Conducting Clinical Trials in Resource-Limited Settings Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The globalization of clinical research has dramatically increased the need for specialized expertise in conducting high-quality clinical trials in Resource-Limited Settings. These environments, often characterized by limited infrastructure, overburdened healthcare systems, unique disease burdens, and diverse socio-cultural dynamics, present significant contextual challenges to traditional research methods. Conducting Clinical Trials in Resource-Limited Settings Training Course is meticulously designed to equip clinical research professionals with the practical knowledge and context-specific strategies necessary to navigate these complexities. We emphasize the integration of core Good Clinical Practice principles with innovative, adaptive methodologies to ensure ethical research, participant safety, and the generation of reliable data that directly contributes to global health equity and evidence-based policy.

This comprehensive curriculum focuses on fostering sustainable research practices and strengthening local research capacity within Low- and Middle-Income Countries. Participants will master skills in protocol adaptation, community engagement (CE), managing regulatory hurdles, and implementing digital health tools for efficient data management in low-connectivity areas. By providing a framework for designing, implementing, and managing ethical and logistically sound trials, this course addresses the critical need for a skilled workforce capable of executing complex studies in challenging field conditions. Successfully completing this program is a clear pathway to becoming a leader in equitable clinical development and broadening the global impact of essential medical research.

Programme Curriculum

Conducting Clinical Trials in Resource-Limited Settings Training Course

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Course Duration

10 days

Course Objectives

Upon completion of this course, participants will be able to:

1. Adapt clinical trial protocols using context-specific modifications for RLS feasibility.
2. Apply ICH-GCP principles with an emphasis on contextual challenges and ethical compliance.
3. Implement effective community engagement (CE) and patient recruitment strategies to overcome trust barriers.
4. Master data management and quality assurance in low-connectivity environments using innovative tools.
5. Navigate complex regulatory and ethical approvals across diverse national and regional bodies.
6. Develop robust pharmacovigilance and adverse event reporting systems in resource-constrained contexts.
7. Manage trial logistics and the investigational product (IP) supply chain efficiently in the field.
8. Ensure participant safety and uphold research ethics when working with vulnerable populations.
9. Conduct remote and centralized monitoring strategies for efficient site oversight.
10. Strengthen local research capacity through mentorship and sustainable team building.
11. Perform site selection and feasibility assessments to mitigate operational risks proactively.
12. Utilize digital health tools and mobile technology for decentralized data collection.
13. Formulate locally relevant research questions that address the priority disease burden in RLS.

Target Audience

1. Clinical Investigators/Physicians (PIs)
2. Clinical Research Coordinators (CRCs)
3. Clinical Research Associates (CRAs)/Monitors
4. Clinical Trial Managers/Project Managers

5. Research Ethics Committee (REC)/IRB Members
6. Public Health and Global Health Professionals
7. Data Managers and Biostatisticians
8. Sponsor/CRO Personnel focusing on LMIC trials

Course Modules

Module 1: Global Health Context & Ethics Foundations

- Defining Resource-Limited Settings and unique operational challenges
- History of unethical research and the imperative for global health equity.
- Ethical issues of inducement and coercion in vulnerable populations.
- Case Study: The Trovafloxacin trial in Nigeria examining ethical breaches and their lasting impact.
- Role of GCP as a flexible standard for international clinical trials.

Module 2: Good Clinical Practice (GCP) Adaptation for RLS

- Translating core ICH-GCP principles to practical, context-specific SOPs.
- Delegation of trial-related duties and establishing a qualified research team with limited skilled personnel.
- Ensuring Source Document Verification where primary records are often paper-based or incomplete.
- Case Study: Adapting a global GCP monitoring plan to account for site-level challenges like poor internet connectivity for eCRF/EDC access.
- Building a basic Quality Management System for a field research site.

Module 3: Effective Community Engagement (CE)

- Strategies for establishing trust and rapport with local communities and leaders.
- The essential role and function of Community Advisory Boards in trial design.
- Overcoming recruitment barriers such as low literacy, cultural beliefs, and language differences.
- Case Study: A successful malaria vaccine trial that partnered with local religious and tribal leaders to achieve high recruitment and retention rates.
- Developing a sustainable post-trial access plan with community input.

Module 4: Protocol Design and Feasibility

- Practical protocol writing that is feasible and locally relevant to the disease burden.
- Conducting comprehensive pre-trial feasibility assessments to identify logistical risks.
- Adapting study design modifications to fit available resources.
- Case Study: Modifying a complex oncology trial protocol for an RLS where advanced imaging is unavailable, requiring a validated alternative endpoint.
- Determining an appropriate and practical sample size given enrollment constraints.

Module 5: Informed Consent Process in RLS

- Tailoring the Informed Consent Form for non-literate or semi-literate participants.
- Using independent witnesses, local languages, and teach-back methods to ensure comprehension.
- Ethical considerations for children, minors, and other vulnerable populations
- Case Study: Developing a culturally and linguistically appropriate consent process for a vaccine trial involving Indigenous populations with distinct social structures.
- Documentation of the consent process, including photograph and thumbprint requirements.

Module 6: Regulatory and Ethical Submissions

- Understanding the roles of local National Regulatory Authorities and IRBs/RECs.
- Navigating parallel submissions and managing complex, multi-site international approvals.
- Strategies for simplifying and accelerating the application and review process for faster activation.
- Case Study: Managing differing requirements between the FDA/EMA and a local African regulatory body for a single multicenter trial.
- Maintaining and managing the Investigator Site File and essential documents.

Module 7: Data Management and Digital Tools

- Implementing a robust Data Management Plan in a low-connectivity environment.
- Utilizing Electronic Data Capture systems that support offline work and mobile technology.
- Strategies for ensuring data quality, source data verification, and resolving data queries with limited internet.
- Case Study: Deployment of an open-source mobile phone-based data collection app for a remote rural cohort study.
- Ensuring patient data privacy and confidentiality with resource constraints.

Module 8: Investigational Product (IP) Logistics

- Establishing and maintaining the cold chain for sensitive study drugs with unreliable electricity.
- Management of IP accountability and inventory in non-ideal storage environments.
- Developing robust systems for drug dispensing and blinding to maintain trial integrity.
- Case Study: Designing a redundant cold-chain system using solar power and thermal packaging for a vaccine trial in a tropical region with frequent power outages.
- Contingency planning for drug stock-outs, damage, or theft.

Module 9: Laboratory and Ancillary Infrastructure

- Requirements for setting up a basic clinical trials laboratory in a resource-poor setting.
- Quality control and Quality Assurance for local lab work and sample processing.
- Logistics for shipping biological specimens to a central reference lab.
- Case Study: Creating a proficiency testing program for a local haematology lab to meet international standards for a malaria drug trial.
- Establishing occupational health and safety standards for research staff.

Module 10: Pharmacovigilance and Safety Reporting

- Developing local procedures for identifying, documenting, and reporting Adverse Events and SAEs.
- Defining and handling Suspected Unexpected Serious Adverse Reactions according to global and local guidelines.
- The role and composition of the Data Safety Monitoring Board in high-risk trials.
- Case Study: Rapid response plan for an unexpected cluster of severe AEs, including the need for immediate reporting and local medical care provision.
- Provision of care for research-related injuries and the role of clinical trial insurance.

Module 11: Monitoring, Audits, and Inspections

- Implementing remote and centralized monitoring to reduce the burden of on-site visits.
- Conducting effective on-site monitoring visits focusing on critical data and essential documents.
- Preparing the site for successful internal and external audits and regulatory inspections.

- Case Study: Using risk-based monitoring principles to prioritize site visits based on data quality and recruitment metrics in a multi-site RLS trial.
- Strategies for responding to Form 483s or other major audit findings.

Module 12: Biostatistics and Data Analysis

- Basic concepts of clinical trial biostatistics, including randomization and blinding.
- Challenges in statistical analysis due to missing data and high dropout rates in RLS.
- Interim analysis, stopping rules, and the role of the DSMB in reviewing trial progress.
- Case Study: Analyzing the impact of participant mobility and migration on final data analysis and intention-to-treat principles.
- Ensuring accurate data analysis and interpretation from diverse, heterogeneous populations.

Module 13: Team Building and Capacity Strengthening

- Strategies for mentorship and training to build a self-sufficient local research team.
- Developing an effective task delegation and succession planning framework.
- Understanding and mitigating "brain drain" by offering competitive professional development.
- Case Study: The successful establishment of a sustainable clinical research center by transitioning leadership and expertise to a local team over a five-year period.
- Grant writing and alternative funding strategies for sustainable site operations.

Module 14: Trial Closeout and Dissemination

- Procedures for premature trial termination and orderly study closeout.
- Investigator obligations for final reporting to regulatory authorities and ethics committees.
- Strategies for disseminating trial results to the local community in an accessible, ethical manner.
- Case Study: A plan for communicating the results of a negative HIV vaccine trial back to the study participants and the wider affected community.
- Archiving essential documents and ensuring long-term data storage with infrastructural limitations.

Module 15: Public Health and Policy Impact

- Translating clinical trial findings into evidence-based healthcare policies in LMICs.
- The role of research in addressing local disease burden priorities.
- Strategies for effective knowledge translation to policymakers and public health officials.
- Case Study: Using trial data on a new tuberculosis regimen to advocate for its inclusion in the National Treatment Guidelines of the host country.
- Measuring the impact and legacy of a clinical trial beyond its scientific output.

Training Methodology

This course employs a dynamic blended learning approach combining theoretical instruction with practical application, ensuring skills are immediately transferable to the field:

- Interactive Workshops and Didactic Lectures.
- Case Studies and Protocol Simulations.
- Role-Playing and Group Exercises.
- Mentored Training and Q&A.
- Low-Bandwidth Digital Tool Demonstrations.

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

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