

Job Description: Country Project Manager

Location: Addis Ababa, Ethiopia

Reports To: Board of Directors

Organization: Horn of Africa Clinical Trials (HACT)

This position is a strategic appointment designed to lead our Ethiopian operations while fulfilling the critical regulatory mandate recently issued by the Ethiopian Food and Drug Authority (EFDA) regarding local Pharmacovigilance representation.

1. Executive Summary

The Country Project Manager will lead the strategic direction, operational execution, and regulatory compliance of HACT in Ethiopia. This individual will serve as the primary face of the organization to the Ethiopian Food and Drug Authority (EFDA)/Ethiopian Ministry of Health (EMOH) and international partners. Crucially, the incumbent will also serve as the **Local Qualified Person for Pharmacovigilance (QPPV)**, ensuring HACT and its partners meet the legal requirements of Proclamation No. 1112/2019 and Directive No. 932/2022.

2. Key Responsibilities

A. Strategic Leadership & Business Development

- Direct the overall activities of HACT Ethiopia in alignment with the HACT Quality Manual and global mission.
- Identify and target local and international business development opportunities to expand HACT's clinical trial portfolio.
- Represent HACT at national and regional conferences and high-level meetings with the Ministry of Health and sponsors.

B. Technical Focal Person: Pharmacovigilance (Local QPPV)

- Establish and maintain the HACT Pharmacovigilance System in Ethiopia.
- Serve as the primary point of contact for the EFDA on all safety matters.
- Oversee the collection, processing, and submission of Individual Case Safety Reports (ICSRs) and reportable serious and non-serious Adverse Drug Reactions (ADRs) to the EFDA or Marketing Authorization holders (MAHs).
- Manage Post-Authorization Safety Studies (PASS) and coordinate inputs for labeling changes with the Regulatory Affairs department.

C. Clinical Trial Oversight & Regulatory Affairs

- Provide hands-on leadership for clinical trial planning, monitoring, and site management.
- Ensure all trials are conducted in strict accordance with Good Clinical Practice (GCP) and EFDA guidelines and international standards.
- Liaise with the EFDA for trial approvals, inspections, and the development of landscape analyses for clinical research in Ethiopia.

D. Quality Management & Compliance

- Act as the final authority on the implementation of the HACT Quality Management System (QMS).
- Ensure all staff maintain up-to-date training records and adhere to Standard Operating Procedures (SOPs).
- Oversee Corrective and Preventive Actions (CAPA) and facilitate third-party audits/regulatory inspections.

3. Required Qualifications & Experience

Education:

- **Bachelor of Pharmacy (B.Pharm)** is mandatory.
- Advanced degree (MPH, MSc, MD, or Ph.D.) in public health, Clinical Research, or a related field is highly preferred.

Experience:

- **Leadership:** Minimum of 8–10 years of experience in the pharmaceutical or clinical research sector, with at least 3 years in a senior management or executive role.
- **Clinical Trials:** Proven "hands-on" experience in managing end-to-end clinical trials (Phase I–IV).
- **Pharmacovigilance:** In-depth knowledge of Ethiopian PV directives and international safety reporting standards (ICH-E2).
- **Regulatory:** Demonstrated success in navigating EFDA regulatory processes and pharmaceutical inspections.
- **Quality Control:** Experience in implementing QMS, SOPs, auditing suppliers, and maintaining GCP/GVP compliance.

Key Competencies:

- Residency in Ethiopia (mandatory).
- Fluency in English (written and spoken).
- Exceptional leadership, communication, and negotiation skills.
- Strong understanding of the African clinical research landscape and WHO standards.

4. Why Join HACT?

HACT is at the forefront of bridging the clinical research gap in Africa. As our leader in Ethiopia, you will play a historical role in establishing a world-class research hub, ensuring the safety of African patients, and driving innovation in a newly upgraded Maturity Level III regulatory environment.

How to Apply:

Qualified candidates are invited to submit their CV, letter of interest, and evidence of pharmacy licensure to support@hacts.org.

HACT is an equal opportunity employer committed to excellence, integrity, and regulatory compliance in clinical research.