### Serious Adverse Event Reporting Format (Clinical trials)

**Title of study:**

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

1. **Participant details:**
   - Initials and Case No./ Age at the time of event Gender Weight:
   - Subject ID Male Height:
   - Female

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

   If Follow-up report, state date of Initial report

   What was the assessment of relatedness to the trial in the initial report?
   - By PI – Related
   - By Sponsor – Related
   - By EC – Related
   - Unrelated

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

4. **Date of onset of SAE:**

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

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:**

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

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

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