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|--|---|---|---|
| EudraCT Number: <input type="text"/> | Participant Gender: <input type="text"/> | Participant Date of Birth: <input type="text"/> | Date of sending report to CTO: <input type="text"/> |
| Participant Randomisation <input type="text"/> | Participant Initials <input type="text"/> | Study Title (short): <input 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 which correlates to eSUSAR E2B criteria "Other Medically Important Condition"*

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

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

Evaluation of Event

4. **Diagnosis (please use medDRA term if known)**

4a. **medDRA Term and code if known:**

5. **Chief or Principal Investigator:**

6. **Sponsor:**

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

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

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

(dd/mmm/yy)

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)

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.

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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.)

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)**

Reactions related to IMP (SARs) must be assessed as expected or unexpected using the current approved reference safety information.

- 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

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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