Great Western Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure: Safety Reporting

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1. BACKGROUND

This SOP covers Trial participant safety and highlights how Adverse Events and Serious Adverse Events should be reported. This will ensure that the rights, safety and wellbeing of trial participants are protected in line with ICH GCP guidance.

The definition of an **adverse event [AE]** is:

"Any untoward medical occurrence in a patient which does not necessarily have a causal relationship with this treatment". This includes "any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study drug". This may include, for example, a cold, or an accident.

The definition of a **serious adverse event [SAE]** is one that fulfils at least one of the following criteria:

- *Is fatal – results in death (NOTE: death is an outcome, not an event)*
- *Is life-threatening*
- *Requires inpatient hospitalisation or prolongation of existing hospitalisation*
- *Results in persistent or significant disability/incapacity*

Or

- *Is a congenital anomaly/birth defect*

The clinical trial protocol may outline how to classify certain events according to the specifics of the condition/medicinal product being investigated. Researchers are expected to refer to the protocol when reporting an AE or SAE.

If any Research staff are in doubt whether to report an occurrence as a SAE contact the clinical trial co-ordinating office for further advice

Some trials also want to collect information of **adverse events of special interest [AESI].** These will be defined in the protocol and the process for reporting them will be described.

2. PURPOSE

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

3. APPLICABLE TO

All research staff and clinicians, who have contact with trial participants, are responsible for noting adverse events as they are reported.
Patients entered into clinical trials must be encouraged from the outset of any study, [once informed consent has been given] to contact their research team at the time of an event occurring.
It is important that if patients are admitted to hospital that research staff are informed of the hospital admission as soon as possible.

The Principal Investigator or appropriately delegated individual is responsible for assessing the grade and potential causality of the event and must sign/date to acknowledge they are aware of the event.

4. PROCEDURE

Information is collected on adverse events that occur from the time of Informed Consent.

Once a patient has been entered into a clinical trial, a medical alert should be created on MEDWAY for that patient so that if they present at hospital, their health status can be communicated appropriately and events reported in a timely manner.

At each visit, or study assessment, adverse events that might have occurred since the previous visit or assessment should be elicited from the patient.

For source documentation verification these events need to be detailed in the patients' medical notes including the start dates/times (if known) of the onset of the event as well as the date the event stopped or changed, if applicable. On some occasions an adverse event log may be sufficient to record the details of the event – use of these should be agreed with the trial sponsor.

Adverse events on-going at completion of the study should be followed up as required by the protocol and as clinically indicated.

If required – information regarding AE's may have to be entered into an electronic case report form for reporting purposes. This should be done in a timely manner, in accordance with the CRF completion SOP or sponsors timelines.

Sponsors may have their own requirements when it comes to reporting adverse events and will provide guidance on these in the protocol and at site initiation.

The ICH GCP Guidelines state that: "All serious adverse events should be reported **immediately** to the sponsor" (trial organisers), and that "immediate reports should be followed promptly by detailed written reports".

SAE's should be reported within 24 hours of research staff becoming aware of an SAE. Follow up information should then be provided as it becomes available until resolution of the event.

Ask the patient about their general health status since their last visit and if they have experienced any untoward medical events or changes in health status.

Elicit as much information as possible and document the event as clearly as possible. For example, the patient may say that they 'felt sick'. This can be interpreted in many ways: they felt nauseated, they may have felt unwell, or they may even have been vomiting.

Ask the patient the date and start and stop time of event. If the patient cannot remember, then approximate as appropriate.

Document the severity – this may be graded by using the toxicity criteria found in the protocol – this needs to be confirmed by the PI.

Document the perceived causality – this needs to be confirmed by the PI

Document the action taken regarding study drug – if any e.g. was the treatment dose reduced, or was study drug/treatment delayed etc.

Document any treatment/medication given for the event, including the dates the treatment/medication was commenced and the date it was stopped/changed, if applicable.

Document the event outcome.

Events on-going at study completion should be followed up as detailed in the protocol and as clinically indicated.

Serious Adverse Events

All adverse events/adverse drug reactions will be documented as above. However, if they come under the Serious Adverse Event definitions then the event will be classed as a serious adverse event:

Inform the trial coordinator/sponsor as soon as possible within 24 hours of the Investigator's knowledge of the event. How the information is forwarded varies, usually by fax or phone. The preferred method will be fully explained in the study protocol, and these procedures must be followed.

Respond promptly to requests for follow-up information from the Sponsor.

Store all completed serious adverse events in case report form or Site File as stipulated by the protocol.

Pregnancy in either a patient or the partner of the patient in a trial taking trial medication should be reported as an SAE.

Suspected unexpected serious adverse reactions (SUSARs)

An adverse reaction is 'unexpected' if its nature and severity are not consistent with the information about the medicinal product in question set out:

- in the case of a product with a marketing authorization, in the summary of product characteristics for that product;
- in the case of any other investigational medicinal product, in the investigator's brochure relating to the trial in question.

A SUSAR which is fatal or life-threatening must be reported as soon as possible.

A SUSAR which is not fatal or life-threatening must be reported as soon as possible and in any event within 15 days after the researchers becoming aware of the event.

Safety Reports

Sponsors will periodically send out reports on all collected safety data.

If these are sent as paper copies, they need to be reviewed by the PI, signed, dated and stored in the site file. An acknowledgement needs to be sent back to the sponsor so that they know they have been received/reviewed.

On occasion, these are reported electronically via an online portal that requires authorised access to review and acknowledge.

CDs may also be received – again, they must be reviewed, acknowledged and filed in the site file.