Serious Adverse Event Report Form

Serious Adverse Event

1. Report type *

If this is the first time the SAE has been reported, please select "Initial report". If you are submitting new, updated or corrected information for a previously reported SAE, please select "Follow-up information".

◯ Initial report ◯ Follow-up information

SAE number *

If this CRF relates to the patient's first SAE, enter 1. If the patient has had more than one SAE, please record the SAE number that this applies to

.....

Form number (for this SAE) *

If this is the initial report, enter 1. If this is a follow-up form, please record the number of CRFs you have attempted to complete for this SAE, including this one

.....

» 2. Site

Site name

.....

Site name (if not in list)

.....

» 2. Site

Site name

.....

Site name (if not in list)

.....

» 3. Participant details

Study number

.....

Participant's initials

.....

Date of birth *

yyyy-mm-dd

.....

Patient's year of birth

.....

Sex

◯ Male ◯ Female

4.1 Adverse event name

Description of SAE in a few words at most e.g. Pneumonia, Seizure, Gastrointestinal bleed

4.2 Adverse Event description

Please record: i) diagnosis if known, ii) an account of the event (including signs and symptoms if diagnosis not known), iii) any interventions given to manage the event (including dates for these), and iv) if the event was fatal, the cause of death if known

5. Start date of SAE

yyyy-mm-dd

Start time of SAE

(hh:mm [24 hr])

6. Stop date of SAE

yyyy-mm-dd

Stop time of SAE

(hh:mm [24 hr])

or Ongoing?

◯ Yes

7. Date site became aware of SAE

yyyy-mm-dd

Time site became aware of SAE

(hh:mm [24 hr])

8. Reason this event is classed as serious

If there is more than one reason which applies then choose the more/most significant one and document other reason(s) in the AE description

◯ Fatal ◯ Life threatening ◯ Requiring/prolonging hospitalisation ◯ Congenital anomaly/birth defect

◯ Significant disability/incapacity ◯ Other important medical event

◯ Event does not fulfil criteria for being serious

The RECOVERY protocol does not require non-serious events to be recorded. Please check your answer.

9. Relevant medical history

Provide a full description of any medical history which could be relevant to this SAE and which may need to be considered by the individual reviewing the event (including co-existing medical conditions, allergies or similar experiences)

10. Laboratory results relevant to the SAE

Please give details of relevant results, dates and reference ranges in the space below or send a printout with these details highlighted and patient identifiable information obscured

If this event is believed to be related to more than one study treatment, please press the + button to add a new row.

11. Specify the study drug details below (for the drug this SAE is believed to be related to)

Study drug name	Dose	Frequency	Route	Date started yyyy-mm-dd	If discontinued, date stopped yyyy-mm-dd

Did the event resolve after stopping study drug?

◯ Yes ◯ No ◯ N/A ◯ Unknown

Did the event reappear after reintroduction?

◯ Yes ◯ No ◯ N/A

Action(s) taken with study drug

- ☐ None
- ☐ Discontinued temporarily
- ☐ Dose reduced
- ☐ Discontinued
- ☐ Dose temporarily reduced

12. Concomitant medication

Leave this question blank if the event is not a SAR (i.e. if it is not thought to be caused by a study treatment)

Concomitant medication?

◯ None

» Describe all non-study medication taken at the time of onset of the event and medication given to treat the SAE including prescription, non-prescription and over-the-counter medication

Medication	Indication	Given to treat SAE?	Dose	Frequency	Route
		◯ Yes			

Date started	If discontinued, date stopped
yyyy-mm-dd	yyyy-mm-dd

13. Outcome of event

◯ Resolved ◯ Resolving ◯ Not Resolved ◯ Resolved with sequelae ◯ Unknown ◯ Fatal

Date of death	**Was a post-mortem performed/is one planned?**
yyyy-mm-dd	◯ Yes ◯ No

Date of post-mortem

yyyy-mm-dd

Further information

14. Is there any further information to come? *

Follow-up information should be submitted on any unresolved event until resolution

◯ Yes ◯ No

When further information is available, please use another SAE Report Form and only report any new or changed information

15. Reporter's Signature

Date of completion

Printed Name

Position

Telephone Number

Further contact details

16. Causality of the SAE

Does the investigator think this event was related to study treatment with reasonable probability? *

◯ Yes ◯ No

17. Assessor's name *

Name of medical doctor who assessed whether this event was serious and related to study treatment.

Investigator's signature

Date

Printed name

Position

Telephone Number

Further contact details

Notes

Please add any additional comments here