

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**.

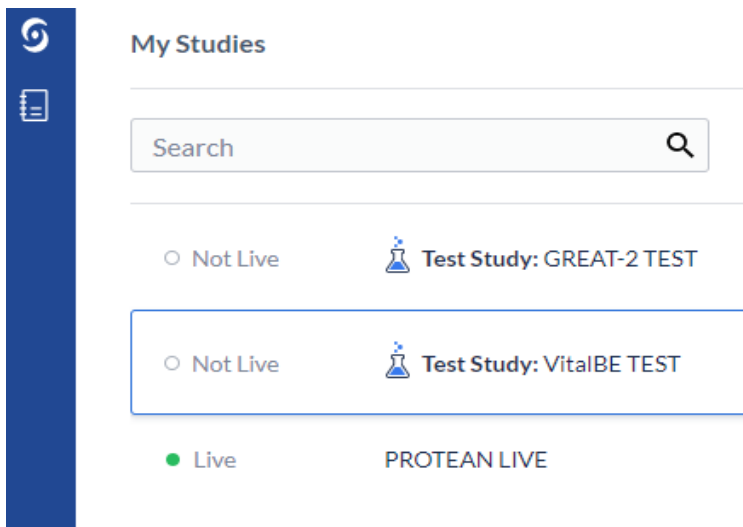
Enter your username and password.

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

☐ Exact match

List Visit Form

<input type="checkbox"/>	Participant...	Site	Progress	Last opened	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

⌵

Automatically populated with your site

Participant ID *

(required)

Enter participant ID and click **Create**

Participant ID is a required field

☐ Create another

Cancel

Create

Participant ID:

The number of digits in a participant ID can vary from trial to trial, it could be 4 or 5 digits.

The **first part** is the site number.

The **second part** is the participant number.

For example, if the participant ID was 5 digits long, the site number could be **01** and the participant number could be **001**, resulting in the full participant ID being **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.

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 bar.

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

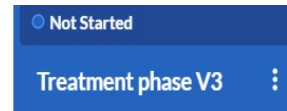
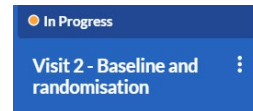
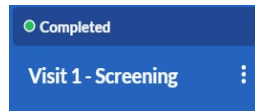
Informed Consent

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

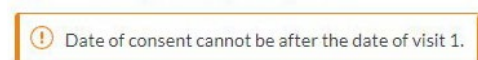
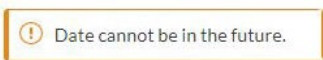
Completed – **green**
In progress – **orange**
Not started – **clear**



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.

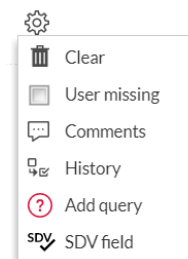
After data is entered, Castor performs validation checks. If there is something inconsistent with the data, an error will appear in an orange box underneath the affected field.
Here are 2 examples of error messages:



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**.

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"/>  (dd-mm-yyyy)
1.2	Consent provided by	<input type="text"/>
1.3	Date of consent	<input type="text"/>  (dd-mm-yyyy)

1.4 Is date of consent on or after date of screening?

Not all values for this calculation are available (yet).

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

Calculation field

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:

- Blood results
- Adverse Events
- Concomitant Medications
- Vital Signs
- Unscheduled 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 measurement.

Participant ID: 55555 ◦ Not Live (v.29.61)

Participant status: Not Set

Visit 2 (Baseline)
16. Adverse Events/Concomitant Medications

Participant: 55555
Not Set
Progress: 89%

Visit 2 (Baseline)
Completed
Informed Consent
Completed
Adverse Events/Concomitant Medications

16.1 Has the participant experienced any Adverse Events since last visit? YES

16.1.1 Record all Adverse Events

2. Click Add measurement

1. Click appropriate form

Created on	Descriptio...	Onset date	Is onset d...	Date repo...	Is Date Re...	Severity
2023-03-22						
2023-02-13	headache	01-02-2023	YES	01-02-2023	NO	2. Moderate
2023-02-13	fever	04-01-2023	YES	04-01-2023	NO	2. Moderate
2023-02-02	Headache	02-12-2022	YES	04-12-2022	NO	1. Mild

Add measurement

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

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.

- Description of adverse event
- Onset date
- Is onset date in the correct format?
- Date reported to Investigator
- Is Date Reported to Investigator before Onset Date?

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

Visit 2 (Baseline)
25. Questionnaires

Click the repeating data button to add a questionnaire

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:

Discontinuation of Trial Medication

Visit 1 (screening) 14. Bloods, 14.2.1 NHS samples taken?

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

Click Repeating Data at top left of screen → click **Add a repeating data instance** → select the required repeating data, e.g. **Discontinuation of Trial Medication** → click **Create** → the repeating data will open and can be completed > click **Close repeating data**.

Visit 1 (screening) 14. Bloods, 14.2.1 NHS samples taken? should be created thus:

In **Visit 1 (screening) 14. Bloods**, if **14.2.1 NHS samples taken?** is answered **Yes**, complete a Blood Results repeating data form:

Click **Repeating Data** at top left of screen > click **Add a repeating data instance** > in repeating data box select **Blood Results** > click **Create** > the **Blood Results** repeating data will open and can be completed > click **Close repeating data**.

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 **All Repeating Data** page will be displayed (below).

All repeating data

Filter by Repeating Data type:
Select Repeating Data type to filter

Filter by Repeating Data:
Select Repeating Data to filter

Filter by status:
Unarchived

Filter by name:

Filter by visit:
Select visit to filter


Add a repeating data instance

Status	Repeating Data	Name	Type	Created on	Created by	Assigned to	
	Concomitant Medication - ...	Concomitant Medication - ...	Repeated measure	2022-11-17 09:43:26	Andrew McKenzie	No parent	
	Progression Assessment - F...	Progression Assessment - F...	Other	2023-01-11 11:17:21	Andrew McKenzie	Visit 4 - Week 12	
	Progression Assessment - I...	Progression Assessment - I...	Other	2022-11-30 14:54:27	Andrew McKenzie	No parent	
	Research Biopsy (Mandato...	Research Biopsy (Mandato...	Repeated measure	2022-11-08 15:25:11	Marcus Achison	No parent	
	Research Biopsy (Mandato...	Research Biopsy (Mandato...	Repeated measure	2022-11-08 15:26:30	Marcus Achison	Visit 2 - Day 1	
	Research Biopsy (Mandato...	Research Biopsy (Mandato...	Repeated measure	2022-11-09 09:51:57	Marcus Achison	Visit 2 - Day 1	
	Research Biopsy (Mandato...	Research Biopsy (Mandato...	Repeated measure	2022-11-08 15:26:44	Marcus Achison	Visit 2 - Day 1	

You can either choose the repeating data of interest by clicking it or use **Filter by Repeating Data** 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 cogwheel  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 from within the cogwheel (be

Use the filters to identify the correct repeating data to be archived

Navigate to a participant's Repeating Data section

Click on the repeating data cogwheel

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

Participant: 55555 Not Set Progress: 89%

Filter by Repeating Data type: Select Repeating Data type to filter Filter by Repeating Data: Select Repeating Data to filter Filter by status: Unarchived Add a repeating data instance

Status	Repeating Data	Name	Type	Created on	Created by	Assigned to
●	Adverse Events	Adverse Events - ...	Repeated measure	2023-02-02 16:2...	Jamie Stobo	Visit 2 (Baseline)
●	Adverse Events	Adverse Events - ...	Repeated measure	2023-02-13 14:5...	Jamie Stobo	Visit 3 (Month 1 +...
●	Adverse Events	Adverse Events - ...	Repeated measure	2023-02-13 15:4...	Jamie Stobo	Visit 5 (Month 6 +...
○	Adverse Events	Adverse Events - ...	Repeated measure	2023-03-22 14:2...	Marcus Achison	Visit 2 (Baseline)
○	Adverse Events	Adverse Events - ...	Repeated measure	2023-03-30 16:4...	Marcus Achison	Visit 2 (Baseline)
●	Concomitant Me...	Concomitant Me...	Repeated measure	2023-02-02 15:2...	Jamie Stobo	Visit 1 (Screening)

Repeating Data 1 - 16 of 16

Select Archive repeating data

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

Confirmation

Are you sure you want to archive this repeating data?

If you are sure you want to continue, please supply a reason below.

Duplicate repeating data created in error.

Archive Cancel


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 **User Missing** 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 cogwheel  to the right of the missing data field and select **User missing**

1. Vital Signs

Please record the most recent values for Screening/Randomisation.

For follow-up, please record results closest to 8am.

1 Pulse bpm
This field is required

2 Is the pulse value within the expected range? Not all values for this calculation are available (yet).

3 Blood Pressure systolic mmHg

Click the cogwheel and select **User missing**

- Clear
- User missing**
- Comments
- Audit trail
- Queries

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

Choose reason for missing value for field Sitting Blood Pressure Systolic.

Choose reason:



- ☒ Measurement failed (-95)
- ☐ Not applicable (-96)
- ☐ Not asked (-97)
- ☐ Asked but unknown (-98)
- ☐ Not done (-99)

Comment: No data was collected because the blood pressure monitor failed and a replacement could not be found.

Save Cancel

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

User missing query raised next to cogwheel

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

Participant ID: 000001 Not Live

Participant status: Not Set

Participant: 000001
Not Set
Progress: 0%

Day 3
1. Day 3

1.1 Date (YYYY-MM-DD)

1.2 Day of data collection from date of first dose Not all values for this calculation are available (yet).

1.3 Data collection via telephone call?

1.4 Not all values for this calculation are available (yet).

Previous Next

1. A Comment should be added to the first field in the visit to explain why the visit was not performed. No date is required to be entered in this field

2. All data fields should remain blank – there is no requirement to record any attempted visit data

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 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			
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 (v260.01)

Participant status: Not Set

Monitoring

Queries Validations Dropped Verifications

Filters

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	Closed	342	
Royal Papworth	28 Jun 2022	Andrew McKenzie	Andrew McKenzie		Visit Completion of Trial/...	please check this date of complet	checked and seems fine	Opened	315	
Royal Papworth	28 Mar 2023	Marcus Achison	Marcus Achison		Visit Visit 1 (Screening)	Please check value.	Value is correct.	Opened	42	
Royal Papworth	28 Mar 2023	Marcus Achison	Marcus Achison		Visit Visit 1 (Screening)	Please check value.	Please check value.	New	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

<input type="checkbox"/>	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.

10. Visual Verification

When data have been entered into the database, **Visual Verification** of the data is required to confirm that the data is correct, and that all data have been entered.

Visual verification consists of the data entry person checking that the entered data has been correctly transcribed from source data.

In some trials **all** data points will be visually verified and in others **only a chosen number** of data points will be visually verified.

The data points to be visually verified will be listed in the trial-specific data entry guidelines.

Visual verification will be performed by the data entry person at the point of data entry.

Visual verification can be carried out per visit, per form or per field.

Verifying a Visit/Form

- Navigate to the completed **visit/form** to be visually verified
- Click the 3 dots next to the **visit/form** to be visually verified
- Select **Custom verification**



The Data Verification dialogue box will open.

Select **Visual Verification**.

Select No.

Click OK.

The visit/form will now be visually verified and marked with the symbol



A banner will be displayed at the top of the page to confirm it has been visually verified.

Repeating data can be visually verified in the same way.

Open participant → click Repeating Data (top left of page) → click the required repeating data → click the 3 dots → select Custom verification → select Visual Verification → No → OK

Visual Verification of the required data is a critical process in data entry. The database cannot be locked until the required data have been visually verified.

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