PROTEUS WORKING INSTRUCTION COL-069 WIOO2

Title	Completion of SAE Safety Reporting on Castor
WI ID	COL-069 WI002
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.

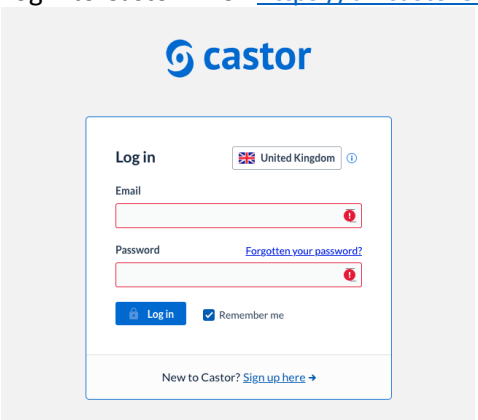
Please send notification of a SAE via email to the PROTEUS inbox (proteus@ultromics.com). A draft SAE notification email can be found in the appendix (Appendix 1).

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

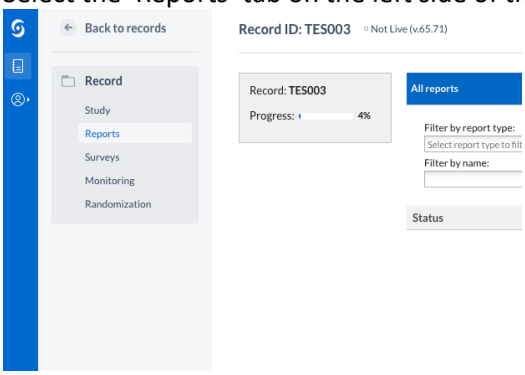
To report a SAE on the Castor database, please follow these steps:

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

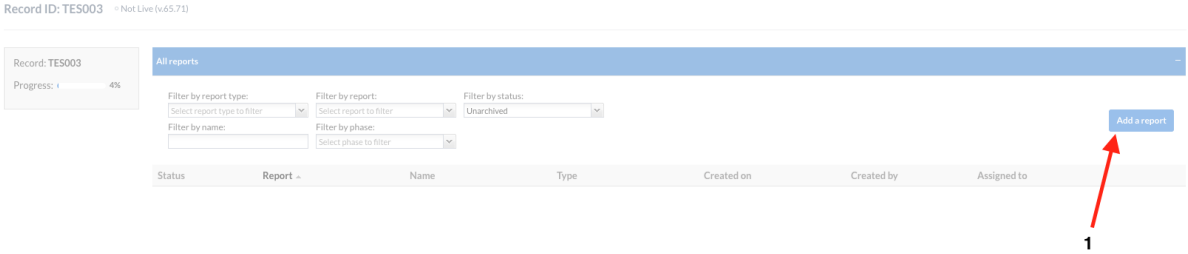


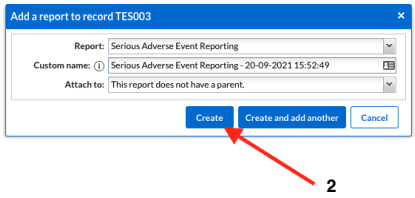
- Click on the record you wish to report the SAE for.

- Select the ‘Reports’ tab on the left side of the page.

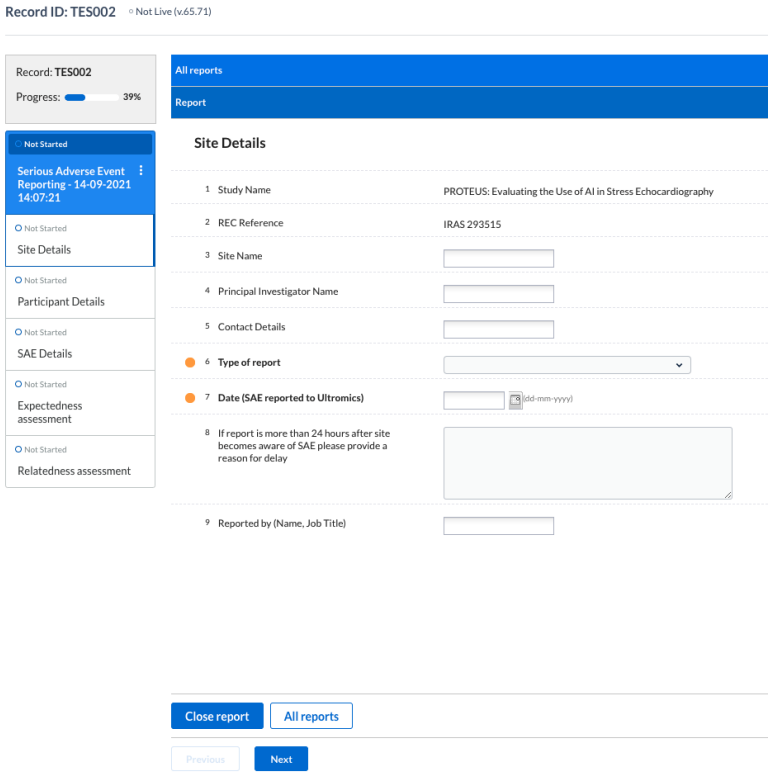


- Click on ‘Add a report’ (1) and Create (2).





- The SAE report form will open.



- 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.