SAE SUMMARY SHEET CTIMPs / Non-CTIMPs

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

|  |  |  |
| --- | --- | --- |
| **Initial Report** | | |
| **Event Classification:**  (If SAR add and complete the Appendix 2 after this table  If SUSAR add and complete Appendices 2 AND 3 after this table)  *Note: F/LT SARs are treated like SUSARs* | **SAE**  **SAR**  **SUSAR**  **Pregnancy** | |
| **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** |  |  |
| **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 SAR add and complete the Appendix 2 after this table / If event classification was updated to SUSAR add and complete Appendices 2 AND 3 after this table)  *Note: F/LT SARs are treated like SUSARs* | **SAE**  **SAR**  **SUSAR**  **Pregnancy** | |
| **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) |  |  |
| **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** |  |  |
| **Comments** (highlight any important documents for printing)**:**  **Outstanding info:** | | |

**APPENDIX 2**

**For blinded study, create a new page with appendices 2 and 3 containing the unblinded info and save it on the restricted access folder on Sharepoint**

**CTIMP:**

|  |  |
| --- | --- |
| **CTIMPs: EXPECTEDNESS ASSESSMENT/RATIONALE ON SAE FORM (IF RELATED TO IMP / NIMP ONLY)** | |
| **Confirmation that expectedness has been checked against approved RSI at the time of event(s) by Sponsor** | |
| ☐ **IMP** | |
| **Name of IMP(s) checked** |  |
| **Revision of text date of RSI sponsor used to assess expectedness (IMP):** |  |
| **MedDRA Term for Diagnosis**  **(PT and SOC)** |  |
| **Is the PT listed in the approved RSI?** | **YES**  **NO** |
| **Is the event expected** | **YES**  **NO** |
| ☐ **NIMP** (delete this section if not applicable) | |
| **Name of NIMP(s) checked** |  |
| **Revision of text date of RSI sponsor used to assess expectedness (NIMP):** |  |
| **MedDRA Term for Diagnosis**  **(PT and SOC)** |  |
| **Is the PT listed in the approved RSI?** | **YES**  **NO** |
| **Is the event expected** | **YES**  **NO** |
|  | |
| **Coded by (Name and date)** |  |
| **Coding QC by (Name and date)** |  |
| **Comments** (highlight any important documents for printing)**:** | |

**Non-CTIMP:**

|  |  |
| --- | --- |
| **Non-CTIMPS : EXPECTEDNESS ASSESSMENT/RATIONALE ON SAE FORM (IF RELATED TO STUDY INTERVENTION / CIA ONLY)** | |
| **Confirmation that expectedness been checked against protocol/IB by Sponsor:** | |
| **Name of Study Intervention / CIA checked** |  |
| **Protocol / IB version number:** |  |
| **Is the event expected** | **YES**  **NO** |
| **Comments** |  |
| **Check performed by (Name and date)** |  |
| **Check QC by (Name and date)** |  |

**APPENDIX 3**

**For blinded study, create a new page with appendices 2 and 3 containing the unblinded info and save it on the restricted access folder on Sharepoint**

**CTIMP:**

|  |  |  |
| --- | --- | --- |
| **CTIMP SUSAR ONLY (related / possibly related and unexpected SAEs)** | | |
|  | **Date** | **Initials** |
| Confirm with site PI that event is unexpected and related |  |  |
| SUSAR sent to CI for review/comment. CI **cannot** downgrade a SUSAR, but comments should be included with report to REC/MHRA.  If CI does not respond within 3 days, further contact should be made. |  |  |
| **For blinded trials**, treatment allocation must be unblinded.  \*\* Do not inform the CI or any of the research team of the unblinded information \*\* |  |  |
| **For blinded trials**  Unblinding information entered onto the unblinding spreadsheet on SHAREPOINT |  |  |
| **Where participant has received study intervention / IMP only**.  The following onward reporting must take place within **7 days** for fatal or life threatening SARs/SUSARs or **15 days** for all other SUSARs: | | |
| SUSARs should be reported to the MHRA using the ICSR web portal (a copy must be filed) |  |  |
| Reported to the REC if required (a copy must be filed) |  |  |
| **ALL SUSARS**: SUSAR reported issued to all sites regardless of whether participant received trial intervention or placebo (make sure you can see all the sites CC in the emails shared by TM, if not TM has to be challenged about that) |  |  |
| **ALL SUSARS:** Is the IMP 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 SUSAR was reported for this IMP** |  |  |
| **SUSAR reports documentation QC:** |  |  |

**Non-CTIMP:**

|  |  |  |
| --- | --- | --- |
| **Non-CTIMP related / possibly related and unexpected SAEs (“SUSAR”)** | | |
|  | **Date** | **Initials** |
| Confirm with site PI that event is unexpected and related |  |  |
| “SUSAR” sent to CI for review/comment. CI **cannot** downgrade a “SUSAR”, but comments should be included with report to REC.  If CI does not respond within 3 days, further contact should be made. |  |  |
| **For blinded trials**, treatment allocation must be unblinded.  \*\* Do not inform the CI or any of the research team of the unblinded information \*\* |  |  |
| **For blinded trials**  Unblinding information entered onto the unblinding spreadsheet on SHAREPOINT |  |  |
| **Where participant has received study intervention / CIA only**.  The following onward reporting must take place within **15 days**: | | |
| Reported to the REC if required (a copy must be filed) |  |  |
| **ALL “SUSARS”**: “SUSAR” reported issued to all sites regardless of whether participant received trial intervention or placebo. |  |  |
| **“SUSAR”  reports 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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|  |  |  |
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