

ESCAPE Trial: Castor Data Entry Guidelines

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Intended User(s): DMT / TMT / Site staff

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1. Getting Started with the Castor DMS

Logging into Castor

At the start of the trial, you will be contacted by the TCTU Data Management Team who will give you access to the Castor TEST Data Management System (DMS). After you have completed test data entry, you will be given access to the live site.

You will then receive an email from Castor.

Your email address is your username.

To log in to the Castor TEST DMS go to <https://uk.castoredc.com/>

Select your region – **UK**.

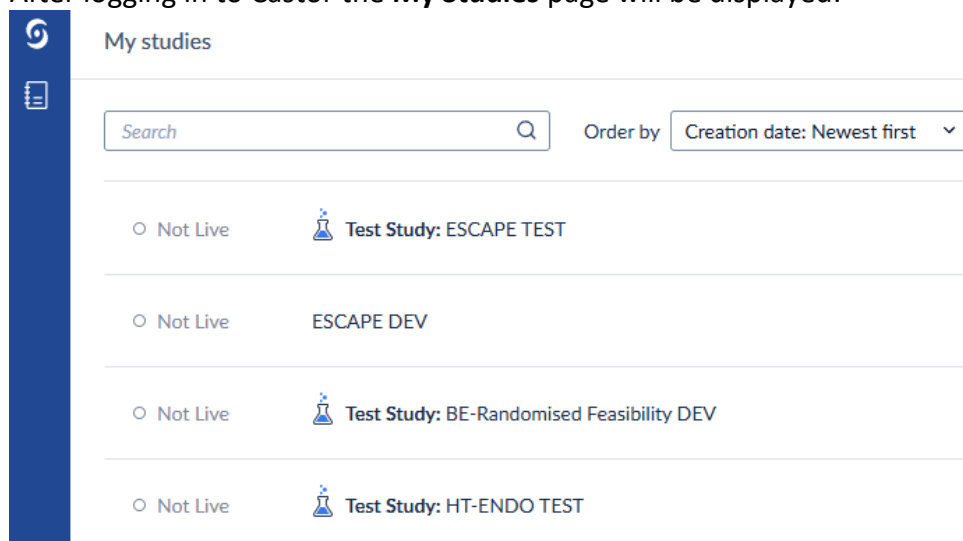
Enter your username and password.

All users should log out after each session by clicking the **Account** icon  at the bottom left of the page and clicking **Log out**.

Castor users will automatically be logged out after 20 min of inactivity.

2. My Studies page

After logging in to Castor the **My Studies** page will be displayed:



My studies	
Search	Order by: Creation date: Newest first
☐ Not Live	 Test Study: ESCAPE TEST
☐ Not Live	ESCAPE DEV
☐ Not Live	 Test Study: BE-Randomised Feasibility DEV
☐ Not Live	 Test Study: HT-ENDO TEST

Click on the trial where you want to enter data (ESCAPE TEST or ESCAPE LIVE).

To return to **My Studies** page from any other page, click either  or  at the top left of the screen.

3. Adding a new participant

To add a new participant to the database, click **+ New** at the top of the participants table.

ESCAPE TEST ▾ Not Live (v.114.61)

Participants

Participant ▾ ☐ Exact match

+ New Actions ▾ Filters ⓘ

List Visit Form

☐ Participant ... ▾	Site ▴▾	Survey co... ▴▾	Progress ▴▾	Last opene... ▴▾	Created on ▴▾	Updated on ▴▾	Status ▴▾	Castor Connect	🔒 ⓘ ⚙
☐ 0101	01-Tayside	-		Gillian Martin	08 Dec 2025	19 Jan 2026	Not set		🔒 ⓘ ⚙
☐ 0102	01-Tayside	0%		Emma Falconer	16 Oct 2025	21 Jan 2026	Not set		🔒 ⓘ ⚙

The **Create New Participant** dialogue box will open:

Create New Participant

Site

TCTU ▾

Participant ID *

(required)

Participant ID is a required field

Participant email

☐ Create another

Cancel Create

Site name will be pre-populated

Enter participant ID (4 numbers with no spaces or dashes) and click **Create**

Enter participant email, if they have agreed to completing electronic diaries

Participant ID:

The participant ID is made up of 4 numbers. The **first part** is the site number. The **second part** is the participant number. There should **not** be a space or dash between site number and participant number. e.g. participant ID 0101 is site 01, participant 01.

When (or if) the participant is randomised on TRuST, the same participant ID must be used that was entered when creating the participant in Castor.

4. Participants Page

After selecting your trial on the **My Studies** page, the **Participants** page will be displayed.

This displays a list of participants with various ways of viewing the participants:

- **List** shows a list of participants with various details
- **Visit** shows the progression of each participant at each visit
- **Form** shows the progression of each participant within each form

In the **Progress** column a **blue** bar means that data entry is incomplete for that participant and a **green** bar means that data entry is complete. At the end of the trial all participants must have a **green** progress

Participants + New Actions Filters

Participant ☐ Exact match

List Visit Form

☐ Participant...	Site	Progress	Last opene...	Created on	Updated on	Status	
☐ 0101	Tayside		Margaret Band	17 Apr 2023	27 Apr 2023	Not Set	
☐ 0102	Betsi Cadwaladr		Mel Sturgess	23 Mar 2023	26 Apr 2023	Not Set	
☐ 0303	Birmingham		Margaret Band	09 Mar 2023	28 Apr 2023	Not Set	

From any data entry page click **Back to participants** at the top left of the screen to return to the **Participants** page.

5. Data Entry

Selecting a Participant

From the **Participants** page, select a participant by clicking on it.

A pre-existing participant might open at the last point of data entry, but a newly created participant will open at Visit 1.

After successfully creating a new participant, you will see a view like the one below. This is the default data entry page for a new participant.

Data collection progress

75%

☒ Show repeating data instances

Visit 1 - Screening 96%

- ☒ Informed Consent
- ☐ Inclusion Criteria
- ☒ Exclusion Criteria
- ☒ Demographics
- ☒ Medical History
- ☒ Concomitant Medications
- ☐ Pregnancy Test
- ☒ ECG
- ☒ Vital Signs

Visit 1 - Screening

1. Informed Consent

✓ 1.1 Date of Screening V1 *
01-08-2023 (dd-mm-yyyy)

✓ 1.2 Date of Informed Consent *
01-08-2023 (dd-mm-yyyy)

✓ 1.3 Is the date of consent after date of screening?
NO

✓ 1.4 Has the participant agreed to be contacted by trial staff for further ethically approved future research *
☒ Yes ☐ No

Back

Next

Visits, Forms and Fields

Data entry consists of:

Visits e.g. Visit 1 - Screening (blue box) - visits contain forms.

Forms e.g. Informed Consent (white box) - forms contain fields.

Fields e.g. Date of Screening V1.

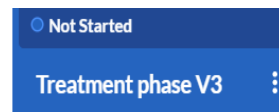
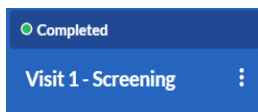
1.1 Date of Screening V1
20-04-2023 (DD-MM-YYYY)

There is also a visit named **Completion of Trial/Early Withdrawal**.

This is not a trial visit but is a mandatory form which **must** be completed for every participant when they complete or withdraw from the trial.

Each **visit**, **form** and **field** have icons which indicate the progress of data entry

Completed – green
In progress – orange
Not started – clear



Click on appropriate **Visit**.
Click on appropriate **Form**.
Enter data for each **Field**.

Some fields have the  icon.
Clicking on this provides additional information relevant to the field.

After data is entered, Castor performs validation checks. If there is something inconsistent with the data, an error will appear in an orange box underneath the affected field.
Here are 2 examples of error messages:

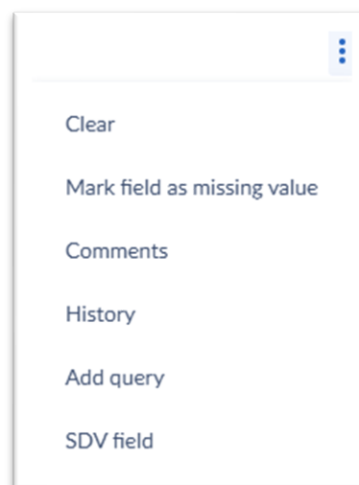
 Date cannot be in the future.

 Date of consent cannot be after the date of visit 1.

It is important to address the error message before continuing

If the data is correct but an error message still shows, add a comment by clicking on the  to the right of the field to explain that the entered data is correct.

- Click the  to the right of the field
- Select **Comments**
- Enter **New comment**, e.g. **age is correct**
- Click **Add comment**
- Click **Close**



A dropdown menu with a blue header bar containing three vertical dots. The menu items are: Clear, Mark field as missing value, Comments, History, Add query, and SDV field.

It is important that error messages are not ignored – make sure they are addressed as they appear, this will avoid data queries being raised.

Dates

Dates will normally be entered using the format **DD-MM-YYYY**.

For date fields that do not have a calendar icon next to the field, it is possible to enter a partial date.

If the day or month of a date is unknown, enter NK in the respective partial date field.

For example, an unknown day in June 2022 would be entered **NK-06-2022**.

Range Error Messages

Out-of-range error messages appear in **RED** text directly below the affected field.

Review the entered data and correct if necessary.

If the data is correct but out-of-range, add a comment to explain that the entered data is correct.

Out-of-range values cannot be saved in the field, they can only be recorded in a comment.

Navigating away from the form results in the data being automatically deleted from the field.

Example of a range error:

Participants must be aged between 18 - 120 or are not eligible for trial.

14 Age

The maximum value for this field is 120

15 Gender

Calculation Fields

Calculation fields are automatically populated once data has been added to a field(s).

They may be used to generate error messages.



1.1	Date of Screening		(dd-mm-yyyy)
1.2	Consent provided by		
1.3	Date of consent		(dd-mm-yyyy)
1.4	Is date of consent on or after date of screening?	Not all values for this calculation are available (yet).	

Calculation field

Default calculation message is shown when not all relevant data have been entered

Screening

1. Informed Consent

1.1	Date of Screening	05-06-2020	(dd-mm-yyyy)
1.2	Consent provided by	Participant	
1.3	Date of consent	05-06-2020	(dd-mm-yyyy)
1.4	Is date of consent on or after date of screening?	YES	

Calculation field automatically populates with a value once all associated fields have been completed

If a calculation field does not populate as expected or generates an error message incorrectly:

- Refresh the page
- If the problem persists, contact the DMT

6. Repeating Data

Whilst the main structure of the database is made up of **visits** and **forms**, the system also contains **REPEATING DATA**.

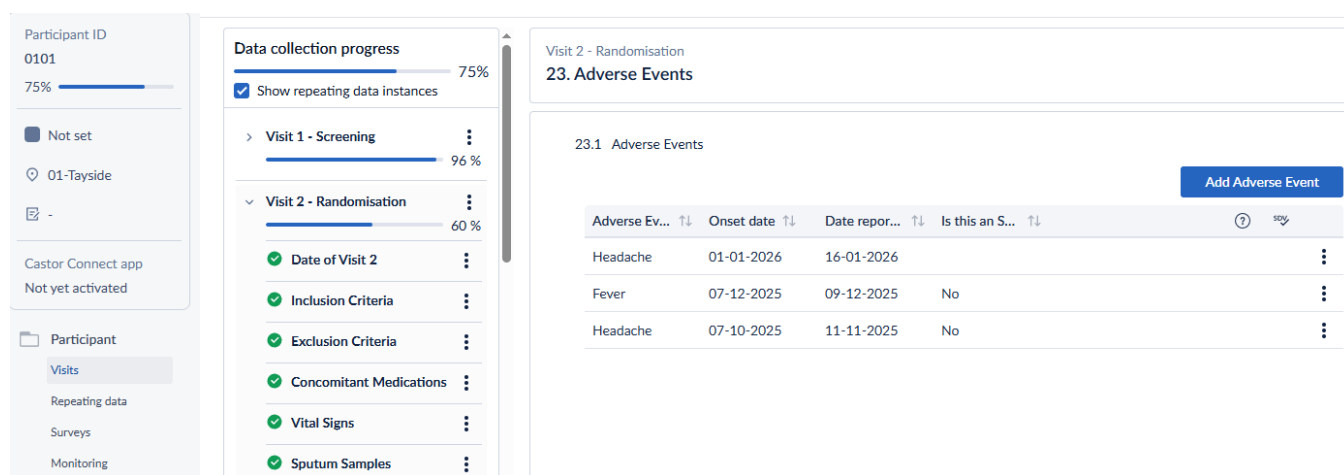
Repeating Data forms are used to either capture data that is recorded for several trial visits or not strictly connected to a visit at all.

Examples:

- Sputum results
- Adverse Events
- Exacerbations
- Concomitant Medications
- Vital Signs
- Questionnaires

Below is an example of how to complete an AE Repeating Data.

Click Add Adverse Event.



Participant ID 0101
75%

Not set
01-Tayside
-

Castor Connect app
Not yet activated

Participant
Visits
Repeating data
Surveys
Monitoring

Data collection progress 75%
☒ Show repeating data instances

Visit 1 - Screening 96 %
Visit 2 - Randomisation 60 %

✓ Date of Visit 2
✓ Inclusion Criteria
✓ Exclusion Criteria
✓ Concomitant Medications
✓ Vital Signs
✓ Sputum Samples

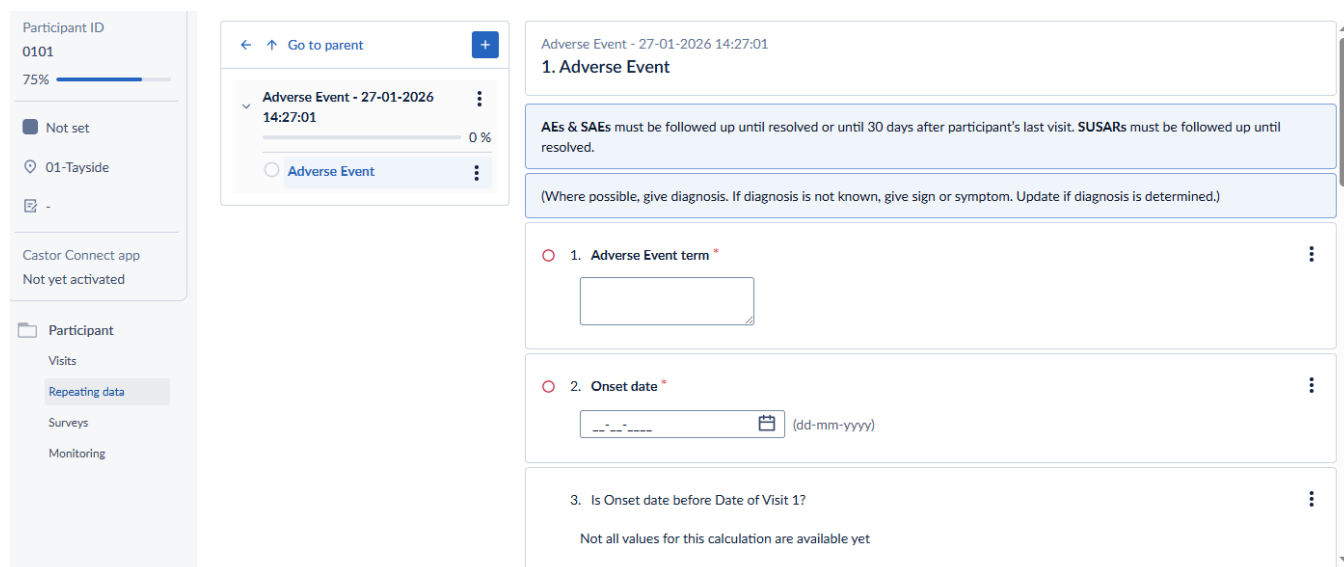
Visit 2 - Randomisation
23. Adverse Events

23.1 Adverse Events

Add Adverse Event

Adverse Ev...	Onset date	Date repor...	Is this an S...
Headache	01-01-2026	16-01-2026	
Fever	07-12-2025	09-12-2025	No
Headache	07-10-2025	11-11-2025	No

The page will automatically redirect to the newly created AE repeating data, as shown below.



Participant ID 0101
75%

Not set
01-Tayside
-

Castor Connect app
Not yet activated

Participant
Visits
Repeating data
Surveys
Monitoring

Adverse Event - 27-01-2026 14:27:01
1. Adverse Event

AEs & SAEs must be followed up until resolved or until 30 days after participant's last visit. SUSARs must be followed up until resolved.

(Where possible, give diagnosis. If diagnosis is not known, give sign or symptom. Update if diagnosis is determined.)

1. Adverse Event term *

2. Onset date *

3. Is Onset date before Date of Visit 1?

Not all values for this calculation are available yet

After entering the data required, click on “Visits” to return to the participant overview. The AE repeating data form that has been completed will appear in the Adverse Event table for each visit.

Add Adverse Event				
Adverse Ev... ↑↓	Onset date ↑↓	Date repor... ↑↓	Is this an S... ↑↓	
				⋮
Headache	01-01-2026	16-01-2026		⋮
Fever	07-12-2025	09-12-2025	No	⋮

Some repeating data can also be added via **REPEATING DATA BUTTONS**. An example of this is shown in the Questionnaires form below.

Participant ID
0101

75%

☐ Not set

☐ 01-Tayside

☐ -

Castor Connect app
Not yet activated

Participant

Visits

Repeating data

Surveys

Monitoring

Data collection progress

75%

☒ Show repeating data instances

> Visit 1 - Screening 96 %

▼ Visit 2 - Randomisation 60 %

☒ Date of Visit 2

☒ Inclusion Criteria

☒ Exclusion Criteria

☒ Concomitant Medications

☒ Vital Signs

☒ Sputum Samples

Visit 2 - Randomisation

18. Questionnaires

18.1

Add CAAT

18.2

Add EQ-5D-5L

18.3

Add QOL-B

After clicking the repeating data button, the following message box will appear. For example, click **Create** to generate a CAAT repeating data.

Create a repeating data instance



Repeating data *

Chronic Airways Assessment Test (CAAT)

Instance name *

For auto-generated names this is a preview. The name that will be actually stored may differ as it will be regenerated upon the actual creation.

Chronic Airways Assessment Test (CAAT) - 27-01-2026 14:37:09

Parent *

A visit

Visit 2. Visit 2 - Randomisation

Cancel

Create

When data have been entered for this questionnaire, click on “visits” to redirect you back to the visit/form from before.

Repeating data should be created for the appropriate visit.

Repeating Data added from the Repeating Data section rather than from a Visit

Some repeating data is created from the Repeating Data section of the eCRF, rather than from a specific visit

Examples of this are:

ESCAPE Paper Symptom Diary

Visit 2 - Randomisation

21. Symptom diary setup

✓ 21.1 Has the participant provided their email address to receive the daily symptom diary? *

☐ Yes ☒ No

 Please provide participant with paper copies of the symptom diary

Repeating data for **ESCAPE Paper Symptom Diary** should be created thus:

Click Repeating Data at the left of the screen → click **+ Create** → select the required repeating data, e.g. **ESCAPE Paper Symptom Diary** → for Parent select **A visit** → click **Create** → the repeating data will open and can be completed.

Accessing previously created repeating data

Select the correct trial from the **My Studies** page.
Select the correct participant.
Click **Repeating Data** from the top left of the screen.
The **Repeating Data** page will be displayed.

You can either choose the repeating data of interest by clicking it or use  to select the repeating data you wish to view.

Archiving Repeating Data Created in Error

Repeating data which are created in error can be removed by the data entry user using Castor's archiving function. Below is an example of how to archive repeating data created in error.

- Navigate to the participant's Repeating data section
- Click the  to the right of the repeating data to be archived.
- Select **Archive repeating data**
- Enter a reason for archiving
- Click **Archive**
- The archived repeating data will disappear.
- Archived repeating data can be viewed by selecting **Archived** from the **Filter by status** menu and unarchived by clicking **Unarchive** repeating data.

Repeating data

+ Create
Filters
⚙

Search by name

Repeating data name ↑↓	Instance name ↑↓	Type ↑↓	Created on ↓	Created by ↑↓	Parent	Progress	
Respiratory Medication	Respiratory Medicat	Repeated measure	08 Dec 2025	Gillian Martin	Visit 1 - Screening	● In progress	
Respiratory Medication	Respiratory Medicat	Repeated measure	08 Dec 2025	Gillian Martin	Visit 1 - Screening	●	Edit
Routine Sputum Results	Routine Sputum Res	Repeated measure	08 Dec 2025	Gillian Martin	Visit 2 - Randomisat	●	Sign this instance
Chronic Airways Assessment Test (CAAT)	Chronic Airways As	Other	08 Dec 2025	Gillian Martin	Visit 2 - Randomisat	●	Print
Exacerbation	Exacerbation - 08-1	Repeated measure	08 Dec 2025	Gillian Martin	Visit 3 - Phone Call	●	Archive
Adverse Event	Adverse Event - 08-	Repeated measure	08 Dec 2025	Gillian Martin	Visit 3 - Phone Call	●	Delete
Routine Sputum Results	Routine Sputum Res	Repeated measure	08 Dec 2025	Gillian Martin	Visit 4	●	

Archive instance



Are you sure you want to archive this repeating data instance?

If so, please supply a reason.

All child instances of this item will be archived as well.

Reason *

Provide a reason and click Archive.
The repeating data will be removed
from the repeating data section

Cancel

Archive instance

7. Missing Data

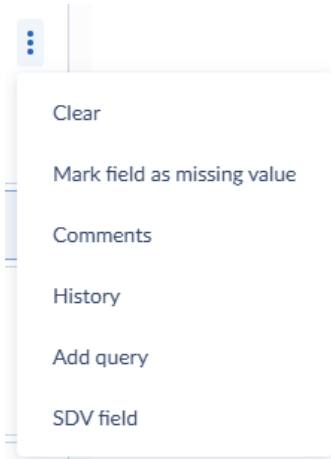
Missing data can either be missing and is able to be retrieved or missing and is never going to be available.

Missing data that can be retrieved should be retrieved and entered into the database.

Missing data that is never going to be available could be because a piece of equipment failed and no data was collected for example. In this case, the **Mark field as missing value** function should be used. For example, blood pressure was not measured because no Bp monitor was available.

Mandatory fields will not be marked as complete unless data is entered or marked as **User Missing**. This will also affect the completion of the participant's progress bar in the participants view.

Click the  to the right of the missing data field and select **Mark field as missing value**.



The field will be **greyed out** and a **User Missing** icon added to the field.

Mark field as missing value ◇ ×

Please select a reason for missing the value on field "Pseudomonas aeruginosa?".

Reason *

☐ Measurement failed (-95)

☐ Not applicable (-96)

☐ Not asked (-97)

☐ Asked but unknown (-98)

☐ Not done (-99)

Comment

Choose a reason and enter a comment to explain why the data is missing

User missing query raised

⋮

8. Missing visits

Where a scheduled visit (either in person or remotely, e.g. a telephone visit) has been missed, notify the Trial Management Team and record in Castor as follows:

- Missed scheduled visits should be recorded by adding a **Comment** to the first field for that visit
- Do **not** record any data for the visit
- This will result in the visit being marked as complete

The Data Management Team will raise queries against participants where data needs to be checked or confirmed.

Participants with outstanding data queries can be identified on the **Participants** page.

The number in the red box in the Queries column (?) shows the number of outstanding queries per participant.

Participants

☐ Exact match

List

Visit

Form

Participant...	Site	Progress	Last opene...	Created on	Updated on	Status		
☐ 0101	Tayside		Margaret Band	17 Apr 2023	27 Apr 2023	Not Set		
☐ 0102	Betsi Cadwaladr		Mel Sturgess	23 Mar 2023	26 Apr 2023	Not Set		
☐ 0303	Birmingham		Margaret Band	09 Mar 2023	28 Apr 2023	Not Set		
☐ 99999	Tayside		Margaret Band	24 Nov 2022	12 Apr 2023	Not Set		

To see all the queries for a particular participant, click on the participant on the Participants page and then click **Monitoring** and then **Queries** from the left side. This will display all queries for a single participant. The figure below shows all the queries for participant 99999.

Participant ID: 99999 - Not Live (v.260.01)

Participant status: Not Set

Monitoring

Queries Validations Dropped Verifications

Site	Created on	Created By	Last updated by	Closed by	Location	First Remark	Last Remark	Status	Query age	View
Royal Papworth	01 Jun 2022	Simon Adamson	Andrew McKenzie	Andrew McKenzie	Visit Visit 1 (Screening)	Please check whether or not a pri typo			342	
Royal Papworth	28 Jun 2022	Andrew McKenzie	Andrew McKenzie		Visit Completion of Trial/...	please check this date of complet checked and seems fine			315	
Royal Papworth	28 Mar 2023	Marcus Achison	Marcus Achison		Visit Visit 1 (Screening)	Please check value.	Value is correct.		42	
Royal Papworth	28 Mar 2023	Marcus Achison	Marcus Achison		Visit Visit 1 (Screening)	Please check value.	Please check value.		42	

To see all the queries for a particular trial, select the trial and without opening a particular participant, click **Monitoring** on the left of the screen and then **Queries** (below).

Queries

Actions ▾										
Filters										
☐	Participant...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query age	Time to res...	View
☐	01001	TCTU	Marcus Achison	Marcus Achison	Missing data - please check	Missing data - please check	New	172	172	
☐	01001	TCTU	Marcus Achison	Margaret Band	Value (165) is out of range -	Close	Closed	11	161	
☐	01001	TCTU	Marcus Achison	Marcus Achison	Age different to that report	Age different to that report	New	172	172	
☐	01001	TCTU	Marcus Achison	Marcus Achison	Sputum obtained on date of	Sputum obtained on date of	New	172	172	
☐	01001	TCTU	Marcus Achison	Margaret Band	Date of visit 2 needs to be ch	close	Closed	11	161	
☐	55555	TCTU	Marcus Achison	Marcus Achison	Test	Test	New	46	46	
☐	01001	TCTU	Marcus Achison	Marcus Achison	check data	hello.	Opened	14	14	

To view or reply to a query, click

Click query icon next to the field

Add **Remark**.

Click **Save changes**.

Do not change the status of the query.

The DMT will review the query.

If you have any questions, contact the TCTU Data Management Team at ESCAPE-DM@dundee.ac.uk