Webinar

What is New in the Clinical Trials Regulation

Overview of the key changes

10 December 2014 I Webinar I 11:00-13:00 CET

FACULTY

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OVERVIEW

The new EU Clinical Trials Regulation is expected to become applicable in 2016. The new legislation will have implications on clinical trial sponsors initiating and conducting clinical trials in the European Economic Area. Member States will have to adapt their procedures for the assessment of clinical trial applications by competent authorities and review by ethics committees. New provisions for public access to an EU clinical trials database will enforce disclosure of clinical trials data and information. This webinar will detail most of these aspects and compare them to the current regulatory environment.

LEARNING OBJECTIVES

- To understand the new requirements and the way implementation is being considered by authorities and clinical trial sponsors including their practical and operational impact
- To gain knowledge about key challenges and opportunities of the new requirements and policies
- Recognise how companies and research institutions are fine-tuning and optimising processes to meet the requirements of the clinical trials Regulation
- Exchange views between regulators, industry, patients, academia and other stakeholders

WHO WILL ATTEND

This webinar is developed for intermediate and experienced professionals from:

- Regulatory agencies
- The pharmaceutical industry and Contract Research Organisations including:
  - -Clinical science and clinical operations
  - -Monitors, auditors of clinical trials
  - -Regulatory affairs
  - -Pharmacovigilance
- Academic institutions
- Physicians
- Patient organisations

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