



# Serious Adverse Event Report Form (Non CTIMP)

Form completion instructions overleaf

1. Report type (tick one) Initial report  Follow-up information

2. Site name: \_\_\_\_\_

3. Participant details

Participant Number

Date of birth  /  /

Sex Male  Female

Weight  g OR  .  kg  
(delete as applicable)

4. ADVERSE EVENT DESCRIPTION:

(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):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

5. Start date and time of SAE:  /  /   :

6. Stop date and time of SAE:  /  /   :  Or ongoing

7. Date and time site became aware of SAE:  /  /   :

Please complete and send this form as soon as possible after becoming aware of the event

PLEASE FAX/EMAIL FORM TO: Trial Co-ordinating Centre



01865 289412



TASMINH4@phc.ox.ac.uk

## General Instructions

- Complete the SAE Reporting Form as soon as possible after becoming aware of the event.
- Refer to the trial protocol for definitions of Adverse Events (AEs) and Serious Adverse Events (SAEs).
- Use a black ball point pen to complete the form.
- Fax/Email the completed form to the Trial Co-ordinating centre **01865 289 412** Expect confirmation of receipt from **TASMINH4@phc.ox.ac.uk**
- 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 **0800 915 8543**
- 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".
- Q3. Record the unique trial number assigned to the participant.  
Enter the participant's weight in grams **OR** kilograms and delete the unit which is not applicable.
- Q5. Enter date and time that the adverse event became serious.
- Q6. 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).
- Q7. Enter the time and date that a member of the site trial/study team became aware of the SAE.

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# Serious Adverse Event Report Form

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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  Congenital anomaly/birth defect   
Significant disability/incapacity  Otherwise significant medical event

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

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

11. 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 the patient identifiable information obscured)*

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

12. Specify details of the investigational intervention(s) administered including start and stop dates:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Did the event abate after stopping investigational intervention(s)?

Yes  No  N/A

Did the event reappear after reintroduction?

Yes  No  N/A

Action taken with investigational intervention(s):

None  Discontinued temporarily

N/A *(Intervention(s) stopped prior to the event starting)*  Discontinued

## Page 2

- Q8. Choose **one** of the severity options to describe the intensity of the event.
- Q9. 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.
- Q10. 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.
- Q12. Record details of the investigational intervention(s) administered. This section must be completed regardless of whether there is a causal relationship between the event and the investigational intervention(s).

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- Q13. Use the table to list all concomitant medications and use additional pages (P3a section 13a) if required.

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## 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	Indication	Given to treat SAE	Dose	Frequency	Route	Date started	If discontinued, date stopped
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY
		<input type="checkbox"/>				DD / MM / YY	DD / MM / YY

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

Yes  No

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

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## 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.

Medication	Indication	Given to treat SAE	Dose	Frequency	Route	Date started	If discontinued, date stopped
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY
		<input type="checkbox"/>				DD/MM/YY	DD/MM/YY

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# Serious Adverse Event Report Form

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

Resolved  Resolving  Not resolved

Resolved with sequelae  Unknown  Fatal

If fatal, give date of death

DD / MM / YY

Was a post-mortem performed/is one planned?

Yes  No

If Yes, give date of post-mortem

DD / MM / YY

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

Yes  No

*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).*

**16. Reporter's signature:** \_\_\_\_\_

Date:

DD / MM / YY

Printed name: \_\_\_\_\_

Position \_\_\_\_\_

Telephone number

□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □

Further Contact Details *(e.g. bleep/pager number, please specify)*

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

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

The Investigator's decision on relationship to the investigational intervention(s)

*(tick one box only)* Not related  Possibly  Probably  Definitely

I confirm that I have reviewed Pages 1, 2, 3 and 4 of the Serious Adverse Event report and that all data are correct.

Investigator's signature: \_\_\_\_\_

DD / MM / YY

Printed name: \_\_\_\_\_

Position \_\_\_\_\_

Telephone number

□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □

Further Contact Details *(e.g. bleep/pager number, please specify)*

If this information is not available at the time the SAE is first reported, please re-send all pages of this report once completed.

## 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.
- Q16. 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.
- Q17. A study physician (Investigator) is responsible for reviewing the SAE and considering whether the event was related to the investigational intervention(s).

**If a medically qualified individual is not available to make the causality assessment, send in the SAE Reporting Form without this information and re-send the form as soon as this assessment has been made.**