o

**Participant Number:**

**Serious Adverse Event**

**Report Form (CTIMP)**

***Form completion instructions overleaf***

**1.**

**Report type** *(tick one)*

Initial report

Follow-up information

**2.**

**Site name:**

**3.**

**Participant details**

**5.**

**6.**

**7.**

**Start date and time of SAE:**

**Stop date and time of SAE:**

Or ongoing

**Date and time site became aware of SAE:**

***Internal Use Only***

SAE Identifier:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **-** |  |  |  | **-** |  |  |  |  |

*pcctuoxf.optimise2@nhs.net*

***Please complete and send this form immediately, no later than 24 hours***

***after becoming aware of the SAE.***

**PLEASE EMAIL FORM TO:** Central Trial Team

*(Please record diagnosis if known, an account of the event including signs and symptoms if diagnosis not known, any*

*interventions given to manage the event including dates for these and if event fatal, cause of death if known):*

**4.**

**ADVERSE EVENT DESCRIPTION:**

**Age at time of event:**

**Gender:**

Other

Non-Binary

Female

Male

Page 1 of 4

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**General Instructions**

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Complete the SAE Reporting Form as soon as possible but no later than 24 hours after

becoming aware of the event.

Refer to the trial protocol for definitions of Adverse Events (AEs), Adverse Reactions (ARs), Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Events (SUSARs).

Use a black ball point pen to complete the form.

Email the completed form to the Trial Co-ordinating centre

Expect confirmation of receipt from *enter details here*.

File a copy of the completed SAE Reporting Form in your Investigator Site File / Study File.

If you have any questions regarding the classification of an adverse event or form completion then please call your Trial Manager.

Guidelines are not provided for data fields which are self-explanatory.

Ensure ALL details of the SAE are documented in the participant’s medical records including the Investigator’s assessment of causality, which the study physician must document in the medical records.

Record ‘NK’ for any data that is not known.

Record all times as 24 hour clock

•

**Page 1**

Q1.

If this is the first time the SAE has been reported then please tick “initial”. If you are

submitting new, updated or corrected information for a previously reported SAE then please tick “follow-up information”.

Record the unique trial number assigned to the participant.

Enter date and time that the adverse event became serious.

Enter date and time that the adverse event stopped being serious (for example, if a participant has a life-threatening condition which was resolved by surgery then the date and time for end of surgery would be entered).

Enter the time and date that a member of the site trial/study team became aware of the

SAE.

Q3.

Q5.

Q6.

Q7.



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Action taken with study drug:

Did the event resolve after reintroduction of withdrawn drug?

Did the event reappear after withdrawing the drug again?

***Internal Use Only***

SAE Identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Number:

Page 2 of 4

**Laboratory results relevant to the SAE:** (*Please give details of relevant results, dates and reference ranges in the space below or attach a printout with these details highlighted and patient identifiable information obscured)*

**Serious Adverse Event Report Form**

***Form completion instructions overleaf***

**8.**

**Please record severity of event:** *(tick one box only)*

Mild

Moderate

Severe

**9.**

**Reason this event is classified as Serious:** *(tick one box only)*

Fatal

Life threatening

Requiring/prolonging hospitalisation

Significant disability/incapacity

Congenital anomaly/birth defect

Other important medical event

**10.**

**Relevant medical history:** *(including co-existing medical conditions, allergies or similar experiences)*

**11.**

**12.**

**Specify the study drug details below:**

Yes

Yes

No

No

N/A

N/A

**Withdrawndrug**

**Dose**

**Frequency**

**Route**

**Date withdrawn**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

**If reintroduced, date restarted**

Restarted at higher dose

Restarted half dose followed by original dose

If other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Restarted at original dose

None

Restarted at lower dose

**Page 2**

Q8.

Q9.

Choose **one** of the severity options to describe the intensity of the event.

Choose **one** of the reasons why the adverse event has been classified 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.

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.

Record details of study drug(s). This section must be completed regardless of whether there is a causal relationship with the study drug(s).

Q10.

Q12.

**Page 3**

Q13. Use the table to list all concomitant medications and use additional pages

(P3a section 13a) if required.

|  |  |  |  |  |  |  |  |  |  |  |
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|  |  | **-** |  |  |  | **-** |  |  |  |  |

Participant Number:

Serious Adverse Event (SAE) Report Form CTIMP

Page 3 of 4

**Serious Adverse Event Report Form**

**13. Concomitant medication** *(generic names only):*

None

**OR**

**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 and medication given to treat the SAE.**

**date stopped**

**Did you document further concomitant medications on the supplementary SAE report page 3a?**

**If Yes,** how many pages did you complete?

Yes

No

**Medication**

**Indication**

**Given to treat SAE**

**Dose**

**Frequency**

**Route**

**Date started**

**If discontinued,**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

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***Internal Use Only***

SAE Identifier:

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Participant Number:

Serious Adverse Event (SAE) Report Form CTIMP

Page 3a of 4

**Serious Adverse Event Report Form**

**13a. Concomitant medication** *(generic names only):*

**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.**

**date stopped**

**Medication**

**Indication**

**Given to treat SAE**

**Dose**

**Frequency**

**Route**

**Date started**

**If discontinued,**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

**D D  /  M M  /  Y Y**

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***Internal Use Only***

SAE Identifier:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **-** |  |  |  | **-** |  |  |  |  |

Participant Number:

***Internal Use Only***

SAE Identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Position:**

Not related

**Serious Adverse Event Report Form**

***Form completion instructions overleaf***

**14. Outcome of event:** *(tick one box only)*

Resolving

Unknown

Not resolved

Fatal

**15. Is there any further information to come?**

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

*(please use another SAE Report Form, and only report any new or changed information).*

Yes

No

**IMPORTANT: This section of the SAE report is to be completed by a medically**

**qualified individual only.**

**17. Causality of the Serious Adverse Event:**

**The Reporting Clinician’s decision on relationship to the IMP** *(tick one box only)*

**I confirm that I have reviewed Pages 1, 2, 3 and 4 of the Serious Adverse Event**

**report and that all data are correct.**

**Assessor’s signature:**

**Print name:**

**Position:**

**Telephone number**

Possibly Probably Definitely

**Further contact details** *(e.g. bleep/pager number, please specify)*:

**Further contact details** *(e.g. bleep/pager number, please specify)*:

**Print name:**

If this information is not available at the time the SAE is first reported, please re-send all

pages of this report once completed.

Resolved

Resolved with sequelae

**If fatal,** give date of death:

Was a post-mortem performed/ is one planned?

**If Yes,** give date of post-mortem:

**/  /**

**D**

**Y**

**D**

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**M**

**Y**

Yes

No

**/  /**

**D**

**Y**

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**Y**

**Date:**

**16. Reporter’s signature:**

**/  /**

**D**

**Y**

**D**

**M**

**M**

**Y**

**Telephone number:**

**/  /**

**D**

**Y**

**D**

**M**

**M**

**Y**

**Date**

Page 4 of 4

**send in the SAE Reporting Form without this information and re-send the form**

**If a medically qualified individual is not available to make the causality assessment send in the**

**Page 4**

Q14.

Select **one** of the outcome options. If the outcome is “Resolving” or “Not Resolved” then

complete a follow-up report when the status of the SAE changes.

Include a telephone number for the person reporting the SAE so that the individual

assessing the event can contact them in case of queries or if clarifications are needed.

A medically qualified individual is responsible for reviewing the SAE and considering whether the event was related to the study drug(s).

Q16.

Q17.

**as soon as this assessment has been made.**