Clinical Pathways

The General Data Protection Regulation and Clinical Trials

Course Description

The General Data Protection Regulation (GDPR) and Clinical Trials course covers how to exchange personal data during and after study conduct while following the GDPR requirements for data protection.

Learning Objectives

1. Determine the importance of subject data protection related to General Data Protection Regulation (GDPR),
2. Describe the process to collect and analyze private data and ensure its security under GDPR, and
3. Recognize potential impacts of the GDPR and how it affects your organization.

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

With the increasingly global nature of clinical trials, it is becoming more common to exchange personal data from the European Union to the United States during study conduct and after. This involves following the requirements of the EU's General Data Protection Regulation.

Learn the answers to these questions and more in the eLearning course.

1. What is applicable to stakeholders in clinical trials?
2. How do you protect data subject personal information collected and analyzed in clinical trials?
3. What impacts does GDPR have for clinical trials and your organization?

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The GDPR and Clinical Trials

1. Background and History of Personal Data Protection
   a. What Data are Personal?
   b. Why Personal Data Protection?
   c. Background and History
   d. Data Privacy in the UK
   e. Important GDPR Definitions
   f. Who Processes and Who Controls Data?
   g. Scenario
2. GDPR and Clinical Trials
   a. GDPR Overview
   b. GDPR and Clinical Trials
   c. Risk-based Data Protection
   d. Eight Rights Under GDPR
   e. Data Privacy Policy / Notice
   f. When is Re-consent Necessary?
   g. Data Privacy and Clinical Trials
   h. GDPR and HIPAA Differences
   i. HIPAA vs. GDPR High Level Differences
   j. Consent to Process Data
   k. Where are Studies Conducted?
   l. Scenario
3. Collecting and Safeguarding Personal Data
   a. Definitions -Data Protection Organizations and Individuals
   b. GDPR Applicability Questionnaire
   c. Privacy Impact Assessment
   d. Transparency Requirements
   e. Requirements of GDPR for Processing Data
   f. Accountability
   g. Data Protection Officer
   h. EU GDPR Data Representative
   i. Elements in a GDPR Consent
   j. Other Legal Basis for Processing Data & Challenges
   k. Data Security Measures
   l. Data Breach
   m. How to Safely Transfer Data – Binding Corporate Rules
   n. Enforcement
   o. Helpful Tips
   p. Scenario
4. 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.