Course Schedule 2024

microLearning

EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

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Find below every microLearning topic available

(a new microLearning is released every month)

1. CLINICAL STUDIES OPERATIONS

- eTMF Reflections
- Informed Consent the Right Way
- What to look for when no 100% SDV?
- How to enhance oversight of the TMF?
- What to verify in an investigator site?
- Optimising Site Selection
- Creating worksheets for Clinical Source Data
- Informed Consent in a Nutshell
- What is drug accountability verification?
- How feasibility can make or break your study
- ALCOA - What does it stand for?
- Lessons Learned
- Kick-off Meeting Strategies
- Using Social Media to connect patient with your studies
- Vendor Oversight
- ATMP Overview: Regulatory Challenges and Case Studies
- Introduction to ATMP Development
- Risk Management
- GMP Essentials
- Electronic Informed Consent
- Liability in Study Contracts

2. DATA MANAGEMENT AND INFORMATICS

- How to deal with incomplete data?

3. ETHICS & PARTICIPANTS SAFETY CONSIDERATIONS

- Applying Ethical Principles in Clinical Research

4. COMMUNICATION

- Using Stakeholder's Analysis to help with you project Communication Plan

5. GCP

- How to write an effective CAPA?
- How to prove adequate Investigator Oversight?
- ICH-GCP E6 (R2) Oversight
- Differences between TMF and ISF
- Preparing for ICH E6 (R3) success
- ISO GCP Version3! What's new?
- Electronic Informed Consent
- Getting around the EMA website
- Getting around the FDA website

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6. HOT TOPICS

- COVID-19 and ongoing Clinical Trials

7. LEADERSHIP AND PROFESSIONALISM

- Remote Managemeent Style: What Works Best
- Leadership topic from Janssen

8. INVESTIGATIONAL PRODUCT DEVELOPMENT AND REGULATION

- A Safety Monitoring Approach during Clinical Trials
- Difference between ISO and ICH GCP
- Difference between Protocol Violation and Deviation
- Linking Trial Documents to Good Clinical Practice Requirements
- Serious Breaches in Clinical Trials
- Using eSource Data in clinical investigations
- A systematic Approach to Safety Monitoring during Clinical Trials
- The European Clinical Trial Regulation 536/2014: A Clear Outline
- How to cope with the development of drug-device combinations?
- ATMP Specific Guidelines
- Introduction to Complex Clinical Trial, Part 1: Definitions
- Introduction to Complex Clinical Trial, Part 2: Regulatory Framework
- The Rise of Health Apps and their value for Clinical Trials
- ICH: From a concept to a guideline

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