



(Annexure 9)

Serious Adverse Event Reporting Format(Clinical trials)

अखिल भारतीय आयुर्वेद संस्थान
ALL INDIA INSTITUTE OF AYURVEDA (AIIA)

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 Weight: (Kg.)
Male Height: (cm.)
Female

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 By sponsor - Related By EC - Related
Unrelated Unrelated 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	<input type="checkbox"/>	Congenital anomaly	<input type="checkbox"/>
Life threatening	<input type="checkbox"/>	Required intervention to prevent permanent impairment / damage	<input type="checkbox"/>
Hospitalization-initial or prolonged	<input type="checkbox"/>	Others (specify)	<input type="checkbox"/>
Disability			

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	<input type="checkbox"/>	Recovered	<input type="checkbox"/>
Continuing	<input type="checkbox"/>	Unknown	<input type="checkbox"/>
Recovering	<input type="checkbox"/>	Other (specify)	<input type="checkbox"/>

15. Was the research subject continued on 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

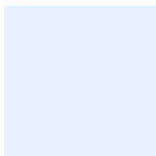
Provide details if communicated (including date)

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.](#)