

**SAE/SUSARS (Form 4.2)**

IRB Protocol Code: Date Received (D/M/Y):

Protocol Title: Sponsor:

Type of AE:

SAE SUSAR

On-site



Off site (International)



Off site (National)

Principal & Sub

Investigators: Site of SAE:

**A: SUMMARY OF SIGNIFICANT DATA:**

|  |  |  |
| --- | --- | --- |
| **Name of the study medicine/medical device:** | **Date Reported to Principal Investigator:** | |
| **Type of report:**   * Initial * Follow-up * Final | |
| **Date of first use:** | **Date of Event:** | |
| **Patient’s Initial/Number:** | **Age:** | * Male * Female |
| **Patient’s Date of Birth:** | **Weight:** kg  **Height:** cm | **SAE/SUSAR Severity:**   * Mild * Moderate * Severe |
| **Relevant medical history and concurrent conditions:** | | |

1. **SAE CRITERIA:**

|  |  |
| --- | --- |
| **Check all appropriate adverse event:**   * Patient died * Involved or prolonged inpatient hospitalization * Involved persistence or significant disability or incapacity | * Life threatening * Congenital anomaly |

1. **SUSPECT DRUG/S INFORMATION:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Suspect drug/s (include generic name):** | | | **Did reaction abate after stopping drug?**   * Yes * No * NA | |
| **Daily dose/s:** | | **Route/s of administration:** | **Did reaction appear after reintroduction?**   * Yes * No * NA | |
| **Indication/s for use:** | | |
| **Therapy date/s: (from/to)** | | **Therapy duration:** | | |
| **Is this reaction** 🞏Unexpected 🞏 Expected 🞏Related 🞏 Unrelated | | | | |
| **Treatment given for Adverse Event (Corrective and Preventive Action):** | | | | |
| **Causality Assessment by Investigator (Using WHO-UMC Causality Assessment System)**   * Certain * Probable * Possible * Unlikely * Unclassifiable | | | | |
| **Outcome of reaction/event at the time of last observation:** | | | | |
| * Recovered * Recovering with sequelae * On-going | * Death * Unknown | | |  |

**INVESTIGATOR’S ATTESTATION**

I certify that the information provided in this report is complete and accurate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature over Printed Name of Principal Investigator Date

*(IRB Use only)* Received by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature over Printed Name Date

**SECTION 2: TO BE FILLED UP BY MEMBER-SECRETARY & PRIMARY REVIEWERS**

|  |
| --- |
| **Type of Review**  **Expedited Full Board** |

**Summary of Recommendations:**

**Decision:**

**( ) Request an amendment to the** protocol **or the consent form.**

**( ) Request further information**

**( ) Recommend further Action (indicate action)**

**( ) Take Note and No Further Action needed**

**( ) Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Acknowledged by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name and Signature of Member- Secretary**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name and Signature of Primary Reviewer**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name and Signature of Primary Reviewer**