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 ***Annexure 2A: AX 02A/SOP12/V2***

***Checklist for Serious Adverse Event (SAE) submission***

***(For Onsite SAE)***

|  |  |
| --- | --- |
| S. No | **Details** |
| 1. | **Country** (Name of the country should be specified) |  |  |
| 2. | **SAE report of death or other than death, Please tick (✓)** | **Death** | **Other than Death** |
| **Yes / No** | **Page No.** |
| 3. | **In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant** (Please specify Yes/No) in the box |  |  |
| 4. | Protocol Title |  |  |
| 5. | Protocol Study No./ ID /Code |  |  |
| 6. | Copy of Clinical Trial permission obtained from CDSCO |  |  |
| 7. | CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09) |  |  |
| 8. | Sponsor(Address with contact no and Email) |  |  |
| 9. | CRO (Address with contact no and Email) |  |  |
| 10. | Initial / Follow-up (FU) |  |  |
| 11. | In case of follow-up: Date & Diary no of initial or recently submitted report information |  |  |
| 12. | **Patient Details** |  |  |
| a. | Initials & other relevant identifier (hospital/OPD record number etc.) |  |  |
| b. | Gender |  |  |
| c. | Age and/or date of birth |  |  |
| d. | Weight |  |  |
| e. | Height |  |  |
| 13. | **Suspected Drug(s)** |  |  |
| a. | Generic name of the drug |  |  |
| b. | Indication(s) for which suspect drug was prescribed or tested |  |  |
| c. | Dosage form and strength |  |  |
| d. | Daily dose and regimen (specify units - e.g., mg, ml, mg/kg) |  |  |
| e. | Route of administration |  |  |
| f. | Starting date and time of day |  |  |
| g. | Stopping date and time, or duration of treatment |  |  |
| 14. | **Other Treatment(s)** |  |  |
|  | Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non- drug therapies, as for the suspected drug(s). |  |  |
| 15. | **Details of the events** |  |  |
| a. | Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.  |  |  |
| b. | Start date (and time) of onset of reaction. |  |  |
| c. | Stop date (and time) or duration of reaction. |  |  |
| d. | Dechallenge and rechallenge information. |  |  |
| e. | Setting (e.g., hospital, out-patient clinic, home, nursing home). |  |  |
| 16. | **Outcome** |  |  |
| a. | Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted. |  |  |
| b. | For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings. |  |  |
| c. | 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. |  |  |
| 17. | **Details about the Investigator** |  |  |
| a. | CT Site Number, if any |  |  |
| b. | Name |  |  |
| c. | Address |  |  |
| d. | Telephone/Mobile Number & Email |  |  |
| e. | Profession (speciality) |  |  |
| f. | Date of reporting the event to Licensing Authority: |  |  |
| g. | Date of reporting the event to Ethics Committee overseeing the site: |  |  |
| h. | Signature of the Investigator |  |  |
| 18. | **Details about the Ethics Committee** |  |  |
| a. | Name & Address |  |  |
| b. | Name of Chairman & Address |  |  |
| c. | Telephone/Mobile Number |  |  |
| d. | Email |  |  |
| 19. | Adverse Event Term/ Details of SAE |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 20. | Causality Assessment (Related/Unrelated) by Investigator. |  |  |
| 21. | Causality Assessment (Related/Unrelated) by Sponsor/CRO |  |  |
| 22. | Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same : |  |  |
| 23. a. | Duly filled SAE Form as per Appendix XI of Schedule Y |  |  |
| b. | Laboratory investigations report /Discharge summary (if available and applicable)  |  |  |
| c. | Post-mortem report (if applicable)/ Any additional documents) |  |  |

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

***Annexure 2B: AX 02B/SOP 12/V2***

***Serious Adverse Event (SAE) Analysis Report***

***(For Onsite SAE)***

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| --- | --- |
| S. No | **Details** |
| 1. | **Country** (Name of the country should be specified) |  |  |
| 2. | **SAE report of death or other than death, Please tick (✓)** | **Death** | **Other than Death** |
| **Yes / No** | **Page No.** |
| 3. | **In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant** (Please specify Yes/No) in the box |  |  |
| 4. | Protocol Title |  |  |
| 5. | Protocol Study No./ ID /Code |  |  |
| 6. | Copy of Clinical Trial permission obtained from CDSCO |  |  |
| 7. | CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09) |  |  |
| 8. | Sponsor(Address with contact no and Email) |  |  |
| 9. | CRO (Address with contact no and Email) |  |  |
| 10. | Initial / Follow-up (FU) |  |  |
| 11. | In case of follow-up: Date & Diary no of initial or recently submitted report information |  |  |
| 12. | **Patient Details** |  |  |
| a. | Initials & other relevant identifier (hospital/OPD record number etc.) |  |  |
| b. | Gender |  |  |
| c. | Age and/or date of birth |  |  |
| d. | Weight |  |  |
| e. | Height |  |  |
| 13. | **Suspected Drug(s)** |  |  |
| a. | Generic name of the drug |  |  |
| b. | Indication(s) for which suspect drug was prescribed or tested |  |  |
| c. | Dosage form and strength |  |  |
| d. | Daily dose and regimen (specify units - e.g., mg, ml, mg/kg) |  |  |
| e. | Route of administration |  |  |
| f. | Starting date and time of day |  |  |
| g. | Stopping date and time, or duration of treatment |  |  |
| 14. | **Other Treatment(s)** |  |  |
|  | Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non- drug therapies, as for the suspected drug(s). |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 15. | **Details of the events** |  |  |
| a. | Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.  |  |  |
| b. | Start date (and time) of onset of reaction. |  |  |
| c. | Stop date (and time) or duration of reaction. |  |  |
| d. | Dechallenge and rechallenge information. |  |  |
| e. | Setting (e.g., hospital, out-patient clinic, home, nursing home). |  |  |
| 16. | **Outcome** |  |  |
| a. | Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted. |  |  |
| b. | For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings. |  |  |
| c. | 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. |  |  |
| 17. | **Details about the Investigator** |  |  |
| a. | CT Site Number, if any |  |  |
| b. | Name |  |  |
| c. | Address |  |  |
| d. | Telephone/Mobile Number & Email |  |  |
| e. | Profession (speciality) |  |  |
| f. | Date of reporting the event to Licensing Authority: |  |  |
| g. | Date of reporting the event to Ethics Committee overseeing the site: |  |  |
| h. | Signature of the Investigator |  |  |
| 18. | **Details about the Ethics Committee** |  |  |
| a. | Name & Address |  |  |
| b. | Name of Chairman & Address |  |  |
| c. | Telephone/Mobile Number |  |  |
| d. | Email |  |  |
| 19. | Adverse Event Term/ Details of SAE |  |  |
| 20. | Causality Assessment (Related/Unrelated) by Investigator. |  |  |
| 21. | Causality Assessment (Related/Unrelated) by Sponsor/CRO |  |  |
| 22. | Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same : |  |  |
| 23. a. | Duly filled SAE Form as per Appendix XI of Schedule Y |  |  |
| b. | Laboratory investigations report /Discharge summary (if available and applicable) |  |  |
| c. | Post-mortem report (if applicable)/ Any additional documents) |  |  |
| **Details of payment for medical management of SAE?** (please give information who paid how much was paid, to whom, with evidence of the same) |
| **What is the investigator’s assessment for the amount of compensation to be paid?** |
| **What is the sponsor’s assessment for the amount of compensation to be paid?** |
| **Has the participant made a claim? Yes No** |
| **If yes, for how much amount** |
| **If no, please ensure that the participant / nominee have been made aware of his/her’ rights regarding compensation. Please submit documentation regarding the same** |
| **Signature of the Principal Investigator : Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |