

MACRO Database Training

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Access to MACRO

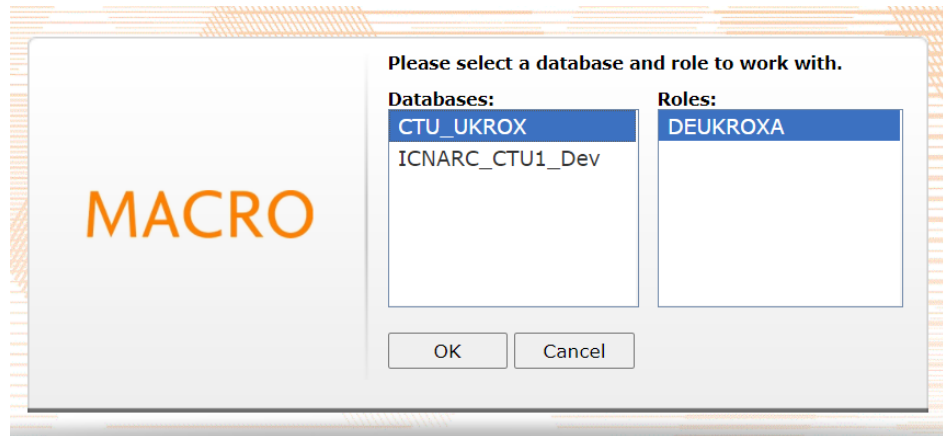
- Access to the PICnIC database is granted to staff members authorised on the delegation log once site has been greenlit
 - <https://ctu.icnarc.org/macro/>
- An existing training video on data entry in the web-portal is available on the website:
 - [ICNARC CTU - training.icnarc.org](https://training.icnarc.org)

Access to MACRO

- Each user will receive an email confirming access has been granted
- Any staff already issued with a MACRO account will use their existing login details
- New users will be issued their MACRO username via email and will be asked to call, or provide a contact number, to receive their temporary password via phone or text

Logging in

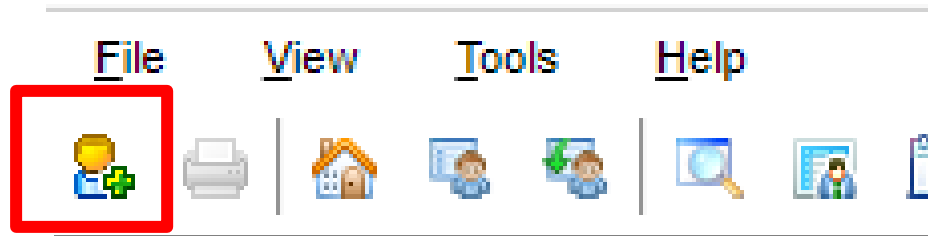
- Once a user account has been created and granted access to a study, the user can login and select the study and role



- Staff who work in more than one study can use the same MACRO account to access different databases.

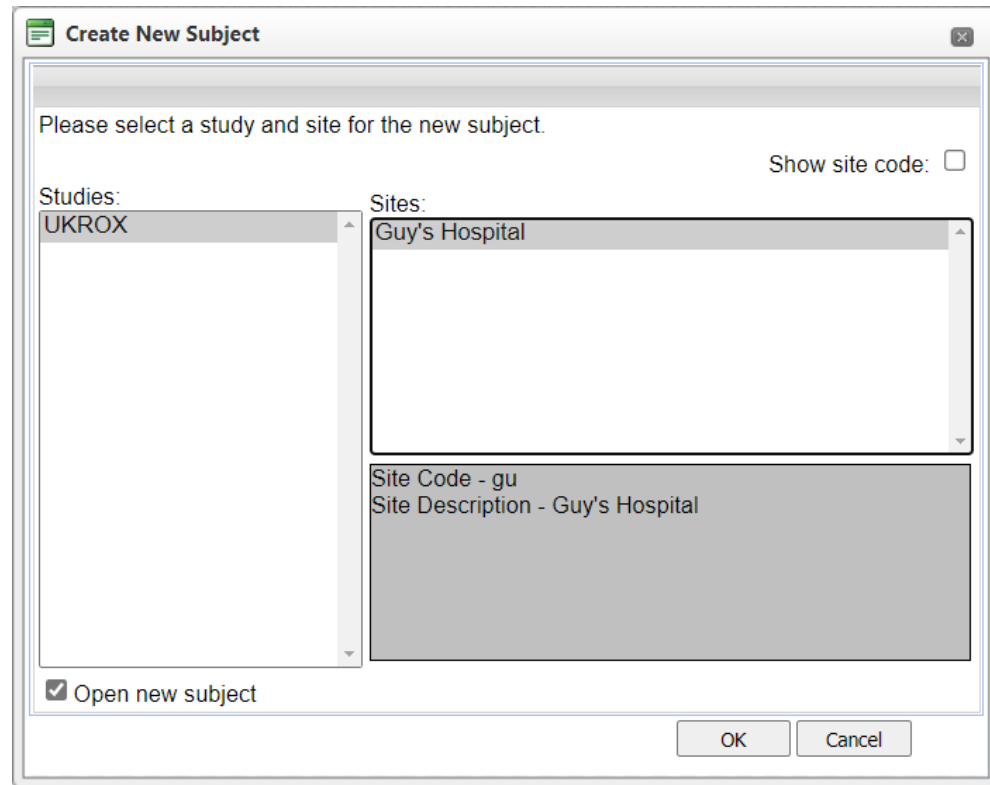
Web-portal: Creating new subjects

- New participant records can be added using the ‘Create a new study subject’ button:



Creating new subjects

- A window will prompt selection of the study and site for the new participant
 - Only those sites available to the specific user will be visible



Creating new subjects

- New subjects created in error cannot be deleted from the system
 - Email the Trial Team if a patient has been created in error
- Good practice: Search for the trial ID before creating a new subject to ensure the participant has not already been entered

Searching for subjects 1

- ‘Open the Subject List page’



- This will produce a list of all the subjects associated with the study and site (e.g. User at site aa will only see aa subjects).
- You can then click on a subject in the list to open their visit schedule

Status	Study	Site	Subject ID	Subject Label	Last Modified
	<input type="text" value="All Studies"/>	<input type="text" value="All Sites"/>			
▲	PICNIC	ap	1	1505	2021/05/13 17:54:45 (GMT+)
▲	PICNIC	ap	2	E7777	2021/05/10 17:35:18 (GMT+)
●	PICNIC	ap	3	E1001	2021/05/13 14:37:41 (GMT+)

Searching for subjects 2

- ‘Open the Recent Subject List page’



- Similar to Subject List, but only shows the 10 most recent records accessed by the user

Searching for subjects 3

- ‘Open the Subject QuickView panel’



- A list of patients will open in a panel on the left of the screen
- You can scroll through the list, and then double click on a patient to access their record

Subjects QuickView
CIRCA/aa/111
CIRCA/aa/111222
CIRCA/aa/123999
CIRCA/aa/23001
CIRCA/aa/23002
CIRCA/aa/777222
CIRCA/aa/(1)
CIRCA/aa/(5)
CIRCA/aa/(6)
CIRCA/aa/(7)
CIRCA/aa/(8)
CIRCA/aa/(10)
CIRCA/aa/(11)
CIRCA/aa/(12)

Searching for subjects

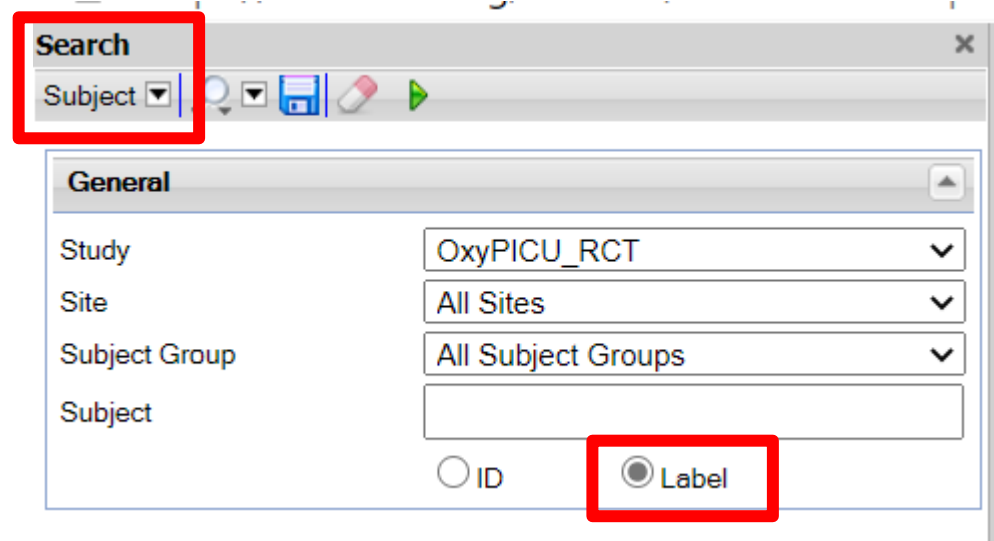
- These methods are useful if there are only a few patients at your site

Searching for subjects 4

- ‘Open the Search panel’

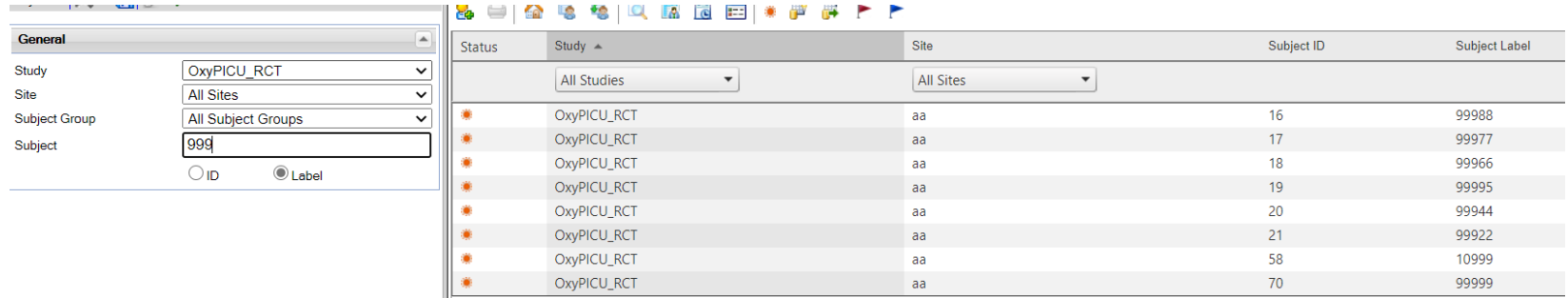


- This allows us to search for specific records by trial ID.
- Ensure the search is set to ‘Subject’ and ‘Label’



Searching for subjects 4

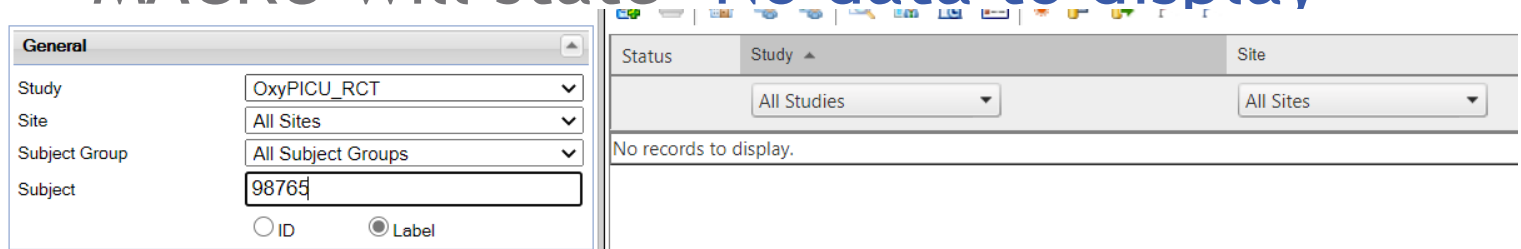
- The Subject/s you are searching for will be displayed



The screenshot shows the MACRO search interface. On the left, the 'General' tab is active, with the following settings: Study: OxyPICU_RCT, Site: All Sites, Subject Group: All Subject Groups, and Subject: 999. The search results table on the right displays the following data:

Status	Study	Site	Subject ID	Subject Label
	All Studies	All Sites		
*	OxyPICU_RCT	aa	16	99988
*	OxyPICU_RCT	aa	17	99977
*	OxyPICU_RCT	aa	18	99966
*	OxyPICU_RCT	aa	19	99995
*	OxyPICU_RCT	aa	20	99944
*	OxyPICU_RCT	aa	21	99922
*	OxyPICU_RCT	aa	58	10999
*	OxyPICU_RCT	aa	70	99999

- If the subject has not yet been created, MACRO will state 'No data to display'

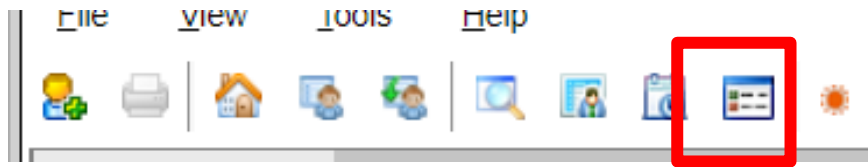


The screenshot shows the MACRO search interface with the following settings: Study: OxyPICU_RCT, Site: All Sites, Subject Group: All Subject Groups, and Subject: 98765. The search results table displays the message: 'No records to display.'

Status	Study	Site
	All Studies	All Sites
No records to display.		

Status symbols

- Symbols indicate the status and history of each data item
- ‘Open the Symbols and Function Keys panel’



- Every question is assigned status based on the responses validations built into it

Symbols and Function Keys

Status

- Invalid
- Not Applicable
- OK
- OK Warning
- Missing
- Not Available
- Warning
- Inform
- Note
- Comment

Lock/Freeze

- Frozen
- Locked


DCR

- Raised
- Responded
- Closed

Data Queries

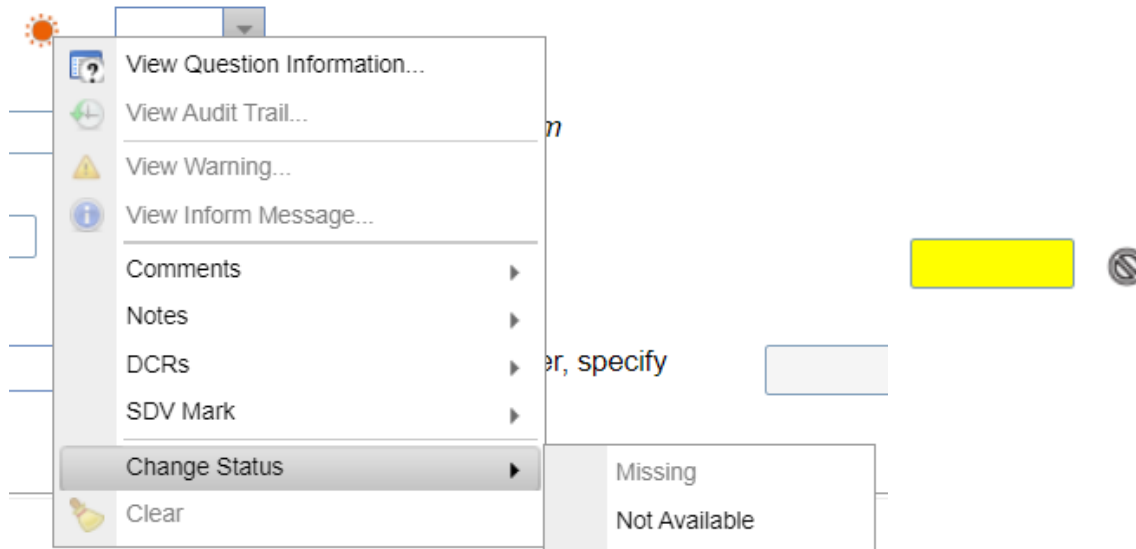
- There are 3 types of data queries that can be raised:
 - Missing Data
 - Validations
 - Data Clarification Requests (DCRs)

Missing data

- If a question is Required question, it will be chased as missing if an answer is not provided 
- If missing data cannot be resolved, questions can be marked Not Available status to stop this from being chased further.
 - Add a comment to inform the Trial Team the reason why the data is not available

Missing data

- Changing a question status to Not Available should only be done where it has been confirmed the data cannot be obtained
 - The status can be changed back to missing using the same method



Comments

- Use comments to provide any additional information to the trial team

The screenshot displays a software interface for managing trial data. A context menu is open over a question entry, with the 'Comments' option highlighted in red. The sub-menu for 'Comments' is visible, showing options: 'Add...', 'View...', and 'Remove All'. A yellow box highlights the date and time '03/04/2021 12:00' associated with the question. A 'Question Information' dialog box is open in the foreground, showing the 'Comments' tab. The dialog box contains a text area with the following comment: 'Exact time not recorded in error, estimated time of sample (+/- 30 minutes) written in notes.' The dialog box also has a 'Remove All Comments' button and a 'Close' button.

Validations

- Three types of validations, composed of a condition and message:
 - Reject: Message appears, data is deleted, no query generated
 - Warning: Message appears and a query is saved in the database
 - Inform: Message appears, no query is generated

Reject data validations

- The database rejects the answer entered and does not save the data - a new answer must be provided



Warning validations


- Warning message will appear when triggered

The screenshot shows a 'Question Information' window with a table for data entry. The table has two columns: 'Name' and 'Age (years)'. The 'Age (years)' column has a value of '101'. Below the table, there is a 'Warnings' section with the text 'The following warnings have been generated:'. A table below this section shows a warning message: 'Patient age is outside of the expected range. Please confirm if this is the correct age.' with a yellow warning icon and a checkbox.

Name	Age (years)
	101

Warnings

The following warnings have been generated:

Message	Over
 Patient age is outside of the expected range. Please confirm if this is the correct age.	<input type="checkbox"/>

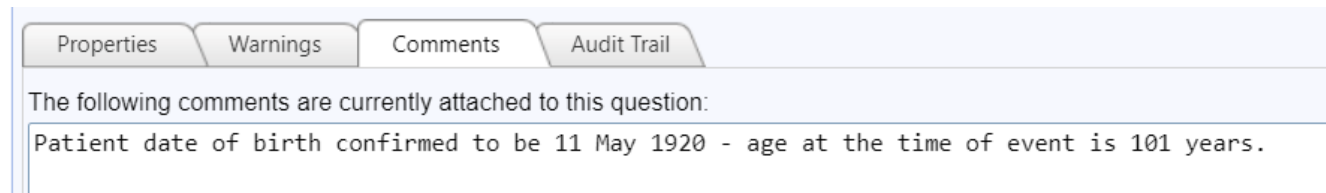
101



- Warning will close when the data is corrected where it no longer fulfils the condition, or can be overruled.

Warning validations

- If a warning fires, check the data entered to ensure it is not a data entry error.
- If the data has been verified to be correct but still fires the warning, add a comment to explain the reason




The screenshot shows a tabbed interface with four tabs: Properties, Warnings, Comments, and Audit Trail. The 'Comments' tab is selected. Below the tabs, a text area contains the following text: "The following comments are currently attached to this question:" followed by a comment box containing the text "Patient date of birth confirmed to be 11 May 1920 - age at the time of event is 101 years."

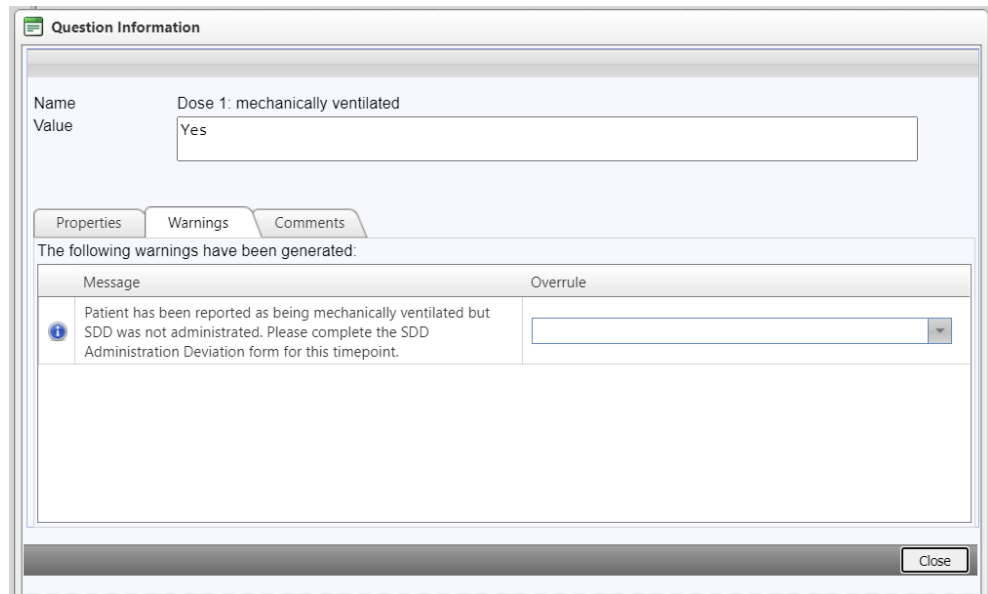
- The trial team will review the reason given, and if acceptable the warning will be overruled. 101 🍌

Inform validations

- The inform status symbol will show after the data has been entered - message does not show automatically
- Inform messages do not require any data to be amended, but provide information to the user




Mechanically Ventilated

Yes 
 No



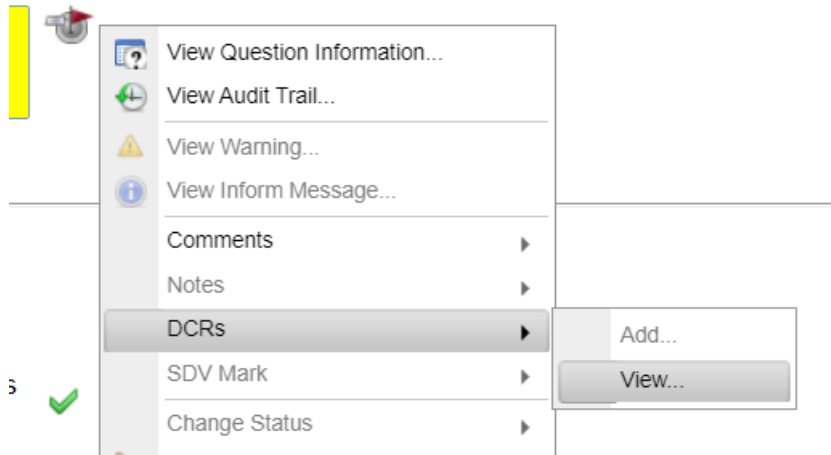
The screenshot shows a 'Question Information' dialog box. At the top, it displays 'Name: Dose 1: mechanically ventilated' and 'Value: Yes'. Below this are tabs for 'Properties', 'Warnings', and 'Comments'. The 'Warnings' tab is active, showing a message: 'The following warnings have been generated:'. A table below lists the warning: 'Patient has been reported as being mechanically ventilated but SDD was not administered. Please complete the SDD Administration Deviation form for this timepoint.' To the right of the message is an 'Override' field with a dropdown arrow. A 'Close' button is located at the bottom right of the dialog.

Data Clarification Requests (DCR)

- Data Clarification Requests are manual queries added to the database. 
- Sites can respond to DCRs, after which the blue flag appears. 
- Once the response has been reviewed by CTU staff and deemed acceptable, the query can be closed shown by a green flag. 

Data Clarification Requests (DCR)

- View and respond to a DCR



DCR Browser

Drag a column header and drop it here to group by that column

Priority	Date	Status	Subject	Visit	eForm	Question	Value	User Name
5	2021/04/22 14:18:41	Raised	UKROX/aa/100001	Randomisation	Basic data collection	Reason for withdrawal/aspects withdrawn from		Alvin Richards-Belle

Drag a column header and drop it here to group by that column

Question	Value	User Name	OC Id	Text	Unique DCR Id	Print Batch
Reason for withdrawal/aspects withdrawn from		Alvin Richards-Belle		hi	aa-19-Server	

Data Clarification Requests (DCR)

- View and respond to a DCR

Value	User Name	OC Id	Text	Unique DCR Id	Print Batch
	Alvin Richards-Belle		hi	10	Server

- Re-raise DCR
- Respond to DCR**
- Close DCR
- Edit DCR
- Set to Received

Set DCR to Responded

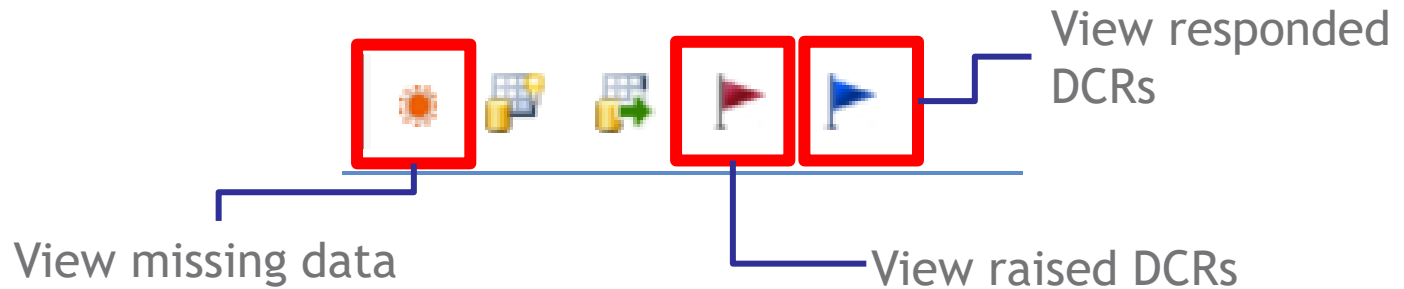
Name Reason for withdrawal/aspects withdrawn from

Text



Query management

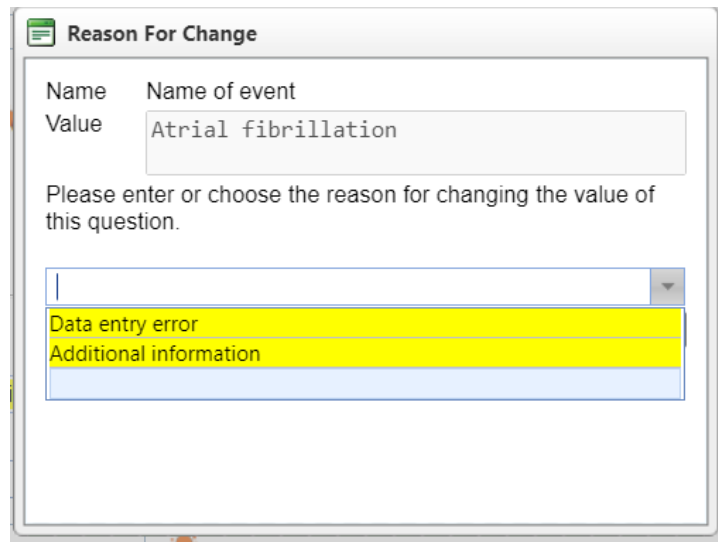
- View all missing data, raised DCRs and responded DCRs for your site



Question	Value	Date and Time
Study/Site/Subject: UKROX/ [redacted] / [redacted] 001		
Visit: Randomisation		
eForm: Basic data collection		
Consultee approached?	☀	2021/05/05 15:03:37 (GMT+1:00)
Regained capacity prior to hospital discharge?	☀	2021/05/05 15:03:37 (GMT+1:00)
Study/Site/Subject: UKROX/ [redacted] / [redacted] 002		
Visit: Randomisation		
eForm: Basic data collection		
Case Mix Programme Admission Number	☀	2021/05/05 15:05:25 (GMT+1:00)
Consultee approached?	☀	2021/05/05 15:05:25 (GMT+1:00)
Regained capacity prior to hospital discharge?	☀	2021/05/05 15:05:25 (GMT+1:00)

Reason for change

- ‘Reason for change’ will be prompted each time data are amended in MACRO after saving
- Reasons can be selected from a list or written as free text



The screenshot shows a dialog box titled "Reason For Change". It contains a table with the following information:

Name	Name of event
Value	Atrial fibrillation

Below the table, the text reads: "Please enter or choose the reason for changing the value of this question."

A dropdown menu is open, showing two options: "Data entry error" and "Additional information". Both options are highlighted in yellow.

Questions?

www.icnarc.org