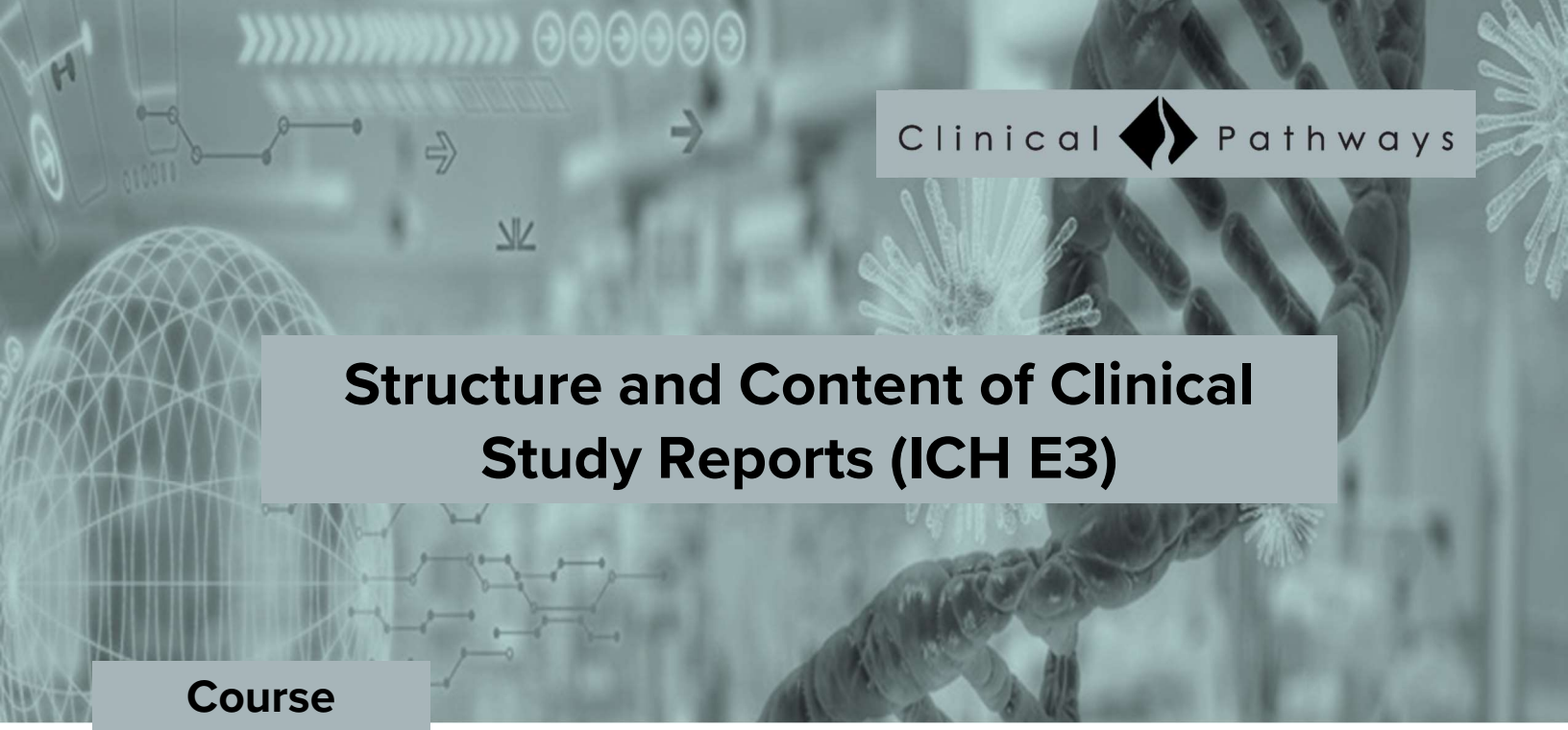


Clinical Pathways

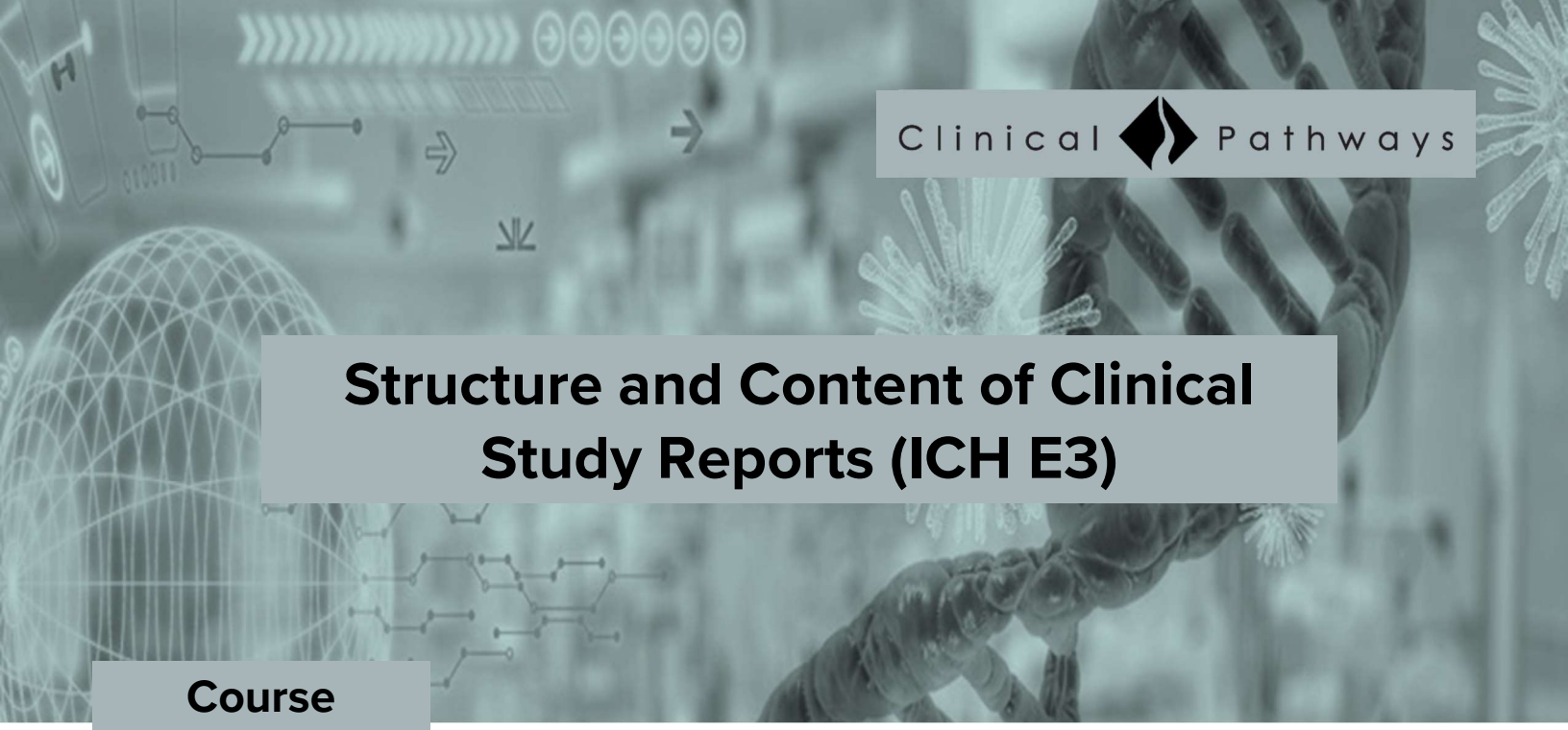
Structure and Content of Clinical Study Reports (ICH E3)

Course Description

This interactive eLearning provides an overview of the international guideline ICH E3, which relates to the structure and content of the Clinical Study Report (CSR).

Learning Objectives

1. Apply critical thinking techniques for effective implementation of the ICH E3 Guideline
2. Learn how the ICH E3 global Guideline affects your role in clinical research
3. Discuss challenges and opportunities in implementing the ICH E3 Guideline



Clinical Pathways

Structure and Content of Clinical Study Reports (ICH E3)

Course Description

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

The purpose of ICH E3 is to harmonize clinical study reports (CSR) across all regulatory authorities. The guideline supports different regulatory requirements while maintaining flexibility and is not a rigid set of requirements or templates. ICH E3 provides guidelines for the sponsor on the format and content of the CSR and guidelines on developing a CSR that is complete, specific, well-organized, and easy for those receiving the CSR to review.

Clinical Pathways

Structure and Content of Clinical Study Reports (ICH E3)

1. Overview of ICH E3
   a. ICH E3 Introduction
   b. ICH E3 Objectives
2. Overview of the CSR
   a. Definition of Clinical Study Report (CSR)
   b. Guideline Design
   c. Purpose of the CSR
   d. Content
3. Body of the CSR
   a. Title Page
   b. Synopsis
   c. Table of Contents for the Individual CSR
   d. Ethics
   e. Investigators and Study Administrative Structure
   f. Introduction
   g. Study Objectives
   h. Investigational Plan
   i. Study Patients
   j. Efficacy Evaluation
   k. Safety Evaluation
   l. Discussion of Scenarios
4. CSR Discussion and Other Considerations
   a. Discussion and Overall Conclusions
   b. Tables, Figures, and Graphs
   c. Reference List
   d. Appendices
   e. Content of Appendices
   f. Annex I – VIII
   g. ICH M4: Common Technical Document
5. ICH E3 Q & A
   a. Question 1
   b. Question 2
   c. Question 3
   d. Question 4
   e. Question 5
   f. Question 6
   g. Question 7
   h. Disposition of Patients Flow Chart
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.