Clinical Pathways

Overview of 21 CFR 312 (IND) and 21 CFR 314 (NDA)

Course Description

This interactive eLearning provides an overview of 21 CFR 312 Investigational New Drug Application and 21 CFR 314 Application for FDA Approval to Market a New Drug.

Learning Objectives

1. Apply critical thinking techniques for effective implementation of 21 CFR Part 312 and 314.
2. Learn how 21 CFR Part 312 and 314 affect your role in clinical research.
3. Discuss challenges and opportunities in implementing 21 CFR Part 312 and 314.

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Overview of 21 CFR 312 (IND) and 21 CFR 314 (NDA)

Course Description

Length: 60 minutes run time plus additional time to complete scenarios and post assessment

The first regulatory step in investigating a new drug is filing an Investigational New Drug application with the FDA before clinical trials can begin. Once the clinical trials are complete, a New Drug Application that demonstrates the drug's safety and efficacy is submitted for the FDA to decide whether to approve the drug for marketing. Helpful tips on terminology and the responsibilities of the sponsor and investigator are included in this interactive, on-demand eLearning course.

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Overview of 21 CFR 312 (IND) and 21 CFR 314 (NDA)

1. 21 CFR 312 Investigational New Drug Application (IND)
   a. 21 CFR 312.1 (a): Scope
   b. 21 CFR 312.3: Definitions
   c. Summary of Stakeholders in Part 312.3
2. Subpart D
   a. Overview of Subpart D
   b. 21 CFR 312.50 - General Responsibilities of Sponsors
   c. 21 CFR 312.52 - Transfer of Obligations to a CRO
   d. 21 CFR 312.53 - Selecting Investigators and Monitors
   e. 21 CFR 312.54 - Emergency Research Under 50.24
   f. 21 CFR 312.55 - Informing Investigators
   g. 21 CFR 312.56 - Review of Ongoing Investigations
   h. 21 CFR 312.57 - Recordkeeping and Record Retention
   i. 21 CFR 312.58 - Inspection of Sponsor's Records and Reports
   j. 21 CFR 312.59 - Disposition of Unused Supply of IP
   k. Sponsor FDA Warning Letter
   l. 21 CFR 312.60 - General Responsibilities of Investigators
   m. 21 CFR 312.61 - Control of the Investigational Drug
   n. 21 CFR 312.62 - Investigator Recordkeeping and Record Retention
2. Subpart D (cont.)
   o. 21 CFR 312.64 - Investigator Reports
   p. 21 CFR 312.66 - Assurance of IRB Review
   q. 21 CFR 312.68 - Inspection of Investigator's Records and Reports
   r. 21 CFR 312.69 - Handling of Controlled Substances
   s. 21 CFR 312.70 - Disqualification of a Clinical Investigator
   t. Investigator FDA Warning Letter
3. 21 CFR 314 NDA
   a. Applications for FDA Approval to Market a New Drug (NDA)
   b. The Drug Development Process
   c. 21 CFR Part 314.1 (a): Scope
   d. 21 CFR Part 314.1 Important Sections
   e. Adequate and Well-controlled Studies
4. Cross-Functional Readiness
   a. Compliance Program Guidance Manual (CPGM)
   b. CPGM's BIMO Basis
   c. Bioresearch Monitoring Program (BIMO)
   d. FDA Sponsor-Monitor Inspection (CPGM 7348.810)
   e. Clinical Investigator / Sponsor-Investigator Inspection
   f. Flow of QRM in GCP
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.