Internal Use Only

Study ID _____ SAE ID _____ Form ID _____

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

Study number ☐☐☐☐☐☐

Participant's initials *(please delete row for collection of participants initials before printing form if PID not been collected in house)* ☐☐☐

Date of birth D D / M M / Y Y

Sex Male ☐ Female ☐ Indeterminate ☐

Weight ☐☐☐ *g* OR ☐☐.☐ *kg*

(last known weight and 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, any sequelae and if event fatal, cause of death if known):

5. Start date and time of SAE D D / M M / Y Y h h m m

6. Stop date and time of SAE D D / M M / Y Y h h m m Or ongoing ☐

7. Date and time site became aware of SAE: D D / M M / Y Y h h m m

Please complete and send this form immediately, as soon as possible after becoming aware of the SAE.

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

+44 (0)1865 289740 neogastric@npeu.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).
- Fax/email the completed form to the Trial Co-ordinating Centre at the NPEU Clinical Trials Unit in Oxford **(fax +44 (0)1865 289740, email neogastric@npeu.ox.ac.uk)**.
  Expect confirmation of receipt from NPEU CTU.
- File 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 ***Elizabeth Nuthall: +44 (0)1865 617927***.
- 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 (if applicable) 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

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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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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 ☐ Other important medical event ☐

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

11. Laboratory results/investigations relevant to or as a result of the SAE

(please give details of relevant results/investigations, dates and reference ranges in the space below or attach a printout with these details highlighted and patient identifiable information obscured)

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

Did the event resolve 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 ☐

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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
		☐				D D / M M / Y Y	D D / M M / Y Y
		☐				D D / M M / Y Y	D D / M M / Y Y
		☐				D D / M M / Y Y	D D / M M / Y Y
		☐				D D / M M / Y Y	D D / M M / Y Y
		☐				D D / M M / Y Y	D D / M M / Y Y
		☐				D D / M M / Y Y	D D / M M / Y Y
		☐				D D / M M / Y Y	D D / M M / Y Y
		☐				D D / M M / Y Y	D D / M M / Y Y

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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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
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY
		☐				DD/MM/YY	DD/MM/YY

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14. Outcome of event:

Resolved ☐ Resolving ☐ Not resolved ☐
Resolved with sequelae ☐ Unknown ☐ Fatal ☐

If fatal, give date of death D D / M M / Y Y

Was a post-mortem performed / is one planned? Yes ☐ No ☐

If Yes, give date of post-mortem D D / M M / Y Y

15. Is there any further information to come? Yes ☐ No ☐

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

16. Reporter's signature _____

Date: D D / M M / Y Y

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 member of the team who is delegated to assess causality.

17. Causality of the Serious Adverse Event

The 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.

Signature _____ D D / M M / Y Y

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.

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Q14. Select **one** of the outcome options. If the outcome is ‘Resolving’ or ‘Not Resolved’ provide follow-up information when it is available.

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 an appropriate delegated 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.

A Physician who is not a member of the study team may offer an opinion as to whether the event was related to the investigational intervention(s) and this opinion should be documented in the participant’s medical records.