Clinical Trial Harmonization in the East African Community (EAC) 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 East African Community (EAC) has emerged as a strategic research hub, yet its fragmented national regulatory landscapes pose significant challenges to efficient, multi-site clinical trial execution. The ambitious EAC Medicines Regulatory Harmonization (EAC-MRH) initiative aims to streamline processes, particularly the crucial Clinical Trial Application (CTA) and ethics review, across its Partner States. This harmonization is critical for unlocking the full potential of regional research, attracting global investment, and expediting patient access to essential medical products and innovative health technologies. This course is specifically designed to bridge the knowledge gap between the regional vision and practical national implementation, focusing on Good Clinical Practice (GCP) within the unique EAC framework.

Clinical Trial Harmonization in the East African Community (EAC) Training Course provides essential regulatory affairs expertise, moving beyond theoretical concepts to practical, cross-border operational excellence. It equips pharmaceutical professionals, researchers, and regulatory personnel with the necessary skills to navigate the joint assessment procedure, ensure compliance with harmonized guidelines, and improve data integrity in multi-country studies. By mastering the standardized EAC-MRH frameworks, participants will become key drivers in reducing time-to-approval, lowering operational costs, and ultimately enhancing the quality and ethical conduct of clinical development throughout the EAC region.

Programme Curriculum

Clinical Trial Harmonization in the East African Community (EAC) Training Course

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Course Duration

10 days

Course Objectives

1. Master the EAC-MRH Clinical Trial Guidelines and Joint Assessment procedures for multi-site studies.
2. Navigate the Regulatory Reliance mechanisms and their application across EAC National Regulatory Authorities
3. Ensure ICH-GCP Compliance within the context of EAC national laws and ethical requirements.
4. Expedite CTA Submission Timelines by utilizing harmonized Common Technical Document (CTD) formats.
5. Develop robust, region-specific Pharmacovigilance Systems for integrated Adverse Event (AE) reporting.
6. Interpret and apply Harmonized Ethics Review standards for EAC Ethics Committees (ECs).
7. Implement best practices for Investigational Medicinal Product (IMP) import/export and Supply Chain Management.
8. Formulate Quality Management Systems (QMS) for regional studies to ensure Data Integrity and audit readiness.
9. Analyze the impact of Digital Health Adoption and Decentralized Clinical Trials (DCTs) in the EAC market.
10. Leverage EAC's diverse patient population to maximize Recruitment Strategy and enhance study feasibility.
11. Collaborate effectively with key regional stakeholders
12. Mitigate Regulatory Risk and successfully manage joint inspections and national audits.
13. Contribute to strengthening Local Regulatory Capacity for sustainable Clinical Development in East Africa.

Target Audience

1. Clinical Research Associates and Clinical Trial Managers
2. Regulatory Affairs Professionals in pharmaceutical, biotech, and CROs.
3. National Regulatory Authority (NRA) staff and Assessors.
4. Ethics Committee (EC) members and Administrators.

5. Principal Investigators (PIs) and Site Research Staff
6. Quality Assurance (QA) Auditors and Compliance Officers
7. Project Managers and Business Development Staff from international Sponsors interested in African research.
8. Public Health Officials and staff from regional health organizations

Course Modules

Module 1: Foundations of EAC Regulatory Landscape

- EAC Treaty, Health Sector Policy, and the mandate of the EAC-MRH Programme.
- Structure and roles of National Regulatory Authorities and their capacity variations.
- Overview of the African Medicines Agency and its regional integration with EAC.
- Understanding the legal basis for Mutual Recognition and Regulatory Reliance.
- Key Global Health Initiatives driving harmonization in the region.
- Case Study Topic: Comparing the statutory powers and structure of PPB (Kenya) and TMDA (Tanzania).

Module 2: EAC Harmonized Ethics Review Process

- Role and composition of EAC Ethics Committees and their oversight framework.
- Harmonized guidelines for Ethics Application Dossier submission and review.
- Informed Consent in vulnerable and diverse populations.
- Managing the relationship between national ECs and the lead EC in a multi-site trial.
- Review turn-around time and strategies for minimizing EC-related delays.
- Case Study Topic: Simulating a joint EC/IRB review of a Malaria Vaccine protocol for cultural sensitivity and fairness.

Module 3: The Clinical Trial Application (CTA) Dossier

- Mandatory use of the Common Technical Document format for EAC-MRH submissions.
- Detailed requirements for the Investigator?ÇÖs Brochure and Protocol documentation.
- Preparing the national and regional components of the CTA for multi-country submission.
- Strategies for quality control and completeness checking of the CTA dossier.
- Handling amendments and variations to an approved CTA across EAC states.
- Case Study Topic: Building a compliant CTA package for an Oncology Trial across three EAC partner states.

Module 4: EAC Joint Assessment and Approval

- Procedural steps and timelines for the EAC Joint Assessment Procedure.
- Role of the Regional Technical Officers and the EAC Secretariat.
- Managing communications and queries from the joint assessment team and NRAs.
- Understanding and responding to the Deficiency Letter and post-assessment requirements.
- The final steps for achieving National Approval and site activation after joint review.
- Case Study Topic: Simulating a Joint Assessment team review meeting for a HIV Prevention Drug trial.

Module 5: Good Clinical Practice (GCP) in the EAC Context

- In-depth review of ICH-GCP E6(R2) and its adoption/adaptation by EAC NRAs.
- Local context considerations.
- Specific EAC requirements for Investigator Qualifications and delegation of duties.
- Ensuring Source Data Verification and Trial Master File quality in a regional setup.

- Sponsor responsibilities for Oversight and management of regional CROs/Vendors.
- Case Study Topic: Addressing a major GCP non-compliance issue at a remote site in a multi-center Tuberculosis trial.

Module 6: IMP Supply Chain and Cold Chain Management

- Harmonized EAC guidelines for the Importation and Exportation of Investigational Medicinal Products
- Customs clearance procedures and managing Cross-Border Logistics challenges.
- Best practices for Cold Chain Management and temperature monitoring in challenging climates.
- IMP accountability, reconciliation, and managing drug destruction/disposition.
- Regulatory requirements for Ancillary Supplies and medical devices in trials.
- Case Study Topic: Developing a temperature excursion management plan for a vaccine trial involving transport between Kigali and Juba.

Module 7: Pharmacovigilance and Safety Reporting (EAC-PV)

- Harmonized EAC requirements for Adverse Event and Serious Adverse Event reporting.
- Establishing a robust regional Safety Monitoring System and data flow pathways.
- Roles and responsibilities of the Data and Safety Monitoring Board in EAC trials.
- Timelines and formats for expedited and aggregate Safety Reporting to NRAs.
- Strategies for managing and reporting safety data from DCT components.
- Case Study Topic: Handling a fatal, unexpected SAE and the subsequent reporting cascade across EAC NRAs within the 7-day timeline.

Module 8: Quality Management Systems (QMS) and Audits

- Principles of Quality Assurance (QA) and Quality Control (QC) for EAC trials.
- Developing and implementing harmonized Standard Operating Procedures for regional use.
- Preparing for and successfully navigating NRA Audits and Inspections
- Conducting Internal/External Audits of multi-site EAC trial operations.
- Developing Corrective and Preventive Actions (CAPA) plans for audit findings.
- Case Study Topic: Preparing a multi-site study for an NRA inspection in Tanzania following a major protocol deviation at one site.

Module 9: Clinical Data Management and Integrity

- EAC regulatory expectations for Electronic Data Capture systems and compliance.
- Ensuring Data Integrity in resource-limited and remote settings.
- Harmonized standards for Data Security, Privacy, and compliance with local laws.
- The role of the Data Management Plan (DMP) in a multi-country EAC trial.
- Preparing the final Clinical Study Report (CSR) for regional submission.
- Case Study Topic: Validating a new EDC system for a trial involving remote data entry from Uganda and DRC sites.

Module 10: Digital Health and Decentralized Trials (DCTs)

- EAC's stance on incorporating Digital Health Technologies and Telemedicine into trials.
- Regulatory challenges and opportunities of implementing Decentralized Clinical Trials
- Ensuring patient privacy and security in the use of Wearables and remote monitoring tools.
- Regulatory approval pathways for Investigational Medical Devices and diagnostics.
- Future trends: leveraging AI/ML in EAC clinical research for Protocol Optimization.

- Case Study Topic: Designing a DCT model for a chronic disease management trial using local mobile health platforms.

Module 11: Site Selection, Initiation, and Capacity Building

- Criteria for selecting high-performing Clinical Trial Sites in EAC partner states.
- Strategies for effective Feasibility Assessment and patient population mapping.
- Executing the Site Initiation Visit (SIV) with a focus on harmonized procedures.
- Developing and monitoring Site-Level Quality Management Plans.
- Investing in Local Research Capacity and mentorship programs at EAC sites.
- Case Study Topic: Troubleshooting a major patient recruitment failure at a new clinical site in Burundi.

Module 12: Biostatistical and Trial Design Considerations

- Harmonized EAC requirements for Statistical Analysis Plans and sample size justification.
- Designing Adaptive Clinical Trials and innovative methodologies for the African context.
- Addressing Genetic Diversity and its implications for study design and results interpretation.
- Regulatory expectations for Interim Analysis and early study termination.
- Ensuring Transparency in data sharing and publication of results in the EAC.
- Case Study Topic: Justifying the statistical power for a non-inferiority trial of a locally manufactured drug.

Module 13: Specialized Trial Types and Populations

- Regulatory guidance for Pediatric Trials and trials involving Vulnerable Populations.
- Specific EAC requirements for Bioequivalence and Generic Drug studies.
- Conducting Traditional Medicine and Herbal Product trials under EAC-MRH.
- Special considerations for Vaccine and Biotherapeutic Product clinical development.
- Compliance for trials involving Biological Samples and export/storage regulations.
- Case Study Topic: Navigating regulatory and ethical consent requirements for a pediatric HIV prophylactic trial.

Module 14: Stakeholder Collaboration and Advocacy

- Effective Communication Strategies with EAC NRAs and the EAC Secretariat.
- Building sustainable partnerships with Local CROs and academic institutions.
- Contributing to The Refinement of EAC Regulatory Policy.
- Leveraging support from the African Medicines Agency and international partners
- Understanding the political and economic factors influencing harmonization progress.
- Case Study Topic: Developing a regional advocacy strategy to accelerate the formal adoption of a new EAC clinical trial guideline.

Module 15: Post-Approval and Market Access

- Transitioning from clinical trial approval to Marketing Authorization in the EAC.
- Utilizing Reliance Mechanisms for faster product registration based on stringent regulatory authority approvals.
- Post-market Surveillance and continued pharmacovigilance commitments.
- Strategies for pricing, reimbursement, and ensuring Affordable Access to Medicines.
- The future of Clinical Development and research capacity after full EAC harmonization.
- Case Study Topic: Charting the regulatory pathway for an already WHO-prequalified product seeking fast-track MA in the EAC.

Training Methodology

The course utilizes the Applied Regulatory Excellence (ARE) methodology, a blended approach combining:

- Expert-Led Lectures.
- Interactive Workshops.
- Real-World Case Studies.
- Practical Tools & Templates.
- Stakeholder Panels.

Register as a group from 3 participants for a Discount

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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
07 Sep 2026	18 Sep 2026	Online	$4,000
14 Sep 2026	25 Sep 2026	Online	$4,000
21 Sep 2026	02 Oct 2026	Online	$4,000
28 Sep 2026	09 Oct 2026	Online	$4,000

Start Date	End Date	Location	Price
05 Oct 2026	16 Oct 2026	Online	$4,000
12 Oct 2026	23 Oct 2026	Online	$4,000
19 Oct 2026	30 Oct 2026	Online	$4,000
26 Oct 2026	06 Nov 2026	Online	$4,000

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