**SAE AND SUSAR ReportS Summary**

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| --- |
| **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
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| **COMMENTS/ ASSESSMENT OF SAE/SUSAR REPORT:** |
|  |
| **SAE COMMITTEE PRIMARY REVIEWER** | Signature  |  |
| Date: <dd/mm/yyyy> | Name | <TITLE, NAME, SURNAME> |