**Notes**

The Adverse Event Log should be used as a template for adverse event (AE) data collection in Clinical Investigational of Medicinal Product (CTIMP) studies. This data set is the minimum that should be collected and should not be altered without the sponsor’s prior agreement.

**Guidance**

1. Ensure members of the research team have initialled the delegation or signature log so individuals initialling the AE log can be identified. If only a signature is collected on the delegation/signature log then the clinician/nurse must sign the AE form rather than just initial it.
2. AE logs should include the subject number and only one identifier containing patient identifiable information, usually this is the patient initials.

Date Resolved: the protocol should clearly identify the time period each adverse event should be followed up.

**MedDRA Codes**

**Please note, this section only applies to CTIMPs registered with EudraCT. If the protocol was submitted through the IRAS combined review system and is registered with ISRCTN, there is not a requirement to code AEs. Please adapt the AE log accordingly.**

As per EudraCT database requirements, there is a need to MedDRA code AEs to System Organ Class (SOC). There are 27 SOCs which are listed below and are for reference only. All adverse events must be coded using the online MedDRA browser (<https://tools.meddra.org/wbb/>).

For guidance on coding AEs to SOC please refer to the training section of the ACCORD website (www.accord.scot) and access the MedDRA Coding for Adverse Event (AE) Logs PowerPoint.

Further information can also be found on MedDRA training topic MedDRA Coding Basics (<http://www.meddra.org/training-materials>) which is available as a presentation and videocast for streaming or downloading.

To gain access to log in details to the MedDRA browser please contact the Pharmacovigilance team at [Safety@accord.scot](mailto:Safety@accord.scot)

Note: The same version of MedDRA should be used to code AEs throughout the duration of the trial.

**MEDDRA CODES**

These are for reference numbering only and should not be used to code. All adverse events must be coded using the online MedDRA browser.

1. Blood and lymphatic system disorders
2. Cardiac disorders
3. Congenital, familial and genetic disorders
4. Ear and labyrinth disorders
5. Endocrine disorders
6. Eye disorders
7. Gastrointestinal disorders
8. General disorders and administration site conditions
9. Hepatobiliary disorders
10. Immune system disorders
11. Infections and infestations
12. Injury, poisoning and procedural complications
13. Investigations
14. Metabolism and nutrition disorders
15. Musculoskeletal and connective tissue disorders
16. Neoplasms benign, malignant and unspecified (incl cysts and polyps)
17. Nervous system disorders
18. Pregnancy, puerperium and perinatal conditions
19. Product issues
20. Psychiatric disorders
21. Renal and urinary disorders
22. Reproductive system and breast disorders
23. Respiratory, thoracic and mediastinal disorders
24. Skin and subcutaneous tissue disorders
25. Social circumstances
26. Surgical and medical procedures
27. Vascular disorders

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| --- | --- | --- | --- |
| **Study Title** | **Site Location** | **Study Ref #** | **Principal Investigator** |
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| **Adverse event** | **Start date** | **SAE\***  1.Yes (also complete SAE form)  2. No | **Severity**  1. Mild  2. Moderate  3. Severe | **Causality**  1. Unrelated  2. Possibly  Related | **Expectedness+**  1. Expected  2. Unexpected  3. N.A. | **DATE of assessment and INITIALS of delegated clinician** | **Outcome**  1. Resolved  2. Ongoing | **Date Resolved** | **AE Recorded by (initials)** | **MedDRA CODE^**  **(number)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Version of MedDRA used** |
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*\*serious adverse event is one that (i) results in death, (ii) is life threatening, (iii) requires hospitalisation or prolongation of existing hospitalisation, (iv) results in persistent or significant disability or incapacity or (v) consists of a congenital anomaly or birth defect (vi) other medically significant event.*

*+ Only complete expectedness if event is possibly related. Where the event is unrelated expectedness should be marked as N.A*

***^*** *Please amend section accordingly. All adverse events must be coded using the online MedDRA browser for trials registered with EudraCT. See notes section above.*

*[Enter instructions here on what should be done with completed forms]*