<Study Title>

Serious Adverse Event Reporting Form

EudraCT number:

Please email the SAE form to the RGIT CTIMP Inbox at RGIT.ctimp.team@imperial.ac.uk within 24h of notification of event.

Patient Study No: ☐☐☐☐☐☐☐☐ Event Number: ☐☐☐☐

Treating Clinician: ..... Hospital/Site: .....

Type of Report
☐ 1=First & Final
2=First
3=Interim
4=Final

Trial Arm
☐ 1=
2=

Sex
☐ 1= Male
2= Female

Height ☐☐☐ cm

Weight ☐☐☐.☐ kg

Date of last trial treatment given prior to SAE
☐☐ ☐☐☐ ☐☐
d d m m m y y

Was the trial treatment given at full protocol doseprior to event?
☐ 0= No, specify .....
1=Yes

Why was the event serious? *(Choose most serious)*
☐
1= Resulted in death
2= Life-threatening
3= Required inpatient hospitalisation or prolongation of existing hospitalisation
4= Resulted in persistent or significant disability/incapacity
5= Resulted in congenital anomaly/birth defect
6= Other medically important event

Where did the SAE take place?
☐
1= Hospital
2= Out-patient clinic
3= Home
4= Nursing home
5= Hospice
6= Other, specify.....

Briefly Describe SAE (*include whether this event is known to be recurrent as per the participant's medical history, relevant symptoms, body site, and relevant lab tests, treatments received)* (**Note**: Continue on a separate sheet if necessary)

Details of SAE

Serious Adverse Event	**Duration of SAE** (dd mmm yy)	**SAE Status** 1= Resolved 2= Resolved with sequelae 3= Persisting 4= Worsened 5= Fatal 6= Not assessable
Name*: **Severity Grade:** ☐	Date of Onset ☐☐ ☐☐☐ ☐☐ Date Resolved ☐☐ ☐☐☐ ☐☐ or tick box if ongoing ☐	☐

Preferred Term in the latest version of the Medical Coding Dictionary to be used* *(record medical coding dictionary name & version here):***

Trial Treatment

Trial Drug(s) Information	*Total Daily Dose*	Start Date of Most Recent Cycle (dd mmm yy)	Currently Ongoing? 0= no 1=Yes	End Date (dd mmm yy)	Action Taken 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment delayed and reduced 4=Treatment permanently stopped

Trial Treatment (*Continued*)

Trial Drug(s) Information *(Please list as above)*	Causal relationship 1=Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related 6=Not assessable	Expectedness 1= Expected* 2= Unexpected 3= N/A**	*RSI Version used to assess Expectedness (IB/SmPC, Version & Date)*

**Was the event one of the recognised undesirable effects of the trial medication as describe in the latest approved Reference Safety Information?*
*** Only to be used in the event the SAE is not attributed to the IMP*

Other treatments at time of event (Please list all relevant concomitant medications, radiotherapy, surgery, etc. (continue on a separate sheet if needed) Exclude any therapy given for management of the SAE.

Treatment Give generic name of drugs/treatment given in the last 30 days.	Total Daily Dose	Route of Administration 1=Oral 2=Intravenous 3=Subcutaneous 4=Other, specify	Start Date (dd mmm yy)	Currently Ongoing? 0= no 1=Yes	End Date (dd mmm yy)	Action Taken 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment delayed and reduced 4=Treatment permanently stopped

Trial NIMPs

☐ Check box if N/A

NIMPs patient received	*Total Daily Dose*	Start Date of Most Recent Cycle (dd mmm yy)	Currently Ongoing? 0= no 1=Yes	End Date (dd mmm yy)	Action Taken 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment delayed and reduced 4=Treatment permanently stopped

Trial NIMPs (*Continued*)

NIMPs patient received *(Please list as above)*	Was SAE due to NIMP interacting with the IMP? 1=Yes 2=No (If yes, report as per IMP)	If answer to prior question was "no", was SAE caused by the NIMP? 1=Yes 2=No 3=N/A	If answer to prior question was "yes", is NIMP authorised or non-authorised? 1=Authorised 2=Non-Authorised	If answer to prior question was "authorised", please confirm event has been reported via yellow card scheme to the MHRA (Check box)	If answer to prior question was "non-authorised", please confirm event has been reported as a SUSAR via ICSR to the MHRA (check box)
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

Other relevant information to facilitate assessment

(Include medical history, drug or alcohol abuse, family history, findings from special investigations)

Additional Information:

☐ **I (PI/Delegated Health Professional) confirm I have reviewed the information entered in this CRF and that, to the best of my knowledge and clinical judgement, it accurately reflects the participant's status and events as reported to me or observed under my supervision.**

Signature .....
Principle Investigator *or Authorised Health Professional as delegated on the Delegation Log*

Print name .....

Contact telephone no

.....

Date of Review ☐☐ ☐☐☐ ☐☐
d d m m m y y

☐ **I (CI) agree with the safety assessments made by the PI for this safety event.**

☐ **I (CI) disagree with the safety assessments made by the PI for this safety event (*if selected, please complete the below*).**

Trial drugs patient wasreceiving when SAE started	**Causal relationship** 1=Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related 6=Not assessable	**Expectedness** 1= Expected* 2= Unexpected 3= N/A** *(*/**Please see above report)*	***RSI Version used to assess Expectedness*** *(IB/SmPC, Version & Date)*
	☐	☐	
	☐	☐	
	☐	☐	
Note: *CI safety assessments for a safety event cannot override the PIs safety assessments but should be noted.*			

Signature
Chief Investigator .....

Print name .....

Contact telephone no

.....

Date of Review ☐☐ ☐☐☐ ☐☐
d d m m m y y

SITES TO COMPLETE

Was SAE drug related? Yes ☐ No ☐ NA* ☐

Was event unexpected? Yes ☐ No ☐ N/A ☐

Was the event a SUSAR? Yes ☐ No ☐

Date site aware ☐☐ ☐☐☐ ☐☐
d d m m m y y

Date reported to CI (if different to the PI above) ☐☐ ☐☐☐ ☐☐
d d m m m y y

Date reported to Sponsor ☐☐ ☐☐☐ ☐☐
d d m m m y y

Comments:

Form completed by
(Staff Name & Signature)

.....

Date ☐☐ ☐☐☐ ☐☐
d d m m m y y

*NA: Not Assessable, if selected, event must always be considered a SUSAR.