

GREAT-2

Castor Data Entry Guidelines

Version: V1

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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.

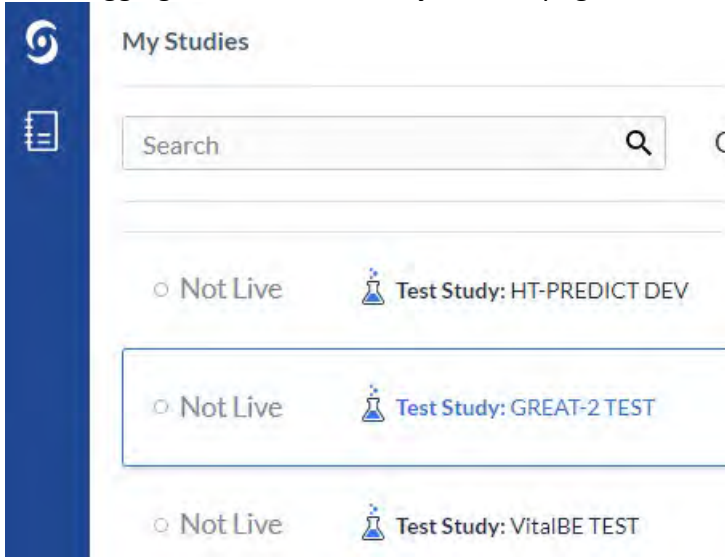
All users should log out after each session by clicking the **Account** icon  at the bottom left of the page and clicking **Log out**.

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



The **GREAT-2 TEST** database is for training, the **GREAT-2 LIVE** database is for real participants taking part in the trial.

2. My Studies page

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

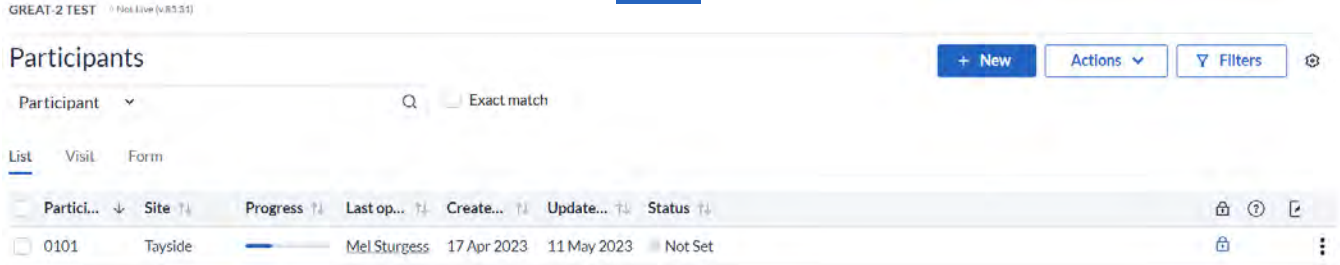


Click on the trial where you want to enter data.

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.



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

Participant ID:

The number of digits in a participant ID for this trial is 4 digits.

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

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

For example, if the participant ID was 4 digits long, the site number could be **01** and the participant number could be **01**, resulting in the full participant ID being **0101**.

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

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

4. Participant ID must be the same as used to randomise that participant on TRuST. 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 Q Exact match

List Visit Form

| Participant... | Site | Progress | Last opene... | Created on | Updated on | Status |
|----------------|-----------------|---|-------------------------------|-------------|-------------|---------|
| 0101 | Tayside | <div style="width: 50%; background-color: blue;"></div> | Margaret Band | 17 Apr 2023 | 27 Apr 2023 | Not Set |
| 0102 | Betsi Cadwaladr | <div style="width: 50%; background-color: blue;"></div> | Mel Sturgess | 23 Mar 2023 | 26 Apr 2023 | Not Set |
| 0303 | Birmingham | <div style="width: 50%; background-color: blue;"></div> | 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.

Participant ID: 0101 Not Live (v.85.31)

GREAT-2
GRemubamab ErAdication Trial

Participant: 0101
Not Set
Progress: 32%
 Show Repeating Data

Visit 1 - Screening
1. Informed Consent

Informed Consent

- 1.1 Date of Screening V1: 20-04-2023 (DD-MM-YYYY)
- 1.2 Date of Informed Consent: 18-04-2023 (DD-MM-YYYY)
- 1.3 Is the date of consent after date of screening? NO
- 1.4 Has the participant provided consent for blood and sputum samples to be stored for future research? Yes (selected) No
- 1.5 Has the participant provided consent for blood samples to be stored for future genetic research? Yes (selected) No

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.

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:

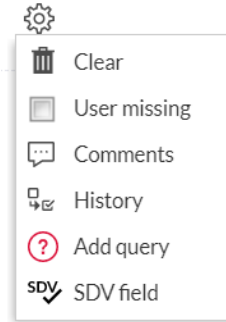
Date cannot be in the future.

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 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

Visit 1 - Screening 1. Informed Consent

Informed Consent

1.1 Date of Screening V1 (DD-MM-YYYY)

1.2 Date of Informed Consent (DD-MM-YYYY)

1.3 Is the date of consent 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

Visit 1 - Screening 1. Informed Consent

Informed Consent

1.1 Date of Screening V1 (DD-MM-YYYY)

1.2 Date of Informed Consent (DD-MM-YYYY)

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

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: 0101 Not Live (v.85.31)



GREAT-2
Gremubamab Eradication Trial

Visit 2 - Baseline and randomisation
24. Adverse Events since last visit

Participant: 0101

Not Set

Progress: 32%

Show Repeating Data

Blood Tests Reviewed

● In Progress

Inclusion Criteria

● In Progress

Exclusion Criteria

● Completed

Concomitant Medications

● Completed

Adverse Events since last visit

● Completed

Adverse Events since last visit

24.1 Repeating Data for each Adverse Event since last visit

[Add measurement](#)


| Created on | Description of adverse event | Onset date |
|------------|------------------------------|------------|
| 2023-04-25 | | ⚙️ |

2. Click add measurement

1. Click appropriate form

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

Participant ID: 0101 Not Live (v.85.31)



Participant: 0101
Not Set
Progress: 32%
 Show Repeating Data

In Progress
Adverse Event - 25-04-2023 09:07:29
In Progress
Adverse Event

All repeating data

Repeating Data

Adverse Event

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

- 1 Did this adverse event occur during administration of trial medication?

Yes
No
- 2 Description of adverse event (i)
- 3 Onset date (i)
- 4 Is Onset date in the correct format? Not all values for this calculation are available (yet).
- 5 Is Onset date in the future? Not all values for this calculation are available (yet).
- 6 Date reported to Investigator (DD-MM-YYYY)
- 7 Is Date reported before Onset date? Not all values for this calculation are available (yet).
- 8 Severity
- 9 Relationship to trial drug
- 10 Is this an SAE?
- 10.1 If YES, has an SAE form been completed? [Click here to open SAE Form](#)
- 11 Action taken (i) 1. None

Close repeating data

All repeating data

When all the data is 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.

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 Not Live (v.85.31)

The screenshot shows the '30. Questionnaires' form for participant 0101. The form is titled 'Visit 2 - Baseline and randomisation'. It lists three questionnaire items:

- 30.1 Has the Quality of Life-Bronchiectasis Questionnaire (QOL-B) been completed? (Yes/No radio buttons)
- 30.2 Has the St George's Respiratory Questionnaire (SGRQ) been completed? (Yes/No radio buttons)
- 30.3 Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed? (Yes/No radio buttons)

Below each item is a 'Repeating Data' button: 'Repeating Data QOL-B', 'Repeating Data SGRQ', and 'Repeating Data BIM'. A callout box points to the 'Repeating Data QOL-B' button with the text 'Click the repeating data button to add a questionnaire'.

After clicking the repeating data button, the following message box will appear. Click **Create** to generate a Questionnaire repeating data. Do not change the custom name.

The dialog box is titled 'Add a repeating data instance to participant 0101'. It contains the following fields:

- Repeating data: Quality of Life-Bronchiectasis questionnaire (QOL-B)
- Custom name: Quality of Life-Bronchiectasis questionnaire (QOL-B) - 18-05-2023 13:57
- Attach to: Visit 2. Visit 2 - Baseline and randomisation

There are 'Create' and 'Cancel' buttons at the bottom.

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

Click **Repeating Data** (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 form will open.

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 |
|--------|------------------------|----------------------------------|------------------|---------------------|----------------|-------------------------------------|
| ● | Adverse Event | Adverse Event - 25-04-2023 09... | Repeated measure | 2023-04-25 09:07:29 | Gillian Martin | Visit 2 - Baseline and randomisa... |
| ○ | Adverse Event | Adverse Event - 09-05-2023 15... | Repeated measure | 2023-05-09 15:50:54 | Gillian Martin | Treatment phase V3 |
| ● | Blood Results | Blood Results - 20-04-2023 10... | Other | 2023-04-20 10:10:45 | Shirley Fraser | Visit 1 - Screening |
| ● | Blood Results | Blood Results - 20-04-2023 10... | Other | 2023-04-20 10:13:06 | Shirley Fraser | Visit 1 - Screening |
| ○ | Blood Results | Blood Results - 20-04-2023 10... | Other | 2023-04-20 10:14:48 | Shirley Fraser | Visit 1 - Screening |
| ○ | Blood Results | Blood Results - 20-04-2023 10... | Other | 2023-04-20 10:18:25 | Shirley Fraser | Visit 1 - Screening |
| ● | Concomitant Medication | Concomitant Medication - 20-0... | Repeated measure | 2023-04-20 09:18:37 | Shirley Fraser | Visit 1 - Screening |
| ● | Concomitant Medication | Concomitant Medication - 20-0... | Repeated measure | 2023-04-20 09:19:11 | Shirley Fraser | Visit 1 - Screening |

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 (below).

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

1. Navigate to a participant's Repeating Data section

3. Click on the repeating data cogwheel

3. Click on the repeating data cogwheel

- Open Repeating Data
- Edit repeating data
- Delete repeating data
- Archive repeating data**
- Print

4. Select Archive repeating data

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

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


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

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

Participant ID: 0101 | Not Live (v.85.31)



Treatment phase V3
32. Date of Visit 3

Participant: 0101
Not Set
Progress: 33%
 Show Repeating Data

Treatment phase V3

32.1 Date of Visit 3

32.2 Is Visit 3 date within visit window?

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

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

List Visit Form

| Participant... | Site | Progress | Last opene... | Created on | Updated on | Status | |
|----------------|-----------------|----------------------------------|---------------|-------------|-------------|---------|---|
| 0101 | Tayside | <div style="width: 50%;"></div> | Margaret Band | 17 Apr 2023 | 27 Apr 2023 | Not Set | |
| 0102 | Betsi Cadwaladr | <div style="width: 100%;"></div> | Mel Sturgess | 23 Mar 2023 | 26 Apr 2023 | Not Set | |
| 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 | |

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.

Monitoring

Filters

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 | 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 has 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.

The data points to be visually verified for this trial are listed below:-

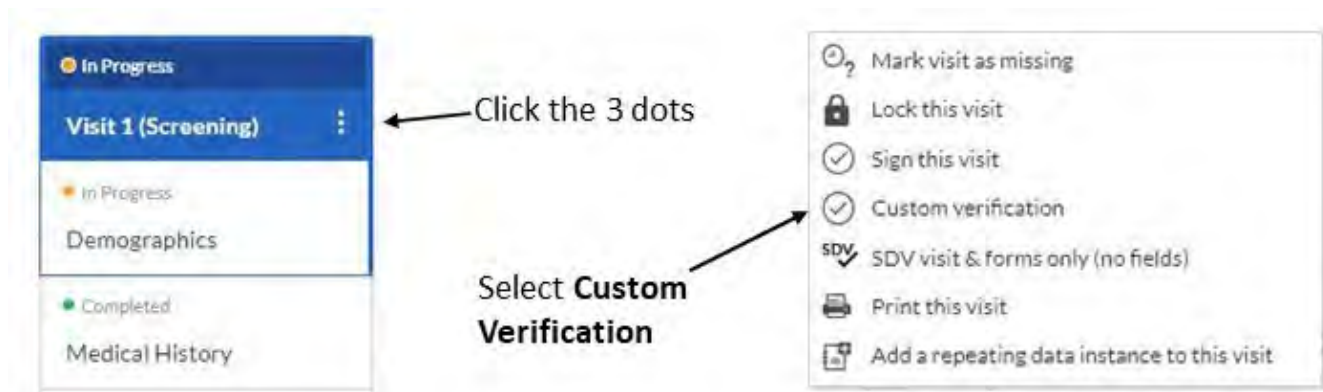
- Adverse events
- Blood tests reviewed
- Exacerbation recording
- Administration of trial medication
- Discontinuation of trial medication (if appropriate)
- Completion/Early withdrawal form
- Spirometry

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.

Data verification

For what reason are you verifying this form:

Visual Verification ← Select Visual Verification

PI Verification

Does the verification need to be removed when data on this form is modified? ⓘ

Yes

No ← Select No

Click OK

OK Cancel

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.

VER This form was verified on 10/05/2023 at 09:59 by Marcus Achison for Visual Verification Remove

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 great-2-dm@dundee.ac.uk