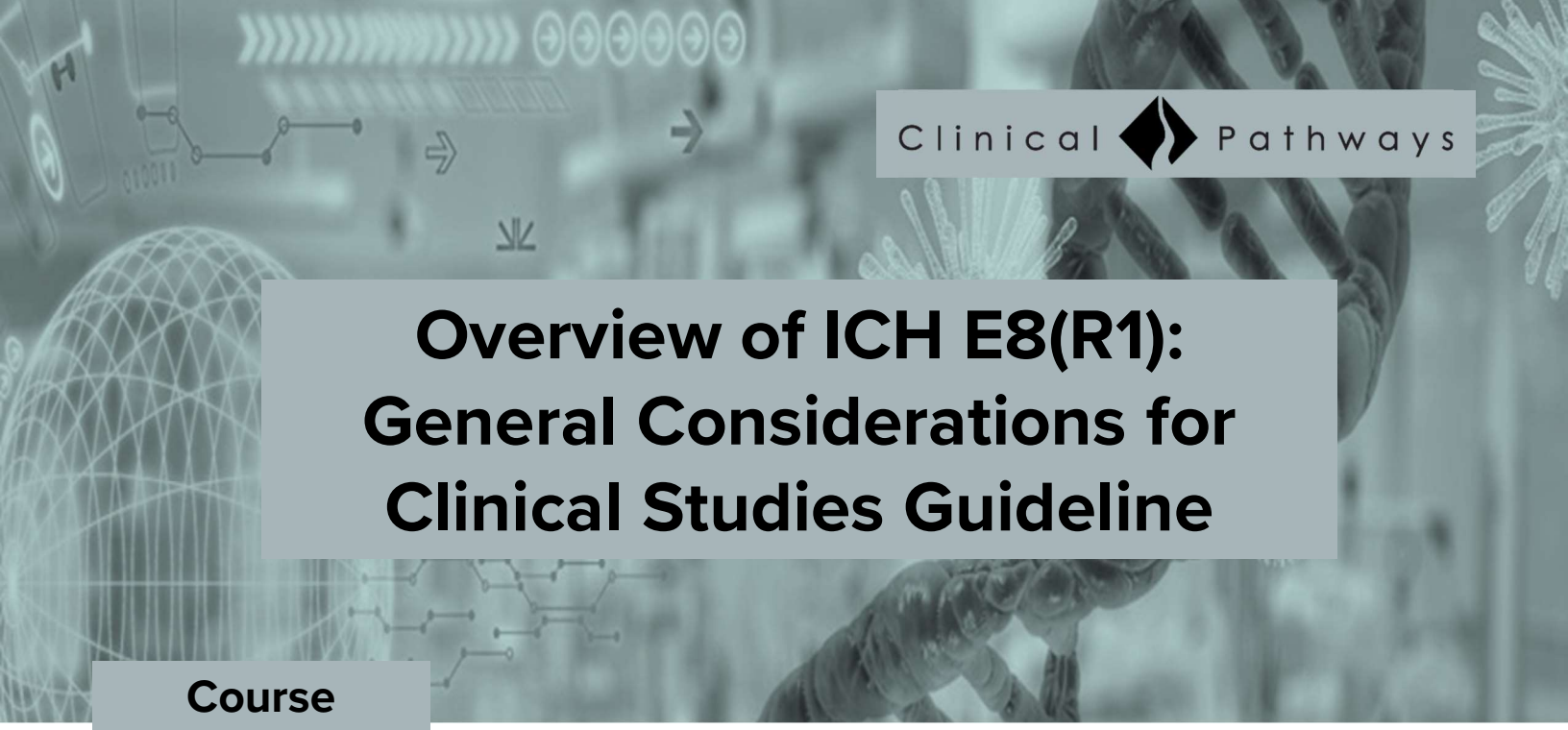


Clinical Pathways

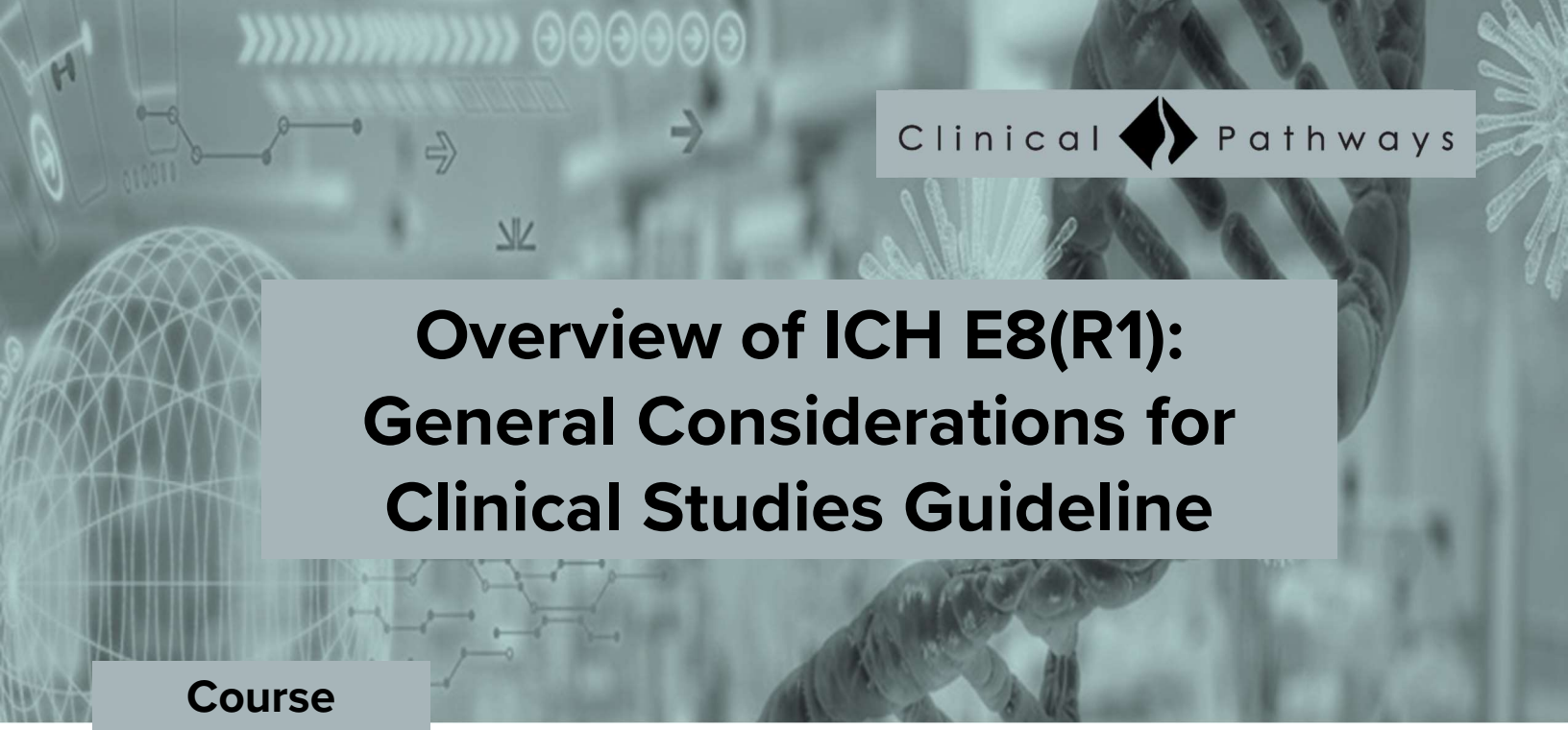
Overview of ICH E8(R1): General Considerations for Clinical Studies Guideline

Course Description

This interactive eLearning course covers the importance of ICH and why a revision to E8 was needed, overarching themes of changes, the introduction of Quality by Design and Critical to Quality applied to clinical trials, an overview of the sections of the Guideline.

Learning Objectives

1. Recognize how ICH E8(R1), the Guideline for General Considerations for Clinical Studies, has changed organizational processes.
2. Apply the Guideline to key concepts in clinical trials.
3. Discuss implementation challenges and opportunities regarding the updates in the Guideline.



Clinical Pathways

Overview of ICH E8(R1): General Considerations for Clinical Studies Guideline

Course Description

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

ICH E8(R1) is the umbrella guideline that maps to all the ICH "E" family, including ICH E6(R3), Good Clinical Practice. The revision modernizes clinical trial design, planning, management, conduct, and reporting and introduces the idea of quality as data being fit for purpose, which is ensuring the protection of study participants, the integrity of the data and reliability of the results, and the ability of the trials to meet their objectives. The key purpose is to design quality into clinical trials, which is supported by the establishment of an appropriate framework for the identification and review of Critical to Quality factors at the time of design and planning of the study, and throughout its conduct, analysis, and reporting.

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Overview of ICH E8(R1)

1. Background for the ICH E8 Revision
   a. Background
   b. Objectives of E8 Revision (Section 1)
   c. GCP Renovation
   d. GCP Renovation Paper Identified Gaps
   e. Principles of Trial Design and Planning
   f. Part 1 Summary
2. Quality by Design and Critical to Quality in ICH E8(R1)
   a. ICH E8(R1) – A Major Revision
   b. Trial Designs & Types of Studies
   c. Focus of Risk in ICH E8(R1)
   d. RBQM Change Management
   e. Primary Goals of ICH E8(R1)
   f. Increased Focus on Electronic Data Sources
   g. Focus of Risk in ICH E8(R1) (Section 3.1)
   h. Quality By Design (QbD) in Clinical Trials - ICH E8(R1)
   i. Considerations in Identifying Critical to Quality Factors (Section 7)
   j. Critical Aspects of a Quality Approach to Study Design (Section 3.3)
   k. Critical to Quality Factors (Section 3.2)
   l. Part 2 Summary
3. High-level Overview of ICH E8(R1)
   a. ICH E8(R1) Table of Contents
   b. ICH E8(R1) Overlying Theme
   c. Scientific Approach (Section 2.2)
3. High-level Overview of ICH E8(R1) (cont.)
   d. Approach to Identifying the Critical to Quality Factors (Section 3.3)
   e. Establishing a Culture that Supports Open Dialogue (Section 3.3.1)
   f. Focusing on Activities Essential to the Study (Section 3.3.2)
   g. Engaging Stakeholders in Study Design (Section 3.3.3) & Patient Input (Section 2.3)
   h. Reviewing Critical to Quality Factors (Section 3.3.4)
   i. Critical to Quality Factors in Operational Practice (Section 3.3.5)
   j. Drug Development Planning (Section 4)
   k. Design Elements and Data Sources for Clinical Studies (Section 5)
   l. Rooted in the Protection of Participants
   m. Study Conduct (Section 6.1)
   n. Participant Safety during Study Conduct (Section 6.2)
   o. Study Reporting (Section 6.3)
   p. ICH E8(R1) Annex
   q. Change Management is Key to Implementing
   r. ICH E8 (and E6) Revisions – Goals and Conclusion
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.