**Ann01/SOP12/v3 Serious Adverse Event (SAE) initial/follow up report**

**(For Onsite SAE)**

**(Please do not edit/delete any titles/subtitles provided in the form)**

***Important information for the Principal Investigator:***

**Initial report to be submitted within 24 hours of the occurrence of the SAE and the first follow up report (due-analysis report) must be submitted within 14 days of SAE occurrence and subsequent follow up reports as and when deemed necessary)**

**Irrespective of who fills in the form, the PI, who signs it is responsible for completeness and factual correctness of the information**

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| --- | --- |
| **S.** **No.** | **Details** |
| 1. | **Country** (Country name should be specified) |  |
| 2. | **SAE report of death or other than death** Please tick (✓) | **Death** | Yes/No |
| **Other than** **death**  | Yes/No |
| 3. | **Nature of the SAE:** Please tick (✓) whichever applicable | **Hospitalization:** **Prolongation of hospitalization:****Permanent disability:** **Life threatening condition:****Congenital Abnormality in the offspring:** |
| 4. | **Protocol Title:**  |  |
| 5. | **Protocol No.:****On-site SAE Number:**  |  |
| 6. | **Clinical Trial permission obtained from CDSCO** | Yes/ No |
| 7. | **CTRI Registration No.**  |  |
|  | **Insurance document** | Yes / NoValidity period from: to: |
| 8. | **Sponsor** (Address with contact no and Email): |  |
| 9. | **CRO** (Address with contact no and Email): |  |
| 10. | **Type of SAE report:**  | Initial report:  | Yes/No  |
| Follow up report: | Yes/ No |
| If Follow up report: | Follow up report No: |
| 11. | **Dates of previous SAE reports:** | Initial report date:Follow up dates:  |
| 12. | **Participant Details:**  | Study Subject ID: |  |
| Initials |  |
| Hospital/OPD record No.: |  |
| Gender:  |  |
| Age and/or date of birth |  |
| 13. | **Nature of the intervention:** 1. **Suspected Drug(s)**
	1. Generic name of the drug
	2. Indication(s) for which suspect drug was prescribed or tested
	3. Dosage form and strength
	4. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
	5. Route of administration
	6. Starting date and time
	7. Stopping date and time, or duration of treatment

b. **Any other intervention (specify)***Provide the same information for concomitant drugs (including non prescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).* |  |
| 14. | **Details of clinical findings:** 1. Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious.
2. In addition to a description of the reported signs and symptoms, whenever possible, assign a specific diagnosis for the reaction.
3. Start date (and time) of onset of reaction.
4. Stop date (and time) or duration of reaction.
5. Dechallenge and rechallenge information (if any)
6. Setting (e.g. hospital, out-patient clinic, home, nursing home).
 |  |
| 15. | **Outcome:**1. Required hospitalization: Yes/No
2. Number of admission days:
3. Please provide results of specific tests and other laboratory reports (if any) that were carried out in relation to the adverse event:
4. Details of the treatment provided (including any procedures or surgeries or any other interventions done in relation to the adverse event):
5. Details on the recovery or other sequelae:
6. If discharge summary is available please provide a copy:
7. Is there a permanent disability or functional loss?
8. Is the adverse event associated with a congenital anomaly?
9. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction (include post mortem findings - if any):
 |  |
| 16.  | **i. Other Information:** *Anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history, findings from special investigations etc***ii. Other related documents:** 1. Investigation reports
2. Discharge summary
3. Copy of eCRF
4. Post-mortem report (if applicable)
5. Any additional documents
 |  |
| 17 | **Has this participant had any previous SAE in this study? If yes, provide details** |  |
| 18.  | **Details about the Investigator** CT Site number, if anyNameAddressTelephone/Mobile Number & EmailProfession (specialty)Date of reporting the event to Licensing AuthorityDate of reporting the event to Yenepoya Ethics Committee – 1 |  |
| 19. | **Details about Yenepoya Ethics Committee - 1**Name and address of ECName of ChairmanTelephone/Mobile NumberEmailWhether EC is recognized by DCGI | Yes/No |
| 20. | **Adverse Event Term/Details** (strike off whichever is not applicable) | Serious / Non-seriousExpected / Unexpected |
| 21. | **Causality assessment** by investigator. | Related/Unrelated |
| 22. | **Causality Assessment** by sponsor/CRO | Related/Unrelated |
| 23. | **Details of compensation provided for injury or death.***In case no compensation has been paid, reason for the same* |  |
| 24. | **Details of payment for medical management of SAE?** (please give information who paid, how much was paid, to whom and evidence of the same) |  |
| 25. | **What is the investigator’s assessment for the amount of compensation to be paid?** |  |
| 26. | **What is the sponsor’s assessment for the amount of compensation to be paid?** |  |
| 27. | **Has the participant made a claim?** | Yes/NoComment  |
| 28. | **If yes for 27, then, for how much amount?** |  |
| 29. | **If no, please ensure that the participant/nominee have been made aware of his/her rights regarding compensation.** *Please submit documentation regarding the same*.  |  |
| 31. | **Form filled by (name & signature with date)****Role in the research team**  |  |
| 30. | **Signature of the Principal Investigator with date** |  |

*Note: Information not relevant to a particular SAE should be marked with NA*