

Standard Operating Procedure

Title: ADVERSE EVENT AND SERIOUS ADVERSE EVENT REPORTING		
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1. BACKGROUND

ICH Good Clinical Practice guidelines require all adverse events and serious adverse events experienced by a research subject to be documented and reported.

1.1. Definitions:

The definitions of adverse event and serious adverse event are applied to any investigational product, including medical devices.

1.1.1. Adverse Event (AE) or Adverse Drug Reaction (ADR)

Any untoward medical occurrence, whether mild, moderate or severe, in a trial subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal (investigational) product. This may include, for example, a cold, or an accident.

1.1.2. Serious Adverse Event (SAE):

Any adverse event (as described above) that:

- Results in death
- Is life-threatening
- Results in patient hospitalisation or prolongs existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect

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1.1.3 Suspected Unexpected Serious Adverse Reaction (SUSAR):

- An adverse reaction, the nature and severity of which is not consistent with the applicable product information (eg as in Investigator's Brochure if product is unlicensed; SmPC if it has a license)

Other important medical events that may not be immediately life-threatening or result in death or hospitalisation, but that may jeopardise the patient or may require intervention to prevent any of the outcomes listed above may also be considered serious.

2. PURPOSE

To describe the procedure for eliciting, recording and reporting adverse and serious adverse events.

3. OTHER RELATED PROCEDURES

SOP 006 Study Files & Filing
SOP 009 Case Report Form (CRF) Completion

4. WHEN

At each visit or study assessment, adverse events that might have occurred since the previous visit, or that are occurring at that time should be elicited. Patients should also be encouraged from the outset of any study to contact the research team at the time of any adverse event where possible.

Adverse events ongoing at study completion should be followed up as per the requirements of the protocol and as clinically indicated.

5. WHO

All staff in contact with trial subjects are responsible for noting adverse events.

6. HOW

6.1. Adverse Event Reporting:

When an adverse event occurs, the following must be recorded in the patient's medical record and the study Case Report Form. Some study protocols may require completion of study-specific adverse event reporting forms. In addition, the Trust Risk Management Department must also be informed.

- Record each untoward occurrence as separate adverse events. For example, nausea and vomiting should be recorded as two adverse events.
- Document the nature of the adverse event(s) in an unambiguous way using precise and specific terminology

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- Record start and stop times and dates of the adverse event(s) as accurately as possible. Refer to the protocol for advice on estimate of dates.
- Document the severity of the adverse event(s) as guided by the study protocol (usually mild, moderate or severe).
- Document any action taken regarding the study drug or study procedures.
- Document any treatment/medication given or action taken in relation to the adverse event(s).
- Document the outcome of the adverse event(s).

6.2. Serious Adverse Event Reporting:

The study investigator shall report any serious adverse event, which occurs in a research participant at a trial site at which he is responsible for the conduct of a clinical trial immediately to the sponsor (except those specified in the protocol as not requiring immediate reporting).

An immediate report (within 24 hours) must be made orally or in writing.

The immediate report must be followed by a detailed written report on the event.

Requests from the sponsor for further information of the serious adverse event must be promptly responded to.

A Sponsor shall ensure that all relevant information about a suspected unexpected serious adverse reaction (SUSAR) which occurs during the course of a clinical trial in the UK is recorded and reported:

- To the MHRA
- To the appropriate Research Ethics Committee
- Not later than **7 days** after the sponsor was first aware of the reaction (fatal or life threatening)
- Not later than **15 days** for those not classified as fatal or life threatening.

Sponsors must ensure that in the UK all investigators are notified of any SUSAR that occurs in relation to that trial. A Sponsor must enter information on Eudravigilance database.