

User Roles

Roles are pre-defined user access levels. Customised roles can also be created.

Data monitors are responsible for checking data, and only require the ability to review forms and raise queries, but do not normally need to edit patient data. The data monitor is responsible for locking forms once all queries have been resolved by site coordinators, project managers or investigators.

Data managers are involved in setting up and maintaining the project, and have full access to all study data. The data manager has the ability to program data quality rules, raise queries, generate reports, assign user rights and export data.

Study managers are members of the primary study team and have a senior administrative role. Study managers can assign existing users to data access groups, raise queries, edit reports and records. They have full access to study data but can download only de-identified data.

Investigators have full user rights and can lock records with an electronic signature if required.

In small projects, study management, data management and data monitoring roles may be shared.

Access level	Site RA	Site Coordinator	Study Manager	Investigator	Data Manager	Data Entry	Data Monitor	Statistician
Assign to DAG	Yes	Yes	No	No	Yes	No	No	No
Design and set up	No	No	No	No	yes	No	No	No
User rights	No	No	No	No	Yes	No	No	No
DAG rights	No	No	No	No	Yes	No	No	No
Data export	No	No	Deidentified/ tagged	Identified	Full	No	No	Deidentified/ tagged
Add/Edit Reports	No	No	Yes	Yes	Yes	No	No	Yes
Stats & Charts	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Survey Tools	No	No	Yes	Yes	Yes	No	No	No
Calendar	Yes	Yes	Yes	Yes	Yes	No	No	No
Import tool	No	No	No	Yes	Yes	No	No	No
Logging	Yes	Yes	Yes	Yes	Yes	No	Yes	No
Data comparison	No	No	No	No	Yes	No	Yes	Yes
File repository	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Data Quality	Execute	Execute	Execute	Create, edit, execute	Create, edit, execute	No	Execute	Create, edit, execute
Queries / data resolution	Respond	Open, respond, close	Open, respond, close	Open, respond, close	Open, respond	Open, respond	Open, respond, close	Open, respond
API	No	No	No	No	Export, Import /Update	No	No	No
Mobile App	No	No	No	No	No	No	No	No
Create Records	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Rename Records	No	No	No	No	Yes	No	No	No
Delete Records	No	No	No	No	Yes (but turn off)	No	No	No
Lock/unlock records	No	No or Yes	Yes	Yes	No	No	Yes	No
Lock all records at once	No	No	No	Yes	No	No	Yes	No
Lock records with e-signature	No	No	No	Yes, if required, otherwise just lock/unlock	No	No	No	No
Data entry rights	View & Edit	View & Edit	View & Edit	View & Edit	View & Edit	View & Edit	View	View
Edit surveys	No	Yes	yes	Yes	No	No	No	No