Clinical Trials for Study Coordinators

Online Training

Date: March 13-14, 2025

Hour: 13:30 GMT+2

Day 1 - 13th of March 2025

13:30 – 14:00	Registration
20 minutes	(Recent) History of Clinical Research
	• Historical events that shaped today's regulatory landscape of clinical research • Nuremberg Code (1947) • Declaration of Helsinki (1964) • The Belmont Report (1979) • ICH GCP (1996) • ISO 14155 (2003)
60 minutes	ICH GCP and CFR 21
	• International Council of Harmonisation Good Clinical Practice Guidelines (ICH GCP) • Principles of Good Clinical Practice (GCP) • Code of Federal Regulations (CFR) Title 21
15 minutes	Coffee Break
30 minutes	Clinical Research Process and Study Design
	• Phases of clinical research • Clinical Study Designs
30 minutes	Understanding the Organization of Clinical Research
	• Investigational Sites • Pharmaceuticals/Biopharma Companies • Contract Research Organizations • Site Management Organizations • Vendors • Independent Ethics Committees (IEC)/Institutional Review Boards (IRB) • Health Authorities
60 minutes	Coffee Break
20 minutes	Investigational Site Staff

	• Investigators • Clinical Research/Study Coordinators • Other research staffs • Delegation Log
50 minutes	Study Protocol and Informed Consent Form (ICF) including practical exercise
	• Clinical Study Protocol • Informed Consent Form (ICF) • Source Documents • Medical Records • Essential Documents (in accordance with ICH GCP)

Day 2 – 14th of March 2025

13:30 – 14:00	Registration
30 minutes	Safety Reporting in Clinical Trials
	• Adverse Events • Serious Adverse Events • Adverse/Medical Events of Special Importance • Concomitant Medication
40 minutes	The Study Coordinator
	• Study Coordinator's Role • Study start up • Recruitment • Preparing On-site and Remote Site Visits • Relationship with site staff and communication lines • Practical exercise
30 minutes	Investigational Medicinal Products (IMP)/Medical devices (MDev)
	• Receipt and storage • IVRS/IWRS • Documentation • Drug compliance
15 minutes	Coffee Break
30 minutes	Inspections and audits
	• Preparing for an audit.
20 minutes	Wrap-up