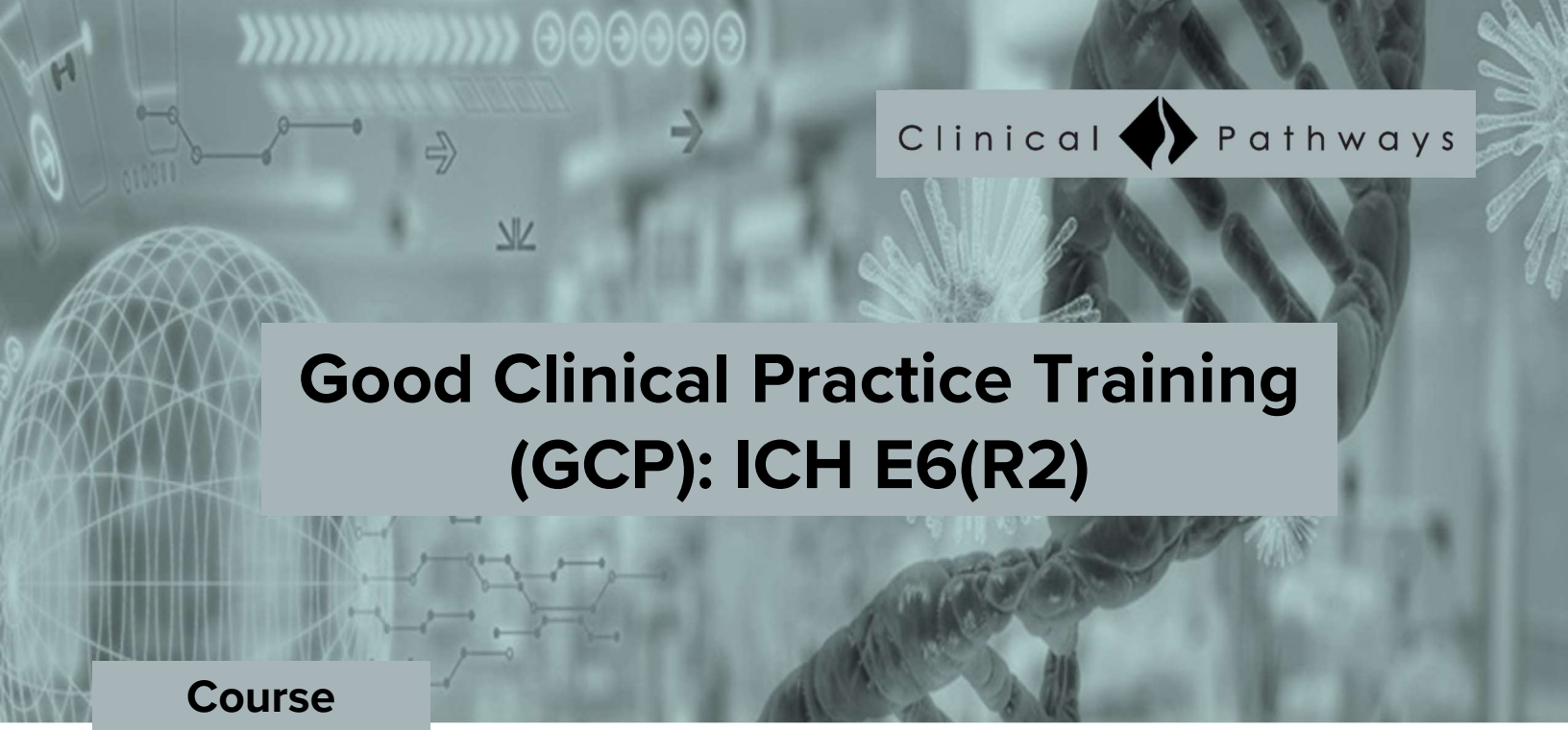


Clinical Pathways

Good Clinical Practice Training (GCP): ICH E6(R2)

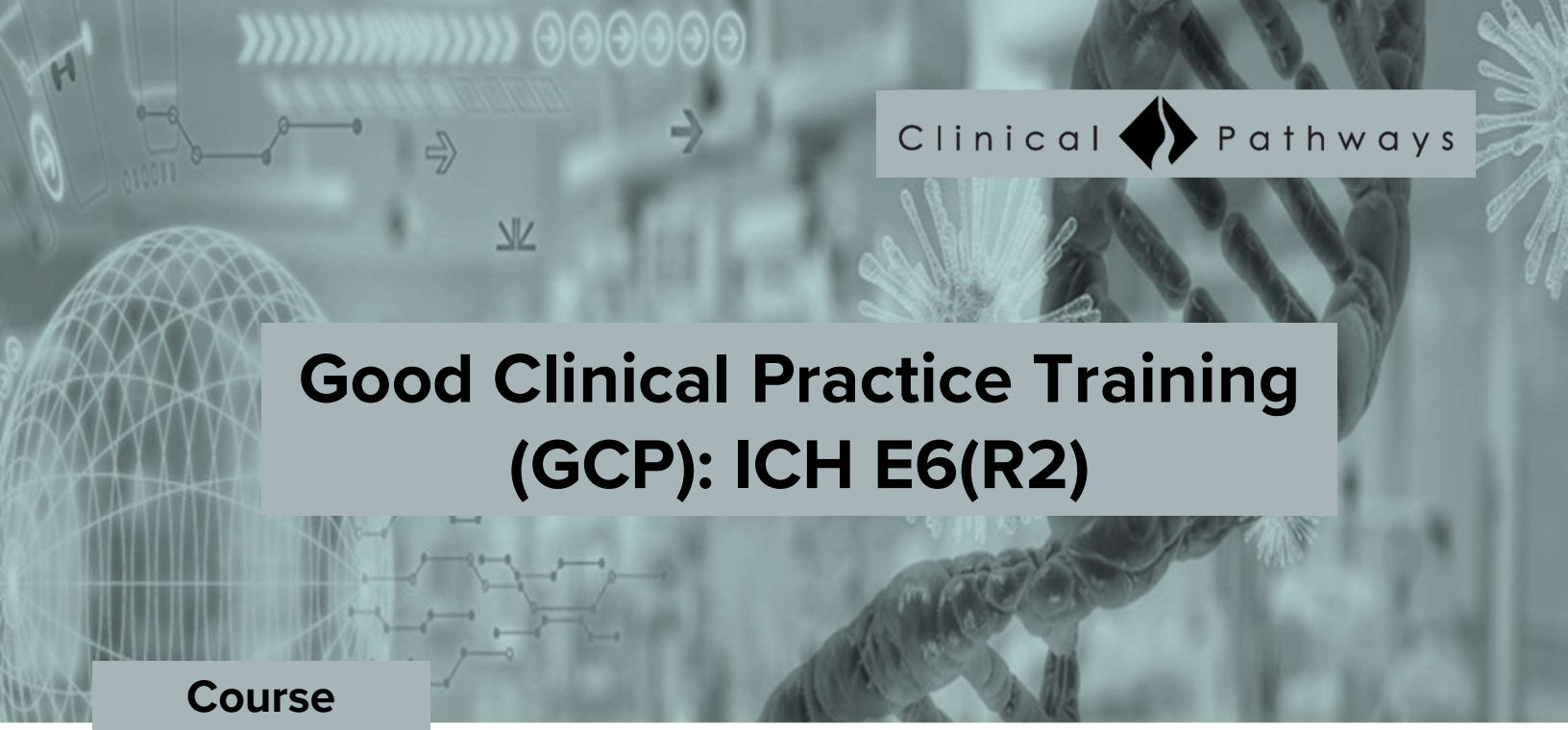
Course Description

This GCP Training: ICH E6(R2) course covers key components of the requirements of GCP for clinical trials found in ICH E6(R2) related to the role and responsibilities of the investigator, sponsor, and other stakeholders.

Recommended for GCP naïve or clinical research professionals who desire a more comprehensive GCP renewal training.

Learning Objectives

1. Apply critical thinking techniques for effective implementation of the global Good Clinical Practice Guideline, ICH E6(R2).
2. Discover how the ICH global guideline affects your role.
3. Reflect on challenges and opportunities in implementing the guideline.
4. Identify practical applications of the guideline in your work processes including identifying methods to assess quality systems and documentation.



Clinical Pathways

Good Clinical Practice Training (GCP): ICH E6(R2)

Course Description

Length: 75 minutes run time plus additional time to complete activities and post assessment

This ICH E6 (R2) GCP Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

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Good Clinical Practice Training (GCP): ICH E6(R2)

1. GCP Overview
   a. What is GCP
   b. GCP Resources
   c. What is ICH
   d. What is E6
   e. Purposes of GCP
   f. Who Does GCP Affect?
   g. ICH E6 Principles
2. Major Regulatory Authorities
   a. Global Health Authorities
   b. The EU and GCP
   c. Transition between Directive and Regulation
   d. The Corpus of GCP in the EU
   e. The US and GCP
   f. The Role of the FDA
   g. Applicable Regulations in the US
   h. Japan and GCP
3. GCP Essential Documentation
   a. The Clinical Trials Protocol
   b. Protocol Amendments vs Deviations
   c. Investigator's Brochure
   d. Essential Documents Definition
   e. Trial Master File (TMF)
   f. Sponsor & Investigator Regulatory Binders/TMF
   g. A Note about Sponsors and Records
4. Sponsor Responsibilities
   a. General Qualifications
   b. Sponsor General Responsibilities
   c. The Sponsor's Representative: The Monitor
   d. Audit vs. Inspection
   e. ICH E6(R2) and QRM
   f. Implementation of a QRM
5. Investigator Responsibilities
   a. General Qualifications
   b. Investigator Agreements and Responsibilities
   c. Pre-Study Responsibilities
   d. Responsibilities During the Study Conduct
   e. Records and Reports
   f. Termination or Suspension
   g. Lack of Oversight
6. Ethics Committee and ICF
   a. What are IRBs/ECs?
   b. IRB/EC Responsibilities
   c. Types of Review and Decisions
   d. What is Informed Consent?
   e. Informed Consent Process
   f. Vulnerable Subjects
   g. Emergency Consent
   h. Elements of Consent
   i. Stakeholder Responsibilities
   j. Informed Consent Tips from Regulators
   k. Informed Consent Amendments
   l. Common Informed Consent Deficiencies
7. ALCOA-C and Good Documentation Practices
   a. Why are Good Documentation Practices Important?
   b. ALCOA / ALCOA-C / ALCOACCEA?
   c. A is for Attributable
   d. L is for Legible
   e. C is for Contemporaneous
   f. O is for Original
   g. Certified Copies – Paper and Electronic
   h. A is for Accurate
   i. C is for Complete
8. 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.