



**Approximate study time:** 2 hours



**Level:** Introductory/advanced



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



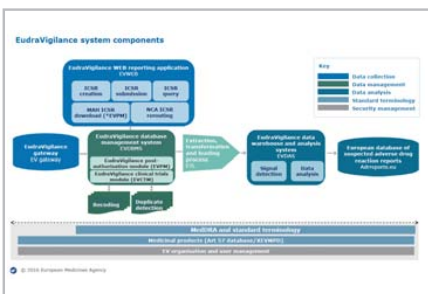
**Category:** Clinical trials, drug safety, regulatory affairs



**Region:** Europe, USA,



**CPD Points:** 2



This course sets out the legal and regulatory requirements for safety reporting in clinical trials of medicinal products under the jurisdictions of the European Union and the USA. It builds on the foundation laid by our companion course CT13, Safety Reporting in Clinical Trials, and provides greater detail of specific requirements in those jurisdictions.



**Who will benefit from this module?**

This course provides essential information for clinical research, drug 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 relevant EU statutes and sources of regulatory guidance
- Identify online portals that are key to safety reporting in clinical trials in the EU
- Summarize investigators' and sponsors' responsibilities under the Clinical Trials Regulation
- Discuss the role of reference safety information in the EU
- Specify sponsors' responsibilities for reporting suspected unexpected serious adverse reactions in the EU
- Describe how to submit electronic reports to EudraVigilance
- Outline sponsors' responsibilities for reporting SUSARs to investigators under the Clinical Trials Regulation
- Identify submissions that sponsors must make to the EU Clinical Trials Information System
- Outline significant differences in requirements under the Clinical Trials Directive
- Identify relevant US statutes and sources of regulatory guidance
- Summarize clinical investigators' responsibilities for reporting to sponsors of trials conducted under an Investigational New Drug application (IND) to the US Food and Drug Administration (FDA)
- Discuss the assessment of causality of serious adverse events
- Summarize sponsors' responsibilities for review of safety information under an IND
- Specify sponsors' responsibilities for IND safety reporting to FDA and investigators
- Describe how to deal with anticipated events according to FDA guidance
- Specify timeframes for IND safety reporting



**Learning objectives (continued)**

- Specify requirements for analysis of similar events and submission of follow-up information
- Describe how to submit IND safety reports to the FDA
- Discuss requirements for electronic submission of IND safety reports
- Discuss requirements for investigators' reporting of unanticipated problems to investigational review boards
- Specify sponsors' responsibilities for submission of IND annual reports



**Module outline**

### Legal and regulatory requirements in the EU

In this session, we set out the legal and regulatory requirements for safety reporting under the EU Clinical Trials Regulation. We specify the responsibilities of investigators and those of sponsors. We distinguish those reports that must be submitted by sponsors to the EudraVigilance portal and those that must be submitted to the Clinical Trials Information System. We specify the format and terminology that must now be used, and we identify the tools and pathways for electronic submission. Finally, we outline significant differences in requirements under the Clinical Trials Directive.

### Legal and regulatory requirements in the USA

In this session, we set out the legal and regulatory requirements for safety reporting in clinical trials conducted (in the USA or elsewhere) under an Investigational New Drug application (IND) to the US Food and Drug Administration (FDA). We specify the responsibilities of investigators and those of sponsors. We describe the criteria for IND safety reports to the FDA, and the content, format and timing of their submission. We discuss investigators' obligation to report unanticipated problems to institutional review boards. Finally, we discuss IND annual reports and other safety reporting issues.