Form 16A.1 SAE and SUSAR Report

**Eastern Visayas Health Research and Development Consortium - Ethics Review Committee**

***SAE AND SUSAR REPORT***

| Principal Investigator: | Protocol Code: | | |
| --- | --- | --- | --- |
| Study Protocol Title: | | | |
| Name of the study medicine/device | | Report Date: <dd/mm/yyyy>  ERC Submission Date: <dd/mm/yyyy>   * Initial * Follow-up   Onset date: <dd/mm/yyyy> | |
| Sponsor: | | Date of first use: | |
| Patient’s Initial/Number: | | Age: | * Male * Female |
| Patient’s Date of Birth: dd/mm/yyyy | | Weight: kg | Height: cm |
| Relevant medical history and concurrent conditions: | | | |

**SAE/SUSAR**

1. **REACTION INFORMATION:**

| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (use CIOMS definition)  List all relevant tests/ lab data: | Check all appropriate to adverse reaction:   * Patient died * Involved or prolonged inpatient hospitalization * Involved persistence or significant disability or incapacity * Life threatening |
| --- | --- |

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 | | | | |
| Treatment given for Adverse Event: | | | | |
| 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 | * Recovering with sequelae * Not recovering | | | * Death * Unknown |

1. **CONCOMITANT DRUG/S AND HISTORY:**

| Concomitant drug/s and dates of administration (exclude drug used to treat reaction) |
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| Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) |

| **RECOMMENDED ACTION: (for ERC use only)**   * NO FURTHER ACTION * REQUEST INFORMATION: (indicate information) * RECOMMEND FURTHER ACTION: (indicate action) * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | |
| --- | --- | --- | --- |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> |