Clinical Pathways

ISO 14155:2020
Medical Device Standard

Course Description

This interactive eLearning provides an overview of the ISO 14155:2020 standard for medical device GCP.

Use with a copy of your organization's standard or purchase a copy from www.iso.org.

Learning Objectives

1. Describe the ISO 14155:2020 standard requirements for Medical Device GCP.
2. Recognize how the ISO 14155:2020 standard applies to activities related to site monitoring and investigator responsibilities.
3. Apply the ISO 14155:2020 standard to study activities.

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Course Description

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

Designing and conducting a clinical trial should be done with Good Clinical Practice (GCP) and quality in mind to ensure the reliability of trial results as well as to follow requirements of regulatory authorities. Organizations usually understand the necessity of following ICH E6(R2) to ensure GCP; however, there is frequently a gap in training internal teams, contractors, CROs, and sites on ISO 14155:2020 GCP for medical devices. Following the standard is a key part of building globally recognized GCP into the full life cycle of the medical device clinical trial and can complement the current GCP training.

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1. Overview of the ISO Standard (Sections 1, 2, and 3)
   a. International Organization for Standardization Background & What are ISO Standards
   b. ISO 14155:2020 Background
   c. ISO 14155:2020 - Table of Contents
   d. Know the Standard Activity and Answer
   e. ISO 14155:2020 and GCP
   f. When is ISO 14155:2020 Enforceable?
   g. CIP vs. Protocol
   h. Important Terminology – Normative vs. Informative
   i. General Changes to ISO 14155:2020
2. Clinical Investigation Planning (Section 6)
   a. Clinical Investigation Plan (CIP)
   b. Annex A
   c. Clinical Procedure Risks and Their Disclosure
   d. ISO 14155:2020: Risk Assessment (Annex H)
   e. Risk Management for Sponsors
   f. Risk Management and the CIP Knowledge Check
   g. Investigator's Brochure (links to Annex B)
   h. Monitoring Plan Overview
   i. Monitoring Plan Elements
   j. Case Report Forms (CRFs) (links to Annex C)
   k. Investigation Site Selection
   l. Know the Standard Activity and Answer
3. Responsibilities of the Sponsor (Section 9)
   a. Site Selection and Training Requirements
   b. Monitoring: Clinical Quality Management
   c. Investigation Site Initiation (7.2)
   d. Monitoring: CIP and Investigators
   e. CRO, Vendor, Site Oversight
   f. Routine Monitoring Visits
   g. Monitoring: Documentation (Informed Consent, eCRF, AE or ADE)
   h. Preparation of Documents
   i. Certified Copies and Validated Systems
   j. Know the Standard Activity and Answer
4. Responsibilities of the Investigator (Section 5 and 10)
   a. Responsibilities of the Investigator Intro
   b. Investigator Qualifications
   c. Investigation Site (7.2, 9.2.1, 7.6, &10.3)
   d. Communication with Ethics Committee (5.6 and 10.4)
   e. Ethics Requirements
   f. Informed Consent (10.5 & 5.8)
   g. Informed Consent Requirements
   h. Responsibilities of the Investigator
   i. Investigator Compliance with the CIP
   j. Know the Standard Activity and Answer
5. Clinical Investigation Conduct and Safety (Section 7)
   a. Section 7: Clinical Investigation Conduct
   b. Know the Standard Activity and Answer
   c. Safety Requirements
   d. ISO 14155:2020: Adverse Events & Device Deficiencies (7.4)
   e. Adverse Events and Device Deficiencies Definitions
   f. ISO 14155:2020: Device Deficiencies
   g. Risk Assessment (Section 7.4.4)
   h. Adverse Event Characterization (AE, SAE, ADE, SADE, USADE, DD)
   i. Annex F
   j. ISO 14155:2020 Annex E Essential Documents
6. Suspension, Termination, and Close-out of Clinical Investigation (Section 8)
   a. Routine Closeout
   b. Termination/Suspension/Close-out, Including Report, Risk Assessment & Conclusions
   c. Document Retention (links to Annex E)
   d. Audits (Annex J)
   e. Clinical Investigation Report (Annex D)
7. Scenario
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.