Clinical Pathways

ICH E6(R2) GCP Training for Investigator Site Personnel

Course Description

This Investigator Site Personnel Good Clinical Practice (GCP) course covers the requirements of GCP for clinical trials found in ICH E6(R2) related to the role of the investigator and site personnel and briefly covers roles of other stakeholders.

Learning Objectives

1. Apply critical thinking techniques for effective implementation of the global Good Clinical Practice Guideline, ICH E6(R2).
2. Discover how the ICH global guideline affects your role.
3. Reflect on challenges and opportunities in implementing the guideline.
4. Identify practical applications of the guideline in your work processes.

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

This ICH E6 (R2) GCP Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

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ICH E6(R2) GCP Training for Sites

1. GCP Overview
    a. What is GCP
    b. GCP Resources
    c. What is ICH
    d. What is E6
    e. Purposes of GCP
    f. Who Does GCP Affect?
    g. ICH E6 Principles
2. Sponsor Responsibilities
    a. General Qualifications
    b. Sponsor General Responsibilities
    c. Investigator's Brochure
    d. The Clinical Trials Protocol
    e. Protocol Amendments vs Deviations
    f. The Sponsor's Representative: The Monitor
    g. GCP Noncompliance
    h. Audit vs. Inspection
    i. ICH E6(R2) and QRM
    j. Implementation of a QRM
3. Investigator Responsibilities
    a. General Qualifications & Definitions
    b. Investigator Agreements and Responsibilities
    c. Pre-Study Responsibilities
    d. Responsibilities During the Study Conduct
    e. Randomization and Blinding
    f. Source Documents and Source Data
    g. Records and Reports
    h. Investigational Product (IP) Responsibilities
    i. Adverse Events
    j. Safety Reporting
    k. Termination or Suspension
    l. Delegation and Oversight
3. Investigator Responsibilities (cont.)
    m. Supervision of Trials
    n. Examples of Inappropriate Delegation & Common Challenges
    o. Factors that Compromise Adequate Supervision
    p. Elements of a Plan for Adequate Supervision
    q. Scenario
4. Ethics Committee and ICF
    a. What are IRBs/ECs?
    b. IRB/EC Responsibilities
    c. Types of Review and Decisions
    d. What is Informed Consent?
    e. Informed Consent Process
    f. Vulnerable Subjects
    g. Emergency Consent
    h. Elements of Consent
    i. Stakeholder Responsibilities
    j. Informed Consent Tips from Regulators
    k. Informed Consent Amendments
    l. Common Informed Consent Deficiencies
    m. Scenario
5. Essential Documents and Good Documentation
    a. Essential Documents Definition
    b. Trial Master File (TMF)
    c. Role of Essential Documentation
    d. Investigator Regulatory Binders/TMF
    e. Why are Good Documentation Practices Important?
    f. ALCOA / ALCOA-C / ALCOACCEA?
    g. 6 Key Elements of Quality Data
    h. Certified Copies – Paper and Electronic
    i. Scenario
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.