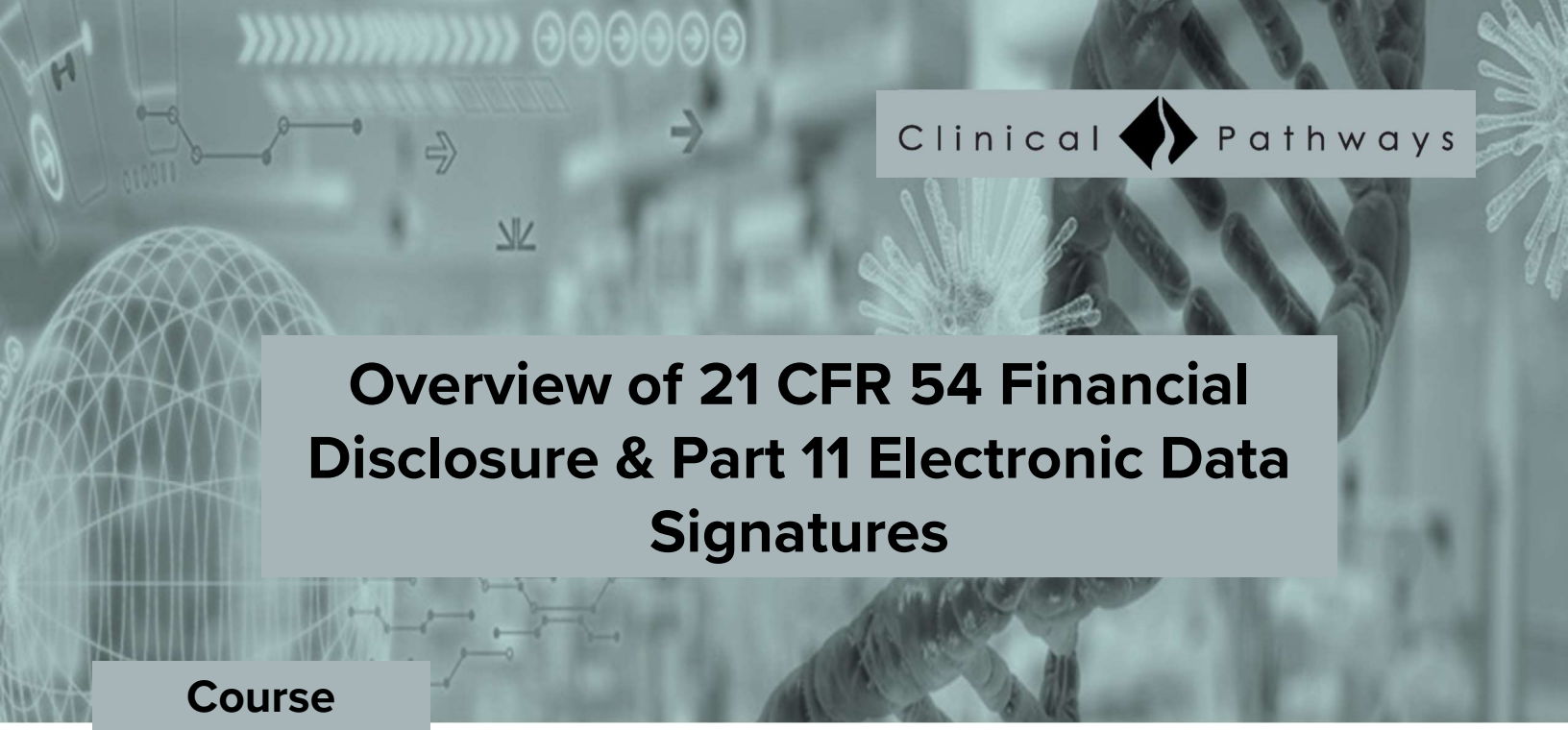


Clinical Pathways

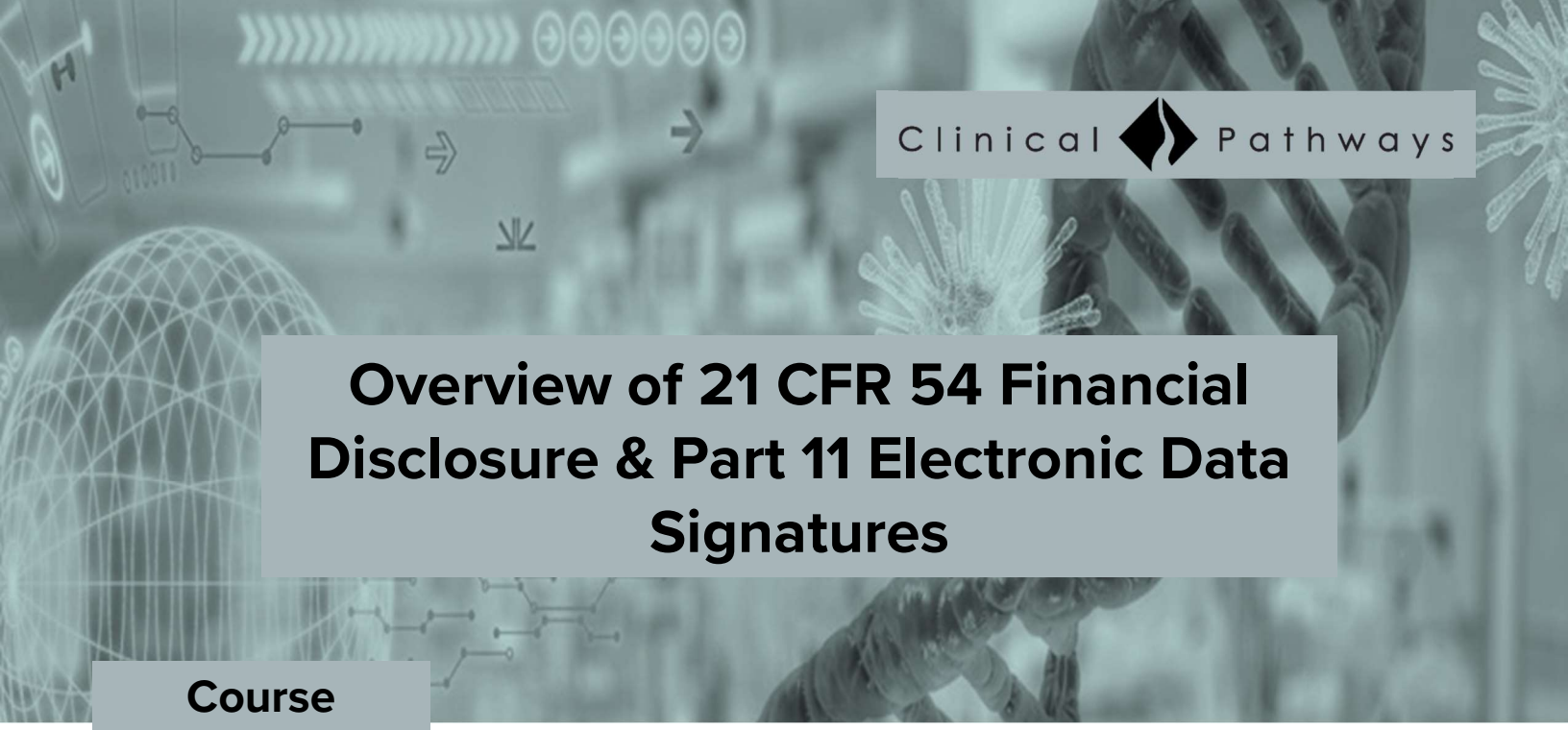
Overview of 21 CFR 54 Financial Disclosure & Part 11 Electronic Data Signatures

Course Description

This interactive eLearning provides an overview of 21 CFR Part 54 Financial Disclosure and Part 11 Electronic Data Signatures.

Learning Objectives

1. Apply critical thinking techniques for effective implementation of 21 CFR Part 54 and Part 11.
2. Reflect on how 21 CFR Part 54 and Part 11 affect your role in clinical research.
3. Discuss challenges and opportunities in implementing 21 CFR Part 54 and Part 11.



Clinical Pathways

Overview of 21 CFR 54 Financial Disclosure & Part 11 Electronic Data Signatures

Course Description

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

This interactive course covers an overview of 21 CFR Part 54 Financial Disclosure and Part 11 Electronic Data Signatures and is applicable to drug, device, and biologic studies. The main topics are financial disclosure, electronic records, and electronic signatures. Required by Part 54, sponsors must request certain financial information from clinical investigators, who are performing their studies before a marketing application is submitted. Part 11 describes the technical and procedural requirements that must be met if an organization chooses to maintain records electronically and/or use electronic signatures.

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Overview of 21 CFR 54 Financial Disclosure & Part 11 Electronic Data Signatures

1. Overview of 21 CFR Part 54: Financial Disclosure
    a. Financial Disclosure by Clinical Investigators
    b. Key Objectives
    c. Purpose / Scope
    d. FDA Certification 3454
    e. FDA Disclosure 3455
    f. Recordkeeping and Record Retention
2. FDA Guidance on Financial Disclosure
    a. FDA Guidance on 21 CFR Part 54 (2013)
    b. Clarification of Key Terms and Concepts
    c. Disclosure Reminders
    d. Threshold for Reporting
    e. Updates and Monitoring
    f. Investigator with Positive Financial Disclosure
    g. Expected Due Diligence
    h. FDA Review of Financial Information
    i. FDA Citations
3. Overview of 21 CFR Part 11
    a. Electronic Records and Signatures
    b. Overview
    c. Part 11 Associated Guidance
3. Overview of 21 CFR Part 11 (cont.)
    d. Computerized Systems and Users
    e. Electronic Records and Systems to Capture Them
    f. FDA's Acceptance of Electronic Source Data
    g. Required Procedures and Controls
    h. System Validation
    i. Record Retention Availability
    j. Records Protected: External Security Safeguards
    k. Audit Trails
    l. Access Controls
    m. Study Protocols and Training
    n. Signature Manifestations
    o. Electronic Signature / Record Linking
4. Regulatory Expectations
    a. Expectations in GCP Inspections & Data Audits
    b. Expected Controls
    c. Validation Expectations
    d. FDA Citations
    e. Recommendations
    f. ALCOA-C Table
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.