|  |  |  |
| --- | --- | --- |
|  | **G:\CTRG\Admin\Logo JRO\JRO_Logo_landscape_small.jpg** | **SAE Report Form Completion Guidelines** |

Serious Adverse Event Reporting Form Completion Guidelines



***Seriousness:*** If there is more than one criterion, applicable to the event, choose the most ***significant*** one. Seriousness is a regulatory definition and should not be confused with severity.

***SAE Identifier:*** Field is for office use only

***Site awareness:*** Enter date and the time that the first member of the study team at site is aware of the SAE

**SAEs must be reported *immediately* i.e., within 24 hours of site awareness**

***Report type:*** The first time the event is reported is the Initial report. Any follow up information (including signatures) is a Follow Up report.

Note: A follow up report is necessary if there is no SAE stop date at the time the initial report is sent (because the event is ‘ongoing’ etc.). The SAE Outcome will usually need to be updated when an SAE Stop Date is added.

***Narrative:*** Provide an account of the event, similar in format to that of a discharge summary. The description must have sufficient details for evaluation by the individuals reviewing the SAE who may not be experts in the disease area or investigational medicinal products (IMPs). Mention and summarise any symptoms, any relevant medical history, underlying disease progression etc. Indicate if there are additional pages being submitted – relevant laboratory or imaging results for example.

***Note:*** Only 1 SAE should be reported on an SAE form. E.g. a heart attack which leads to a road traffic accident in which the participant fractures their skull, is at least 2 separate SAEs, the cardiac event, and the head fracture. Two separate SAE forms should be used to report the events.

**\*Events excluded from immediate reporting\*:** Check the protocol safety section - is the event being assessed for reporting as an SAE excluded from immedaite reporting in the protocol? There is no requirement to submit SAE reports for such events. Reports received for non-reportable events will not be assigned an SAE identifier, and will not be processed as SAEs. ***Please contact the Trial Office if in any doubt.***

***Expectedness:*** Events that are reported as being ***causally*** related to an intervention **must** also be assessed for expectedness.

See further guidance on this in the coding section

***Causality***: Causality must to be assessed by a medically qualified investigator (i.e. by a GMC registered medical doctor) at the site

***Participant ID:*** Do not enter participant (i.e., personal) identifiable data on the SAE report form

***Age:*** Enter age in years in years at time the event occurred.

*Do not enter Date of Birth***.**

**Study Name, EudraCT & REC reference**: If not pre-populated, then complete with Protocol Long or Short title & REC or EudraCT information as printed on the protocol title page

***Diagnosis:*** Report diagnosis using the MedDRA Preferred Term. Symptoms should be reported in the narrative section. In the case of death, please note that ‘death’ is not an event. Death is an outcome for an event. It is the cause of death that should be reported as the event.

***Severity***: This should not be confused with seriousness. Check protocol for relevant severity scale e.g. Mild, Moderate, Severe, or Grade 1, or 2 or 3 or 4 etc.



Last line item here is for use by studies required by protocol to report to the Joint OUH/ UoO TSG only. Do not complete it if N/A to study

**CODE LIST A-E**

**Expectedness for CTIMPs:** expected events are listed in the current Sponsor and Regulator approved reference safety information – which is a specific section of the IB or SmPC. ***Contact the Trial Office if in any doubt.***

**Note for OU sponsored studies required by Protocol to report to the Joint OUH/ UoO TSG, if the event is “related”, it is mandatory to provide the assessment of expectedness. The TSG medical monitor will not make that assessment on behalf of the trial team.**

***Reporter versus causality assessor:***

The reporter may be a different person from the person who assesses causality. Causality must be assessed and assigned by a medically qualified doctor

|  |
| --- |
| **Guidance on expedited reporting of events that are Related and Unexpected**  |
| **Study type** | **Unexpected + related to**  | **Coordinating centre to expedite the report to** |
| **CTIMP** | The trial IMP | This is a SUSAR. Report the SUSAR to the MHRA and to the REC within statutory reporting timelines. See protocol safety section for further details.  |
| **CTIMP** | A possible interaction between the trial IMP and trial non-IMP | This is a SUSAR. Report the SUSAR to the MHRA and to the REC within statutory reporting timelines. See protocol safety section for further details. |
| **CTIMP** | A trial challenge agent  | Not a SUSAR. See protocol for additional safety related requirements  |
| **CTIMP** | The protocol mandated rescue medicines e.g., antibiotics following challenge agent  | Not a SUSAR. See protocol for additional safety related requirements |
| **Non-CTIMP** | Any of the invasive research procedures | This is an SAE that is related and unexpected. Report to the REC that gave favourable opinion to the study. See Protocol safety section for timelines and any additional requirements. |

***Other treatments***: Supplemental medications pages and CRF print outs may be attached to the SAE report form so long as they cover the information as defined by the column headers here.

*Be alert* ***not to send personally identifiable data*** *on any of the supplemental pages*

Add ***reason for late reporting*** of the SAE here (if applicable)

***Remember to sign the SAE form before submitting it***

If not already outlined in narrative section overleaf then please describe ***relevant medical history, family history*** ***etc.*** The description must have sufficient details for evaluation by the individuals reviewing the event who may not be experts in the disease area.

Please include the participant ID number (and SAE identifier if known) on any additional pages sent with the SAE report form