

EudraCT Number: <input style="width:95%;" type="text"/>	Participant Gender: <input style="width:95%;" type="text"/>	Participant Date of Birth: <input style="width:95%;" type="text"/>	Date of sending report to CTO: <input style="width:95%;" type="text"/>
Participant Randomisation Number: <input style="width:95%;" type="text"/>	Participant Initials: <input style="width:95%;" type="text"/>	Study Title (short): <input style="width:95%;" type="text"/>	

1. **What are you reporting:** SAE SUSAR* Pregnancy SAR IME**

*Note: If you are reporting a SUSAR the randomisation code for this patient will have to be unblinded.

**Important Medical Event

2. **Report Type:** Initial Report Follow up Report Follow up Report #: _____

3. **Protocol Title and Version Number:**

Evaluation of Event

4. **Diagnosis :**

5. **Chief or Principal Investigator:**

6. **Sponsor:**

7a. **Date of Onset:**
(dd/mmm/yy)

7b. **Time of Onset:**
(if available; hh:mm)

9. **Criteria for definition as Serious:**

- Resulted in Death
- Life threatening
- In-patient hospitalization or prolongation
- Persistent or significant disability
- Congenital anomaly/birth defect
- N/A (IME or Pregnancy only)

8. **Date person completing report became aware of event:**

(dd/mmm/yy)

*If there is more than one criterion, choose the more/most significant one.
Seriousness is a regulatory definition and should not be confused with severity.*

10. **Describe Event:** (A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.)

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11. In the Investigator's opinion was the event related to the Investigational Medicinal Product?

- Definitely*
- Likely*
- Possibly*
- Unlikely
- Not Related

* This will be reported as a SAR

12. Action Taken With Study Drug

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

13. If related to IMP was this reaction unexpected (Suspected Unexpected Serious Adverse Reaction – SUSAR)

- Yes
- No
- Not Applicable

14. Did event/reaction abate after stopping drug?

- Yes
- No
- Not Applicable

15. Did event/reaction reappear after reintroduction of drug?

- Yes
- No
- Not Applicable

16. IMP & Concomitant Medication Information

Drug Details <i>(include daily dose(s) & generic name)</i>	Therapy Start Date <i>(dd/mmm/yy)</i>	Therapy End Date <i>(dd/mmm/yy)</i>	Date of dose prior to SAE onset <i>(dd/mmm/yy)</i>	Route(s) of administration	Indications for Use

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17. Have Urgent Safety Measures been implemented?

- Yes
- No
- Not Applicable

If yes, please detail below:

Outcome of Event

18. What is the outcome of the SAE?

- Recovered
- Recovered with sequelae
- Continuing
- Resulted in Death
- Unknown

19. Date event resolved: (dd/mmm/yy)

20. Date patient died: (dd/mmm/yy)

21. Cause of death obtained from (if patient died):

- Coroner's inquest
- Death Certificate
- Working diagnosis

Contact & Signatures

Please supply contact details where further information may be obtained:

22. Person to contact:

22a. Centre (if multicentre trial):

23. Phone number:

24. Email address:

Signature (person completing report)

Print Name

Date

Principal Investigator Signature (If multicentre trial)

Print Name

Date

Chief Investigator Signature (If not completing report)

Print Name

Date