TRAINING MANUAL: REDCAP

GETTING STARTED WITH REDCAP

Training Prerequisites:

- Brain-CODE Portal Overview Training Module
- Brain-CODE Subject Naming Convention Training Module

What is REDCap?

REDCap stands for Research Electronic Data Capture. It is a platform within the Brain-CODE portal used for collecting clinical data electronically.

TRAINING MANUAL OVERVIEW

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OVERVIEW OF CLINICAL ELECTRONIC DATA CAPTURE (EDC)

Brain-CODE studies use web-based data capture. REDCap collects patient-reported and clinician administered measures.

What are the ways in which clinical electronic data capture can occur?

- Data may be captured electronically at its source (direct EDC).
 This ensures the accuracy and completeness of the data. Furthermore, electronic prompts can be utilized to alert users of missing or inconsistent data.
- 2. Data may be captured via paper form and later transcribed into the EDC system.

Direct EDCs allow for the promotion of real-time data entry during subject visits. An eCRF is the source document. Direct EDCs ensure that no transcription errors occur.

DATA CAPTURE WORKFLOW

Clinician Administered Scales

Site clinical staff use paper CRFs and transcribe to REDCap eCRFs

- Paper CRFs are the source documents
- Potential for incomplete data, transcription errors
- Site monitoring

Site clinical staff enter directly to REDCap eCRF

- eCRF is the source document
- Warning, prompts for missing or inconsistent responses; range checks
- No Transcription errors
- eCRFs are designed as data capture tools not just data entry
- Preferred

Patient Paper PRO (Transcribed at site) REDCap ePRO REDCap Database

Paper CRF

REDCap eCRF

REDCap

Database

(Transcribed at site)

Clinician

Patient- Reported Outcomes:

Option 1: Patients enter data directly into ePROs (REDCap)

- ePRO is source document
- Warning, prompts for missing or inconsistent responses; range checks
- In Clinic or at home (email)

Option 2: Patients use paper PROs and site clinical staff transcribes to ePROs

- If preferred by patient and for selected scales
- Paper PRO is source document
- Potential for incomplete data, transcription errors
- Site monitoring

ROLES AND ACCESS

There are two primary roles within REDCap.

1. Data Entry Role

- a. Add and manage subjects for your site
- b. View and enter data into eCRFs for events
- c. Add notes and discrepancies

2. Data Monitor Role

a. Add and manage subjects for your site

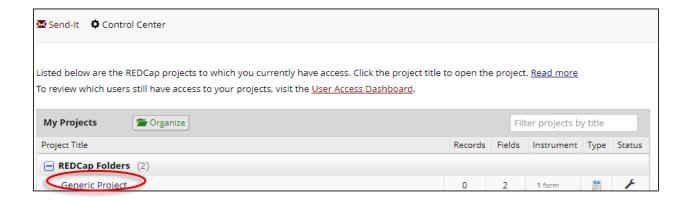
- b. View and enter data in eCRFs for events
- c. Add notes and discrepancies
- d. Check data integrity

NAVIGATION TO PROJECTS

1. Select "My Projects"

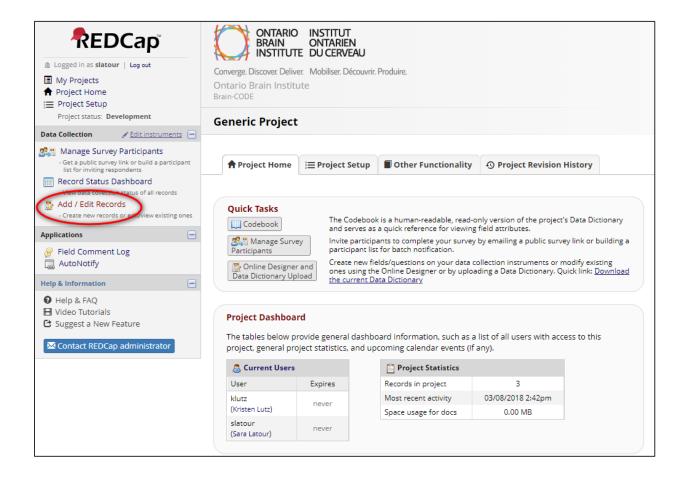


2. Select the title of your study



3. You will now see your Project Homepage

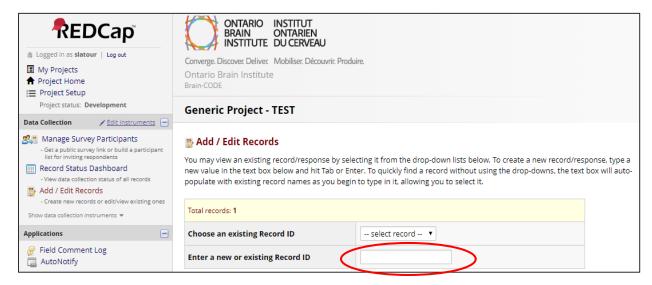
4. To add a new record or edit a pre-existing one, select "Add / Edit Records" from the navigation panel within the Project Home page view.



ADDING NEW SUBJECTS

Adding Subjects for Studies without Arms:

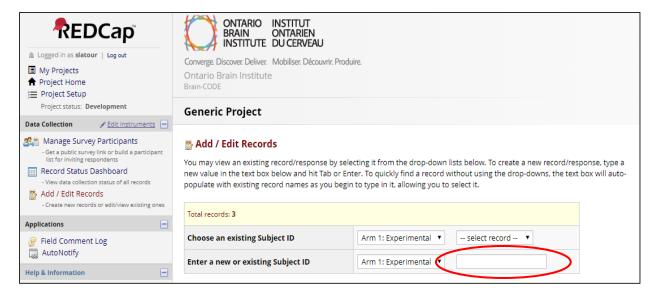
- 1. Enter a new Subject ID by typing into the text field.
 - a. Ensure that the participant ID conforms with the standard Brain-CODE naming convention. If you require clarification on the Brain-CODE naming standards please refer to the "Subject Naming Convention Training Module".



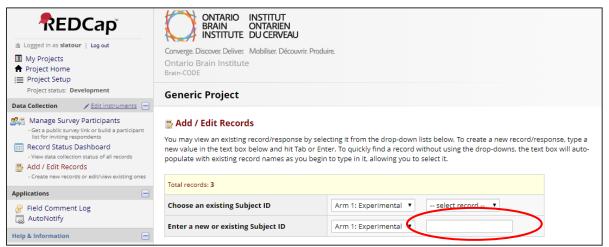
Adding Subject for Studies with Arms:

If your study has arms (Example: Experimental and Control), you will need to select the arm for which you are adding a new subject to before entering the Subject ID.

1. Select the arm of the study of interest.



2. Enter the standard Brain-CODE Subject ID



*Note: Ensure you have selected the appropriate study arm before beginning to add a new ID. Otherwise data may be inappropriately added to the incorrect study arm.

VISIT SCHEDULE

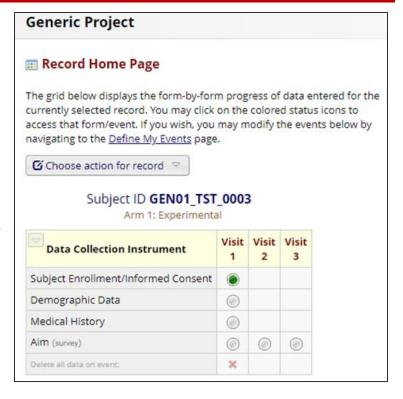
What is the Visit Schedule?

The Visit Schedule is a grid which communicates to users which forms have been completed.

How is the Visit Schedule used?

After you add successfully add a new subject ID you will be redirected to the Visit Schedule page. Select the bubble icon to enter data into a form. Each column represents a study visit.

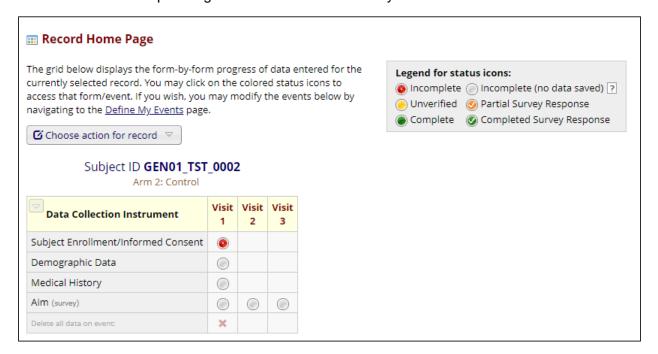
Ensure the subject is entered in the correct form. This is important since you cannot transfer data between events and will have to re-enter all data into the appropriate form/visit. Be sure to check for the correct visit in the study event schedule *before* starting data entry.



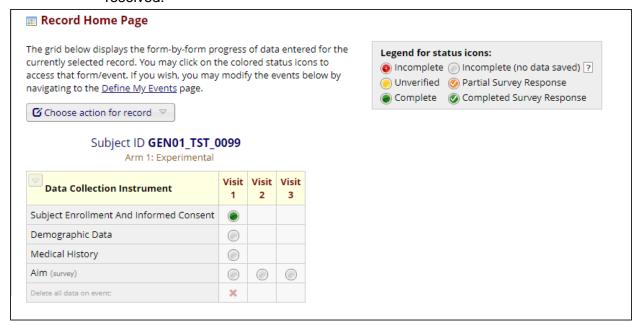
ENTERING DATA: CLINICIAN ADMINISTERED SCALES

Form Statuses:

- 1. A red bubble indicates that the form is "Incomplete".
 - a. Incomplete signifies the form is NOT ready for review

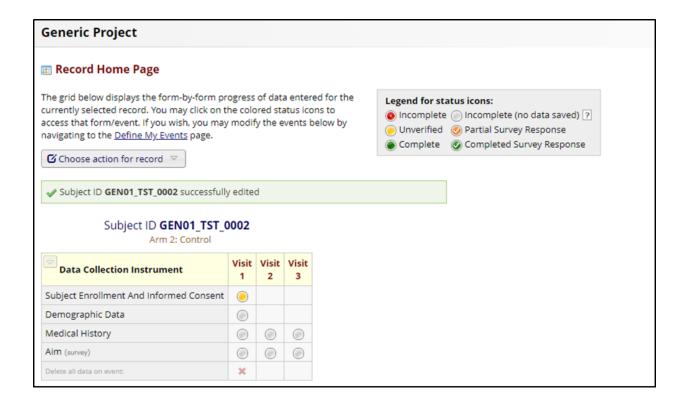


- 2. A green bubble indicates that the form is marked as "Complete".
 - a. Complete signifies all data entry is complete and all discrepancies have been resolved.



3. A yellow bubble indicates the form is "Unverified".

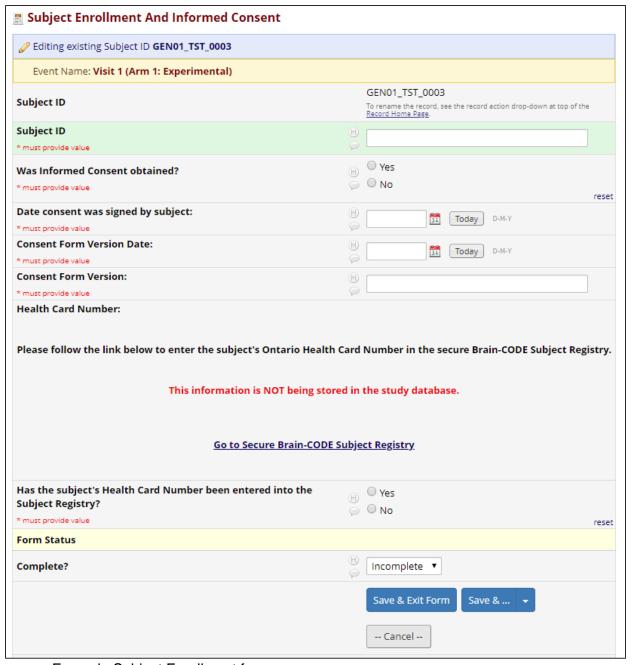
- a. Unverified signifies that the form is ready for review.
- b. For studies with verification procedures only though.
- c. Please check with your data monitor to ensure your study utilizes a verification procedure.



Subject Enrollment and Informed Consent Forms:

What are Subject Enrollment/ICFs?

Subject Enrollment and Informed Consent Forms (ICFs) are usually the first form for data entry. Only at the point this form is filled out and completed will a subject be confirmed within the database.



Example Subject Enrollment form

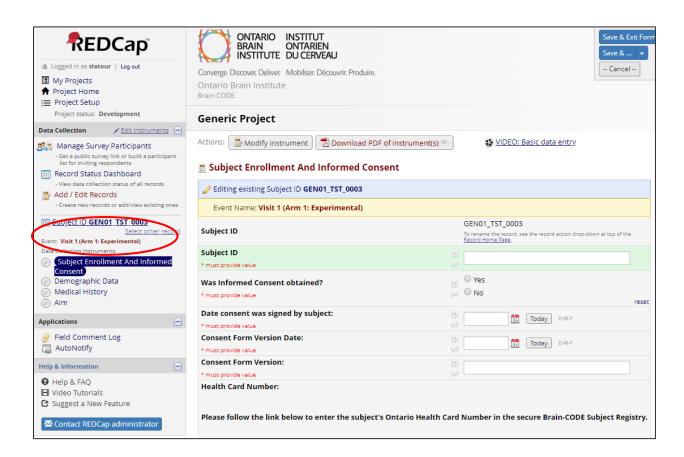
Navigating to Other Forms During Data Entry:

Within a form there are a few options to navigate to the another form for the same Subject ID.

The first is to select the next form directly from the navigation panel on the left side of the form in progress. The second option is to navigate back to the "Visit Schedule" overview page where you are able to select another form. You may also select another form from the "Save Options"

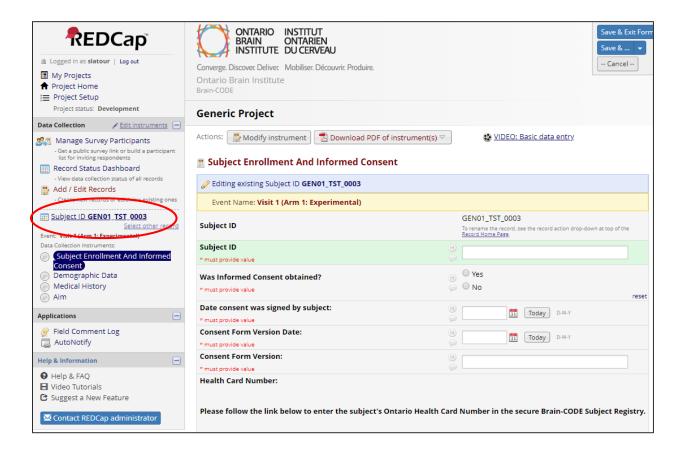
Option 1: Navigation Panel

 This is a good option when you want to remain within the same arm/event and for the same Subject ID.



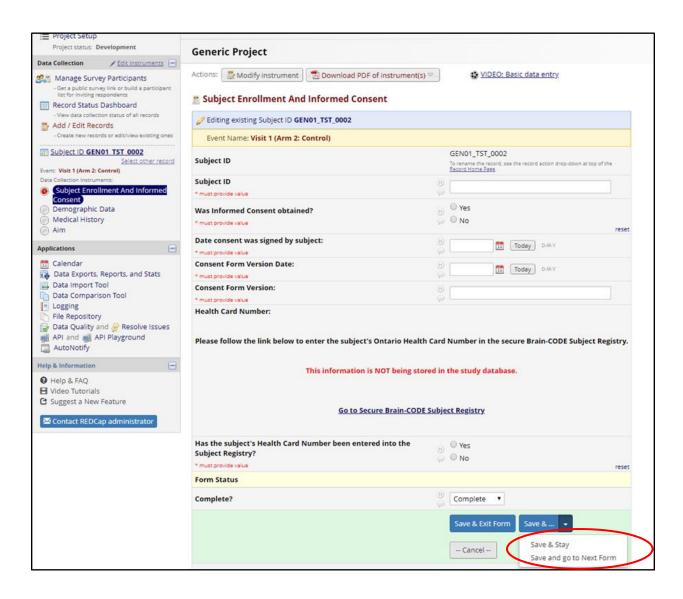
Option 2: Visit Schedule

 Select the calendar icon to return to the "Visit Schedule" page where you can select the next form



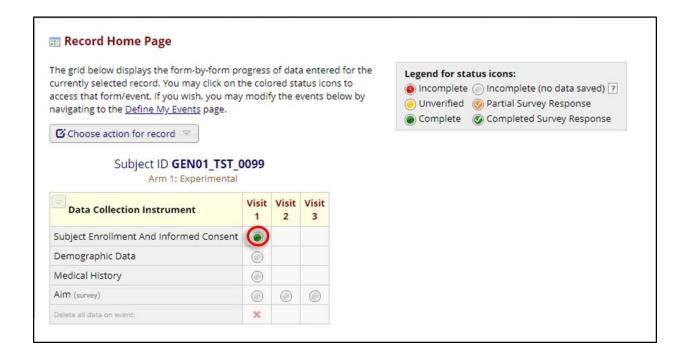
Option 3: Save Options

You can select "Save and go to Next Form" to Navigate to the next form within the event.



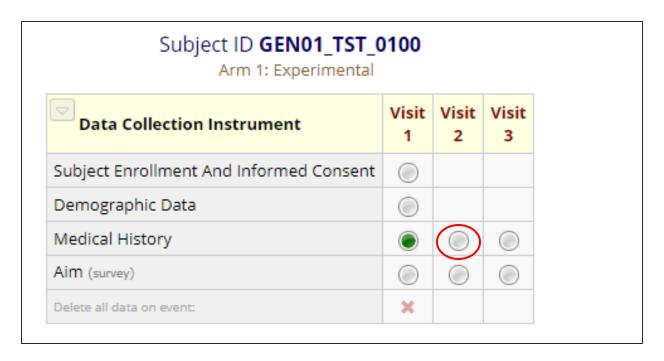
Editing Data on a Completed eCRF:

Before a form is locked, any form can be entered and edited.



Entering Data for the Next Event:

1. Navigate to the Visit Schedule and select a form from the next visit column.



NOTES AND DISCREPANCIES

What are Notes and Discrepancies?

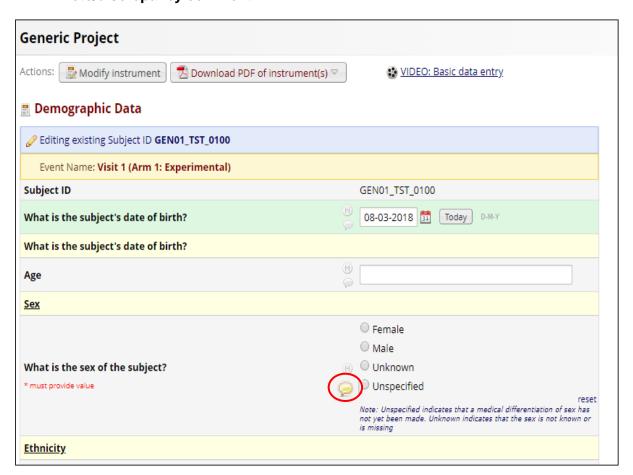
A means for users to document, communicate, and manage issues about data in a clinical trial, in order to facilitate verification of the accuracy and completeness of the data.

How are they useful?

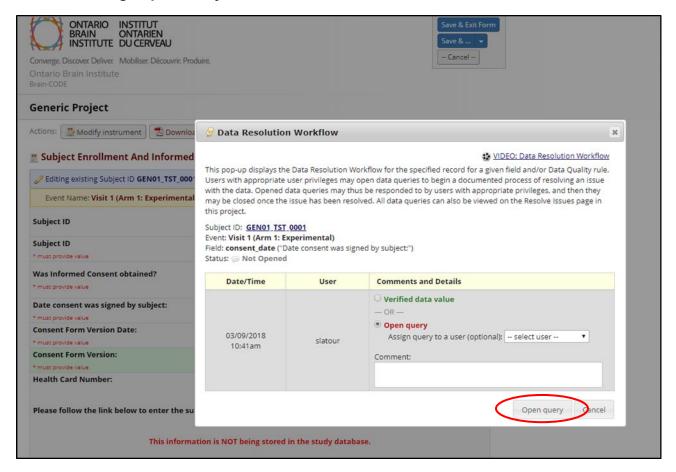
- To flag an item as incomplete or as having a value that is not expected.
- A means for users to communicate within REDCap
 - Not a replacement for notes fields (Notes field type).

Entering Notes and Discrepancies:

1. Select the comment bubble icon next to the field for which you want to open a note/discrepancy comment.



2. Open a new query by entering in the note/discrepancy in the text field and selecting "Open Query"



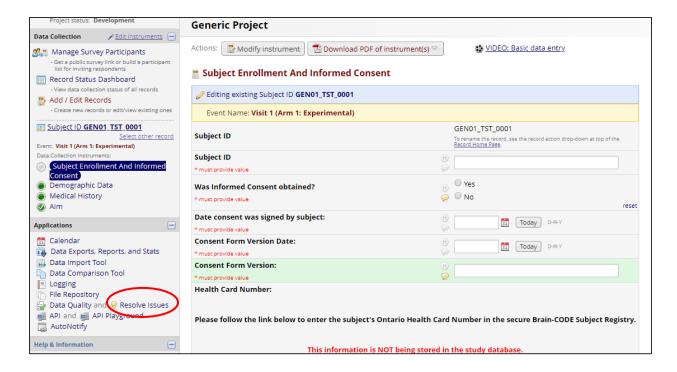
What is the Data Resolution Workflow View?

It is a view of all the fields for which there are notes or queries made. Assigned queries will be visible to you on this page. Queries may be assigned to an individual or a group of users. Any queries assigned to either you or the group will be visible on this page. You will not be notified when a data query is assigned to you, you must check this dashboard regularly!

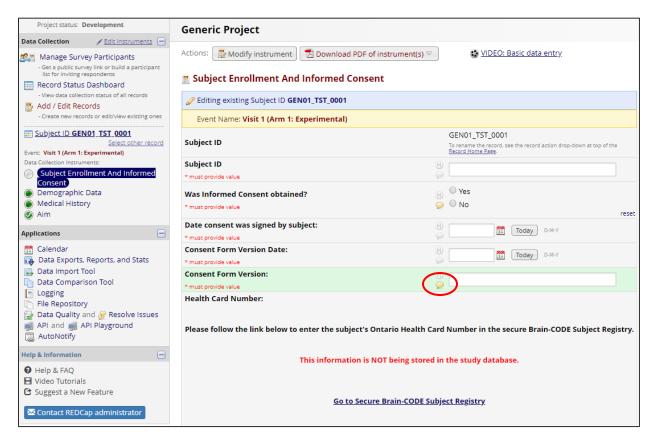
Responding to Data Queries:

In order to access the Data Resolution workflow you have two options. The first of which is to access the Data Resolution workflow by selecting "Resolve Issues" within the REDCap toolbar. The second option is to directly access the Data Resolution workflow from selecting the comment bubble icon directly next to a discrepant field.

Option 1: Select the "Resolve Issues" icon within the REDCap toolbar on the left hand side.

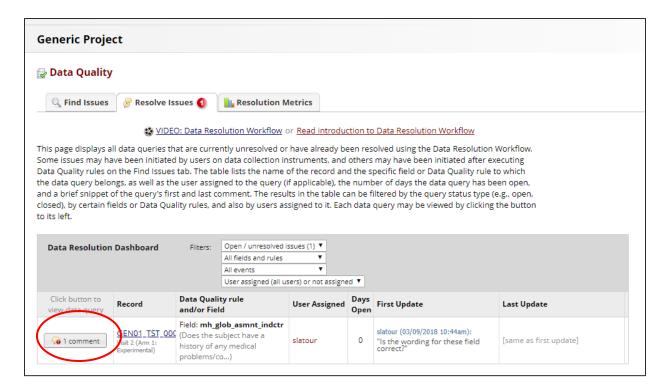


Option 2: Accessible next to the field on the form by selecting the comment bubble icon.

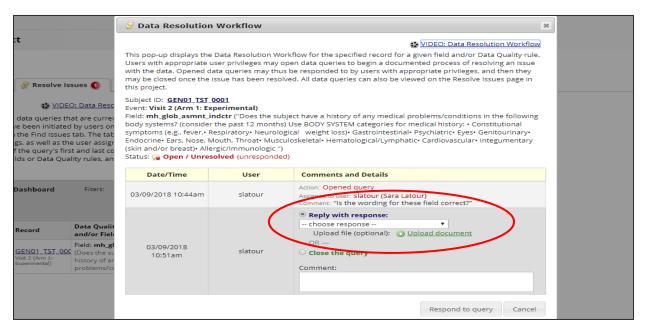


Responding to Data Queries:

1. In order to respond to a query, navigate to the Data Resolution Workflow view and select the comment button next to the field of interest.

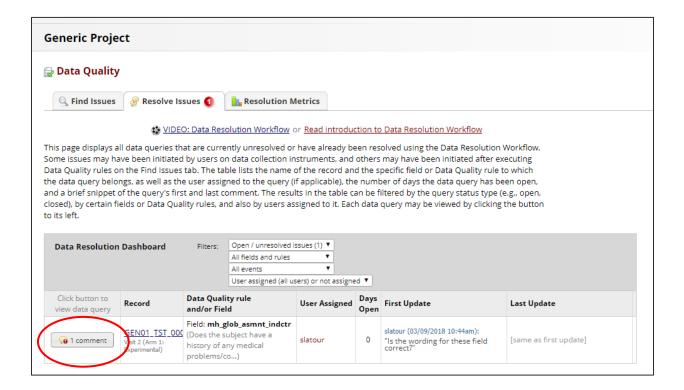


2. This opens up a window to select the option to "Reply with a Response". You can select a response to the query from the drop-down menu and also include text comments.

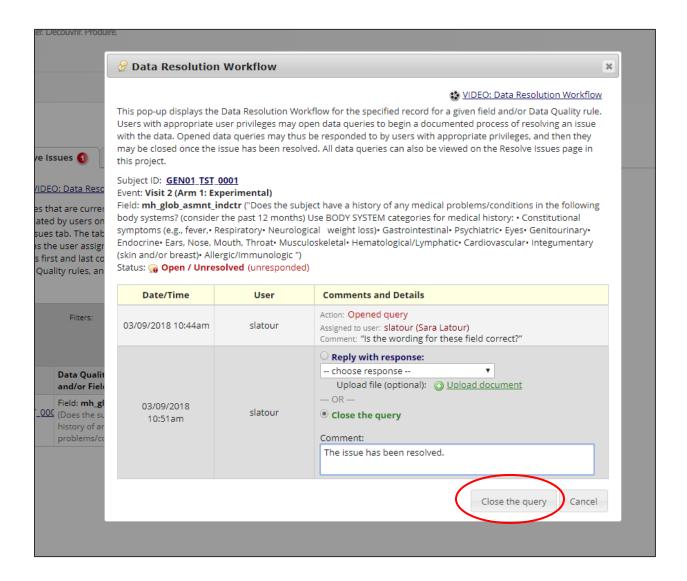


Closing Data Queries:

1. To close a data query, ensure that the issue/discrepancy was resolved and then navigate to the Data Resolution Workflow. Select the comment button next to the field of interest.

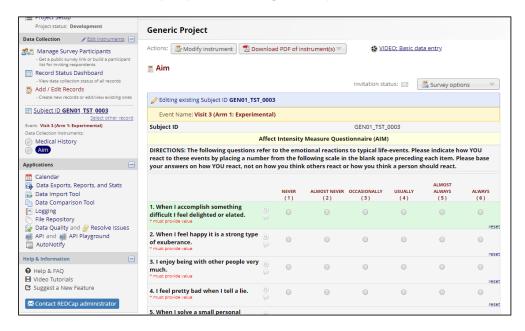


2. This opens up a window to select the option to "Close the query". Text comments may also be included.



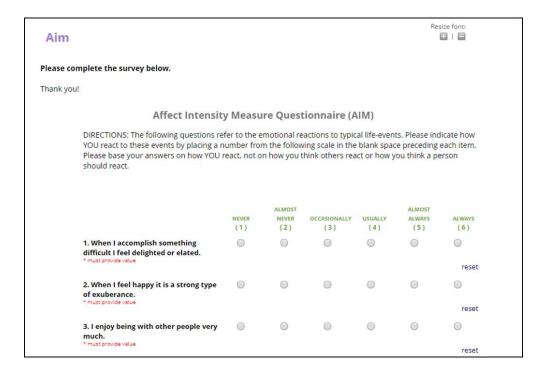
ENTERING DATA: PATIENT REPORTED OUTCOMES (SURVEYS)

Patient Scales Example (Transcribing a PRO):



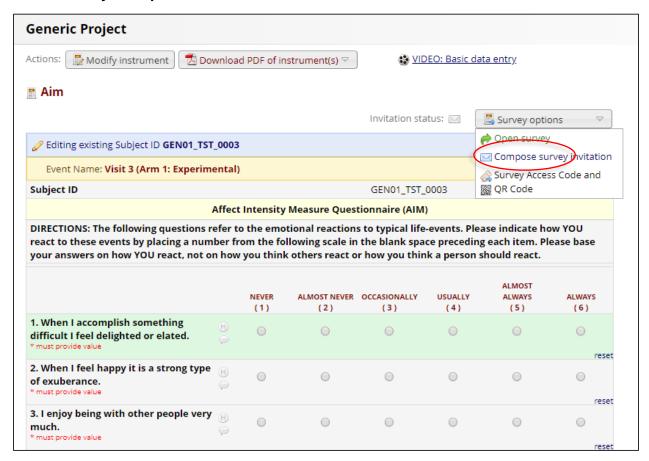
Above is the **Data Entry View** for transcribing a PRO.

Below is an example of a Survey View/ Patient View for the same PRO:



Administering an ePRO in Clinic:

1. Within the clinic Login to REDCap and select "Open Survey" within the form. The survey will open in a new tab.



2. Log out of REDCap in the original tab to ensure that your information/account credentials remain private.

CONTACT INFORMATION

REDCap Administrator: redcapadmin@braincode.ca

Brain-CODE Administrator: help@braincode.ca

RESOURCES

Brain-CODE Portal:

https://www.braincode.ca/

REDCap Brain-CODE Training Video:

https://www.youtube.com/watch?v= DEmbodf0es

REDCap Resources:

https://projectredcap.org/resources/videos/