

**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**