

Data Management Training

PI Verification

It is the responsibility of the site Principal Investigator (PI) to sign off several parts of the eCRF within the Castor database.

These include:

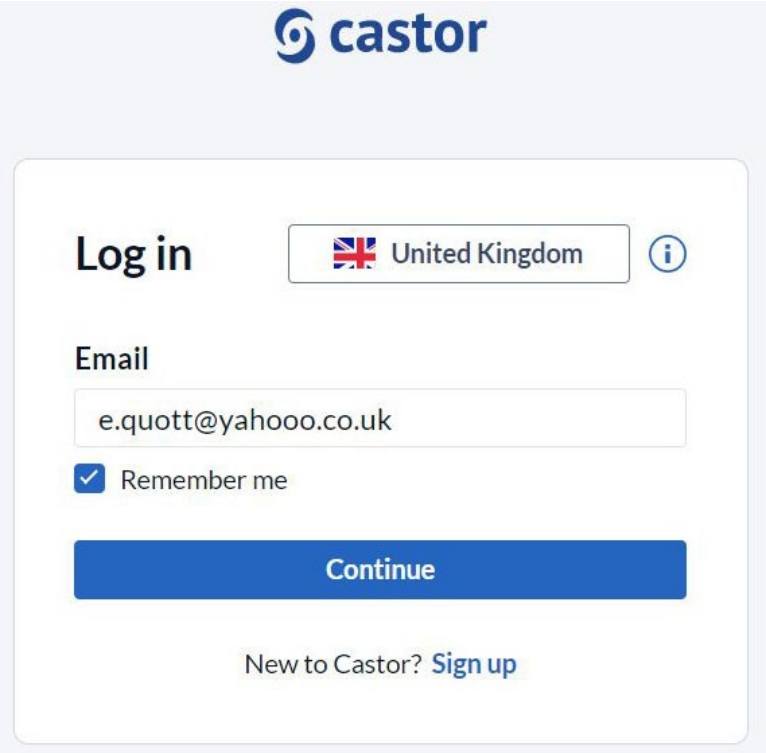
- Completion of Trial/Early Withdrawal form
- Each Adverse Event added to the database

Logging in to Castor

- To access Castor, a username and password are required
- This will be set up for you by the TCTU Data Management Team
- When your account has been activated, you will receive a confirmation email from Castor
- Follow the instructions in the email
- You will be required to provide a new password for your account (if you forget your password, contact the Data Management Team)
- Your username for Castor is your email address

Log into Castor here:

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



The screenshot shows the Castor login interface. At the top is the Castor logo. Below it, the text 'Log in' is displayed next to a dropdown menu showing 'United Kingdom' with a flag icon and an information icon. Underneath is an 'Email' input field containing 'e.quott@yahooo.co.uk'. A 'Remember me' checkbox is checked. A blue 'Continue' button is positioned below the input fields. At the bottom, there is a link that says 'New to Castor? Sign up'.

My Studies – Castor Homepage

- ❑ When you log in to Castor, you will land on the **My Studies** homepage
- ❑ All of the Castor trials connected to your account will be visible here
- ❑ Click on the trial of interest to access the eCRF

My Studies

Search Order by

<input type="radio"/> Not Live	Test Study: HT-PREDICT DEV	Monocenter	UK Server	<input type="button" value="⋮"/>
<input type="radio"/> Not Live	Test Study: GREAT-2 TEST	Multicenter	UK Server	<input type="button" value="⋮"/>
<input type="radio"/> Not Live	Test Study: VitalBE TEST	Multicenter	UK Server	<input type="button" value="⋮"/>

Participants Homepage

- ❑ When you have selected a trial, Castor will open the participants homepage
- ❑ This contains a list of all the participants at your site and information about each participant
- ❑ Double click a participant ID to open it

VitalBE TEST ◦ Not Live (v.29.61)

Participants

Exact match

[+ New](#) [Actions](#) [Filters](#)

[List](#) [Visit](#) [Form](#)

<input type="checkbox"/>	Participant... ↓	Site ↑↓	Progress ↑↓	Last opene... ↑↓	Created on ↑↓	Updated on ↑↓	Status ↑↓			
<input type="checkbox"/>	01001	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Marcus Achison	18 Nov 2022	23 Mar 2023	Not Set		5	
<input type="checkbox"/>	01002	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Marcus Achison	05 Jan 2023	23 Mar 2023	Not Set			
<input type="checkbox"/>	55555	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Marcus Achison	02 Feb 2023	31 Mar 2023	Not Set		1	
<input type="checkbox"/>	55556	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Marcus Achison	15 Feb 2023	22 Mar 2023	Not Set			
<input type="checkbox"/>	55557	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Marcus Achison	23 Feb 2023	22 Mar 2023	Not Set			
<input type="checkbox"/>	55558	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Marcus Achison	06 Mar 2023	21 Mar 2023	Not Set			
<input type="checkbox"/>	55559	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Marcus Achison	06 Mar 2023	06 Mar 2023	Not Set			
<input type="checkbox"/>	99999	TCTU	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Fiona McLaren-Ne	23 Feb 2023	04 Apr 2023	Not Set			

1 - 8 of 8 Items per page: 25

To Verify the Completion of Trial/Early Withdrawal form

Participant ID: 55555 Not Live (v.29.61) Participant status: Not Set

Participant: 55555
Not Set
Progress: 89%

Completion of Trial/Early Withdrawal

55.3 Did the participant attend the last visit BUT was never randomised? NO

55.4 Date last trial medication taken? 01-02-2023

55.5 Is the date last trial medication in the correct format? YES

55.6 Date of completion/withdrawal 02-02-2023 (DD-MM-YYYY)

If participant did not complete the trial, what was the main reason (tick one only)

55.2.2 Reason Participant's choice

Context menu options:
Mark form as missing
Lock this form
Sign this form
Custom verification
SDV visit form
Print this form

1. Navigate to **Completion of Trial/Early Withdrawal** (blue box)

2. Navigate to the **Completion of Trial/Early Withdrawal form** (white box)

3. Click the **vertical ellipsis** (3 dots) within the Completion of Trial/Early Withdrawal form and select **Custom Verification**

To Verify the Completion of Trial/Early Withdrawal form

1. When you have reviewed and confirmed that the eCRF has been completed, select **PI Verification**

2. Select **No**

3. Click **OK**

Data verification

For what reason are you verifying this form:

Visual Verification

PI Verification

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

Yes

No

OK Cancel

To Verify the Completion of Trial/Early Withdrawal form

Participant ID: 09248 Not Live (v.260.01)

Participant status: Not Set ▼

VitalBE
Value of inhaled treatment with aztreonam lysine in bronchiectasis

Participant: 09248
Not Set
Progress: 96%

Completion of Trial/Early Withdrawal
55. Completion of Trial/Early Withdrawal

VER This form was verified on 07/04/2023 at 10:09 by Marcus Achison for PI Verification Remove

This form should be completed for every patient entered into the trial, i.e. consented and attended for screening visit, including screen fail patients.

55.1	Was the participant randomised?	YES	⚙️
55.2	Did the participant attend the last trial visit (Visit 6)?	YES	⚙️
55.3	Did the participant attend the last visit BUT was never randomised?	NO	⚙️
55.4	Date last trial medication taken?	12-05-2022	⚙️
55.5	Is the date last trial medication in the correct format?	YES	⚙️
55.6	Date of completion/withdrawal	12-05-2022 (DD-MM-YYYY)	⚙️

Participant who did not complete the trial must be assessed by doctor. Changes to participant's medication and any other actions taken must be recorded in the participant's medical notes and their GP informed.

Previous Next

Completion of Trial/Early Withdrawal
Completed **VER**

Confirmation that Completion of Trial/Early Withdrawal has been verified by the PI

Completion of Trial/Early Withdrawal form marked as Verified

To Verify an Adverse Event

This is performed as for Completion of Trial/Early Withdrawal:

- Click on participant ID to open it

- Click **Repeating Data** on left of screen

- In centre of screen click **Filter by Repeating Data**

- Select **Adverse Events** - adverse events will be displayed

- Click an Adverse Event to open it

- Verify it as before:
Click **ellipsis** → **Custom Verification** → **PI Verification** → **No** → **Verify**

If you need assistance with anything contact the TCTU Data Management Team: vitalbe-dm@dundee.ac.uk