UK-ROX MACRO Database Training
Agenda

- UK-ROX data collection and database training
- MACRO training: for new users or refresher
UK-ROX DATA COLLECTION AND DATABASE TRAINING
Overview

- MACRO is used for basic data collection, SAE and enhanced data collection
  - Sealed Envelope will be used for collection of randomisation data only
- Paper CRFs can be used optionally
- All patients randomised to UK-ROX should be entered on MACRO
Access to MACRO

- Access to the UK-ROX 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 MACRO data entry 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. You can use the password reset function to receive a temporary password via email before logging in for the first time.
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.
Homepage

- The welcome message may be updated with relevant news
Visit Schedule

- Upon initial creation of a new patient record only basic data collection will be available

<table>
<thead>
<tr>
<th>UKROX/gu/(4)</th>
<th>Randomisation</th>
<th>Treatment</th>
<th>Follow-up</th>
<th>Serious Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic data collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Basic data collection eForm

- To be completed for all patients
  - You will be regularly notified of randomised patients who have not been added to MACRO

- Randomisation details should match details on the randomisation notification email

Randomisation

- Trial Number: 333001
- Date/time of randomisation: 10/05/2021 09:45
- Treatment allocation: Conservative Oxygen Therapy

Case Mix Programme (CMP) Admission Number: 20213672

Site name: Kings College Hospital
Basic data collection eForm

- Consultee opinion - Select ‘Yes’ if a consultee was approached to provide consultee opinion on behalf of the patient and provide opinion details.

- Patient consent - Select ‘Yes’ if patient regained capacity prior to discharge from your hospital. If ‘Yes’, patient must be approached for consent.

Consent procedures

Consultee opinion

Consultee approached?
- Yes
- No

Type of consultee
- Personal consultee
- Nominated consultee

Patient consent

Regained capacity prior to hospital discharge?
- Yes
- No

Date of consent/refusal

Consent options

Continued participation and data collection?
- Yes
- No

Sharing of anonymised data?
- Yes
- No

Follow-up questionnaire?
- Yes
- No
Basic data collection eForm

- Patient details should be left blank if patient refused consent OR if consultee refused opinion and patient did not regain capacity

<table>
<thead>
<tr>
<th>Patient details</th>
<th>(leave blank if patient refused consent OR if consultee refused opinion and patient did not regain capacity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Number</td>
<td></td>
</tr>
<tr>
<td>Date of birth</td>
<td></td>
</tr>
</tbody>
</table>

- Withdrawal details can be left blank unless consent/opinion has been withdrawn

<table>
<thead>
<tr>
<th>Withdrawal of consent/opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of withdrawal</td>
</tr>
<tr>
<td>Reason for withdrawal</td>
</tr>
<tr>
<td>aspects withdrawn from</td>
</tr>
</tbody>
</table>
Basic data collection eForm

- For ICNARC use only section cannot be completed by site

For ICNARC use only

Patient number

Has this participant been selected for enhanced data collection?
- Yes
- No
Visit Schedule

- Upon completion of the basic data collection eForm, other eForms will open
  - Enhanced data collection patients

<table>
<thead>
<tr>
<th>UKROX/ga/503001</th>
<th>Randomisation</th>
<th>Treatment</th>
<th>Follow-up</th>
<th>Serious Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic data collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enhanced data collection (00:00-23:00)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enhanced data collection (08:00-07:00)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up (ICNARC only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health (ICNARC ONLY)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health services (ICNARC ONLY)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Event</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Events (ICNARC Only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Enhanced data collection

- 15% of patients
  - First 10 patients randomised at each site - the relevant forms will open automatically for these patients
  - Retrospectively selected patients - ICNARC will activate the relevant forms and will notify sites each month which patients have been selected
Visit Schedule

- Upon completion of the basic data collection eForm, other eForms will open
  - Basic data collection patients

<table>
<thead>
<tr>
<th>UKROX/tw/512832</th>
<th>Randomisation</th>
<th>Treatment</th>
<th>Follow-up</th>
<th>Serious Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic data collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Event</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Events (ICNARC Only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Enhanced data collection eForm

- Access to specific eForms is based on your role - ICU chart day start time detailed on site contacts form.

Error if user attempts to access a form not allowed for their role.
Enhanced data collection eForm

- Observations should be recorded from randomisation (day 0) up to the end of day 10, discharge from ICU, death, refusal of consent/opinion (whichever comes first).

  - Enter the date for each timepoint, a warning will fire if date entered does not match expected date

  The date entered does not match the date expected for Day 0.
  Please check the date and day number
Enhanced data collection eForm

- The date should match the ICU chart start date
  - For sites using 08:00-07:00 charts, this may mean Day 0 is the calendar date prior to randomisation

**Enhanced data collection: Day 0**

ICU chart start date: 21/05/2021
Enhanced data collection eForm

- Observations should be recorded in the hour immediately after randomisation
  - E.g. patient randomised at 09:45, observations start at 10:00

### Hourly values (08:00 - 15:00)

<table>
<thead>
<tr>
<th>Time</th>
<th>08:00</th>
<th>09:00</th>
<th>10:00</th>
<th>11:00</th>
<th>12:00</th>
<th>13:00</th>
<th>14:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory support received</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>SpO2 (%)</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>FiO2 (decimal)</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>PaO2</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>SaO2 (%)</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>If data collection ended, reason</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
</tbody>
</table>
Enhanced data collection eForm

- Observations should be recorded in the hour immediately after randomisation
  - E.g. patient randomised at 10:00 exactly, observations start at 10:00

### Hourly values (08:00 - 15:00)

<table>
<thead>
<tr>
<th>Time</th>
<th>08:00</th>
<th>09:00</th>
<th>10:00</th>
<th>11:00</th>
<th>12:00</th>
<th>13:00</th>
<th>14:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory support received</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>SpO2 (%)</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>FiO2 ( (\text{decimal}) )</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>PaO2 ( \text{mmHg/kPa} )</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>SaO2 (%)</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
<tr>
<td>If data collection ended, reason</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
<td>![Input field]</td>
</tr>
</tbody>
</table>
Enhanced data collection eForm

- Example: Patient randomised 10/05/2021 at 23:45 using 00:00-23:00 chart

### Enhanced data collection: Day 0

<table>
<thead>
<tr>
<th>Time</th>
<th>Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>21:00</td>
<td></td>
</tr>
<tr>
<td>22:00</td>
<td></td>
</tr>
<tr>
<td>23:00</td>
<td></td>
</tr>
</tbody>
</table>

### Enhanced data collection: Day 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>00:00</td>
<td></td>
</tr>
<tr>
<td>01:00</td>
<td></td>
</tr>
<tr>
<td>02:00</td>
<td></td>
</tr>
</tbody>
</table>

**Respiratory support received**

- **SpO2 (%)**
- **FiO2 (decimal)**
- **PaO2 (mmHg)**
- **SaO2 (%)**
- **If data collection ended, reason**

MACRO User Training
Enhanced data collection eForm

- Example: Patient randomised 10/05/2021 at 07:30 using 08:00-07:00 chart

Enhanced data collection: Day 0

09/05/2021

Enhanced data collection: Day 1

10/05/2021
Enhanced data collection eForm

- Required data collection on observations form:

  - PaO2 and SaO2 only need to be recorded if they are measured as part of standard care.
    - If it was not recorded at a given hour, the field can be left blank.
Enhanced data collection eForm

Observations should be recorded on the hour (+/- 15 minute time window)

Closest to measurement time
- (e.g. if measured at 14:20, record values once in 14:00)
### Enhanced data collection eForm

- **Respiratory support received:**

<table>
<thead>
<tr>
<th>Respiratory support</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Invasive mechanical ventilation</em></td>
<td>Invasive mechanical ventilatory support applied via a translaryngeal tube or applied via a tracheostomy.</td>
</tr>
<tr>
<td><em>Non-invasive ventilation (CPAP/BiPAP)</em></td>
<td>Non-invasive ventilation such as mask/helmet/hood CPAP/BiPAP.</td>
</tr>
<tr>
<td><em>HFNC</em></td>
<td>High Flow Nasal Cannula.</td>
</tr>
<tr>
<td><em>Face mask/nasal specs</em></td>
<td>Standard oxygen therapy/low flow oxygen</td>
</tr>
<tr>
<td><em>ECMO</em></td>
<td>Extracorporeal membrane oxygenation.</td>
</tr>
<tr>
<td><em>HBOT</em></td>
<td>Hyperbaric oxygen therapy.</td>
</tr>
</tbody>
</table>

- Also detailed in data collection SOP
Enhanced data collection eForm

• For all subsequent days, all timepoints will be available for entry for up to 10 days, until a reason for stopping data collection is entered.

Hourly values (16:00 - 23:00)

<table>
<thead>
<tr>
<th>Time</th>
<th>Respiratory support received</th>
<th>SpO2 (%)</th>
<th>FiO2 (decimal)</th>
<th>PaO2 (mmHg)</th>
<th>SaO2 (%)</th>
<th>If data collection ended, reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>16:00</td>
<td>Invasive mechanical</td>
<td>80</td>
<td>0.21</td>
<td>400.0</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>17:00</td>
<td>Invasive mechanical</td>
<td>81</td>
<td>0.24</td>
<td>400.0</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>18:00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Discharged</td>
</tr>
<tr>
<td>19:00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Enhanced data collection eForm

- If patient met one of the data collection stopping rules prior to the end of day 10, select code for the reason once, at the closest appropriate time-point.
  - Observations beyond this point can be left blank.

<table>
<thead>
<tr>
<th>Respiratory support</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharged alive from ICU</td>
<td>Patient was discharged from ICU, prior to the end of day 10.</td>
</tr>
<tr>
<td>Died</td>
<td>Patient died, prior to the end of day 10.</td>
</tr>
<tr>
<td>Consent/opinion refused</td>
<td>Patient/consultee refused consent/opinion, prior to the end of day 10.</td>
</tr>
</tbody>
</table>
Enhanced data collection eForm

• Trigger to identify potential deviations:
  – where SpO2 remains above 92% for three consecutive hours
  – FiO2 is not reduced or at the lower limit of 0.21

• Sites contacted to find out reasons why oxygen was not reduced
  – Important that reasons are documented locally
Follow Up eForm

- At hospital discharge details should be completed for all enhanced data collection patients

**At hospital discharge**

Status at discharge from your hospital
- Alive [✓]
- Dead

*If alive*

- Date of discharge: 23/04/2021 [✓]
- Discharge location: Home

*If other hospital, please indicate*

Ultimate discharge from hospital
- Status
  - Alive
  - Dead
- Date

MACRO User Training
Follow Up eForm

- Patient details for follow up will only be available for entry if the patient or a Consultee have agreed to questionnaire follow-up - detailed on the basic data collection form

Patient details for follow-up

<table>
<thead>
<tr>
<th>Title</th>
<th>Mr</th>
</tr>
</thead>
<tbody>
<tr>
<td>First name</td>
<td>Albus</td>
</tr>
<tr>
<td>Surname</td>
<td>Dumbledore</td>
</tr>
<tr>
<td>Address 1</td>
<td>Hogwarts</td>
</tr>
<tr>
<td>Address 2</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td>Hogsmeade</td>
</tr>
<tr>
<td>Postcode</td>
<td>MA91 C66</td>
</tr>
<tr>
<td>Country</td>
<td>Scotland</td>
</tr>
</tbody>
</table>

If patient does not speak English

Preferred language for questionnaire: French
Follow Up eForm

- Death after hospital discharge should be completed for all enhanced data collection patients, if site becomes aware of patient passing away
Follow Up

- Only the Follow-Up eForm will be completed by site
  - All other eForms are for ICNARC use only

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Site to complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up (ICNARC only)</td>
<td></td>
</tr>
<tr>
<td>Health (ICNARC ONLY)</td>
<td></td>
</tr>
<tr>
<td>Health services (ICNARC ONLY)</td>
<td></td>
</tr>
</tbody>
</table>
Serious Adverse Event Reporting eForm

- SAE Forms should be completed for all patients experiencing SAEs (both basic and enhanced data collection patients)
- All questions on this form are required
- Refer to the Safety Monitoring SOP for specific SAE completion guidance

**SAE details**

- **Name of Event**: Mesentric ischaemia
- **Severity**: Life threatening
- **Start Date/Time**: 13/04/2021 15:22
- **Date resolved**: 16/04/2021

*Must be after Date/Time of randomisation.*

*If patient died during event, use date of death.*
Serious Adverse Event Reporting eForm

- Free text fields allow sites to report event narrative and medical history
  - Do not enter any identifiable information

Event summary

Give a concise medical description (including dates) of all relevant diagnoses, symptoms, test/lab results and treatments. Include SpO2 values. If Event was fatal, then give cause of death if known.

06/05/2021 04:30 developed sinus tachycardia, followed by atrial fibrillation. ECG taken. Administered amiodarone 300mg IV at 06:31, then 900mg over 24 hours. SpO2 52%. Admitted for acute pancreatitis
Serious Adverse Event Reporting eForm

- Member of staff assessing SAE must be entered
  - Must be authorised to assess severity and relatedness on Site Delegation Log
- Member of staff reporting SAE is optional, only to be entered if different

Local sign off

SAE Assessed by: Dr Jones
Medically qualified investigator on delegation log

Date: 13/04/2021

Reported by (if different):

Date: 

MACRO User Training
Missing data

- Required questions will be chased as missing
  - If values are not available, mark as Not Available and provide a reason

The following comments are currently attached to this question:

Respiratory support received was not recorded in notes in error. Corrective action plan discussed with UK-ROX Trial Team on 09/05/2021
Database validations

- Validations are programmed in the database to check data at the point of entry
  - Reject data validations must be resolved by providing data within the permitted conditions
Database validations

- Validations are programmed in the database to check data at the point of entry
  - Warning validations will allow data to be entered
    - Check the value entered and amend the data if required. If confirmed to be correct, add a comment to explain
    - UK-ROX team will review comments and if acceptable will overrule the warning
Data Clarification Requests

- Data Clarification Requests (DCRs) will be added with specific queries relating to data entered
- DCR responses will be reviewed by the trial team and closed if the response is sufficient
Missing pages

- Notifications of missing data will be sent regularly

<table>
<thead>
<tr>
<th>TrialNo</th>
<th>Message</th>
<th>Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456</td>
<td>The Basic Data Collection page for this patient is incomplete. Please can you update this page?</td>
<td>N/A</td>
</tr>
<tr>
<td>123456</td>
<td>The Enhanced Data Collection page for this patient is incomplete. Please can you update this page?</td>
<td>0</td>
</tr>
<tr>
<td>123456</td>
<td>The Enhanced Data Collection page for this patient is incomplete. Please can you update this page?</td>
<td>2</td>
</tr>
<tr>
<td>123456</td>
<td>The Follow Up page for this patient is missing. Please can you update this page?</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- Please review the queries and enter any missing data or set as Not Available and explain the reason why
Questions?

- Any UK-ROX database specific questions?

uk-rox@icnarc.org

020 7269 9277

icnarc.org/Our-Research/Studies/UK-ROX
MACRO USER TRAINING
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 studies and 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 number 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.
Subject list

- Use filters to adjust the subject list
- **Subject ID** is assigned chronologically each time a patient is created - this does not need to correspond with the trial number
- **Subject label** refers to the trial number

<table>
<thead>
<tr>
<th>Status</th>
<th>Study</th>
<th>Site</th>
<th>Subject ID</th>
<th>Subject Label</th>
<th>Last Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UKROX</td>
<td>sc</td>
<td>1</td>
<td>419001</td>
<td>2021/06/10 13:23:44 (GMT+1:00)</td>
</tr>
<tr>
<td></td>
<td>UKROX</td>
<td>sc</td>
<td>2</td>
<td>419002</td>
<td>2021/06/11 12:27:09 (GMT+1:00)</td>
</tr>
<tr>
<td></td>
<td>UKROX</td>
<td>sc</td>
<td>3</td>
<td>419003</td>
<td>2021/06/17 10:59:35 (GMT+1:00)</td>
</tr>
<tr>
<td></td>
<td>UKROX</td>
<td>sc</td>
<td>4</td>
<td></td>
<td>2021/06/16 14:10:15 (GMT+1:00)</td>
</tr>
</tbody>
</table>
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 number.

- 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 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
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

- Right click on the question to open the menu

Date/ Time of liberation from respiratory support*
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

- Message appears as soon as data entered

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

- To view a warning
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.

Patient date of birth confirmed to be 11 May 1920 - age at the time of event is 101 years.
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

<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>hi</td>
<td>a 10 Server</td>
<td>Re-raise DCR</td>
<td>Respond to DCR</td>
</tr>
</tbody>
</table>

Set DCR to Responded

- Name: Reason for withdrawal/aspects withdrawn from
- Text: Patient declined to provide reason for withdrawal

MACRO User Training
Query management

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

View missing data
View raised DCRs
View responded DCRs

<table>
<thead>
<tr>
<th>Question</th>
<th>Value</th>
<th>Date and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study/Site/Subject: UKROX/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit: Randomisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>eForm: Basic data collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultee approached?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regained capacity prior to hospital discharge?</td>
<td></td>
<td></td>
</tr>
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<td>Study/Site/Subject: UKROX/</td>
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<td>Case Mix Programme Admission Number</td>
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</table>

MACRO User Training
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?

- datamanagement@icnarc.org