Clinical Pathways

Regulatory Requirements for Clinical Trials in Europe (EU CTR)

Course Description

This interactive eLearning provides an overview of clinical trials in the European Union with a focus on the transition from the EU Clinical Trials Directive to the Clinical Trials Regulation.

Learning Objectives

1. Explain an overview of how clinical trials are conducted in Europe and to recognize some major changes.
2. Discuss the transition between the Clinical Trials Directive (2001/20/EC) and the Regulation (EU No 536/2014).
3. Review the current GCP guidelines.
4. Describe the revisions to the Clinical Trial Directive.

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Length: 45 minutes run time plus additional time to complete scenarios and post assessment

From the EU Clinical Trials Directive to the Clinical Trials Regulation, the content includes an overview of the requirements for the conduct of clinical trials in the European Union, the EU Regulation and ICH E6(R2), the EU Portal and Database (Clinical Trials Information System or CTIS), highlights of the EU Regulation 536/2014 (the Clinical Trials Regulation), and running clinical trials in the EU.

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Regulatory Requirements for Clinical Trials in Europe

1. Requirements for the Conduct of CTs in the EU
   a. Background to EU Regulations
   b. Background for UK and EU
   c. European Commission's Legal Tools
   d. Legal Framework for EU Regulation 536/2014
   e. EU Regulation 536/2014 Timeline
   f. EU Regulation 536/2014 Overview
   g. CT Regulation's Entry into Application
   h. Transition between Directive and Regulation
   i. Major Developments Prior to Application
   j. Enforcement Pilots
2. EU Regulation and ICH E6
   a. Mapping ICH E6 to Reg EU No 536/2014
   b. The Corpus of GCP in the EU
   c. GCP Definition
   d. From Supervisory to Evidence Based Research
   e. EU Views on Risk Assessment
   f. EU GCP Compliance Assurance
3. The EU Portal and Database
   a. EU Clinical Trial Portal and Database – CTIS
   b. EMA Guidance and Support for Using CTIS
3. The EU Portal and Database (cont.)
   c. Online CTIS Training Module Link
   d. CTIS Components
   e. Transparency
4. Highlights of the EU Regulation 536/2014
   a. 10 Main Characteristics of the New Regulation
   b. Regulation Content
   c. Annexes
   d. Most Impacting Changes
   e. Scope
   f. Impact on Investigators and Consent
   g. Safety Reporting
   h. Safety Reporting Changes
   i. Monitoring Impacts
   j. Clinical Trials Conducted Outside the EU
   k. Orphan Drugs (Regulation EC 141/2000)
5. Running Clinical Trials in the EU
   a. CTA Process Under Directive 2001/20/EC
   b. CTA Under EU 536/2014
   c. Key Areas Covered in the Regulation
   d. Contact Points
6. 10 Question Post Assessment

Meet the Subject Matter Expert

Sam Sather
MS, BSN, CCRC, CCRA

Sam Sather's current focus of consulting is to promote clinical quality systems for Sponsors/CROs and Investigators/Research Institutions. She has over 35 years of clinical experience, has a Bachelor of Science degree in Nursing and a Master of Science degree in Education with a Specialization in Training and Performance Improvement. Sam has been dual certified by the Association for Clinical Research Professionals (ACRP) for over 15 years as a CCRA and CCRC. She is a current ACRP Fellow, which is awarded to individuals who have made substantial contributions to the Association and the industry at large.

Sam is a frequent speaker at industry conferences and has authored dozens of courses for clinical research training programs in various functional areas. She has multiple training, monitoring, and project management experiences of diverse size and objectives with a variety of global clients.

About Clinical Pathways

Clinical Pathways, LLC is a one-of-a-kind consulting and training firm whose purpose is to deliver affordable, customized, high quality clinical research services in an efficient, amiable, and professional manner. Understanding how to focus on what is essential and truly matters to promote better clinical quality systems for our clients is the key to our approach. Our agile consulting services adapt to the client's unique needs. Whether it is vendor management, SOP development, inspection readiness, RBQM, or an impact and gap analysis, Clinical Pathways has you covered.