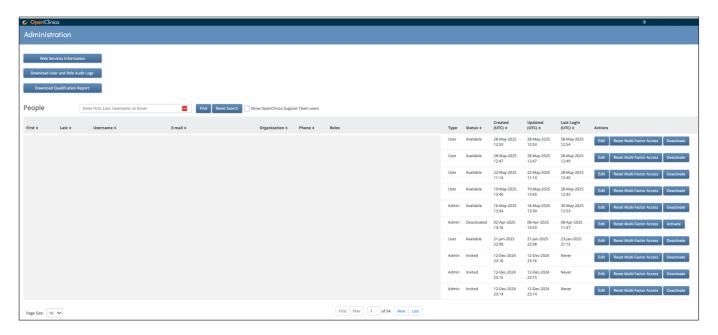
- 1. Go to the My Studies screen.
- 2. Click the **Share** button below the study you want to manage users in. (You can also access the **Share** button from **Study Designer** or the **Settings** screen.)
- 3. On the study-specific **User Administration/Share** screen, click the **Invite**, **Edit**, or **Remove** buttons to perform those actions as needed. Click the **Resend Invitation** button to resend an invitation if the user accidentally deleted the original invitation or it expired.



Central User Administration

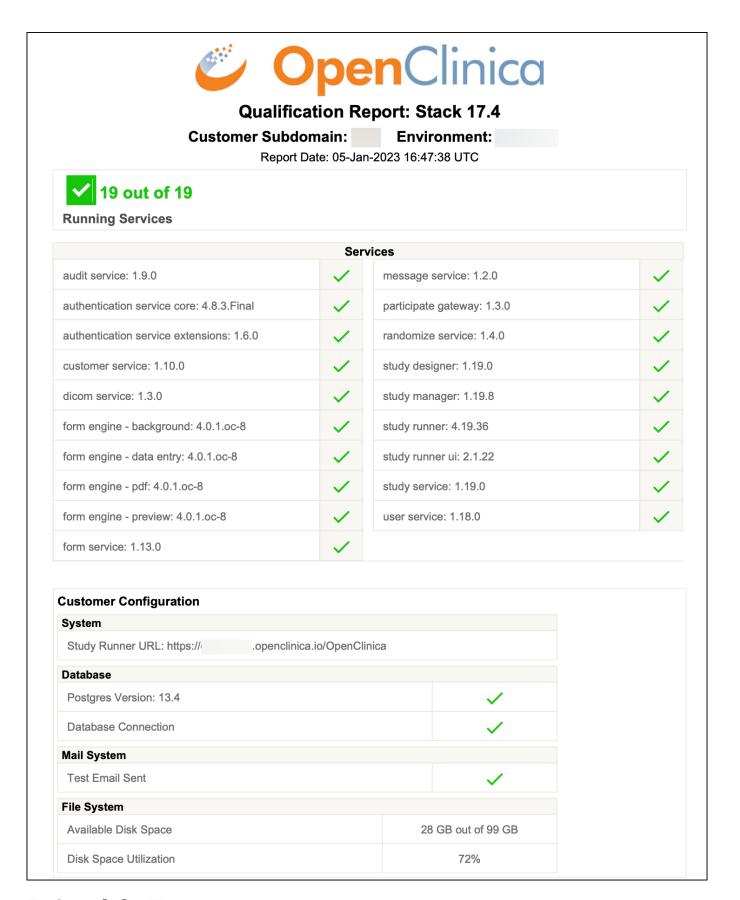
Only **Administrators** can access the **Administration** where user accounts can be edited, deactivated, or re-activated across all environments. Administration is available in the user menu in the upper right-hand corner.

Note: OpenClinica Team users are hidden by default. If you need to view the members of the OpenClinica Team with access to your study, click the **Show OpenClinica Team users** checkbox.



Download Qualification Report:

The Download Qualification Report button will download the most recent qualification report. This is updated for each release and includes the information in the sample report below:



To Search for Users:

- 1. Click the **User** menu in the upper right-hand corner and select **Administration**.
- 2. Enter a first name, last name, username, or email into the search box.
- 3. Click the **Find** button to search.

You can click the **Reset Search** button to clear your search criteria and display all users in the

table.

Note: Search results appear on a single page, with a maximum of ten users displayed. You will be asked to refine your search criteria if the system finds more than ten results or zero results. You cannot sort the table when search criteria has been entered.

To Edit User Accounts:

- 1. From the **User** menu, select **Administration**.
- 2. On the **Administration** screen, click the **Edit** button to the right of the user whose account you want to edit. You can edit everything except for the username.
- 3. Click the **Save** button.

To Deactivate/Activate User Accounts:

- 1. From the **User** menu, select **Administration**.
 - 1. On the **Administration** screen, click the **deactivate** button to the right of the user whose account you want to deactivate. The user can no longer log into **OpenClinica**.
 - 2. To reactivate a deactivated account (across all studies/environments), click the **Activate** button to the right of the user whose account you want to activate.

The Possible Statuses for a User are as Follows:

Status	Description
Created	The user account has been created, but no User Roles have been assigned.
Invited	The user account has been created, and at least one User Role has been assigned, but the user has never accessed/activated the account.
Available	The user account is active and available for use.
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Deactivated The user account has been removed. The user can no longer log into OpenClinica.

Note: User accounts cannot be deleted.

Web Services Swagger Interface

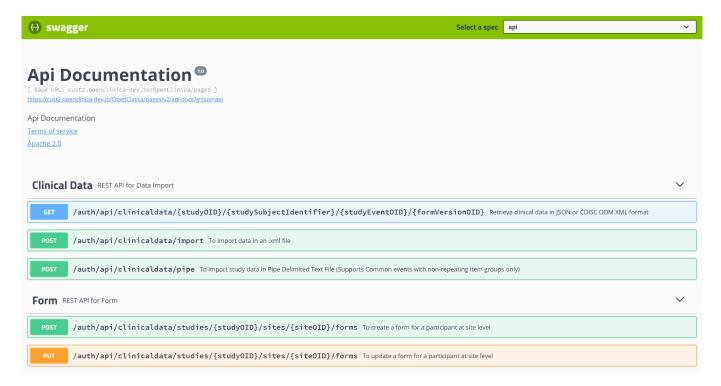
OpenClinica[]s Web Services provides **RESTful APIs** that allow programmersyou to transfer data between systems and perform bulk actions within the system. Web services documentation is included in the **OpenClinica 4 Technical Documentation**, and an interactive version of the documentation for developers (using **Swagger**) is accessible from the **Administration** screen.

You Can Use Web Services to:

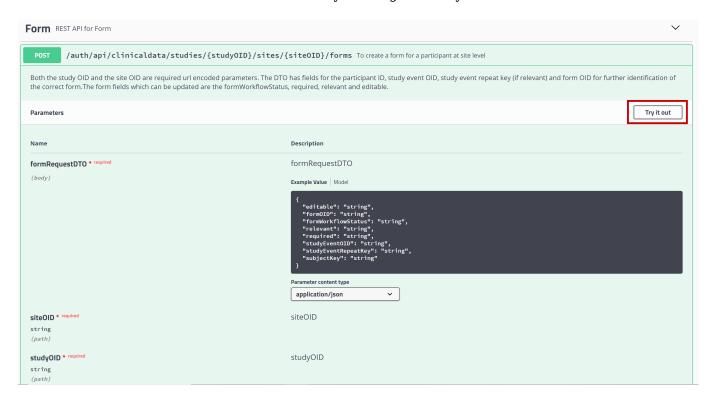
- Retrieve clinical data in JSON or XML or PDF
- Import clinical data in XML
- Get Participant data
- Get a list of Participant IDs
- Add a site or study-level Participant
- Add a set of site or study-level Participants

To Access the Web Services Swagger UI:

- 1. From the **User Menu**, select **Administration**.
- 2. Click **Web Services Information**.



You can access the documentation for an API by clicking the API you want to use.



To call an API, click **Try it Out**, provide the requested information in the displayed fields, and click **Execute**.

CAUTION: Using the **Try it Out** interface will actually execute your API calls in the target study environment (based on the study OID you provide, and only when you have a role assigned in the study). Many of OpenClinica\[\text{s} APIs can add an update data in a study. BE CAREFUL AND BE AWARE OF THE CONSEQUENCES, especially if you provide the OID of a study in Production.

The **Responses** section shows the results of the operation. If there were any errors in the information you provided, a descriptive error message is listed in the results.

User and Role Audit Log

You can download the User and Role Audit Logs from the **Administration** screen. The downloaded XLS spreadsheet displays specific events, when the event occurred, and which user performed/experienced the event.



The User and Role Audit Log Includes the Following Events:

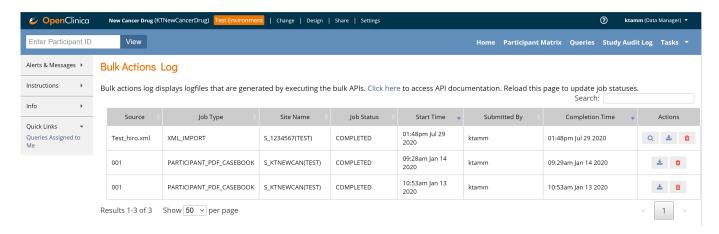
- Successful Logins/Logouts
- Failed Logins
- Password Changes
- User Role Changes
- User Role Definitions (edited User Role fields with old and new values)
- User Profile Changes (edited User Profile fields with old and new values)

To Access the User Role and Audit Log:

- 1. From the **User Menu**, select **Administration**.
- 2. Click **Download User and Role Audit Logs** button.

The Bulk Actions Log

When performing a bulk action, you can access the resulting log in Study Runner.



To Go to the Bulk Actions Log:

Click **Tasks**, and select **Bulk Actions Log**.

You can also view the Bulk Actions Log to check the progress of an action. It also logs information such as Source File Name, Job Type, Site Name, etc. depending on the action it is carrying out. Once an action is complete, you can select **View**, **Download**, or **Delete**.

For more information on Web Services, see the **OpenClinica 4 Technical Documentation**.

Note: APIs may require you to provide Object Identifiers (OIDs) that are specific to your study. OIDs

are are unique identifiers that are automatically generated for objects you create (for example, there is a unique OID for each: Study, Site, Event, Form, Item Group, Item, and Study Participant). For information on locating any of the OIDs for your study, see **Locating Object Identifiers**.

Approved for publication by Kate Lambert. Signed on 2025-06-02 3:06PM

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