CT07 An Introduction to Clinical Trials and Drug Development

Approximate study time: 1.5 hours

Level: Foundation

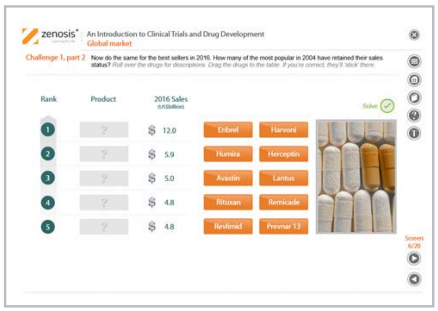
Audience: Research, Regulatory, Compliance, Other

Category: Clinical, Regulatory Submissions

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Overview
- History
- Codes and regulations
- Drug development
- Global market
- Assessment



This module provides an understanding of how clinical trials fit into the drug development process. It outlines the key historical events leading to the development of controlled clinical trials. It specifies the purpose of trials, describes their characteristics, and identifies codes of practice and regulations that apply to them. Finally, it discusses the environment of cost control in which the modern pharmaceutical industry operates.

Who will benefit from this module?

This introductory module is an ideal primer for those new to the fields of clinical research or regulatory affairs. It will also provide valuable background information for administrative, sales and other staff in the pharmaceutical and biotechnology industries, enabling them to understand better the context in which they work.

Learning objectives

- Describe the key events in the historical development of the modern pharmaceutical industry
- Outline the key codes of practice and regulatory processes
- Explain how clinical trials fit within the drug development process
- Describe the economic environment within which pharmaceutical companies operate

Module outline

Overview
The context of the pharmaceutical industry and modern medicine is established. The module's four perspectives on clinical trials are set out.

History
Factors that gave rise to the modern framework of regulation of clinical trials are traced.

Codes and regulations
The principal elements of regulation of clinical trials are set out. The regulatory frameworks of the USA, Europe and Japan are outlined. International harmonisation of requirements through the work of ICH is discussed, with particular reference to Good Clinical Practice.

Drug development
The long and financially risky process of developing a drug is described. The various stages of discovery, nonclinical and clinical development are detailed.

Global market
Commercial considerations in drug development are described. Issues such as financial risk, pharmacoeconomics, patent life and generics are discussed.

Assessment
Multiple-choice mastery assessment.