


AIR-NET Castor Database Training

Simply follow the instructions below and then inform the TCTU Data Management Team (DMT) when you are finished (air-net-dm@dundee.ac.uk).

Logging in to Castor

- You will receive an email from Castor inviting you to log in.
- Your log in details are your **email** and your **password** (you create this).
- Log in and click **AIR-NET TEST**.
- Castor users will automatically be logged out after 20 min of inactivity.

Creating a new participant in Castor

- Always create a new participant to start your training.
- Create a new participant by clicking 
- Give the participant an ID.
- The participant ID consists of **5** digits.
- Do not enter any spaces or hyphens.
- **For example**, the first **2** digits refers to the trial site, e.g. 01 for Tayside.
- The next **3** digits refer to the number of the participant (allocated in order of them starting the trial), e.g. **001** would be the first participant enrolled.
- Therefore, the first participant at Tayside would be **01001**.
- If another site was taking part whose site number was 03, their first participant in would be 03001 and the second participant would be 03002 etc.

Data Entry

The Castor database consists of:

Visits e.g. Visit 1 - Screening (visits contain forms)

Forms e.g. Informed Consent (forms contain fields)

Fields e.g. Date of Screening V1

Whilst the main structure of the database is made up of **Visits, Forms and Fields**, 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
- Safety Visits
- Discontinuation of Trial Medication

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

Follow the instructions and enter the example data.

Date Warnings

- Navigate to **Visit 1 - Screening 1. Informed Consent**.
- At **1.2 Date of Screening V1** enter **01-01-2023**.
- At **1.3 Date of Informed Consent** enter **02-01-2023**.
- Because Date of consent is after Date of V1 a warning is displayed:

 Date of consent cannot be after date of screening

It is important that error messages are not ignored.

- When entering data on a **LIVE** trial, 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 you would inform the TCTU DMT.
- To resolve the issue in this example, make both **Date of Screening V1** and **Date of Informed Consent: 01-01-2023**
- The warning will disappear.

Out of Range Warnings

- **Navigate to Visit 1 -Screening 8. Physical Examination.**
- At **8.1 Height** enter **2.14**.
- Because the data entered is out of range, a warning is displayed:

 Height must be between 0.95m and 2.00m.

It is important that error messages are not ignored

- When entering data on a **LIVE** trial, you would now need to check the **Height** to see if 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 **2.14** is correct, you need to add a **Comment** to confirm that although the value is out of range, it is correct.
- To add a **Comment**, click the cogwheel to the right of the field containing the questionable data.
- Select **Comments**.
- In the **Comment** box, state that the height measurement is correct, e.g. ***"2.14 is the correct height"***.
- Click **Add comment**.
- Click **Close**.

Missing Value

- 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 8. Physical Examination.**
- At **8.3 Weight** enter a value of **201.3** (which will fire a warning) and then remove the **201.3** and leave it blank.
- A red letter warning is displayed next to Weight – this means the value 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 (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**.
- Add a **comment**, e.g. *“scales used for weight measurement malfunctioned so weight was not recorded.”*
- Click **Save**.

Repeating Data

Repeating Data forms are used to either capture data that is recorded for multiple trial visits or not connected to a visit at all, e.g. Adverse Events, ConMeds, Questionnaires etc.

- Navigate to **Visit 2 17. Adverse Events**.
- At **17.1 Adverse events** click the button Add AE.
- A new **Adverse Event** will be created.

- To access the new AE, click on the row that appears in the table.
- This opens the new AE. If other Repeating data have previously been created, they will be located here too. If other AEs are already here, you can locate the new one you have just created by looking for the date in the **Created on** column.
- Click the new AE to open it.
- Use your own data to complete all of the data fields in this form (ensure you have reached the bottom of the page).
- To return to Repeating data section, click **Close & return** at the bottom of the screen.

Concomitant Medications



- Another example of Repeating Data is **Concomitant Medications**.
- All **Concomitant Medications** being taken by the participant should be recorded.
- Each **Concomitant Medication** should be recorded on a separate **Concomitant Medication** repeating data form.
- At Visit 1 all ConMeds already being taken should be marked **Yes to 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 marked **Yes to Ongoing at end of trial**.
- Navigate to **Visit 1 - Screening 4. Concomitant Medications** and create a new ConMeds repeating data by clicking the button **Add other ConMeds**.
- Populate all of the fields of the new ConMeds repeating data with your own data.

Archiving Repeating Data

- On some occasions, a Repeating Data can be created in error.
- It can be archived (removed from view) from the Repeating Data section.

- Go to the Repeating Data section by clicking Repeating data on the left of the screen.
- Click the 3 dots to the right of the repeating data to be archived.
- Select **Archive**.
- Enter a reason for archiving, e.g. *“created in error.”*
- Click **Archive instance**.
- The archived repeating data will disappear from view.
- The archived repeating data can be viewed by selecting **Archived** from the **Filters** menu.
- The Repeating data can be unarchived by clicking **Unarchive** from within the cogwheel.

Dealing with Queries

- While the trial is running, the TCTU DMT will raise queries 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 next to the data field in question.
- A query raised by TCTU DMT may be along the lines of *“Data missing, please enter data”* or *“Please check data as it is out of range”*.
- Open a query by clicking it.
- You can reply to the query 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.
- **Please respond to all queries as soon as possible.**

End of training