Clinical Pathways

Clinical Trial eSystems Inspection Readiness

Course Description

The FDA regulates electronic systems, electronic records, and electronic signatures used to create and maintain records required for studies per 21 CFR Part 11. Part 11 is a companion regulation to other FDA regulations and laws called "predicate rules," where specific requirements for recordkeeping, record content, signatures, and record retention are addressed.

Learning Objectives

1. Recognize the requirements for eSystems used in a clinical trial and the sponsor's responsibilities to ensure compliance.
2. Apply the eSystems regulations to identifying what inspection readiness activities are needed.
3. Discuss common pitfalls and tips for success.

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Course Description

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

The use of electronic systems to support critical endpoint and safety data continues to increase. A clinical eSystem is an electronic system used to support the clinical trial, such as to collect, handle, and manage clinical trial data, manage investigational product, or informed consent. Clinical eSystem is not a regulatory term, but the FDA regulates electronic systems, electronic records, and electronic signatures used to create records required for studies per 21 CFR Part 11. Part 11 is a companion regulation to other FDA regulations and laws called "predicate rules," where specific requirements for recordkeeping, record content, signatures, and record retention are addressed. Part 11 is complex, and guidance documents have been published for sponsors and CROs to understand how to maintain compliance. Sponsor oversight of the electronic systems used by CROs and sites is not only a best practice to ensure quality data and participant safety but also is a regulatory requirement.

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1. Regulatory Requirements for Clinical eSystems Used in Clinical Trials
    a. What Are Clinical eSystems?
    b. Part 11 – A Companion to Predicate Rules
    c. Part 11 Related Guidance Documents
    d. eSystems Q&A Draft Guidance
    e. eSystems Guideline - EMA
    f. UAT and Usability Testing
    g. eSystems Validation
    h. Computerized Systems Used in Clinical Investigations Guidance (2007) - Expected Procedures for Clinical eSystems
    i. Change Control and Training
    j. SOPs and Documentation – Part 11
    k. Electronic Audit Trail
2. Proactive Inspection Readiness for eSystems in Clinical Trials
    a. Sponsor BIMO CPGM eSystems
    b. Sponsor/CRO eSystems Items Inspected by the FDA
    c. Selecting the RIGHT Subject Matter Experts
    d. eSystems Essential Documents
    e. eSystems Vendor Recommendations
2. Proactive Inspection Readiness for eSystems in Clinical Trials (cont.)
    a. Example of Clinical Trial Data Flow Chart
    b. Risk Based Validation and Changes
    c. Clinical eSystems Tips for Inspection
    d. Evidence Associated with Validation and UAT
3. What to Expect in an Inspection
    a. Process Improvement Focus
    b. Clinical eSystems – eSource
    c. eSystems Vendor Selection Process
    d. Information / Cyber Security
    e. Computer Validation / SDLC
    f. Quality Management System
    g. Operational Documents, Files, and Data
    h. Key Operational Topics
    i. Inspection READY!
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.