

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.

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:44AM

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

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 <u>Administration module</u>):

- 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 <u>Permissions for User Roles and Types</u> and <u>User Matrix</u>.

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 <u>Permissions for User Roles and Types</u> and <u>User Matrix</u>.