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The Threshold for Platelets study: Database Training

FUNDED BY NIHR | National Institute for Health Research

UNIVERSITY OF OXFORD

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

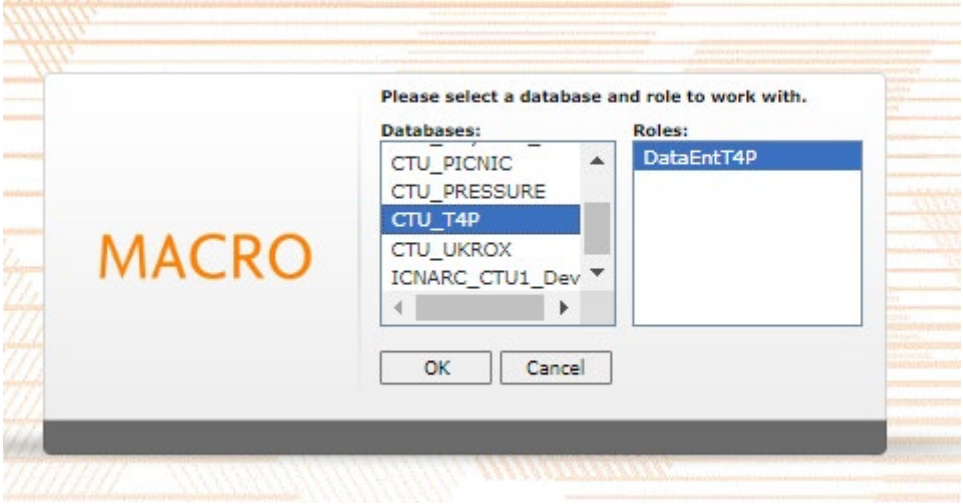
- Access to the T4P database is granted to staff members authorised on the delegation log once is has been greenlighted for recruitment
    - https://ctu.icnarc.org/macro/
- An existing training video on MACRO data entry is available on the website:
    - ICNARC CTU – training.icnarc.org

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

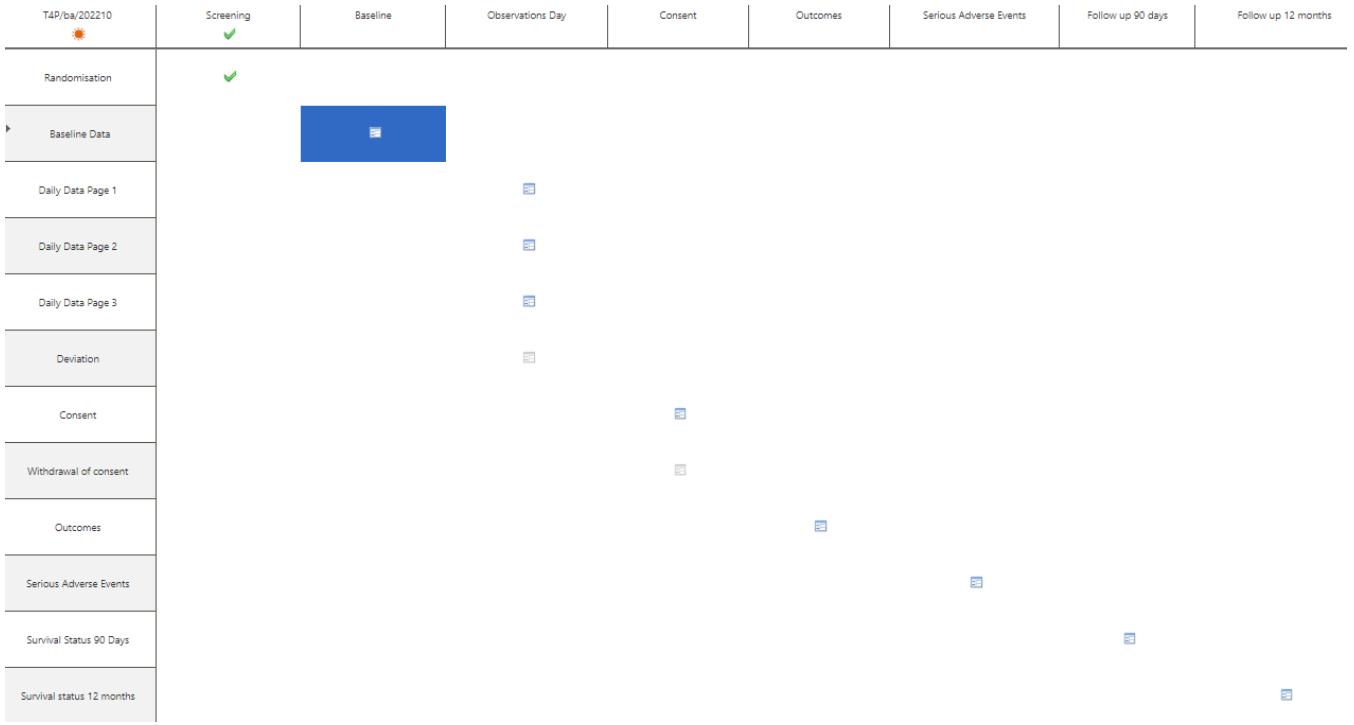
- The welcome message may be updated with relevant news

Visit Schedule

- Upon initial creation of a new patient record, only the Randomisation Form will be available

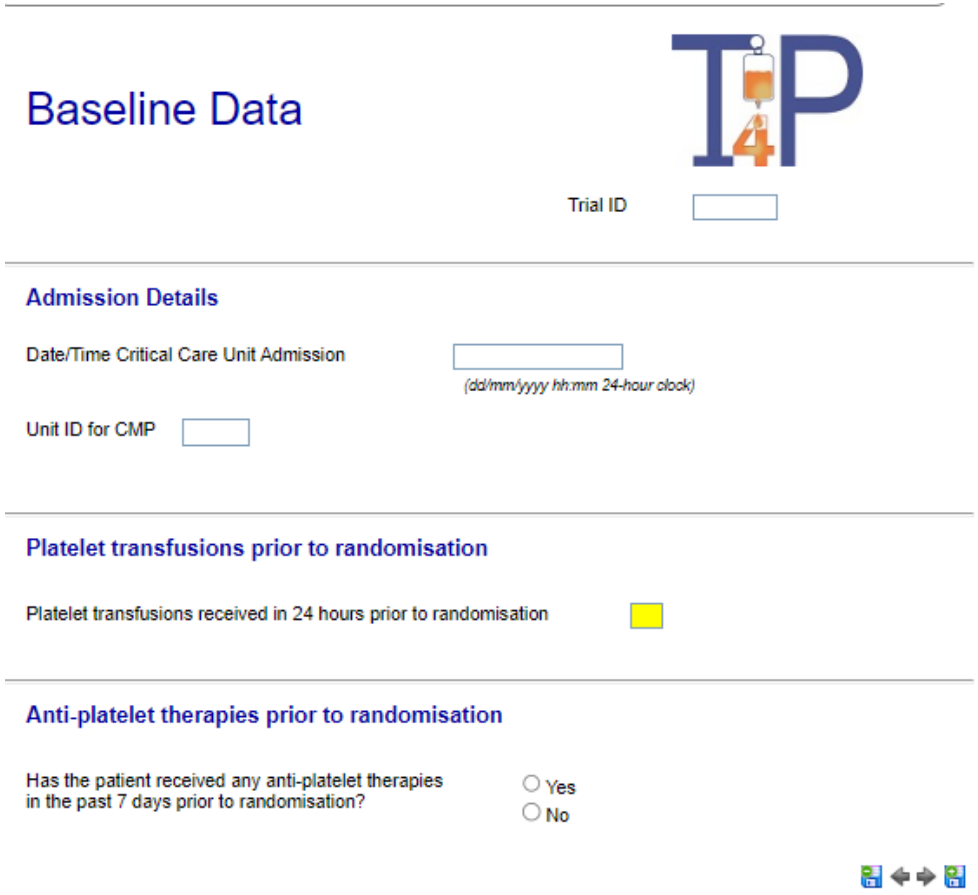
Randomisation Form

- 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



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

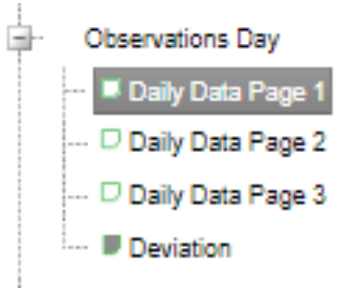
Has the patient received any anti-platelet therapies in the past 7 days prior to randomisation?

Yes

No

Daily Data Forms

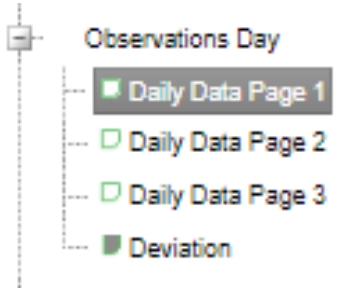
- Daily Data is split into 3 pages



  - Complete all 3 pages for each day

Daily Data Forms

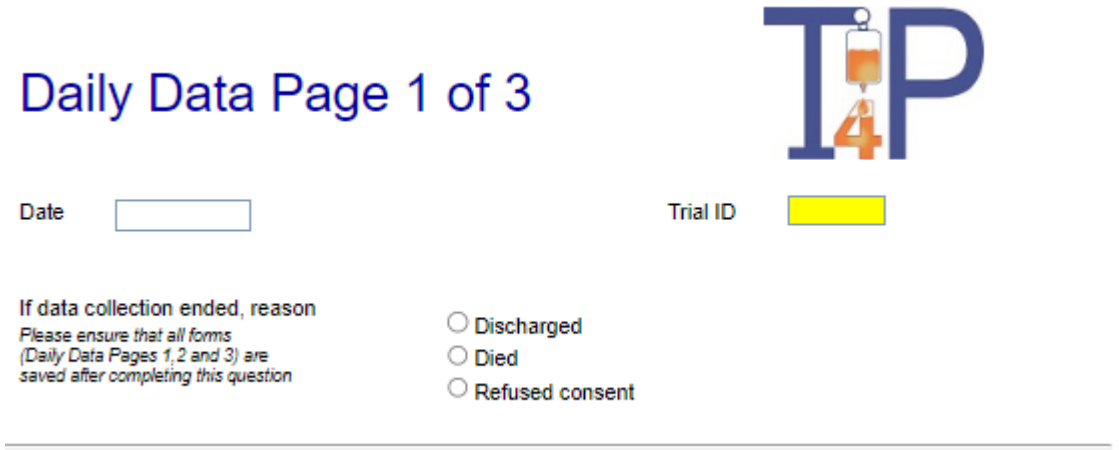
- Daily Data is split into 3 pages



  - 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



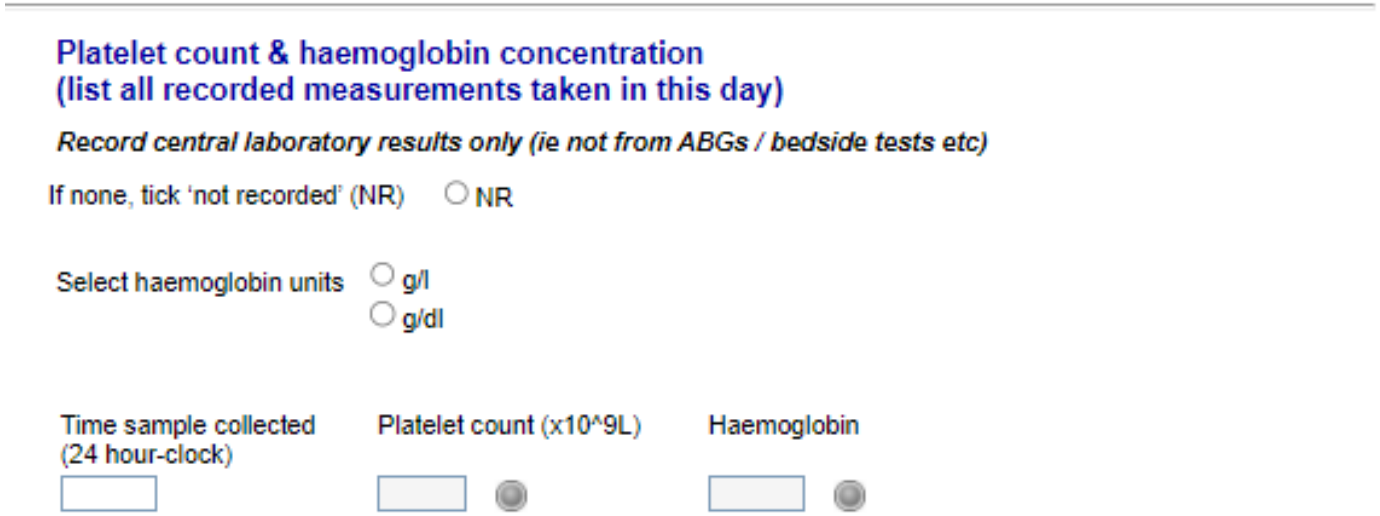
- Enter the reason of why daily data collection has ended if applicable. This will stop creating further Daily Data Pages

- 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

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)

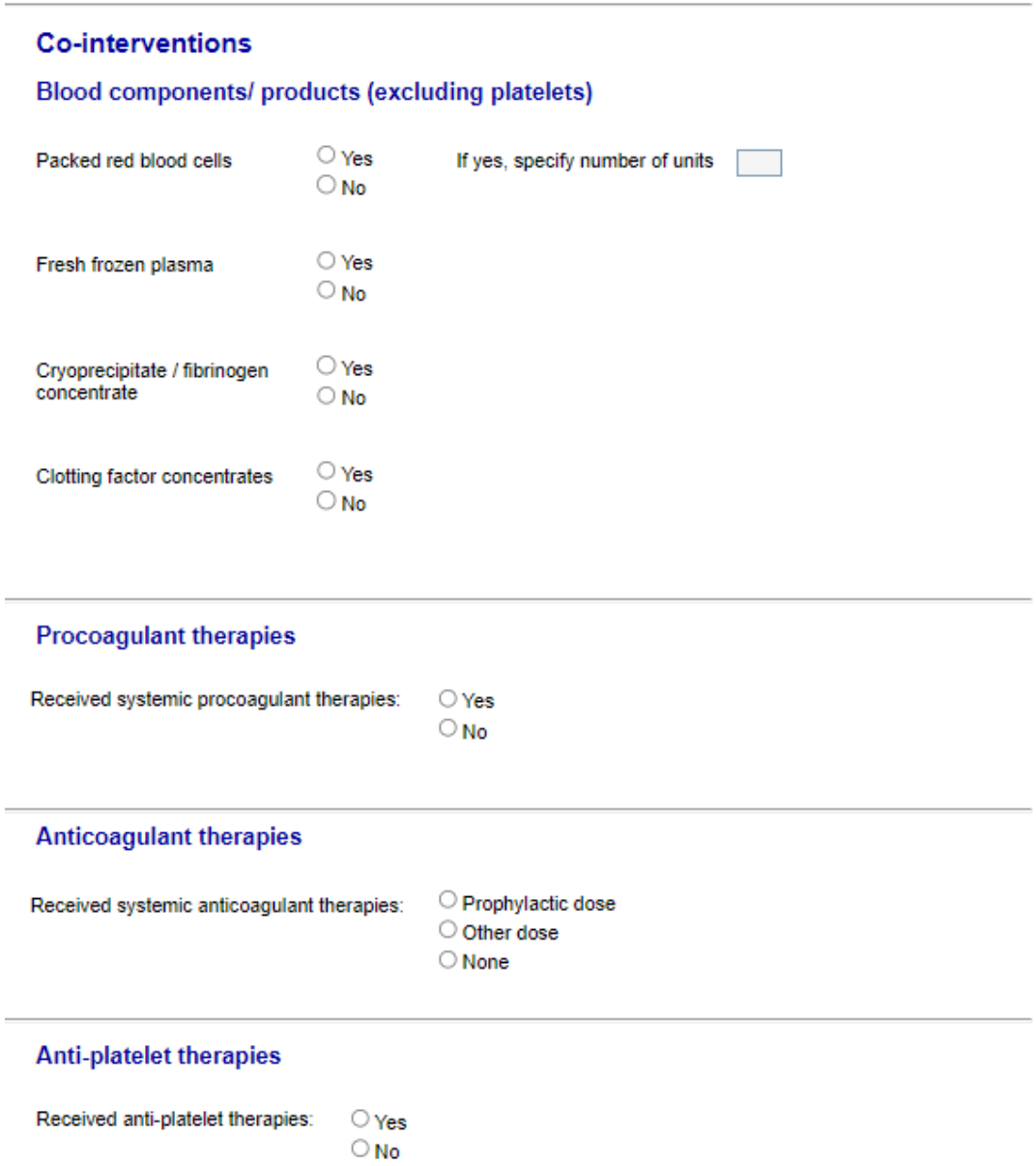
If none, tick 'not recorded' (NR) ○ NR

Select haemoglobin units ○ g/l ○ g/dl

Time sample collected (24 hour-clock)	Platelet count (x10^9L)	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	○ Yes ○ No	If yes, specify number of units
Fresh frozen plasma	○ Yes ○ No	
Cryoprecipitate / fibrinogen concentrate	○ Yes ○ No	
Clotting factor concentrates	○ Yes ○ No	

Procoagulant therapies

Received systemic procoagulant therapies: ○ Yes ○ No

Anticoagulant therapies

Received systemic anticoagulant therapies: ○ Prophylactic dose ○ Other dose ○ None

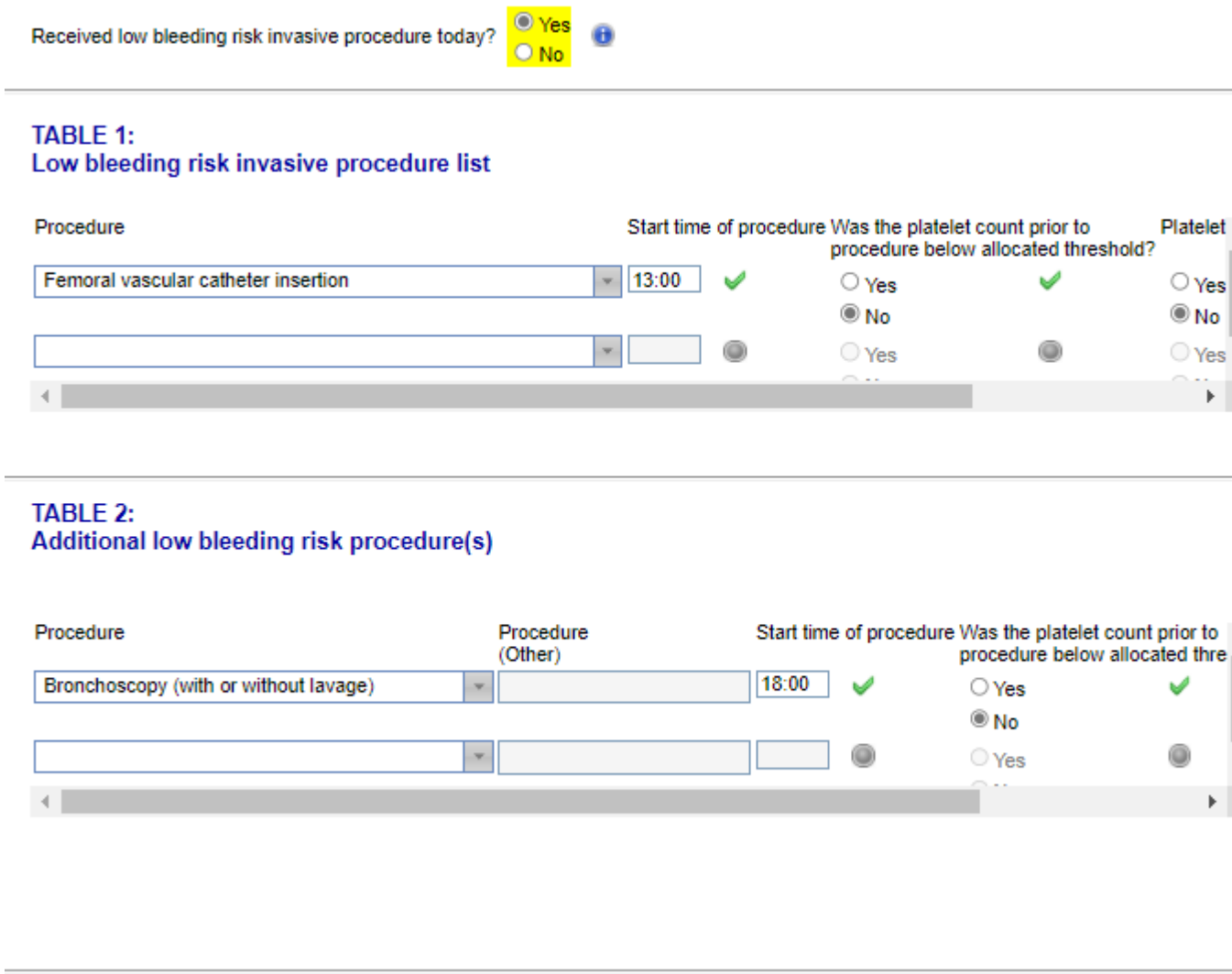
Anti-platelet therapies

Received anti-platelet therapies: ○ Yes ○ No

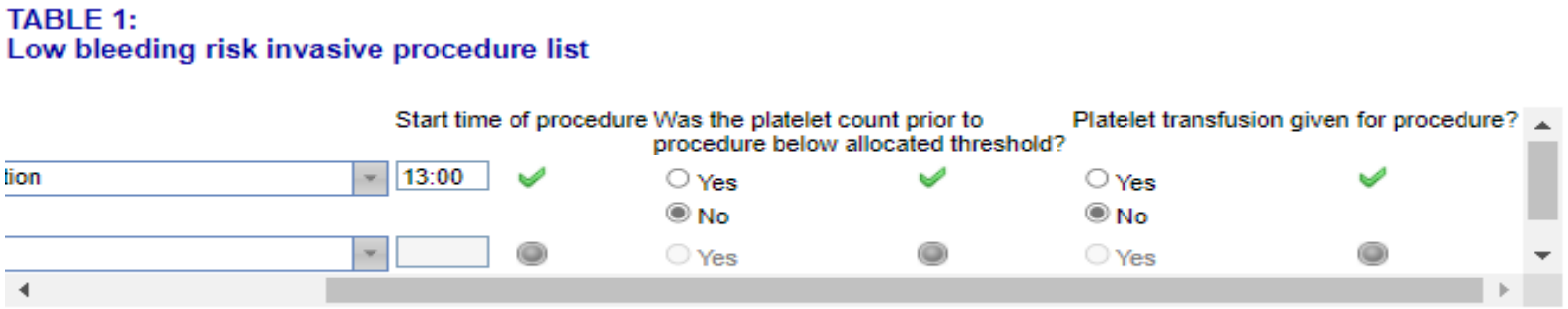
Daily Data Page 2

Low bleeding risk procedures

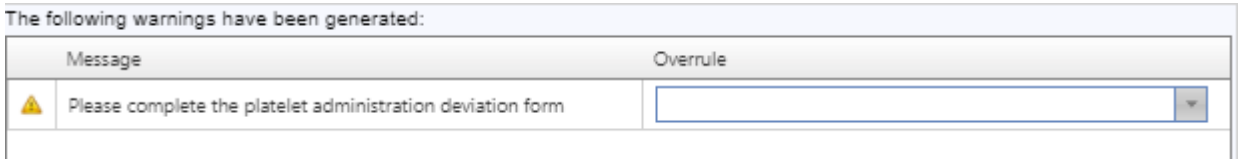
- If yes
  - Select procedure on Tables 1 and/or 2
  - Procedures can be selected multiple times
  - If low bleeding risk procedure is not in either table
    - Select other and state which low bleeding risk procedure has been undertaken



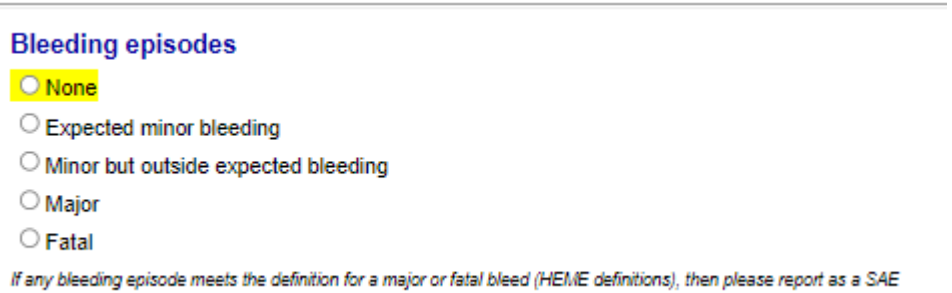
Daily Data Page 2



- 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:



Daily Data Page 3

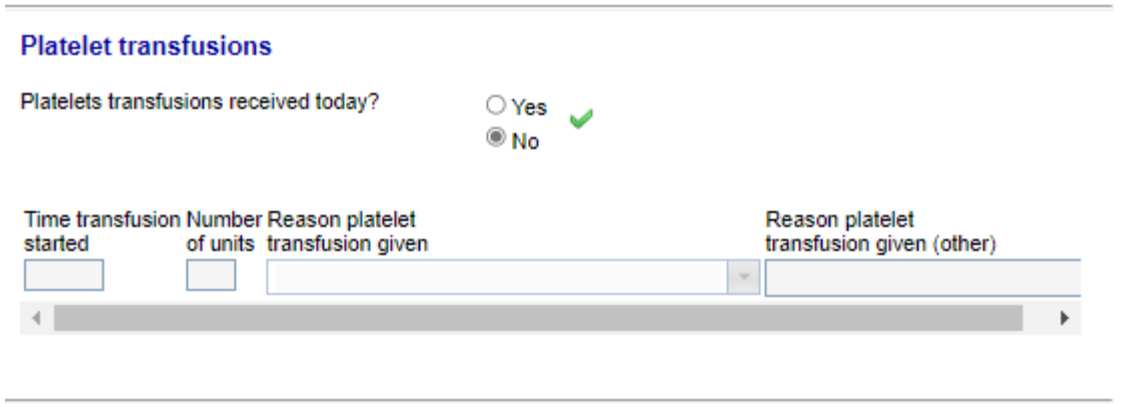


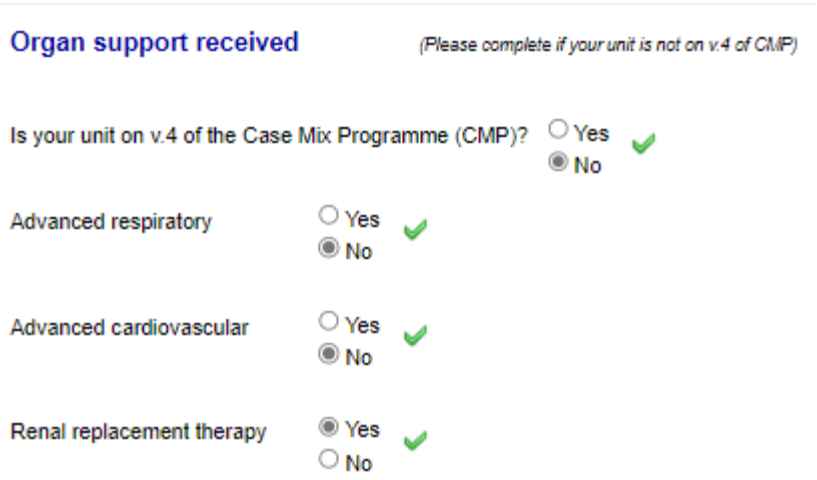
Bleeding episodes

- If any MAJOR or FATAL → Report SAE

Platelet transfusions

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





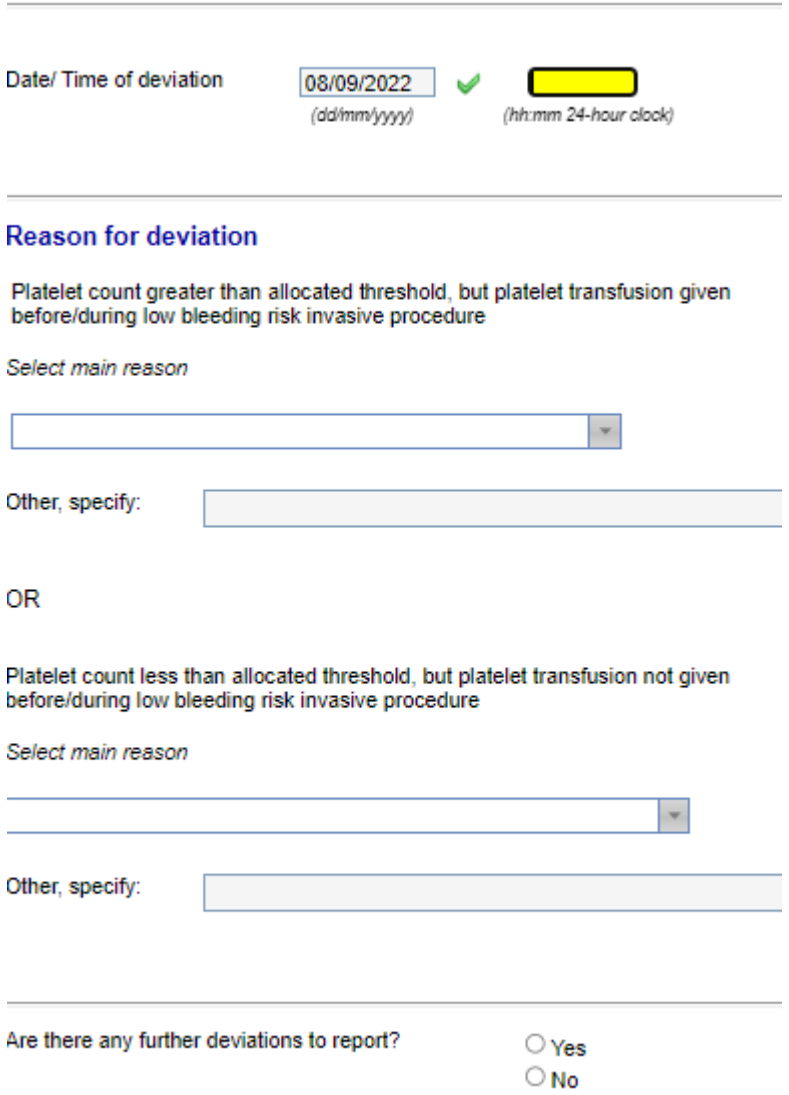
Organ Support

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

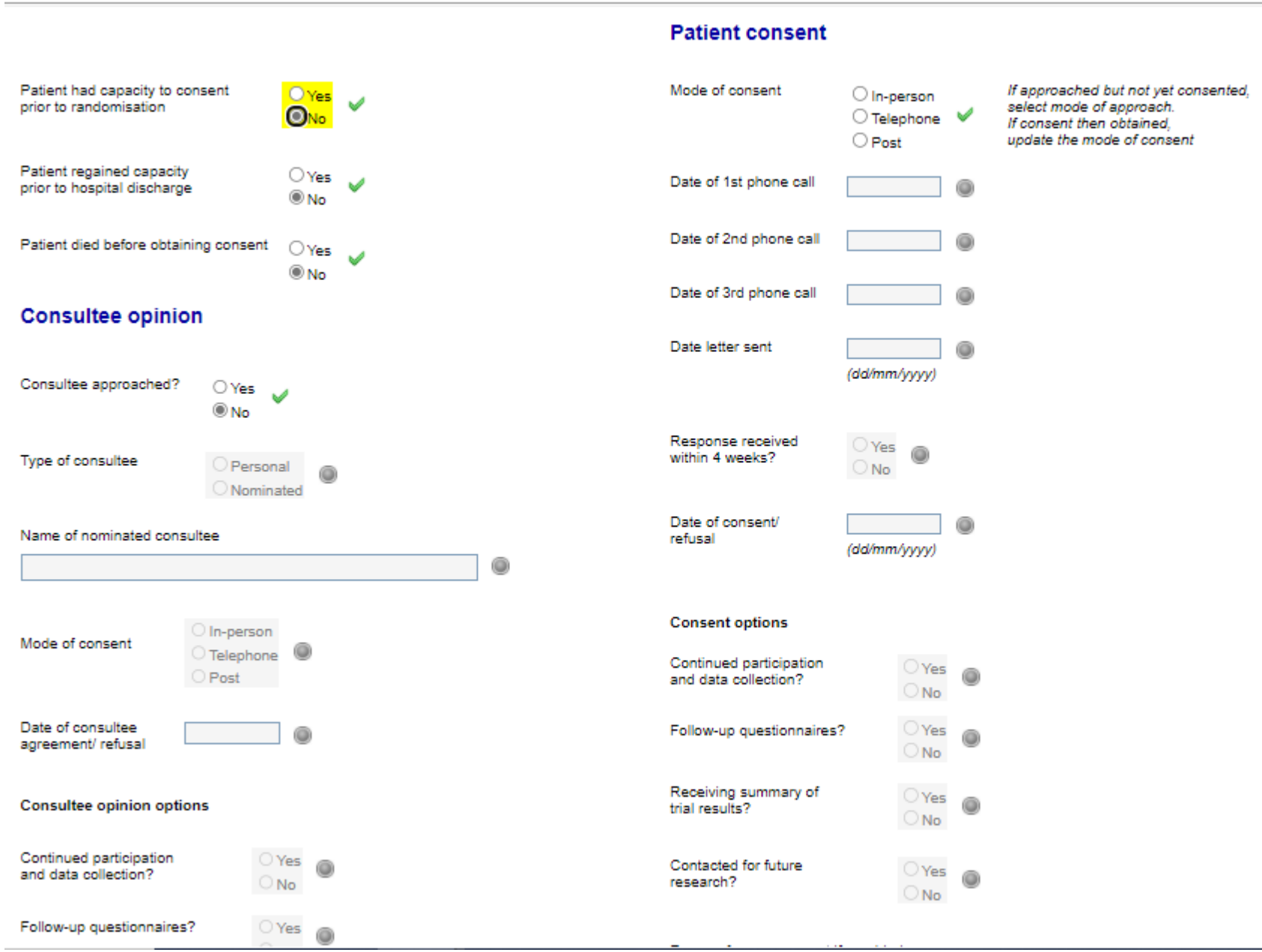
T4

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'

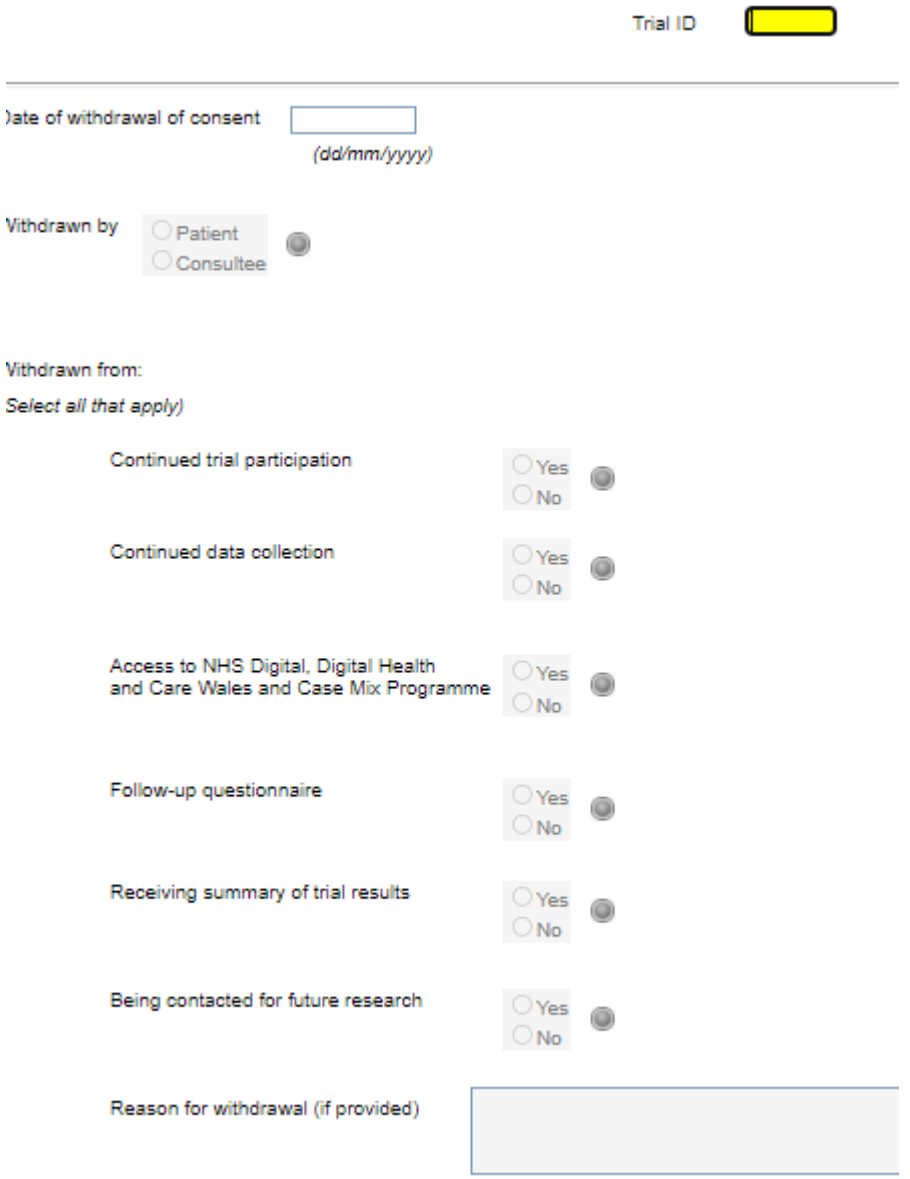


Consent


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
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

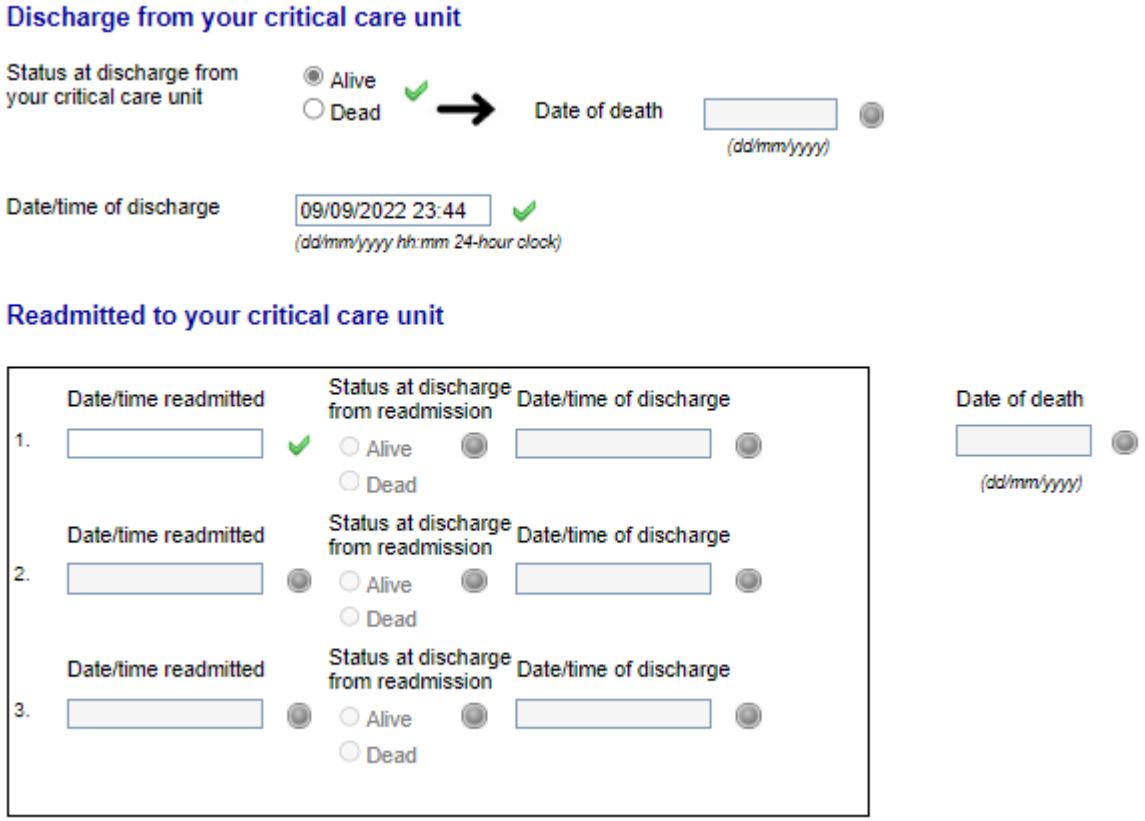
Consent Withdrawal

- 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



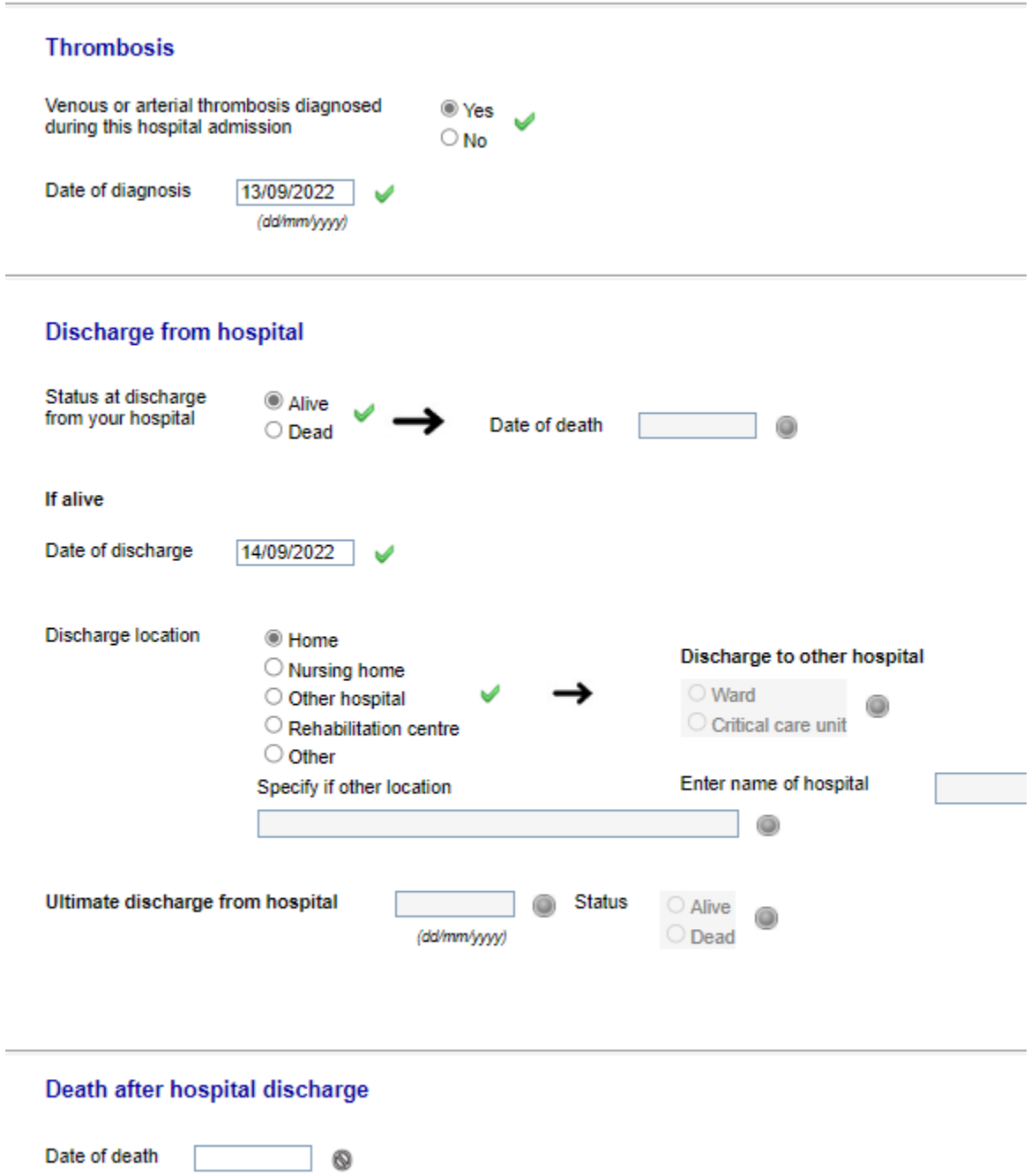
Outcomes

- 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.



Outcomes

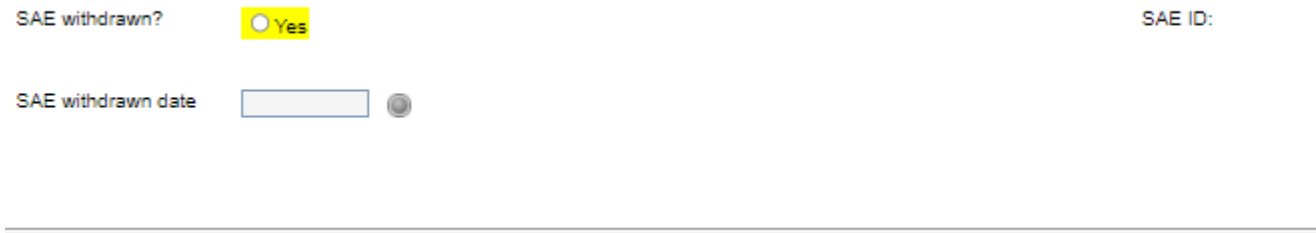
- Enter details of thrombosis episodes
- Enter details of discharge from your hospital for this admission
- Ultimate* discharge from hospital may be from your hospital, or another hospital if they were discharged there
  - This may require communication with the receiving hospital team to find out ultimate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



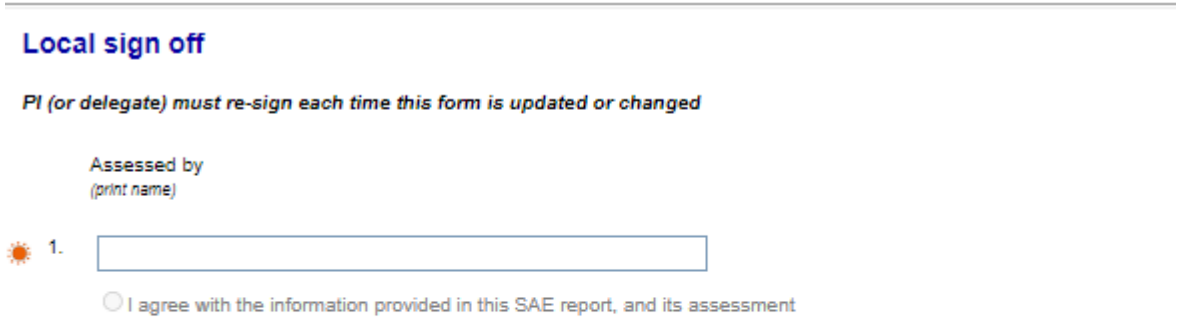
• latest documented date of the admission being physically within an acute in-patient bed in an acute hospital, the acute hospital care having been continuous since discharge from your unit

SAE

- If SAE is withdrawn please click ‘yes’ and state withdrawal date

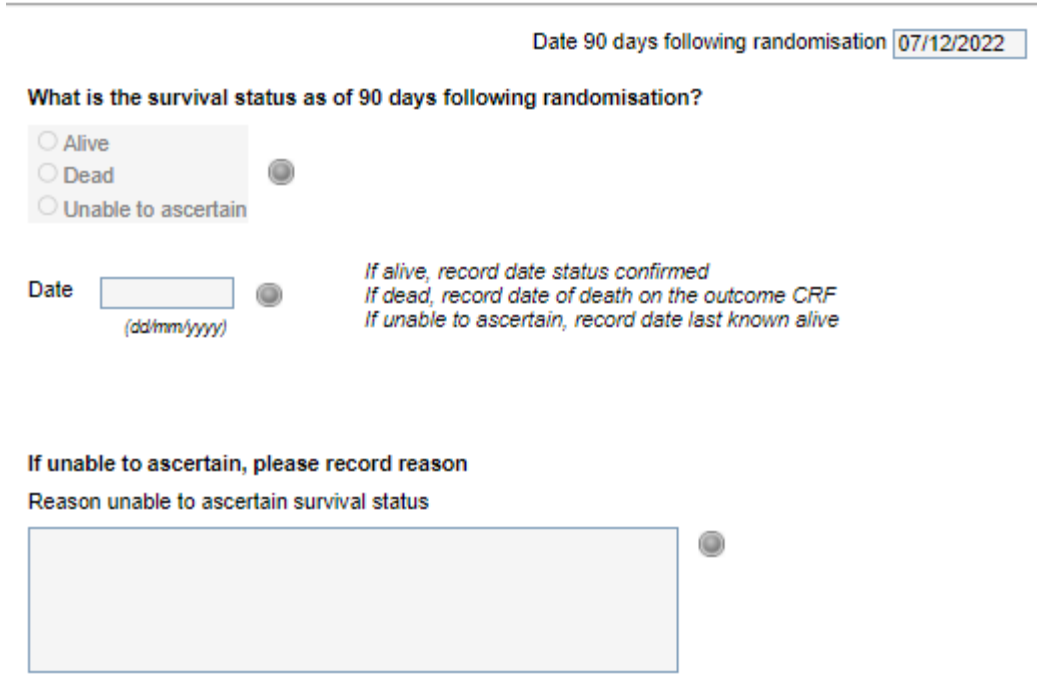


- Every time the form is modified the PI or assigned delegate will need to sign it off to confirm the changes



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)



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?

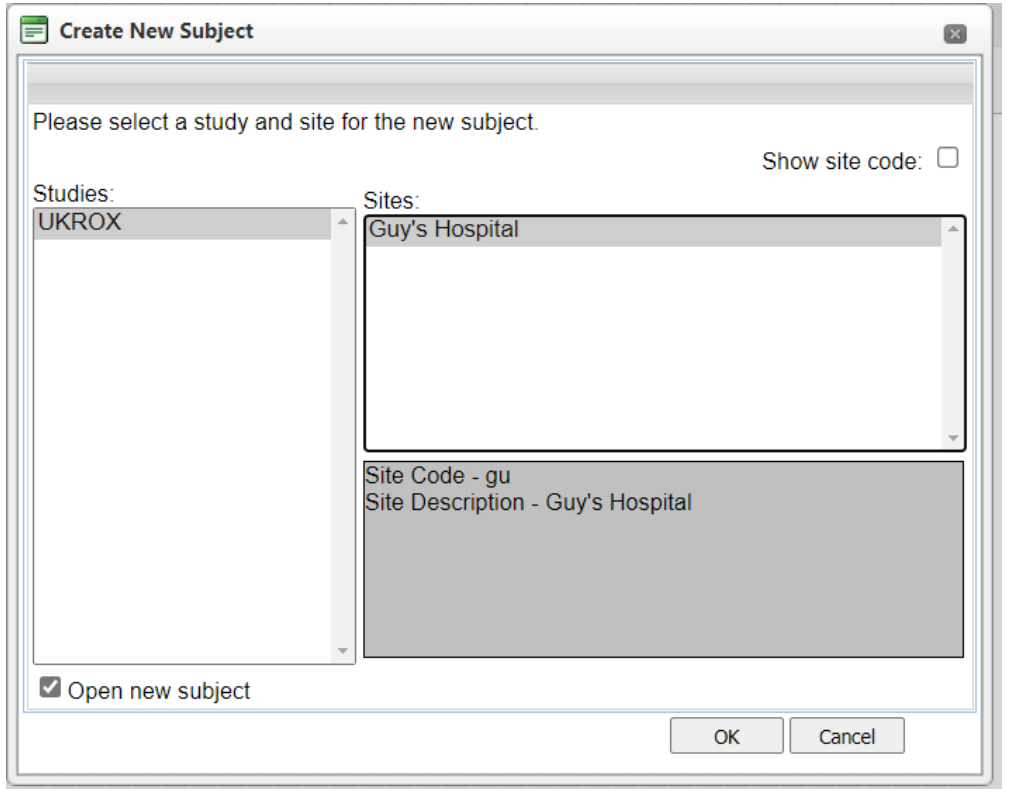
MACRO User Training

Creating new subjects

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

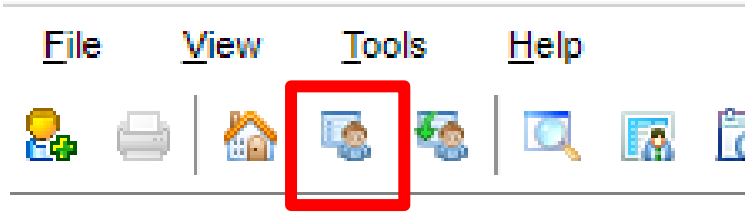
Creating new subjects

- 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	20290000
	REMAPCAP	aa	39	10170000

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)

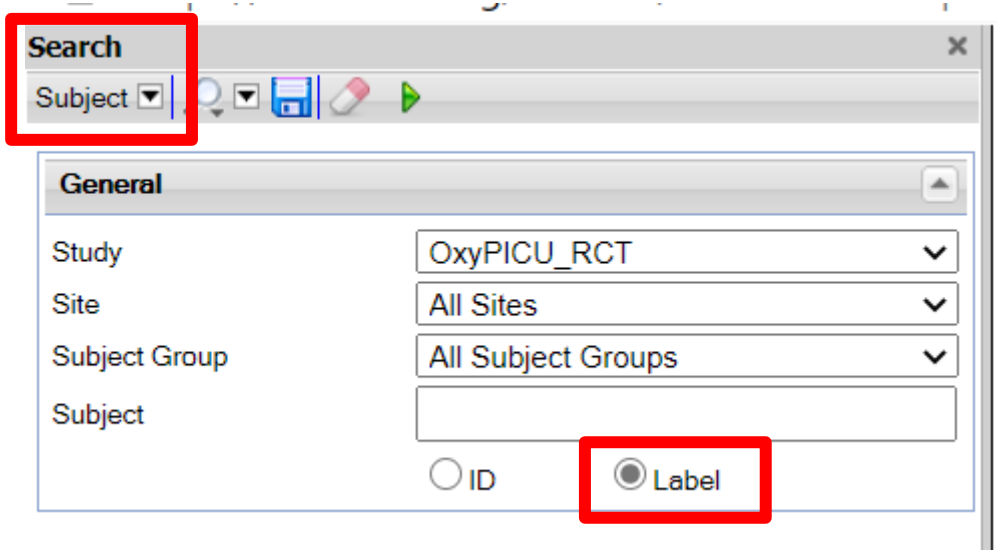
Searching for subjects

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

Searching for subjects 4

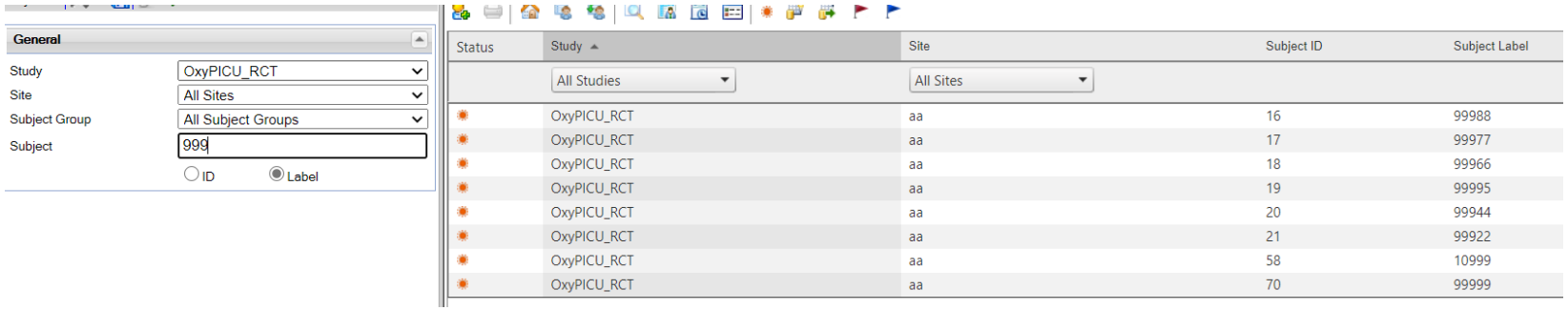
- ‘Open the Search panel’

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

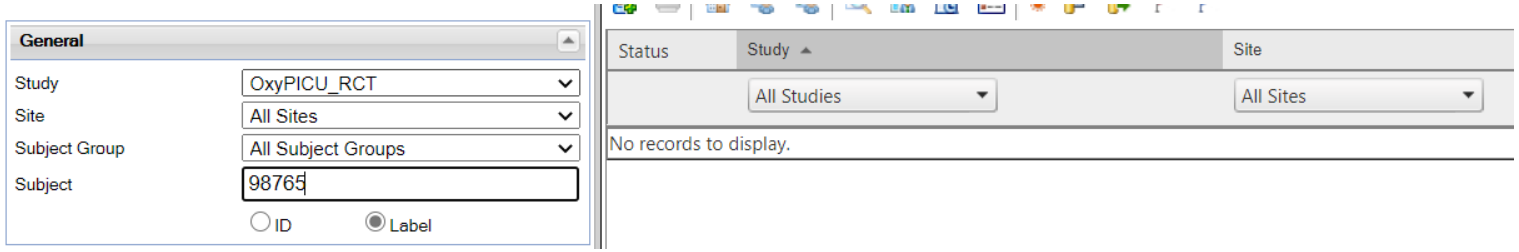


Searching for subjects 4

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

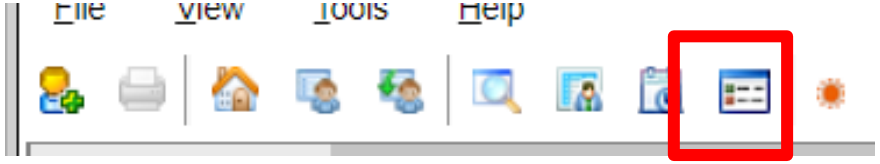


- If the subject has not yet been created, MACRO will state 'No records to display'

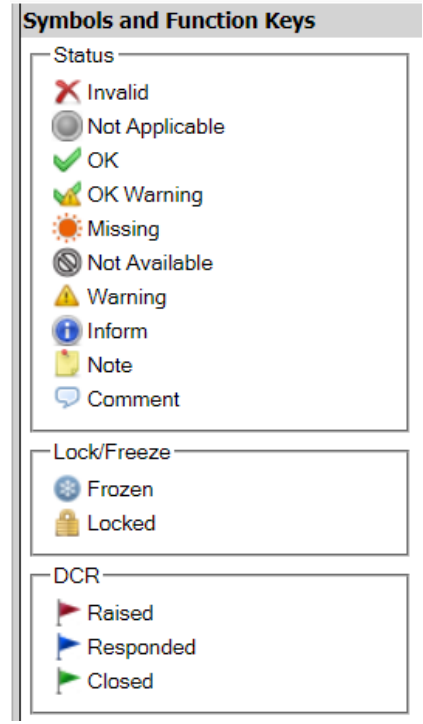


Status symbols

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



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



Data Queries

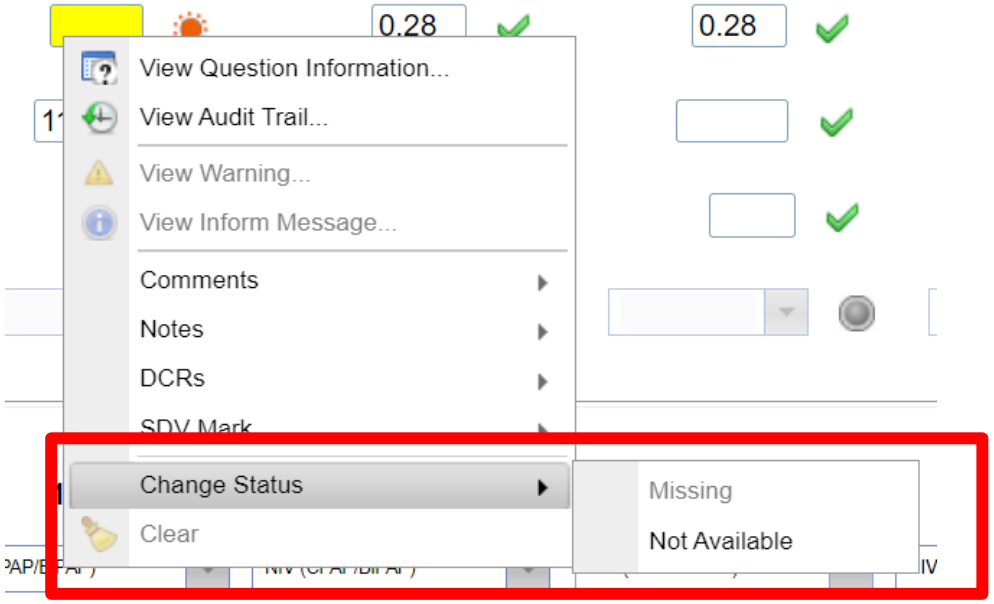
- There are 3 types of data queries that can be raised:
- Missing Data
- Validations
- Data Clarification Requests (DCRs)

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

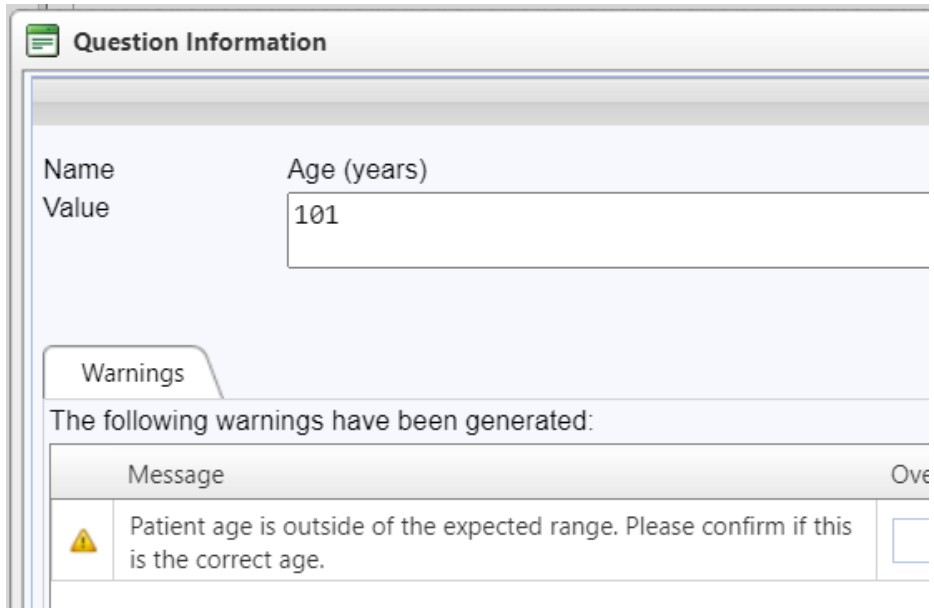
- Three types of validations, composed of a condition and message:
  - Reject: Message appears, data is deleted, no query generated
  - Warning: Message appears, and a query is saved in the database
  - Inform: Message appears, no query is generated

Reject data validations

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

Warning validations

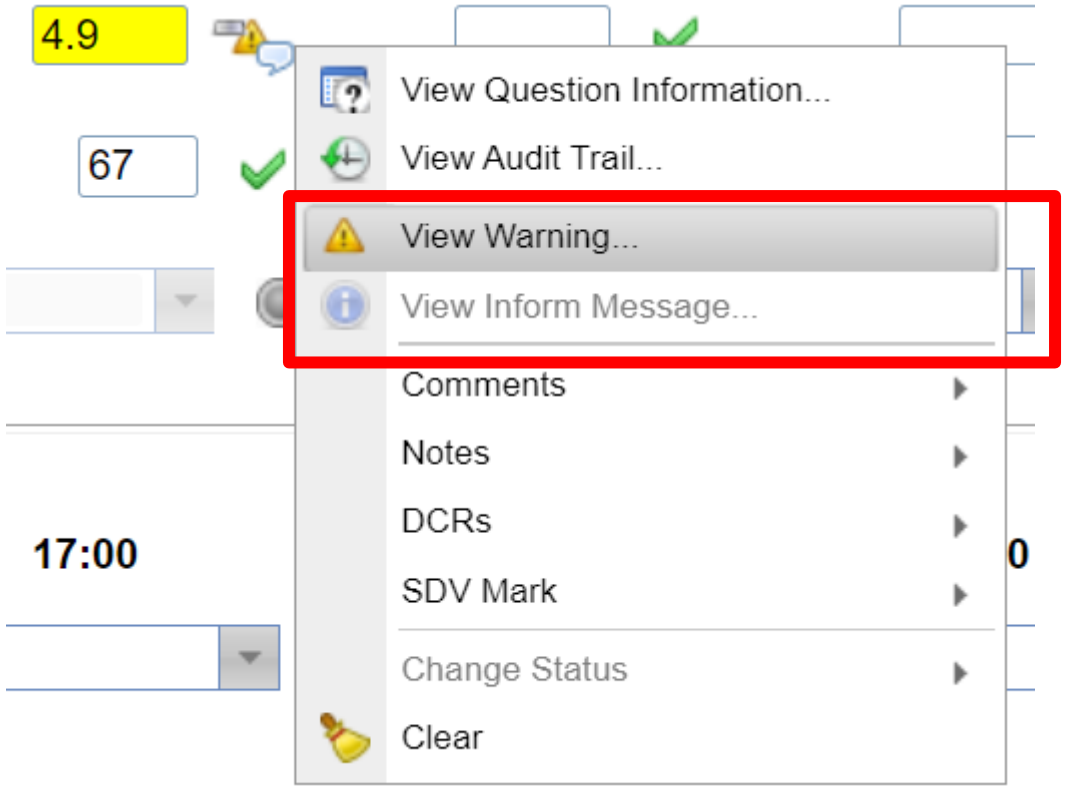
- Message appears as soon as data entered



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

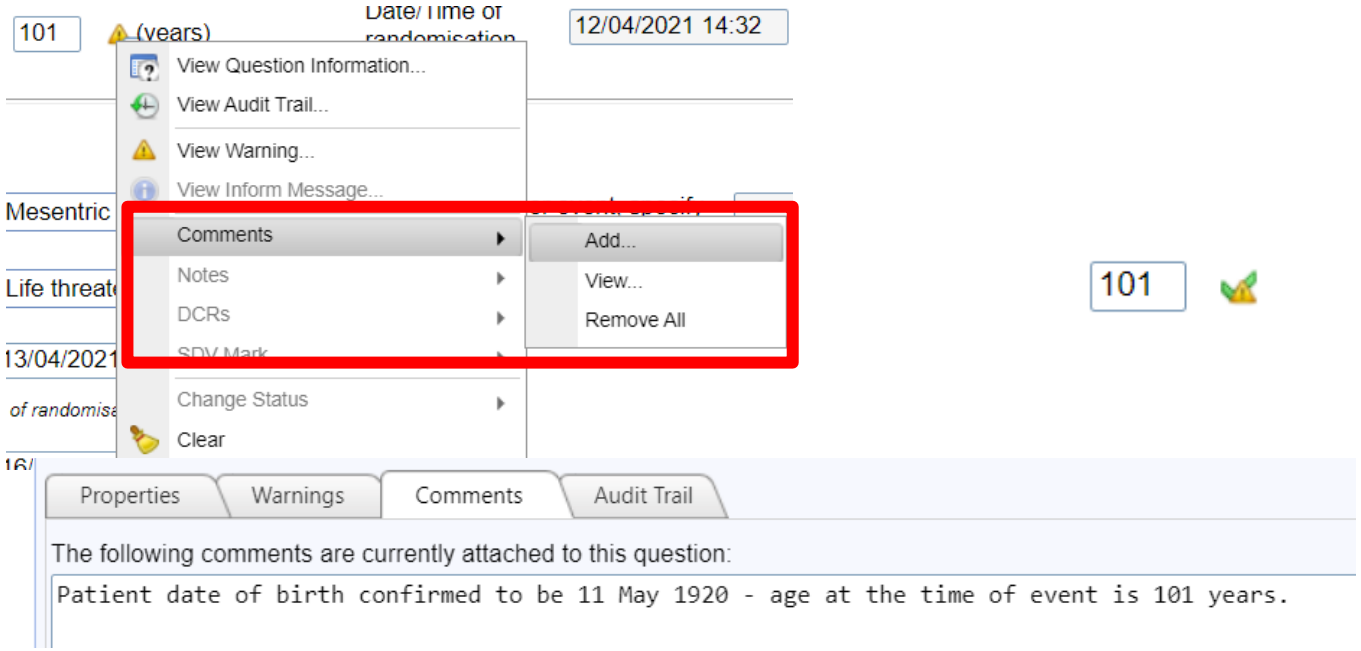
Warning validations

- To view a warning



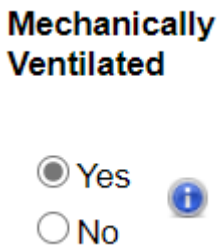
Warning validations

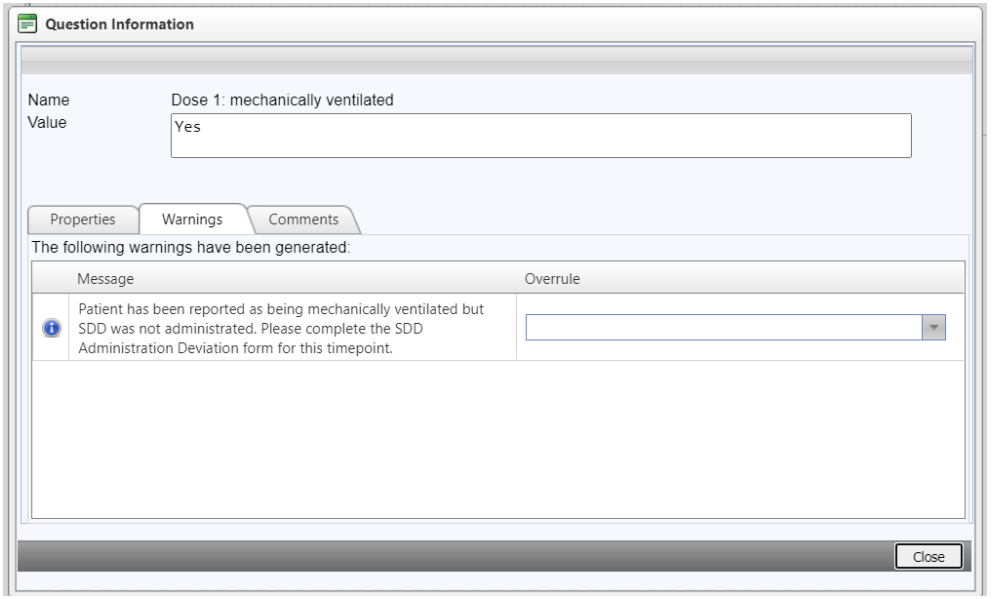
- If a warning fires, check the data entered to ensure it is not a data entry error.
- If the data has been verified to be correct but still fires the warning, add a comment to explain the reason



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



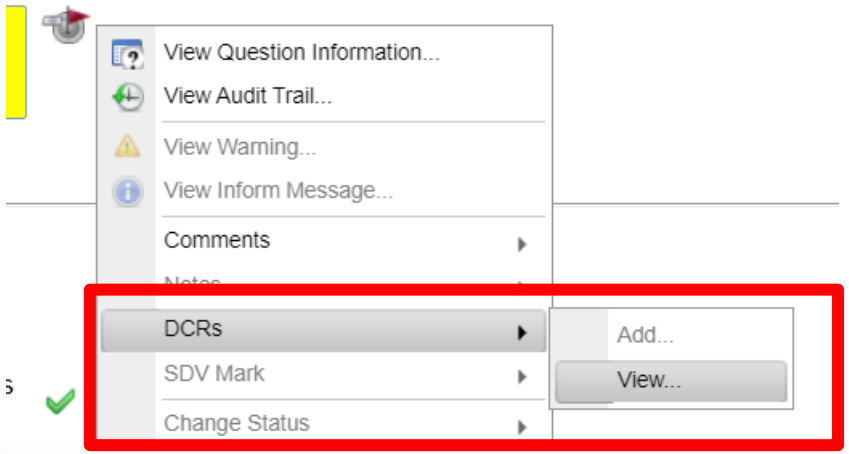


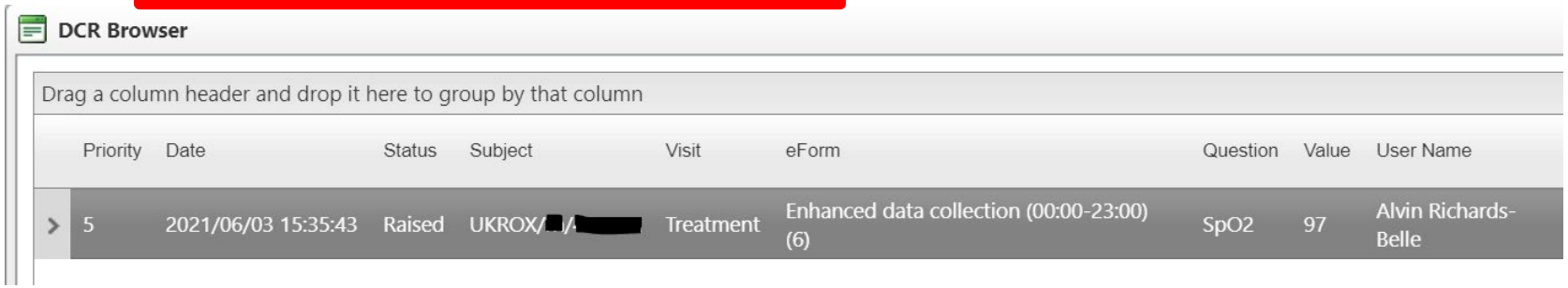
Data Clarification Requests (DCR)

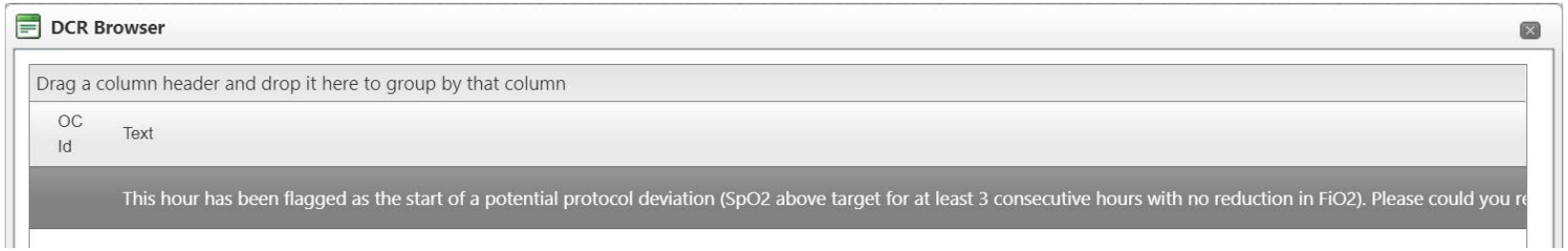
- Data Clarification Requests are manual queries added to the database. 
- Sites can respond to DCRs, after which the blue flag appears. 
- Once the response has been reviewed by CTU staff and deemed acceptable, the query can be closed shown by a green flag. 

Data Clarification Requests (DCR)

- View and respond to a DCR

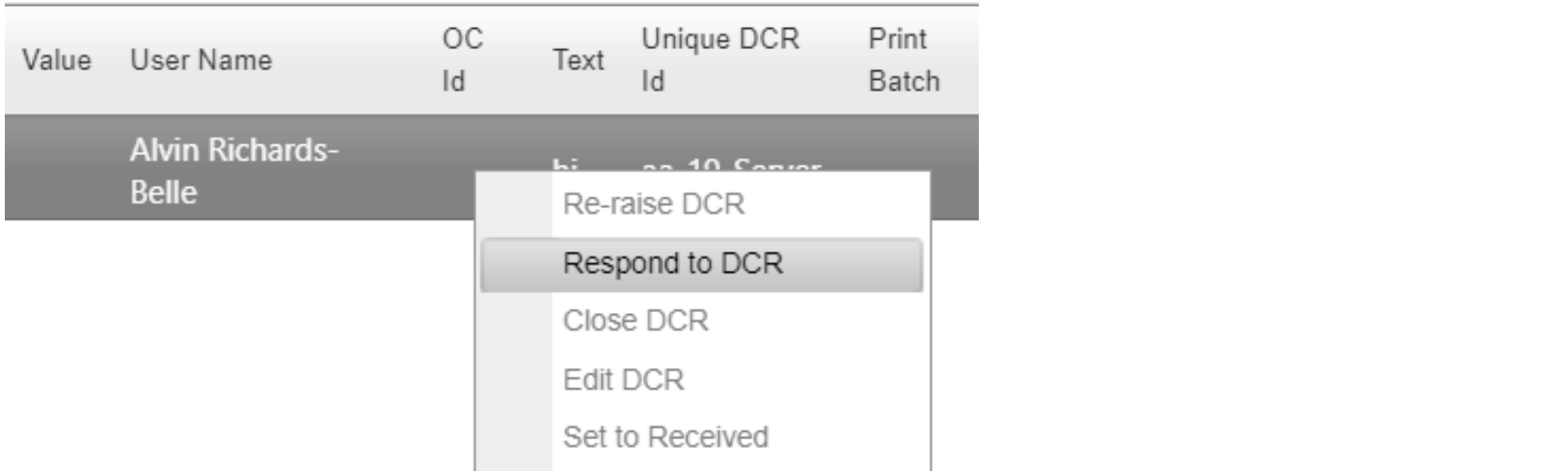






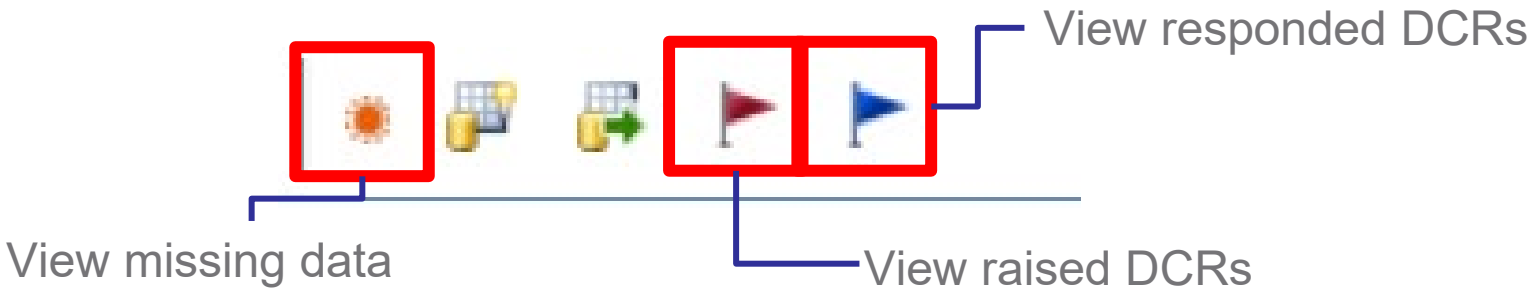
Data Clarification Requests (DCR)

- View and respond to a DCR



Query management

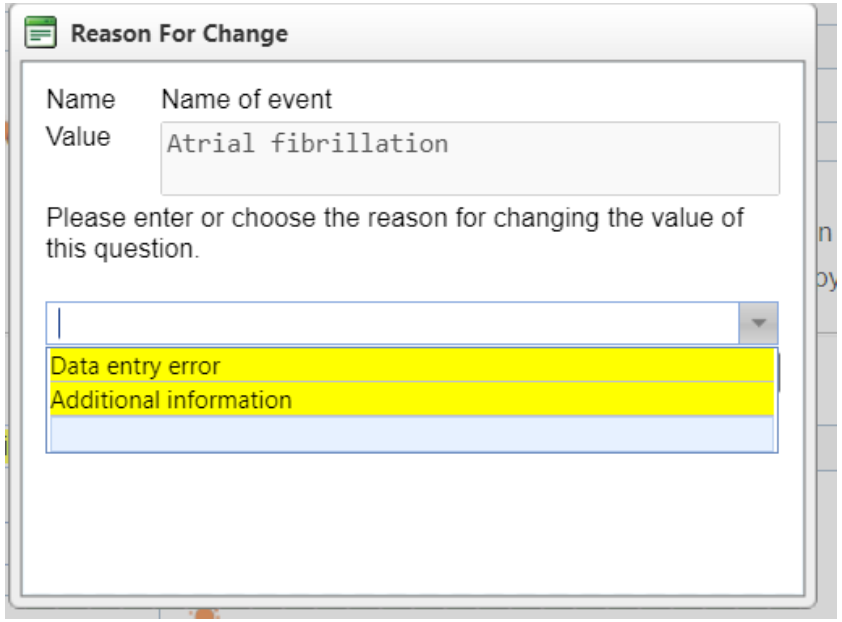
- View all missing data, raised DCRs and responded DCRs for your site



Question	Value	Date and Time
Study/Site/Subject: UKROX/[redacted]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]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?

- datamanagement@icnarc.org