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|  | **G:\CTRG\Admin\Logo JRO\JRO_Logo_landscape_small.jpg** | **Guidance for customising the** **Template SAE Report Form** |

Guidance for customising the Template SAE Report Form

**University of Oxford Sponsored trials:**

CTIMP trials required by protocol to submit SAE reports to the Joint OUH/University of Oxford Trial Safety Group for oversight purposes, should submit their customised SAE Form as part of the trial sponsorship review process.

Other CTIMP and non-CTIMP trials sponsored by the University of Oxford that do not report to the Joint TSG may customise the template SAE Form as appropriate to their research project before use. *Note: all trials, regardless of the source of their SAE form, may be required to a provide a copy of the trial specific SAE form as part of the sponsorship review process.*

All researchers should review the generic SAE Report Form Completion Guidelines Document that accompanies the SAE Form template and consider if any additional completion guidance may be needed as a result of the changes made, and how best to provide that guidance to investigator(s) site(s).

***SAE identifier:*** State if field is for office use only. If the site will complete it then consider providing an example of the format. If the SAE identifier has a site-specific suffix or prefix consider prepopulating that element on the form at site set-up.

***SAE Form Header:*** Make the trial’s SAE Form easily identifiable by

inserting trial logo, short title / acronym, sponsor logo etc.

Consider adding ‘office only’ fields to the header for each page for data that may be useful

when processing the SAE at the coordinating centre. See Example section at end of document.



***Study Name:*** Complete with Protocol Long or Short title at study set-up to mitigate error

***EudraCT or REC reference:*** Complete appropriate identifier field(s) at study set-up to mitigate error; ***Site & PI name*** consider prepopulating at site set-up.

***Height & Weight:***if using these fields then specify the unit of measurement.

For CTIMPs, note that the MHRA eSUSAR Reporting form requires height in metres and weight in kilos.

***Age: Do not use D.O.B.***

Paediatric trials could consider if “Age in months at time of event occurrence” is useful.

***Time:***if not using this field**,** delete field or make it clear that completion of time field is not required.

***Severity:*** Ensure SAE Form reflects the system for grading the severity of AEs detailed in the trial protocol.

***Note severity does not determine if the event meets the definition of seriousness.***

***Diagnosis or Main Event Term:*** If the protocol requires the SAE reporter to provide the main diagnosis or ‘Main Event Term’ in accordance with a coding system such as MedDRA, then add an instruction to that effect to the SAE form or to the trial’s SAE completion guidance document. Specify the level of term required to avoid unnecessary data queries. E.g. ‘Use *MedDRA* *Preferred Level Term* when reporting SAEs’.

Following any ***adaptations to coded items*** on the SAE Form - ensure that the Code list on page 2 of the SAE form remains consistent with the changes and with the trial protocol.

Consider pre-populating the **Study Drug / Intervention column** with the actual name(s) of the relevant interventions. Where coded names are used e.g. *IMP 1*, *Study Drug 1, Surgical Intervention 1* etc. then a Code list should be added to the Coding table on Page 2 of the SAE Form.

***Study Medication / Intervention section:* Adapt the column headers and the number of columns in line with the type of study intervention, level of blinding\* and whether the assessment of expectedness is being made at site level (as here on the template SAE Form) or centrally by the CI or CTU team etc. (\***see note **on Double-blind trials** bottom of page 3).

***Expectedness:*** if the assessment of expectedness will **not** be made at site level delete field or make it clear that the completion of the field is not required. If deleting, then remove the column for that assessment from the Study Medication /Intervention section, and update the code list references above the assessment columns and the Code list on page 2 of the form. Consider who will be making the assessment of expectedness and how that will be recorded – e.g., on a separate additional SAE Form page used at the coordinating centre only, or using an *‘Office only’* field on the SAE Form itself (which would be added when customising the SAE Form template) etc.

‘Other treatments’ section and ‘Additional information’ sections capture **alternative causes for the SAE** being reported.

If providing the SAE form to investigator(s) site(s) as a PDF to be printed and completed by hand, then consider lengthening the free text sections of the SAE Form before finalising it , or providing an extra page badged with the SAE Form Header and Footer for use as an ‘Additional Information’ page.



***Causality:*** The template coding options are ‘unrelated’ and ‘related’. If the trial protocol specifies degrees of causality e.g. definitely related, probably related, possibly related, not related etc., then update the coding table in the SAE Form template in line with the protocol before finalising the trial specific SAE Form for use.

Consider setting up a generic trial specific email address, or a dedicated safety reporting email address to ensure SAEs are picked up by the central trial management team asap.

If there are fields on the template SAE form – including in the CODE LIST - that are non-applicable to the trial delete the fields or make it clear that completion of those fields is not applicable so as to avoid unnecessary data completion queries.

If the assessment of ***expectednes***s will be made a site level then insert instructions on where to find the list of expected events into the code list.

For CTIMPs, expected events are listed in the current approved reference safety information - i.e., a specified section of the IB or SmPC.

For non-CTIMPs, expected events would be listed in a specified section of the protocol.

***Double-blind trials****:* The protocol should include instructions on when and how unblinding can be undertaken and how that impacts on the trial’s safety reporting processes. Unless the blind has been broken, the reporter at site will not know which intervention a participant has received, and therefore would not know the name of the intervention/drug, dose information or batch number. Consider what information site(s) can provide without breaking the blind; perhaps that is the date(s) of administration only. Adapt the ***Study Medication / Intervention and Code list*** sections of the SAE Form accordingly to avoid confusion and unnecessary queries from investigator(s) site(s). Add clear instruction in the Code list on page 2 of the SAE Form template so the reporter knows how to complete the assessment of causality [e.g., that the reporter should assume that the intervention was received, and assess against that rather than the placebo.]

**EXAMPLES**

1. Example administrative fields for headers or footers of each SAE page

|  |  |
| --- | --- |
| ***Example - Office use only*** | |
| SAE identifier |  |
| Participant ID |  |
| Date received |  |
| Number of pages |  |

2. Example footer with SAE Form template and Trial specific SAE Form versioning information

SAE Form Template\_v3.0\_01Oct2020 ©Copyright The University of Oxford 2020 (with acknowledgment to the MRC SAE form)

Study title or acronym\_SAE Form\_v2.0\_02Oct2020 Page X of Y

3. Example Study Intervention section with completed event assessments (using code lists from template SAE form).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Example A: Study Medication / Intervention** | | | | Refer to code list C, D, E for below | | |
| **Study Drug / Intervention**  (List all study interventions and for study drugs indicate their route using code list B) | **Date of first administration**  dd/mm/yyyy | **Date of most recent administration**  dd/mm/yyyy | **Actual dose given at most recent administration with batch number** | **Causal**  **relationship to SAE** | **Expectedness\*\*(For related events only)** | **Action taken due to SAE** |
| IMP NAME 1 (route 1) | 12/02/2020 | 08/09/2020 | 20mg (GK1234) | 0 |  | 0 |
| IMP NAME 2 (route 2) | 02/03/2020 | 27/08/2020 | 112mg (AF1234) | 1 | 1 | 1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Example B: Study Medication:** | | | Refer to code list C, D, E for below | | |
| **Study drug start date**  dd/mm/yyyy | **Stop date / most recent dose date**  dd/mm/yyyy | | **Causal**  **relationship to SAE** | **Expectedness (For related events only)** | **Action taken due to SAE** |
| 01/08/2020 | 23/09/2020 | | 0 | n/a | 0 |
| **Blind broken?** | No | Yes |  | | |
| **If blind broken name of study intervention** | |  | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Example C: Study intervention:** | | | Refer to code list C, D, E for below | | |
| **Date of surgery**  dd/mm/yyyy | | | **Causal**  **relationship to SAE** | **Expectedness (For related events only)** | **Action taken due to SAE** |
| 01/09/2020 | | | 1 | 2 | 0 |
| **Blind broken?** | No | Yes |  | | |
| **If ‘Yes’, confirm if Test intervention or Standard of care (SOC) received?** | | Test intervention | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Example D: Study intervention** | | | | Refer to code list C, D, E for below | | |
| **Study Drug / Intervention** | **Date of surgery and IMP**  **administration (dd/mm/yyyy)** | | **Route** (Code B) | **Causal**  **relationship to SAE** | **Expectedness (For related events only)** | **Action taken due to SAE** |
| ‘Surgical Intervention 1’ | 01/09/2020 | | n/a | 1 | 2 | 2 |
| ‘IMP NAME 1’ |  | |  |  |  |  |
| IMP administered? | No | Yes |  | | | |