Clinical Research Associate (CRA) Entry Level

Online Training

Date: January 30-31, 2025

Hour: 13:30 GMT+2

Day 1 - 30th of January 2025

13:30 – 14:00	Registration
14:00 – 15:30	General Overview Of Clinical Trials
	• Drug development and various types of clinical trials • The Principles of ICH GCP (International Council for Harmonization guidelines for Good Clinical Practice) • Declaration of Helsinki • Running a clinical trial - the steps
15:30 – 16:30	Responsibilities
	• Investigators' responsibilities • Monitoring responsibilities and limits • Sponsor's responsibilities
16:30 – 16:45	Coffee Break
16:45 – 17:15	Essential Documents In Clinical Trials
	• The significance of various documents in clinical trials • The patient file and other source documents in clinical trials (practical approach) • Medical history and physical examination • Concomitant medical conditions and related medication • Non-clinical investigations in clinical trials • ALCOAC principles in practice
17:15 – 18:00	Informed Consent
	• The Informed Consent Procedure • Legal representative, witness

Day 2 – 31st of January 2025

13:30 – 14:00	Registration
14:00 – 15:00	Safety Reporting In Clinical Trials
	• Investigators to sponsor • Sponsor to authorities • The unblinding procedure
15:00 – 15:15	Coffee Break
15:15 – 16:20	Audits And Inspections
	• Audits and inspections including frequent audit findings • FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), sponsor inspections
16:20 – 17:30	Miscellaneous
	• Data management, statistical analysis • Archiving of clinical trials at the site (ISF) and sponsor (TMF) • Site contracts and investigators/institutions payment • Subcontracted vendors
17:30 – 18:00	Questions and answers
18:00	Test
	• Test (multiple choices) Note: Due to the interactive nature of the Agenda, the timing may change.