

# Adverse Event Reporting

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**Clinical S.O.P. No.: 15**

Version 2.0

Compiled by:	<i>Shona Brearley</i>
Approved by:	<i>[Signature]</i>
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## DOCUMENT HISTORY

<b>Version number</b>	<b>Detail of purpose / change</b>	<b>Author / edited by</b>	<b>Date edited</b>
1.0	New SOP	Shona Brearley	
2.0	Further information included regarding reporting of adverse events	Louise Greig	June 2012

## 1. Introduction

ICH GCP states that 'systems with procedures that assure the quality of every aspect of the trial should be implemented'. This SOP details the procedure to be used for reporting any adverse events during a clinical trial.

## 2. Background

This SOP was developed to ensure that the process used to document and report adverse events is standardised throughout all studies adopted by SDRN.

ICH GCP (1997) guidelines 1.2 define an adverse event as "Any untoward medical occurrence in a patient or clinical investigation 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 or unintended sign (including an abnormal laboratory finding) symptom, or disease temporarily associated with the use of medicinal (investigational) products, whether or not related to the medicinal (investigational) product."

## 3. Procedure

- All trial staff and clinicians in contact with patients are responsible for noting adverse events that are reported by the patient and making them known to appropriate medical staff.
- It is the responsibility of the PI, at each trial site, to evaluate each AE for seriousness, causality, severity and expectedness.
- Patients entered into clinical trials must be encouraged from the outset of any study to contact their research nurse/team at the time of an event occurring.
- At each study visit the study participant should be asked if he/she has had any illnesses and/or untoward signs and symptoms since last being asked.
- If the study participant reports any change from their normal state, this should be recorded as an Adverse Event.

The assessment of intensity/severity of an adverse event will be based on the Investigator's clinical judgement using the following standard definitions:

**Mild:** An event that is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities.

**Moderate:** An event that is sufficiently discomforting to interfere with normal everyday activities.

**Severe:** An event that prevents normal everyday activities.

NB When specific events are assessed for **clinical severity** (intensity defined as: mild, moderate or severe), **severity** must not be confused with 'serious' which is a regulatory definition based on subject/event outcome or action criteria.

- ICH GCP guidelines state that Adverse Events should be recorded from the moment the study participant takes his first dose of investigational medicinal product (IMP), unless otherwise defined in the protocol.
- Study protocols should list known AE/Rs contained within the manufacturer's product information.
- Most pharmaceutical companies will record all changes from normal once the patient has signed the informed consent document as Adverse Events.
- If the study nurse is in any doubt about whether to record an event as an Adverse Event or not, then she should report it.
- Most sponsors of clinical trials will provide their own documentation for recording Adverse Events. Research staff should ensure that they are clear about completing these forms before the study starts.
- If the sponsor does not provide an Adverse Event form, the research nurse should use the standardised SDRN Adverse Event Reporting form (see Appendix 1). All boxes must be completed for each event.
- When recording Adverse Events, try to give an accurate medical diagnosis for all symptoms listed, e.g. Angina pectoris, coryza.
- If a medical diagnosis is impossible, please record the symptoms as described by the study participant. Only one symptom can be recorded on each Adverse Event form, e.g. Nausea and vomiting will require 2 Adverse Event forms.
- Adverse Events should be followed up till they are resolved or stable and the study participant should be asked regarding the progress of any ongoing Adverse Event at each visit.
- All study participants should have a contact phone number to report any Adverse Events or changes to existing Adverse Events between study visits.
- Any laboratory abnormalities identified during the trial should be recorded as Adverse Events and followed up as any other Adverse Events.
- ICH GCP says that all Adverse Events should be followed up for 30 days once the study participant has completed the trial, with 2 major exceptions.
  1. If the investigational medicinal product (IMP) has a particularly long half life, the study participant should be followed up at the end of the trial till the Investigator is sure that the IMP has been totally washed out of the study participant.
  2. If the Adverse Event is pregnancy, this must be followed up till a termination occurs or the baby is born, irrespective of the duration of the trial.

## (APPENDIX 1)

**SDRN: Scottish Diabetes Research Network**

### Adverse Event Form

Date Event Started:

Description of Event:

Event Status:-  Resolved  Ongoing

Date of Resolution of Event:

Related to Study Procedure:-  Definitely Related  Probably Related   
 Possibly Related  Not related

Follow-up Information:-  Yes  No  Not Applicable

Nurse's Name *(Please Print)*:

Nurse's Signature:  Date: