King's Health Partners Clinical Trials Office

A partnership for clinical research

Serious Adverse Event Form

Email to: jcto.pharmacovigilance@kcl.ac.uk

EudraCT Number:	Participant Gender:	Participant Age:	Date of sending report to CTO:

Participant Randomisation Number:	Participant Initials:	Study Title (short):

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:**

4b. Code:

5. **Chief or Principal Investigator**:

6. **Sponsor**:

7a**. Date of Onset**:
(dd/mm/yyyy)

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

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

(dd/mm/yyyy)

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 *(include daily dose(s) & generic name)*	***Therapy Start Date*** *(dd/mm/yyyy)*	***Therapy End Date*** *(dd/mm/yyyy)*	***Date of dose prior to SAE onset*** *(dd/mm/yyyy)*	***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?**

- ☐ Resolved
- ☐ Resolved with sequalae
- ☐ Continuing
- ☐ Resulted in Death
- ☐ Unknown

19. Date event resolved: *(dd/mm/yyyy)*

20. Date patient died: *(dd/mm/yyyy)*

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:

23. Phone number:

24. Email address:

25. Centre (if multicentre trial):

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**