# Data Monitoring

## Data Monitoring

To ensure high-quality data, a trial should be monitored. **Data monitors** are responsible for ensuring that eCRFs are accurate and complete, and for query management. This may involve source documentation verification, if data are transcribed from hard copy, checking for missing data, screening for errors and outliers, and execution of data quality rules. Data monitors usually can read eCRFs but not edit their content.

The following REDCap data workflow is suggested:

- Data entry at source by local research staff or at the coordinating centre
- When the instrument is empty the status is set to "incomplete" (red), i.e., instrument or assessment is incomplete and data cannot be obtained
- When data entry is incomplete and the instrument is still being worked on, the status is set to "unverified" (yellow)
- When the form is ready for data monitoring (no more data will be available), the status is set to "complete" (green)
- Data monitor reviews complete/green instruments and raises queries, which are directed to the study or site coordinators (send an email or use REDCap messenger to notify study personnel that queries have been raised)
- The study or site coordinator responds to the queries
- Data monitor accepts and closes the queries
- Data monitor locks the instrument
- Forms that are missing (no data expected) are left incomplete (red) and locked
- If required, the PI performs a final check of locked instruments and applies an e-signature (this will be cleared if the instrument is subsequently unlocked)

Data entry staff and coordinators can add comments to data fields to assist the data monitor, e.g., to explain missing values, or the reassure the monitor that outliers are true values.

In small studies, data monitoring and coordination roles may be shared, but it is still important that data are checked after entry.

## Instrument Locking

Record locking can be used by the data monitor to track which forms have been monitored. Records that are locked cannot be edited without first being unlocked. If a study is using electronic signatures then unlocking a form also clears the signature associated with the form.

Although not strictly part of the monitoring process eSignatures can be used to signal the investigator's review and approval of the study data. Unlocking a form to make changes will clear any signature associated with that form. eSignatures are not necessarily required to demonstrate accountability (as required by GCP).

An overview can be obtained from the dashboard by selecting status type, as appropriate.



### ▦ Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

**Legend for status icons:**
- 🔴 Incomplete    ⚪ Incomplete (no data saved)  ?
- 🟡 Unverified    🟠 Partial Survey Response
- 🟢 Complete      ✅ Completed Survey Response

Displaying record  "1001" through "1058" ⌄  of **16** records

Displaying:  Instrument status only | Lock status only | All status types

| Study ID | Demography | tracking | Vision Motor | Asttle | Cantab | HAF | SDQpa | BRIEFpa | CHQ2 | AQ | Teacher | SDQte | BRIEFte | MRI screening |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1001 | 🟢 | 🟢 | 🔴 | ⚪ | 🔴 | ✅ | ✅ | ✅ | ✅🔒 | ✅ | 🔴 | ⚪ | ⚪ | ⚪ |
| 1002 | 🔴 | ⚪ | ⚪ | ⚪ | ⚪ | ✅ | 🔴 | 🔴 | 🔴 | ✅ | ⚪ | ⚪ | ⚪ | ⚪ |
| 1003 | 🟢 | 🔴 | 🔴 | ⚪ | 🔴 | 🔴 | ⚪ | ⚪ | ⚪ | ⚪ | 🟢🔓 | 🟢 | 🟢 | ⚪ |
| 1005 | 🔴 | ⚪ | ⚪ | ⚪ | ⚪ | ✅ | 🔴 | 🔴 | 🔴 | ✅ | ⚪ | ⚪ | ⚪ | ⚪ |

Form status is also displayed at the end of each record.



|  |  | Expand |
|---|---|---|
| **Form Status** | | |
| **Complete?** | | Complete ⌄ |
| **Lock this record for this form?** If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it. | | ☐ 🔒 Lock |
| | | **Save Record** |
| | | Save and Continue |
| | | Save and Go To Next Form |

## Data Quality Rules

REDCap's data quality module allows the study team to implement data quality rules (edit checks). Typically these rules would be developed and used by data management staff. However they could also be developed for use by study monitors (traditionally monitoring and data management roles have some similarity/overlap). Data quality is accessed from the right hand panel in REDCap.



## Data Queries

These are raised by clicking on the speech bubble next to the data field. It is important to assign the query to an right person so that it appears in their data quality work flow. Once queries have been raised, send study personnel an email or use REDCap messenger (which can be programmed to send an automated email) to notify them that queries have been raised.