# 7.2 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.

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# 7.2.1 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:<br>• Add and Manage Subjects<br>• View, Schedule, and Enter Data into CRFs for Events<br>• No Waiting to Perform Double Data Entry After Initial Data Entry<br>• Import Data<br>• Notes and Discrepancies<br><br>Monitor and Manage Data:<br>• Study Audit Log and Source Data Verification<br>• Manage Groups<br>• Create, Edit, and Manage CRFs<br>• Rules<br><br>Extract Data<br>Study Setup:<br>• View and Build Study<br>• Assign Users<br><br>Home page presents summary of current Study or Site. |
| **Study Director** | Submit Data:<br>• Add and Manage Subjects<br>• View, Schedule, and Enter Data into CRFs for Events<br>• No Waiting to Perform Double Data Entry After Initial Data Entry<br>• Import Data<br>• Notes and Discrepancies<br><br>Monitor and Manage Data:<br>• Study Audit Log and Source Data Verification<br>• Manage Groups<br>• Create, Edit, and Manage CRFs<br>• Rules<br><br>Extract Data<br>Study Setup:<br>• View and Build Study<br>• Assign Users<br><br>Home page presents summary of current Study or Site. |
| **Data Specialist** | Submit Data:<br>• Add and Manage Subjects<br>• View, Schedule, and Enter Data into CRFs for Events<br>• Import Data<br>• Notes and Discrepancies<br><br>Sign Subject data<br>Extract Data |
| **Monitor** | Monitor and Manage Data:<br>• View Subjects<br>• View Events<br>• Study Audit Log and Source Data Verification<br>• Notes and Discrepancies<br><br>Extract Data |

| User Role | Modules and Main Features |
|---|---|
| **Data Entry Person** | Submit Data:<br>• Add and Manage Subjects<br>• View, Schedule, and Enter Data into CRFs for Events<br>• Import Data<br>• 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:<br>• Add and Manage Subjects<br>• View, Schedule, and Enter Data into CRFs for Events<br>• Import Data<br>• Notes and Discrepancies<br>Sign Subject Data<br>Extract Data |
| **Monitor (site)** | Monitor and Manage Data:<br>• View Subjects<br>• View Events<br>• Study Audit Log and Source Data Verification<br>• Notes and Discrepancies<br><br>Extract Data |
| **Clinical Research Coordinator** | Submit Data:<br>• Add and Manage Subjects<br>• View, Schedule, and Enter Data into CRFs for Events<br>• Import Data<br>• Notes and Discrepancies |
| **Data Entry Person**<br>(Same as Clinical Research Coordinator; use to differentiate office job titles for similar job function if necessary.) | Submit Data:<br>• Add and Manage Subjects<br>• View, Schedule, and Enter Data into CRFs for Events<br>• Import Data<br>• Notes and Discrepancies |

# 7.2.2 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 by Data Manager, Study Director, or Monitor.

For information about features in the module, see Submit Data.

# 7.2.3 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. |

# 7.2.4 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.

# 7.2.5 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.

# 7.2.6 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.

# 7.2.7 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.