Adverse Event Log

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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)** |
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*\*A 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.*

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

**Notes**

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

Certain types of study will require additional data to be collected:

1. For studies using a non-investigational medicinal product (NIMP) the causality data must be extended to include:
   1. Causality: IMP
   2. Causality: NIMP
   3. Causality IMP/NIMP

Additional information relevant to each particular study may also be collected if appropriate.

**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.