CT01 How to Gain and Maintain Approval for Clinical Research Under the EU Clinical Trials Directive

Approximate study time: 3 hours

Level: Intermediate

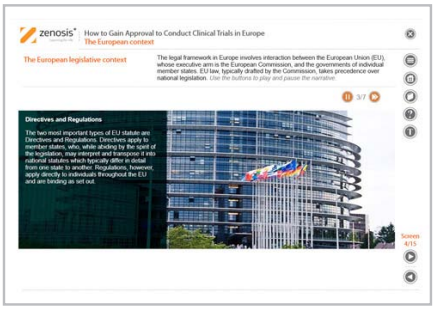
Audience: Regulatory, Compliance, Manager, Other

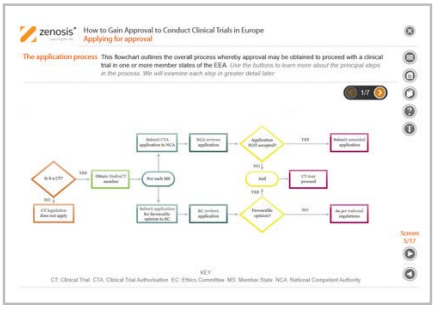
Category: Clinical, Regulatory Submissions

Region: Europe

CPD Points: 3

Module outline
- Module overview
- The European context
- Applying for approval
- Application for clinical trial authorisation
- Application for ethics committee favourable opinion
- Maintaining authorisation
- The Clinical Trials Regulation
- Assessment





To conduct a clinical trial in the European Economic Area under the Clinical Trials Directive the sponsor must apply for authorisation from the national competent authority (i.e. medicines regulator), and favourable opinion must be obtained from a research ethics committee, in each member state in which the trial is to take place. This module sets out the requirements for successful compilation, submission and maintenance of the applications.

During the first year of transition to the Clinical Trials Regulation, sponsors have the option of applying for approval under the Directive, and they can continue trials under that regime until 31 January 2025.

Who will benefit from this module?

The module will benefit:

- regulatory affairs professionals and other staff of pharmaceutical or biotechnology companies involved in clinical development of medicinal products; and
- healthcare professionals conducting clinical research as sponsor-investigators.

It will be of particular value to those who are new to European regulatory affairs, but familiarity with the basics of Good Clinical Practice is assumed.

Learning objectives

- Outline the legal and regulatory framework that governs clinical trials in the European Economic Area.
- Summarise the procedures that must be carried out to gain approval to proceed with a trial under the Directive.
- Identify the principal components of an application to a national competent authority for clinical trial authorisation and describe their contents.
- Discuss the principal areas of concern to an ethics committee and describe the information to be submitted to one.
- Specify what measures must be taken to maintain the authorisation of a trial in progress under the Directive.
- Outline the changes to regulatory requirements that are brought about by the implementation of the Clinical Trials Regulation, and describe the arrangements for transition from the Directive to the Regulation

Module outline

Module Overview
An outline of the module's scope and objectives, and notes on terminology.

The European context
This session explains the legal and regulatory framework for clinical trials in Europe.

Applying for approval
This session outlines the application procedures for clinical trial authorisation (CTA) and for ethics committee (EC) favourable opinion. It provides a decision tree through which you can determine whether your prospective investigation is a clinical trial. It describes how to register a trial with the EudraCT database and obtain a EudraCT number. It summarises the contents of applications and the processes and outcomes of reviews.

Application for clinical trial authorisation
The contents of a CTA application are discussed in more detail, focusing on the investigator's brochure, investigational medicinal product (IMP) dossier, circumstances in which a simplified IMPD or Summary of Product Characteristics may be substituted, and other IMP-related data. Online compilation of the application form is explained.

Application for ethics committee favourable opinion
Significant features of an application for EC favourable opinion are discussed in more detail, including the clinical protocol, informed consent form, and subject recruitment materials.

Maintaining authorisation
This session deals with the regulatory compliance activities that have to be carried out once a clinical trial has been approved. It examines the procedure for submitting substantial amendments, safety reporting requirements, and declaration of the end of a trial.

The Clinical Trials Regulation
This short session outlines the changes brought about by the implementation of the Clinical Trials Regulation, and it sets out the provisions that apply during the 3-year period of transition from the Directive to the Regulation.

Assessment
Multiple-choice mastery assessment.