MACRO Database Training

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icnarc intensive care national audit & research centre

Access to MACRO

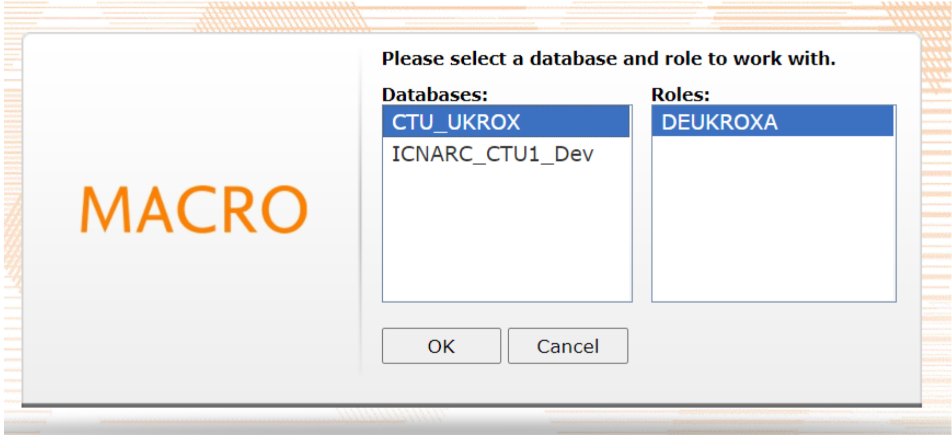
- Access to the PICnIC database is granted to staff members authorised on the delegation log once site has been greenlit
  - https://ctu.icnarc.org/macro/
- An existing training video on data entry in the web-portal is available on the website:
  - ICNARC CTU – training.icnarc.org

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



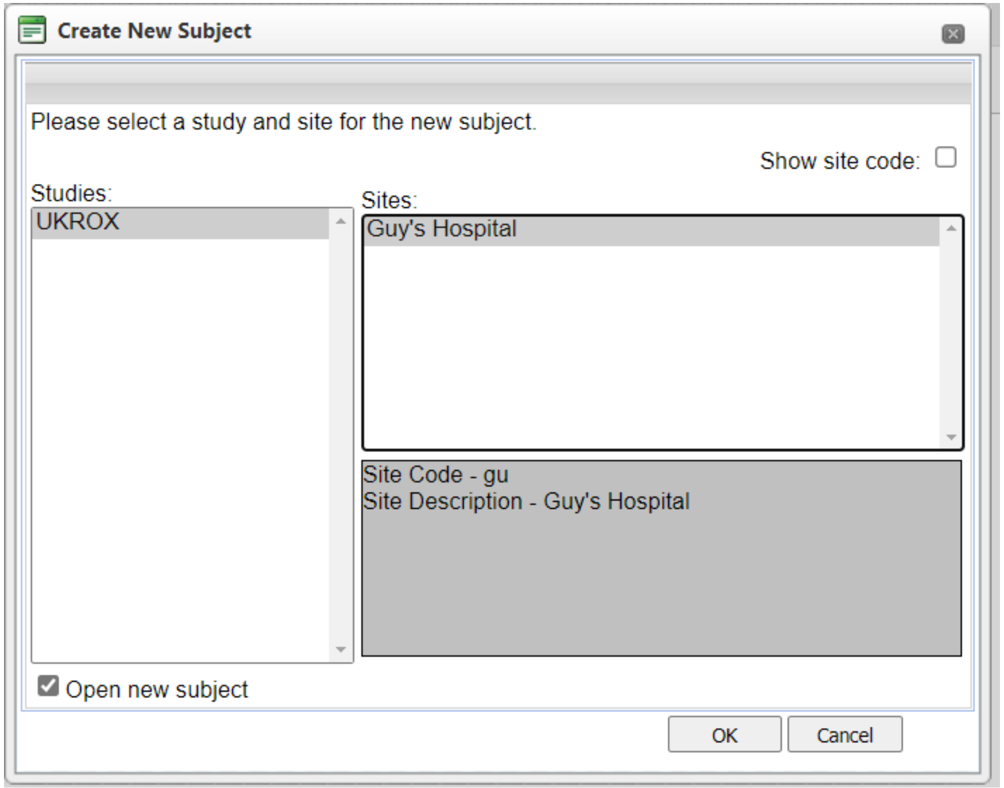
- Staff who work in more than one study can use the same MACRO account to access different databases.

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
	All Studies	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

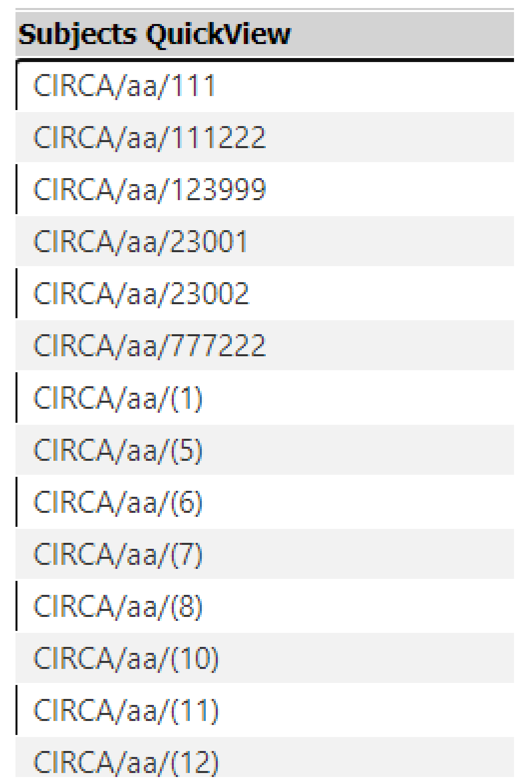
- ‘Open the Recent Subject List page’

- 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



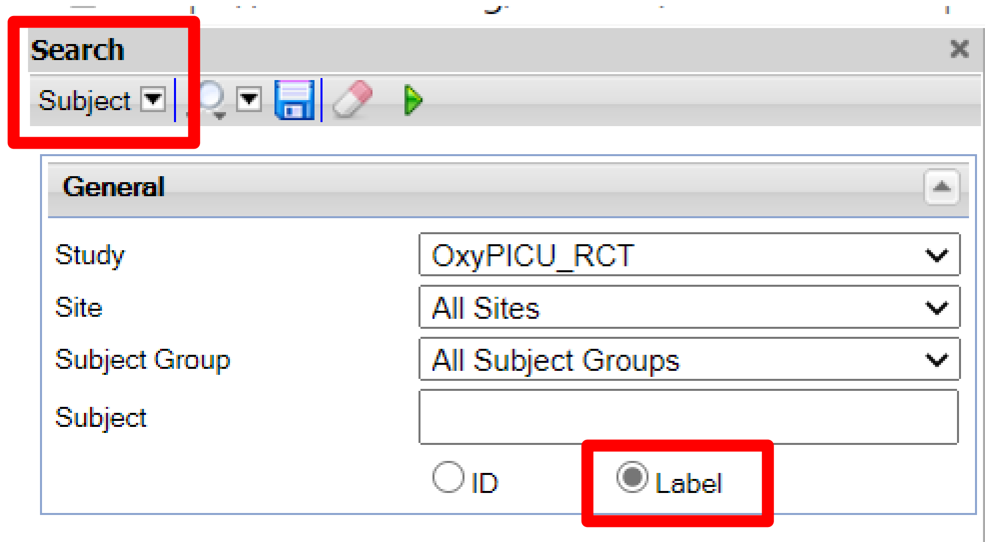
Searching for subjects

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

Searching for subjects 4

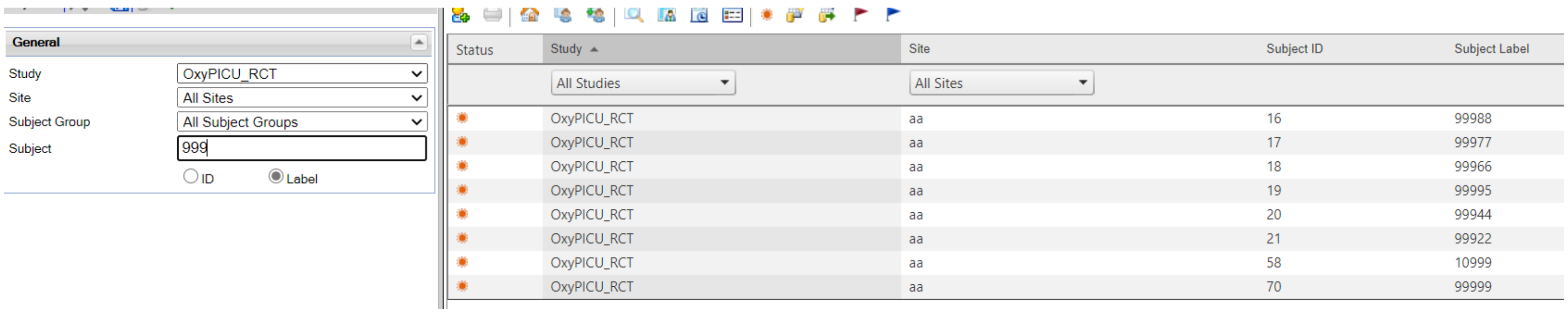
- ‘Open the Search panel’

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

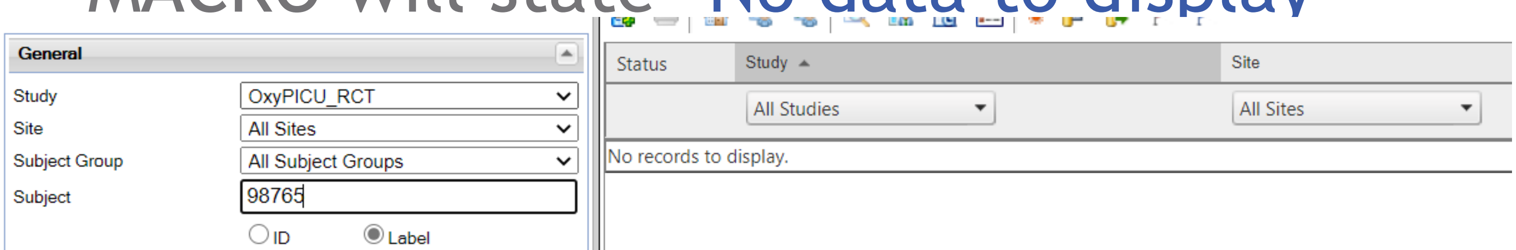


Searching for subjects 4

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

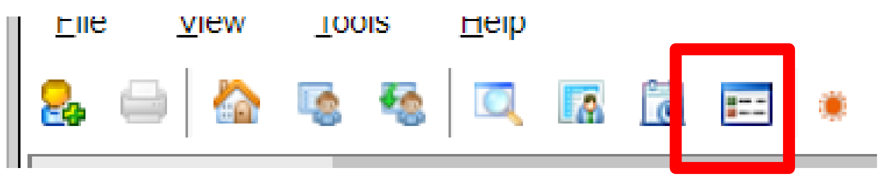


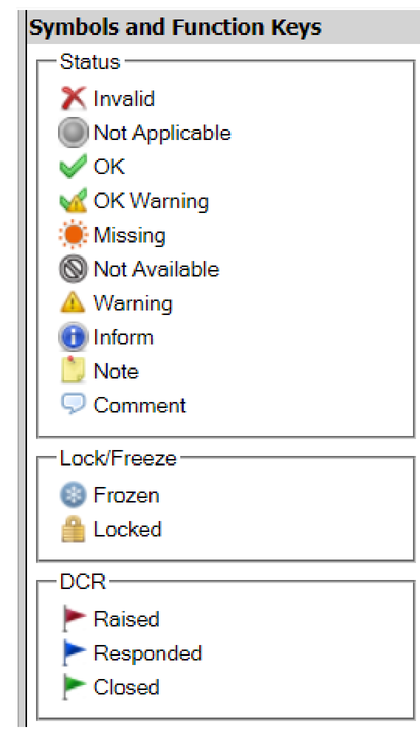
- If the subject has not yet been created, MACRO will state ‘No data to display’



Status symbols

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



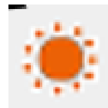


- Every question is assigned status based on the responses validations built into it

Data Queries

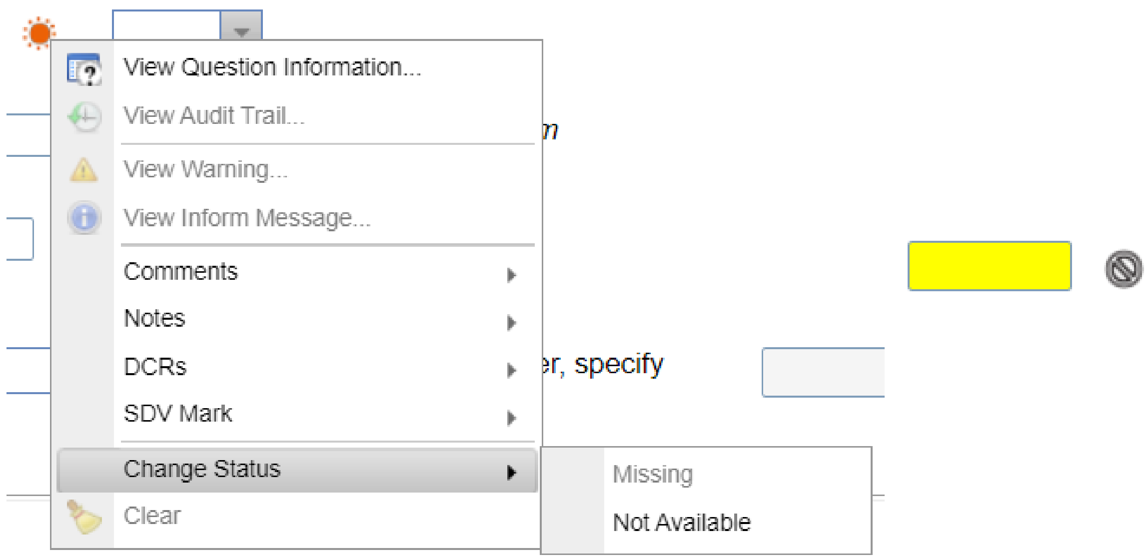
- There are 3 types of data queries that can be raised:
  - Missing Data
  - Validations
  - Data Clarification Requests (DCRs)

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



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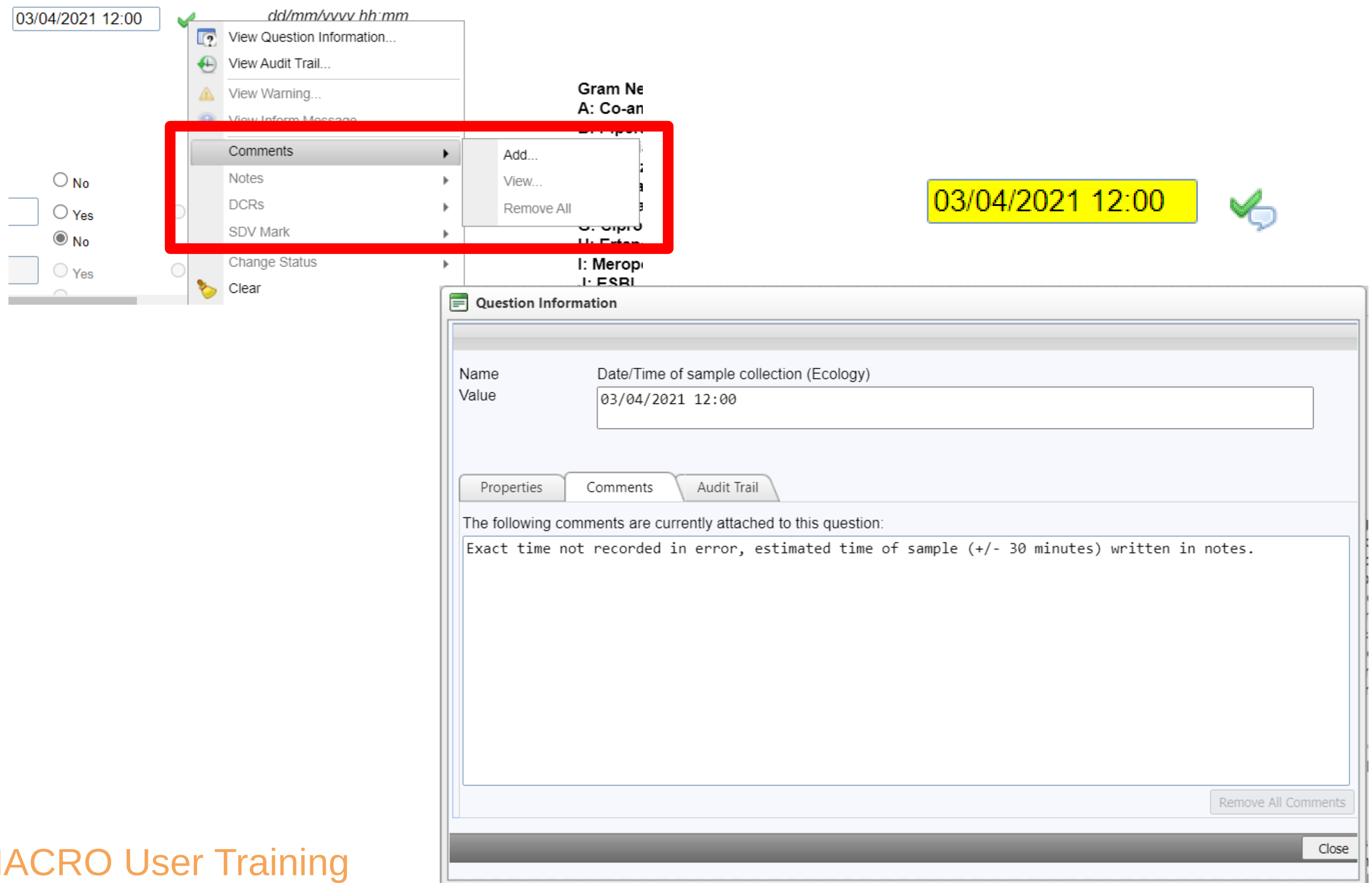
Comments

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



Validations

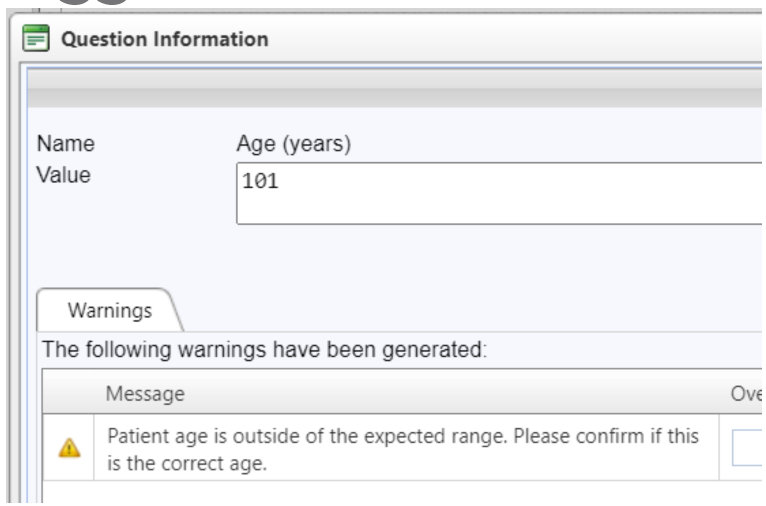
- Three types of validations, composed of a condition and message:
  - Reject: Message appears, data is deleted, no query generated
  - Warning: Message appears and a query is saved in the database
  - Inform: Message appears, no query is generated

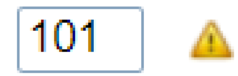
Reject data validations

- 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





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

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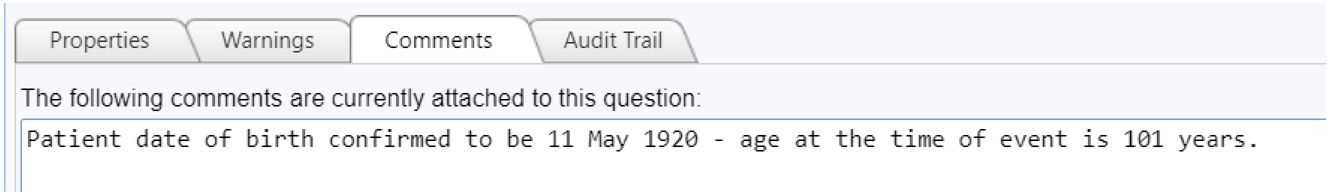
Warning validations

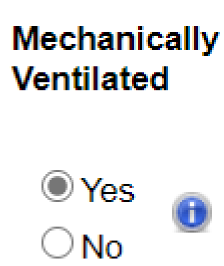
- If a warning fires, check the data entered to ensure it is not a data entry error.
- If the data has been verified to be correct but still fires the warning, add a comment to explain the reason

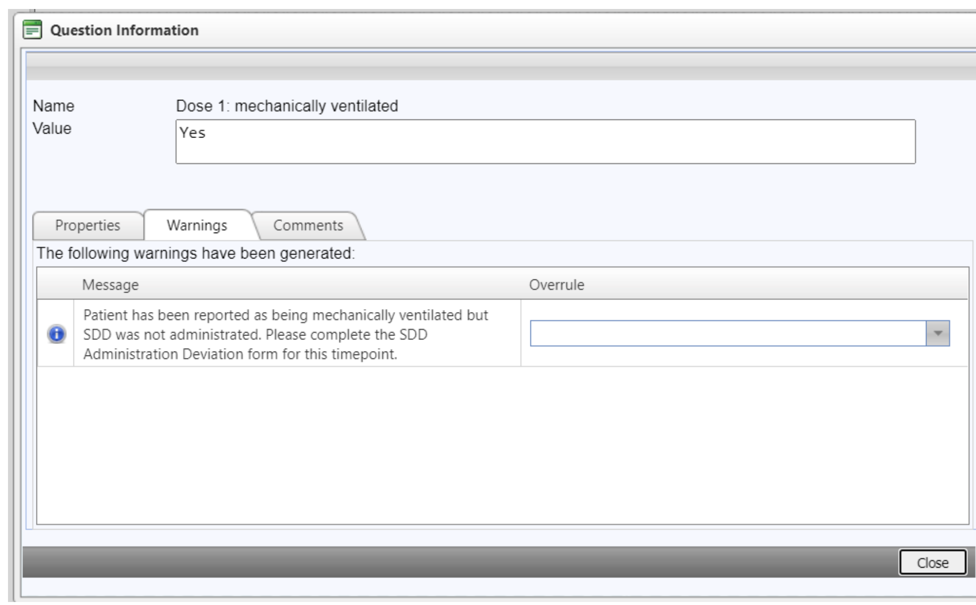


- The trial team will review the reason given, and if acceptable the warning will be overruled.

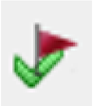
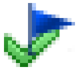
Inform validations

- 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



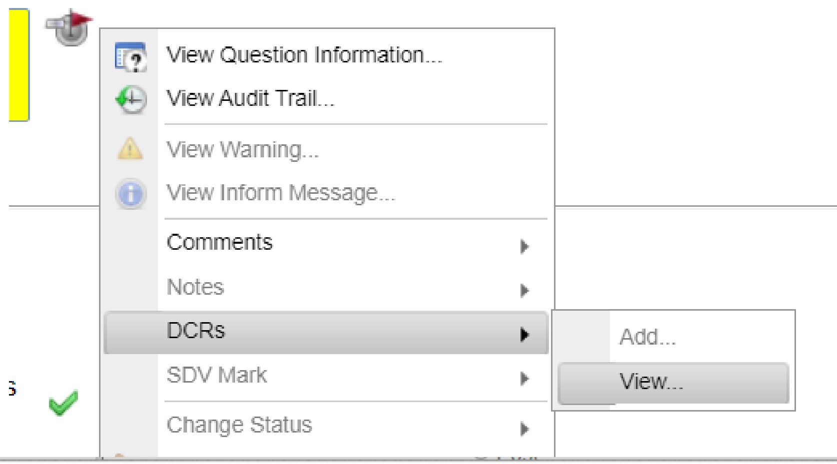


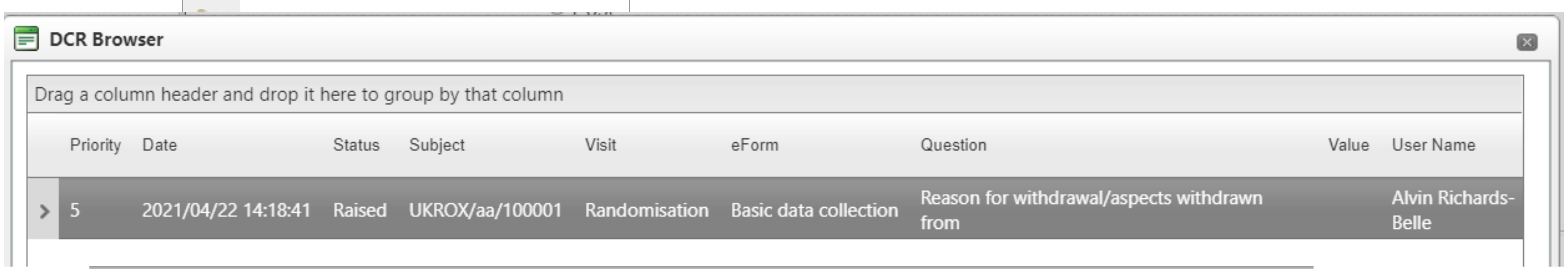
Data Clarification Requests (DCR)

- 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)

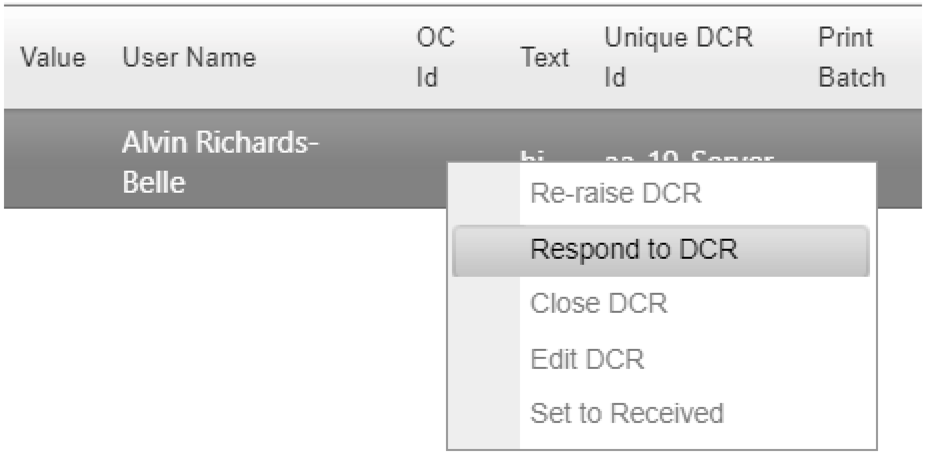
- View and respond to a DCR

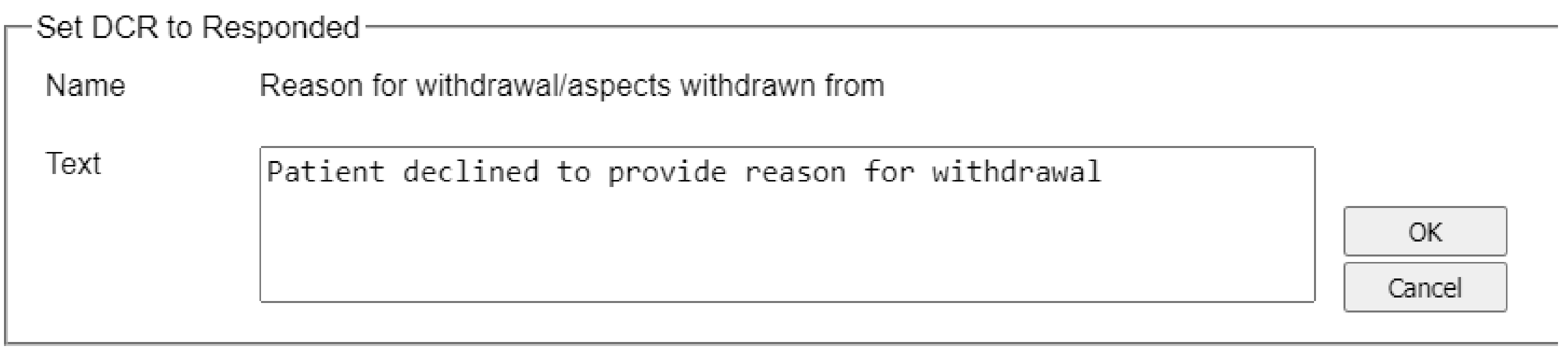


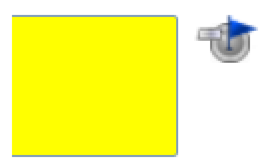


Data Clarification Requests (DCR)

- View and respond to a DCR

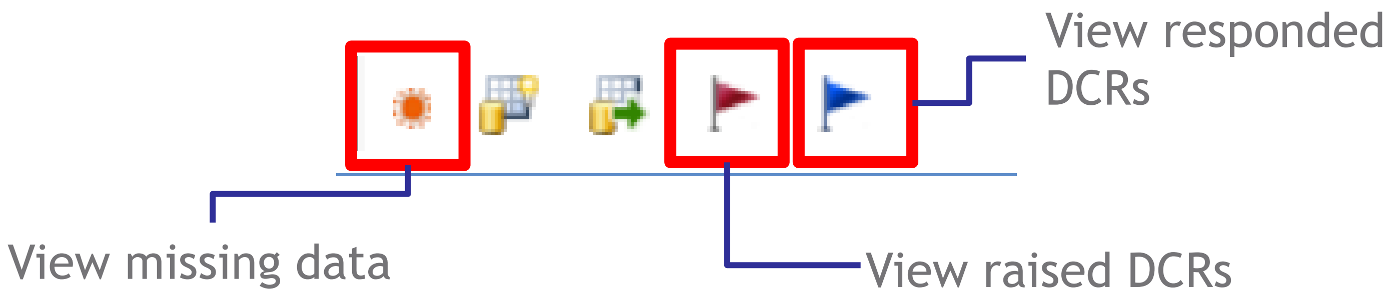






Query management

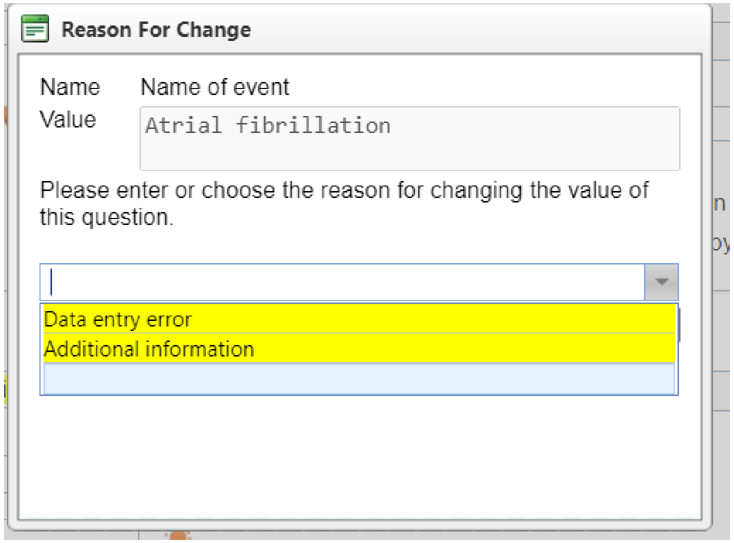
- View all missing data, raised DCRs and responded DCRs for your site



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



Questions?

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