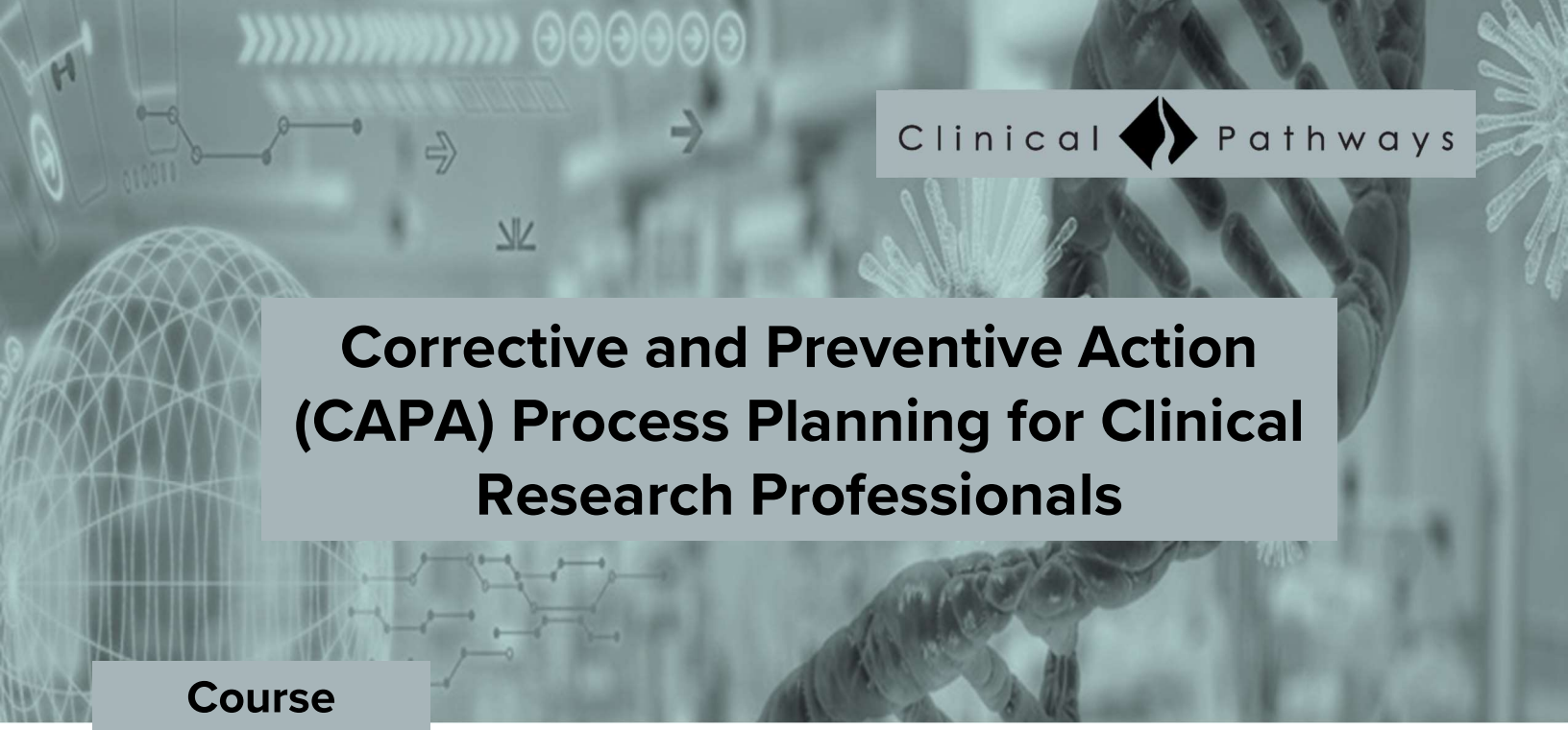


Clinical Pathways

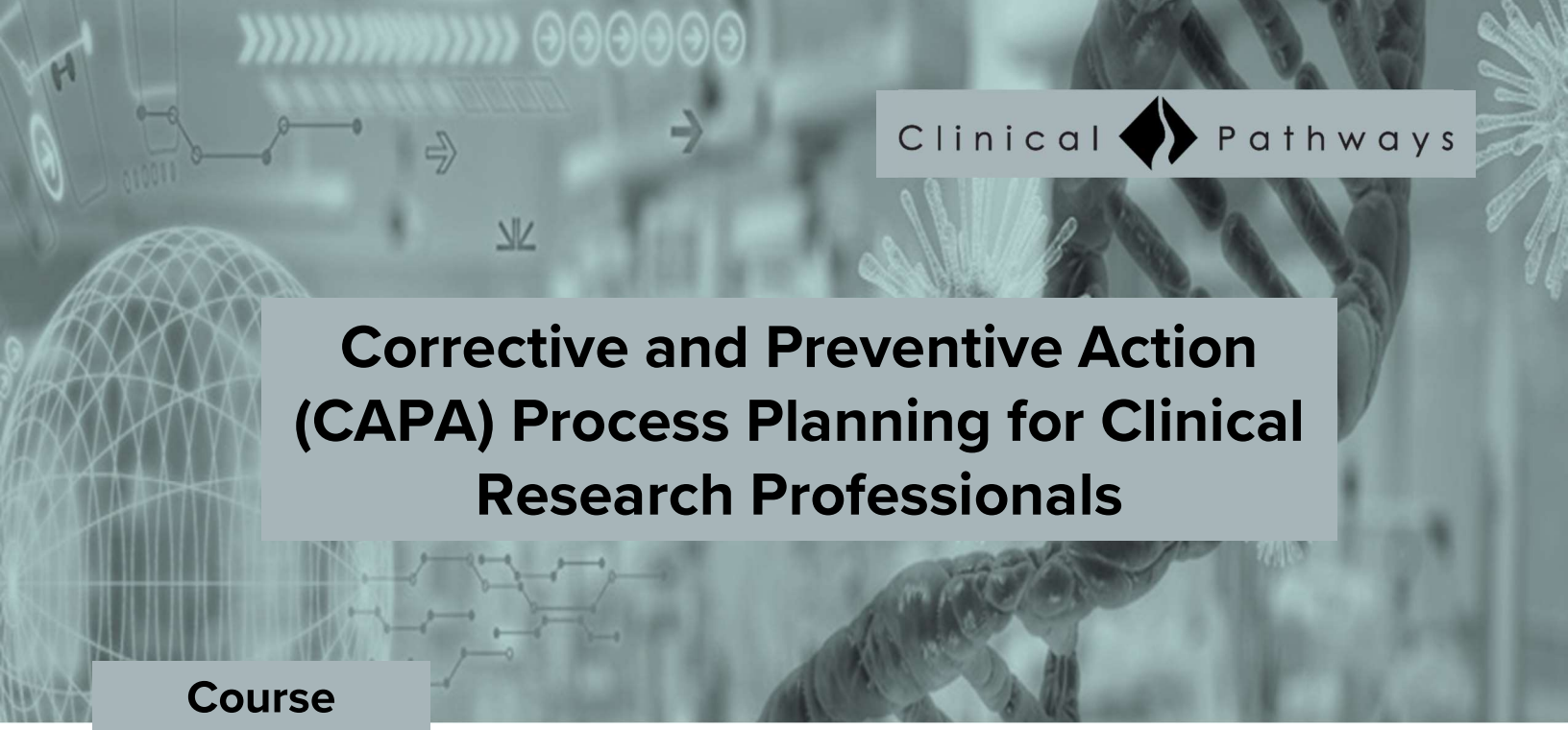
Corrective and Preventive Action (CAPA) Process Planning for Clinical Research Professionals

Course Description

This interactive eLearning provides a foundation for the CAPA process and supports understanding through GCP industry specific case scenarios and other application exercises. This training is an essential companion to training on a company specific CAPA system.

Learning Objectives

1. Recognize why corrective and preventive actions are essential in maintaining quality in a clinical trial.
2. Apply the steps of the CAPA process in clinical trial scenarios.
3. Discuss challenges in performing CAPA activities and review potential solutions.



Clinical Pathways

Corrective and Preventive Action (CAPA) Process Planning for Clinical Research Professionals

Course Description

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

Sponsors, CROs, and research sites are required by regulatory authorities and GCP to have an effective process to manage significant noncompliance through corrective and preventive action (CAPA) plans. These stakeholders should have procedures to support their CAPA system and documentation. Team members must understand a CAPA process and how it links into quality risk management. This training is designed to provide this background and is an essential companion to training on a company specific CAPA system. It is also a foundation for the CAPA process and supports understanding through GCP industry specific case scenarios and other application exercises in each section.

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CAPA Process Planning

1. Introduction to CAPA Process Training
2. Foundations of Quality Systems
    a. Clinical Quality Management System
    b. What is a QMS?
    c. QMS Elements
    d. Quality Risk Management
    e. ICH E6(R2) 5.0
    f. Risks That Matter
    g. Issues That Matter
    h. Complete Risk-Based Approach Map
3. Risks and Issues That Matter
    a. Regulatory Inspection Example
    b. Cost of Poor Performance
    c. What Happened Next?
    d. Regulatory Authorities and Noncompliance
    e. What is a Noncompliance
    f. Significant Noncompliance Links to Regulatory Requirements
    g. Noncompliance Significance
4. The CAPA Process
    a. Example Scenario
    b. A CAPA Decision Process
    c. Source of Information for Risks and Issues That Matter
    d. The CAPA Process Steps
    e. Additional Key Activities
5. The CAPA Case Scenario
    a. Case Scenario #1
    b. A CAPA Decision Process Walk Through
    c. Case Scenario #2
    d. Common CAPA Challenges
    e. Opportunity for Additional Case 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.