SDRN: Scottish Diabetes Research Network

Serious Adverse Event Reporting

Clinical S.O.P. No.: 17

Version 1.0

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Approved by:	
Review date:	November 2016

CHIEF SCIENTIST OFFICE

DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Shona Brearley	

1. Introduction

ICH GCP states that 'systems with procedures that assure the quality of every aspect of the trial should be implemented'. Scottish law also now demands that the reporting of Serious Adverse Events is standardised and subjected to the time restrictions set out in the EU Directive on Clinical Trials.

2. Background

ICH GCP (1997) guidelines define a serious adverse event as any untoward medical occurrence that at any dose results in:

- Death
- Or 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 added definition of "is an important medical event" allows Research Nurses/Investigators scope to report changes as SAEs even if they do not fit the previously defined categories.

SUSARS are defined as Serious Unexpected Suspected Adverse Drug reactions and the procedure for dealing with these will also be explained in this SOP.

This SOP was developed to ensure that the process used to document and report Serious Adverse Events and SUSARS is standardised throughout all studies adopted by SDRN.

3. Procedure

- At each study visit the study participant should be asked if he/she has had any illness 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.
- If the Adverse Event meets the definition of a Serious Adverse Event it should also be reported as a Serious Adverse Event.
- For most pharmaceutical company sponsored studies, the sponsor will provide a Serious Adverse Event form to be completed.
- If the sponsor does not provide a Serious Adverse Event form, a standard SDRN form **(Appendix 1)** should be completed.

- Serious Adverse Events must, by law, be reported to the study sponsor within 24hours of the study team becoming aware of the Serious Adverse Event. At this stage details may be very sketchy, e.g., subject admitted to hospital with chest pain, but should be reported to the sponsor with as many details as possible.

- Follow-up details on the Serious Adverse Event should be forwarded as soon as possible to the study sponsor, ideally within 15 working days.

- It is the study sponsor's responsibility to notify the Ethics Committee who approved the study of the Serious Adverse Event but in the case of single-centre academic studies, higher institutions, e.g., Universities and NHS boards, often delegate this responsibility to the investigator who will assume responsibility for this task.

- If you suspect that the Serious Adverse Event may be a SUSAR, then the patient's treatment should be unblinded.

- If you unblind the treatment and the patient was on an active IMP (investigative medicinal product) then you should inform the sponsor within 24 hour time limit.

- The sponsor then has time limits for reporting the SUSAR to the MHRA (Medicines and Healthcare Regulatory Authority) If the SUSAR is fatal, the sponsor must report it within 24 hours to the MHRA. If the SUSAR is non-fatal, the sponsor must report it within 15 days to the MHRA.

- If you unblind the treatment and the patient was on placebo or the comparator drug, this is **not** a SUSAR but it is still a Serious Adverse Event and should be reported to the sponsor.

- SUSARs should be followed up in the same way as Serious Adverse Events with the research team trying to obtain complete data regarding the event as soon as possible.

- If there is any doubt about whether a Serious Adverse Event is a SUSAR or not, please contact your local R&D Manager or the medical advisor to your local ethics Committee to ask for advice.

- The study participant should have a contact telephone number to report any potential Serious Adverse Events or SUSARs between study visits.

(APPENDIX 1)

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Serious Adverse Event Form

Date Form Completed:

Classification of SAE:-

❑ Patient Died — Date of Death: _____

❑ Involved or prolonged inpatient hospitalisation — Date of Admission: _____

Date of discharge: _____

Date Event Started:

Event Status:- Resolved ❑ Ongoing ❑

Description of Event:

Date of Resolution of Event:

Related to Study Procedure:- Definitely Related ❑ Probably Related ❑

Possibly Related ❑ Not related ❑

Follow-up Information:

Nurse's Name *(Please Print):*

Nurse's Signature: **Date:**