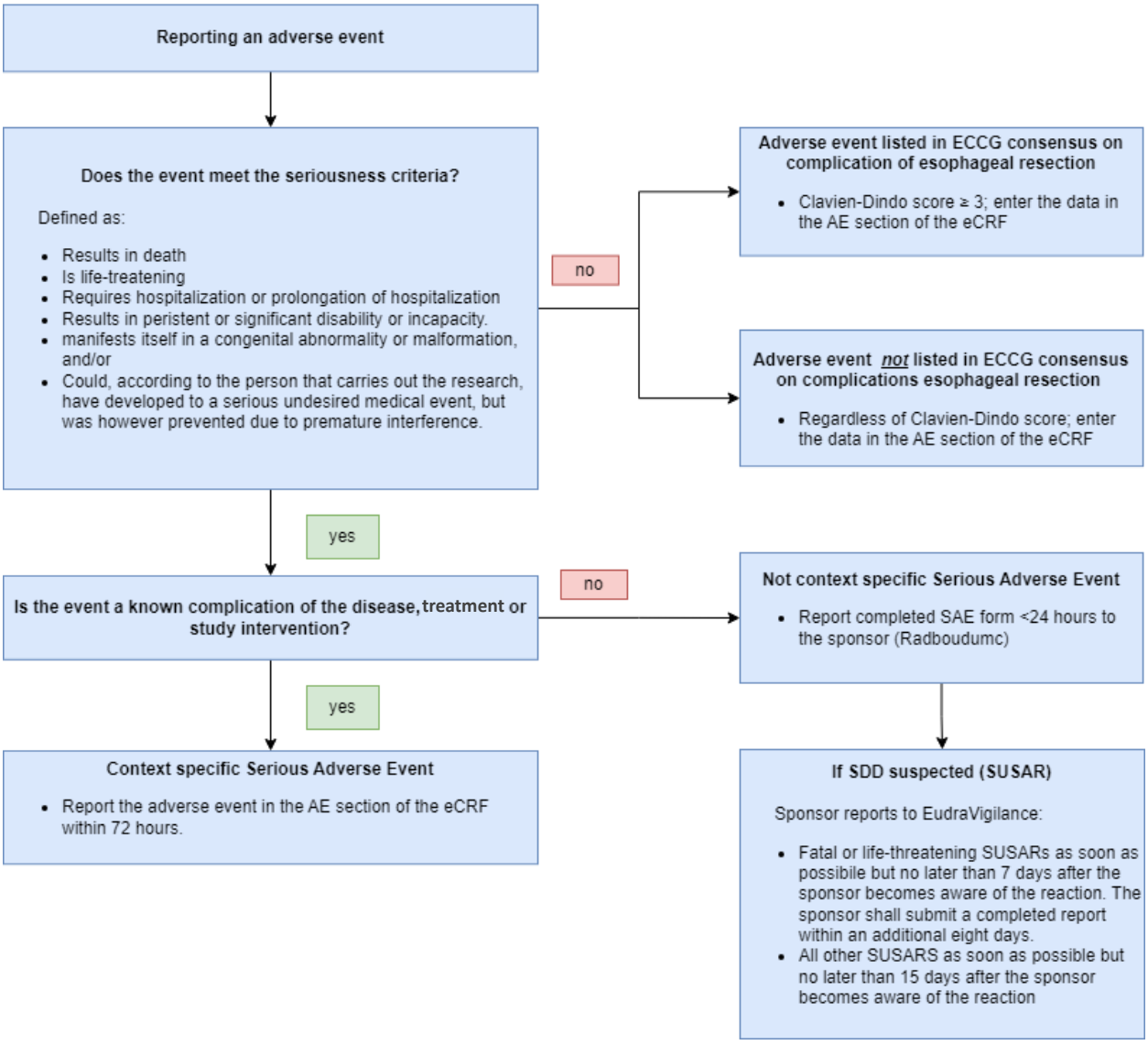
SOP (S)AE registration PERSuaDER trial

This SOP outlines procedures for registering AEs, and reporting SAEs and SUSARs for adverse events that happen during the course of the PERSuaDER trial

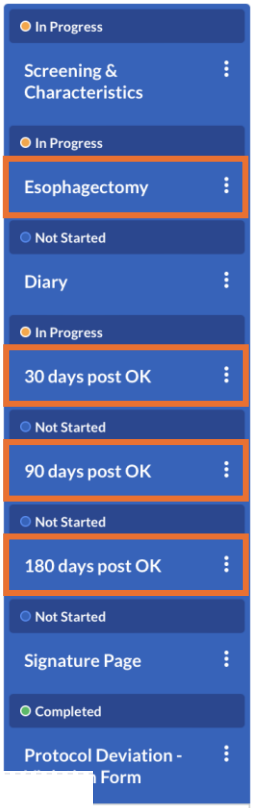
Abbreviations:

SOP	Standard operating procedure
AE	Adverse event
SAE	Serious adverse event
SUSAR	Suspected unexpected serious adverse reaction
SDD	Selective decontamination of the digestive tract
CD score	Clavien-Dindo score, a scale of surgical complications
eCRF	Electronic case report form

Flowchart (Serious) Adverse Events and SUSARs



AE registration

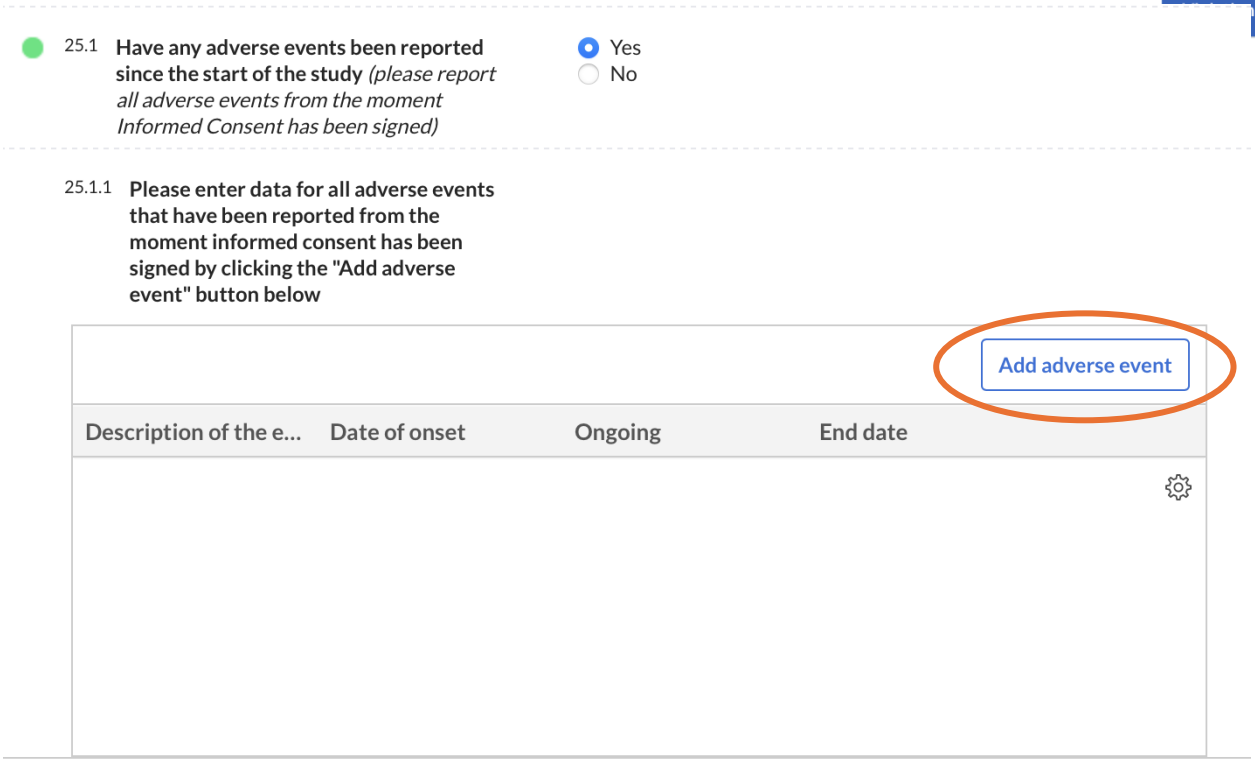


Log in on your account on Castor and open the eCRF of the patient in question.

Enter either one of the following tabs, whichever is most applicable at the time: Esophagectomy, 30 days post OK, 90 days post OK, 180 days post OK.

Be aware that complications that are listed in the ECCG consensus on complications of esophageal resection (https://esodata.net/web/complication-definitions) with a Clavien-Dindo score of <III, need not be separately registered as an AE.

Start the reporting process by indicating that an adverse event has been reported.
Then add your adverse event (AE) by clicking on the “Add adverse event” button.



Complete the provided AE form:

1 **Description of the event** *(please use medical terms as precise as possible)*

Steven-Johnson syndrome

2 **Is the adverse event listed in the ECCG consensus**

- ○ Yes
- ◉ No

If an adverse event, NOT LISTED in the ECCG consensus, meets the SAE criteria it needs to be reported as an SAE report within 24 hours of notification

3 **Date of onset** 04-06-2024 (DD-MM-YYYY)

4 **Ongoing**

- ○ Yes
- ◉ No

4.1 **End date** 12-06-2024 (DD-MM-YYYY)

5 **Severity**

- ○ Mild
- ○ Moderate
- ○ Severe
- ◉ Life-threatening or disabling
- ○ Fatal

If, by the information you have already provided, it is clear that the event is a serious adverse event (SAE), the following will appear:

ⓘ Please be aware this adverse event meets the serious adverse event (SAE) criteria and IF NOT LISTED IN THE ECCG CONSENSUS it needs to be reported in the SAE section of the eCRF within 24 hours of notification

Complete the remaining part of the AE form, and if you wish to report a SAE, please indicate so in the last question:

6 **Relationship to study intervention** *(SDD)*

- ○ Not applicable *(if in control group)*
- ○ Not related
- ○ Unlikely related
- ○ Possibly related
- ○ Probably related
- ◉ Definitely related

7 **Action required**

- ☐ No action required
- ☐ (Prolongation of) Hospitalization
- ☐ Trial medication discontinued
- ☑ Medical intervention
- ☑ Start/change/stop concomitant medication
- ☐ Other

8 **Outcome**

- ○ Recovered/resolved
- ◉ Recovering/resolving
- ○ Not recovered/not resolved
- ○ Recovered/resolved with sequelae
- ○ Fatal
- ○ Unknown

9 **Is this adverse event serious**

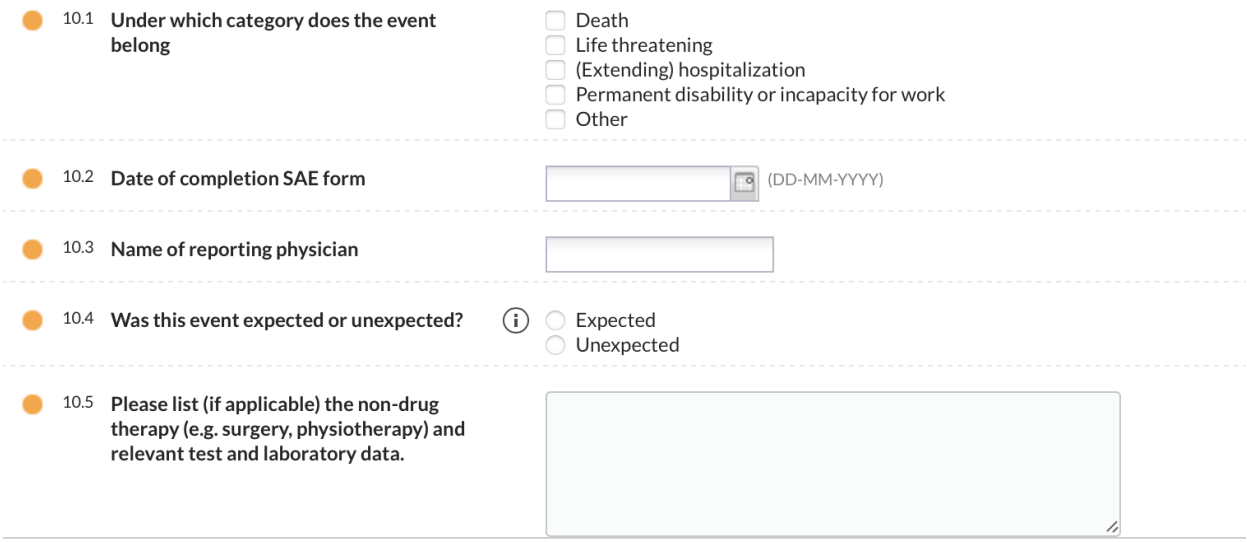
- ◉ Yes
- ○ No

SAE and SUSAR reporting

A SAE or SUSAR can be reported either through the eCRF, or by email/fax by using a paper-based form.

With eCRF

If you have completed the AE form, and in the last question you have indicated that we are dealing with a serious adverse event, the SAE registration form will appear:



Complete the SAE form according. Question. 10.4: “Was this event expected or unexpected?”, will differentiate between a SAE and a SUSAR

With paper-based form

If electronic access to the eCRF is not possible, it is possible to report the SAE or SUSAR by using a paper-based form. The form should be completed, scanned, and sent to Persuader.heel@radboudumc.nl within 24 hours after becoming aware of the SAE or SUSAR.
The paper-based form can be retrieved from the PERSuaDER website (persuader.org) or from the procedural book.

Note: Even when the SAE or SUSAR has been reported with the paper-based form, the SAE must also be reported in the eCRF within a reasonable time after occurrence of the SAE.