

SOPHIST Castor User Guide

Data Entry Guidelines

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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 SOPHIST 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**.

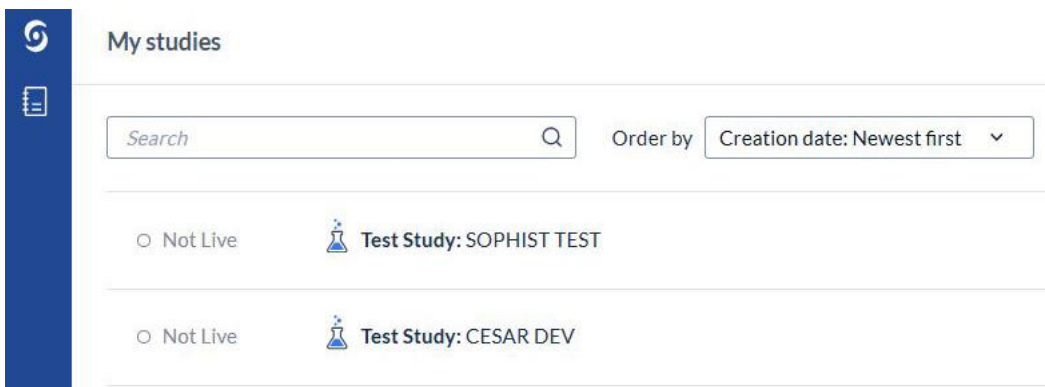
Enter your username and password (you create the password).

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:



The screenshot shows the 'My studies' page in the Castor DMS. On the left is a dark blue sidebar with a Castor logo and a document icon. The main content area has a title 'My studies' and a search bar with the placeholder text 'Search'. To the right of the search bar is an 'Order by' dropdown menu set to 'Creation date: Newest first'. Below these are two study entries, each with a radio button set to 'Not Live' and a flask icon. The first entry is 'Test Study: SOPHIST TEST' and the second is 'Test Study: CESAR DEV'.

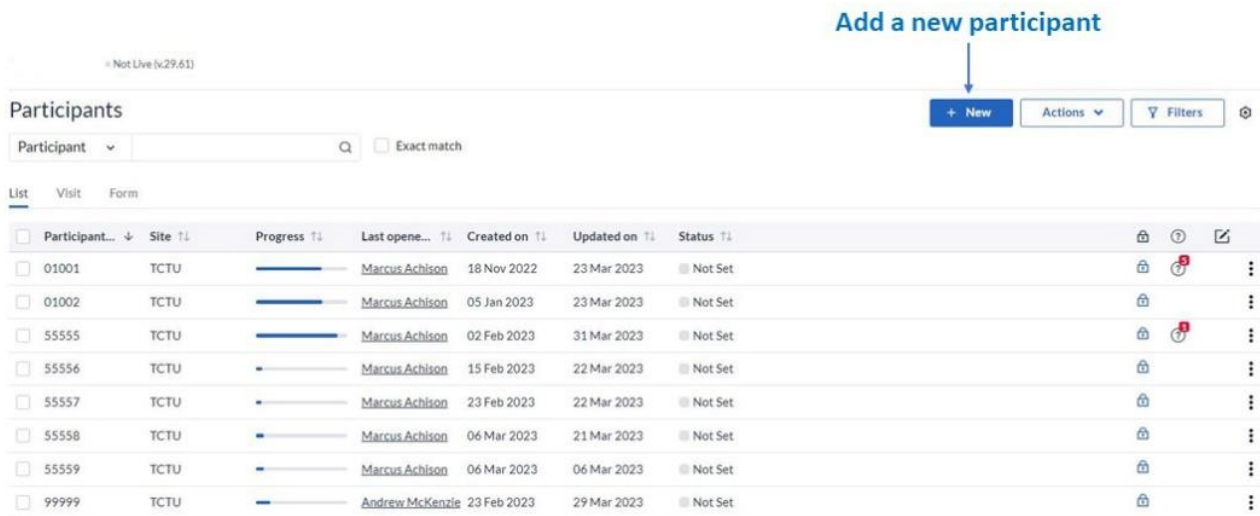
Click on the trial where you want to enter data.

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

List Visit Form

Participant...	Site	Progress	Last opene...	Created on	Updated on	Status	
<input type="checkbox"/> 01001	TCTU	<div style="width: 100%;"></div>	Marcus Achison	18 Nov 2022	23 Mar 2023	Not Set	
<input type="checkbox"/> 01002	TCTU	<div style="width: 100%;"></div>	Marcus Achison	05 Jan 2023	23 Mar 2023	Not Set	
<input type="checkbox"/> 55555	TCTU	<div style="width: 100%;"></div>	Marcus Achison	02 Feb 2023	31 Mar 2023	Not Set	
<input type="checkbox"/> 55556	TCTU	<div style="width: 10%;"></div>	Marcus Achison	15 Feb 2023	22 Mar 2023	Not Set	
<input type="checkbox"/> 55557	TCTU	<div style="width: 10%;"></div>	Marcus Achison	23 Feb 2023	22 Mar 2023	Not Set	
<input type="checkbox"/> 55558	TCTU	<div style="width: 10%;"></div>	Marcus Achison	06 Mar 2023	21 Mar 2023	Not Set	
<input type="checkbox"/> 55559	TCTU	<div style="width: 10%;"></div>	Marcus Achison	06 Mar 2023	06 Mar 2023	Not Set	
<input type="checkbox"/> 99999	TCTU	<div style="width: 10%;"></div>	Andrew McKenzie	23 Feb 2023	29 Mar 2023	Not Set	

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

Create New Participant ×

Site

Participant ID*
(required)

Participant email

Create another

← Automatically populated with your site

← Enter participant ID and click **Create**

← **Do not** enter participant email

Participant ID:

The number of digits in a participant ID for the SOPHIST 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 Exact match

List Visit Form

Participant...	Site	Progress	Last opene...	Created on	Updated on	Status	
<input type="checkbox"/> 0101	Tayside	<div style="width: 50%; background-color: blue;"></div>	Margaret Band	17 Apr 2023	27 Apr 2023	Not Set	
<input type="checkbox"/> 0102	Betsi Cadwaladr	<div style="width: 50%; background-color: blue;"></div>	Mel Sturgess	23 Mar 2023	26 Apr 2023	Not Set	
<input type="checkbox"/> 0303	Birmingham	<div style="width: 50%; background-color: blue;"></div>	Margaret Band	09 Mar 2023	28 Apr 2023	Not Set	
<input type="checkbox"/> 99999	Tayside	<div style="width: 100%; background-color: green;"></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 visits contain forms.

Forms e.g. Informed Consent - forms contain fields.

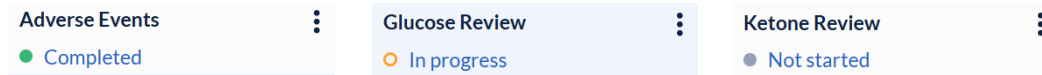
Fields e.g. Date of Screening V1.

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. See examples below:



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

- Click the 3 dots to the right of the field
- Select **Comments**
- Enter **Comment**, e.g. **age is correct**
- Click **Add comment**
- Click **Close**

2.1 Age *



85 years

Age should be 18 years to 84 years.

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**.

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 (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?

Calculation field

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

Screening

1. Informed Consent

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?

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
- 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 (v8.61)

Data collection progress: 3%
Show repeating data instances:

Visit 1 - Screening: 6%
Visit 2: 0%

Date of Visit 2: Not started
Concomitant Medications: Completed
Adverse Events: Completed
Glucose Review: Not started

Visit 2
16. Adverse Events

16.1 Adverse Events

Add AE

Created on ↑	Descriptio... ↑↓	Is the 'Date... ↑↓	?	SD↓
26-11-2024				
16-10-2024	XYZ	NO		

Clicking **Go to parent** will return to the parent visit and the AE will be displayed in the table.

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

SOPHIST TEST ◦ Not Live (v.8.61)

Visit 3 - Baseline
26. Questionnaires

✓ 26.1 Has the KCCQ questionnaire been completed? *

YES

26.1.1

Add KCCQ

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

Create a repeating data instance

Repeating data *

Cardiomyopathy Questionnaire (Kansas City) - KCCQ

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.

Cardiomyopathy Questionnaire (Kansas City) - KCCQ - 26-11-2024 14:38:18

Parent *

A visit

Visit 3. Visit 3 - Baseline

Cancel Create

Click **Create** and KCCQ repeating data will be open. 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.

An example of this is **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	SDV	🔒	✎
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 3 dots to the right of the field concerned

Select **Mark field as missing value** and select a reason and add a comment

Click **Mark as missing**.

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 (i.e. Date of 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	Queries
0101	Tayside	<div style="width: 50%;"></div>	Margaret Band	17 Apr 2023	27 Apr 2023	Not Set	0
0102	Betsi Cadwaladr	<div style="width: 100%;"></div>	Mel Sturgess	23 Mar 2023	26 Apr 2023	Not Set	0
0303	Birmingham	<div style="width: 50%;"></div>	Margaret Band	09 Mar 2023	28 Apr 2023	Not Set	1
99999	Tayside	<div style="width: 100%;"></div>	Margaret Band	24 Nov 2022	12 Apr 2023	Not Set	0

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
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 reporte	Age different to that reporte	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 sophist-dm@dundee.ac.uk