

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

You will be contacted by the TCTU Data Management Team who will give you access to the Castor TEST Data Management System (DMS).


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**.

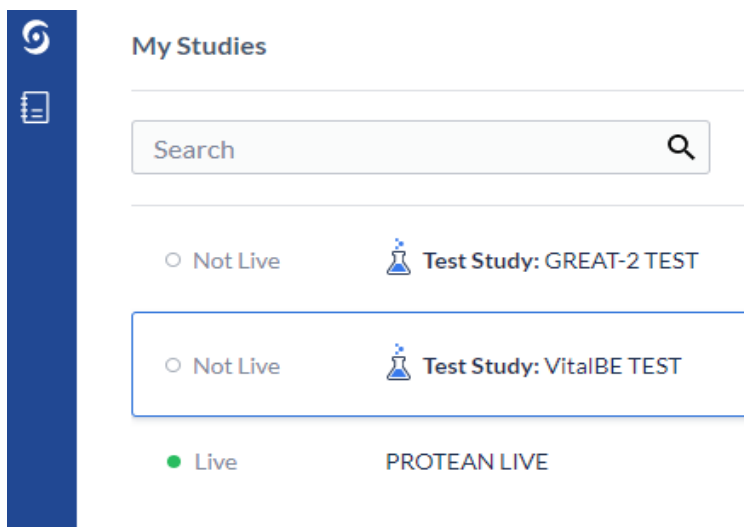
Enter your username and password.

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:



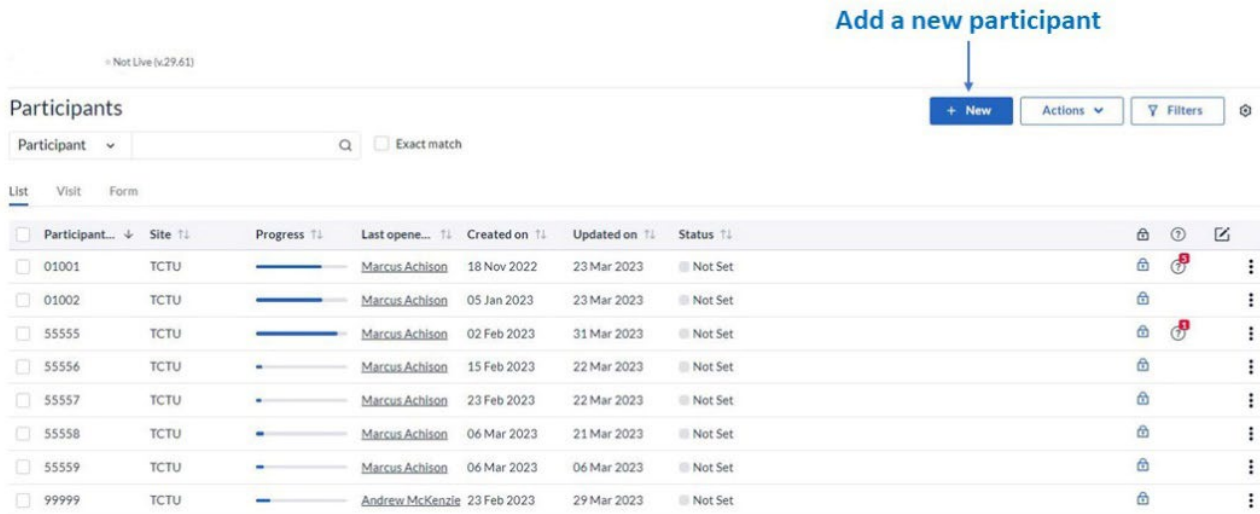
Click on the trial where you want to enter data.

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.

Add a new participant



Participants

Participant ☐ Exact match

+ New Actions Filters

Participant...	Site	Progress	Last opene...	Created on	Updated on	Status	
<input type="checkbox"/> 01001	TCTU	<div><div></div></div>	Marcus Achison	18 Nov 2022	23 Mar 2023	Not Set	
<input type="checkbox"/> 01002	TCTU	<div><div></div></div>	Marcus Achison	05 Jan 2023	23 Mar 2023	Not Set	
<input type="checkbox"/> 55555	TCTU	<div><div></div></div>	Marcus Achison	02 Feb 2023	31 Mar 2023	Not Set	
<input type="checkbox"/> 55556	TCTU	<div><div></div></div>	Marcus Achison	15 Feb 2023	22 Mar 2023	Not Set	
<input type="checkbox"/> 55557	TCTU	<div><div></div></div>	Marcus Achison	23 Feb 2023	22 Mar 2023	Not Set	
<input type="checkbox"/> 55558	TCTU	<div><div></div></div>	Marcus Achison	06 Mar 2023	21 Mar 2023	Not Set	
<input type="checkbox"/> 55559	TCTU	<div><div></div></div>	Marcus Achison	06 Mar 2023	06 Mar 2023	Not Set	
<input type="checkbox"/> 99999	TCTU	<div><div></div></div>	Andrew McKenzie	23 Feb 2023	29 Mar 2023	Not Set	

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

Create New Participant

Site

TCTU

Participant ID *

(required)

Participant email

☐ Create another

Cancel

Create

Automatically populated with your site

Enter participant ID and click **Create**

Enter participant email if the participant would like to use ePRO via email or CastorConnect App

Participant ID:

The number of digits in a participant ID for the AIR-NET trial is **5** digits.

The **first part (i.e. first two numbers)** is the site number.

The **second part (i.e. three last numbers)** is the participant number.

For example, if the site number is **01** and the participant number is **001**, the full participant ID will be **01001**.

This means participant **001** is the first participant at site **01**.

There should **not** be a space or dash between site number and participant number!

The participant ID used when creating the participant in Castor should also be used when (or if) the participant is to be randomised on TRuST (i.e. Participant ID in TRuST should match Participant ID 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.

Participants

+ New Actions Filters

Participant Participant Exact match

List Visit Form

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

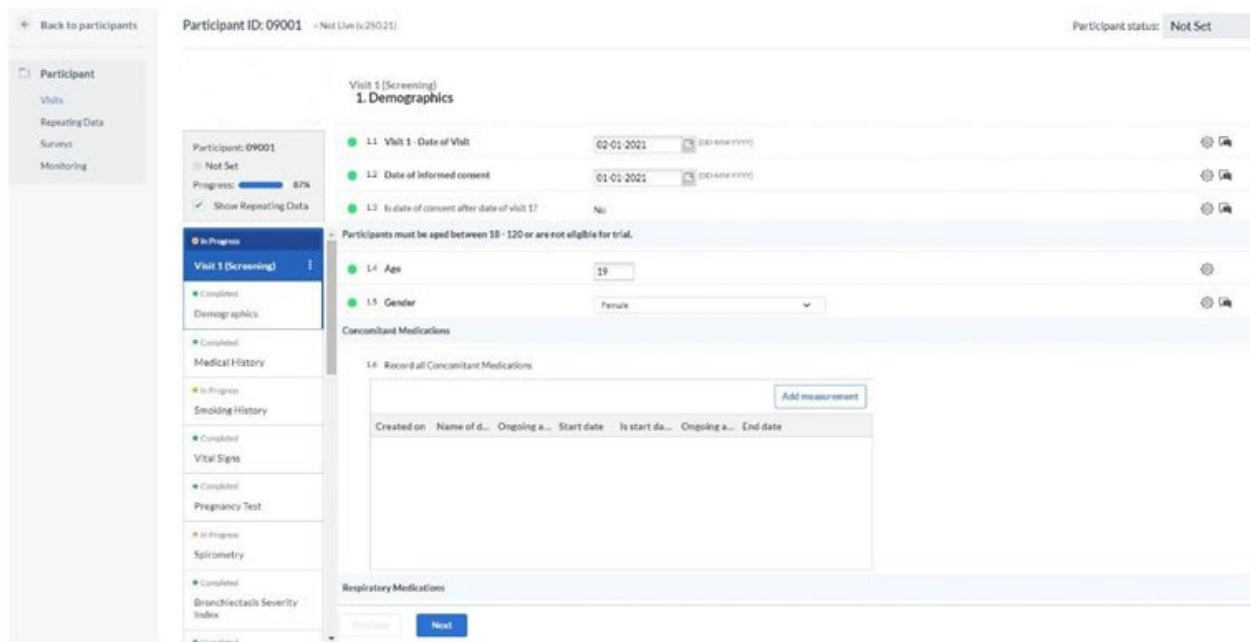
5. Data Entry

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.



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)

Visit 1 - Screening

Completed

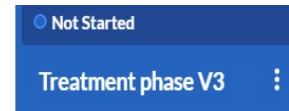
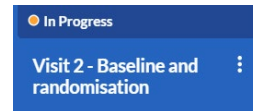
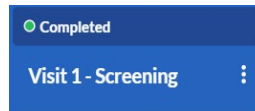
Informed Consent

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.

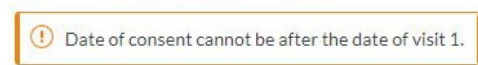
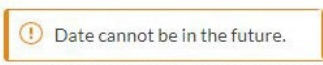
Each **visit**, **form** and **field** have icons which indicate the progress of data entry

Completed – **green**
In progress – **orange**
Not started – **clear**




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.

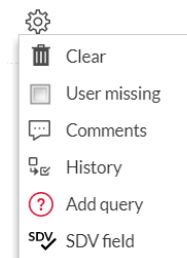
Here are 2 examples of error messages:



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 cogwheel to the right of the field to explain that the entered data is correct.

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



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.

1.4 Age

The maximum value for this field is 120

1.5 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

Screening

1. Informed Consent

1.1	Date of Screening	<input type="text" value=""/>	(dd-mm-yyyy)
1.2	Consent provided by	<input type="text" value=""/>	
1.3	Date of consent	<input type="text" value=""/>	(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	<input type="text" value="05-06-2020"/>	(dd-mm-yyyy)
1.2	Consent provided by	<input type="text" value="Participant"/>	
1.3	Date of consent	<input type="text" value="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:

- Blood results
- Adverse Events
- Concomitant Medications
- Vital Signs
- Safety Visits
- Discontinuation of Trial Medication

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

Click the Adverse Events/Concomitant Medications form.

Click **Add AE**.

SOPHIST TEST ◦ Not Live (v.8.61)

The screenshot shows the SOPHIST TEST interface. On the left, a sidebar displays 'Data collection progress' with a 3% completion bar and a list of forms: 'Visit 1 - Screening' (6%), 'Visit 2' (0%), 'Date of Visit 2' (Not started), 'Concomitant Medications' (Completed), 'Adverse Events' (Completed), and 'Glucose Review' (Not started). The 'Adverse Events' form is selected. The main area shows 'Visit 2' and '16. Adverse Events'. Below this, a table lists adverse events with columns: 'Created on', 'Description...', 'Is the Date...', and a status icon. The table contains two rows: one for '26-11-2024' and another for '16-10-2024' with description 'XYZ' and status 'NO'. A blue 'Add AE' button is circled in red in the top right corner of the table area.

Created on	Description...	Is the Date...	Status
26-11-2024			
16-10-2024	XYZ	NO	

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

Participant ID: 55555 → Not Live (v29.61) Participant status: Not Set

All repeating data +
Repeating Data -

Participant: 55555
Not Set
Progress: 89%

Not Started
Adverse Events - 30-03-2023 16:45:34
Not Started
Adverse Event

Adverse Event

Adverse Events Log

AEs & SAEs must be followed up until resolved or 30 days after last trial visit. If still ongoing at last visit contact participant 30 days after last trial visit and update AE log if required. SUSARs must be followed up until resolved.

- 1 Description of adverse event
- 2 Onset date
- 3 Is onset date in the correct format? Not all values for this calculation are available (yet).
- 4 Date reported to Investigator (DD-MM-YYYY)
- 5 Is Date Reported to Investigator before Onset Date? Not all values for this calculation are available (yet).

Close repeating data All repeating data Add another

When all the data are entered into the AE repeating data, click Close repeating data and this will redirect you back to the visit/form.

After clicking on **Close repeating data**, the recently added AE repeating data will now appear in the AE table (below).

Visit 2 - Day 1
10. AEs and ConMeds

Please add an AE and/or ConMeds report if the participant has experienced any AEs or had any changes to ConMeds since last visit

10.1 Adverse Events




Add measurement						
Created on	Descripti...	Onset date	Is Onset d...	Date repo...	Is Date re...	Severity
2023-03-...	pain post ...	05-05-20...	YES	06-05-20...	NO	1. Mild

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

Participant ID: 55555 Not Live (v.29.61) Participant status: Not Set ▼

Click the repeating data button to add a questionnaire

Visit 2 (Baseline)
25. Questionnaires

Participant: 55555 Not Set Progress: 89% Sputum, Viral Nasal Swab and Research Bloods Completed Questionnaires Completed	25.1 Questionnaire completed?	YES ▼	
	25.1.2	Questionnaire	
	25.2 Questionnaire completed?	YES ▼	
	25.3 Questionnaire completed?	YES ▼	
	25.3.2	Questionnaire	

After clicking the repeating data button, the following message box will appear. Click **Create** to generate a Questionnaire repeating data.

Add a repeating data instance to participant 09001 ✕

Repeating data: Questionnaire ▼

Custom name: ⓘ Questionnaire - 05-10-2022 13:28:10

Attach to: Visit 2. Visit 2 (Baseline) ▼

Create **Cancel**

When data have been entered for this questionnaire, click on the **Close repeating data** button. This will redirect you back to the visit/form from before.

Repeating data should be created from 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:

Safety Visit

Discontinuation of Trial Medication

Repeating data for **Discontinuation of Trial Medication** should be created thus:

Whilst in a participant record, click Repeating Data at left of screen → click **Create** (top right) → select the required repeating data, e.g. **Discontinuation of Trial Medication** → click **Create** → the repeating data will open.

Accessing previously created repeating data

Click **Repeating Data** on left of screen.

The **Repeating Data** page will be displayed showing all the previously created repeating data.

Repeating data + Create Filters

Search by name

Repeating d...	Instance name	Type	Created on	Created by	Parent	Progress		
Safety Bloods	Safety Bloods - 18-0	Repeated measure	18 Jul 2024	Marcus Achison	No parent	Completed		
Concomitant Medic	Concomitant Medic	Repeated measure	23 Jul 2024	Marcus Achison	No parent	Completed		
Adverse Events	Adverse Events - 23	Repeated measure	23 Jul 2024	Marcus Achison	No parent	In progress		

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 3 dots to the right of the repeating data to be archived.
- Select **Archive**

- Enter a reason for archiving, e.g. *“created in error”*
- Click **Archive instance**
- 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** from within the 3 dots.

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, for example, because a piece of equipment failed and no data was collected.

In this case, the **Mark field as missing value** function should be used.

For example, blood pressure (BP) was not measured because no BP monitor was available.

Click the cogwheel to the right of the field concerned

Select **User missing** and select a reason and add a comment

Click **Save**.

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

9. Queries

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

+ New Actions Filters

Participant ☐ Exact match

List Visit Form

Participant...	Site	Progress	Last opene...	Created on	Updated on	Status		
<input type="checkbox"/> 0101	Tayside	<div></div>	Margaret Band	17 Apr 2023	27 Apr 2023	Not Set		
<input type="checkbox"/> 0102	Betsi Cadwaladr	<div></div>	Mel Sturgess	23 Mar 2023	26 Apr 2023	Not Set		
<input type="checkbox"/> 0303	Birmingham	<div></div>	Margaret Band	09 Mar 2023	28 Apr 2023	Not Set		
<input type="checkbox"/> 99999	Tayside	<div></div>	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** (on left of screen) and then **Queries** (top left of screen).

This will display all queries for a single participant.

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
<input type="checkbox"/> 01001	TCTU	Marcus Achison	Marcus Achison	Missing data - please check	Missing data - please check	New	172	172	
<input type="checkbox"/> 01001	TCTU	Marcus Achison	Margaret Band	Value (165) is out of range -	Close	Closed	11	161	
<input type="checkbox"/> 01001	TCTU	Marcus Achison	Marcus Achison	Age different to that reporte	Age different to that reporte	New	172	172	
<input type="checkbox"/> 01001	TCTU	Marcus Achison	Marcus Achison	Sputum obtained on date of	Sputum obtained on date of	New	172	172	
<input type="checkbox"/> 01001	TCTU	Marcus Achison	Margaret Band	Date of visit 2 needs to be cl	close	Closed	11	161	
<input type="checkbox"/> 55555	TCTU	Marcus Achison	Marcus Achison	Test	Test	New	46	46	
<input type="checkbox"/> 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 air-net-dm@dundee.ac.uk.