Form 16A.2 SAE and SUSAR Summary Report

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

***SAE AND SUSAR SUMMARY REPORT***

**☐ ONSITE / ☐ OFFSITE**

|  |  |
| --- | --- |
| **PROTOCOL TITLE** |  |
| **DRUG/INTERVENTION** |  |
| **ERC CODE** |  |
| **TITLE** |  |
| **PRINCIPAL INVESTIGATOR** |  |
| **DATE OF REPORT/S** |  |
| **DATE OF MEETING** |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Report No.** | **Reaction (Initial/Follow-up)** | **Report Date/ Date Received by ERC** | **Off-site / On-site** | **Onset/ Stop of SUSAR/ Outcome** | **Date Drug Started/ Stopped** | **Age** | **Sex** | **Country** | **Comorbidities** | **Causality/Assessment of Investigator** | **Causality/Assessment of Sponsor** | **Action** | **Reviewers Causality Assessment/ Comments/ Reason** |
| **1.** | <Reaction>  **(Initial/Follow-up)** |  |  |  |  |  |  |  |  |  |  |  |  |
| **2.** | <Reaction>  **(Initial/Follow-up)** |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Total Number of New Events | = |  | Total Number of Unclassifiable | = |  |
| Total Number of Certain | = |  | Total Number of Deaths | = |  |
| Total Number of Probable | = |  | Items Which Need Follow-up | = |  |
| Total Number of Possible | = |  |  |  |  |
| Total Number of Unlikely | = |  |  |  |  |
| Total Number of Conditional | = |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **RECOMMENDED ACTION: (for EVHRDC-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 | | | |
| **COMMENTS/ ASSESSMENTS OF SAE/SUSAR REPORT:** | | | |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> |