7 Using OpenClinica as an Administrator

Administrators manage **settings, users, roles, sites, modules,** and **publishing** for all studies within the OpenClinica domain. They can also assign **Study Designer** and **Study Runner** roles to themselves or other users for any study. **Warning:** Administrator access should be granted to a limited number of users within your organization. For more information on manage settings, users, roles, sites, modules, refer to **Study Settings, User Roles, Modules.**

Administrator Capabilities

Administrators are the only user type with access to the following actions:

- Create a study
- Perform Central User Administration
- Access User and Role Audit Logs
- Access the Web Services (Swagger) Interface

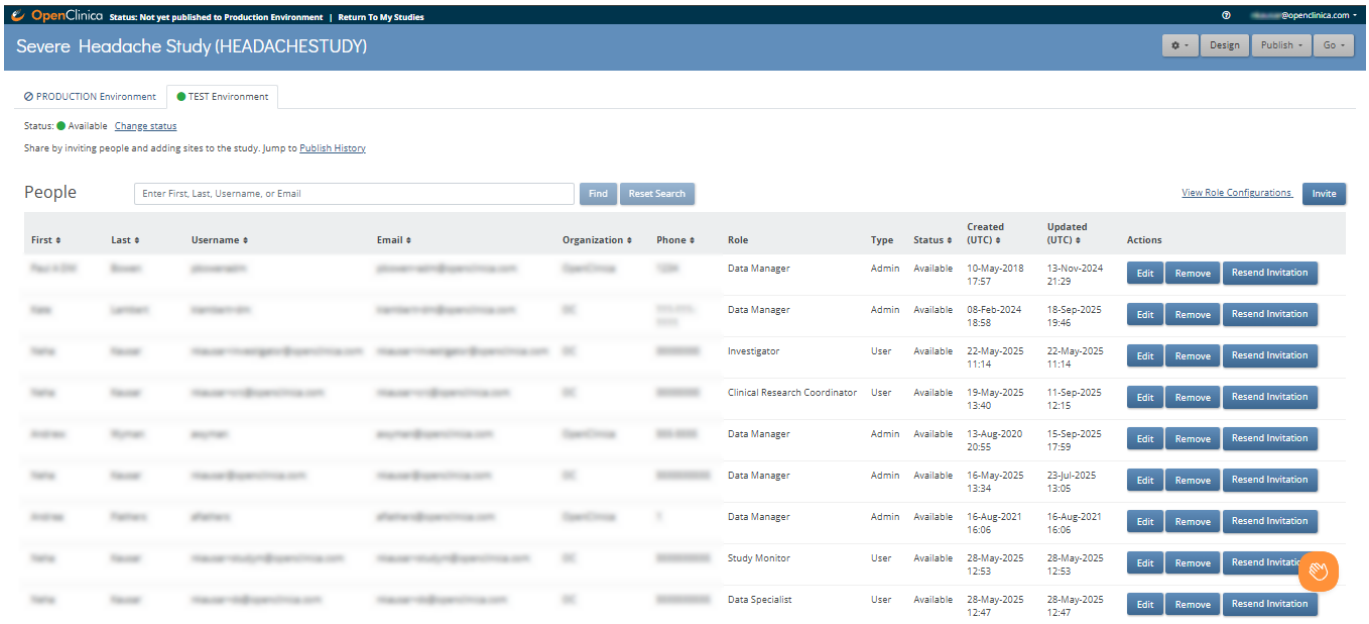
Study-Specific User Administration

Users with the **Data Manager** role in the **Test** or **Production** environments can manage user accounts for studies in those environments.

To Manage Users for a Study

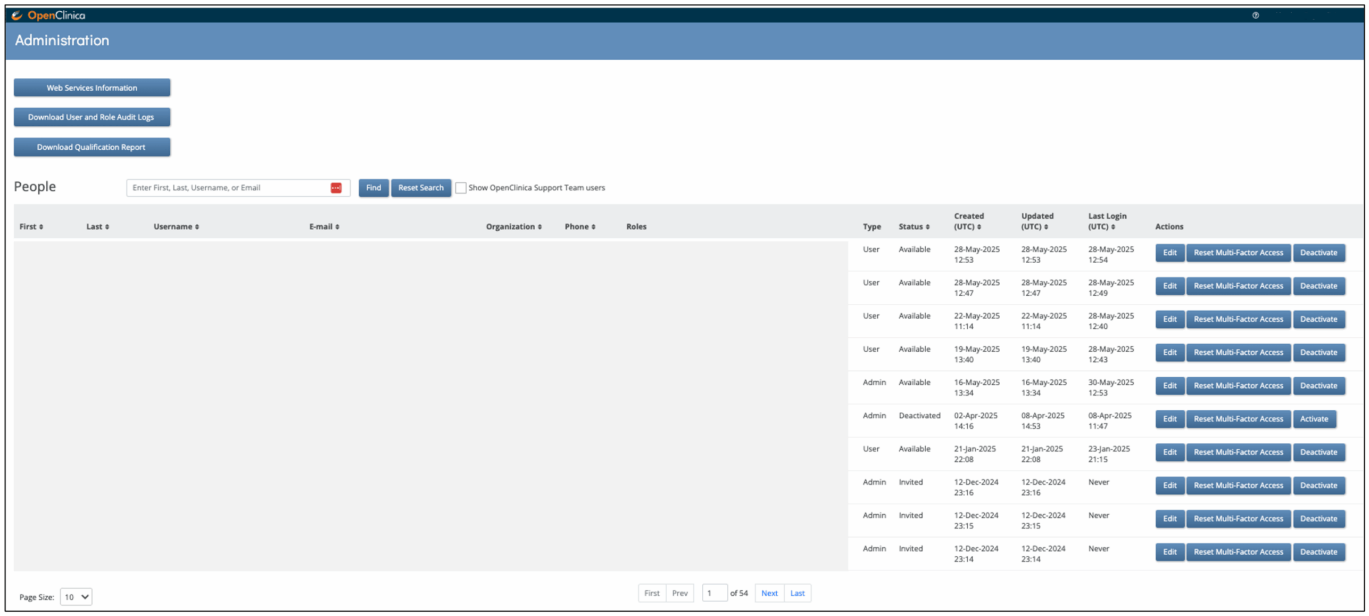
1. Go to the **My Studies** screen.
2. Click the **Share** button below the study you want to manage.
    - You can also access the **Share** button from **Study Designer** or **Settings**.
3. On the **User Administration / Share** screen, click:
    - Invite
    - Edit
    - Remove
    - Resend Invitation

Tip: Use the **Resend Invitation** option if a user accidentally deletes or misses their original invitation email.



Central User Administration

Only Administrators can access the **Administration** screen, available from the **User Menu** (upper-right corner). From this screen, Administrators can edit, deactivate, or reactivate accounts across **all studies and environments**. **Note:** OpenClinica Team users are hidden by default. To view them, select the **Show OpenClinica Team Users** checkbox.



Searching for Users

1. From the **User Menu**, select **Administration**.
2. Enter a **First Name**, **Last Name**, **Username**, or **Email** in the search box.
3. Click **Find**.
4. To clear your search and display all users, click **Reset Search**.

Warning: Search results show a maximum of **10 users per page**. If your search returns too many or too few results, refine your criteria. Sorting is not available when search filters are applied.

Editing User Accounts

1. From the **User Menu**, select **Administration**.
2. On the **Administration** screen, click **Edit** next to the user account you want to update.
3. Update the required fields (you cannot change the username).
4. Click **Save**.

Activating or Deactivating User Accounts

1. From the **User Menu**, select **Administration**.
2. On the **Administration** screen:
    - Click **Deactivate** to disable a user account. The user will no longer be able to log in.
    - Click **Activate** to reactivate a deactivated account across all studies and environments.

Possible User Statuses

Status	Description
Created	The User account has been created but no roles have been assigned.

Invited	The user account has been created, and at least one role assigned, but the user has not yet activated the account.
Available	The user account is active and available for use.
Deactivated	The user account has been removed. The user can no longer log into OpenClinica.

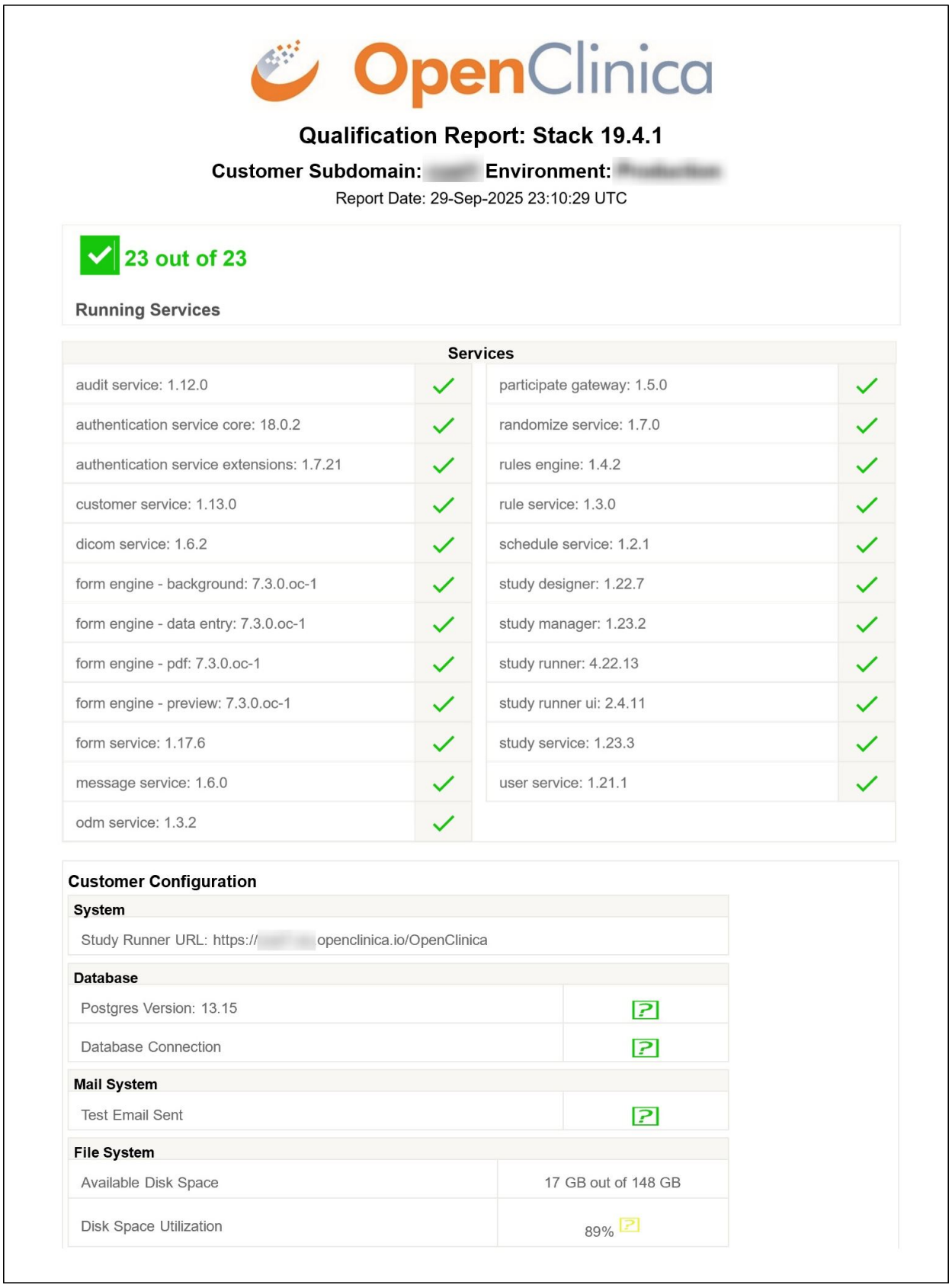
 Note: User accounts **cannot be deleted**.

Downloading the Qualification Report

The **Qualification Report** includes details on the system configuration and is updated for each OpenClinica release. **To Download the Qualification Report**

1. From the **User Menu**, select **Administration**.
2. Click **Download Qualification Report**.

The latest qualification report is downloaded automatically in your browser.



OpenClinica

Qualification Report: Stack 19.4.1

Customer Subdomain: [redacted] **Environment:** [redacted]

Report Date: 29-Sep-2025 23:10:29 UTC

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Running Services

Services			
audit service: 1.12.0	✓	participate gateway: 1.5.0	✓
authentication service core: 18.0.2	✓	randomize service: 1.7.0	✓
authentication service extensions: 1.7.21	✓	rules engine: 1.4.2	✓
customer service: 1.13.0	✓	rule service: 1.3.0	✓
dicom service: 1.6.2	✓	schedule service: 1.2.1	✓
form engine - background: 7.3.0.oc-1	✓	study designer: 1.22.7	✓
form engine - data entry: 7.3.0.oc-1	✓	study manager: 1.23.2	✓
form engine - pdf: 7.3.0.oc-1	✓	study runner: 4.22.13	✓
form engine - preview: 7.3.0.oc-1	✓	study runner ui: 2.4.11	✓
form service: 1.17.6	✓	study service: 1.23.3	✓
message service: 1.6.0	✓	user service: 1.21.1	✓
odm service: 1.3.2	✓		

Customer Configuration

System	
Study Runner URL: https://[redacted]openclinica.io/OpenClinica	
Database	
Postgres Version: 13.15	?
Database Connection	?
Mail System	
Test Email Sent	?
File System	
Available Disk Space	17 GB out of 148 GB
Disk Space Utilization	89% ?

User and Role Audit Log

Study Administrators can download the **User and Role Audit Log** from the **Administration** screen. This log records all user- and role-related actions in the study, including account activity, authentication via Single Sign-On (SSO), event type, timestamp, and the user associated with each change. **To Download the User and Role Audit Log**

1. From the **User Menu**, select **Administration**.
2. Click **Download User and Role Audit Log**.
    - The **User and Role Audit Log** modal opens.
3. In the **modal window**, the **Start Date** and **End Date** fields are required. Both fields display in **DD-MMM-YYYY** format and can be entered manually or selected from the calendar.
    - By default, the Start Date is set to today's date minus 30 days (UTC).
    - The End Date defaults to today's date (UTC).
    - You can adjust these fields to select a custom range of up to **368 days (approximately one year)**.
4. Click **Download** to download the audit log file.

 Notes:

- Dates are based on the UTC time zone, which may differ from your local time. Confirm that your selected dates align with UTC to ensure all expected records are included.
- If an error occurs—for example, if the selected date range exceeds one year—an error message appears directly below the title and subtitle. Adjust the date range as needed and click **Download** again.

The system downloads an **.XLS** file containing detailed records of user and role activity, The downloaded file (.XLS) contains:

- **Event type**
- **Date and time (UTC)**
- **Associated user**
- **User who made the change**
- **Details of the change**

The log file includes all entries from the selected Start Date through the End Date (inclusive) and excludes any entries outside that range.

AUDIT EVENT	DATE/TIME	TARGET OBJECT	BY	VALUE TYPE	OLD VALUE	NEW VALUE
SUCCESSFUL_LOGIN	2020-12-11T16:29:21.502Z	Kerry Tamm (ktamm)	Kerry Tamm (ktamm)			
SUCCESSFUL_LOGIN	2020-12-11T04:53:23.140Z	Paul U SiM Bowen (pbowenusim)	Paul U SiM Bowen (pbowenusim)			
PASSWORD_CHANGED	2020-12-11T04:53:22.994Z	Paul U SiM Bowen (pbowenusim)	Paul U SiM Bowen (pbowenusim)			
SUCCESSFUL_LOGIN	2020-12-11T04:50:03.538Z	Paul U CRC Bowen (pbowenucrc)	Paul U CRC Bowen (pbowenucrc)			
SUCCESSFUL_LOGOUT	2020-12-11T04:49:56.558Z	Paul A DM Bowen (pbowenadm)	Paul A DM Bowen (pbowenadm)			
ROLE_CHANGE	2020-12-11T04:49:38.306448Z	Paul U SiM Bowen (pbowenusim)	Paul A DM Bowen (pbowenadm)	PAB 37 (Test)-Site 1		Site Monitor
ROLE_CHANGE	2020-12-11T04:49:19.747630Z	Paul U CRC Bowen (pbowenucrc)	Paul A DM Bowen (pbowenadm)	PAB 37 (Test)-Site 1		Clinical Research Coordinator

Events Included in the Log

- Successful Logins/Logouts
- Failed Logins
- Password Changes
- User Role Changes
- Role definition edits (old vs. new values)
- User profile edits (old vs. new values)

For information on audit logs related to participant data, refer to **Participant Audit Log**.

Web Services (Swagger Interface)

OpenClinica Web Services provide **RESTful APIs** that enable data exchange and bulk operations between systems.

For background information on RESTful APIs, see RESTful APIs.

The **Swagger UI**, available from the *Administration* menu, allows developers to view API documentation and interact with endpoints directly.

Access the Web Services Swagger UI

1. From the **User Menu**, select **Administration**.
2. Click **Web Services Information**.
3. Click an API name to open its documentation.

Web Services Capabilities

You can use Web Services to:

- Retrieve clinical data in JSON, XML, or PDF formats
- Import clinical data in XML format
- Retrieve participant data and IDs
- Add one or more participants at the study or site level
- Add new sites

Use the Swagger UI

1. Click **Try it out**.
2. Complete the required fields.
3. Click **Execute**.

 Note: Some APIs require **Object Identifiers (OIDs)** specific to your study.
OIDs are unique identifiers automatically generated for each object you create, such as studies, sites, events, forms, item groups, items, and participants. For details on finding OIDs for your study, see **Locating Object Identifiers.**

For more information on Web Services, refer to **OpenClinica 4 Technical Documentation**.

For more information on the Swagger UI, refer to **Swagger.**

For more information on APIs, refer to **How and When to Use APIs.**

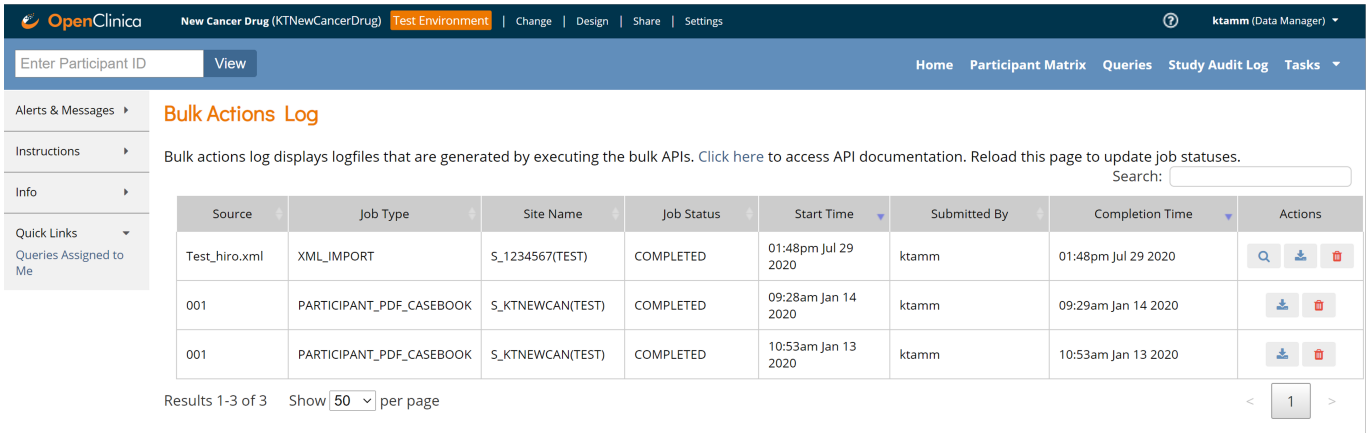
Important

When you use **Try it out**, API calls are executed in the **target environment** based on the study OID you provide and your assigned study role.
APIs can **add or update study data**, so use extreme caution when working in a **Production environment**.

The **Responses** section shows the outcome of the operation.
If any errors occur, a descriptive message appears in the results.

Bulk Actions Log

The **Bulk Actions Log** tracks the progress and outcomes of bulk operations performed in **Study Runner**.



To View the Bulk Actions Log

1. Click **Tasks** in the navigation menu.
2. Select **Bulk Actions Log**.

The log displays:

- Source file name
- Job type
- Site name
- Status and completion time

Once an action is complete, you can **View**, **Download**, or **Delete** the log entry.

Approved for publication by Kate Lambert. Signed on 2025-11-10 10:31AM

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