

5 Users and Roles

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5.1 About User Roles and Types

In the OpenClinica system, each user is assigned a User Type. For each Study or Site a user is assigned to, the user is also assigned a Role that relates to the work they do in the OpenClinica system at that Study or Site. The User Type and Role determine the OpenClinica modules and features the user can access.

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5.1.1 User Types

There are three User Types: "user," "business administrator," and "technical administrator." When a user is created, they are assigned their User Type. The User Type for an existing user can be changed.

Users assigned to the User Type "business administrator" or "technical administrator" can perform these tasks in OpenClinica (the tasks are in the [Administration module](#)):

- Create new Studies
- Work with information across multiple Studies
- Manage user accounts
- Schedule data import and export jobs

When the User Type is "technical administrator," the user can create, modify, and remove a user of any User Type. A "business administrator" User Type cannot create, modify, or remove a "technical administrator" User Type.

When the User Type is "user," the user cannot access the features in the Administration module. They can access features for working on Studies or Sites, such as adding Study Subjects, scheduling Study Events, and completing CRFs.

The User Type applies to all Studies and Sites in the system. A user cannot have different User Types at different Studies and Sites.

See also the full list of the [Permissions for User Roles and Types](#) and [User Matrix](#).

5.1.2 User Roles

User Roles in OpenClinica are based on the roles typically found in clinical trials or and other forms of clinical research. In the OpenClinica system, the User Role determines the features a user can access within a particular Study or Site. The User Role is specified when the user is assigned to the Study or Site, and can be changed after that. A user can have a different Role at each Study and Site they are assigned to.

The Roles available at the Study level are different from the Roles available at the Site level. The features accessible at the Study level are different than the features that can be accessed at the Site level.

- A user whose Role is at the Study level can perform tasks at the Study level, can perform tasks at each Site within that study, and can set the current level to Study or any Site within the Study.
- A user whose Role is at the Site level can only perform tasks at that Site, although a user can be assigned to multiple Sites.

In OpenClinica some Roles have very similar permissions:

Study Level Role	Site Level Role	Notes
Study Director	n/a	Similar to Data Manager
Data Manager	n/a	Similar to Study Director
Monitor	Monitor	Roles are the same
Data Specialist	Investigator	Roles are similar
Data Entry Person	Clinical Research Coordinator	Roles are similar
Data Entry Person	Data Entry Person	Roles are similar

See also the full list of the [Permissions for User Roles and Types](#) and [User Matrix](#).

5.2 Permissions for User Roles and Types

The OpenClinica features you can access depend on your User Type and Role. When your User Type or Role does not have permission for a module or feature, OpenClinica does not present it as an option. If you are trying to use a module or feature in OpenClinica but cannot find it where the User Documentation indicates it should be, it's probably because your User Role or Type does not have permission for it.

To see the modules and main features that a User Role has permissions for, refer to the table in [Summary of Features Available to User Roles](#) or view the [User Matrix](#).

To see which users have permission to use a module, and to see further restrictions of features within a module, see the section for that module on this page.

5.2.1 Summary of Features Available to User Roles

The following tables summarize the modules and features available to each of the User Roles at the Study and Site levels.

Summary of Available Modules and Features for User Roles at the Study Level

User Role	Modules and Main Features
Data Manager	Submit Data: <ul style="list-style-type: none">• Add and Manage Subjects• View, Schedule, and Enter Data into CRFs for Events• No Waiting to Perform Double Data Entry After Initial Data Entry• Import Data• Notes and Discrepancies
	Monitor and Manage Data: <ul style="list-style-type: none">• Study Audit Log and Source Data Verification• Manage Groups• Create, Edit, and Manage CRFs• Rules
	Extract Data Study Setup: <ul style="list-style-type: none">• View and Build Study• Assign Users

[Home page](#) presents summary of current Study or Site.

User Role	Modules and Main Features
Study Director	Submit Data: <ul style="list-style-type: none"> • Add and Manage Subjects • View, Schedule, and Enter Data into CRFs for Events • No Waiting to Perform Double Data Entry After Initial Data Entry • Import Data • Notes and Discrepancies
	Monitor and Manage Data: <ul style="list-style-type: none"> • Study Audit Log and Source Data Verification • Manage Groups • Create, Edit, and Manage CRFs • Rules
	Extract Data Study Setup: <ul style="list-style-type: none"> • View and Build Study • Assign Users
Data Specialist	Home page presents summary of current Study or Site. Submit Data: <ul style="list-style-type: none"> • Add and Manage Subjects • View, Schedule, and Enter Data into CRFs for Events • Import Data • Notes and Discrepancies
	Sign Subject data Extract Data Monitor and Manage Data: <ul style="list-style-type: none"> • View Subjects • View Events • Study Audit Log and Source Data Verification • Notes and Discrepancies
Monitor	Extract Data Submit Data: <ul style="list-style-type: none"> • Add and Manage Subjects • View, Schedule, and Enter Data into CRFs for Events • Import Data • Notes and Discrepancies
Data Entry Person	Extract Data Submit Data: <ul style="list-style-type: none"> • Add and Manage Subjects • View, Schedule, and Enter Data into CRFs for Events • Import Data • Notes and Discrepancies

Summary of Available Modules and Features for User Roles at the Site Level

User Role	Modules and Main Features
Investigator	Submit Data: <ul style="list-style-type: none"> • Add and Manage Subjects • View, Schedule, and Enter Data into CRFs for Events • Import Data • Notes and Discrepancies
	Sign Subject Data Extract Data

Monitor (site)	Monitor and Manage Data: <ul style="list-style-type: none"> • View Subjects • View Events • Study Audit Log and Source Data Verification • Notes and Discrepancies
Clinical Research Coordinator	Extract Data Submit Data: <ul style="list-style-type: none"> • Add and Manage Subjects • View, Schedule, and Enter Data into CRFs for Events • Import Data • Notes and Discrepancies
Data Entry Person (Same as Clinical Research Coordinator; use to differentiate office job titles for similar job function if necessary.)	Submit Data: <ul style="list-style-type: none"> • Add and Manage Subjects • View, Schedule, and Enter Data into CRFs for Events • Import Data • Notes and Discrepancies

5.2.2 Submit Data Module - Permissions

To access the Submit Data module, your User Role cannot be Monitor. Restricted features in the Submit Data Module for other User Roles are listed here.

Subject Features

- To remove a Subject from a Study or Site or to restore a Study Subject, your User Role cannot be Data Entry Person or Clinical Research Coordinator.
- To assign a Subject to another Site within the Study, your User Role must be Data Manager or Study Director.

Signing Events and Subject Casebooks

- To sign a Study Event or a Subject casebook, your User Role must be Investigator or Data Specialist.

CRF Data and Event Features

- To remove and restore Study Event CRFs, remove and restore Study Events, or delete Study Events, your User Role must be Study Director or Data Manager.
- To delete Study Event CRFs, your User Type must be "business administrator" or "technical administrator."
- To set Study Event Status to "locked," your User Role must be Data Manager or Study Director, or your User Type must be "business administrator" or "technical administrator."

Notes and Discrepancies Features

- To set the status of a Discrepancy Note to "closed," your Role must be Data Manager, Study Director, or Monitor.

For information about features in the module, see [Submit Data](#).

5.2.3 Monitor and Manage Data Module - Permissions

To access the monitoring features in the Monitor and Manage Data module, your User Role must be Monitor, Data Manager, or Study Director. For information about features in the module, see [Monitor and Manage Data](#).

The features within the module that you can access depend on your User Role and User Type:

Role	Features	Notes
Monitor	Subject Matrix	Can only view. Cannot make changes to information.
	View Events	Can only view. Cannot make changes to information.
	Source Data Verification	No restrictions.
	Study Audit Log	No restrictions.
	Notes and Discrepancies	Can create only the Query type of Discrepancy Note. Can only update or close an existing Discrepancy Note.
Study Director or Data Manager	Source Data Verification	No restrictions.
	Study Audit Log	No restrictions.
	Rules	Study level only.
	Group	Study level only.
	CRFs	Study level only. User Type must be "business administrator" or "technical administrator" to edit, remove, restore, or delete CRFs.

5.2.4 Extract Data Module - Permissions

To access the Extract Data module, your User Role cannot be Data Entry Person or Clinical Research Coordinator. Other restricted features in the Extract Data are listed here:

- To remove or restore dataset definitions you created, your User Role must be Data Manager.
- To remove or restore dataset definitions you did not create, your User Type must be "business administrator" or "technical administrator."

For information about features in the module, see [Extract Data](#).

5.2.5 Study Setup Module - Permissions

To access the Study Setup module, your User Role must be Data Manager or Study Director.

- Only users whose User Type is "business administrator" or "technical administrator" can edit, remove, restore, or delete CRFs.

For information about features in the module, see [Study Setup](#).

5.2.6 Administration Module - Permissions

To access the Administration module, your User Type must be "business administrator" or "technical administrator." You can access all the features in the Administration module no matter what your user Role is. For more about Administration module permissions, see [User Types](#).

For information about features in the module, see [Administration](#).

5.2.7 Module for Other Features - Permissions

No features in the Other module are restricted based on User Role or Type. All users can change their own profile and log out.

For information about the features in the module, see [Getting Started with OpenClinica](#).

5.3 View, Assign, and Modify Users and Roles

See these sections for details to view, assign, and modify users at the current Study or Site, which you do using the Study Setup module:

- [View Users and Roles at Current Study or Site](#)
- [Assign Users to Current Study or Site](#)
- [Change User Role at Current Study or Site](#)
- [Remove User from Current Study or Site](#)

See these sections for details to create, view, assign, and modify users in the OpenClinica system, across Studies and Sites, which you do using the Administration module:

- [Create a New User](#)
- [View and Modify User Information](#)
- [Remove or Restore User](#)

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5.4 User Matrix

The OpenClinica features you can access depend on your User Type and Role. When your User Type or Role does not have permission for a module or feature, OpenClinica does not present it as an option.

[Click here to view the User Matrix](#) which provides a summary of system access including modules

and features available to each of the User Roles and User Types at the Study and Site level.

See also a written summary of system access in [Permissions User Roles and Types](#).

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5.5 Light Weight Directory Access Protocol(LDAP) Users

Starting from OpenClinica 3.1.4, OpenClinica can be set up to authenticate users against an LDAP/Active Directory server to support single user accounts across the multiple applications and systems used in the organization.

The integration with an Active Directory server supports the following capabilities:

- Querying available Active Directory accounts within OpenClinica
- Assignment of study roles and user privileges within OpenClinica
- Authentication of username and password via Active Directory

Ldap/Active directory authentication can be turned off or on from the datainfo properties. These settings are described as [under](#).

Adding an LDAP user to OpenClinica is described [here](#). These users should already be existing in the active directory.

The SOAP based webservices are not supported for LDAP users.

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5.5.1 LDAP/Active Directory Configuration

In order to have OpenClinica configured to authenticate users using LDAP/Active Directory, these configuration values need to be defined in datainfo properties. As of 3.1.4, these are the new properties that are added to the datainfo properties and need to be set in order to enable LDAP.

Property name	Description
ldap.enabled	Set to true if LDAP/ActiveDirectory should be used to authenticate users in OpenClinica. Values allowed for this field are true and false.
ldap.host	LDAP/ActiveDirectory server host address. Example: ldap://ldapserver:389
ldap.userDn	Distinguished name (DN) of the user account which can authenticate to LDAP/ActiveDirectory, to perform the authentication of OpenClinica users. This user must have privileges to search the LDAP structure. We recommend creating a dedicated LDAP/ActiveDirectory account to be used in this property. Example: CN=openclinica,OU=example,OU=com
ldap.password	Password of the user configured in the property ldap.userDn.
ldap.loginQuery	Query used during login to retrieve an LDAP account by username, where the placeholder {0} is replaced by the username typed in the login screen. This query must never return more than one account. To increase overall application security, this query should never return a user account that has no access to OpenClinica (e.g., by filtering accounts that belong to a specific group). Example: ((&(memberOf=CN=group,OU=example,OU=com)(sAMAccountName=*{0}*))
ldap.passwordRecoveryURL	URL to redirect LDAP/ActiveDirectory users when the forgotten password link is clicked.
ldap.userSearch.baseDn	Base DN to search for user accounts in LDAP/ActiveDirectory. Only user accounts that belong to this base DN can be configured as an OpenClinica user account. Example: OU=example,OU=com
ldap.userSearch.query	LDAP query used to search for users in the LDAP Users Search screen, where the placeholder {0} is replaced by the text entered in the Search field. To increase overall application security, this query should never return a user account that has no access to OpenClinica (e.g., by filtering accounts that belong to a specific group). Example: ((&(memberOf=CN=group,OU=example,OU=com)(sAMAccountName=*{0}*))
ldap.userData.distinguishedName	Name of the LDAP property from which the distinguished name (DN) will be retrieved.
ldap.userData.username	Name of the LDAP property from which the username will be retrieved.
ldap.userData.firstName	Name of the LDAP property from which the first name will be retrieved.
ldap.userData.lastName	Name of the LDAP property from which the last name will be retrieved.
ldap.userData.email	Name of the LDAP property from which the email will be retrieved.
ldap.userData.organization	Name of the LDAP property from which the organization will be retrieved.

5.5.2 Adding a LDAP User to OpenClinica.


The first time you log in to OpenClinica, you must use a local account with Business or Technical Administrator privileges (i.e. root). Once you have created the first LDAP/Active Directory account in OpenClinica with Business or Technical Administrator privileges, you will not need the local account again (unless you are using web services.)

Follow these quick steps to add an LDAP/Active Directory

1. Select Tasks > Users (under the Administration section)
2. Select the Create New User link and you will be presented with the Create a User Account page.

Create a User Account

* indicates required field.

User source:	<input checked="" type="radio"/> LDAP - <input type="radio"/> Local
User Name:	<input type="text"/>  *
First Name:	<input type="text"/> *
Last Name:	<input type="text"/> *
Email:	<input type="text"/> (username@institution) *
Institutional Affiliation:	<input type="text"/> *
Active Study:	<input type="text" value="-Select-"/> ▼ *
Role:	<input type="text" value="-Select-"/> ▼ *
User Type:	<input type="text" value="user"/> ▼

3. When LDAP/Active Directory authentication is enabled, the LDAP radio button will be pre-selected

4. Select the + next to the User Name field and a popup window will appear

LDAP Users

Search:

5. Enter search criteria in the text box to find an account in the LDAP/Active Directory system based on either user name or email address and select Find

Only users that have been assigned to a particular Group in the LDAP/Active Directory system will be searched against. The Group is defined by your Systems Administrator in the Administration > Users > Configure Password Requirements screen.

LDAP Users

Search:

Username	First name	Last name	Email	Actions
ldap1	ldap1			
ldap3	ldap3			
ldap5	User5	Ldap	example@example.com	
ldap6		Ldap	example@example.com	
ldap7	User7		example@example.com	
ldap8	User8	Ldap		
ldap9	User9	Ldap	example@example.com	
ldap10	ldap10			
ldap11	John	Doe		

6. Select the to populate the users information to the Create a User Account page
7. The popup window will close and you will be brought back to the Create a User Account page
 - a. Depending on the amount of information contained in the LDAP system, the following fields will be populated:
 - i. User Name
 - ii. First Name
 - iii. Last Name
 - iv. Email
 - v. Institutional Affiliation
 - b. The following fields will still need to be configured:
 - i. Active Study
 - ii. Role
 - iii. User Type

LDAP Users

Search:

Username	First name	Last name	Email	Actions
ldap1	ldap1			<input data-bbox="810 353 853 392" type="button" value="+"/>
ldap3	ldap3			<input data-bbox="810 398 853 436" type="button" value="+"/>
ldap5	User5	Ldap	example@example.com	<input data-bbox="810 443 853 481" type="button" value="+"/>
ldap6		Ldap	example@example.com	<input data-bbox="810 488 853 526" type="button" value="+"/>
ldap7	User7		example@example.com	<input data-bbox="810 533 853 571" type="button" value="+"/>
ldap8	User8	Ldap		<input data-bbox="810 577 853 616" type="button" value="+"/>
ldap9	User9	Ldap	example@example.com	<input data-bbox="810 622 853 660" type="button" value="+"/>
ldap10	ldap10			<input data-bbox="810 667 853 705" type="button" value="+"/>
ldap11	John	Doe		<input data-bbox="810 712 853 750" type="button" value="+"/>

The user account is now created. This user can log in to OpenClinica and the system will authenticate with the LDAP system. All Study or Site privileges will continue to be managed by OpenClinica. This new user can be assigned to any other Study or Site you determine

8. Select or Enter values for the remaining required fields as indicated by the * symbol to the right of the field. Select the 'Submit' button.