**Suspected, Unexpected, Serious Adverse Event/Reaction/s Report**

|  |  |
| --- | --- |
| Principal Investigator: | UPMREB Code: |
| Study Protocol Title:  |
| Initial Approval Date: <dd/mm/yyyy> |
| Date of Last Continuing Review Approval: <dd/mm/yyyy>Reason, if no CRA Approval:* Pending SJREB Approval
* Less than 10 months since last initial approval
* No CRA Submission
* Others (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| Version and date of latest approved protocol: |
| Version and date of latest approved ICF: |
| Name of the study medicine/device  | Report Date: dd/mm/yyyyIREB 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:  |

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) |
| 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
 |  |

|  |
| --- |
| **RECOMMENDED ACTION: (for UPMREB 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> |