

## User Guide Contents

Section	Page
Error! Not a valid result for table.	1
<b>Access to REDCap</b>	<b>1</b>
<b>Logging into REDCap</b>	<b>1</b>
<b>Data Entry</b>	<b>3</b>
Selecting a patient record	3
Selecting a form to enter data	4
Adding data to the database	5
Missing Data	6

Section	Page
Comments	6
Form statuses	7
<b>Data Queries</b>	<b>8</b>
Responding to data queries	8
<b>PI sign-off</b> of data	<b>11</b>
<b>Consent for ROCSS-EX</b>	<b>11</b>

## Background

The purpose of this user guide is to provide guidance for staff on the use of the ROCSS-EX REDCap data entry portal used for all data needed for the trial.

Ideally, data will be entered directly in to electronic Case Report Forms (eCRFs) within the REDCap database. Alternatively data may initially be collated on paper versions of the eCRFs, and then uploaded into REDCap later on. Completed worksheets should be retained and filed in the ISF but do not need be sent to the ROCSS-EX Trial Office.

REDCap can be accessed via all typical web browsers.

## Access to REDCap

To be provided with access to the ROCSS-EX REDCap database staff must be delegated the task of “Completion of electronic CRFs/data entry including data query resolution” on the ROCSS-EX Site Signature and Delegation Log. The Site Signature and Delegation Log document is available for [download](#) and will need to be completed, signed and returned to BCTU before access can be provided to the REDCap database.

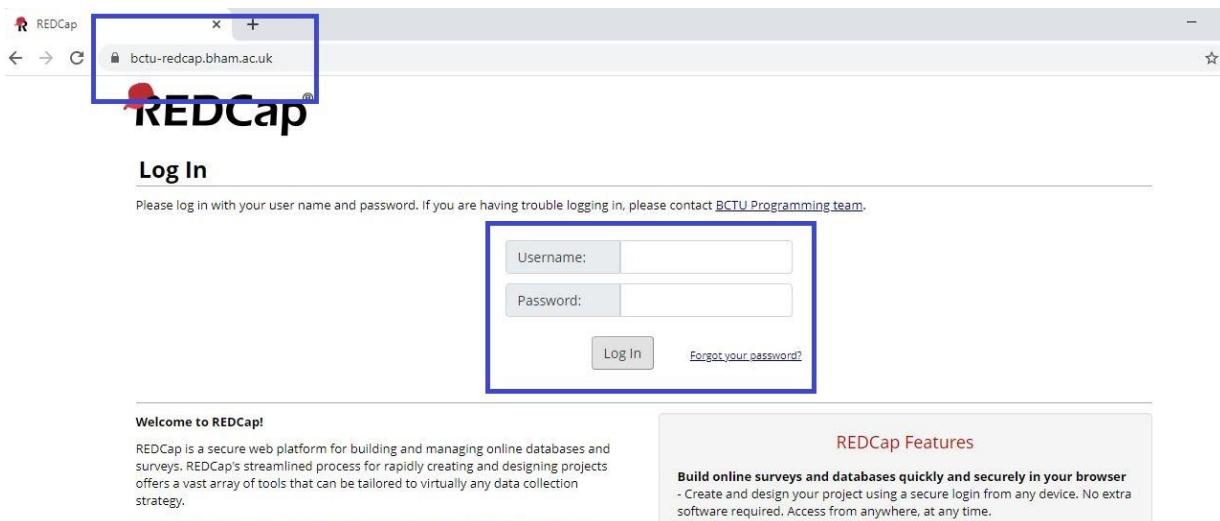
To request a username and password for REDCap, send a request to the trial mailbox ([rocss@trials.bham.ac.uk](mailto:rocss@trials.bham.ac.uk)).

Your username will be assigned by BCTU and returned via email along with instructions on how to set up a password. Please do not reveal this username and password to anyone.

## Logging into REDCap

The ROCSS-EX REDCap database is located online at <https://bctu-redcap.bham.ac.uk>.

- Enter **UserName** and **Password** on the REDCap homepage.



Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

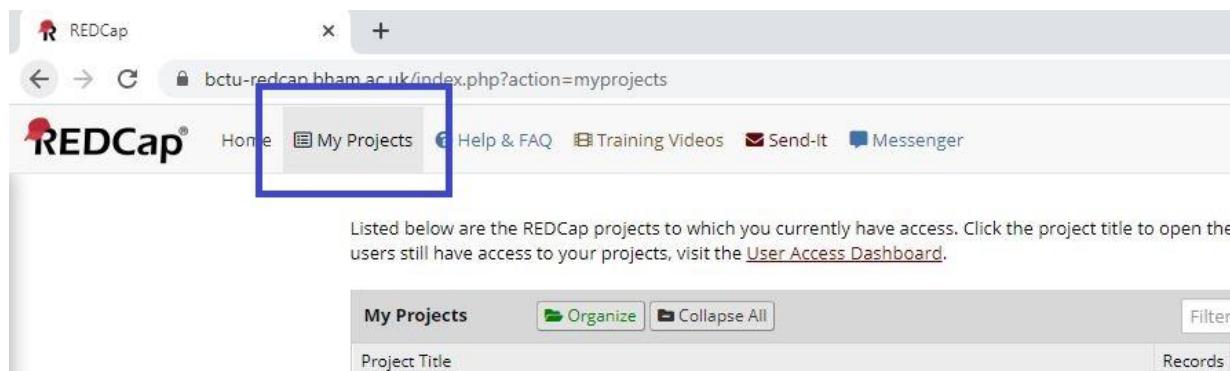
REDCap provides automated export procedures for seamless data download to

REDCap Features

Build online surveys and databases quickly and securely in your browser

- Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.

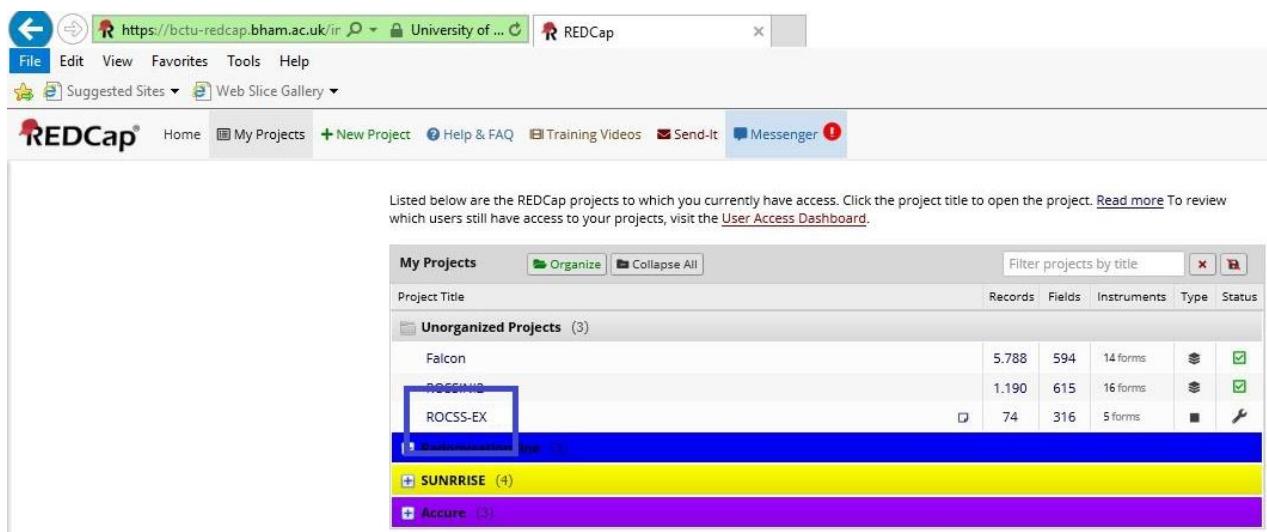
- If access to REDCap has been granted, the database is located within 'My Projects'.



Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

Project Title	Records	Fields	Instruments	Type	Status
Falcon	5,788	594	14 forms		
ROCSS-EX	1,190	615	16 forms		
SUNRISE	74	316	5 forms		
Accure					

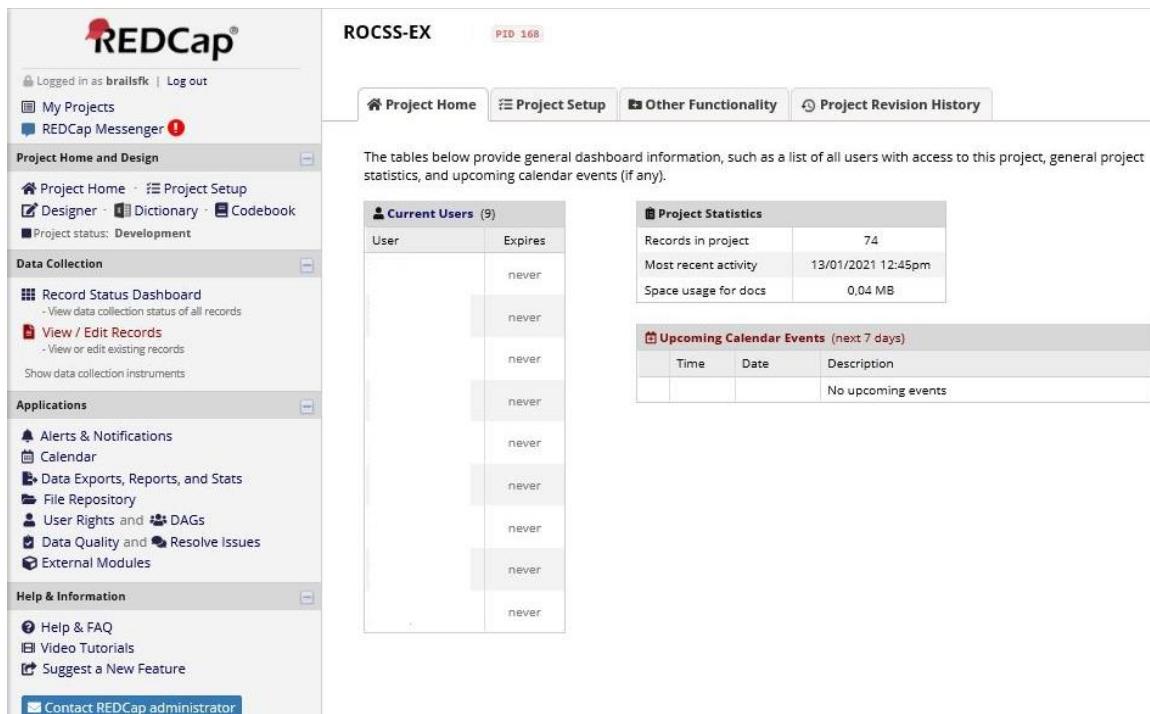
- Select ROCSS-EX to enter the database.



Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

Project Title	Records	Fields	Instruments	Type	Status
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ROCSS-EX	1,190	615	16 forms		
SUNRISE	74	316	5 forms		
Accure					

- The **Project Home** dashboard is the starting point for all data entry/activity.



**Project Home** **Project Setup** **Other Functionality** **Project Revision History**

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users (9)		Project Statistics	
User	Expires	Records in project	74
	never	Most recent activity	13/01/2021 12:45pm
	never	Space usage for docs	0.04 MB
	never		

Upcoming Calendar Events (next 7 days)		
Time	Date	Description
		No upcoming events

- You can return to the **Project Home** dashboard by clicking on the Project Home Tab from any page in the database.



The tables below provide general dash statistics, and upcoming calendar events

Current Users (9)	
User	Expires

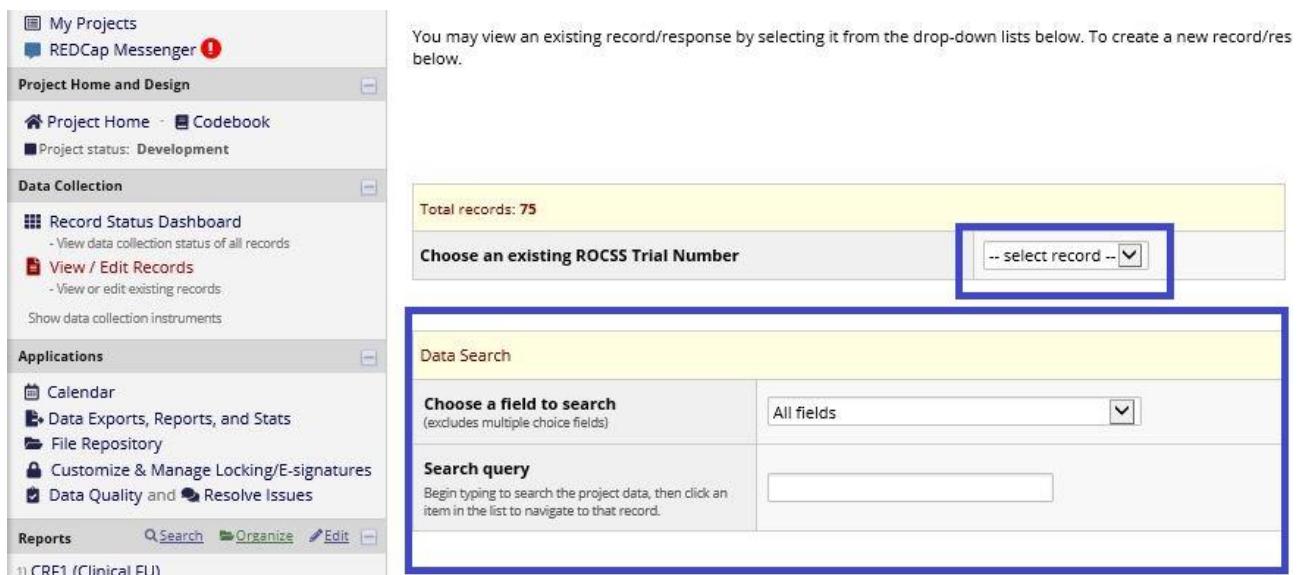
## Data Entry

### Selecting a patient record

- To view and edit a patient's record click on '**View/Edit Records**' under Data Collection in the navigation pane to the left of the screen.



- A participant's trial number can then be selected from the dropdown menu. This will navigate to the '**Record Home Page**' for the selected patient.



You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the 'New Record' button.

Total records: 75

Choose an existing ROCSS Trial Number

-- select record --

Data Search

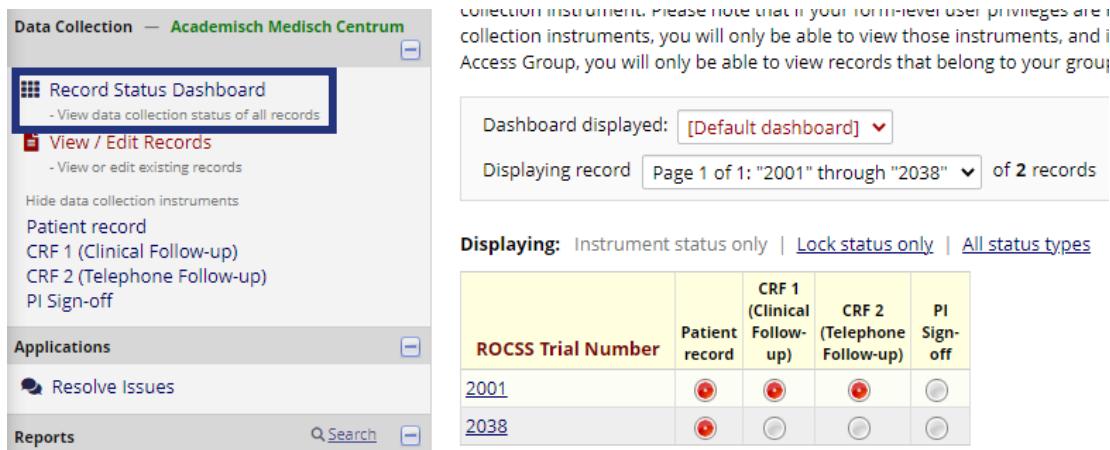
Choose a field to search  
(excludes multiple choice fields)

All fields

Search query

Begin typing to search the project data, then click an item in the list to navigate to that record.

- The “Data Search” section can also be used. Here simply type in the search term (trial number, patient name, hospital number etc.) and you will be shown a list of records that meet the search criteria.
- Alternatively, select “Record Status Dashboard” under Data Collection in the navigation pane to the left of the screen. This will show you all the records for your site, and the status of each of the forms for that record. Red indicates the form has not been completed.



Collection instruments. Please note that if your form never user privileges are given to collection instruments, you will only be able to view those instruments, and if your user is in an Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] ▾

Displaying record Page 1 of 1: "2001" through "2038" ▾ of 2 records

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

ROCSS Trial Number	Patient record	CRF 1 (Clinical Follow-up)	CRF 2 (Telephone Follow-up)	PI Sign-off
2001	●	●	●	○
2038	●	○	○	○

## Selecting a form to enter data

- In ROSS-EX there are 4 forms;

Form	Role	Access
Patient Record	Site Staff	View & Edit
	Site PI	View & Edit
CRF 1 (Clinical Follow-up)	Site Staff	View & Edit
	Site PI	View & Edit

Form	Role	Access
CRF 2 (Telephone Follow-up)	Site Staff	View & Edit
	Site PI	View & Edit
PI Sign-off	Site Staff	Read only
	Site PI	View & Edit

- Each form has a corresponding circular icon which must be clicked to access the form. If you click on the Trial number, this will be your view.
  - Also see ‘Form Status’ section



REDCap Messenger

Project Home and Design

Project Home · Codebook

Project status: Development

Data Collection — Academisch Medisch Centrum

Record Status Dashboard

View / Edit Records

ROCSS Trial Number 2001 Select other record

Applications

Data Quality and Resolve Issues

Help & Information

Help & FAQ

Video Tutorials

Record Home Page

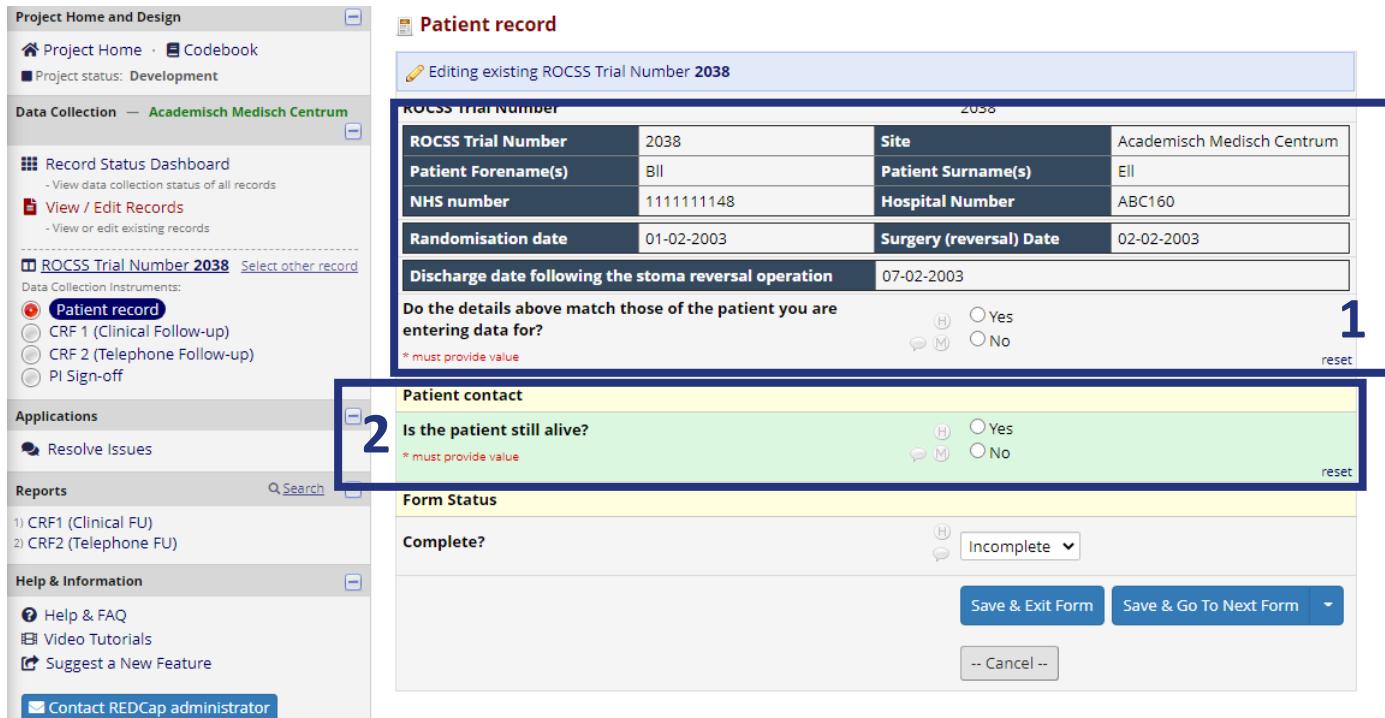
The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

ROCSS Trial Number 2001

Data Collection Instrument	Status
Patient record	●
CRF 1 (Clinical Follow-up)	●
CRF 2 (Telephone Follow-up)	●
PI Sign-off	○

- Patient Record should be accessed first – it contains:
  - Summary of the participant details – this should match the ROSS Patient Identification Log within the Investigator Site File (ISF), and there is a check question for this.

2. Patient contact – there are a series of questions to establish the participant's status; are they alive, have they been contacted and have they agreed to participate. **Answers are required to 'unlock' data entry for the CRFs 1 and CRF 2 - also see Figure 1.**



**Patient record**

Editing existing ROCSS Trial Number 2038

ROCSS Trial Number			
ROCSS Trial Number	2038	Site	Academisch Medisch Centrum
Patient Forename(s)	Bill	Patient Surname(s)	Elli
NHS number	1111111148	Hospital Number	ABC160
Randomisation date	01-02-2003	Surgery (reversal) Date	02-02-2003
Discharge date following the stoma reversal operation <span style="float: right;">07-02-2003</span>			
Do the details above match those of the patient you are entering data for? <span style="float: right;">1</span>			
<input type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small>			

**Patient contact**

Is the patient still alive? 2

\* must provide value

Yes  No

**Form Status**

Complete? Incomplete

**Actions**

Save & Exit Form | Save & Go To Next Form | -- Cancel --

## Adding data to the database

- Please complete every field on the form.
  - Fields where data is mandatory are indicated by '**\* must provide value**'
  - If an exact date is not known for any relevant field, enter the approximate date of month and year with 15th for the day component AND a comment added to tell us this has been done – see '*Comments' section*'
  - If exact duration is not known for any medication field, enter the best estimate AND a comment added to tell us this has been done – see '*Comments' section*'
- Whilst entering data, alerts may appear as some data fields have in built validations. For example, the number of ITU days exceeds the number of total inpatients day. Any data prompting an alert should be checked to ensure it is correct.
- Once data entry for the form has been completed, select '**Unverified**' from the dropdown list at the bottom of the form and then '**Save and Exit Form**'. The form will now have a **yellow** status icon which alerts the BCTU that the form is ready for review.
  - *Also see 'Form Status' section*



**Form Status**

Complete? Unverified

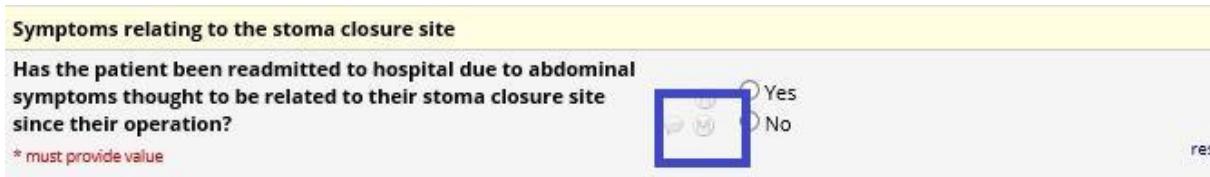
**Actions**

Save & Exit Form | Save & Go To Next Form | -- Cancel --

- When saving data prompts may appear to inform you:
  - mandatory data fields have been left blank
  - data quality checks have identified a possible error
 Any data prompting an alert should be checked to ensure it is correct.
- Data entry on CRF1 and CRF2 will not be immediately available – if you access the forms, instructions on what is required to enable/‘unlock’ data entry are given, usually requiring an update to ‘Patient Record’, or you will be informed if data entry cannot be unlocked. *For instance, CRF2 data entry fields will only be available if it has been confirmed that the patient has agreed to participate in ROCSS-EX.*
  - Where instructions inform that data entry cannot be unlocked, ‘Unverified’ is still to be selected from the dropdown list at the bottom to demonstrate acknowledgment of the circumstances.

## Missing Data

- If data is unavailable and can never be provided/collected “Missing Data Codes” are to be used, and are added using the ‘M’ icon next to data field AND should be accompanied by a comment to explain – see ‘Comments’ section



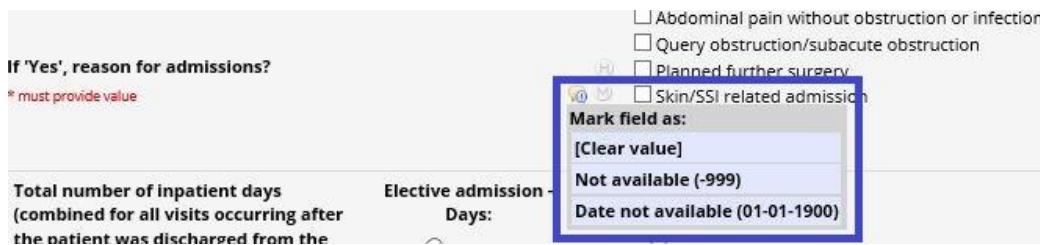
**Symptoms relating to the stoma closure site**

**Has the patient been readmitted to hospital due to abdominal symptoms thought to be related to their stoma closure site since their operation?**

\* must provide value

Yes  No

- Selecting the missing icon displays the available codes that identified as not available:
  - Not available (-999) – to be used for any field except dates fields
  - Data not available (01-01-1900) – to be used for date fields only



**If 'Yes', reason for admissions?**

\* must provide value

**Total number of inpatient days (combined for all visits occurring after the patient was discharged from the**

**Elective admission - Days:**

Abdominal pain without obstruction or infection  
Query obstruction/subacute obstruction  
Planned further surgery  
Skin/SSI related admission  
[Clear value]  
**Not available (-999)**  
Date not available (01-01-1900)

## Comments

There may be times when comments or notes need to be added to a data field to make us aware of any issues or to provide an explanation of the data provided.

- Comments can be added by clicking the speech bubble icon to the left of the data field.



**Do the details above match those of the patient you are entering data for?**

\* must provide value

Yes  No

**Patient contact**

**Is the patient still alive?**

\* must provide value

Yes  No

- Add text to the comment box leaving “Verified Data value” selected and click ‘Verified data value’ button to save.

**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.

ROCSS Trial Number: **2001**  
 Field: **pt\_detailscheck** ("Do the details above match those of the patient you are entering data for?")  
 Status:  **Not Opened**

Date/Time	User	Comments and Details
06/01/2021 4:25pm		<p><input checked="" type="radio"/> <b>Verified data value</b></p> <p>— OR —</p> <p><input type="radio"/> <b>Open query</b></p> <p>Assign query to a user (optional): <b>-- select user --</b></p> <p>Notify this user of their assignment using: <input type="checkbox"/> Email <input type="checkbox"/> REDCap Messenger</p> <p><b>Comment (optional):</b> Unsure</p> <p><b>Verified data value</b> <b>Cancel</b></p>

- The speech bubble icon will change once a comment has been saved.

**Do the details above match those of the patient you are entering data for?**

\* must provide value   Yes  No [reset](#)

**Patient contact**

**Is the patient still alive?**

\* must provide value   Yes  No [reset](#)

## Form statuses

The form status can fall into one of four categories and the status of all patient forms can be viewed on the 'Record Status Dashboard':

Icon & Status	Meaning
 Incomplete (no data saved)	No data has been saved.
 Incomplete	Some data has been entered and saved by site.
 Unverified	Data has been entered and saved by site, and the form has been marked as 'Unverified' by the site to indicate data entry is finished and is ready to be reviewed by BCTU - <b>it is essential that sites mark data that is due to be checked as 'unverified'.</b>
 Complete	Data reviewed by BCTU and is now verified as complete. <b>Forms should only be marked as complete by the site when instructed by BCTU.</b>

- The Trial Office is automatically notified when a form is saved with an ‘**Unverified**’ status. The data will be reviewed, and if any queries are identified these will be raised using the Data Resolution Workflow. If there are no queries, or once they are resolved, the Trial Office will notify sites by email that they can set the form status to ‘**Complete**’.
  - Unfortunately, REDCap lacks the functionality that would allow the Trial Office to modify a single data field within a form – access is managed at the form level.
- The Trial Office is automatically notified when a form is saved with a ‘**Complete**’ status. The form will then be locked to prevent any changes to the data.
  - If further changes are required, contact the Trial Office to request the form be unlocked.

## Data Queries

Any questions from the BCTU team querying any data entered at your site will be conducted through the ROCSS-EX REDCap database using the Data Resolution Workflow.

### Responding to data queries

- Data queries raised by the ROCSS-EX Trial Office can be viewed by clicking ‘**Resolve Issues**’ under ‘**Applications**’ in the navigation pane on left of the screen.



- All queries raised for the specific site are displayed on the ‘**Data Quality**’ page.

#### Data Quality



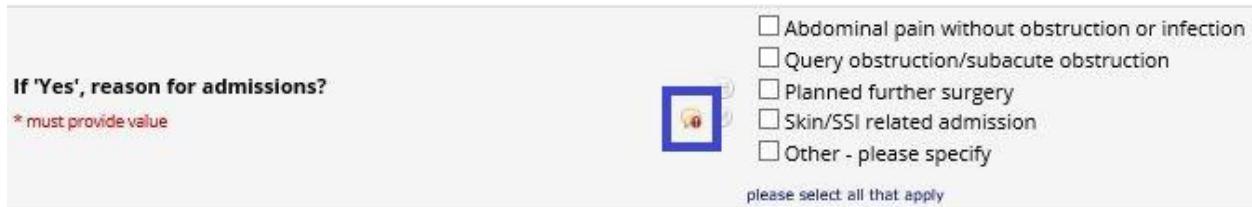
[VIDEO: Data Resolution Workflow](#) or [Read introduction to Data Resolution Workflow](#)

This page displays all data queries that are currently unresolved or have already been resolved using the Data Resolution Workflow. Some issues may have been initiated by users on data collection instruments, and others may have been initiated after executing Data Quality rules on the Find Issues tab. The table lists the name of the record and the specific field or Data Quality rule to which the data query belongs, as well as the user assigned to the query (if applicable), the number of days the data query has been open, and a brief snippet of the query's first and last comment. The results in the table can be filtered by the query status type (e.g., open, closed), by certain fields or Data Quality rules, and also by users assigned to it. Each data query may be viewed by clicking the button to its left.

Data Resolution Dashboard		Filters:					
		Open / unresolved issues (1)	All fields and rules	All data access groups	User assigned (all users) or not assigned		
<a href="#">Export</a>							
Click button to view data query	<a href="#">Record (Sorted by DAG)</a>						
	<a href="#">2006 (Doncaster Royal Infirmary)</a>	<a href="#">Data Quality rule and/or Field</a>	<a href="#">User Assigned</a>	<a href="#">Days Open</a>	<a href="#">First Update</a>	<a href="#">Last Update</a>	
	<a href="#">1 comment</a>	Field: <b>reasons_for_admission</b> (If 'Yes', reason for admissions?)	-	0	"This field has been left blank, please provide a response or explanation why a response is not pos..."	[same as first update]	

- The ‘**Record**’ column lists the patient trial numbers and forms which have been queried. The ‘**Data Quality rule and/or Field**’ column identifies the data field that has been queried.

- You can click the button in the first column to view the query but you can also access it from within the form the query is on (see below)
- To address a query, click on the patient trial number in the ‘Record’ column - this will navigate to the field being queried, which will have a red data query icon on the left hand side.



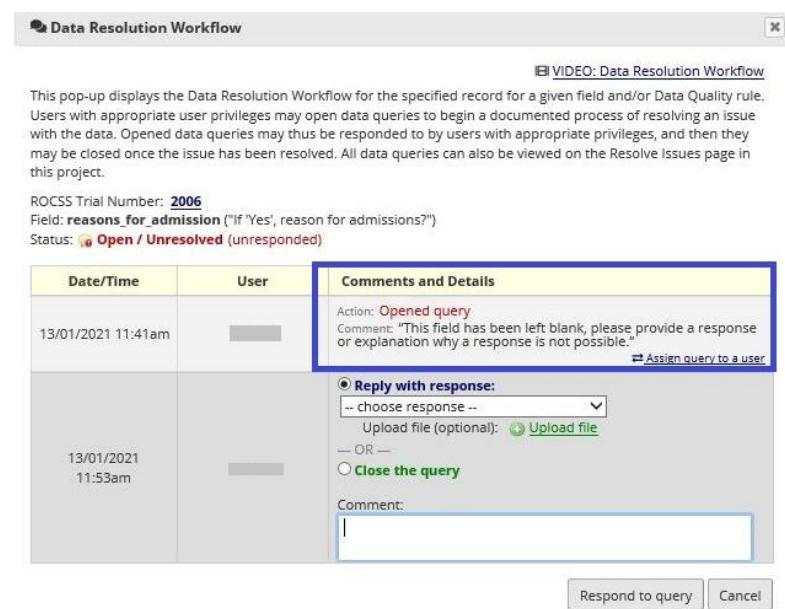
If 'Yes', reason for admissions?

\* must provide value

Abdominal pain without obstruction or infection  
 Query obstruction/subacute obstruction  
 Planned further surgery  
 Skin/SSI related admission  
 Other - please specify

please select all that apply

- Click the red data query icon to access the query.



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.

ROCSS Trial Number: 2006  
Field: **reasons\_for\_admission** ("If 'Yes', reason for admissions?")  
Status: **Open / Unresolved** (unresolved)

Date/Time	User	Comments and Details
13/01/2021 11:41am		Action: <b>Opened query</b> Comment: "This field has been left blank, please provide a response or explanation why a response is not possible." <input type="button" value="Assign query to a user"/>
13/01/2021 11:53am		<input checked="" type="radio"/> <b>Reply with response:</b> -- choose response -- Upload file (optional): <input type="button" value="Upload file"/> -- OR -- <input type="radio"/> <b>Close the query</b> Comment: <input type="text" value=" "/>

Respond to query   Cancel

- Click ‘Cancel’ to return to the form to then edit the data address to address the query and save the form.



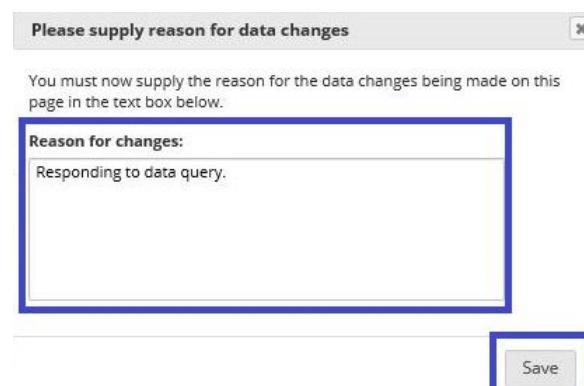
If 'Yes', reason for admissions?

\* must provide value

Abdominal pain without obstruction or infection  
 Query obstruction/subacute obstruction  
 Planned further surgery  
 Skin/SSI related admission  
 Other - please specify

please select all that apply

- Because the data has been amended, a prompt will appear asking to provide ‘Reason for changes’. Please provide a reason why the data was amended e.g. responding to a data query, and save.



Please supply reason for data changes

You must now supply the reason for the data changes being made on this page in the text box below.

Reason for changes:

- Once the edit has been saved the Data Resolution Workflow may re-open. If not, click the red data query icon to access the query. From the drop-down list select a response which is in line with the edit made to the data in response to the query raised, e.g. where missing data was queried and has now been added, select 'Corrected - Data missing'.
  - A comment is to be added to the query to provide further details regarding the response. To save the response click 'Respond to query'.

**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.

ROCSS Trial Number: **2006**  
Field: **reasons\_for\_admission** ("If 'Yes', reason for admissions?")  
Status: **Open / Unresolved** (unresponded)

Date/Time	User	Comments and Details
13/01/2021 11:41am	██████████	Action: <b>Opened query</b> Comment: "This field has been left blank, please provide a response or explanation why a response is not possible." <a href="#">Assign query to a user</a>
13/01/2021 11:59am	██████████	<div style="border: 1px solid #ccc; padding: 5px; width: fit-content; margin-bottom: 5px;">           -- choose response --             <b>Corrected - Data missing</b> (highlighted)                       Corrected - Typographical error                       Corrected - Wrong source used                       Verified - Confirmed correct (no error)                       Other         </div> Comment:

[Respond to query](#) [Cancel](#)

ROCSS Trial Number: **2006**  
Field: **reasons\_for\_admission** ("If 'Yes', reason for admissions?")  
Status: **Open / Unresolved** (unresponded)

Date/Time	User	Comments and Details
13/01/2021 11:41am	██████████	Action: <b>Opened query</b> Comment: "This field has been left blank, please provide a response or explanation why a response is not possible." <a href="#">Assign query to a user</a>
13/01/2021 11:59am	██████████	<div style="border: 1px solid #ccc; padding: 5px; width: fit-content; margin-bottom: 5px;"> <input checked="" type="radio"/> <b>Reply with response:</b>             Corrected - Data missing                       Upload file (optional): <a href="#">Upload file</a>             — OR —             <input type="radio"/> <a href="#">Close the query</a> </div> Comment: Data missed in error.

[Respond to query](#) [Cancel](#)

- The query icon next to the data field will appear blue once a response has been provided to the query.

**If 'Yes', reason for admissions?**  
\* must provide value



Abdominal pain without obstruction or infection  
 Query obstruction/subacute obstruction  
 Planned further surgery  
 Skin/SSI related admission  
 Other - please specify

please select all that apply

## PI sign-off of data

PI sign-off of the data is required – it is their responsibility to ensure that the information that has been provided is up-to-date and accurate.

- Only the Site PI has can complete the **PI Sign-off** form – other members of the local research team have read only access.
- The **PI Sign-off** form should be completed once all data has been entered and queries resolved – this is indicated by Status Icon button for Patient Record, CRF1 and CRF2 being **green**.
  - The ROCSS Trial Office will prompt PIs when data sign-off is appropriate.
- The forms will have been locked by BCTU, so please if PIs wish to make changes the data in Patient Record, CRF1 and CRF2, the Trial Office should be contacted by email to request a form be unlocked.
  - The status of the form where data is changed should be set back to '**Unverified**' and the process described above (in *Adding data to the database* and *Form statuses*) will begin again.
- As with the other forms, the PI Sing-off should be saved with the status 'unverified' once completed.

## Consent for ROCSS-EX

The availability of data entry fields within the ROCSS-EX eCRFs is dependent upon what consent is in place. This is determined by the consent form completed during the original ROCSS trial and responses to questions in "Patient Record" within the Patient Contact section. Figure 1 presents the requirements for data entry to be enabled.

- **CRF 1 (Clinical Follow-up)** – data entry is enabled when:
  - There is pre-existing consented to long-term follow-up using routinely collected data, which is already present in the background of the database (i.e. site input is not required).
  - the participant agrees to take part ROCSS-EX where there was is not pre-existing consented to long-term follow-up using routinely collected data, which is recorded in the Patient Contact section of "Patient Record".
- **CRF 2 (Telephone Follow-up)** – data entry is enabled when the participant agrees to take part in ROCSS-EX, which is recorded in the Patient Contact section of "Patient Record".

## General Information

- All trial data entered onto the REDCap database via the online web application/data entry portal is TSL encrypted and the system is hosted on servers at the University of Birmingham campus.
- The Trial Team at BCTU have read only access to the data entry fields present in Patient Record, CRF1, CRF2 and PI data sign-off.
- Once data entry is completed and checked, forms will be locked. This will prevent any changes to the data. If further changes are required, contact the Trial Office to request the form be unlocked.

Figure 1 - Flowcharts for each CRF demonstrating the condition required to enable data entry

