An Introduction to Clinical Trial Safety Reporting

Introduction

Patient safety should always be paramount during research. It is essential that any Adverse Events (AEs) or safety issues that occur during a research project are appropriately managed, reviewed and followed up to ensure the continuing safety of study participants. For Clinical Trials of Investigational Medicinal Products (CTIMPs) there is a legal requirement for the management and reporting of AEs in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

Specific requirements/procedures must be clearly defined in the study protocol, including the specific timelines to be followed. This includes details of delegated responsibilities where appropriate. The overarching study timeframe for reporting AEs must also be specified e.g. to record AEs from point of consent or from point of study intervention.

Definitions

Adverse Events (AE)

The standard AE definition is 'Any untoward medical occurrence in a patient or clinical trial participant administered an investigational product, which does not necessarily have a causal relationship with the study treatment. AEs can include abnormal laboratory findings, unfavourable symptoms or diseases.

Adverse Reaction (AR)

Any untoward and unintended response in a subject of an investigational product which is related to any dose administered to that subject.

Serious Adverse Events (SAE) Serious Adverse Reaction (SAR) Unexpected SAR

Any adverse event, adverse reaction or unexpected adverse reaction respectively that:

- results in death
- is life-threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital abnormality or birth defect

Suspected Unexpected Serious Adverse Reaction (SUSAR)

Any AR that is classified as serious and is suspected to be caused by the investigational product that is not consistent with the known safety information listed in the Investigator Brochure (IB) or Summary of Product Characteristics (SmPC).

Responsibilities

Causality assessment decisions must be made by a medically qualified doctor as these decisions require medical and scientific judgements to be used as well as knowledge of the subject concerned. The trial delegation log should reflect this.

SAE reporting should follow a robust process to ensure that reporting of SAEs to the Sponsor is within 24hrs of the trial team's awareness of the event.

What to do if you are unsure

Reference safety information is used for assessing whether an adverse reaction is expected. This is contained in either the investigators brochure (IB) or the summary of product characteristics (SmPC).

CTIMP Acronyms

AE	Adverse Event
AR	Adverse Reaction
SAE/R	Serious Adverse Event/Reaction
SUSAR	Suspected Unexpected Serious Adverse Reaction
IB	Investigator Brochure
SmPC	Summary of Product of Characteristics
CTIMP	Clinical Trial of Investigational Medicinal Products