

SAE Reporting Guidance

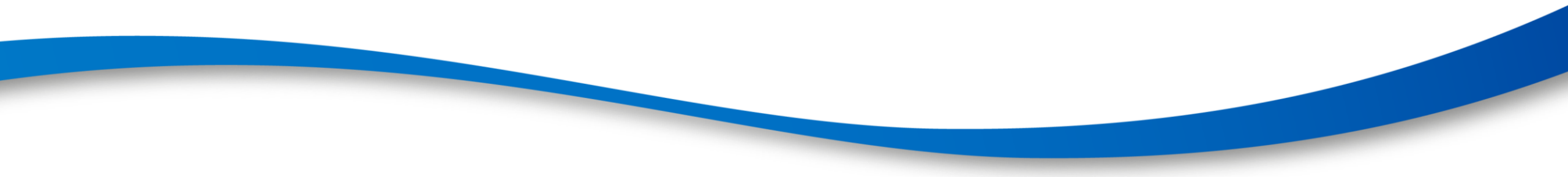


Events that require reporting

- Sites should **report all Serious Adverse Events** other than the exemptions defined in the protocol (section 11.2.1)
- Refer to the protocol section 11.1 for the definition of what constitutes a Serious Adverse Event
- SAEs that are related to a pre-existing condition are not required to be reported.
- Non-serious adverse events do not need to be recorded
- **All serious adverse events/reactions which relate to the administration of the pre-hospital WB, standard of care components (RBC and FFP) or LyoPlas must be reported as Serious Adverse Events**

SAE's that do not require reporting (Exemptions)

The following are regarded as **anticipated SAEs** (i.e. are recognised complications/consequences of major trauma) and **are excluded from recording and reporting:**

- Death (related to trauma)
 - Organ failure
 - Multi-organ dysfunction syndrome
 - Acute respiratory distress syndrome
 - Infection (any anatomical site)
 - Venous thromboembolism: deep vein thrombosis or pulmonary embolism
 - SAEs that are related to a pre-existing condition are not required to be reported
- 

Reporting Procedure (1)

Reporting Period

- SAE's should be **reported from the date/time of commencement of the protocol defined treatment**, i.e. date/ time trial box was opened (this will be recorded on the pre-hospital form)
 - SAE's should be reported up to 14 days post-treatment or until discharge from acute care (whichever occurs first)
 - SAE reporting is only required during the primary hospital admission
- 

Reporting Procedure (2)

Initial Reporting

- An SAE form should be completed within 24 hours after becoming aware of the event (this may be a few days after the start date of the event)

Follow up Reporting

- Additional and further information (follow-up or corrections to the original case) should be added when available
- Participants should be followed-up until resolution or stabilisation of the event
- If the eCRF is unavailable for any reason, a paper version of the form should be emailed to serious_adverse_events@nhsbt.nhs.uk

PI Responsibility

- The PI is responsible for assessing causality of events
 - Sign off of SAE forms on eCRF
- 

Completing SAE forms on OpenClinica (1)

SAE forms are scheduled on the participant page, underneath the visits section.

To add an SAE – click 'Add New' and complete all information within the form.

SAE's need to be added to the database within 24 hours of awareness of the SAE. An automatic email is sent to the SAE mailbox at the CTU as soon as an SAE form is completed in the database.

PI signature is needed once the SAE form is completed. This needs to be done every time the form is updated.
To sign an SAE please ensure (1) The form is marked as 'COMPLETE' (2) The PI is signed into OpenClinica using their own account (3) The 'SIGN' icon is selected from the SAE action column of the relevant SAE.

SAE

Form 10 - Serious Adverse Events

Add New

Search here

Actions

Form Status

↑↓

Last Updated

↑↓

Updated By

↑↓

SAE

Form 10 - Serious Adverse Events

Add New

Search here

Actions

Form Status

↑↓

Last Updated

↑↓

Updated By

↑↓

⋮

data entry started

09-May-2023

ndallas

Result 1-1 of 1

Show

10

per page

<

1

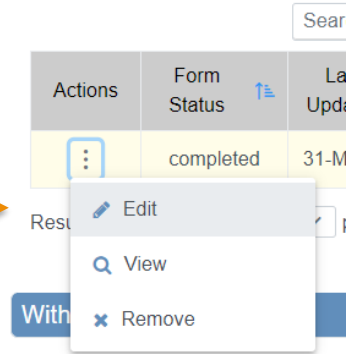
>

Completing SAE forms on OpenClinica (2)

To add follow-up information to an SAE, the initial report **should be over-written** with the follow up information (do not create a new SAE form):

- Open the initial report and select “Edit” from the SAE Action column
- Select “Follow-up 1” for the first follow-up information added, “Follow-up 2” for the second time you make amendments and so on.
- Amend / update the applicable field(s) with the relevant follow-up information.
 - When updating the Free Text fields in the SAE form, you can either overwrite existing text (as this will be stored in the OpenClinica audit trail) or add any updates to the already existing text. If adding text, it’s a good idea to use headings such as “Follow-up 1” followed by your updates to help you keep track of which information was added when.

Form 10 - Serious Adverse Events



The screenshot shows a table with columns: Actions, Form Status, and Last Updated. A row is highlighted with a status of 'completed' and a date of '31-M'. A dropdown menu is open from the Actions column, showing options: Edit (with a pencil icon), View (with a magnifying glass icon), and Remove (with an 'x' icon). An orange arrow points from the text 'Open the initial report and select “Edit” from the SAE Action column' to this dropdown menu.

Type of report

- ☐ Initial
- ☒ Follow-up 1
- ☐ Follow-up 2
- ☐ Follow-up 3
- ☐ Follow-up 4

Please enter a reason for change at bottom of page.

Completing SAE forms on OpenClinica (3)

- Each time you make a change to a field in the SAE form, you will be asked to enter a reason for change at the bottom of the page. If the reason is applicable to all updated / amended fields, tick “Apply to all” to save you having to enter a reason for each individual field.

Looks like you've made some updates. Please tell us why:

Follow-up1 information added	☒ Apply to all
Type of report	
Follow-up1 information added	
Describe SAE	
Follow-up1 information added	
Treatment/ Test given	
Follow-up1 information added	
Seriousness of the event	
Follow-up1 information added	

- Ensure that the “Date of form completion” date is updated to tie in with the date the form was amended and update the “Form completed by” field if the update was made by a different person.

Form completed by	Date of form completion
Test	2023-05-31

- Remember that each update / amendment needs PI sign-off!

Other SAE Considerations

Pregnancy

- The intervention is no different to standard care in this context no specific additional follow up of these participants is necessary
- Safety monitoring of these participants will be achieved as per standard practice

Blood Components

- Expected transfusion reactions relevant to the blood components under investigation (WB, FFP, RBC) are listed in the protocol
 - All serious adverse reactions and adverse events related to manufactured blood products and Lyoplas should be reported on the Yellow Card scheme
- 