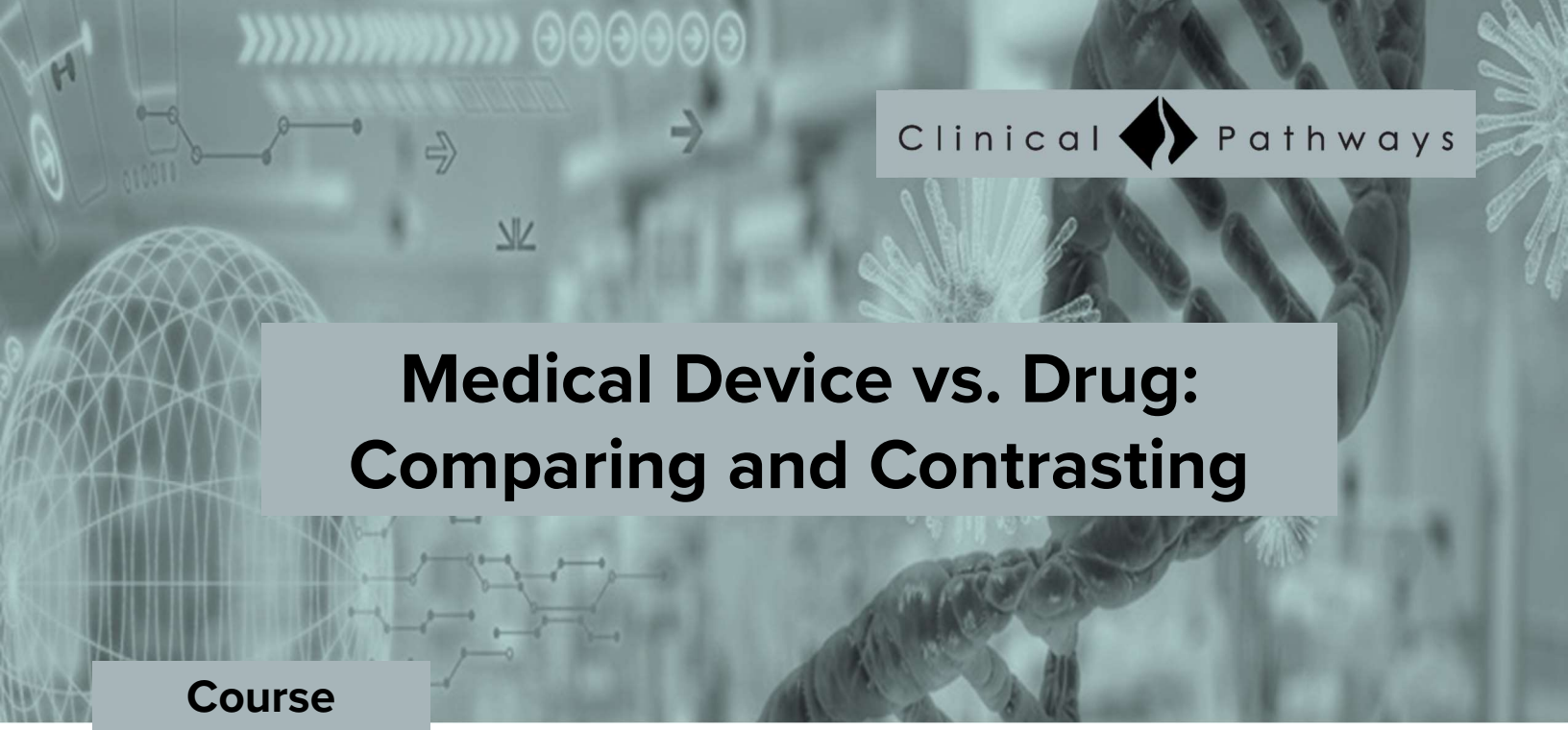


Clinical Pathways

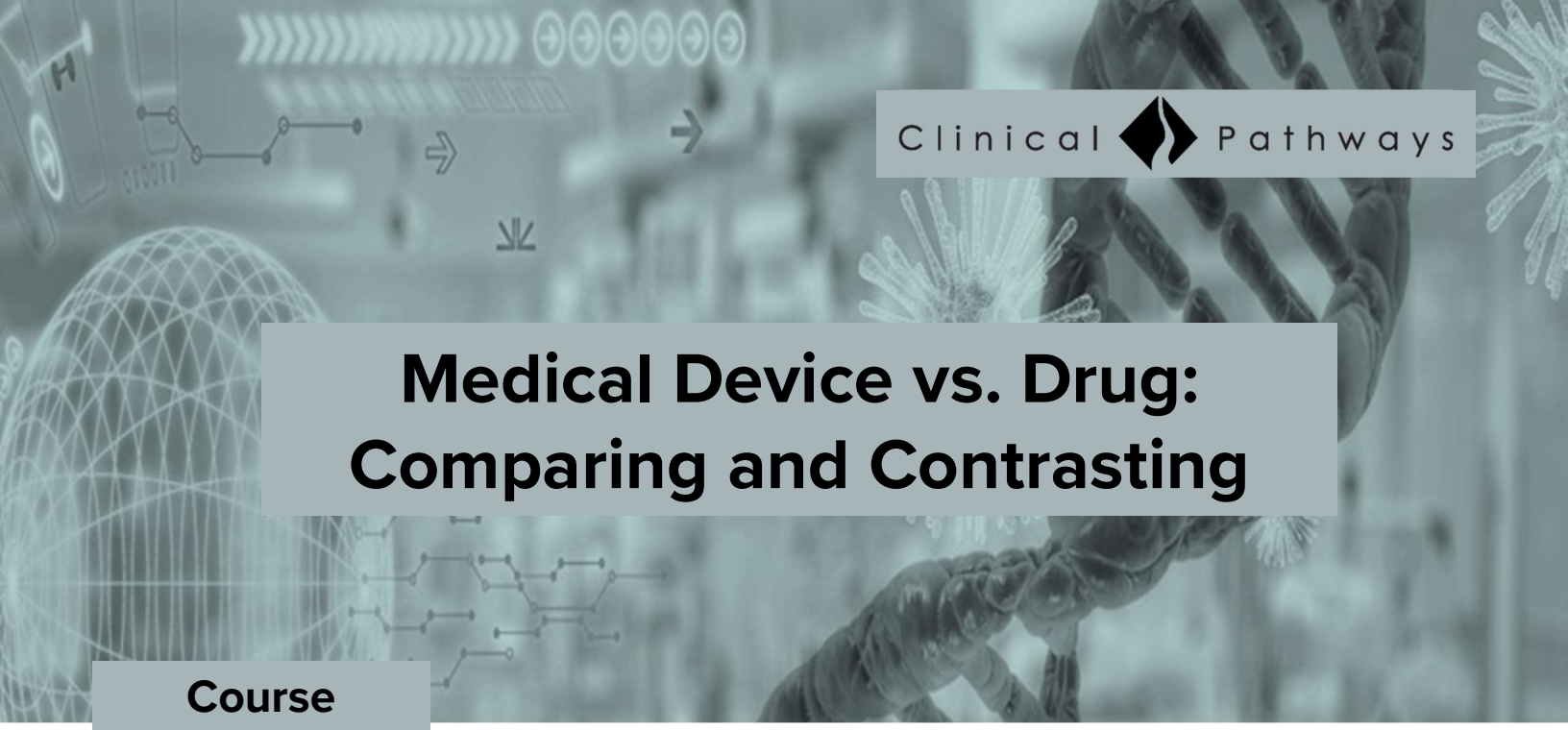
Medical Device vs. Drug: Comparing and Contrasting

Course Description

This interactive eLearning provides an overview of the differences between medical device and drug clinical trials from an FDA (U.S.-centered) perspective and covers GCP and some global regulatory perspectives.

Learning Objectives

1. Describe key definitions related to drug and medical device clinical investigations.
2. Recognize the differences between their regulatory development and approval processes.
3. Identify key differences in safety reporting, IRB duties, and oversight.



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Medical Device vs. Drug: Comparing and Contrasting

Course Description

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

When visualizing clinical trials, many automatically think about drug studies, especially if that has been their experience. Although there are similarities, there are quite a few differences between medical device and drug or biologic clinical trials, including:

- Safety reporting
- Patient populations
- Trial design
- Regulatory pathways
- Postmarket surveillance

Having a good understanding how medical device clinical trials are distinct from drug clinical trials provides a foundation for a successful outcome while protecting participants and data quality.

Clinical Pathways

Medical Device vs. Drug: Comparing and Contrasting

1. Overview of Differences
   a. Drug vs. Device
   b. More Product Definitions
   c. Device Regulatory Principles
   d. US & EU Device Classifications
   e. Examples of Device Classes
   f. Substantial Equivalence
   g. Significant Risk Device
   h. FDA Regulations
   i. ISO 14155:2020
2. FDA Divisions, BIMO, CIOMS
   a. FDA DIVISIONS
   b. FDA CDER
   c. FDA CBER
   d. FDA CDRH
   e. FDA's BIMO
   f. FDA BIMO Inspection Triggers
   g. BIMO Inspection Metrics
   h. FDA's Inspectional Activities
   i. FDA's International Inspectional Activities
   j. Warning Letter Initiative
   k. CIOMS
3. Regulatory Process, & Approvals and Applications
   a. Device Terminology and Comparisons
   b. The Drug Development Process
   c. IND's Legal Definition & Regulatory and Administrative Components
   d. Marketing Approval
   e. The Device Development Process
   f. 510(k)
   g. Premarket Approval
   h. US Approval Pathway (Class III)
   i. Device: Postmarket Surveillance & Reporting
4. Safety Reporting, IRB Duties, and Oversight
   a. Overview of Major Differences
   b. Adverse Event Characterization – Drug (FDA)
   c. Adverse Event Characterization – Device (FDA)
   d. Adverse Event Categorization – Device (ISO 14155)
   e. Safety Reporting: Adverse Event Definitions
   f. Adverse Events and Device Effects Decision Chart
   g. UADE vs. SUSAR – Expedited Reporting
   h. Post Market (Post Approval) Device Studies
   i. Summary of High-Level Differences
   j. Similarities
   k. Device vs. Drug Protocol Standards
   l. Additional Differences
   m. IRB/EC Role in Device Approval
5. Scenarios
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.