Clinical Pathways

Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (ICH E2A)

Course Description

This interactive eLearning provides an overview of the international guideline ICH E2A, which relates to Clinical Safety Data Management and expedited reporting.

Learning Objectives

1. Apply critical thinking techniques for effective implementation of the ICH E2A guidelines.
2. Reflect on how the ICH E2A global guideline affects your role in clinical research.
3. Discuss challenges and opportunities in implementing the guideline.

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Course Description

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

ICH E2A provides guidance on how to handle expedited safety reporting and includes definitions and terminology related to clinical safety reporting. Safety event terminology can be confusing. This eLearning course helps you understand the differences between the terms with explanations and examples with scenarios. Following harmonized clinical safety reporting for investigational products ensures Good Clinical Practice (GCP).

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Clinical Safety Data Management (ICH E2A)

1. ICH E2A Overview
   a. From Conference to Council – ICH Background
   b. Background for Topic E
   c. Background for ICH E2A
   d. Introduction to ICH E2A
2. Definitions and Terminology
   a. Definitions and Terminology Associated with Clinical Safety Experience
   b. Adverse Event or Adverse Experience (AE)
   c. Sign, Symptom, or Disease
   d. Adverse Drug Reaction (ADR)
   e. Unexpected Adverse Drug Reaction (UADR)
   f. Scenario
   g. Serious Adverse Event (SAE) or Adverse Drug Reaction (ADR)
   h. Severe vs. Serious
   i. Scenario
   j. Expectedness of an Adverse Drug Reaction
   k. Scenario
   l. Safety Reporting Assessment Flowchart
3. Standards for Expedited Reporting
   a. What Should be Reported
   b. Reporting Time Frames - Fatal or Life-Threatening Unexpected ADRs
   c. Reporting Time - All Other Serious, Unexpected ADRs
   d. Minimum Criteria for Reporting
   e. Scenario
4. Procedures for Expedited Reporting
   a. How to Report
   b. Managing Blinded Therapy Cases
   c. Breaking the Blind
   d. Miscellaneous Issues
   e. Informing Investigators and ECs/IRBs of New Safety Information
5. Quality Management Systems
   a. ICH E6 5.0 Quality Management
   b. Sponsors and Noncompliance
   c. Common Root Causes of Source Documentation Deficiencies
   d. Corrective and Preventive Actions
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.