**Serious Adverse Event/s Report**

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| --- | --- | --- | --- |
| Principal Investigator: | MMMC-RERC Code: | | |
| Study Protocol Title: | | | |
| Name of the study medicine/device | | Report 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: | | | |

1. **REACTION INFORMATION:**

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| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (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: | | Routes 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 Naranjo Algorithm – ADR probability Scale)  ≥ 9 Definite  5 to 8 Probable  1 to 4 Possible  0 Doubtful | | | | |
| 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) |
| Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) |

1. **MANUFACTURER’S INFORMATION**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name and address of manufacturer: | | | | |  |
| Manufacturer control no. | | |  | |  |
| Date received by manufacturer: dd/mm/yyyy | | | Report source  Study  Literature  Health professional | |  |
| Date of this report: dd/mm/yyyy | | | Report type  Initial  Follow-up | |  |
| **PRINCIPAL INVESTIGATOR SIGNATURE:** | | | | | |
| Causality Assessment By PRIMARY REVIEWER (Using Naranjo Algorithm – ADR probability Scale)  ≥ 9 Definite  5 to 8 Probable  1 to 4 Possible  0 Doubtful | | | | | |
| **RECOMMENDED ACTION:** *(for MMMC-RERC use only)*  Acknowledged/No further action  Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks  Recommend implementation of additional procedures for protecting/ safeguarding participants;  Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency)  Request information  Recommend suspension of the entire study | | | | | |
| **PRIMARY REVIEWER** |  | Signature | |  | |
| Date: <dd/mm/yyyy> |  | Name | | <Title, Name, Surname> | |
| **CHAIRMAN** |  | Signature | |  | |
| Date: <dd/mm/yyyy> |  | Name | | <Title, Name, Surname> | |