**AX1-V6/SOP09/V6**

**SERIOUS ADVERSE EVENT REPORT**

|  |  |
| --- | --- |
| **AX-V6/SOP9/V6****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**

**Any untoward medical occurrence (due to the participation in the concerned trial)**

**that at any dose that:**

* + **Results in death,**
	+ **Is life-threatening,**
	+ **Requires inpatient hospitalization or prolongation of existing hospitalization,**
	+ **Results in persistent or significant disability/incapacity,**

 **or**

* + **is a congenital anomaly/birth defect**

**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 |
| 6. | Study Arm to which subject is randomized : □ Test □ 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 SAE Event term : B] CTCAE Grade : (Kindly refer to CTCAE V5.0 where applicable) (where applicable) |
| 10. | Does the Principal Investigator feel this SAE is related to participation in the trial  □ Yes □ No □ NAPrincipal 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 □ OthersIn 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 □ NAIf 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 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 (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 subject: 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 subject 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?□ Yes □ No □ NAIf 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/DSMU 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 14 days or earlier (of occurrence of the SAE) to the IEC |