**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-upOnset 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:**

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| --- |
| 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> |