

Data Management Training: Verifying Steps in the STAR-COVID19 Trial



Signing off forms in Castor EDC

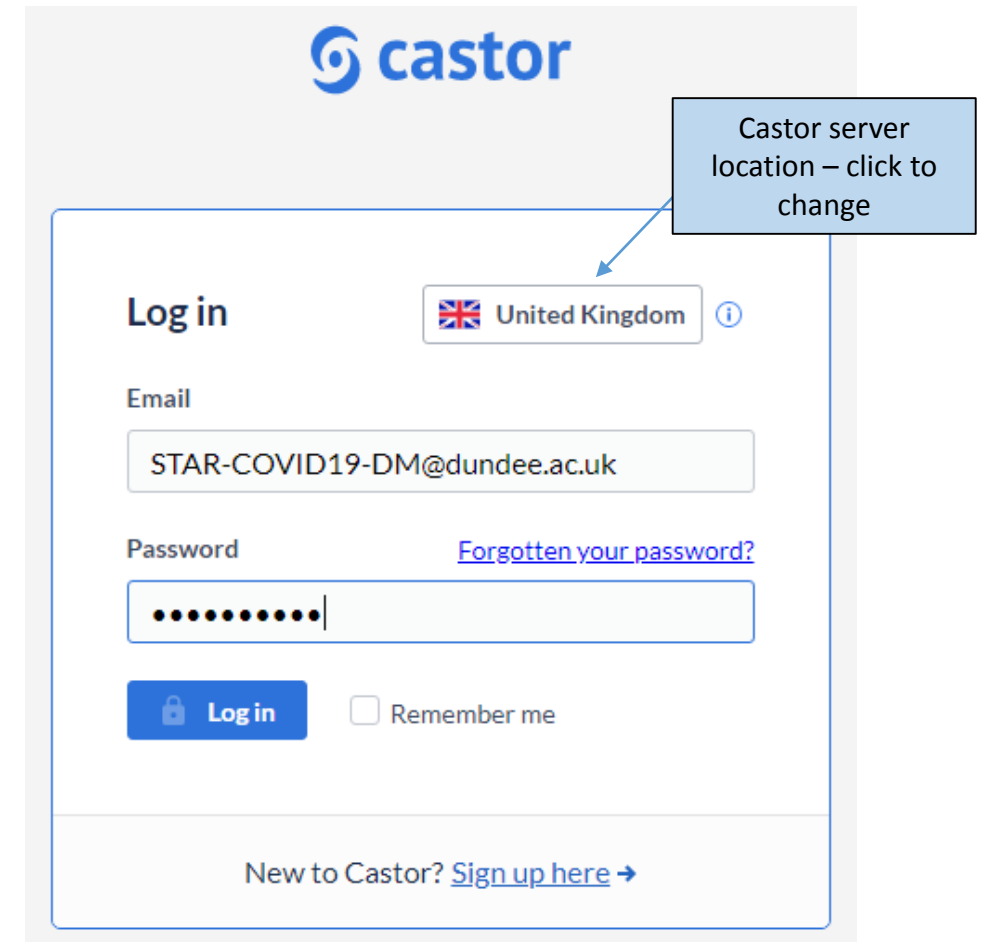
- The Castor EDC allows for sections of an eCRF to be verified by a user
- In the STAR-COVID19 trial, the Completion of Trial forms are required to be electronically verified by the Principal Investigator (PI) at each study site
- Each Adverse Event is also required to be electronically verified by the PI at each study site
- This presentation is designed to guide you through the process of electronically verifying forms in the STAR-COVID19 eCRF



Logging into the STAR-COVID19 eCRF

- In order for you to gain access to the STAR-COVID19 eCRF, a username and password is required – this will be set up for you by a member of the TCTU Data Management Team
- Once your account has been activated, you will receive a confirmation email
- Follow the instructions in this email – you will be required to provide a new password for your account
- Your username for Castor is your email address

NOTE: The default server location for STAR-COVID19 is the United Kingdom. The Castor login page should automatically revert to this. However, please check that the server location is set to the United Kingdom before logging into the eCRF.

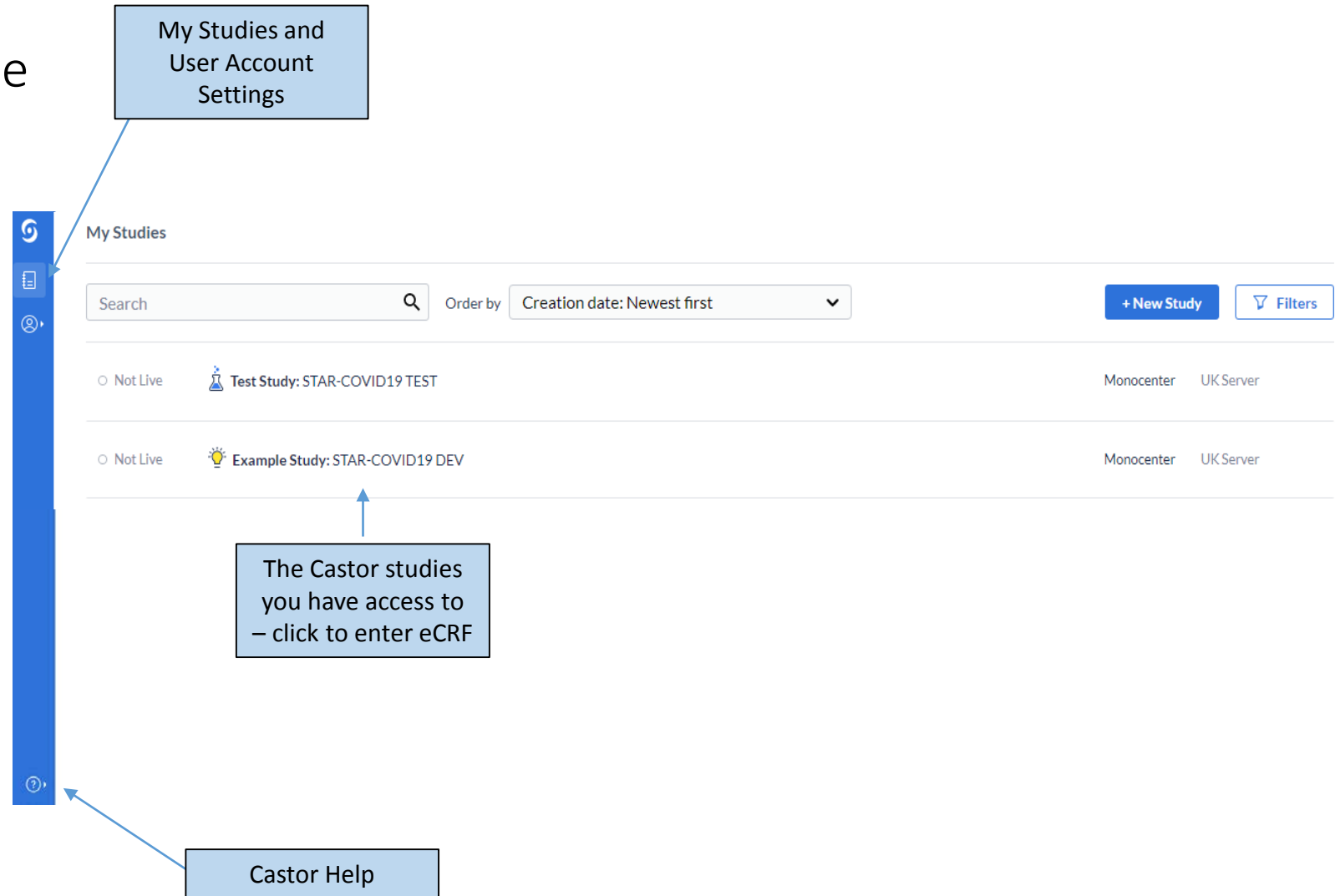


The screenshot shows the Castor login interface. At the top right is the Castor logo. Below it, a blue box contains the text "Castor server location – click to change" with an arrow pointing to a dropdown menu showing "United Kingdom" with a flag icon and an information icon. The main login form includes a "Log in" heading, an "Email" field with the text "STAR-COVID19-DM@dundee.ac.uk", a "Password" field with masked characters and a "Forgotten your password?" link, a "Log in" button with a lock icon, and a "Remember me" checkbox. At the bottom, there is a link for "New to Castor? Sign up here →".

Log into Castor here:
<https://uk.castoredc.com/>

My Studies – Castor Homepage

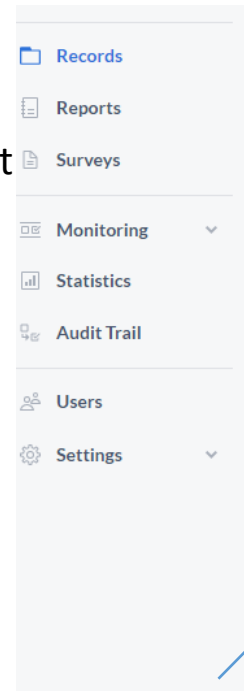
- Once you log into the system, you will be re-directed to the “My Studies” homepage
- All of the Castor studies connected to your account will appear here
- Click on the STAR-COVID19 LIVE study to access the STAR-COVID19 eCRF
- You can also access your account settings and some Castor help pages in the “My Studies” area



The screenshot shows the 'My Studies' homepage. A vertical blue sidebar on the left contains icons for home, list, user, and help. Callout boxes point to these icons: 'My Studies and User Account Settings' points to the user icon, and 'Castor Help' points to the help icon. The main content area is titled 'My Studies' and features a search bar, an 'Order by' dropdown set to 'Creation date: Newest first', a '+ New Study' button, and a 'Filters' button. Below this are two study entries, both marked as 'Not Live': 'Test Study: STAR-COVID19 TEST' and 'Example Study: STAR-COVID19 DEV'. A callout box points to the 'Example Study' entry with the text: 'The Castor studies you have access to – click to enter eCRF'. The 'Example Study' entry shows 'Monocenter' and 'UK Server' details.

STAR-COVID19 Records Page

- Once you have selected the appropriate study, the page will automatically redirect to the study records home page
- This contains a list of the participants at your given site, along with specific information about each record
- Double click a record to open it for data entry



List of participants at your site

Search: in Record Exact match 🔄 📄 List view + New Filters

<input type="checkbox"/> Record	Institute	Last open...	Last open...	Progress	Created by	Created on	Updated on	Updated by	Qu...	Actions
<input type="checkbox"/> 00000	TCTU	22 Oct 20...	Hasithi U...	<div style="width: 20%;"></div>	Eva Lahnst...	10 Oct 2020	14 Oct 2020	Eva Lahnst...		
<input type="checkbox"/> 01MB	TCTU	17 Oct 20...	Margaret ...	<div style="width: 60%;"></div>	Margaret B...	14 Oct 2020	17 Oct 2020	Margaret B...		
<input type="checkbox"/> 02MB	TCTU	19 Oct 20...	Margaret ...	<div style="width: 40%;"></div>	Margaret B...	14 Oct 2020	19 Oct 2020	Margaret B...		
<input type="checkbox"/> 01002	TCTU	21 Oct 20...	Hasithi U...	<div style="width: 30%;"></div>	Marcus Ac...	07 Oct 2020	21 Oct 2020	Hasithi Um...		
<input type="checkbox"/> 01003	TCTU	21 Oct 20...	Eva Lahn...	<div style="width: 70%;"></div>	Eva Lahnst...	30 Sep 2020	19 Oct 2020	Eva Lahnst...		
<input type="checkbox"/> 01004	TCTU	16 Oct 20...	Eva Lahn...	<div style="width: 10%;"></div>	Eva Lahnst...	16 Oct 2020	16 Oct 2020	Eva Lahnst...		
<input type="checkbox"/> MB03	TCTU	19 Oct 20...	Margaret ...	<div style="width: 15%;"></div>	Margaret B...	17 Oct 2020	19 Oct 2020	Margaret B...		
<input type="checkbox"/> 99998	TCTU	22 Oct 20...	Andrew ...	<div style="width: 80%;"></div>	Andrew M...	01 Oct 2020	22 Oct 2020	Andrew M...		
<input type="checkbox"/> 99999	TCTU	22 Oct 20...	Andrew ...	<div style="width: 90%;"></div>	Andrew M...	29 Sep 2020	22 Oct 2020	Andrew M...		
<input type="checkbox"/> LB001	TCTU	19 Oct 20...	Lewis Beer	<div style="width: 75%;"></div>	Lewis Beer	19 Oct 2020	19 Oct 2020	Lewis Beer		


⏪ Page 1 of 1 ⏩ 🔄 | Records per Page 25 | 🔒 Lock selected | 🔓 Unlock selected | 🖨️ Print selected Displaying records 1 - 10 of 10

Hover over the 'Actions' icon and click on the first icon

Completion of Trial/Early Withdrawal



Record: 01002

Progress:  40%

Day 11

In Progress

Day 15

In Progress

Day 29

Completed

Completion of Trial/Early Withdrawal

Completed

Completion of Trial/Early Withdrawal

Completion of Trial/Early Withdrawal 37. Completion of Trial/Early Withdrawal

37.1.2.3 Number of tablets remaining?

37.1.1.1 Date of completion/withdrawal (date of Day 29) 01-09-2020

37.1.3 Is the date of completion before last trial medication taken? NO

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

Adverse Event

- Mark phase as missing
- Lock this phase
- Sign this phase
- Custom verification**
- SDV all steps in this phase
- Print this phase
- Add a report to this phase

4. Click on the vertical ellipsis next to the right of the Completion of Trial step and select "Custom verification"

1. Navigate to the Completion of Trial/Early Withdrawal phase

2. Navigate to the Completion of Trial/Early Withdrawal step

I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the trial information obtained for this participant. All entries were made either by myself or by a person under my supervision who has signed the Delegation and Signature Log.

Previous

Next

3. Review and confirm the eCRF has been completed

Completion of Trial/Early Withdrawal

1. Select "PI Verification"

2. Select "No"

3. Click "OK"

Data verification

For what reason are you verifying this phase:

Visual Verification

PI Verification

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

Yes

No

OK Cancel

Completion of Trial/Early Withdrawal



Record: 01002

Progress: 40%

Day 11

In Progress

Day 15

In Progress

Day 29

Completed

Completion of Trial/Early Withdrawal

Completed



Completion of Trial/Early Withdrawal

Completion of Trial/Early Withdrawal 37. Completion of Trial/Early Withdrawal

✓ This step was verified on 22/10/2020 at 11:08 by Hasithi Umagiliya Bandara for PI Verification

[Remove](#)

Completion of Trial/Early Withdrawal

●	37.1	Was the participant randomised?	YES	
●	37.1.1	Did the participant complete the trial (reach Day 29)?	YES	
●	37.1.2.2	Date last trial medication taken?	<input type="text" value="01-09-2020"/> <small>(dd-mm-yyyy)</small>	
●	37.1.2.3	Number of tablets remaining?	<input type="text" value="13"/>	
●	37.1.1.1	Date of completion/withdrawal (date of Day 29)	<input type="text" value="01-09-2020"/>	
●	37.1.3	Is the date of completion before last trial medication taken?	NO	

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

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

Completion of Trial/Early Withdrawal Form is now marked as verified

Verifying Adverse Events

- When an Adverse Event is added to the eCRF, you will receive an email similar to the one in this picture
- This will contain the study name, date, time and record ID related to the Adverse Event. It will also contain the username of the individual who recorded the Adverse Event
- Log into Castor via the URL provided in the email

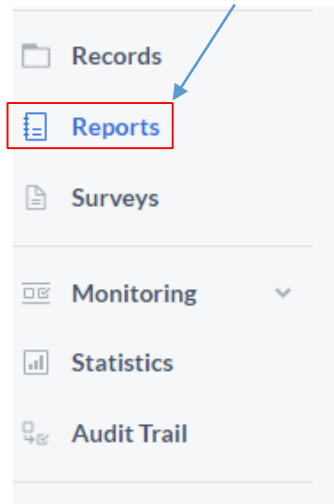


****STAR-COVID19 TEST**** A new Adverse Event report named 'Adverse Events - 22-10-2020 09:48:12' has been added to record 99998 by Andrew McKenzie (a.z.mckenzie@dundee.ac.uk) on 22-10-2020 at 09:48:12. Please log on to Castor (<https://uk.castoredc.com/>) to review and verify the AE.

Castor Electronic Data Capture
www.castoredc.com

Verifying Adverse Events

Navigate to the Reports tab



You can use the filters here to identify the appropriate Adverse Event – this example uses the name of the Adverse Event taken from the email

Filter by institute:

Filter by name:

Filter by report type:

Filter by status:

Filter by record id:

Filter by report:

Filter by phase:

Status	Record ID	Report	Name	Type	Created on	Created by	Assigned to	Menu
●	99998	Adverse Events	Adverse Events - 22...	Repeated measure	2020-10-22 09:48:12	Andrew McKenzie	Day 3	⚙️

Double click on the appropriate Adverse Event row to open the data entry form

Verifying Adverse Events



Record: 99998

Progress: 98%

● In Progress

Adverse Events - 22-10-2020 09:48:12

● In Progress

Adverse Event

- Lock this report
- Sign this report
- Custom verification
- SDV all steps in this report
- Print this report

3. Click on the vertical ellipsis next to the right of the Adverse Event step and select "Custom verification"

All reports+

Report-

Adverse Event

● 7 Severity 1. Mild

● 8 Relationship to Trial Drug 2. Possible

SAE form been completed? YES

1. None
 2. Hospitalisation
 3. IMP temporarily stopped
 4. IMP permanently stopped
 5. Con Meds commenced
 6. Other (specify)

Close reportAll reports

1. Review the Adverse Event content

2. Complete 'Severity' and 'Relationship to Trial Drug' fields

- 1. None
- 2. Hospitalisation
- 3. IMP temporarily stopped
- 4. IMP permanently stopped
- 5. Con Meds commenced
- 6. Other (specify)

Verifying Adverse Events

Data verification

For what reason are you verifying this phase:

Visual Verification

PI Verification

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

Yes

No

OK Cancel

1. Select "PI Verification"

2. Select "No"

3. Click "OK"

Verifying Adverse Events



Record: 99998

Progress: 98%

In Progress VER ✓

Adverse Events - 22-10-2020 09:48:12

In Progress VER ✓

Adverse Event

Adverse Event is now marked as verified

All reports
+

Report
-

Adverse Event

VER ✓ This step was verified on 22/10/2020 at 11:38 by Hasithi Umagiliya Bandara for PI Verification [Remove](#)

Adverse Events Log

AEs & SAEs must be followed up until Recovered / Recovered with sequelae / Death OR for 30 days after participant's day 29, whichever happens first. If still Ongoing at last day of data collection, then contact participant 30 days after last trial involvement and update AE log if required. SUSARs must be followed up until resolved.

●	1 Description of adverse event	<input type="text" value="Fever"/>	⚙
●	2 Identification of new infection	<input type="text" value="YES"/>	⚙
●	2.1 Name of new infection	<input type="text"/>	⚙

Close report
All reports

Confirmation that Adverse Event step has been verified by the PI



Help

- If you have any questions, please contact the TCTU Data Management team.

STAR-COVID19-DM@dundee.ac.uk

