**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)
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| **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
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