

<b>EudraCT Number:</b> <input type="text"/>	<b>Participant Gender:</b> <input type="text"/>	<b>Participant Date of Birth:</b> <input type="text"/>	<b>Date of sending report to JCTO:</b> <input type="text"/>
<b>Participant Randomisation Number:</b> <input type="text"/>	<b>Participant Initials:</b> <input type="text"/>	<b>Study Title (short):</b> <input type="text"/>	

1. What are you reporting: SAE  SUSAR\*  Pregnancy

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

2. Report Type: Initial Report  Follow up Report  Follow up Report #: \_\_\_\_\_

3. Protocol Title and Version Number:

**Evaluation of Event**

4. Event / Reaction: (keywords; e.g.: body site, symptoms, severity, treatment)

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 SAE:

- Resulted in Death
- Life threatening
- In-patient hospitalization or prolongation
- Persistent or significant disability
- Congenital anomaly/birth defect

8. Date person completing report became aware of SAE/ SUSAR:

(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.)

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

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

- Definitely
- Likely
- Possibly
- Unlikely
- Not Related

**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

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

<b>EudraCT Number:</b> <input type="text"/>	<b>Participant Gender:</b> <input type="text"/>	<b>Participant Date of Birth:</b> <input type="text"/>	<b>Date of sending report to JCTO:</b> <input type="text"/>
<b>Participant Randomisation Number:</b> <input type="text"/>	<b>Participant Initials:</b> <input type="text"/>	<b>Study Title (short):</b> <input type="text"/>	

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?

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

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

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

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