

# 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**.

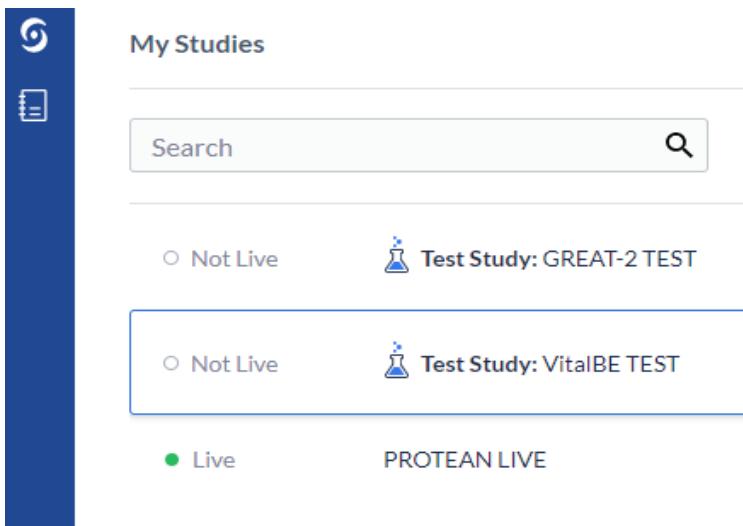
Enter your username and password.

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:



Study Status	Study Name
Not Live	Test Study: GREAT-2 TEST
Not Live	Test Study: VitalBE TEST
Live	PROTEAN LIVE

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  at the top of the participants table.

**Add a new participant**



Participants							
Participant	Site	Progress	Last opened	Created on	Updated on	Status	
01001	TCTU		Marcus Achison	18 Nov 2022	23 Mar 2023		   
01002	TCTU		Marcus Achison	05 Jan 2023	23 Mar 2023		   
55555	TCTU		Marcus Achison	02 Feb 2023	31 Mar 2023		   
55556	TCTU		Marcus Achison	15 Feb 2023	22 Mar 2023		   
55557	TCTU		Marcus Achison	23 Feb 2023	22 Mar 2023		   
55558	TCTU		Marcus Achison	06 Mar 2023	21 Mar 2023		   
55559	TCTU		Marcus Achison	06 Mar 2023	06 Mar 2023		   
99999	TCTU		Andrew McKenzie	23 Feb 2023	29 Mar 2023		   

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						
Participant	Site	Progress	Last opened	Created on	Updated on	Status
0101	Tayside		Margaret Band	17 Apr 2023	27 Apr 2023	Not Set
0102	Betsi Cadwaladr		Mel Sturges	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

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.

Participant ID: 09001 - Not Live (v250.21)

Participant status: Not Set

**Participant**

- Visits
- Repeating Data
- Surveys
- Monitoring

Progress: 87%  Show Repeating Data

**Visit 1 [Screening]**

**1. Demographics**

1.1 Visit 1 - Date of Visit: 02-01-2023 (DD-MM-YYYY)

1.2 Date of informed consent: 01-01-2021 (DD-MM-YYYY)

1.3 Is date of consent after date of visit? 1: No

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

1.4 Age: 19

1.5 Gender: Female

**Concomitant Medications**

1.6 Record all Concomitant Medications

Created on	Name of d...	Ongoing a...	Start date	Is start da...	Ongoing a...	End date
------------	--------------	--------------	------------	----------------	--------------	----------

**Respiratory Medications**

**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

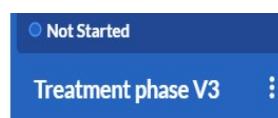
Completed – **green**



In progress – **orange**



Not started – **clear**



Click on appropriate **Visit**.

Click on appropriate **Form**.

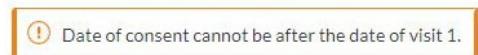
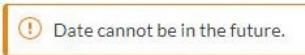
Enter data for each **Field**.

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.

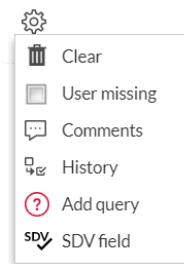
Here are 2 examples of error messages:



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" value="dd-mm-yyyy"/>
1.2 Consent provided by	<input type="text"/>
1.3 Date of consent	<input type="text" value="dd-mm-yyyy"/>
1.4 Is date of consent on or after date of screening?	<input type="text"/> 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 <input data-bbox="1019 559 1052 601" type="button" value="..."/> (dd-mm-yyyy)
1.2 Consent provided by	Participant <input data-bbox="1346 623 1379 665" type="button" value="..."/>
1.3 Date of consent	05-06-2020 <input data-bbox="1019 707 1052 749" type="button" value="..."/> (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**

Add measurement

Created on	Description	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

**1. Click appropriate form** ↗

**2. Click 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

All repeating data      Repeating Data

**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?      4 Date reported to Investigator      5 Is Date Reported to Investigator before Onset Date?

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

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 Questionnaire

25.2 Questionnaire completed? YES Questionnaire

25.3 Questionnaire completed? YES 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**.

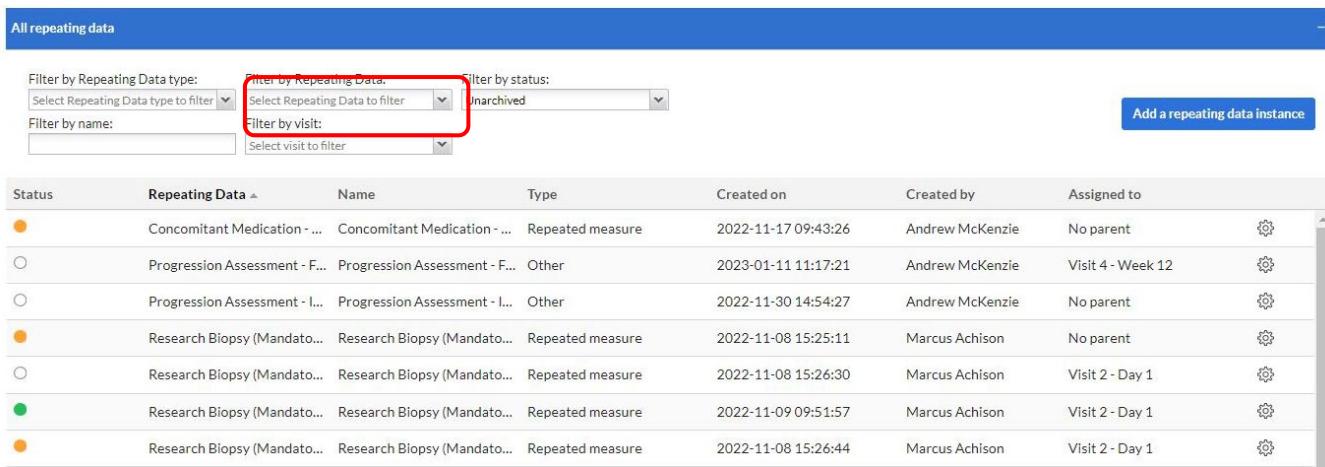
## Accessing previously created repeating data

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).



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

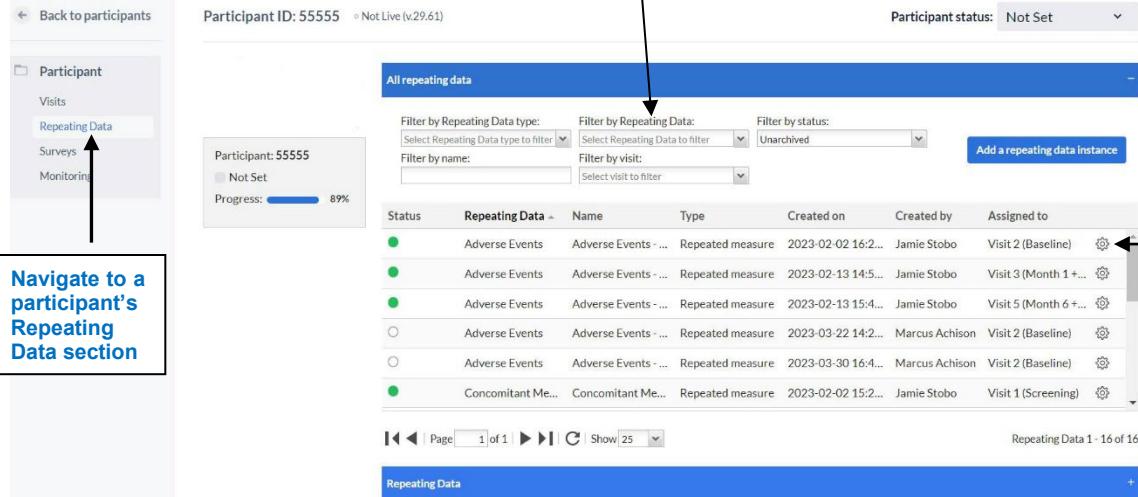
**Use the filters to identify the correct repeating data to be archived**

**Navigate to a participant's Repeating Data section**

**Click on the repeating data cogwheel**

**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	<input type="text"/> bpm <small>This field is required</small>	 Clear <input checked="" type="checkbox"/> User missing <span>Comments</span> <span>Audit trail</span> <span>Queries</span>
2 Is the pulse value within the expected range?	Not all values for this calculation are available (yet).	
3 Blood Pressure systolic	120 mmHg	

**Click the cogwheel and select User missing**

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:	<input checked="" type="radio"/> Measurement failed (-95) <input type="radio"/> Not applicable (-96) <input type="radio"/> Not asked (-97) <input type="radio"/> Asked but unknown (-98) <input type="radio"/> Not done (-99)
Comment:	No data was collected because the blood pressure monitor failed and a replacement could not be found.
<input type="button" value="Save"/> <input type="button" value="Cancel"/>	

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

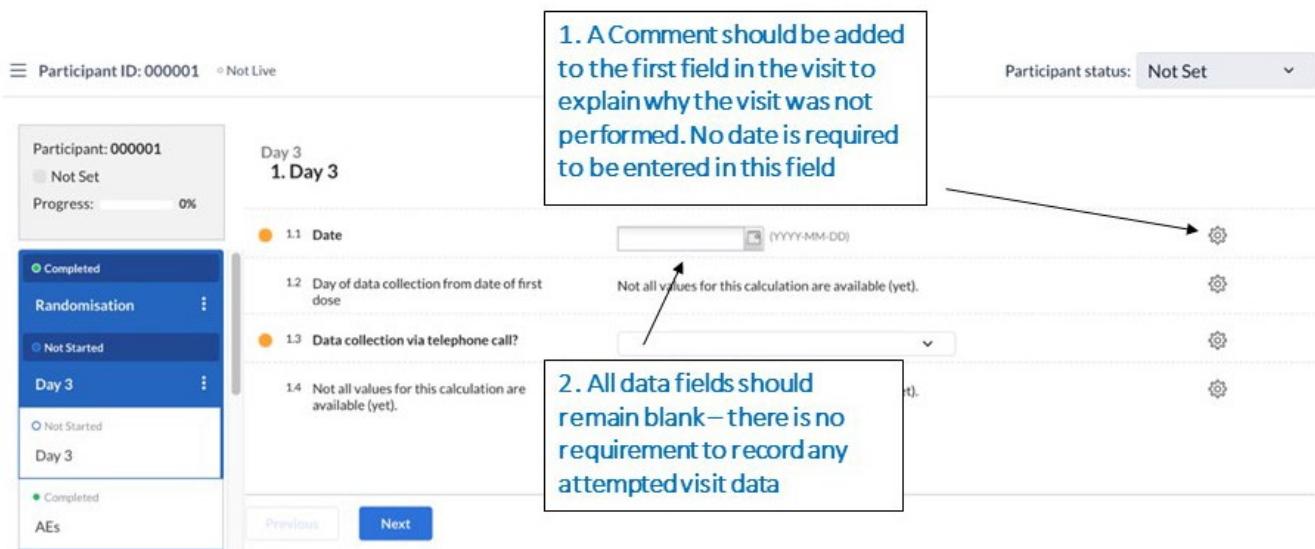
User missing query raised next to cogwheel

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

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

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

**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**

Previous Next

## 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										<a href="#">+ New</a>	<a href="#">Actions</a>	<a href="#">Filters</a>	<a href="#">⚙️</a>	
Participant														
Participant														
Participant...	Site	Progress	Last opened...	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 <small>Not Live (v.260.01)</small>										Participant status: Not Set			
Monitoring										<a href="#">Filters</a>			
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 comple...	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**

	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 ch	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**

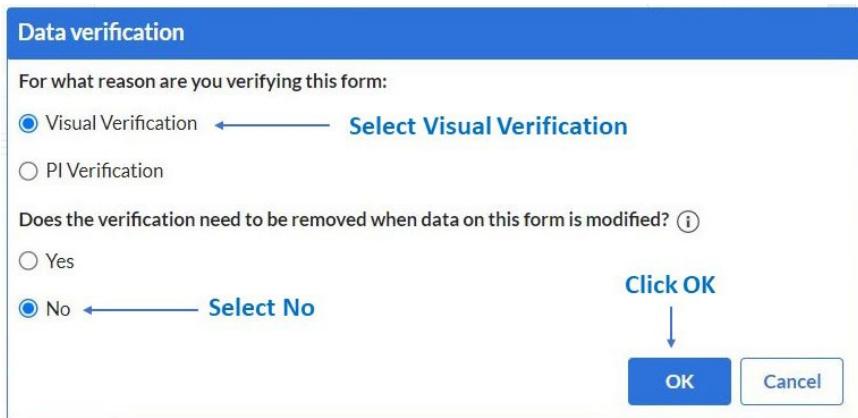


The Data Verification dialogue box will open.

Select **Visual Verification**.

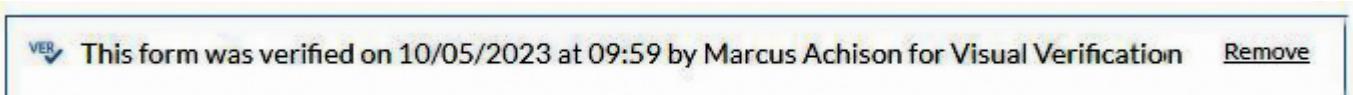
Select No.

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