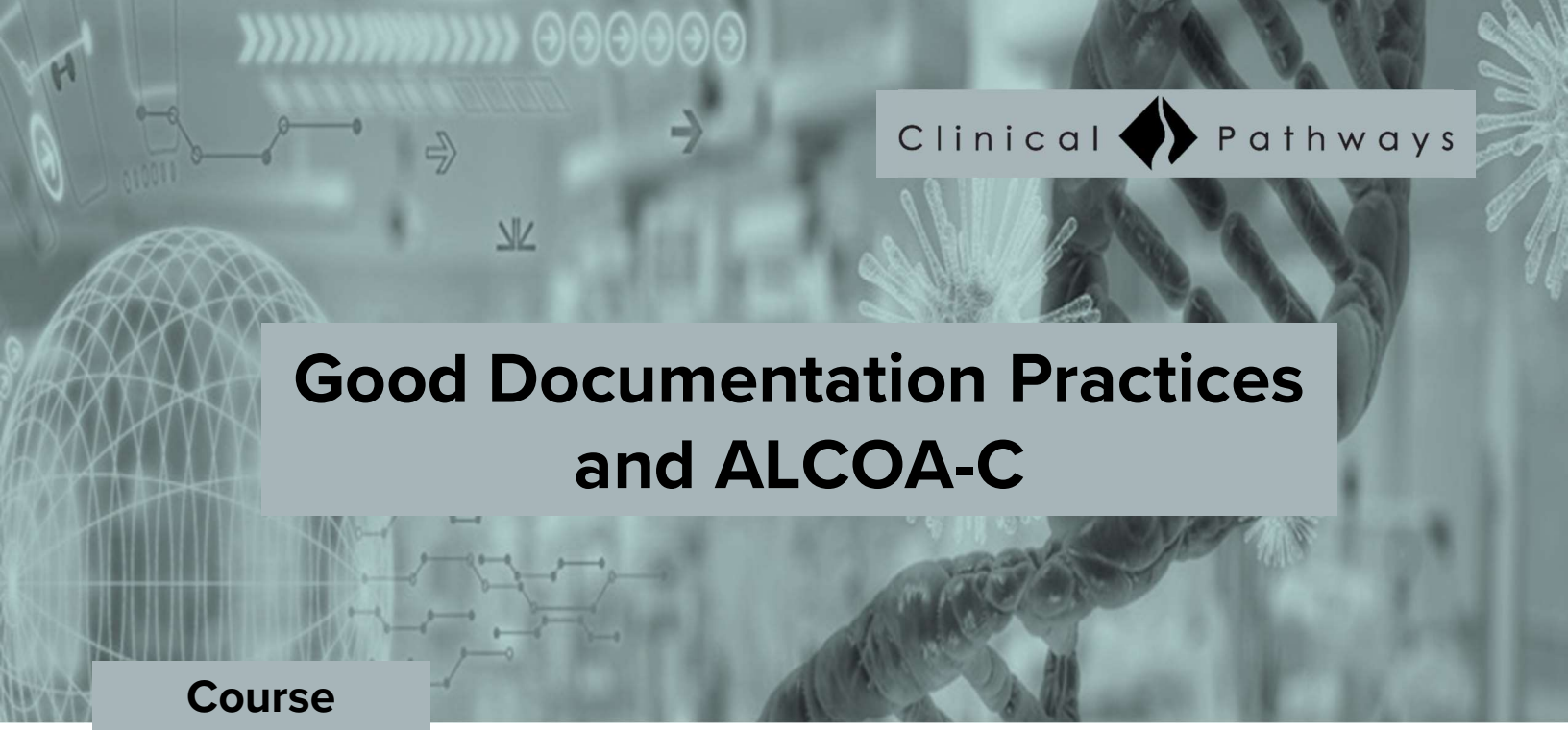


Clinical Pathways

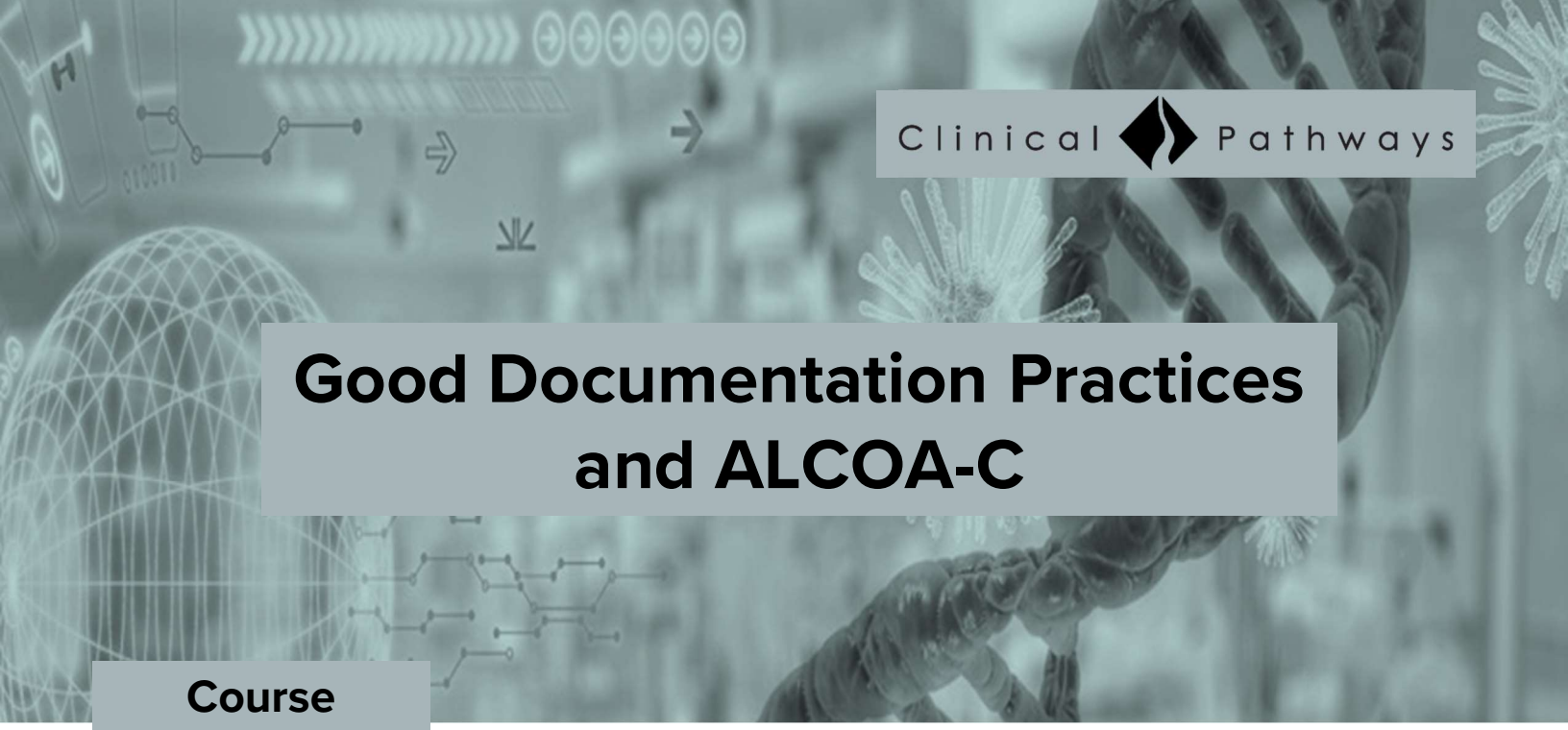
Good Documentation Practices and ALCOA-C

Course Description

In this course, you will learn about Good Documentation Practices, including the ALCOA-C principles, notes to file, and other general documentation procedures. Good Documentation Practices are necessary to ensure product quality and safety.

Learning Objectives

1. Practice applying ALCOA-C to paper and electronic documentation.
2. Identify methods to assess quality documentation to support inspection of clinical trials.
3. Recognize appropriate ways to address deficiencies in documentation.



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Good Documentation Practices and ALCOA-C

Course Description

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

Includes the Following Resources:

1. ALCOA-C Exercises Workbook
2. Why Good Documentation Practices Handout
3. Six Key Elements of Quality Data Handout
4. Investigator Warning Letter
5. Sponsor Warning Letter
6. NTF Warning Letter

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Course Description

1. Overview of Good Documentation Practices
   a. Importance of Good Documentation Practices (GDP)
   b. Why are Good Documentation Practices Important?
   c. Essential Documentation
   d. 6 Reasons Why We Do What We Do... for Good Documentation Practices
   e. ALCOA / ALCOA-C / ALCOACCEA?
   f. ICH E6 R2: 4.9.0
   g. Good Documentation Practices Apply Regardless of Media Used
2. A is for Attributable
   a. ALCOA-C Exercises 1a & 1b
   b. Attributable
   c. GDP Tips
3. L is for Legible
   a. ALCOA-C Exercise 2a & 2b
   b. Legible
   c. GDP Tips related to Legible
4. C is for Contemporaneous
   a. ALCOA-C Exercise 3
   b. Contemporaneous
   c. GDP Tips Related to Contemporaneous
5. O is for Original
   a. ALCOA-C Exercise 4a & 4b
   b. Original
   c. Certified Copies & When They Are Used
5. O is for Original (cont.)
   d. Certified Copies for Paper or Manual Print-outs
   e. Certified Copies for Paper or Print-outs from an Electronic Record
   f. Copies from an Electronic System
6. A is for Accurate
   a. ALCOA-C Exercise 5
   b. Accurate
   c. GDP Tips Related to Accurate
7. C is for Complete
   a. ALCOA-C Exercise 6
   b. Complete
   c. GDP Tips Related to Complete
8. General Procedures for GDP
   a. Six Key Elements of Quality Data
   b. Electronic Forms or Records Tips
   c. Inspection Readiness Tips
   d. Version Control and Document Labeling Tips
   e. Warning Letter Examples
9. Notes to File
   a. Why NTF are Used
   b. Concerns about NTF
   c. GDP Tips Related to NTF
   d. Issues Management
   e. Note to File Sample Exercise
   f. Inaccurate, Incriminating, and Incomplete NTF
   g. NTF Discussion - FDA
10. 10 Question Post Assessment

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Agenda

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.