Logo of the Institute

(Annexure 9)

Serious Adverse Event Reporting Format (Clinical trials)

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(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

Initials and Case No./ Subject ID

.....

.....

Age at the time of event

.....

Gender

Male ☐

Female ☐

Weight:.....(Kgs)

Height:.....(cms)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

What was the assessment of relatedness to the trial in the initial report?

By PI – Related ☐ Unrelated ☐

By Sponsor – Related ☐ Unrelated ☐

By EC – Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd mm yy Date of reporting: dd mm yy

5. Onset lag time after administration of intervention: .....

Location of SAE (Clinic/Ward/Home/Other) .....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd mm yy Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

   If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

   If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

   I. Concomitant drug (s) and date of administration: dd mm yy

   .....

   .....

   II. Relevant test/laboratory data with dates: dd mm yy

   .....

   .....

   III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

   .....

   .....

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

   .....

   .....

12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
Life threatening	☐	Required intervention to prevent	
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others *(specify)*	☐

   .....

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

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   .....

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

   .....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

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17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

   Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

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Signature of PI: ..... dd mm yy