Serious Adverse Event Form

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

Study Title		IRAS Number:	

Participant Study ID	Participant Initials	Participant Gender	Participant Age

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

Evaluation of Event

3a. Diagnosis (please use MedDRA term if known):

3b. MedDRA Lower Level Term (LLT):	**3c. Code:**
3d. MedDRA Preferred Term (PT)	**3e. Code:**
4. Principal Investigator:	**5. Sponsor:**
6a. Date of Onset: (dd/mmm/yyyy) **6b. Time of Onset: (if available; hh:mm):**	**8. Criteria for definition as Serious*:** ☐ **Resulted in Death** ☐ **Life threatening** ☐ **In-patient hospitalisation or prolongation** ☐ **Persistent or significant disability** ☐ **Congenital anomaly/birth defect** ☐ **N/A (IME or Pregnancy)**
7. Date person completing report became aware of event:	

***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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9. 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.)

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

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

* These will be reported as a SAR .

Blank entries will also be reported as a SAR.

11. Action Taken with Study Drug due to the event?

- ☐ None
- ☐ Dose reduced
- ☐ Dose increased
- ☐ Drug withdrawn
- ☐ Unknown

12. Did event/reaction abate after stopping drug?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

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

- ☐ Yes
- ☐ No
- ☐ Not Applicable

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14. IMP & Concomitant Medication Information

IMP and Medication Details (include daily dose(s) & generic name)	**Therapy StartDate** (dd/mmm/yyyy)	**Therapy End Date** (dd/mmm/yyyy)	**Date of dose prior to SAE onset** (dd/mmm/yyyy)	**Route(s) of administration**	**Indications for Use**

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Outcome of Event

15. What is the outcome of the SAE?	16. Date event resolved: (dd/mmm/yyyy): 17. Date patient died: (dd/mmm/yyyy): 18. Cause of death obtained from (if patient died):
☐ Resolved ☐ Resolved with sequelae ☐ Continuing ☐ Resulted in Death ☐ Unknown	☐ Coroner's inquest ☐ Death Certificate ☐ Working diagnosis

Contact & Signatures

Please supply contact details where further information may be obtained:

19. Person to contact:	
20. Phone number:	
21. Email address:	
22. Centre (if multicentre trial):	

Signature (person completing report)	Print Name	Date (dd/mmm/yyyy)
Principal Investigator Signature	Print Name	Date (dd/mmm/yyyy)