**CHECKLIST FOR REVIEW OF SUBMITTED SERIOUS ADVERSE EVENT (SAE)**

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| --- | --- |
| **Name of reviewer** |  |
| **Designation in IEC** |  |
| **Date of SAE Review Meeting** |  |
| **Protocol ID** |  |
| **Date of receipt of SAE** |  |
| **Principal Investigator** |  |

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| --- | --- | --- |
| **Serial**  **No.** | **Details** | **Observation** |
| 1. | Copy of Clinical Trial permission obtained from CDSCO | Available/ Not available |
| 2. | CTRI Registration No. | Available/ Not available |
| 3. | Sponsor(Address with contact no and Email) | Available/ Not available |
| 4. | Initial / Follow-up (FU) | Available/ Not available |
| 5. | **Patient/Participant Details** |  |
|  | Initials & other relevant identifier (hospital/OPD record number  etc.) | Available/ Not available |
| Age & Gender | Available/ Not available |
| Address | Available/ Not available |
| 6. | **Details of Therapy/drug** |  |
|  | \*Suspected Drug(s) | Available/ Not available |
| \*Generic name of the drug | Available/ Not available |
| \*Indication(s) for which suspect drug was prescribed or tested | Available/ Not available |
| \*Dosage form and strength | Available/ Not available |
| \*Daily dose and regimen (specify units - e.g., mg, ml, mg/kg) | Available/ Not available |
| \*Route of administration | Available/ Not available |
| \*Starting date and time of day g) Stopping date and time, or duration of treatment | Available/ Not available |
| \*Other Treatment(s): (including nonprescription/ OTC Drugs) and non drug therapies, as for the suspected drug(s) | Available/ Not available |
| 7. | \*Details of the events: Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious | Available/ Not available |

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|  | Date (and time) of onset of reaction  Stop date (and time) or duration of reaction | Available/ Not available |
| 8. | \*De-challenge and re-challenge information | Available/ Not available/ NA |
| 9. | \*\*Setting (e.g., hospital, out-patient clinic, home, nursing home) |  |
| 10. | **Outcome** |  |
|  | \*\*Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted. | Available/ Not available |
| \*\*For a fatal outcome, cause of death and a comment on its  possible relationship to the suspected reaction; any post-mortem findings. | Available/ Not available/ NA |
|  | - Laboratory investigations report /Discharge summary (if available and applicable) | Available/ Not available |
|  | - Post-mortem report (if applicable)/ Any additional  documents) | Available/ Not available/  NA |
| 11. | \*\*Causality Assessment (Related/ Unrelated) by Investigator | Done/ Not done |
| 12. | \*\*Causality Assessment (Related/ Unrelated) by sponsor | Received/ Not received |
| 13. | \*Details about the Investigator | Available/ Available |
| 14. | \*Duly filled SAE Form as per Appendix XI of Schedule Y | Yes/ No |
| 15. | \*\*\*\*Has the participant made a claim? | Yes/ No |
| 16. | ADDITIONAL DOCUMENTS REQUIRED FROM INVESTIGATOR (if any): | |
| 17. | Other comments [if any]: | |

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| --- | --- | --- |
| **18** | **At SAE Review Meeting** |  |
|  | \*What is the investigator’s assessment for causality | Related/ Not related |
|  | \*\*\*Basic Scientist assessment based on IB [latest version] |  |
|  | \*\*\*\*Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with  evidence of the same) |  |
|  | **Recommendations:** | |

**Mandatory for:**

\*Clinician

\*\*Lay person, Social Scientist

\*\*\*Basic Scientist

\*\*\*\*Legal Expert

**Signature with date**