



# Clinical Data Management System (CDMS) Guidelines

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**Project:** SWEET

**Document Version:** 1.0

**Issue Date:** 05.02.2024

## Contents

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1	List of Abbreviations .....	3
2	Version History.....	4
3	Document Overview .....	4
3.1	Purpose and scope.....	4
3.2	Audience .....	4
4	Clinical Data Management System (CDMS).....	5
4.1	How to access the system.....	5
4.2	How to find your IP address.....	7
4.3	Navigating the system.....	7
4.4	Recruitment .....	8
4.5	How to Register a patient .....	8
4.6	How to randomise a participant .....	12
5	Data Management .....	16
5.1	Participant Manager .....	16
5.2	General guidance for data entry.....	18
5.2.1	Dates .....	18
5.2.2	Required fields and validations.....	18
5.2.3	Sub-forms.....	20
5.2.4	Unobtainable flag.....	21
5.2.5	Form completed by.....	21
5.2.6	Form status .....	21
5.2.7	Saving forms.....	22
5.2.8	Unscheduled events (forms) .....	22
5.2.9	Editing data .....	23
5.3	Form Manager.....	24
5.4	Query Manager .....	25
5.5	Form Queries .....	28
6	Data return schedule (Appendix 1).....	29
7	Self-Evident Corrections (SECs). (Appendix 2) .....	30

# 1 List of Abbreviations

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<b>Abbreviation</b>	<b>Explanation</b>
CDMS	Clinical Data Management System
CI	Chief Investigator
CRF	Case Report Form
DEC	Data Entry Clerk
eCRF	Electronic Case Report Form
NHS	National Health Service
SAE	Serious Adverse Event
SEC	Self-Evident Correction
UK	United Kingdom
WCTU	Warwick Clinical Trials Unit

## 2 Version History

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Document versioning is used to control and track the CRF and CDMS Guidelines. For every approved iteration of this document a new row is added to table 1, detailing the version number, the author(s) of the version, the date that version was approved and a summary of the reason for creating a revised version.

Version Number	Author	Issue Date	Description of Change
1.0	Alice Longe & Raegan Barrows	05.02.2024	Initial version

## 3 Document Overview

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### 3.1 Purpose and scope

To describe the timelines for data entry, and how data can be entered and managed on the database.

### 3.2 Audience

The site research team inputting and managing the data at their site.

## 4 Clinical Data Management System (CDMS)

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### 4.1 How to access the system

Individual access to the SWEET CDMS will be given once training has been completed, staff members have been added on the delegation log and the site has received greenlight to commence trial activities. (Site Training logs & Delegation logs need to be provided to WCTU as evidence)

The database can be accessed using the URL: <https://ctu.warwick.ac.uk/SWEET>.

The database is compatible with the following internet browsers: Google Chrome & Microsoft Edge.



#### Sign In

If you are a Warwick University staff member you can sign in using your University account.

Non Warwick University users must use the credentials assigned to them by the SWEET Warwick CTU Trial Team.

Your account must be activated before you can sign in. Requests to activate an account can only be made by the System Owner.

User name:  
enter your user name

Password:  
enter your password

Sign In

[Forgotten Password](#)

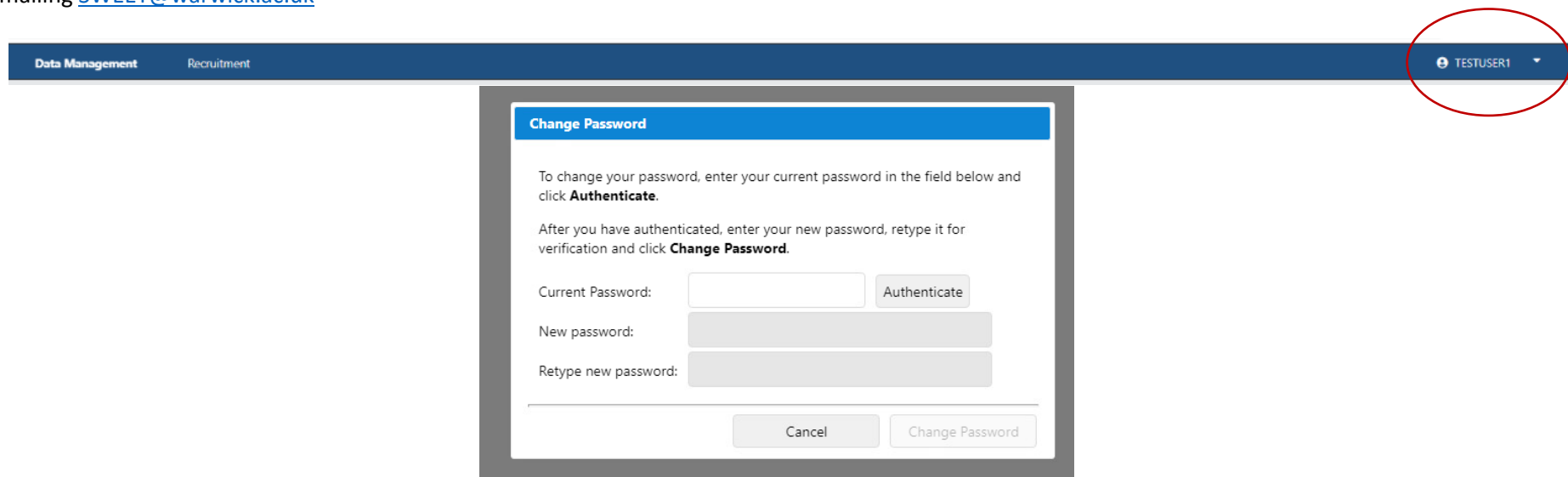
During site set up you will also need to provide your departments IP address to the SWEET team, so that the computers that will be used to access the database are 'whitelisted' by our programming team. You will then be provided with a username and temporary password. When you first login you will immediately be prompted to change your password.

Valid passwords must comply to the following rules:

- **must be at least 12 characters**
- **must contain at least one lower case letter, one upper case letter, one digit and one non-alphanumeric character**

If you need to change your password in the future, you will need to do so by clicking on the arrow next to your username along the top of the page and selecting 'Change Password'. This will then bring up a new dialog window where you can add the new password.

Please note that failure to input the correct password on 5 consecutive occasions will lock you out of the database. We recommend you use the forgotten password link on the log in page if you cannot remember your password. If you are locked out of the database, you will need to re-request access by emailing [SWEET@warwick.ac.uk](mailto:SWEET@warwick.ac.uk)



The screenshot shows a web application interface with a dark blue header. On the left, there are links for 'Data Management' and 'Recruitment'. On the right, a user profile dropdown menu shows 'TESTUSER1' with a downward arrow, which is circled in red. A modal dialog box titled 'Change Password' is open in the center. The dialog box has a blue header and contains the following text and fields:

To change your password, enter your current password in the field below and click **Authenticate**.

After you have authenticated, enter your new password, retype it for verification and click **Change Password**.

Current Password:

New password:

Retype new password:

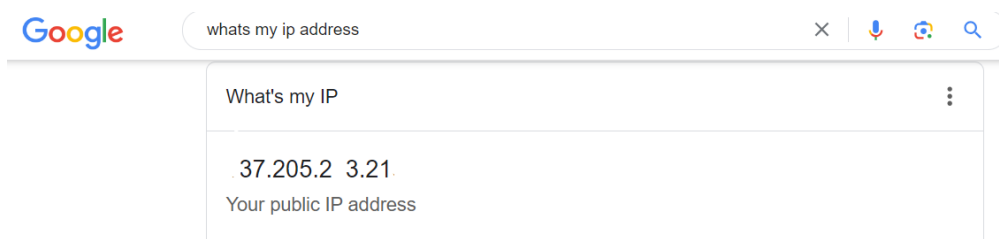
At the bottom of the dialog box, there are two buttons: 'Cancel' and 'Change Password'.

## 4.2 How to find your IP address

The servers on which the database works block connections from external IP addresses, by default. We therefore require you to provide your public IP address, so we can grant access. IPs are allowed through based on the first 3 numbers, which are generally common to users at the same site.

You can easily find out your public IP address through a Google search using the following link: <https://www.google.com/search?q=what+is+my+ip>. Please copy and paste your IP address as displayed and email to [SWEET@warwick.ac.uk](mailto:SWEET@warwick.ac.uk).

Alternatively, if the link above does not work, open Google in your preferred browser and type/copy in to the Google search bar 'What's my IP address'. The first result returned is your IP address. It usually only requires 1 person at each site to do this.



If on logging into the database, you receive a 401 error- you will need to re-provide us with your current IP address to reauthorise. Sometimes sites will have multiple IP addresses and your device may transfer from one to the other. This is usual, so please at that time follow the steps above and email the SWEET Team

## 4.3 Navigating the system

Once you have signed in, along the top of the page you will see the Data Management and Recruitment and tabs.

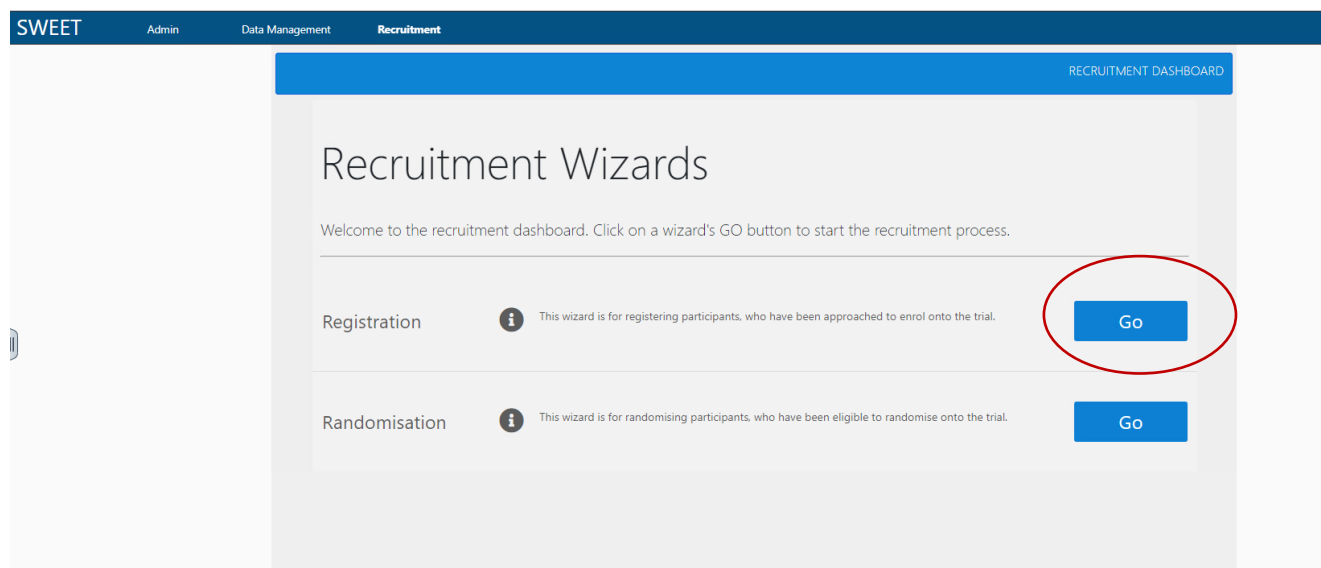


## 4.4 Recruitment

To access the recruitment wizard, you need to click on the recruitment tab. Once in the recruitment wizard you can complete a new registration or complete an existing registration (where you have not been able to proceed with a registration and saved the details for later). **Informed consent must have been received before a participant is registered.**

## 4.5 How to Register a patient

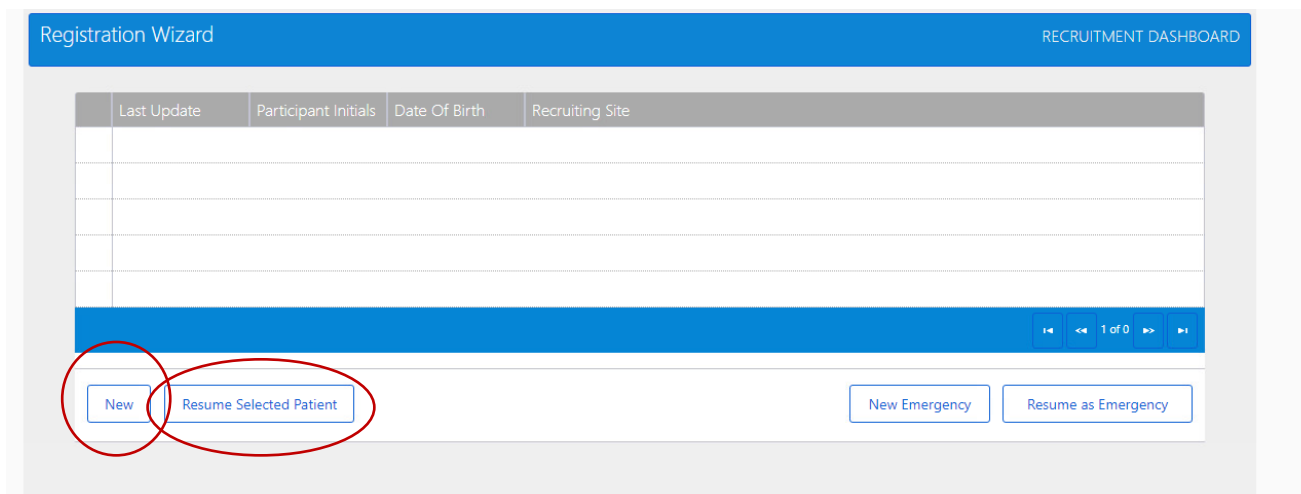
On the recruitment wizard page, you will see the Registration option. To the right you will see a blue 'GO' tab, click this button to start the registration process. This will open the new registration wizard page.



Selecting 'New' will allow you to register a new participant.



If you have had to leave the registration process part way through, these details will be saved on this page, select the relevant participant from table and when you are ready to proceed with the registration, click 'Resume Selected Patient'.



The screenshot shows the 'Registration Wizard' interface. At the top, there is a blue header bar with 'Registration Wizard' on the left and 'RECRUITMENT DASHBOARD' on the right. Below the header is a table with the following columns: 'Last Update', 'Participant Initials', 'Date Of Birth', and 'Recruiting Site'. The table is currently empty. Below the table is a blue bar with navigation controls: a left arrow, a double left arrow, '1 of 0', a double right arrow, and a right arrow. At the bottom of the interface, there are four buttons: 'New', 'Resume Selected Patient', 'New Emergency', and 'Resume as Emergency'. The 'New' and 'Resume Selected Patient' buttons are circled in red.

You will need to complete the details on each page before progressing to the next page to do this you need to click on the 'Next' button on the bottom right-hand side of the page. If at any point you need to correct information added on a previous page, please click the 'Previous' button on the bottom right-hand side of the page.

**Tip!**

**Initials must be entered as a 3 digits and must be entered as capital letters only i.e. A-A or AAA**

**All months must be entered in 3 character format i.e. JUN**

Participant Details And Consent RECRUITMENT DASHBOARD

Site name	UNIVERSITY HOSPITAL (COVENTRY) ▼
Participant initials	A-A
Date of birth	01-JAN-1970
Date informed consent form received from participant	12-DEC-2023
Name of person obtaining informed consent	Miss joe bloggs ▼

Cancel Previous Next

If at any point you need to leave the registration process, select 'Cancel'. The details will automatically be saved and will appear on the main recruitment dashboard for you to resume when you need to. Please remember to **resume** these patients if required to avoid duplicate registrations of the same patient.

You will be asked to confirm the information you have entered is correct. Select 'confirm'

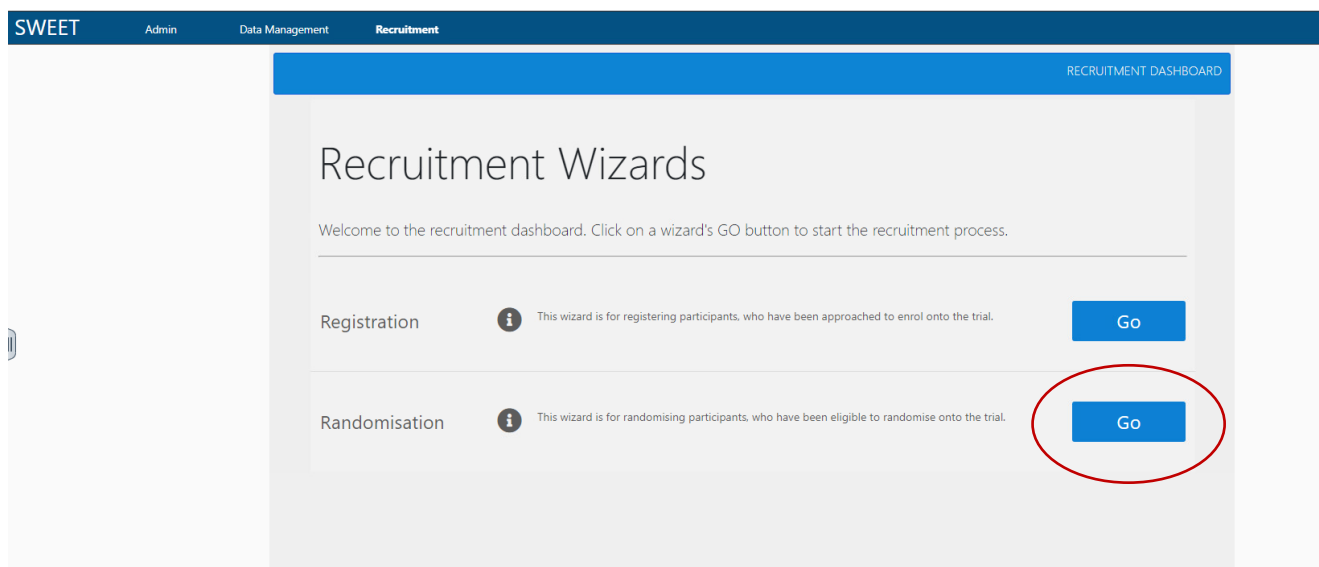
REGISTRATION CONFIRMATION		RECRUITMENT DASHBOARD
Site	UNIVERSITY HOSPITAL (COVENTRY)	
Participant initials	A-A	
Date of Birth	01-JAN-1970	
Date informed consent form received from participant	12-DEC-2023	
Name of person obtaining informed consent	Miss joe bloggs	

Cancel  Previous Confirm

Once registered you will receive the participants **trial number** and can complete the baseline pre-randomisation pack which contains the Eligibility, and Contact Details CRF (see section 5). The baseline questionnaire should also be completed prior to randomisation. **If the participant has opted to complete these electronically, WCTU will organise distribution of these through the database. If the participant has opted to complete these on paper, you will need to confirm these have been completed prior to randomisation.**

## 4.6 How to randomise a participant

On the recruitment wizard page, you will see the Randomisation option. To the right you will see a blue 'GO' tab, click this button to start the randomisation process. This will open the new randomisation wizard page.



This will bring up all registered participants at your site, awaiting randomisation. Please select the correct participant and select 'resume selected patient'.

Randomisation Wizard
RECRUITMENT DASHBOARD

**SWEET TRIAL NUMBER (TNO): 0003 | PARTICIPANT INITIALS: A-A | DATE OF BIRTH: 01-JAN-1970 | RANDOMISING SITE: UNIVERSITY HOSPITAL (COVENTRY)**

	Last Update	SWEET Trial Number (TNO)	Participant Initials	Date Of Birth	Randomising Site
<input checked="" type="checkbox"/>	19-Dec-2023 13:00	0003	A-A	01-Jan-1970	UNIVERSITY HOSPITAL (COVENTRY)

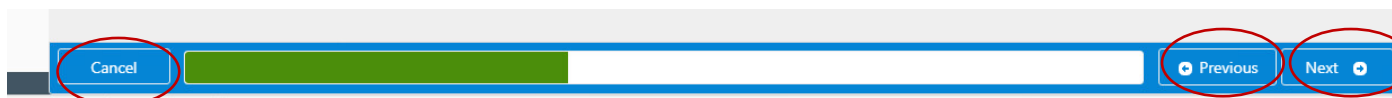
⏪ << 1 of 1 >> ⏩

Resume Selected Patient

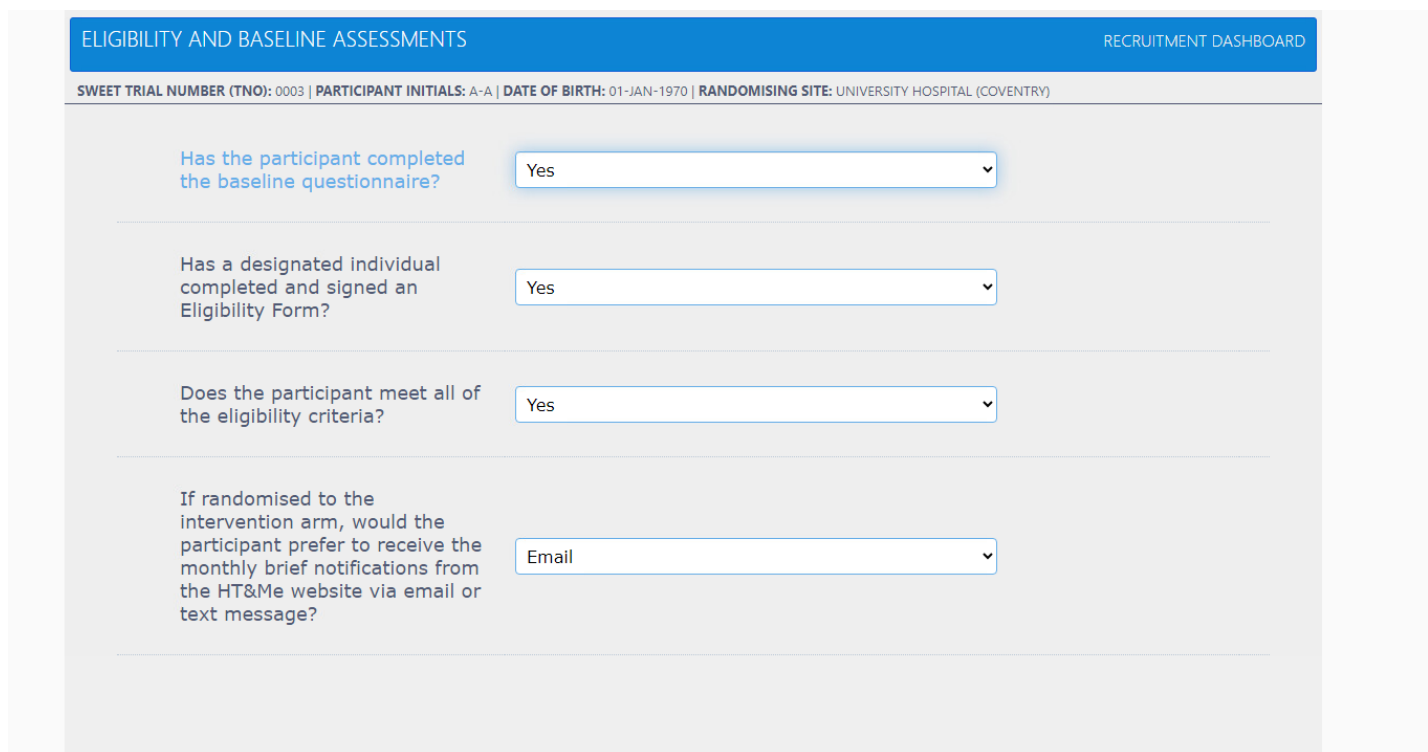
Resume as Emergency

You will need to complete the details on each page before then clicking on the 'Next' button on the bottom right-hand side of the page. If at any point you need to correct information added on a previous page, please click the 'Previous' button on the bottom right-hand side of the page.

If at any point you need to leave the randomisation process before randomisation, select 'Cancel'. The details will automatically be saved and will appear on the main recruitment dashboard for you to resume when you need to.



Prior to randomisation, you will need to confirm that the baseline questionnaire, and eligibility form have been completed. It is important from a methodological perspective that a participant **does not** know their trial allocation prior to completing their baseline questionnaire.



ELIGIBILITY AND BASELINE ASSESSMENTS RECRUITMENT DASHBOARD

SWEET TRIAL NUMBER (TNO): 0003 | PARTICIPANT INITIALS: A-A | DATE OF BIRTH: 01-JAN-1970 | RANDOMISING SITE: UNIVERSITY HOSPITAL (COVENTRY)

Has the participant completed the baseline questionnaire?	Yes
Has a designated individual completed and signed an Eligibility Form?	Yes
Does the participant meet all of the eligibility criteria?	Yes
If randomised to the intervention arm, would the participant prefer to receive the monthly brief notifications from the HT&Me website via email or text message?	Email

You will be asked to confirm all details are correct before proceeding with the randomisation.

RANDOMISATION CONFIRMATION RECRUITMENT DASHBOARD

SWEET TRIAL NUMBER (TNO): 0003 | PARTICIPANT INITIALS: A-A | DATE OF BIRTH: 01-JAN-1970 | RANDOMISING SITE: UNIVERSITY HOSPITAL (COVENTRY)

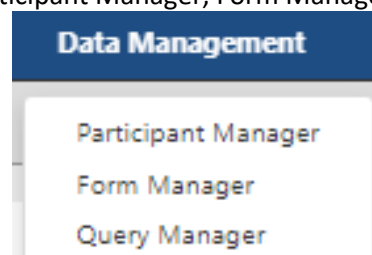
SWEET trial Number (TNO)	0003
Site	UNIVERSITY HOSPITAL (COVENTRY)
Date of birth	01-Jan-1970
Age at trial entry	>= 50 years
Current prescribed adjuvant endocrine therapy	Tamoxifen
Treatment complexity: Which of the following has the participant been prescribed, or is planned to receive as part of their breast cancer treatment?	No chemotherapy, no anti- HER2, no CDK4/6i (i.e., abemaciclib)

Once confirmed, you will then receive the participants trial allocation. The site PI, randomising practitioner, SWEET study nurse and main site contact will also receive a notification by email to confirm which arm the participant has been randomised to. Please save these emails appropriately as they are required within your ISF.

RANDOMISATION SUMMARY		RECRUITMENT DASHBOARD
SWEET TRIAL NUMBER (TNO): 0003   PARTICIPANT INITIALS: A-A   DATE OF BIRTH: 01-JAN-1970   RANDOMISING SITE: UNIVERSITY HOSPITAL (COVENTRY)		
SWEET trial Number (TNO)	0003	
Treatment allocation	HT&Me Intervention + usual care	

## 5 Data Management

Under the Data Management tab, you will see 3 headers: Participant Manager, Form Manager, Query Manager.



### 5.1 Participant Manager

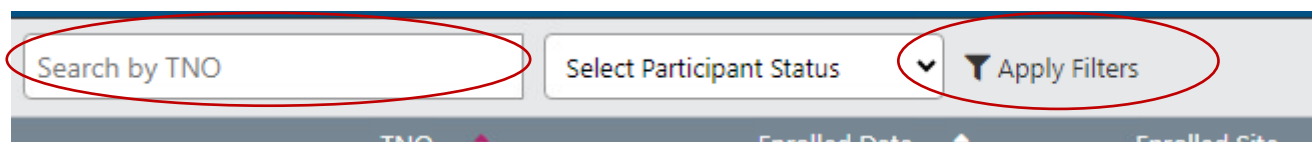
This shows a list of all the participants that have been enrolled at your site and will show an 'at glance' view of their form status.



	TNO	Enrolled Date	Enrolled Site	Completed Forms	Incomplete Forms	Overdue Forms	Unobtainable Forms	Missing Fields
<a href="#">View Forms</a>	0001	06-Jun-2023	Queen Elizabeth Hospital	1	44	0	0	0
<a href="#">View Forms</a>	0002	07-Jun-2023	University Hospital (Coventry)	1	30	0	0	0

You can search for a specific participant using the 'Search by TNO' feature, or you can filter by participant status using the drop-down arrow and apply filters button to only display:

1. Registered participants only
2. Randomised to the HT&Me intervention + usual care
3. Randomised to usual care alone



For each participant, you will see a 'View Forms' button, on the left-hand side which will allow you to access all of the forms for that participant.

	TNO	Enrolled Date	Enrolled Site	Completed Forms	Incomplete Forms	Overdue Forms	Unobtainable Forms	Missing Fields
<a href="#">View Forms</a>	0001	06-Jun-2023	Queen Elizabeth Hospital	1	44	0	0	0

Once on this view you can see the individual status of each form by clicking on the form you want to look at on the left, (this example shows the forms expected at baseline) and then on the right-hand side, you can click on 'View Form' to open the eCRF to complete, edit or review.

TNO: 0001 | Enrolled Date: 15-Dec-2023 | Site: Queen Elizabeth Hospital

< Participant Search

Scheduled Events	Pre Randomisation Pack - Expected: 15-Dec-2023										
Registration form	Eligibility <span>Form Options</span> <span>View Form</span>										
Pre Randomisation Pack <span>⚠</span>	<table border="1"> <thead> <tr> <th>Data Summary</th> <th>Audit Summary</th> </tr> </thead> <tbody> <tr> <td>Data entry status <span>Pending</span></td> <td>Created date</td> </tr> <tr> <td>Form status</td> <td>Created by</td> </tr> <tr> <td>User Notes 0</td> <td>Last modified date</td> </tr> <tr> <td>Open Queries 0</td> <td>Last modified by</td> </tr> </tbody> </table>	Data Summary	Audit Summary	Data entry status <span>Pending</span>	Created date	Form status	Created by	User Notes 0	Last modified date	Open Queries 0	Last modified by
Data Summary	Audit Summary										
Data entry status <span>Pending</span>	Created date										
Form status	Created by										
User Notes 0	Last modified date										
Open Queries 0	Last modified by										
Randomisation form											
Baseline Form <span>⚠</span>											
Nurse checklist appointment 1 <span>⚠</span>											
Nurse checklist appointment 2 <span>⚠</span>	<table border="1"> <thead> <tr> <th>Data Summary</th> <th>Audit Summary</th> </tr> </thead> <tbody> <tr> <td>Data entry status 100%</td> <td>Created date 15-Dec-2023 12:36:56</td> </tr> <tr> <td>Form status N/A</td> <td>Created by u2171544</td> </tr> <tr> <td>User Notes 0</td> <td>Last modified date 15-Dec-2023 12:37:39</td> </tr> </tbody> </table>	Data Summary	Audit Summary	Data entry status 100%	Created date 15-Dec-2023 12:36:56	Form status N/A	Created by u2171544	User Notes 0	Last modified date 15-Dec-2023 12:37:39		
Data Summary	Audit Summary										
Data entry status 100%	Created date 15-Dec-2023 12:36:56										
Form status N/A	Created by u2171544										
User Notes 0	Last modified date 15-Dec-2023 12:37:39										
5 months follow up <span>⚠</span>											
12 months follow up <span>⚠</span>											

## 5.2 General guidance for data entry

### 5.2.1 Dates

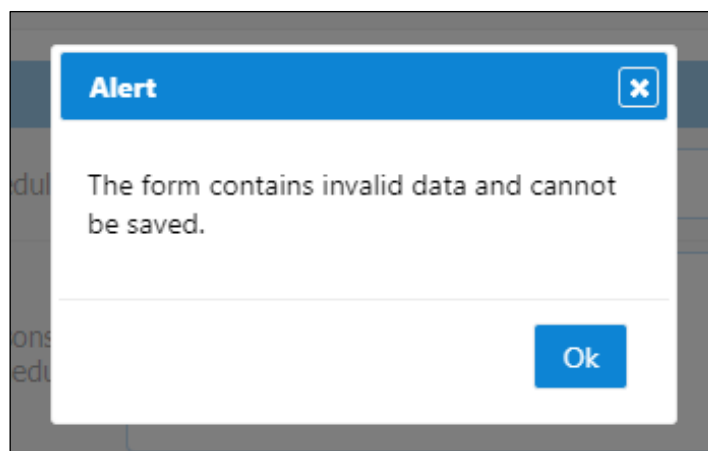
The database requires the date to be entered in the format dd-mmm-yyyy. If only a partial date is known, apply these rules:

- If the day is unknown, enter as **15**-mmm-yyyy

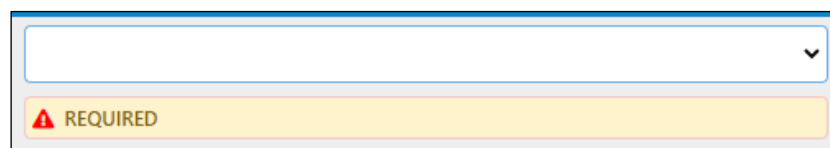
If the day and month are unknown, the field should be left blank and marked as unobtainable (see section 5.2.4 for how to do this).

### 5.2.2 Required fields and validations

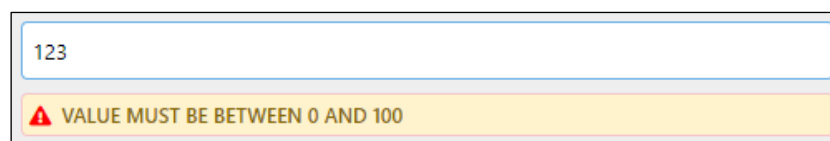
Some fields are required within the database, this means that data must be inputted into these fields before a form can be saved. If you try to save a form with a required field missing, you will receive the following error message:



Once you select 'Ok' the system will flag the relevant required field within the form, to prompt you to enter the missing data. A form cannot be saved until this data is complete.



Validations are also used in some places within the database to ensure data is entered logically and in the correct format (i.e. dates/ numerical values). If data is entered in an incorrect format, the following flag will appear below the relevant field indicating the required data format.



### 5.2.3 Sub-forms

There are some instances within the database where a response to a question will activate a sub-form. This is common (but not exclusively) where the paper CRF has a data table. A sub-form allows you to enter several records against one question item. An example of a sub-form is on the Baseline Form; if a participant has any changes to their prescription, these will need to be added on to the sub-form.

To add a new record to the sub-form, select the plus (+) icon; you can add as many records as required.

CHANGES TO THE PRESCRIPTION DETAILS +

Date started:	<input type="text"/>	DD-MON-YYYY	...
Date stopped:	<input type="text"/>	DD-MON-YYYY	...
Previous endocrine therapy:	<input type="text"/>	▼	...
Please detail below:	<input type="text"/>		...
Reason for drug change:	<input type="text"/>	▼	...
Please detail below:	<input type="text"/>		...

« < 1 of 2 > » +

Records added in error can be deleted using the **dustbin** icon.



#### 5.2.4 Unobtainable flag

If a data item is not available and is expected to be so for the duration of the study therefore cannot be entered, the unobtainable flag can be set by clicking on the three-dot button (ellipsis) to the right of each field and selecting 'Set unobtainable flag'.

A screenshot of a form field labeled "Ethnic origin (please select one):". The field is empty. To the right of the field is a three-dot menu button. A red circle highlights the menu button, and a dropdown menu is open, showing the option "Set Unobtainable Flag".

If needed, you can remove the unobtainable flag by clicking on the three-dot button again and selecting 'Remove unobtainable flag' if the data which was previously unobtainable becomes available.

#### 5.2.5 Form completed by

At the bottom of each form, you may be required to select who the form has been completed by from the drop-down menu. If you are entering directly from source data onto the database this must be your name. If you are entering a paper form completed by a colleague you can select their name, but they must have signed the paper copy of the form which should be filed in your Investigator Site File.

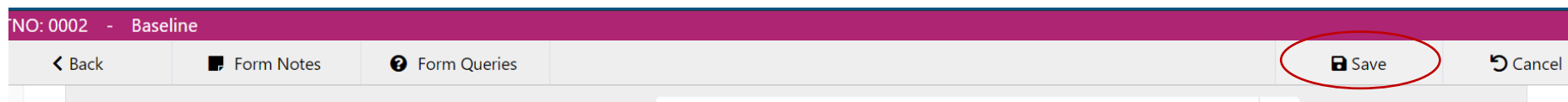
#### 5.2.6 Form status

At the bottom of each form, you will be required to select the status of the form from the following list:

- **Complete:** The form is complete, and data has been entered into all applicable fields.
- **Complete with unobtainable missing data:** All known data has been entered and unknown data has been marked as unobtainable (see section 5.2.4).
- **Query in progress:** A data query is in progress; this can be selected by site users or the Warwick trial team.
- **Data entry in progress:** Data entry has commenced but is not yet complete, this tells the trial team that you haven't finished entering the form yet.

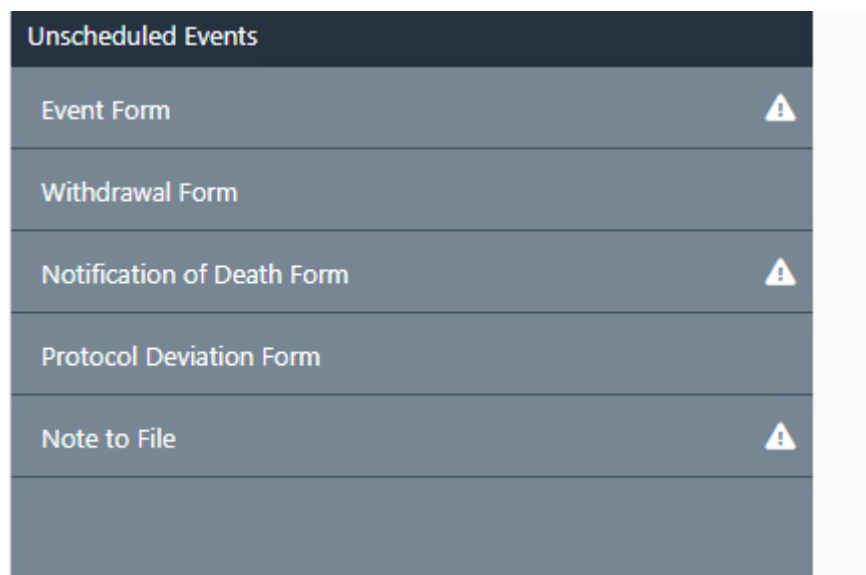
### 5.2.7 Saving forms

Once you have completed data entry, save the form using the 'Save' button at the top right.



### 5.2.8 Unscheduled events (forms)

To add a form for an unscheduled event (e.g. participant withdrawal, notification of death, protocol deviation), navigate to the list of unscheduled events in the left-hand menu. Adding a new form will enable you to enter data for these 'events' where needed.





Select the '+New Form' button to commence data entry.

TNO: 0001 | Enrolled Date: 15-Dec-2023 | Site: Queen Elizabeth Hospital

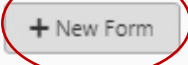
< Participant Search

### Scheduled Events

- Registration form
- Pre Randomisation Pack 
- Randomisation form
- Baseline Form 

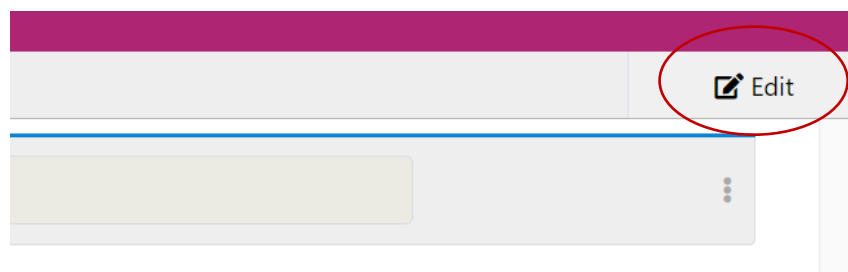
### Withdrawal Form

No forms have been entered for this event.

 + New Form

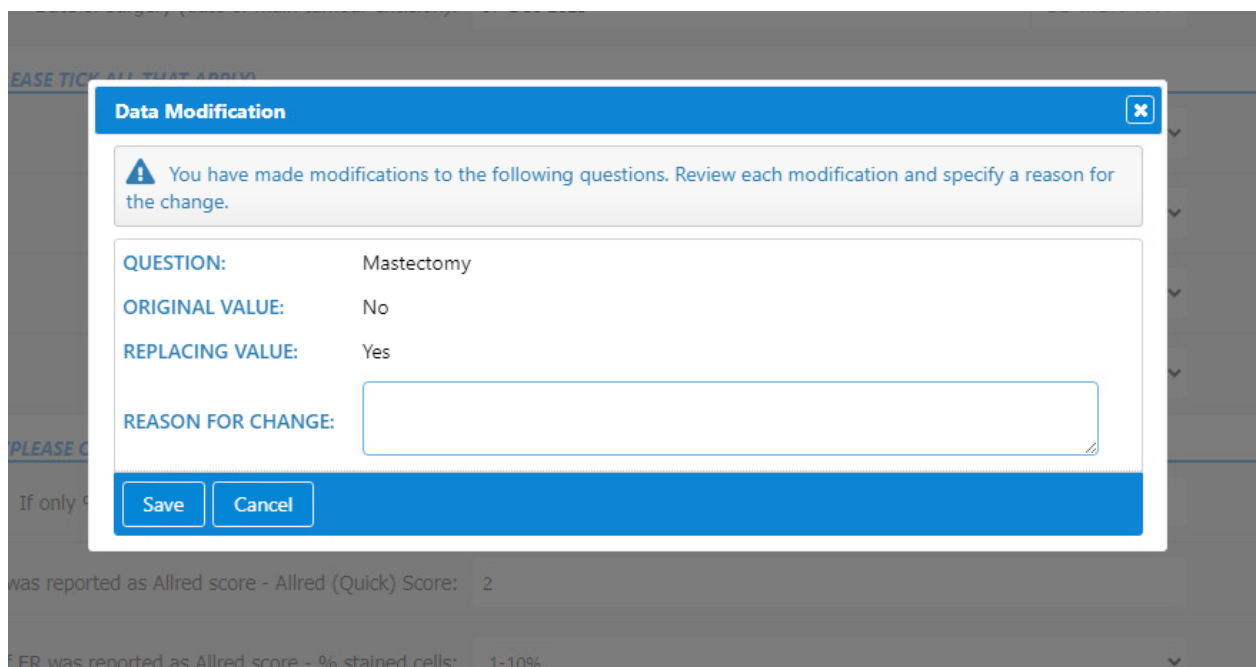
### 5.2.9 Editing data

If data has been entered and the form saved, but you wish to edit, click on the 'View Form' button for the form you would like to edit. Then click the 'Edit' button in the top right corner.



The image shows a close-up of the 'Edit' button in the top right corner of a form view. The button is a grey rectangle with a pencil icon and the text 'Edit'. It is circled in red. Below the button is a light grey bar with a vertical ellipsis menu icon.

If you change data that has already been entered, when you click the 'Save' button to save your changes, the following pop-up will appear:



**Data Modification**

⚠ You have made modifications to the following questions. Review each modification and specify a reason for the change.

QUESTION:	Mastectomy
ORIGINAL VALUE:	No
REPLACING VALUE:	Yes

REASON FOR CHANGE:

Save Cancel

Please enter text in the 'Reason for change' field to fully explain the reason that you are changing the data.

### 5.3 Form Manager

The form manager tab will show a list of all forms for all participants at your site and show the status of completion. There are several options that you can sort by, for example, you can sort by TNO, form name, date expected etc. To use a more comprehensive set of filters, you can open the filter bar further by selecting the 2 way arrow in the top left corner.



Form	Expected	Received	TNO	Data Entry Status	Notes / Queries	Created	Last Modified
*** Registration form	15-Dec-2023		0001	100%		15-Dec-2023 12:04:53 @ u2171544	15-Dec-2023 12:04:53 @ u2171544
*** Contact Details	15-Dec-2023		0001	100%		15-Dec-2023 12:36:56 @ u2171544	15-Dec-2023 12:37:39 @ u2171544
*** Eligibility	15-Dec-2023		0001	Pending			

## 5.4 Query Manager

Queries will be raised by the DEC, Trial Coordinator or Trial Manager at WCTU on each applicable data item on the eCRFs. You will be able to tell if an item has a query as there will be a burgundy coloured '?' next to the data item. To view the query, click on the 3 dots on the right-hand side and select 'Show Queries', this will bring up the query and allow you to post a response to the query.

### PARTICIPANT DETAILS

Height: 1.90 ? (1) ⋮

### PARTICIPANT DETAILS

Height: 1.90 
 Show Notes  
 Show Queries

## ? Height ×

Post a query:

height correct

[Post as response](#) [Post as new query](#)

---

Posted by [u2171544](#) on 07-Jun-2023 13:29:12 ✎ 🗑

Please confirm height is correct

**Remember**, if the data item query requires you to amend a field or enter missing data, please update the form values as well as responding to the queries. You can state in your query response that the form has been updated

You can also see a full list of all queries under the 'Query Manager' tab. Which will show you a list of the TNO, the form, the data item, and the query. They are coloured in a traffic light system:

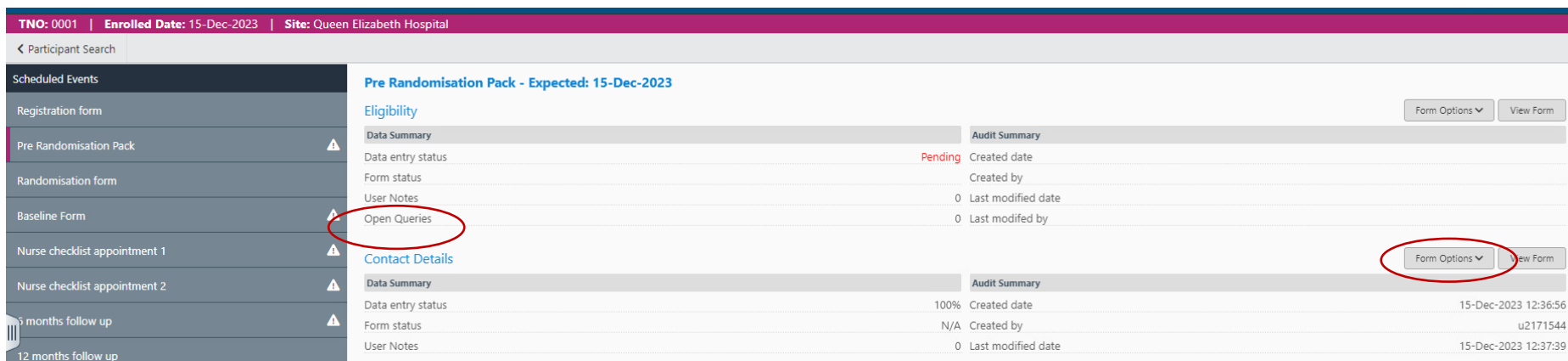
Red	A query has been added and requires a response from site
Orange	A site has responded to the query and will need WCTU staff to check the response, once we are happy with the response, we will resolve the query.
Green	Resolved queries

You have the option to filter this page to see only unresolved ('red') queries. You can complete these queries on a regular basis, however once a month the DEC at WCTU will run a report which highlights all unresolved queries raised for each participant at each site. These lists will be sent to sites for review and response. The response to the queries can be managed directly in the database, by replying to the query comment and updating the data field as per the query. If the data item is missing and the data is unable to be obtained, then the field can be marked as unobtainable (see section 5.2.4). This is only to be used if the data will never be able to be obtained.

Participant TNO: <input type="text"/>	Participant enrolled site: <input type="text" value="Display All"/>				
Event name: <input type="text" value="Display All"/>	Form name: <input type="text" value="Display All"/>				
Sort By: <input type="text" value="TNO"/> <input type="button" value="⌵"/>	Query State: <input type="text" value="Unresolved (Red or Orange)"/>				
<input type="button" value="⏪"/> <input type="button" value="⏩"/> Page <input type="text" value="1"/> of 1 <input type="button" value="⏪"/> <input type="button" value="⏩"/>					
TNO	Event	Form	Data Item	State	Query
0001	Baseline	Baseline	Height	●	please confirm height is correct
0001	Baseline	Eligibility	(Whole form)	●	Missing

## 5.5 Form Queries

Queries can also be raised on an entire form and will be available to view under the 'Query Manager tab'. To view a form query, navigate to the participants record and select the **Form options** drop-down menu next to the eCRF that the query has been raised against. You can then select **View/Add Form Queries** to view the query for this form.



The screenshot shows a participant record for TNO: 0001, enrolled on 15-Dec-2023 at Queen Elizabeth Hospital. The 'Scheduled Events' list includes 'Pre Randomisation Pack', 'Randomisation form', 'Baseline Form', 'Nurse checklist appointment 1', 'Nurse checklist appointment 2', '3 months follow up', and '12 months follow up'. The 'Pre Randomisation Pack' form is highlighted in red. The 'Open Queries' link is circled in red. The 'Form Options' dropdown menu is also circled in red.

Eligibility		Audit Summary	
Data entry status	Pending	Created date	
Form status		Created by	
User Notes	0	Last modified date	
Open Queries	0	Last modified by	

Contact Details		Audit Summary	
Data entry status	100%	Created date	15-Dec-2023 12:36:56
Form status	N/A	Created by	u2171544
User Notes	0	Last modified date	15-Dec-2023 12:37:39

The form query raised by the WCTU trial team will be listed and you can write a response in the **Post a query** field. The response can then be posted using the **Post as response** button as listed in section 5.4.

**Remember**, if the data item query requires you to amend a field or enter missing data, please update the form values as well as responding to the queries. You can state in your query response that the form has been updated

## 6 Data return schedule (Appendix 1)

Approx Week No.	0-1		4-5	16-17	Follow up		
	Baseline	Randomisation	Consultation 1 HT&Me arm	Consultation 2 HT&Me arm	6months	12months	18months
1. Registration	x						
2. Eligibility	x						
3. Participant contact details	x						
Baseline Questionnaire	x						
4. Randomisation		x					
5. Baseline		x					
Consultation 1 checklist (HT&Me only)			x				
Consultation 2 checklist (HT&Me only)				x			
6. Follow up					x	x	x
Follow up questionnaire					x	x	x
<b>UNSCHEDULED FORMS</b>							
(to be completed if any of the events below occur from Randomisation to 18 months post randomisation)							
7. Event form							
8. Withdrawal form							
9. Notification of death							
10. Protocol Deviation							

Green = Site responsibility to complete & enter in CDMS

Orange = WCTU responsibility to enter in CDMS

Purple = Site or BCN responsibility to complete & enter in CDMS

## 7 Self-Evident Corrections (SECs). (Appendix 2)

Self-Evident Correction – Pre agreed with trial investigators. No action required from site.	
Action by WCTU	Item
<ol style="list-style-type: none"> <li>1. Document SEC on the database</li> <li>2. Correct CRF in green pen (where paper CRFs are received)</li> <li>3. Initial and date in green pen. (where paper CRFs are received)</li> <li>4. Annotate 'SEC' on CRF and write out corrected wording next to data item. (where paper CRFs are received)</li> <li>5. Annotate 'SEC' on specific data item on eCRF (electronic CRFs)</li> <li>6. If it is a multiple choice question where only 1 answer can be entered, circle the answer which has been entered into the online application. (where paper CRFs are received)</li> <li>7. No query needs to be raised, and no updated CRFs need to be sent to site for their records.</li> </ol>	<p><b>Unknown dates</b> If the day is unknown, enter as <b>15/mmm/yyyy</b> If the day and month are unknown, the field should be left blank and marked as unobtainable. <b>Where this information does not fit with inbuilt validations in the database, or the dummy dates are illogical, this should be marked as unobtainable. Advice should be sought from the TM or statistician if there are any concerns.</b></p>
	<p><b>Decimal places</b> Where decimal places cannot be entered into the online application. These should be <b>rounded up/down</b> using standard rounding rules.</p>
	<p><b>Spelling mistakes and grammatical errors</b> Obvious spelling mistakes should be corrected. Any spelling mistakes which are unclear / ambiguous should be checked with the TC/TM. Anything we are not able to correct with certainty should be queried with site under the standard query process.</p>
	<p><b>Tick box logic</b> If a tick box (yes/no) is blank but the data below this tick box confirms the tick box above should be completed as yes or no. (as applicable) then this can be completed. <b>Confirm with TC/TM in first instance.</b></p>
	<p><b>Database Bugs</b> <b>If the validation on the database will not allow you to enter the data exactly as it is written, check with TM/TC.</b> If a decision is taken to enter data differently than it appears on the CRF, this must be agreed with TM/TC first and documented on the CRF in green pen, dated and initialled.</p>
	<p><b>The use of "arrows"</b> If the site/participant have used "arrows" indicating the information has been recorded in the incorrect boxes, following TC/TM agreement this can be documented and entered in the correct field.</p>
	<p><b>Reason codes</b> If a reason has been documented as "other", but the comment clearly fits into a pre-coded category, this can be updated as an SEC.</p>
	<p><b>Patient Questionnaire:</b> If the date of completion has been left blank:</p>

Self-Evident Correction – Pre agreed with trial investigators. No action required from site.	
Action by WCTU	Item
	<ul style="list-style-type: none"> <li>fill in the date the booklet was received in green pen. Initial and date the addition.</li> </ul> <p>Enter the date the booklet was received as the “date of completion” on the database.</p>
	<p><b>Patient Questionnaire:</b> If only the initials have been entered on the questionnaire booklet, the TNO can be entered via SEC provided there is <u>sufficient</u> evidence to confirm which patient it is relating to. <b>This should be confirmed by the TM / TC, and the SEC should be initial and dated by the TM / TC.</b></p> <p>If only the TNO has been entered on the questionnaire booklet, the Initials can be entered via SEC. This can be added by any SWEET staff but should be initial and dated in green pen.</p>
	<p><b>Patient Questionnaire ONLY:</b> If the Time-point has obviously been selected incorrectly, this can be corrected via SEC provided there is <u>sufficient</u> evidence to confirm which time-point is the correct one. <b>This should be confirmed by the TM / TC / Statistician, and the SEC should be initial and dated by the TM / TC.</b></p>
	<p><b>Patient Questionnaire ONLY:</b> If more than one answer is provided per question, enter the “worst” case scenario. Circle the answer you have inputted and initial and date in green pen.</p>
	<p><b>Patient Questionnaire ONLY:</b> If any of the values provided have been completed as a range (i.e. 3-4 days), enter the median/middle value. If the values are clearly documented in the wrong units (i.e. patient has recorded days instead of hours / weeks instead of days), please convert the numbers into the correct units. <b>This should be confirmed by the TM / TC before amending.</b> Confirm what has been entered onto the online application by documenting the value in green pen at the side of the relevant question. Initial and date in green pen.</p>