

PROTEUS WORKING INSTRUCTION COL-069 W1002

Title	Completion of SAE Safety Reporting on Castor
WI ID	COL-069 W1002
Version	1.0
Date	20 September 2021

1. SAE reporting

When a SAE occurs at a site, the study team will access the Castor database to log a report. SAEs include any adverse event, adverse reaction or unexpected adverse reaction respectively that:

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect.

The NHS study team/PI must immediately report to the sponsor and CCRF team any SAE that occurs for a subject at a trial site at which they are responsible for the conduct of the PROTEUS trial. It is expected that any SAEs must be reported within 24 hours of the PI's knowledge of the event.

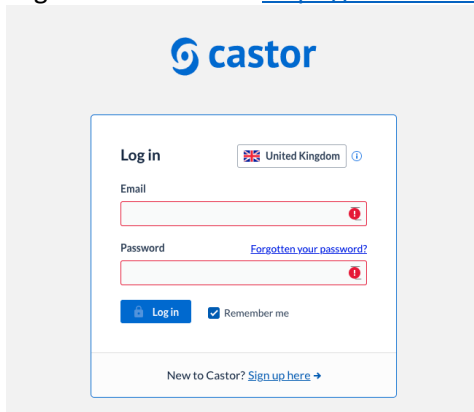
Please send notification of a SAE via email to the PROTEUS inbox (proteus@ultromics.com). A draft SAE notification email can be found in the appendix (Appendix 1).

A full report must be completed in the Castor database. It is possible to record this on paper but it will then need to be transcribed into Castor.

2. Reporting on Castor

To report a SAE on the Castor database, please follow these steps:

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

The image shows the Castor EDC login interface. At the top is the Castor logo. Below it is a 'Log in' section with a dropdown menu set to 'United Kingdom'. There are input fields for 'Email' and 'Password', both with red error icons. A 'Forgot your password?' link is next to the password field. Below the fields are 'Log in' and 'Remember me' buttons. At the bottom, it says 'New to Castor? Sign up here' with a right-pointing arrow.

- Click on the record you wish to report the SAE for.

- Select the 'Reports' tab on the left side of the page.

The screenshot shows a web interface for managing records. On the left, a sidebar contains a 'Records' section with a 'Reports' tab highlighted. The main area displays 'Record ID: TES003' with a progress bar at 4%. There are filters for 'Report type', 'Report name', and 'Status'. A red arrow points to the 'Reports' tab in the sidebar.

- Click on 'Add a report' (1) and Create (2).

The screenshot shows the 'Add a report' dialog box. The dialog has fields for 'Report' (Serious Adverse Event Reporting), 'Custom name' (Serious Adverse Event Reporting - 20-09-2021 15:52:49), and 'Attach to' (This report does not have a parent). There are 'Create', 'Create and add another', and 'Cancel' buttons. A red arrow points to the 'Add a report' button in the top right corner of the main interface, labeled '1'. Another red arrow points to the 'Create' button in the dialog box, labeled '2'.

- The SAE report form will open.

The screenshot shows the 'Site Details' form for a Serious Adverse Event report. The form is titled 'Site Details' and contains several sections: 'Study Name' (PROTEUS: Evaluating the Use of AI in Stress Echocardiography), 'REC Reference' (IRAS 293515), 'Site Name', 'Principal Investigator Name', 'Contact Details', 'Type of report' (dropdown), 'Date (SAE reported to Ultramics)' (calendar), 'If report is more than 24 hours after site becomes aware of SAE please provide a reason for delay' (text area), and 'Reported by (Name, Job Title)'. The form is labeled 'Record ID: TES002' with a progress bar at 39%. A red arrow points to the 'Add a report' button in the top right corner of the main interface, labeled '1'.

- There are 5 sections to complete on the form: Site details, Participant details, SAE details, Expectedness assessment, Relatedness assessment.
- Once all forms have been completed, select 'Close Report'. This will take you back to the overview Reports page. A notification will be sent to Ultromics about the completed SAE report form.

Appendix

1. Draft SAE email

Dear Sponsor,

Trial ID – PROTEUS 21/NW/0199

Protocol title - A PROspective randomised controlled Trial Evaluating the Use of artificial intelligence in Stress echocardiography.

We would like to inform you that a recent SAE occurred at our site.

Site – [INSERT HERE]

PI - [INSERT HERE]

Date of occurrence – [INSERT HERE]

A report has been filed on CASTOR as per instructions on [INSERT DATE].

Please contact the site if further information is required.