**SAE AND SUSAR ReportS Summary**

|  |  |
| --- | --- |
| **STUDY PROTOCOL INFORMATION** | |
| Drug/Intervention: |  |
| UPMREB Code: |  |
| Title: |  |
| Principal Investigator: |  |
| Date of Report/s: |  |
| Date of Meeting: |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Report No.** | **Reaction**  **(Initial/Follow-up)** | **Report Date/**  **Date Received by UPMREB** | **Offsite/**  **Onsite** | **Onset/**  **Stop of SUSAR/**  **Outcome** | **Date Drug Started/ Stopped** | **Age** | **Sex** | **Country** | **Comorbidities** | **Causality Assessment of Investigator** | **Causality Assessment of Sponsor** | **Action** | **Reviewer’s Causality Assessment/**  **Comments/**  **Reasons** |
| 1 | **<Reaction>**  **(Initial/Follow-up)** |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | **<Reaction>**  **(Initial/Follow-up)** |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Total Number of New Events | = |  | | |
| Total Number of Certain | = |  | | |
| Total Number of Probable | = |  | | |
| Total Number of Possible | = |  | | |
| Total Number of Unlikely | = |  | | |
| Total Number of Conditional | = |  | | |
| Total Number of Unclassifiable | = |  | | |
| Total Number of Deaths | = |  | | |
| Items Which Need Follow-up | = |  | | |
|  | | | | |
| **RECOMMENDED ACTION:**   * No further action * Request information: (indicate action) * Recommend further action: (indicate action) * Pending, if major clarifications are required before a decision can be made | | | | |
|  | | | | |
| **COMMENTS/ ASSESSMENT OF SAE/SUSAR REPORT:** | | | | |
|  | | | | |
| **SAE COMMITTEE PRIMARY REVIEWER** | | | Signature |  |
| Date: <dd/mm/yyyy> | | | Name | <TITLE, NAME, SURNAME> |