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

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| 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/yyyy  IREB 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:**

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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: | | 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:**

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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 |  |

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| **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> |