Clinical Pathways

Contract Research Organization (CRO) Oversight

Course Description

This interactive eLearning provides an overview of the key concepts and best practices for CRO management in a global clinical trial setting. It also includes the global regulatory landscape regarding CRO management, primarily focusing on EMA, FDA, and ICH E6(R2)

Learning Objectives

1. Describe the Sponsor regulatory requirements for oversight of CROs.
2. Recognize key components for effective Sponsor CRO oversight.
3. Identify adequate CRO oversight procedures, oversight plans, and documentation management.

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Length: 60 minutes run time plus additional time to complete scenarios and post assessment

CRO and vendor oversight is a topic that is important to all Sponsors that are outsourcing clinical trial duties or activities to support the factors that are critical to success of their product development. Sponsors outsource for many reasons, including but not limited to, meeting the temporary need for a large expanded workforce, additional and sometimes unique expertise, technology, and quality systems. To make these partnerships work, Sponsors must have systems in place to oversee the quality of the CRO's work for the protection of study participants and the reliability of data.

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CRO Oversight

1. Sponsor's Regulatory Requirements for using a CRO
    a. Increased Scrutiny on Sponsor's Oversight of CROs
    b. ICH E6(R2), section 5.2 Contract Research Organization (CRO)
    c. EMA 2013 Reflection Paper on Risk Based Quality Management (RBQM) in Clinical Trials
    d. EMA RBQM Requirements Noted that Specifically Apply to Vendor Management
    e. FDA 2013 Oversight of Clinical Investigations A Risk-Based Approach to Monitoring
    f. Identification of Critical Processes & Data
    g. FDA BIMO CPGM 2021, Part III Inspectional
    h. BIMOs Updated Sponsor CPGM
    i. Sponsor BIMO CPGM: Organization and Personnel
    j. Sponsor BIMO CPGM: Focus
    k. Gathering & Organizing Knowledge for Reminders
2. Key Components of Effective Sponsor CRO Oversight
    a. Optimal Relationship Between the CRO and Sponsor
    b. Key Sub-Areas of Sponsor CRO Oversight Components
    c. Sponsor CRO Oversight Components
    d. Critical Success Factors for Oversight
    e. Keys to a Successful Relationship
    f. What do CROs Want?
    g. Examples of Critical Success Factors Metric Categories
3. Oversight Procedures, Plans, and Documentation Management
    a. Establish Clear Expectations to Ensure Acceptable Performance by CROs of Critical Activities
    b. Clinical QMS Elements Integrating RBQM
    c. Core QMS Elements: Both Stakeholders
    d. Sponsor QMS Elements for CRO Oversight
    e. CRO QMS Elements for Quality Performance
    f. Sponsor's Oversight Plan & CRO Project Plan Commonality
    g. Factors that Impact the CRO Project Plan & the Sponsor's Oversight Plan
    h. Clarifying Boilerplates in Guidance and Regulations
    i. Identifying the SOPs Being Followed for the Trial
    j. Multi-vendor Teams & More than One CRO
    k. Working with CROs: Sponsor Documentation
    l. Oversight Documentation
    m. Define Roles and Responsibilities
    n. Communication Plan
4. Real-life Case Scenarios
5. 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.