

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
- Unverified
- Complete
- Incomplete (no data saved) ?
- Partial Survey Response
- Completed Survey Response

Displaying record through 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?

Lock this record for this form? **Lock**
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

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.

REDCap
Record Status Dashboard
Add / Edit Records

Data Collection Instruments:

- Demography tracking
- Vision Motor
- Asttle
- Cantab
- HAF
- SDQpa
- BRIEFpa
- CHQ2
- AQ
- Teacher
- SDQte
- BRIEFte
- MRI screening

Applications

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- User Rights and DAGs
- E-signature and Locking Mgmt
- Data Quality and Resolve Issues
- REDCap Mobile App

link next to each: [Read more detailed instructions.](#)

Data Quality Rules

Execute rules: All All except A&B All custom Clear

Apply to: -- All records --

Rule #	Rule Name	Rule Logic (Show discrepancy only if...)	Real-time execution ?	Total Discrepancies	Delete rule?
A	Missing values*	-		Execute	
B	Missing values* (required fields only)	-		Execute	
C	Field validation errors (incorrect data type)	-		Execute	
D	Field validation errors (out of range)	-		Execute	
E	Outliers for numerical fields (numbers, integers, sliders, calc fields)	-		Execute	
F	Hidden fields that contain values**	-		Execute	
G	Multiple choice fields with invalid values	-		Execute	
H	Incorrect values for calculated fields	-		Execute	

Add

Enter descriptive name for new rule
(e.g., Participants below age 18)

Enter logic for new rule
(e.g., [age] < 18)
[How do I use special functions?](#)

Execute in real time on data entry forms ?

* The Missing Values rules above automatically exclude fields hidden by branching logic when searching for missing values. If a field is hidden by branching logic on a data entry form or survey, then it is expected that such a field would not have a value. Thus for these cases, the values for those hidden fields will not be classified as missing. Additionally, checkbox fields are also excluded since an unchecked checkbox is itself often considered to be a real value.

** The term "hidden fields" refers to any fields on a survey or data entry form that are not being displayed because branching logic is hiding them, which assumes that the field's value should be blank/null.

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.

Demography

Editing existing Study ID 1001

Study ID

Study ID

Child Details

Child first name

Child last name

DOB

EDD

Child's sex

NHI checked and child alive

Date NHI checked

Current corrected age (years)

Data Resolution Workflow

[VIDEO: Data Resolution Workflow](#)

This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.

Study ID: 1001
Field: sex ("Child's sex")
Status: Not Opened

Date/Time	User	Comments and Details
13/06/2017 5:59am	cdor005	<input type="radio"/> Verified data value — OR — <input checked="" type="radio"/> Open query Assign query to a user (optional): <input type="text" value="cdor005 (Chris McKinlay)"/> Comment: <input type="text"/>

Open query Cancel