CT13 Safety Reporting in Clinical Trials

Approximate study time: 2 hours

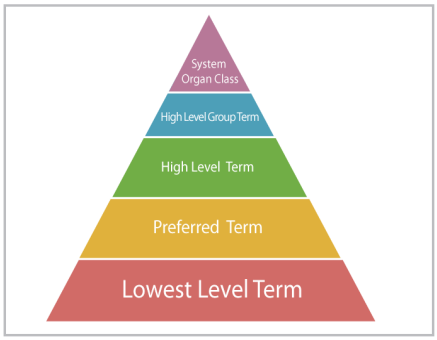
Level: Introductory/intermediate

Audience: Clinical research, drug safety and regulatory affairs staff, healthcare professionals

Category: Clinical trials, drug safety, regulatory affairs

Region: Europe, USA, other

CPD Points: 2



This course explains the regulatory requirements for the reporting of adverse events and suspected adverse reactions in clinical trials. It describes how investigators should report to sponsors, and how sponsors should report to regulatory authorities and other stakeholders in the safety of investigational products. It explains how events are characterized as serious or non-serious, expected or unexpected, and it distinguishes the requirements for each category. It describes controlled vocabularies used for coding of events in reports.

Who will benefit from this module?

This course provides essential information for clinical research, investigational product safety, and regulatory affairs staff of sponsors of clinical trials, as well as investigators and other healthcare professionals who undertake clinical trials.

Learning objectives

- Identify sources of legal requirements, regulatory guidance, and other requirements for the conduct of clinical trials
- Define reportable events and reactions in drug trials
- Discuss criteria for causality, expectedness, and seriousness of events
- Summarize investigators' responsibilities for reporting to sponsors and research ethics committees
- Specify requirements for expedited reporting by sponsors
- Outline the role of data monitoring committees
- Describe typical procedures for handling safety reports
- Outline follow-up procedures and the content of case narratives
- Describe trial monitoring activities related to safety reporting
- Discuss the handling of reports concerning marketed products
- Discuss the handling of reports of pregnancy and other special cases
- Outline the management of blinding
- Outline a typical timeframe for actions taken by a sponsor in response to reports of serious adverse events
- Identify requirements for periodic aggregate reporting
- Describe characteristics of the Medical Dictionary for Regulatory Activities
- Specify the levels of the MedDRA hierarchy
- Outline the use of MedDRA
- Outline the ISO standards for the identification of medicinal products

Module outline

Adverse events and safety reporting
In this session we explain the rationale for safety reporting in clinical trials, and we describe fundamental regulatory requirements. We discuss criteria for reporting, including causality, expectedness and seriousness. We set out the responsibilities of sponsors and investigators for individual-case expedited and aggregate reporting.

Safety reporting by drug sponsors
In this session we describe drug safety operations that will typically be carried out by a sponsor company or contract research organization engaged in clinical trials of medicinal products, and we outline some typical safety-reporting scenarios.

Controlled vocabularies
In this session we explain the requirement for the use of controlled vocabularies of medical terms in safety reporting. We describe the Medical Dictionary for Regulatory Activities (MedDRA) and identify the ISO standards for the identification of medicinal products (IDMP).

Assessment
Multiple-choice mastery assessment.