

# Data Management Training: Verifying Steps in the STOP-COVID19 Trial

STOP-  
COVID19 | Superiority Trial  
Of Protease  
inhibition in  
COVID-19



## Signing off forms in Castor EDC

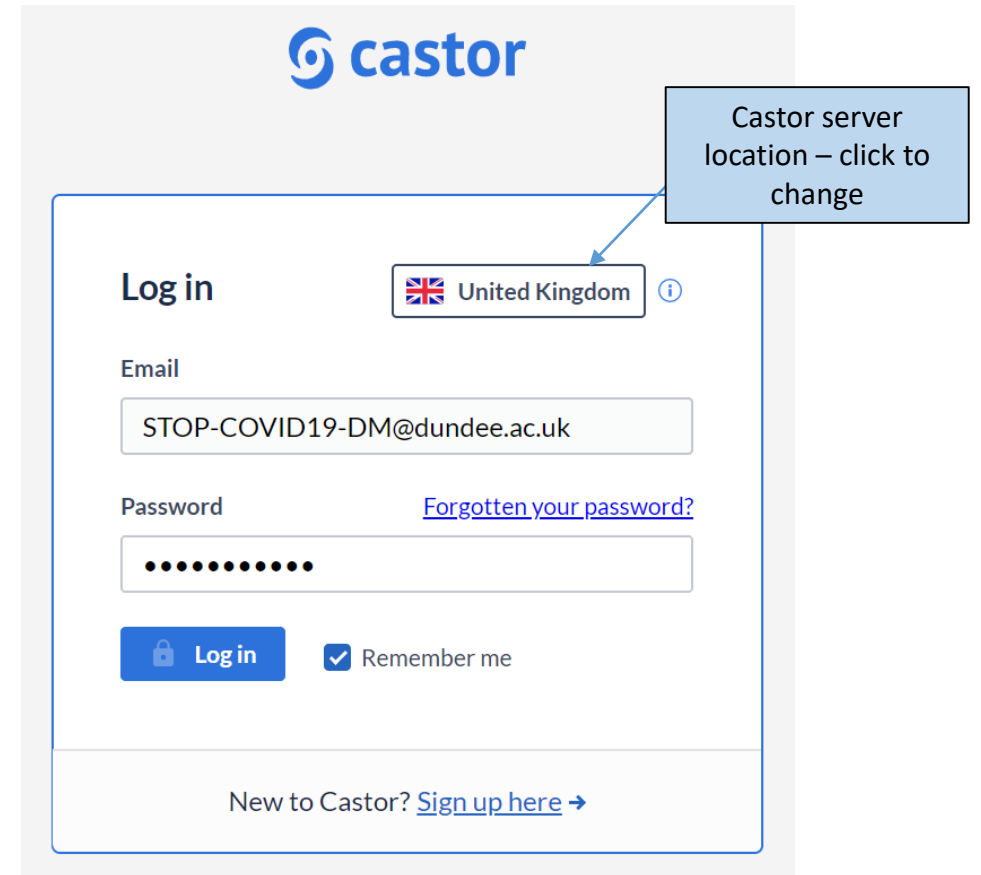
- The Castor EDC allows for sections of an eCRF to be verified by a user
- In the STOP-COVID19 trial, the Eligibility and Completion of Trial forms are required to be electronically verified by the Principal Investigator (PI) at each study site
- Each Adverse Event is also required to be electronically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



## Logging into the STOP-COVID19 eCRF

- In order for you to gain access to the STOP-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 STOP-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.

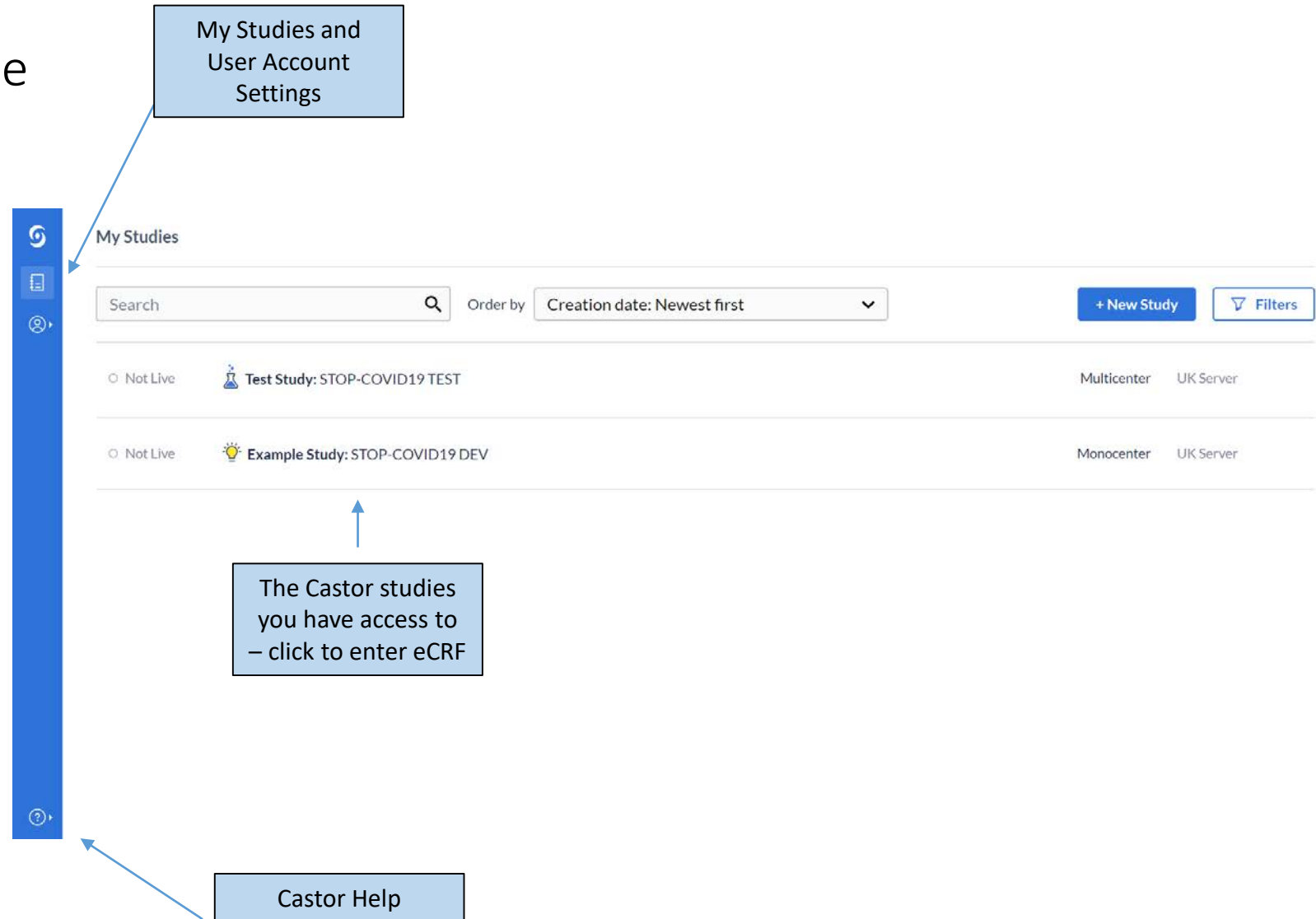


The screenshot shows the Castor login interface. At the top right, there is a callout box with the text "Castor server location – click to change" and an arrow pointing to a dropdown menu. The dropdown menu is currently set to "United Kingdom" with a small information icon to its right. Below this, there are input fields for "Email" (containing "STOP-COVID19-DM@dundee.ac.uk") and "Password" (masked with dots). A "Log in" button is present, along with 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 STOP-COVID19 LIVE study to access the STOP-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 blue sidebar on the left contains icons for home, list, user, and help. The main content area is titled 'My Studies' and includes 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:

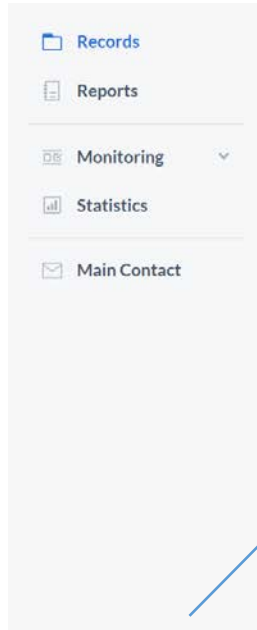
Status	Study Name	Center Type	Server
Not Live	Test Study: STOP-COVID19 TEST	Multicenter	UK Server
Not Live	Example Study: STOP-COVID19 DEV	Monocenter	UK Server

Callouts in the image:

- A box labeled 'My Studies and User Account Settings' points to the top of the sidebar.
- A box labeled 'The Castor studies you have access to – click to enter eCRF' points to the study list.
- A box labeled 'Castor Help' points to the help icon in the sidebar.

# STOP-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

STOP-COVID19 TEST Not Live (v.33.31)

Search:  in Record  Exact match

Record	Institute	Last open...	Last open...	Progress	Created by	Created on	Updated on	Updated by	Qu...	Actions
<input type="checkbox"/> 01001	Tayside	07 Jun 2...	Eva Lah...	<div style="width: 50%;"></div>	Simon Ad...	19 May 2...	06 Jun 20...	Eva Lahns...		
<input type="checkbox"/> 01002	Tayside	04 Jun 2...	Andrew ...	<div style="width: 20%;"></div>	Marcus A...	19 May 2...	21 May 2...	Marcus A...		
<input type="checkbox"/> 01003	Tayside	03 Jun 2...	Andrew ...	<div style="width: 75%;"></div>	Marcus A...	20 May 2...	02 Jun 20...	Marcus A...		
<input type="checkbox"/> 01004	Tayside	02 Jun 2...	Andrew ...	<div style="width: 10%;"></div>	Hasithi U...	01 Jun 20...	01 Jun 20...	Hasithi U...		
<input type="checkbox"/> 01005	Tayside	05 Jun 2...	Data Ent...	<div style="width: 10%;"></div>	Simon Ad...	02 Jun 20...	05 Jun 20...	Data Entr...	<input checked="" type="checkbox"/>	
<input type="checkbox"/> 01006	Tayside	04 Jun 2...	Data Ent...	<div style="width: 10%;"></div>	Data Entr...	03 Jun 20...	04 Jun 20...	Data Entr...	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 01007	Tayside	06 Jun 2...	Margare...	<div style="width: 80%;"></div>	Margaret ...	04 Jun 20...	05 Jun 20...	Margaret ...		
<input type="checkbox"/> 99997	Tayside	06 Jun 2...	Margare...	<div style="width: 20%;"></div>	Andrew ...	03 Jun 20...	06 Jun 20...	Margaret ...		
<input type="checkbox"/> 99998	Tayside	03 Jun 2...	Andrew ...	<div style="width: 70%;"></div>	Andrew ...	01 Jun 20...	02 Jun 20...	Andrew ...		
<input type="checkbox"/> 99999	Tayside	05 Jun 2...	Kristina ...	<div style="width: 85%;"></div>	Andrew ...	27 May 2...	05 Jun 20...	Kristina P...		

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

# Eligibility Check

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

Randomisation  
16. Eligibility Checks

Record: 01005  
Progress: 26%  
 Show Reports

16.1 Were all INCLUSION and EXCLUSION criteria met? YES

16.2 Is the participant eligible to take part in the trial? YES

16.3 Was eligibility reviewed by a doctor within 24 hours of date of screening? YES

16.4 Was eligibility signed off by a doctor within 24 hours prior to randomisation? YES

The doctor needs to confirm eligibility by electronically signing this step.

Mark step as missing  
Lock this step  
Sign this step  
Custom verification  
SDV this step  
Print this step

1. Navigate to the Randomisation phase

2. Navigate to the Eligibility Checks step

3. Ensure all inclusion/exclusion criteria are met  
\*\*NOTE: Please check that all fields related to the inclusion/exclusion criteria have been completed correctly prior to verifying the eligibility check section\*\*

4. Click on the vertical ellipsis next to the Eligibility Checks step and select "Custom verification"

# Eligibility Check

1. Select "PI Verification"

2. Select "No"

3. Click "OK"

### Data verification

For what reason are you verifying this step:

Source data verification

Other

PI Verification

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

Yes

No

# Eligibility Check



## Randomisation 16. Eligibility Checks

Confirmation that Eligibility Checks step has been verified by the user

Record: 01005

Progress:  26%

Show Reports

- In Progress
- Screening
- In Progress
- Randomisation**
- Completed
- Randomisation
- Completed
- Inclusion Criteria
- Completed
- Exclusion Criteria
- Completed VER
- Eligibility Checks

Eligibility Checks is now marked as verified

VER This step was verified on 08/06/2020 at 14:21 by Data Entry User Data Entry User for PI Verification

Eligibility must be checked prior to randomisation by a doctor delegated this task in the Delegation Log

<span style="color: green;">●</span> 16.1	Were all INCLUSION and EXCLUSION criteria met?	YES
<span style="color: green;">●</span> 16.2	Is the participant eligible to take part in the trial?	YES
<span style="color: green;">●</span> 16.3	Was eligibility reviewed by a doctor within 24 hours of date of screening?	YES
<span style="color: green;">●</span> 16.4	Was eligibility signed off by a doctor within 24 hours prior to randomisation?	YES

The doctor needs to confirm eligibility by electronically signing this step.



# Completion of Trial/Early Withdrawal

## Completion of Trial/Early Withdrawal 45. Completion of Trial/Early Withdrawal

Record: 01005  
 Progress:  26%  
 Show Reports

- Completed
- Daily Data Collection while in Hospital
- Not Started
- Day 3
- Not Started
- Day 5
- Not Started
- Day 8
- Not Started
- Day 11
- Not Started
- Day 15
- In Progress
- Day 29
- Completed
- Completion of Trial/Early Withdrawal
- Completed
- Completion of Trial/Early Withdrawal

Completion of Trial/Early Withdrawal

45.1	Was the participant randomised?	YES	
45.1.1	Did the participant complete the trial (reach Day 29)?	YES	
45.1.1.1	Date of completion/withdrawal (date of Day 29)	02-06-2020	
45.1.2.1	Date last trial medication taken?	02-06-2020	
45.1.3	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)

45.2 Reason

To be signed electronically once participant has completed the trial.

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

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

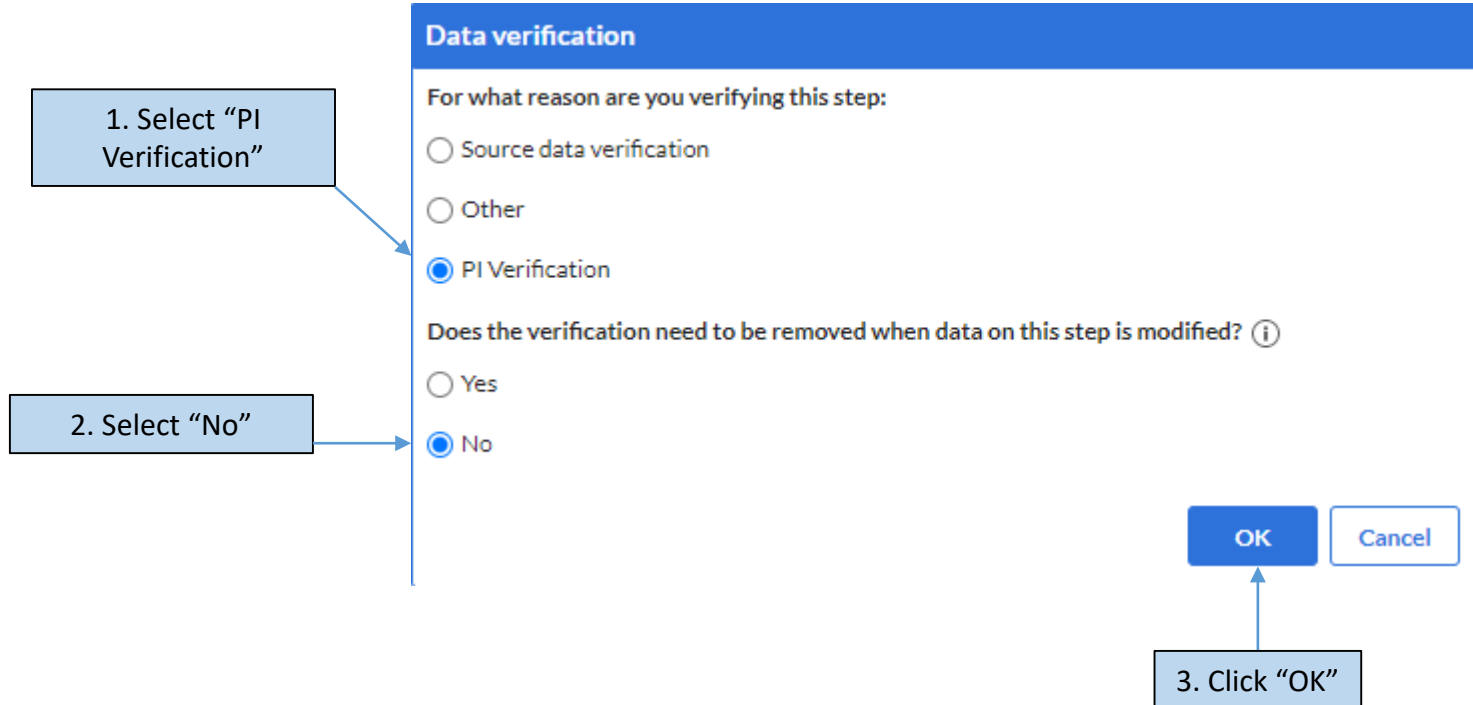
2. Navigate to the Completion of Trial/Early Withdrawal step

3. Review and confirm the eCRF has been completed

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

- Mark step as missing
- Lock this step
- Sign this step
- Custom verification
- SDV this step
- Print this step

# Completion of Trial/Early Withdrawal



# Completion of Trial/Early Withdrawal

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

## Completion of Trial/Early Withdrawal 45. Completion of Trial/Early Withdrawal

Record: 01005  
 Progress:  26%  
 Show Reports

[View](#) This step was verified on 08/06/2020 at 19:38 by Data Entry User Data Entry User for PI Verification [Remove](#)

### Completion of Trial/Early Withdrawal

<input checked="" type="radio"/>	45.1	Was the participant randomised?	YES	
<input checked="" type="radio"/>	45.1.1	Did the participant complete the trial (reach Day 29)?	YES	
	45.1.1.1	Date of completion/withdrawal (date of Day 29)	02-06-2020	
	45.1.2.1	Date last trial medication taken?	02-06-2020	
<input checked="" type="radio"/>	45.1.3	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)

45.2 Reason

To be signed electronically once participant has completed the trial.

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](#)

- Completed
- Daily Data Collection while in Hospital
- Not Started
- Day 3
- Not Started
- Day 5
- Not Started
- Day 8
- Not Started
- Day 11
- Not Started
- Day 15
- In Progress
- Day 29
- Completed [View](#)
- Completion of Trial/Early Withdrawal [View](#)
- Completion of Trial/Early Withdrawal [View](#)

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 in the individual who recorded the Adverse Event
- Log into Castor using via the URL provided in the email



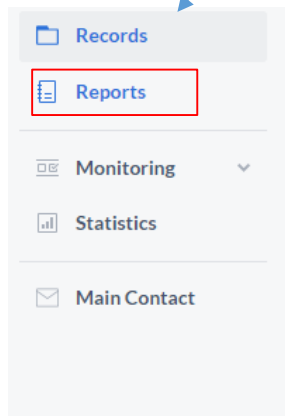
**\*\*STOP-COVID19 TEST\*\*** A new Adverse Event report named 'Adverse Events - 08-06-2020 14:39:20' has been added to record 01005 by Simon Adamson ([s.z.adamson@dundee.ac.uk](mailto:s.z.adamson@dundee.ac.uk)) on 08-06-2020 at 14:39:20. Please log on to Castor (<https://uk.castoredc.com/>) to review and sign the AE.

Castor Electronic Data Capture  
[www.castoredc.com](http://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



Records  
Reports  
Monitoring  
Statistics  
Main Contact

STOP-COVID19 TEST Not Live (v.40.71)

Filter by institute: All Institutes  
Filter by name: Adverse Events - 08-06-2020 14:39:20  
Filter by report type: Select report type to filter  
Filter by status: Unarchived  
Filter by record id:  
Filter by report: Select report to filter  
Filter by phase: Select phase to filter  
Reset

Status	Record ID	Report	Name	Type	Created on	Created by	Assigned to	Menu
●	01005	Adverse Events	Adverse Events - 08-06-2...	Repeated measure	2020-06-08 14:39:20	Simon Adamson	Day 5	⚙️

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

# Verifying Adverse Events

STOP-COVID19  
Superiority Trial  
Of Protease  
inhibition in  
COVID-19

All reports

Report

Record: 01005

Progress:  26%

In Progress

Adverse Events - 08-06-2020 14:39:20

In Progress









Adverse Event

-  Mark step as missing
-  Lock this step
-  Sign this step
-  Custom verification
-  SDV this step
-  Print this step

## 1. Adverse Event

### 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 contact participant 30 days after last trial involvement and update AE log if required. SUSARs must be followed up until resolved.

1	Name of adverse event	<input type="text" value="Chest pain"/>	
2	Date of onset	<input type="text" value="06-06-2020"/>	
3	Reported in the correct format?	YES	
4	Date reported to Investigator	<input type="text" value="08-06-2020"/> (dd-mm-yyyy)	
5	Is date reported before date of onset?	NO	
6	Severity	<input type="text" value="1. Mild"/>	
7	Relationship to Trial Drug	<input type="text" value="1. None"/>	
8	Is this an SAE?	<input type="text" value="NO"/>	

1. Review the Adverse Event content

2. Complete severity and relationship to trial drug fields

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

# Verifying Adverse Events

The image shows a 'Data verification' dialog box with the following content:

- Data verification** (header)
- For what reason are you verifying this step:
  - Source data verification
  - Other
  - PI Verification
- Does the verification need to be removed when data on this step is modified? ⓘ
  - Yes
  - No
- Buttons: **OK** (highlighted) and Cancel

Three callout boxes with arrows point to the following elements:

1. Select "PI Verification" (points to the selected radio button)
2. Select "No" (points to the selected radio button)
3. Click "OK" (points to the OK button)

# Verifying Adverse Events

STOP-COVID19 Superiority Trial Of Protease Inhibition in COVID-19

Record: 01005  
 Progress:  26%

**In Progress** VER ✓

Adverse Events - 08-06-2020 14:39:20

**In Progress** VER ✓

Adverse Event

Adverse Event is now marked as verified

All reports +  
 Report -

**Adverse Event**

VER This step was verified on 08/06/2020 at 16:20 by Data Entry User Data Entry User 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 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	Chest pain	ⓘ	⚙️
2	Onset date	06-06-2020	ⓘ	⚙️
3	Is onset date in the correct format?	YES		⚙️
4	Date reported to Investigator	08-06-2020 <span style="font-size: small;">(dd-mm-yyyy)</span>		⚙️
5	Is date reported before date of onset?	NO		⚙️
6	Severity	1. Mild		⚙️
7	Relationship to Trial Drug	1. None		⚙️
8	Is this an SAE?	NO		⚙️
9	Signature of PI or delegated doctor	YES		⚙️
9.1	Date of signature	08-06-2020 <span style="font-size: small;">(dd-mm-yyyy)</span>		⚙️
10	Action taken	<input checked="" type="checkbox"/> 1. None <input type="checkbox"/> 2. Hospitalisation <input type="checkbox"/> 3. IMP temporarily stopped	ⓘ	⚙️

Close report
All reports

Confirmation that Adverse Event step has been verified by the user



## Help

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

[STOP-COVID19-DM@dundee.ac.uk](mailto:STOP-COVID19-DM@dundee.ac.uk)

