**SAE/SUSAR REPORTING FORM**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *Please complete this form. Attach any documents (photo document, other related written document) that may support your SAE/SUSAR report.*

**PROTOCOL GENERAL INFORMATION**

|  |  |
| --- | --- |
| **PSURERC Code** |  |
| **Protocol Title** |  |
| **Principal Investigator** |  |
| **Protocol Approval Date/s** *(indicate dates of continuing review and/or protocol amendment dates, if applicable***)** |  |
| **Start Date** *(stated in the approved protocol; start of study includes the start of all data collection-related activities post-approval, e.g., communication with recruitment party, invitation, etc.; if not started, indicate target date; if started, indicate actual start date\ )* |  |
| **Target Completion Date** *(as stated in the approved protocol)* |  |
| **Study Site** |  |
| **Sponsor** |  |
| **Sponsor Contact Person and Contact Details** |  |
| **Current Status** (*specify the current stage of the study)* |  |

**SAE/SUSAR DETAILS**

|  |  |
| --- | --- |
| **Report Date** |  |
| **Report Type** | <initial or follow-up> |
| **Name of the study medicine/device** |  |
| **Onset Date** |  |
| **Date of First Use** |  |
| **Patient’s Initial/Number:** |  |
| **Patient’s Details** | Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_ Sex: \_\_\_  Age: \_\_\_\_\_ Weight: \_\_\_\_ Height: \_\_\_\_\_ |
| **Relevant medical history and concurrent conditions:** |  |
| **REACTION INFORMATION** | |
| **Type of SAE** |  Results in Death   Life-threatening   Hospitalization or prolongation of hospitalization   Persistent or significant disability or incapacity   Congenital anomaly or birth defect   “Other” important medical event. If “Other”, please describe: |
| **Event Description and Severity** (e.g., body site, symptoms) |  |
| **Is the SAE likely to be a**  **reaction to one of the IMPs or medical devices in the trial?** |  |
| **Is the SAE expected?** |  |
| **Is the SAE due to the**  **progression of an underlying illness?** |  |
| **Is the event classified as a SUSAR? (i.e., RELATED**  **to one of the IMPs and UNEXPECTED)** |  |
| **Action taken with the study treatment:** | Continued Reduced  Permanent stop  Temporary stop Increased  Patient withdrawn |
| **SUSPECT DRUG/S INFORMATION** | |
| **Suspect drug/s (include generic name)** | Name:  Daily dose/s:  Route’s administration: |
| **Indication/s for use** |  |
| **Therapy date/s: (from/to)** |  |
| **Therapy duration:** |  |
| **Did reaction abate after stopping drug?** |  |
| **Did reaction appear after reintroduction?** |  |
| **Treatment given for Adverse Event:** |  |
| **Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System)** |  Certain  Probable  Unclassifiable   Possible  Unlikely  Conditional |
| **Outcome of reaction/event at the time of last observation** |  Recovered  Recovering with sequelae  Death   Recovering  Not recovering  Unknown |
| **CONCOMITANT DRUG/S AND HISTORY** | |
| **Concomitant drug/s and dates of administration** (exclude drugs used to treat reactions) |  |
| **Other relevant history** (e.g., diagnostics, allergies, pregnancy with last month of period, etc.) |  |
| **MANUFACTURER’S INFORMATION** | |
| **Name and address of manufacturer** |  |
| **Manufacturer control no.** |  |
| **Date received by manufacturer** |  |
| **Report source** |  |

**Principal Investigator: <Name and Signature>**

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*To be filled out by PSURERC Primary Reviewer*

**REVIEWER’S ASSESSMENT**

|  |  |
| --- | --- |
| **Causality assessment** |  |
| **Reason/Comment** |  |
| **Adequacy of Treatment of SAE** |  |
| **RECOMMENDATIONS:** |  Request further action:<indicate action>   Pending: <indicate reason>   Suspend the study   Terminate the study   Withdraw approval |
| **Primary Reviewer** | *<Name and Signature>* |
| **Date of Recommendation** | *<Date>* |