SAE SUMMARY SHEET Clinical Investigations of Medical Devices (CIMD)

|  |  |  |
| --- | --- | --- |
| **Study Title:** |  |  |
|  |  |  |
| **Participant ID:** |  |  |
|  |  |  |
| **Date of Onset:** |  |  |
|  |  |  |
| **TARA Case Number:** |  |  |

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| --- | --- | --- |
| **Initial Report** | | |
| **Event Classification:**  (If SADE or USADE add and complete the Appendix 2 after this table) | **SAE**  **SADE** **USADE**  **Device deficiency** | |
| **Date received:** |  | |
|  | **Date** | **Initials** |
| **Acknowledgement of reception (AOR) sent:**  (including request of missing/unclear information and clarification about events that might have been reported in error as per protocol, check that correct version of the form was used) |  |  |
| **Onward reporting (OR) performed if required**  **(N/A if not required):** |  |  |
| **Electronic copy of SAE + AOR + OR (if performed) saved in appropriate folder on Sharepoint:** |  |  |
| **Entered on SAE database**  **(Within 5 working days of receipt)** |  |  |
| **Database case QC performed** |  |  |
|  | | |
| **Is the report completed?** | **YES**  **NO** | |
|  | **Date** | **Initials** |
| **If Yes: Completed SAE form printed and filed in paper folder** |  |  |
| **If No: FU scheduled in TARA Tracker** |  |  |
| **ALL SAES** | | |
| **Add event to cumulative excel spreadsheet for SAE reporting for the CIMD** |  |  |
| **Cumulative spreadsheet sent to MHRA** (within 2 calendar days for SAEs which indicate an imminent risk of death, serious injury or serious illness and that requires prompt remedial action for other subject/users or other persons. All other SAES must be reported within 7 calendar days) |  |  |
| **Documentation QC** |  |  |
| **Comments** (highlight any important documents for printing)**:**  **Outstanding info:** | | |

*Copy/Paste appendices here if necessary*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **GOVERNANCE SIGN OFF** | | | | |
| To be signed once all follow-up/queries are resolved, database has been updated and QC of the database completed | | | | |
| Print Name: |  | Date: |  |  |

**Please note, Appendices are for copy/paste if necessary, they are not for being printed if not used**

**APPENDIX 1**

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| --- | --- | --- |
| **Follow-up Report number xxx** | | |
| **Event Classification:**  (If event classification was updated to SADE or USADE add and complete the Appendix 2 after this table) | **SAE**  **SADE** **USADE**  **Device deficiency** | |
| **Date received:** |  | |
|  | **Date** | **Initials** |
| **Acknowledgement of reception (AOR) sent:** |  |  |
| **Onward reporting (OR) performed if required**  **(N/A if not required):** |  |  |
| **Electronic copy of SAE + AOR + OR (if performed) saved in appropriate folder on Sharepoint:** |  |  |
| **Entered on SAE database**  **(Within 5 working days of receipt)** |  |  |
| **Database case QC performed** |  |  |
|  | | |
| **Is the report completed?** | ​​  ​ **YES**  ​ **NO** | |
|  | **Date** | **Initials** |
| **If Yes: Completed SAE form printed and filed in paper folder** |  |  |
| **If No: FU scheduled in TARA Tracker + insert FU table from Appendix 1 under this table** |  |  |
| **ALL SAES** | | |
| **Add event to cumulative excel spreadsheet for SAE reporting for the CIMD** |  |  |
| **Cumulative spreadsheet sent to MHRA** (within 2 calendar days for SAEs which indicate an imminent risk of death, serious injury or serious illness and that requires prompt remedial action for other subject/users or other persons. All other SAES must be reported within 7 calendar days) |  |  |
| **Documentation QC** |  |  |
| **Comments** (highlight any important documents for printing)**:**  **Outstanding info: :** | | |

**APPENDIX 2**

**For blinded study, create a new page with appendix 2 containing the unblinded info and save it on the restricted access folder on Sharepoint**

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| --- | --- | --- |
| **EXPECTEDNESS ASSESSMENT/RATIONALE IF RELATED TO DEVICE ONLY** | | |
| **Confirmation that expectedness has been checked against protocol/CIP by Sponsor:** | | |
| **Name of device(s) checked** |  | |
| **Protocol/CIP version number:** |  | |
| **Is the event expected** | ​​  ​ **YES**  ​ **NO** | |
| **Comments** |  | |
| **Check performed by (Name and date)** |  | |
| **Check QC by (Name and date)** |  | |
| **USADEs ONLY** | | |
|  | **Date** | **Initials** |
| Reported to the REC (a copy must be filed) |  |  |
| Reported to all sites  (make sure you can see all the sites CC in the emails shared by TM, if not TM has to be challenged about that). |  |  |
| Is the Device also used in another open trial?  ☐ YES – name of the trial(s):  ☐ NO |  |  |
| If Yes: CI from the other trial(s) informed that a potential USADE was reported for this Device |  |  |
| **Documentation QC** |  |  |

**APPENDIX 4**

*To be added at the end of the document and contain all FU requests that were sent for that case*

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| --- | --- | --- |
| **Chasing for missing info – Follow-up requests** | | |
| **Date FU request sent** | **Initials** | **Comments (if applicable)** |
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