

VitalBE Data Entry Training

The following instructions will provide experience of entering data into the Castor Data Management System using specific examples.

Functions of Castor such as warnings, missing data, repeating data and visual verification will be demonstrated.

For full instructions on how to use Castor, refer to the **Castor Data Entry Guidelines**, which will provide more detail.

Logging into Castor

Open Castor: <https://uk.castoredc.com/>

Sign into Castor (Email + password)

Select trial (**Vital-BE TEST**)

A list of previously created participants is displayed.

See **Getting Started with the Castor DMS** section of the **Castor Data Entry Guidelines**

Creating a new participant:

A participant ID consists of **2** digits for the site and **3** digits for the participant number (no spaces/hyphens/dots or anything else).

For example, **04001** (site number = **04** and participant number = **001**).

See **Adding a New Participant** section of the **Castor Data Entry Guidelines**

Data Entry

Shown below are examples of data entry and warnings that may be displayed by Castor.

It is important that error messages are not ignored

Date Warnings

Navigate to Visit 1 (Screening) 1. Demographics

At **1.1 Visit 1 - Date of Visit** enter **01-01-2023**

At **1.2 Date of Informed consent** enter **02-01-2023**

Because date of informed consent is after date of visit 1 a warning is displayed in an orange box:

Date of consent cannot be after the date of visit 1.

When entering real data when the trial has started you would now need to check the dates of both **Visit 1 – Date of Visit** and **Date of Informed Consent**.

If they were not correct you would enter the correct dates and the warning should disappear.

If this didn't resolve the issue, inform the TCTU Data Management Team (DMT).

To resolve the issue in this example, make both **Date of Visit 1** and **Date of Informed Consent** **01-01-2023**

See **Data Entry** section of the **Castor Data Entry Guidelines**

Out of Range Warnings


Navigate to Visit 1 (Screening) 4. Vital Signs

At **4.1 Height** enter **214**

Because the data entered is out of range, a warning is displayed in an orange box:

Height should be 100-213 cm

You would now need to check the **Height** to ensure the data is correct. If it is incorrect, the correct **Height** can be entered and the warning should disappear as long as the correct height is within range. If **214** is correct you need to add a **Comment** to confirm the value entered is correct.

To add a **Comment**, click the cogwheel  to the right of the field containing the questionable data → select **Comments** → in the **New comment** box add the correct data for **height** stating that it is correct, e.g. *"214 is the correct height"* → click **Add comment** → click **Close**.

User Missing

The **User Missing** function is used when a piece of data is missing but there is an explanation as to why it is missing.

In the example below, **Weight** is missing but we know why, e.g. measurement failed.


Navigate to Visit 1 (Screening) 4. Vital Signs

At **4.2 Weight** enter 25 and then delete the 25 and leave it blank.

A red letter warning is displayed:

This field is required

You would now need to check to see if a value for weight is available. If it is, the value can be entered. If it is not (say for example measurement failed) then you need to confirm the value as missing data.

Click the cogwheel  to the right of **Weight** → select **User Missing** → choose a **reason**, i.e.

Measurement failed and add **comment** (if required) → **Save**.

See ***Missing Data*** section of the ***Castor Data Entry Guidelines***

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.

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

Set **16.1 Has the participant experienced any Adverse Events since last visit?** to Yes.

A table appears with previously created **Adverse Events** (if there are any) and a button labelled **Add measurement**.

Click **Add measurement** → a new **Adverse Event** repeating data form opens.

Populate this form with data of your own choice and then click **Close Repeating Data**.

Concomitant Medications


Another example of Repeating Data is **Concomitant Medications**

All **Concomitant Medications** being taken by the participant should be recorded and each **Concomitant Medication** should be recorded on a separate **Concomitant Medication** repeating data form

At Visit 1 all medications should be ticked as **ongoing at start of trial**.
Any new medications started during the trial should have a **start date**.
Any medications stopped during the trial should have an **end date**.
At last visit all medications should have either an **end date** or ticked as **ongoing at end of trial**.
[See **Repeating Data** section of the Castor Data Entry Guidelines](#)

Archiving Repeating Data

If a Repeating Data is created in error, it can be archived from the Repeating Data section within a participant's record.

Click the cogwheel  to the right of the repeating data to be archived → select **Archive repeating data** → enter a reason for archiving → **Archive**. The archived repeating data will disappear.

The 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.

[See **Repeating Data** section of the Castor Data Entry Guidelines](#)

Visual Verification

Visual Verification is a way of checking entered data and the database cannot be closed until this is completed for the following sections:

- **Adverse Events**
- **Bloods**
- **Pulmonary exacerbation record**
- **Trial Medication**
- **Discontinuation of Trial Medication**
- **Completion of trial/Early withdrawal form**
- **Spirometry**

Select a Visit or Repeating Data and Visually Verify it, firstly by checking that all the required data is present and correct.

For example, select **Visit 3** (blue box labelled **Visit 3 (Month 1 +/- 2 weeks) Follow-up Phone call**)



Click on the ellipsis (3 vertical dots) in the white box labelled **Trial Medication** → select **Custom verification** → for *For what reason are you verifying this visit* select **Visual Verification** → for *Does the verification need to be removed when data on this visit is modified?* select **No** → **OK**.

A blue tick with **VER** will appear in the **Trial Medication** white box and a blue bar will appear at the top of the page stating when the form was verified and by whom.

[See **Visual Verification** section of the Castor Data Entry Guidelines](#)

Dealing with Queries

While the trial is running the TCTU DMT will raise queries against participants where there is something we would like checked or confirmed.

Queries appear as numbers in red boxes above a question mark   to the right of the cogwheel on the right of the screen.

If you open a query within a participant's record you can reply to the question by entering text in the **Remark** field and clicking **Save changes**.

Do **not** manually change the status of a query at any time - simply add a response as necessary.

This will give you an opportunity to reply to queries created by the TCTU DMT.

See **Queries** section of the **Castor Data Entry Guidelines**

When you have completed the VitalBE Data Entry Training, contact the TCTU DMT at:

vitalbe-dm@dundee.ac.uk

We can then provide you with feedback and any assistance you may require.