Annexure 15. Serious Adverse Event Reporting Form (Clinical trials)

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: (Kg) Height: (cm)

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

   If Follow-up report, state date of Initial report Click here to enter a date.

   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: Click here to enter a date. Date of reporting: Click here to enter a date.

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: Click here to enter a date. Stop date: Click here to enter a date.

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 study drugs history and lab investigations:
I. Concomitant study drug (s) and date of administration: Click here to enter a date.

II. Relevant test/laboratory data with dates:Click here to enter a date.

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	☐	Congenital 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).

14. Outcome of SAE:

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

15. Was the research subject continuing the trial? Yes ☐ No ☐ NA ☐

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

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)

Signature of PI: Click here to enter a date.