

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 |