MACRO Database Training

Carly Au
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/](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
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’

  ![Search panel screenshot]

- This allows us to search for specific records by trial ID.

- Ensure the search is set to ‘Subject’ and ‘Label’

![Search settings screenshot]
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
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.
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 following comments are currently attached to this question:

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.
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
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

<table>
<thead>
<tr>
<th>Value</th>
<th>User Name</th>
<th>OC Id</th>
<th>Text</th>
<th>Unique DCR Id</th>
<th>Print Batch</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alvin Richards-Belle</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Set DCR to Responded

Name: Reason for withdrawal/aspects withdrawn from

Text: Patient declined to provide reason for withdrawal

[Options: OK, Cancel]
Query management

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