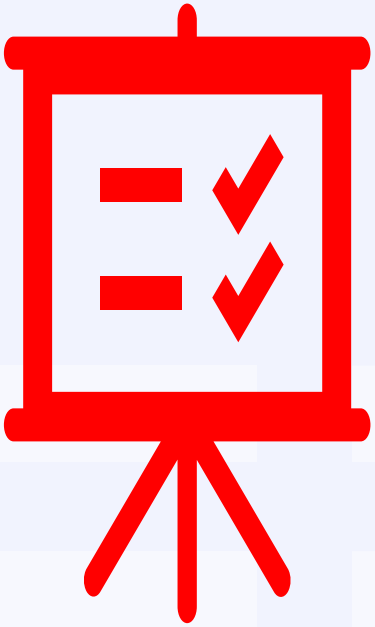
Role of local Clinical Research Organizations in clinical trials capacity building

Nick Kisengese
Director, ClinWin Research Services

Outline

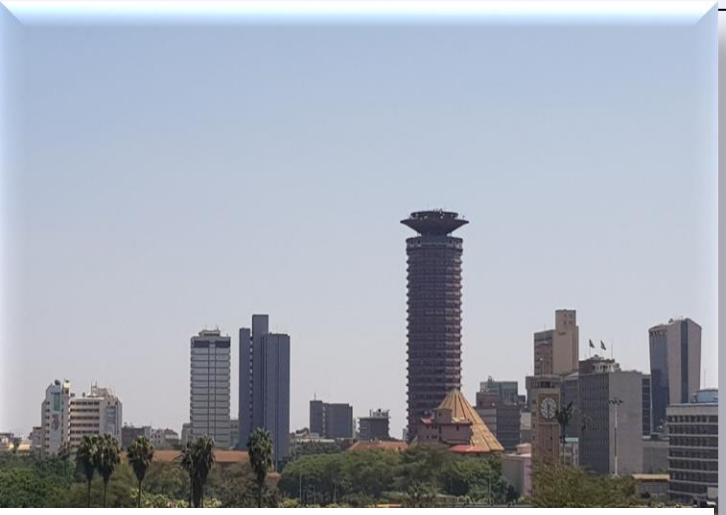


- Introduction
- About ClinWin
- Rationale
- Successes
- Opportunities
- Way forward

Introduction

- Contract Research Organization (CRO) - A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. ICH GCP 1.20
- Demand for clinical trial personnel has been increasing, with average compound annual growth in monthly job postings activity of 9.3 percent across all clinical research positions.
- East Africa is home to locally registered and international CROs.
- Qualified and experienced team is critical to bring new products to market quicker.

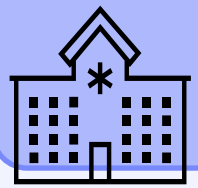
About us



- ClinWin is a mid-sized Contract Research Organization (**CRO**) based in Nairobi, Kenya, with regional offices at Kampala, Uganda and Kigali, Rwanda. With locally based Clinical trials Monitoring Consultants in Khartoum, Sudan; and Tanzania.
- Provides outsourced Clinical Development and Strategic Consulting Services
- We subscribe to One Health approach in our service offerings
- We have expertise in projects delivery and deployment of life saving health technologies and interventions in resource limited settings.
- Expertise in Early, Late-Phase and Real-World Evidence

Our Services

Feasibility and Study Start Up



- Feasibility and Site Identification.
- Ethical and Regulatory Approvals.
- Trial Site Capacity Development.

Clinical Monitoring and Management

- Clinical Trials Monitoring.
- Clinical Quality Assurance Audits.
- Medical monitoring and Safety
- Investigational Product Management

Project Management

- Study Management.
- Quality Management.
- Team and Vendor Management.
- Project Administration.

Data Science and Technology

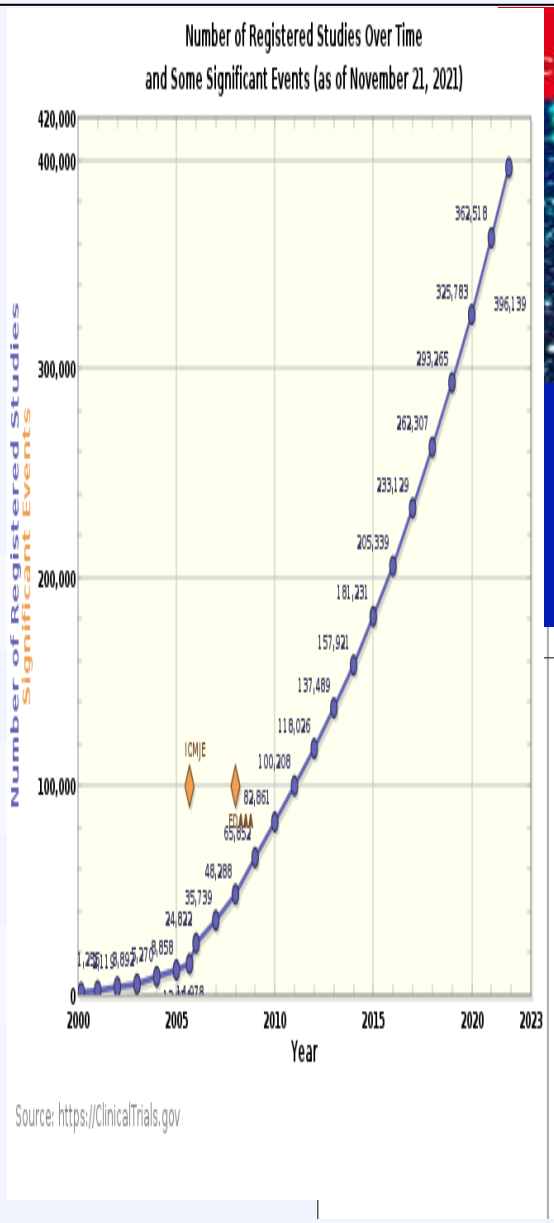
- Data Management and Analytics.
- Artificial Intelligence
- Technology Solutions

Strategic Consulting

- Clinical Research and CRA training.
- Clinical Study Documents Development.
- Regulatory affairs consulting
- Functional Services Provision

The Rationale for Local Capacity Building

- Global priority to develop clinical trials work force to meet increasing CR workload needs
- Emerging new technologies
- Increasing number of clinical trials conducted locally
- Wellbeing and safety of research participants
- Need for qualified and competent workforce to conduct clinical research
- Local and global regulatory compliance
- ICH GCP compliance
- Public confidence in clinical research
- Efficiency and quality



Economist Report Issues Call to Action: Invest in Clinical Research Workforce
https://acrpnet.org/2018/07/10/economist-report-issues-call-to-action-invest-in-clinical-research-workforce/

www.picronline.org

Training needs of clinical research associates

Clinical research is a relatively new field in our country that has seen very rapid growth in the last few years. Availability of personnel appropriately trained to the specific requirements of the role they will perform in clinical research is critical for capacity expansion. Our study attempts to understand the specific areas of knowledge and skills that are important for the role of a clinical research associate. The survey was conducted among clinical research professionals from

Our Approach to Clinical Trials Site Development

We conduct site assessments and design capacity development plan based on site needs.

Specifically, we conduct the following:

- Project Management and Site Operations
- Clinical Research Training and Professional Development
- Quality Assurance *(trials site QMS development)*
- Physical infrastructure assessments *(Labs, Pharmacy, patient reception areas, samples storage)*
- Data Management
- Study Management
- Protocols, ICFs and and other Source documents development

Clinical Research Training

ClinWin in partnership with KAVI Institute of Clinical Research, University of Nairobi conducts short courses in Clinical Research.

We offer skills-based and tailored courses in:

CLINWIN RESEARCH SERVICES
Efficiency, Quality, Ethics

KAVI-ICR

COURSE ANNOUNCEMENT

Entry Level Clinical Trial Monitoring (Clinical Research Associate) course.

We are pleased to announce Entry Level Clinical Trials Monitoring Course offered by ClinWin Research Services in partnership with KAVI Institute of Clinical Research, Department of Microbiology, University of Nairobi. The course will be held on 09 - 14 November 2020, Nairobi, Kenya.

INTRODUCTION

Clinical Research Associate (CRA); also, commonly known as Monitor, oversees the progress of a clinical trial, and ensures that it is conducted, recorded, and reported in accordance with the protocol, SOPs, Good Clinical Practice and applicable regulatory requirements.

WHO SHOULD ATTEND?

The course is designed for individuals with at least two years' work experience in clinical research work at Investigator site level, Sponsor (academic, Pharmaceutical or not for profit research organizations) or related health care industry.

COURSE COST

The cost of the training is Ksh 100,000 (Hundred thousand), to cater for the course materials, lunch, morning and afternoon tea and Certificate. The training fee should be paid on or before 02 November 2020. Please email us the payment confirmation once completed.

COURSE CERTIFICATION

The training is organized in collaboration with University of Nairobi, KAVI Institute of Clinical Research. The training involves classroom presentations, practical's and group discussions. Pre and post course assessments will be administered. The participants will be issued with Certificate of Completion upon successful completion of the course.

PRE-COURSE WORK

Visit our website news and events page to view teh advert with the links and emal us certificates on or before 31st Cotober 2020.

Please email us your CV and motivation letter to
info@clinwinresearch.com and copy
training-coordinator@kaviuon.org & training@clinwinresearch.com

VENUE
KAVI Institute of Clinical Research, Department of Microbiology, University of Nairobi.

CONTACT US
Tel: +254 (0)721 515 009 / 0715 679 365 / 0722 899 532
Office: +254 20 3673526 / 0730 173 526
Fax no: +254 20 273740

www.clinwinresearch.com | http://kaviuon.org/training

- **Entry and Advanced Level Clinical Trials Monitoring**
- **Clinical Trials Coordination and Site Management**
- **Good Clinical Practice**
- **Data Management**
- **Bioethics**
- **Good Clinical Laboratory Practice**
- **Vaccinology**

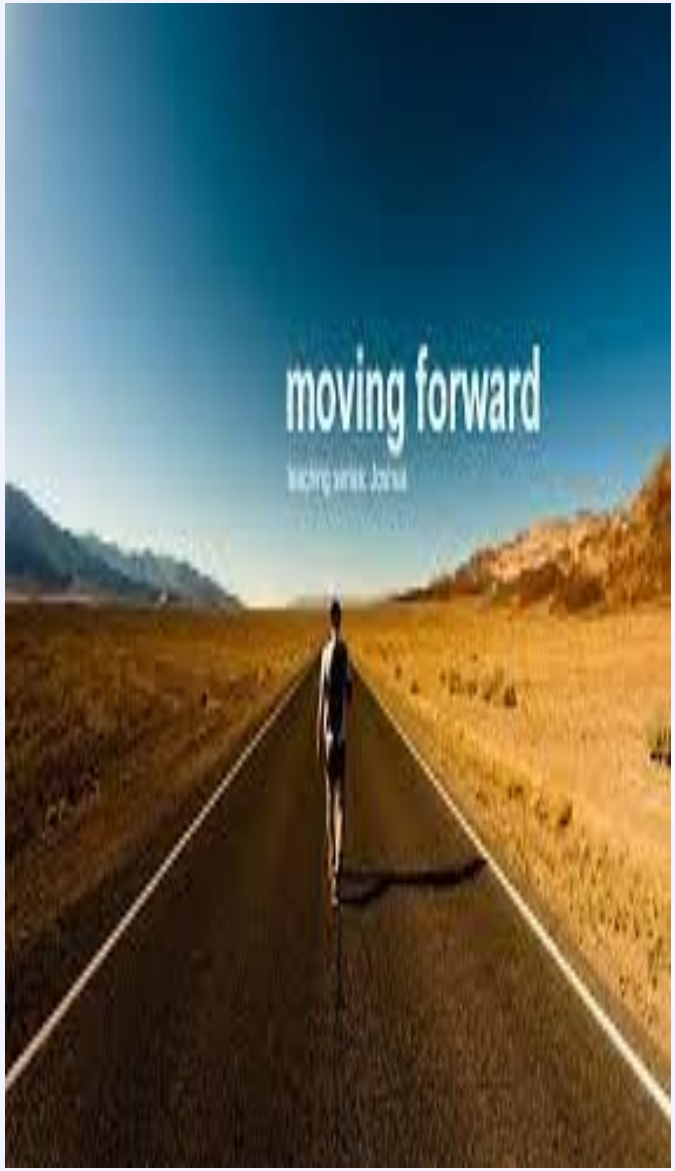
Successes

- Conducts site staff and facilities needs assessments
- Supports in site and trial management
- On-site and web-based site staff trainings
- Entry level and advanced clinical monitoring training for site Monitors – with 50+ CRAs trained to date.
- Site staff training on GCP and HSP
- On-site monitoring and oversight
- Mentorship and internship for entry level clinical research professionals at CROs
- Partnerships with local Universities to offer skilled based trainings

Opportunities

- Partnership with medical schools to offer skill-based courses and academic programs – Msc, PhDs
- Mentorship by experienced clinical researchers based at CROs, Pharma and AMC
- Student internships at CROs and other academic Medical centers
- Clinical Research Methods to be offered to all medical students
- Linkages with global clinical research training consortiums e.g. CTTI, Transcelerate.
- Pre-qualification/Pre-site assessments
- Investigator meeting and Site Initiation Visits
- On-site/Remote monitoring visit

Way Forward ……..



- Invest in clinical research workforce development at all levels, from high schools Science clubs and Colleges.
- Identify training needs for existing clinical research workforce, offer relevant training and mentorship.
- Stimulate interest in clinical research enterprise among scientists and medical graduands.
- Provide legal and regulatory for certification of clinical research professionals.
- Form clinical research professional association.

Thank you

www.Clinwinresearch.com