Clinical Trial Coordinator Training Agenda

Day 1 - 17th of October, 2024	
Topic	Session length (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)
	20

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	60
Coffee break	15
Clinical Research Process and Study Design • Phases of clinical research • Clinical Study Designs	30
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	30
Lunch	60
Investigational Site Staff • Investigators • Clinical Research/Study Coordinators • Other research staffs • Delegation Log	20

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)	50
Day 2- 18th of October, 2024	
Safety Reporting • Adverse Events • Serious Adverse Events • Adverse/Medical Events of Special Importance • Concomitant Medication	30
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	40
Investigational Medicinal Products (IMP)/Medical devices (MDev) • Receipt and storage • IVRS/IWRS • Documentation • Drug compliance	30
Coffee break	15
Inspections and audits • Preparing for an audit	30
Wrap-up	20