Sheffield Health and Social Care
NHS Foundation Trust

Research Development Unit
Research Governance Office
Centre Court
Atlas Way
Sheffield
S4 7QQ

www.shsc.nhs.uk
Telephone: 01142716731

Information and guidance for primary care sites on safety reporting in research

The purpose of this guide is to provide primary care sites with guidance on what safety reporting in clinical research is, the different events and how they need to be recorded and reported.

1. What is safety reporting?

Safety reporting is vital for all research studies to ensure the safety of the study participants and the safety of current and future patients. Safety reporting involves recording adverse events reported by a participant whilst they are part of a study. Each study protocol explains how to report adverse events and who needs to be notified. In clinical trials of investigational medicinal products (CTIMPs) this reporting is also known as pharmacovigilance.

2. Who is responsible for safety reporting?

The Principal Investigator (PI) has overall responsibility for safety reporting at their site but may delegate some aspects to members of their local study team. All members of the local study team need to know the protocol requirements regarding safety reporting for each individual study they are working on.

3. How should events recorded?

All reportable events should be documented in the patient's clinical record, and then also on a case report form (CRF/eCRF) and/or on a safety reporting form as specified by the study

sponsor. If the sponsor does not provide a form please see the website for the template: SAE report form

4. Who assesses events?

It is the responsibility of the PI to assess all events to determine seriousness, causality, intensity and expectedness. The protocol will specify which events need to be reported to the study sponsor.

5. How are events classified?

- Adverse Event (AE) - any untoward medical occurrence. There does not need to be causal relationship between the occurrence and the study or any treatment administered.
- Adverse Reaction (AR) - an AE that is causally related to the treatment or intervention.
- Serious Adverse Event (SAE) - an AE that meets at least one of the serious criteria listed in the protocol.
- Serious Adverse Reaction (SAR) - an AE that meets at least one of the serious criteria AND is causally related to the treatment or intervention.
- Suspected Unexpected Serious Adverse Reaction (SUSAR) - an AE that meets at least one of the serious criteria AND is causally related to the treatment or intervention AND is unexpected.

Please see website for information on Decision Trees to aid with classification of events for Adverse events reporting for CTIMP, non-CTIMP and all studies.

6. What is causality?

This refers to if the event is related/caused by the study procedures, device or treatment. It is the PI who assesses and decides causality for each reported event.

7. What is expectedness?

This is an assessment of whether the event is a known side effect of the procedure, device or treatment. The safety reporting section in the protocol will include information about known side effects. For CTIMPs the Summary of Product Characteristics (SmPC) or Investigator Brochure (IB) should be referred to.

8. What does intensity mean?

The intensity of an event is also known as ‘severity’ in research and relates to the impact an event has on a participant’s daily life. The terms used are as follows:

- Mild = an event causing minimal discomfort and not interfering with normal everyday activities.
- Moderate = an event causing sufficient discomfort that interferes with normal everyday activities.

- Severe = an event that prevents normal everyday activities.

9. What about pregnancy?

Pregnancy is not necessarily an adverse event but needs to be reported if occurs whilst in receipt of an Investigational Medicinal Product (IMP). The pregnancy will be monitored and followed-up until full term.

10. What if there is an urgent safety concern?

If there is an immediate hazard to patient health and safety the PI can take Urgent Safety Measures (USM) and deviate from the protocol to protect the patient. The PI is required to report USM to the study sponsor as soon as possible.

11. What is unblinding?

CTIMPs are often 'blinded' to prevent bias. It may only be the participant that is blinded to which treatment they are having (single blind), or the study team may not know either (double-blind).

In the event of a medical emergency, it may be necessary to 'unblind' a study participant so that appropriate treatment can be given. Instructions regarding 'unblinding 'will be provided by the study sponsor. Participants may be asked to carry a card which has the study information and contacts in case of such an emergency.

12. Where can I find out more about safety reporting?

Bitesize Safety Reporting training can be found on NIHR Learn:

https://learn.nihr.ac.uk/course/view.php?id=939 (accessed 20/02/2023)

13. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk