Quality Control Document:

Serious Adverse Event (SAE) Form Template

# Purpose

This document contains a template form that can be used to document any serious adverse events (SAE), as they occur in participants during clinical trials of investigational medicinal products (CTIMPs). Its use is optional. This template can also be adapted for use in other types of research projects.

# Instructions

1. Remove this first instruction page.
2. When using this template, please amend it to make it project specific, e.g. text in red.
3. Update the identifier in the header e.g. study/trial identifier or research group.
4. Update the footer, retaining the document reference information relating to this quality control document (QCD).
5. Site staff or the investigator who has been delegated the responsibility for completing SAE forms will complete the initial sections of the record (I to III and section V).
* An SAE report should only record details of a single event, as each event must be assessed individually to determine the possibility of any causal relationship.
1. The investigator (medically qualified or, when appropriate, a qualified dentist) will complete the causality assessment decisions (section IV and section VI).
2. The chief investigator (CI) (or delegate) will review the form and perform the expectedness assessment (sections VII to IX).
3. The CI (or delegate) will record all adverse events reported as per the Internal Process Example for SAE Handling (UoB-AES-QCD-002).
4. File completed versions of this record and all related correspondence in the relevant study/trial master file.

# Related documents

* UoB-AES-QCD-002 Internal Process Example for Serious Adverse Event (SAE) Handling
* UoB-AES-QCD-003 Pregnancy Notification Form
* UoB-AES-SOP-001 Adverse Event Reporting

Note the UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

I. Event information

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Participant id | Participant initials(first, last) | Country | Date of birth | Age | Sex | Event onset | Date site aware of onset | Event end date if known1 |
|  | Day | Month | Year | Years |  | Day | Month | Year | Day | Month | Year | Day | Month | Year |
| Describe event(s) and outcome (including relevant tests/lab data)1 | Check all appropriate to Adverse event:[ ]  Participant died[ ]  Life threatening[ ]  Involved or prolonged inpatient hospitalisation[ ]  Involved persistence or significant disability or incapacity [ ]  Congenital anomaly /birth defect[ ]  Other |

1: If outcome unknown, please forward follow up information when known

II. Suspect drug(s)/intervention information

|  |
| --- |
| Suspect drug/intervention: Drug dosage/details of intervention:Drug dosage interval:Form:Route of administration:Indication:Drug/intervention start date:Drug/intervention end date:Action taken: |
|
|
|
|
| Did event abate after stopping drug/ intervention?[ ]  yes [ ]  no [ ]  na | Did event reappear after reintroduction?[ ]  yes [ ]  no [ ]  na |

III. Concomitant drug(s) and history

|  |
| --- |
|  Concomitant drug(s) and dates of administration (exclude those used to treat event) |
|  Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)  |

IV. Causality

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  Other cause

|  |  |
| --- | --- |
| **Causality code** | **Category** |
| 1 | Unrelated |
| 2 | Unlikely to be related |
| 3 | Possibly related |
| 4  | Probably related |
| 5 | Definitely related |

Indicate below if this SAE was caused by another treatment (not listed above). For example **screening procedure, other drugs (including NIMPS), research project procedure, surgery, radiotherapy.** Cause:  Causality assessment (see codes): □ |

V. Person completing the form

|  |
| --- |
| Print name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Signature: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:** DD / MON / YYYY(You must have signed the site signature log) |

VI. Investigator

|  |
| --- |
| Print name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Signature: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:** DD / MON / YYYY**In signing this form the investigator confirms the seriousness, causality and outcome of the event** |

VII. Review of causality and assessment of expectedness

|  |
| --- |
| **For office use only:**Unique SAE reference number: review causality and assessment of expectednessAn assessment of expectedness should be performed if the SAE is classified as related (causality code 3-5) to the research project ***<medication/treatment>***. An assessment is not required if deemed related to “other cause”. If appropriate, enter the relevant code in the box below:If *<medication/treatment>* has yet to be given leave the assessment box blank |
|  Research project *medication/intervention* | Review of causalityEnter code | Assessment of expectednessEnter code |
|  Blinded treatment |       |       |
|  Specify imp 1 |       |       |
|  Specify imp 2 etc |       |       |
|  Specify research intervention |       |       |
|

|  |  |  |  |
| --- | --- | --- | --- |
| Causality Coded |  | Expectedness Codes |  |
| Unrelated | 1 | Expected | 1 |
| Related | 2 | Unexpected | 2 |

  |
| 1. Unexpected and related SAEs need to be reported in an expedited fashion:

CTIMPs: Non-fatal/non-life threatening SUSAR: Report to competent authority, ethics committee (15 days)CTIMPs: Fatal/life threatening SUSAR: Report to competent authority, ethics committee (7 days) Non-CTIMPs: Unexpected and Related SAE; Report to ethics committee (15 days) Unexpected and related SAE/SUSAR reports also need to be reported to the following: All reports: to Principal Investigators in a timely fashionAs applicable, all reports to the Sponsor contact as per their timelines |

VIII. Chief investigator or delegate performing expectedness assessment (if applicable):

|  |
| --- |
| Print name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Signature: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:** DD / MON / YYYY |

IX. Details of individual categorising SAE:

|  |
| --- |
| Print name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Signature: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:** DD / MON / YYYY |