Investigator Initiated Clinical Trials

Course Description

This interactive eLearning course covers investigator initiated trials (IIT), including identifying roles and expectations in IITs, steps involved in conducting an IIT, and identification of actions to mitigate risks of common pitfalls.

Learning Objectives

1. Recognize the importance of identifying roles in investigator initiated trials and ensuring clear expectations.
2. Review the steps involved in initiating an investigator initiated trial.
3. Identify actions that can help minimize risks associated with investigator initiated trials by identifying and learning to prevent common pitfalls.

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Length: 30 minutes run time plus additional time to complete scenarios and post assessment

What are investigator initiated trials, and are they truly initiated by investigators, or by industry sponsors? Investigators may have an idea for a clinical trial with an investigational or approved product. Such trials can help answer important questions about medical products and devices. When investigators initiate the clinical trial, they also must fill the role of a sponsor. From the regulatory side, there is not a lot of guidance on such trials, but there is a focus on them for inspections. The sponsor-investigator is ultimately responsible for the regulations that are applicable for sponsors AND investigators. Do you know which regulations and guidelines are applicable and that they have different definitions?

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1. Overview of IITs, Guidance, and Regulations
    a. Definitions in IIT
    b. Federal Regulations for IITs
    c. Guidance for IND in IITs
    d. FDA IND Submissions for IITs
    e. Warning Letters in IITs
    f. Industry Collaboration
    g. Purpose of IIT
    h. Sponsor-Investigator WL Example & Discussion
2. Considerations before Starting IIT
    a. Relationship with Manufacturer
    b. Pros and Cons to Manufacturer Involvement
    c. Independent Compounding of Investigational Product (IP)
    d. Requests for IP
    e. Shipments of IP
    f. Conflict of Interest and Bias
    g. IRB Review
    h. Regulatory Reporting Requirements
    i. Sponsor-Investigator Regulatory Deficiencies
3. Minimizing Pitfalls
    a. FDA Scrutiny
    b. Risk Mitigation
    c. Objectivity in IITs
    d. Reducing Protocol Bias
    e. Independent Monitoring and Data
    f. Safety Reporting - Drug and Device
    g. IP Accountability
    h. Essential Documentation
4. 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.