Clinical Trials Management Training Course

Professional Development Training Course Outline

Category	Public Health	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Clinical Trials Management is a high-demand, regulated, and innovation-driven field at the core of modern clinical research, drug development, and evidence-based healthcare. Clinical Trials Management Training Course is designed to equip learners with advanced competencies in GCP (Good Clinical Practice), ICH-GCP guidelines, clinical data management, regulatory compliance, pharmacovigilance, and trial operations. With the rapid growth of AI in clinical trials, decentralized trials (DCTs), real-world evidence (RWE), and digital health technologies, professionals must stay updated with evolving global standards.

This program provides a structured pathway to mastering end-to-end clinical trial lifecycle management, from protocol development to study closeout. Participants will gain hands-on expertise in site management, investigator coordination, ethics committee submissions, eCRF design, CDISC standards, patient recruitment strategies, and clinical monitoring systems. The course integrates real-world case studies and industry best practices to prepare learners for roles in CROs, pharmaceutical companies, biotech firms, and clinical research organizations worldwide.

Programme Curriculum

Clinical Trials Management Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Understand ICH-GCP guidelines & global regulatory compliance frameworks
2. Master clinical trial lifecycle management (Phase I–IV studies)
3. Apply risk-based monitoring (RBM) and quality-by-design (QbD) principles
4. Develop skills in clinical data management and CDISC standards (SDTM, ADaM)
5. Implement pharmacovigilance and adverse event reporting systems
6. Gain expertise in decentralized clinical trials (DCTs) and hybrid models
7. Learn protocol development and study design optimization
8. Understand electronic data capture (EDC) and eClinical systems
9. Improve patient recruitment and retention strategies using digital tools
10. Apply AI and machine learning in clinical trial analytics
11. Strengthen knowledge of regulatory submissions (FDA, EMA, MHRA)
12. Enhance clinical site management and investigator coordination
13. Build competencies in clinical trial auditing and inspection readiness

Target Audience

- Clinical Research Associates (CRA)
- Clinical Trial Coordinators (CTC)
- Pharmacovigilance Specialists
- Medical Doctors in Research Roles
- Biostatisticians and Data Managers
- Regulatory Affairs Professionals
- Pharmacy Graduates entering clinical research
- Life Sciences and Biotechnology Students

Course Modules

Module 1: Introduction to Clinical Trials

- Basics of clinical research and drug development
- Phases of clinical trials (I–IV)
- Stakeholders in clinical trials
- Regulatory landscape overview
- Ethical principles in human research
- **Case Study:** Pfizer COVID-19 vaccine Phase III trial design

Module 2: ICH-GCP Guidelines

- Principles of Good Clinical Practice

- Investigator responsibilities
- Sponsor obligations
- Ethics committee roles
- Compliance requirements
- **Case Study:** GCP violation in oncology trial audit

Module 3: Clinical Trial Design

- Randomized controlled trials (RCTs)
- Adaptive trial designs
- Blinding and randomization techniques
- Sample size determination
- Endpoint selection
- **Case Study:** Adaptive design in oncology drug approval

Module 4: Protocol Development

- Writing clinical protocols
- Inclusion/exclusion criteria
- Study objectives and endpoints
- Risk mitigation planning
- Protocol amendments
- **Case Study:** Protocol redesign in diabetes clinical study

Module 5: Regulatory Submissions

- IND/CTA applications
- FDA & EMA submission processes
- Ethics approval workflow
- Documentation requirements
- Regulatory timelines
- **Case Study:** Delayed FDA approval due to documentation gaps

Module 6: Clinical Data Management

- Data collection methods
- CRF and eCRF design
- Data validation and cleaning
- Database lock process
- CDISC standards
- **Case Study:** Data discrepancy in multi-site cardiovascular trial

Module 7: Electronic Data Capture (EDC)

- EDC systems overview
- System validation
- Data entry workflows
- Query management
- Integration with analytics tools
- **Case Study:** Implementation of Medidata Rave in oncology trials

Module 8: Pharmacovigilance

- Adverse event reporting
- Signal detection methods
- Safety reporting timelines
- Risk management plans
- Regulatory safety compliance
- **Case Study:** Drug withdrawal due to post-market adverse events

Module 9: Clinical Monitoring

- On-site monitoring
- Remote monitoring (RBM)
- Source data verification
- Site performance evaluation
- Monitoring visit reports
- **Case Study:** Monitoring failure in multi-country HIV trial

Module 10: Patient Recruitment & Retention

- Recruitment strategies
- Digital patient engagement tools
- Inclusion diversity practices
- Retention improvement techniques
- Recruitment analytics
- **Case Study:** Low enrollment in rare disease clinical trial

Module 11: Clinical Trial Operations

- Site selection and activation
- Supply chain management
- Trial logistics coordination
- Vendor management
- Timeline tracking
- **Case Study:** Supply chain disruption in vaccine trial

Module 12: Biostatistics in Clinical Trials

- Statistical study design
- Hypothesis testing
- Survival analysis
- Interim analysis
- Data interpretation
- **Case Study:** Misinterpretation of oncology survival data

Module 13: Clinical Trial Auditing

- Audit preparation
- Internal quality checks
- Inspection readiness
- CAPA (Corrective Actions)
- Compliance reporting
- **Case Study:** FDA inspection findings in Phase III trial

Module 14: Decentralized Clinical Trials (DCTs)

- Virtual trial models
- Wearable technologies
- Telemedicine integration
- Remote data collection
- Patient-centric approaches
- **Case Study:** COVID-era decentralized vaccine trial

Module 15: AI & Digital Transformation in Clinical Trials

- AI in drug discovery
- Predictive analytics in trials
- Machine learning for patient selection
- Blockchain in data integrity
- Digital biomarkers
- **Case Study:** AI-driven patient stratification in oncology trials

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

Ready to enroll or request a customized program? Book online or contact us:

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