GREAT-2 Data Entry Training

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

Other 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 (**GREAT-2 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 **2** digits for the participant number (no spaces/hyphens/dots or anything else).
For example, **0401** (site number = **04** and participant number = **01**).
Do **NOT** enter participant email
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.
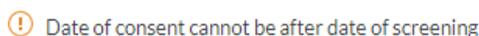**It is important that error messages are not ignored**
Date Warnings
Navigate to Visit 1 - Screening
1. Informed Consent
At **1.1 Date of Screening V1** enter **18-05-2023**
At **1.2 Date of Informed Consent** enter **19-05-2023**
Because date of informed consent is after date of screening a warning is fired in the orange box:

> ⚠ Date of consent cannot be after date of screening

When entering real data when the trial has started you would now need to check the dates of both **Date of Screening V1** 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 Screening V1** and **Date of Informed Consent** 18-05-2023

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

Out of Range Warnings

Navigate to Visit 1 - Screening

2. Demographics, Height & Weight

At **2.6 Weight** enter **180.1**

Because the data entered is out of range a warning is fired in the orange box:

(!) The maximum value for this field is 150.0

You would now need to check the **Weight** to ensure the data is correct. If it is incorrect, the correct **Weight** can be entered, and the warning should disappear. If 180.1 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** → enter **New comment** → click **Add comment** → **Close**.

See *Range Error Messages* section of the Castor Data Entry Guidelines

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.

Navigate to Visit 1 - Screening

6. Vital Signs – click the button | Repeating Data Vital Signs |

At **4 Temperature** enter 36.0 and then delete the 36.0 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 Temperature is available. If it is, the value can be entered. If it is not (say for example it was never recorded) then you need to confirm the value as missing data.

Click the cogwheel ⚙ to the right of **Temperature** → select **User Missing** → choose a **reason** 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 1 - Screening

5. Concomitant Medications

A table appears with previously created **Respiratory** and **Concomitant Medications** (if there are any) and buttons labelled **Add Respiratory Medication and Add other Concomitant Medication.**

Click **Add Respiratory Medication** ➜ a new **Respiratory Medication** repeating data form opens.

Populate the form with the first line of data in the *GREAT-2 Data Worksheet for eCRF Training V1 23-05-23.pdf* document page 5. then click **Close Repeating Data**.
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 tests reviewed**
- **Exacerbation recording**
- **Administration of trial medication**
- **Discontinuation of trial medication (if applicable)**
- **Completion/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 2** (blue box labelled **Visit 2 - Baseline and randomisation**)

Click on the ellipsis (3 vertical dots) in the white box labelled **Administration of 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 **Administration of 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 ⚙ ⑦¹ 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 GREAT-2 Data Entry Training, contact the TCTU DMT at:
great-2-dm@dundee.ac.uk
We can then provide you with feedback and any assistance you may require.