**Suspected Unexpected Serious Adverse Reaction (SUSARs) Summary Report**

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| **STUDY PROTOCOL INFORMATION** | | | | | | | |
| **MMMC-RERC Code:** | |  | | | | | |
| **Study Protocol Title:** | |  | | | | | |
| **Principal Investigator:** | | <Title, Name, Surname> | | | | | |
| **No. of Events:**  **No. of Offsite Events:** | |  | | | | | |
|  | |  | | | | | |
| **Date of Event** | **Case ID** | **Age** | **Country** | **Event** | **Co-morbidities** | **Outcome of Event** | **Causality Assessment of Sponsor** |
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| **Signature of Principal Investigator**  Date: <dd/mm/yyyy> |
| **RECOMMENDED ACTION:**   * No actions required, study to continue * 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 enrollment of new participants or research procedures among participants who are currently enrolled (check consistency) |
| **JUSTIFICATION FOR RECOMMENDED ACTION** *(To be filled out by MMMC-RERC)* |
| **PRIMARY REVIEWER** Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** <dd/mm/yyyy> Name <Title, Name, Surname>\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **CHAIR** Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** <dd/mm/yyyy> Name <Title, Name, Surname>\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **RERC ACTION:**   * No further action * Recommend further action * Request information |