Research & Innovation

North Bristol NHS
NHS Trust

Guidance Document

Safety Reporting: Studies other than Clinical Trials of Investigational Medicinal Products (non-CTIMPs)

This guidance accompanies RI/QMS/SOP/013 (Safety Reporting: Clinical Trials of Investigational Medicinal Products (CTIMPs))

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1. PURPOSE AND SCOPE

This Guidance Document outlines the definition of different safety events that may be identified in the course of undertaking a research study, and the principles for recording and reporting these events. The Guidance focuses on studies other than Clinical Trials of Investigational Products (non-CTIMPs).

2. DEFINITIONS/ABBREVIATIONS

CRF	Case Report Form
CI	Chief Investigator
CTIMP	Clinical trials of Investigational Medicinal Products
GCP	Good Clinical Practice
NBT	North Bristol NHS Trust
PI	Principal Investigator
R&I	NBT Research & Innovation Office
REC	Research Ethics Committee
NBT	North Bristol NHS Trust
SOP	Standard Operating Procedure
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research

3. BACKGROUND

Safeguarding the dignity, rights, safety and wellbeing of research participants must be the primary consideration in any research project, prevailing over the interests of science and society. The reporting of safety events is one of the most important aspects of clinical research management and quality control.

The Medicines for Human Use (Clinical Trials) Regulations 2004 apply to the conduct of clinical trials of Investigational Medicinal Products (CTIMPs) in the UK, and details on the process for handling safety events for CTIMPs are detailed in the SOP on Safety Reporting: Clinical Trials of Investigational Medicinal Products (CTIMPs) (RI/QMS/SOP/013). However, there are also reporting requirements for safety events occurring in non-CTIMPs.

4. RESPONSIBILITIES

The CI, who may also be the PI if the study is single-site study, has responsibility for the conduct of a study. For multi-centre projects, the local PI at each site is required to inform the CI of all safety events that occur at the site.

The responsibility for completing and submitting adverse event reports is the responsibility of the sponsor. Where NBT is the sponsor, this responsibility is delegated to the Chief Investigator.

5. DEFINITIONS

5.1. Adverse Events (AEs)

Additional definitions of different safety events are provided in **Appendix A**.

6. RECORDING AND REPORTING SAFETY EVENTS

6.1. Adverse Events

The CI can decide how to record and report AEs and this information should be detailed in the protocol. AEs are usually described on a CRF, and must also be recorded in the participant's medical notes.

This recording should include a description of the event, the date/time that it started and stopped, the severity of the event and details of any actions taken in response to the event. The participant should be followed up by the research team until the event subsides.

6.2. Serious Adverse Events

(a) Reporting to R&I:

As with AEs, a record of all SAEs must be kept in the Investigator site file and also documented within the participant's medical notes. All SAEs must also be notified to the R&I using the SAE/SAR Initial Report Form for non-CTIMP studies (RI/QMS/SOP/013d) , and followed up as necessary using the SAE/SAR Follow Up Report Form for non-CTIMP studies (RI/QMS/SOP/013e).These forms are available on the R&I website.

(b) Reporting to REC:

If a research participant experiences a SAE and the CI determines the event to have been related to the study procedures **AND** unexpected then the event should also be reported to the Research Ethics Committee that gave a favourable opinion of the study (the 'main REC') by the CI within **15 days** of the occurrence. When reporting to REC, the CI should use the non-CTIMP report form published on the Health Research Authority (HRA) website:

www.hra.nhs.uk/resources/during-and-after-your-study/progress-and-safety-reporting

Any SAEs that occur should also be included in the Annual Progress Report to the REC. The process for submitting these reports is detailed in the SOP on Periodic Reporting to the REC and MHRA (RI/QMS/SOP/009).

5. RELATED SOPS AND DOCUMENTS

- Department of Health
  Research Governance Framework for Health & Social Care, 2nd Edition, April 2005
  www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962

- ICH Secretariat
  Guidelines for Good Clinical Practice (GCP) (E6 R1 Step 4, 1996)
  www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/013d	SAE/SAR Initial Report Form for non-CTIMP studies
RI/QMS/SOP/013e	SAE/SAR Follow Up Report Form for non-CTIMP studies
RI/QMS/SOP/013	Safety Reporting: Clinical Trials of Investigational Medicinal Products (CTIMPs)
RI/QMS/SOP/009	Periodic Reporting to the REC and MHRA

Appendix A

Abbreviations & Definitions

Term	Abbreviation	Definition
Adverse Event	AE	*Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product, medical device or intervention and which does not necessarily have a causal relationship with this treatment.* An AE can be any unfavourable or unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with the research procedure, whether or not considered related. AEs require continuous assessment.
Adverse Reaction	AR	The distinguishing feature between an AR and AE is whether there is evidence to suggest there is a causal relationship between the event and the research procedure.
Serious Adverse Event	SAE	Any untoward medical occurrence that: – Results in death; – Is life-threatening;* – Requires hospitalisation or prolongation of existing hospitalisation; – Results in persistent or significant disability or incapacity; or – Consists of a congenital abnormality or birth defect." * Life-threatening refers to an event where the subject was at risk of death at the time of the event; not to an event that hypothetically might have caused death if it was more severe. Medical judgement should be exercised in deciding whether an SAE/SAR is serious in other situations. Those events that are not immediately life-threatening or do not result in death or hospitalisation, but may jeopardise the subject or may require intervention to prevent one or more of the other outcomes listed, should be considered serious.
Serious Adverse Reaction	SAR	Any SAE that is classed in nature as serious and there is evidence to suggest there is a causal relationship between the event and the research procedure.
Suspected Unexpected Serious Adverse Reaction	SUSAR	Any SAE that is classed in nature as serious and there is evidence to suggest there is a causal relationship between the event and the research procedure, but where that event is unexpected.
Accidents Incidents or near Misses	AIMS	The AIMS system is common in many NHS Trusts and implements and NHS Trust's policy on Incident Reporting – including relevant AEs that occur in relation to research and during normal clinical practice.