**SAE / SUSAR REPORT SUMMARY**

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| **STUDY PROTOCOL INFORMATION** |
| **MMMC-RERC Code:** |  |
| **Study Protocol Title:** |  |
| **Principal Investigator:** | <Title, Name, Surname> |
| **No. of Events:** |  |
| **No. of Onsite Events:**  |  |
| **Date Report** | **Report #** | **Case ID** | **Number of****Events** | **Nature of Events** | **Initial/****Follow Up** | **Follow Up of Event** | **Final Diagnosis/Outcome of Event (Resolved, Stable, Improving, Progressing, Death** |
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| **Signature of Principal Investigator**Date: <dd/mm/yyyy>  |
| **RECOMMENDED ACTION:**[ ] Acknowledged/No further action [ ] 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)[ ] Request information [ ] Recommend suspension of the entire study |
| **JUSTIFICATION FOR RECOMMENDED ACTION** *(To be filled out by MMMC-RERC)* |
| **PRIMARY REVIEWER** | SignatureName |  |
| Date: | <Title, Given Name, Surname> |
| **CHAIR** | Signature |
| Date: | Name | <Title, Given Name, Surname> |