AX1-V6.1/SOP09/V6.1

AX-V6.1/SOP9/V6.1 **SERIOUS ADVERSE EVENT REPORT** **Tata Memorial Centre**	**TMC PROJECT NO:**
	Regulated by DCGI: Yes / No **CTRI Reg. No:** **BE/CT NOC No –** **CDSCO SUGAM SAE Report Application number-**

As per ICH-GCP:

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) is

An untoward medical occurrence during clinical trial resulting in

- **Death**
- **Permanent disability**
- **Hospitalization of the trial subject where the trial subject is an outdoor patient or ahealthy person,**
- **Prolongation of hospitalization where the trial subject is an indoor-patient**
- **Persistent orsignificant disability or incapacity,**
- **Congenital anomaly**
- **Birth defect**
- **Life threatening event**

Investigator(s) shall report all SAE's including Death to the IEC, Sponsor and CDSCO within 24 hours of their occurrence of the knowledge of the PI. If a delay is expected kindly notify the same by email.

1.	Title of project:
2.	Principal Investigator:
3.	Date of Occurrence of SAE :
4.	Report Date : Report Type : □ Initial □ Follow-up _____If Follow-up report, State Date of Initial report_____ □ Final _____If Final report, State Dates of Initial &Follow up report _____
	If report is delayed, provide reasons- _____

5.	Subject Case No: Subject Trial ID:	5a. Age: 5b. Gender: □ Male □ Female 5c. Occupation:
	Study Arm to which subject is randomized :□Test/Experimental Arm□ Standard Arm □ NA	
7.	Mention the total number of SAE (prior) occurred at this site: _____ Other site(s): _____	
8.	Mention number of similar SAEs (prior) occurred for same study at this site:_____ Other site(s): _____	
9.	A] State Serious Adverse Event term: (Kindly refer to CTCAE V5.0 where applicable)	B] CTCAE Grade: (where applicable)
10.	Does the Principal Investigator feels this SAE is related to participation in the trial? □ Yes □ No □ NA Principal Investigator to provide justification for causality assessment-	
11.	Tick whichever is applicable for serious adverse event: (Kindly note that this refers to IP/intervention being evaluated and NOT disease process) A] □ Expected Event □ Unexpected Event	
	B] □ Hospitalization □ Increased hospital stay □ Death □ Others In case of Death, state probable cause of death _____ (If others, please specify): Kindly provide number of days of the hospitalization :_____ In case of discharge from hospital, state Discharge date :_____	
	C] □ No permanent significant functional/ cosmetic impairment □ Permanent significant functional/ cosmetic impairment □ Not applicable	
12.	The cost of treatment/hospitalization was borne by, □ Patient □ Institute □ Sponsor/CRO Reimbursement done- □ Yes □ In process □ No □ NA If Yes, attach proof of reimbursement	
	Drug information (refers to drug/ device/ procedure under investigation)	
13.	IP/ Placebo (include generic name)/device/intervention:	

14.	Dose: Dosage Form:	15.	Route(s) of administration:
16.	Therapy Dates (From/To) :	17.	Therapy duration :

	Was study intervention discontinued due to event? □ Yes □ No □ NA
18.	Did the reaction decline after stopping the drug / procedure (Dechallenge&Rechallenge information) □ Yes □ No □ NA
	Concomitant drugs and history (drugs that the patient maybe on)
19.	Concomitant drug(s) and date of administration :
20.	Patient relevant history (e.g. diagnosis, allergies): (Tick in the applicable box) (This is applicable only for regulated clinical trials) R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under: a) 0.5 Terminally ill patient (expected survival not more than (NMT) 6 months) □ b) 1.0 Patient with high risk (expected survival between 6 to 24 months) □ c) 2.0 Patient with moderate risk □ d) 3.0 Patient with mild risk □ e) 4.0 Healthy Volunteers or subject of no risk □

	SAE Details
21.	Description of serious adverse event-Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event(indicate if this is follow-up report and if so, include follow-up information only)
22.	Describe the medical treatment provided (if any) to the research participant: This is an update on treatment given during hospitalization and /or used for management of the SAE.

Medication	Dose	Start date	End date

23.	Outcome was □ Resolved □ Ongoing □ Death
24.	Was the research participant continued on the research protocol? □ Yes □ No □ NA (Mark 'NA' in case of death)

25.	What phase of the research protocol is the patient in? □ On active treatment □ Short term follow-up □ Long term follow-up □ Surveillance/ Monitoring
26.	In your opinion, does this report require any alteration in trial protocol/ICF? □ Yes □ No □ NA If yes then please specify. Name of Principal investigator : Profession (Specialty) : Signature of Principal investigator _____ Date: _____ Contact No. of PI: _____ Upon receipt of this report, the IEC will decide whether additional information is needed or whether further investigation of the incident is required. A follow-up report with further details should be submitted by PI within 14days or earlier (of occurrence of the SAE) to the IEC
For IEC use only	

Final Assessment of IEC (strike out what is not applicable)
Related / Unrelated
Expected / Unexpected
On active treatment / Short term follow-up / Long term follow-up / Surveillance / Monitoring
Resolved / Ongoing / Death
SAE treatment borne by: Institute/ Sponsor/participant
Compensation warranted: Yes/ No
If yes- please tick □ Adverse effect of investigational product(s) □ Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representativeor the investigator leading to serious adverse event; □ Failure of investigational product to provide intended therapeutic effect where, the required standard care orrescue medication, though available, was not provided to the subject as per clinical trial protocol; □ Not providing the required standard care, though available to the subject as per clinical trial protocol in theplacebo controlled trial; □ Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approvedprotocol;

□ Adverse effect on a child in-utero because of the participation of the parent in the clinical trial;

□ Any clinical trial procedures involved in the study leading to serious adverse event.

I ____ agree _____ disagree with the assessment of the principal investigator.

IEC Reviewer_____ date: _____ Explanation: