



The Threshold for Platelets study: Database Training

Agenda

- T4P data collection and database training
- MACRO training: for new users or refresher

T4P Data Collection and Database Training

Overview

- MACRO is used for all data collection except randomisation
 - Sealed Envelope will be used for collection of randomisation data only
- Paper worksheets can be used optionally (apart from the Randomisation Form)
- All patients randomised to T4P should be entered on MACRO

Access to MACRO

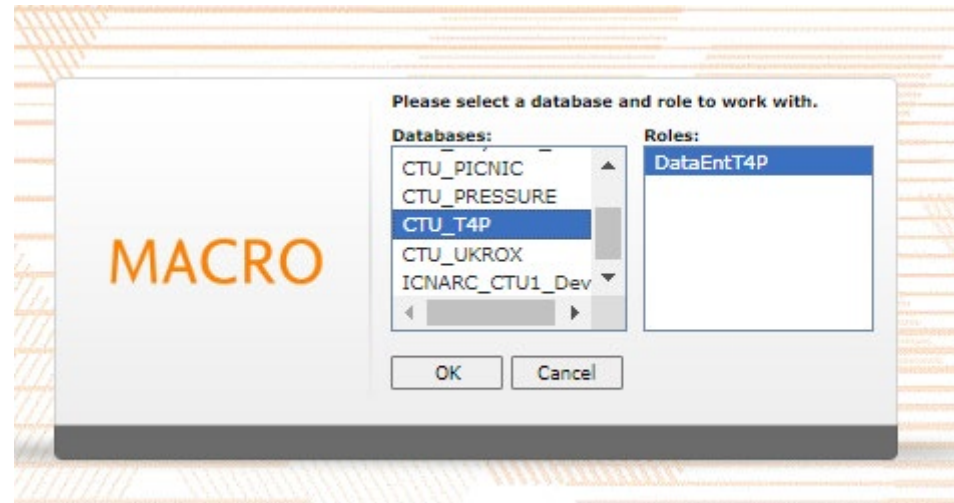
- Access to the T4P database is granted to staff members authorised on the delegation log once it has been greenlighted for recruitment
 - <https://ctu.icnarc.org/macro/>
- An existing training video on MACRO data entry is available on the website:
 - [ICNARC CTU - training.icnarc.org](https://www.icnarc.org/training)

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 the Randomisation Form will be available

T4P/ba/(6)	Screening	Baseline	Observations Day	Consent	Outcomes	Serious Adverse Events	Follow up 90 days	Follow up 12 months
Randomisation								
Baseline Data								
Daily Data Page 1								
Daily Data Page 2								
Daily Data Page 3								
Deviation								
Consent								
Withdrawal of consent								
Outcomes								
Serious Adverse Events								
Survival Status 90 Days								
Survival status 12 months								

Randomisation Form


- To be completed for all patients
 - You will be regularly notified of randomised patients who have not been added to MACRO
- Upon completion of the Randomisation Form, other Forms will open

T4P/ba/202210	Screening	Baseline	Observations Day	Consent	Outcomes	Serious Adverse Events	Follow up 90 days	Follow up 12 months
	✓							
Randomisation	✓							
Baseline Data								
Daily Data Page 1								
Daily Data Page 2								
Daily Data Page 3								
Deviation								
Consent								
Withdrawal of consent								
Outcomes								
Serious Adverse Events								
Survival Status 90 Days								
Survival status 12 months								

Baseline Data Form

- This form needs to be completed on Day 1 (i.e., day of randomisation)

Baseline Data



Trial ID

Admission Details

Date/Time Critical Care Unit Admission
(dd/mm/yyyy hh:mm 24-hour clock)


Unit ID for CMP

Platelet transfusions prior to randomisation

Platelet transfusions received in 24 hours prior to randomisation

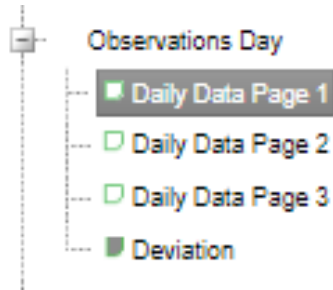
Anti-platelet therapies prior to randomisation

Has the patient received any anti-platelet therapies in the past 7 days prior to randomisation? Yes No



Daily Data Forms

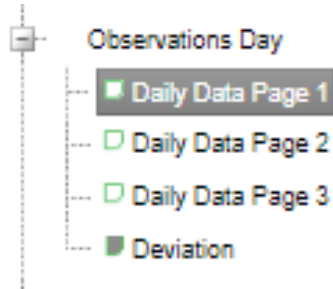
- Daily Data is split into 3 pages



- Complete all 3 pages for each day

Daily Data Forms

- Daily Data is split into 3 pages



- Please note: Day 1 is the day of randomisation
 - This will potentially be a partial day. E.g., Patient is randomised at 16:00. Day 1 will finish at 23:59 on that day
- Final Day is the last day in critical care unit from 00:00 until discharge, death or refusal of consent for further data collection
- If patient is readmitted → re-start data Daily Data collection until ultimate discharge

Daily Data Page 1

- Enter the Trial ID and date
- Enter the reason of why daily data collection has ended if applicable. This will stop creating further Daily Data Pages
- If patient is re-admitted. Clear the response and save the form. This will then allow you to continue entering data.

Daily Data Page 1 of 3



Date

Trial ID

If data collection ended, reason
Please ensure that all forms
(Daily Data Pages 1, 2 and 3) are
saved after completing this question

- Discharged
- Died
- Refused consent

Daily Data Page 1

Platelet count & haemoglobin concentration

- Record all lab results on this day.
- If none → NR (not recorded)
- Otherwise:
 - Enter time when sample was collected
 - Platelet count
 - Haemoglobin concentration

Platelet count & haemoglobin concentration (list all recorded measurements taken in this day)

Record central laboratory results only (ie not from ABGs / bedside tests etc)

If none, tick 'not recorded' (NR) NR

Select haemoglobin units g/l
 g/dl

Time sample collected
(24 hour-clock)

Platelet count (x10⁹L)

Haemoglobin

Daily Data Page 1

Co-interventions

- The CRF Guidance document lists examples of procoagulant, anticoagulant and anti-platelet therapies under each section to help identify these in the medical notes

Co-interventions

Blood components/ products (excluding platelets)

Packed red blood cells	<input type="radio"/> Yes <input type="radio"/> No	If yes, specify number of units <input type="text"/>
Fresh frozen plasma	<input type="radio"/> Yes <input type="radio"/> No	
Cryoprecipitate / fibrinogen concentrate	<input type="radio"/> Yes <input type="radio"/> No	
Clotting factor concentrates	<input type="radio"/> Yes <input type="radio"/> No	

Procoagulant therapies

Received systemic procoagulant therapies: Yes
 No

Anticoagulant therapies

Received systemic anticoagulant therapies: Prophylactic dose
 Other dose
 None

Anti-platelet therapies

Received anti-platelet therapies: Yes
 No

Daily Data Page 2

Low bleeding risk procedures

- If yes
 - Select procedure on Tables 1 and/or 2
 - Procedures can be selected multiple times
 - If low bleeding risk procedure is not in either table
 - Select other and state which low bleeding risk procedure has been undertaken

Received low bleeding risk invasive procedure today? Yes No ?

TABLE 1:
Low bleeding risk invasive procedure list

Procedure	Start time of procedure	Was the platelet count prior to procedure below allocated threshold?	Platelet
Femoral vascular catheter insertion	13:00 ✓	<input type="radio"/> Yes <input checked="" type="radio"/> No ✓	<input type="radio"/> Yes <input checked="" type="radio"/> No
		<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No

TABLE 2:
Additional low bleeding risk procedure(s)

Procedure	Procedure (Other)	Start time of procedure	Was the platelet count prior to procedure below allocated threshold?	Platelet
Bronchoscopy (with or without lavage)		18:00 ✓	<input type="radio"/> Yes <input checked="" type="radio"/> No ✓	<input type="radio"/> Yes <input checked="" type="radio"/> No
			<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No

Daily Data Page 2

TABLE 1:
Low bleeding risk invasive procedure list

	Start time of procedure	Was the platelet count prior to procedure below allocated threshold?	Platelet transfusion given for procedure?
lion	13:00 ✓	<input type="radio"/> Yes ✓ <input checked="" type="radio"/> No	<input type="radio"/> Yes ✓ <input checked="" type="radio"/> No
		<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No

- Enter start time
- The most current platelet count should have been used to guide intervention
- Reference to platelets given prophylactically for the procedure
 - IF!
 - ‘Yes’ was answered to platelets being below allocated threshold and NO was answered for platelet transfusion given OR vice versa → A warning will appear prompting you to complete a deviation form:

The following warnings have been generated:

Message	Override
⚠ Please complete the platelet administration deviation form	<input type="text"/>

Daily Data Page 3

Bleeding episodes

- None
- Expected minor bleeding
- Minor but outside expected bleeding
- Major
- Fatal

If any bleeding episode meets the definition for a major or fatal bleed (HEME definitions), then please report as a SAE

Platelet transfusions

- If yes
 - Enter start time
 - Number of units (min. 1)
 - Reason

Organ support received

(Please complete if your unit is not on v.4 of CMP)

Is your unit on v.4 of the Case Mix Programme (CMP)? Yes No ✓

Advanced respiratory Yes No ✓

Advanced cardiovascular Yes No ✓

Renal replacement therapy Yes No ✓

T4

Bleeding episodes

- If any MAJOR or FATAL → Report SAE

Platelet transfusions

Platelets transfusions received today? Yes No ✓

Time transfusion started	Number of units	Reason platelet transfusion given	Reason platelet transfusion given (other)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Organ Support

- If your unit is not on CMP V4 → required to complete all fields

Deviation

- Select the main reason why the deviation occurred. Only one answer from scenario 1 or 2 can be selected.
- If another deviation needs to be reported → select ‘YES’

Date/ Time of deviation ✓
 (dd/mm/yyyy) (hh:mm 24-hour clock)

Reason for deviation

Platelet count greater than allocated threshold, but platelet transfusion given before/during low bleeding risk invasive procedure

Select main reason

Other, specify:

OR

Platelet count less than allocated threshold, but platelet transfusion not given before/during low bleeding risk invasive procedure

Select main reason

Other, specify:

Are there any further deviations to report?

Yes
 No

Consent

Patient had capacity to consent prior to randomisation Yes No ✓

Patient regained capacity prior to hospital discharge Yes No ✓

Patient died before obtaining consent Yes No ✓

Consultee opinion

Consultee approached? Yes No ✓

Type of consultee Personal Nominated

Name of nominated consultee

Mode of consent In-person Telephone Post

Date of consultee agreement/ refusal

Consultee opinion options

Continued participation and data collection? Yes No

Follow-up questionnaires? Yes No

Patient consent

Mode of consent In-person Telephone Post *If approached but not yet consented, select mode of approach. If consent then obtained, update the mode of consent*

Date of 1st phone call

Date of 2nd phone call

Date of 3rd phone call

Date letter sent (dd/mm/yyyy)

Response received within 4 weeks? Yes No

Date of consent/ refusal (dd/mm/yyyy)

Consent options

Continued participation and data collection? Yes No

Follow-up questionnaires? Yes No

Receiving summary of trial results? Yes No

Contacted for future research? Yes No

Consent Withdrawal

- If previously given consent/opinion is withdrawn please complete the consent withdrawal form
- If at least one option on the Consent form has been answered 'Yes' the Withdrawal of Consent form will be available for entry

Trial ID

Date of withdrawal of consent
(dd/mm/yyyy)

Withdrawn by Patient Consultee

Withdrawn from:
Select all that apply

Continued trial participation Yes No

Continued data collection Yes No

Access to NHS Digital, Digital Health and Care Wales and Case Mix Programme Yes No

Follow-up questionnaire Yes No

Receiving summary of trial results Yes No



Being contacted for future research Yes No


Reason for withdrawal (if provided)

Outcomes





- Date of discharge from your critical care unit should be the same as the final observations day date
- Record all re-admission(s) and discharge(s) as appropriate.

Discharge from your critical care unit

Status at discharge from your critical care unit Alive Dead  Date of death 
(dd/mm/yyyy)

Date/time of discharge 
(dd/mm/yyyy hh:mm 24-hour clock)

Readmitted to your critical care unit

	Date/time readmitted	Status at discharge from readmission	Date/time of discharge	Date of death
1.	<input type="text"/>	<input checked="" type="radio"/> Alive <input type="radio"/> Dead	<input type="text"/> 	<input type="text"/>  <small>(dd/mm/yyyy)</small>
2.	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead	<input type="text"/> 	
3.	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead	<input type="text"/> 	

Outcomes

- Enter details of thrombosis episodes
- Enter details of discharge from your hospital for this admission
- Ultimate* discharge from hospital may be from your hospital, or another hospital if they were discharged there
 - This may require communication with the receiving hospital team to find out ultimate discharge

• latest documented date of the admission being physically within an acute in-patient bed in an acute hospital, the acute hospital care having been continuous since discharge from your unit

Thrombosis

Venous or arterial thrombosis diagnosed during this hospital admission Yes No ✓

Date of diagnosis ✓
(dd/mm/yyyy)

Discharge from hospital

Status at discharge from your hospital Alive Dead ✓ → Date of death ⌵

If alive

Date of discharge ✓

Discharge location Home Nursing home Other hospital ✓ Rehabilitation centre Other →

Discharge to other hospital Ward Critical care unit ⌵

Specify if other location ⌵ Enter name of hospital

Ultimate discharge from hospital ⌵ Status Alive Dead ⌵
(dd/mm/yyyy)

Death after hospital discharge

Date of death ⌵

SAE

- If SAE is withdrawn please click 'yes' and state withdrawal date
- Every time the form is modified the PI or assigned delegate will need to sign it off to confirm the changes

SAE withdrawn? Yes SAE ID:

SAE withdrawn date

Local sign off

PI (or delegate) must re-sign each time this form is updated or changed

Assessed by
(print name)

1.

I agree with the information provided in this SAE report, and its assessment

Survival Status 90 Days and 12 Months

- Sections will be available for data entry once the time point has passed. Complete forms as close after the due date as possible (i.e., Day 91 and Day 366)

Date 90 days following randomisation

What is the survival status as of 90 days following randomisation?

Alive

Dead

Unable to ascertain

Date (dd/mm/yyyy)

If alive, record date status confirmed
If dead, record date of death on the outcome CRF
If unable to ascertain, record date last known alive

If unable to ascertain, please record reason

Reason unable to ascertain survival status

Missing data

- Required questions will be chased as missing
- Notifications of missing data will be sent regularly
 - Please review the queries and enter any missing data or set as Not Available and explain the reason why

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
 - T4P 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

Questions?

- Any T4P database specific questions?

MACRO User Training

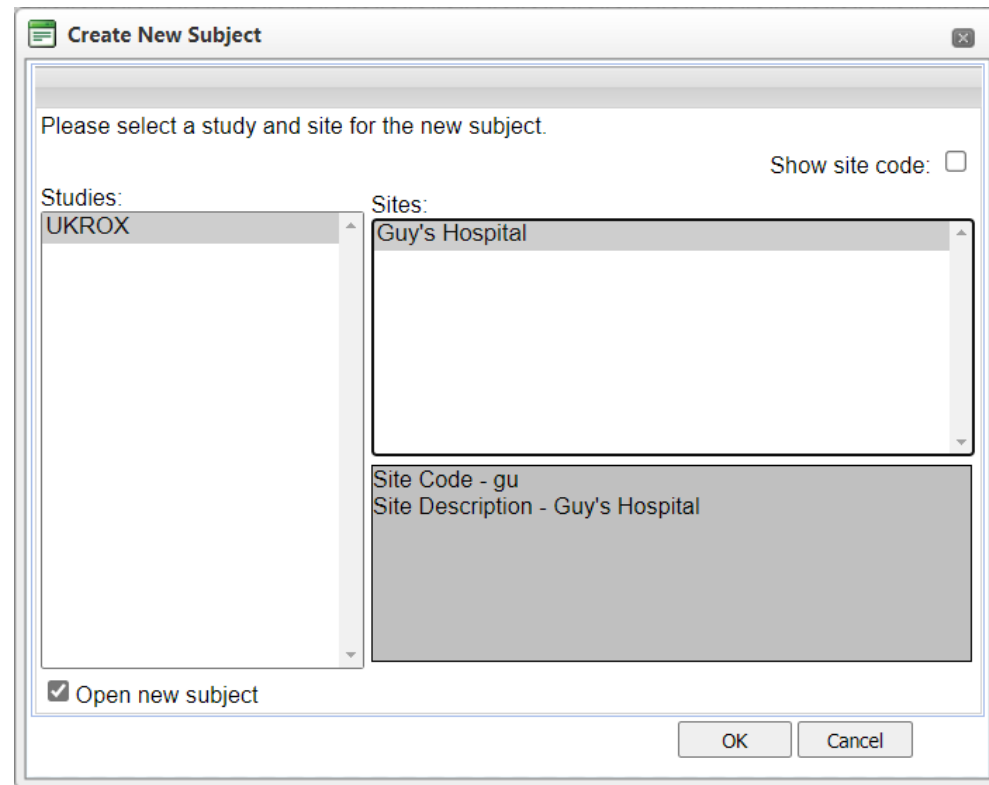
Creating new subjects

- 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



Searching for subjects

- ‘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
	FirstABCstudy ▼	All Sites ▼			
▲	FirstABCstudy	aa	1	99999D	2019/08/08 15:25:29 (GMT+)
▲	FirstABCstudy	ab	1	12345U	2019/08/08 12:23:03 (GMT+)
▲	FirstABCstudy	aa	2	67001D	2019/08/05 14:16:31 (GMT+)
☀	FirstABCstudy	aa	3		2019/07/25 09:52:01 (GMT+)
▲	FirstABCstudy	aa	4	12312U	2019/08/05 17:21:22 (GMT+)

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

Status	Study	Site	Subject ID	Subject Label	Last Modified
	All Studies ▼	sc ▼			
 	UKROX	sc	1	419001	2021/06/10 13:23:44 (GMT+1:00)
	UKROX	sc	2	419002	2021/06/11 12:27:09 (GMT+1:00)
	UKROX	sc	3	419003	2021/06/17 10:59:35 (GMT+1:00)
	UKROX	sc	4		2021/06/16 14:10:15 (GMT+1:00)

Searching for subjects 2

- ‘Open the Recent Subject List page’

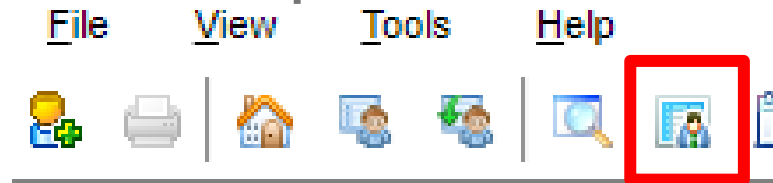


- Similar to Subject List, but only shows the 10 most recent records accessed by the user

Status	Study ▲	Site	Subject ID	Subject La
	All Studies ▼	All Sites ▼		
⚠	CIRCA	ad	2	999222
⚠	CIRCA	aa	14	777222
⚠	CIRCA	ai	11	333999
⚠	FirstABCstudy	aa	39	22222U
⚠	FirstABCstudy	aa	1	99999D
⚠	FirstABCstudy	aa	49	10002D
⚠	FirstABCstudy	aa	16	29999U
⚠	OxyPICU_RCT	aa	50	20292
⚠	REMAPCAP	aa	36	2029000
⚠	REMAPCAP	aa	39	1017000

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

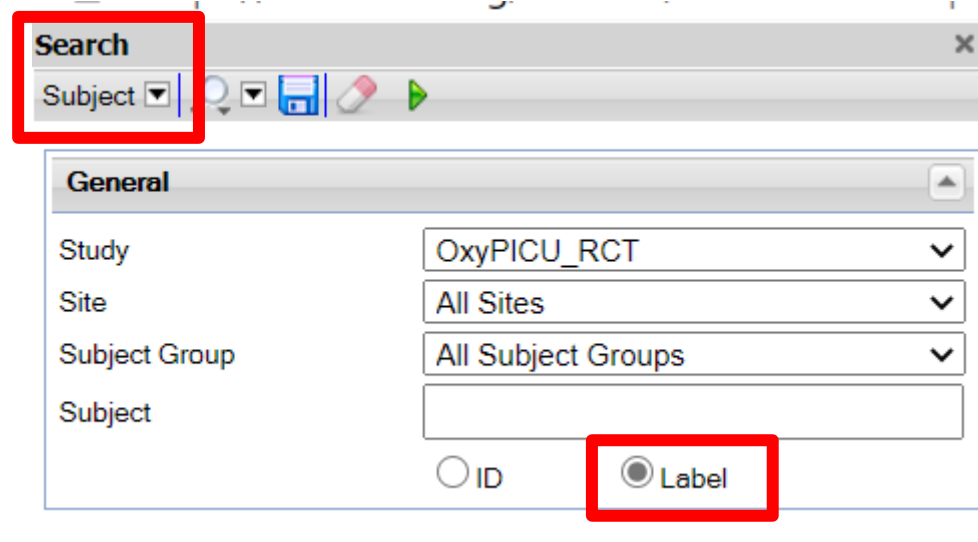
- These methods are useful if there are only a few patients at your site

Searching for subjects 4

- ‘Open the Search panel’



- This allows us to search for specific records by trial number.
- 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 'General' search panel on the left 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
*	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

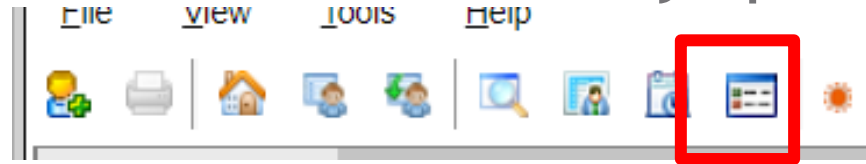
- If the subject has not yet been created, MACRO will state 'No records to display'

The screenshot shows the 'General' search panel on the left with the following settings: Study: OxyPICU_RCT, Site: All Sites, Subject Group: All Subject Groups, and Subject: 98765. The search results table on the right displays the following data:

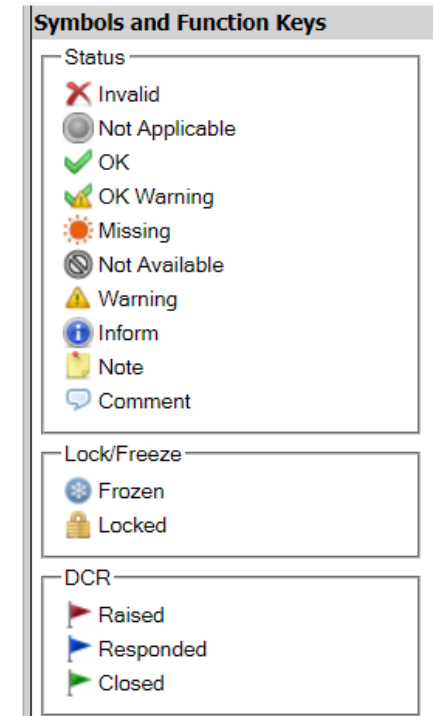
Status	Study	Site
No records to display.		

Status symbols

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




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



Data Queries

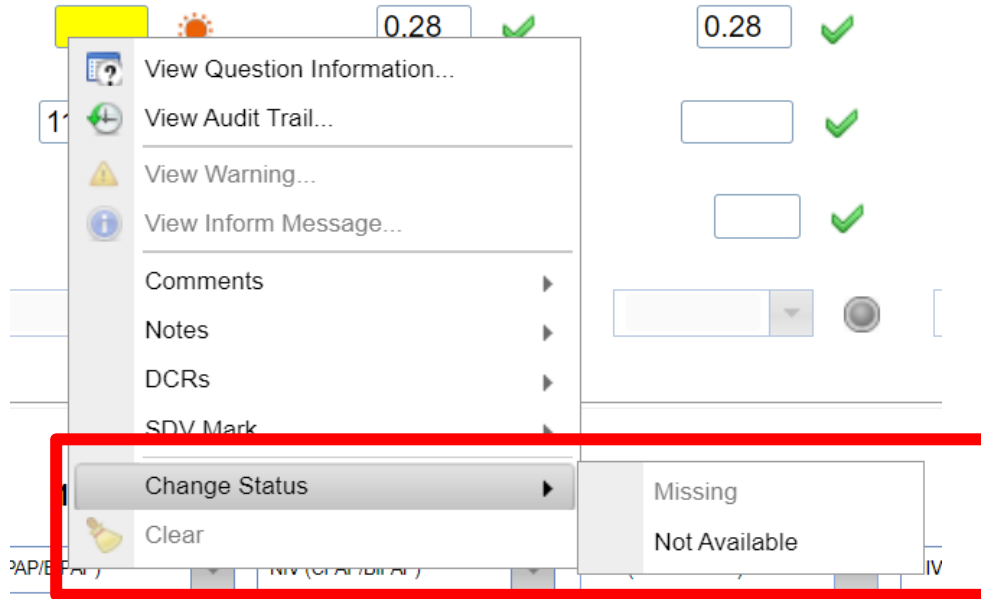
- There are 3 types of data queries that can be raised:
- Missing Data
- Validations
- Data Clarification Requests (DCRs)

Missing data

- If a question is Required, 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

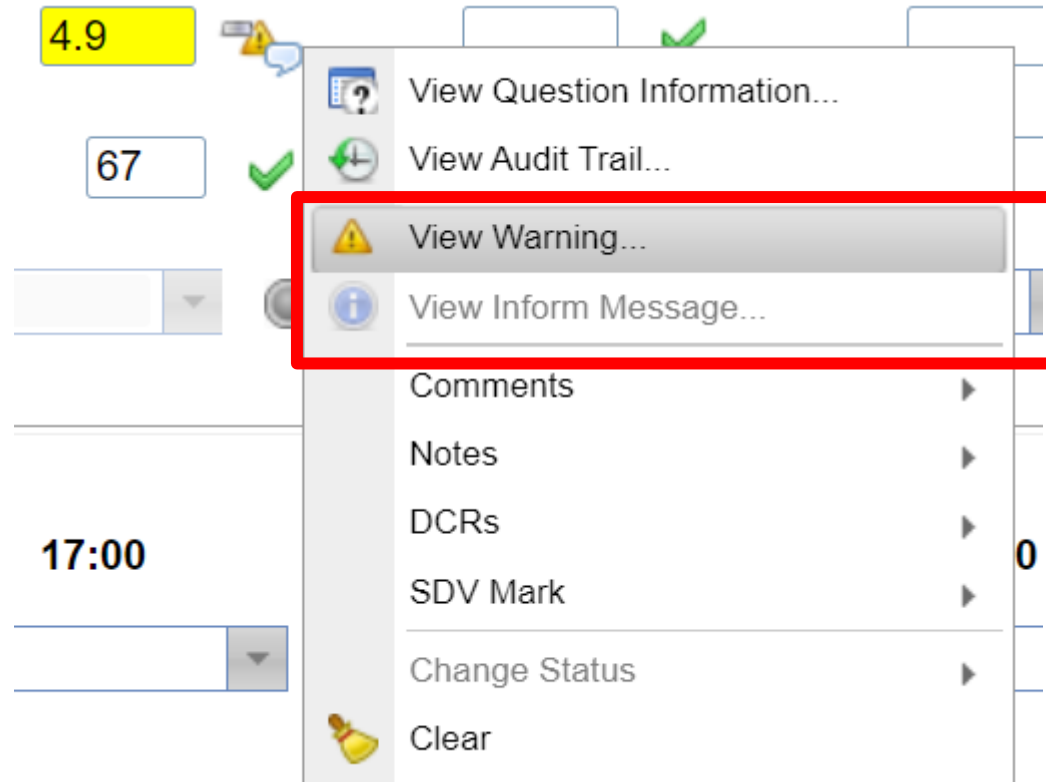
- Message appears as soon as data entered

The screenshot shows a 'Question Information' form with two input fields: 'Name' and 'Age (years)'. The 'Age (years)' field contains the value '101'. To the right of the form, the value '101' is shown in a separate box with a yellow warning triangle icon next to it. Below the form, a 'Warnings' section is visible, containing a message: 'Patient age is outside of the expected range. Please confirm if this is the correct age.' with a checkbox.

- 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

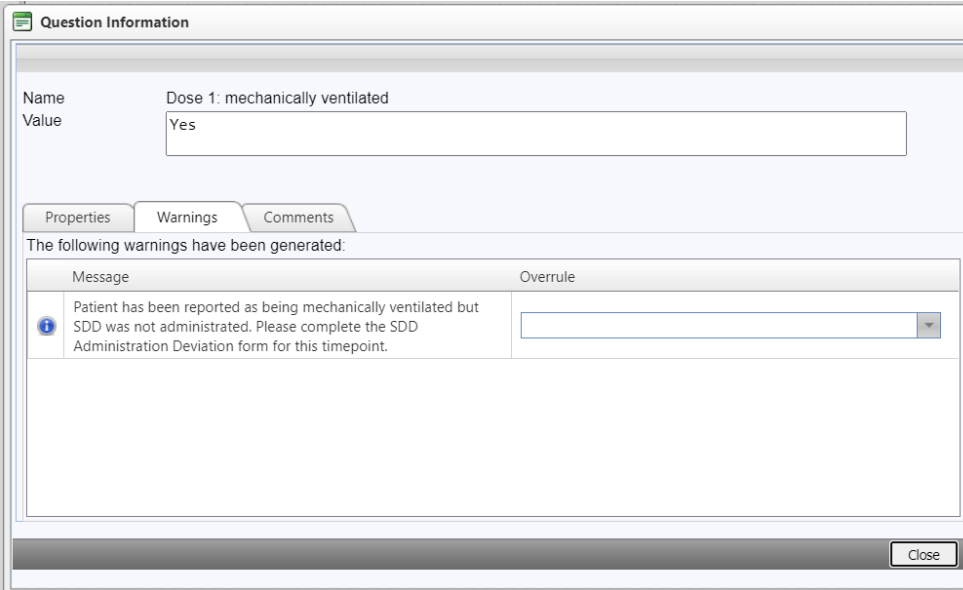
The screenshot displays a data entry form for a patient's age. The value '101' is entered in a field labeled '(years)'. A warning icon (yellow triangle) is visible next to the field. A context menu is open over the field, listing several actions: 'View Question Information...', 'View Audit Trail...', 'View Warning...', 'View Inform Message...', 'Comments', 'Notes', 'DCRs', 'SDV Mark', 'Change Status', and 'Clear'. The 'Comments' option is highlighted with a red box, and its sub-menu is open, showing 'Add...', 'View...', and 'Remove All'. Below the form, there are tabs for 'Properties', 'Warnings', 'Comments', and 'Audit Trail'. The 'Comments' tab is selected, showing a list of comments attached to the question: '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




**Mechanically
Ventilated**

Yes 
 No



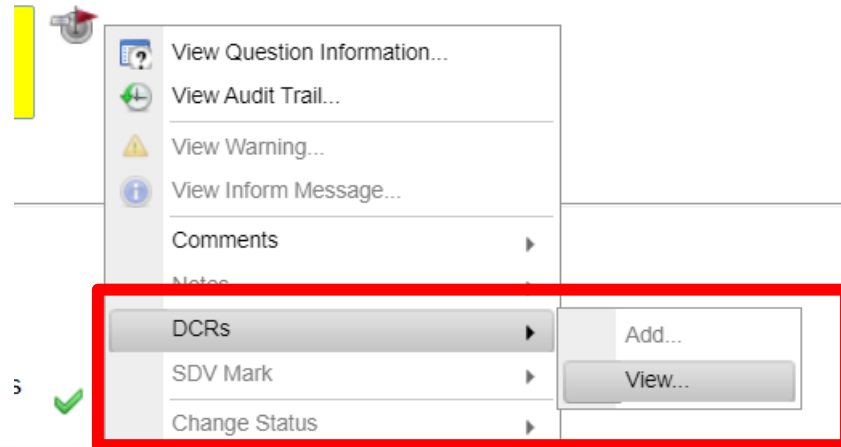
The screenshot shows a 'Question Information' dialog box. The 'Name' field is 'Dose 1: mechanically ventilated' and the 'Value' field is 'Yes'. Below the fields are tabs for 'Properties', 'Warnings', and 'Comments'. The 'Warnings' tab is active, showing a message: 'Patient has been reported as being mechanically ventilated but SDD was not administrated. Please complete the SDD Administration Deviation form for this timepoint.' There is an 'Override' dropdown menu next to the message. A 'Close' button is at the bottom right.

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	2021/06/03 15:35:43	Raised	UKROX/ [REDACTED]	Treatment	Enhanced data collection (00:00-23:00) (6)	SpO2	97	Alvin Richards-Belle

DCR Browser

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

OC Id	Text
	This hour has been flagged as the start of a potential protocol deviation (SpO2 above target for at least 3 consecutive hours with no reduction in FiO2). Please could you re

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

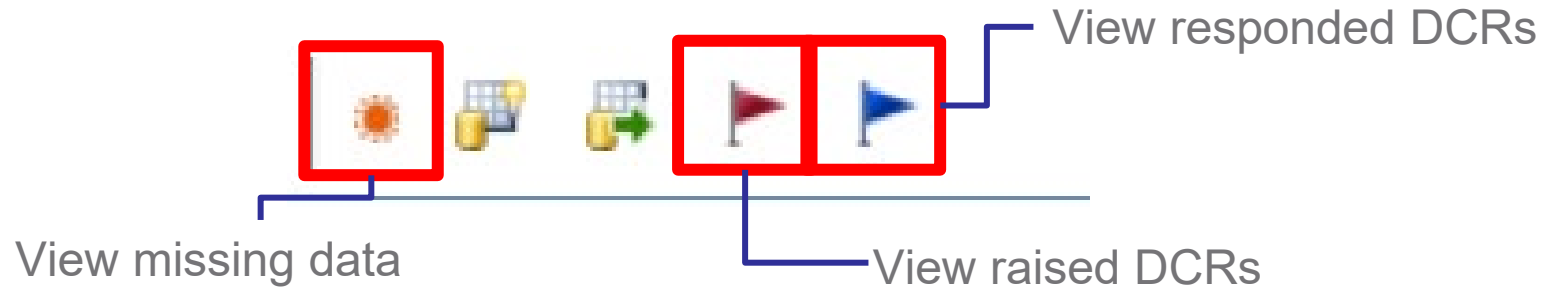
Set DCR to Responded

Name	Reason for withdrawal/aspects withdrawn from
Text	<input type="text" value="Patient declined to provide reason for withdrawal"/>



Query management

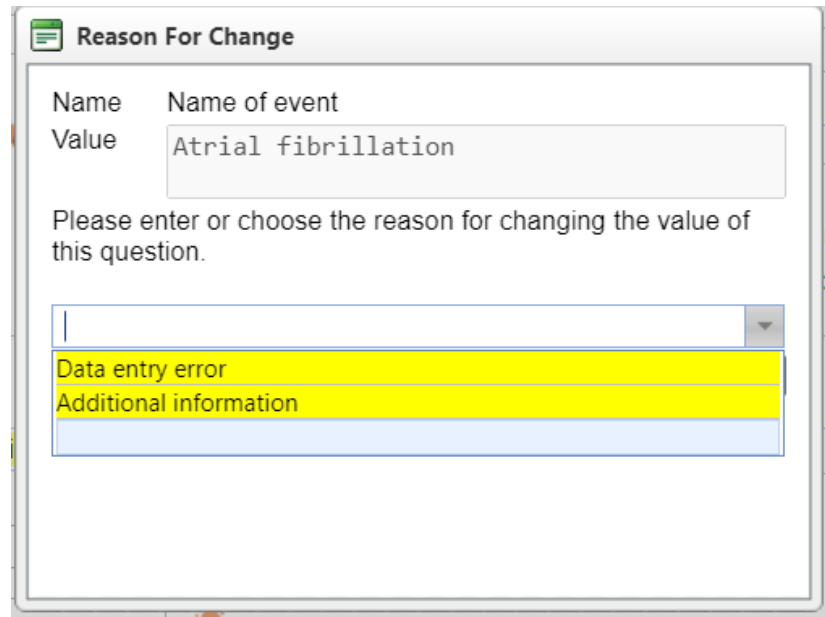
- View all missing data, raised DCRs and responded DCRs for your site



	Question	Value	Date and Time
	<input type="text"/>	<input type="text"/>	<input type="text"/>
Study/Site/Subject: UKROX/ [redacted] / [redacted] 01			
[-] 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 the following fields and text:

- Name:** Name of event
- Value:** Atrial fibrillation
- Instruction:** Please enter or choose the reason for changing the value of this question.
- Reasons List:** A dropdown menu with two options: "Data entry error" and "Additional information". Both options are highlighted in yellow.

Questions?

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