ClinWin Research Services

Efficiency . Quality . Ethics

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

Mission and Vision

To partner with biopharmaceutical companies, academia, Government and CRO clients to support the successful outcome of their projects and programs.

Our Values

We advance our clients' assigned projects through integrity, teamwork, quality and accountability

Our Guiding Principles

Efficiency, Quality and Ethics

Our History

2011

Registered as research services business in Kenya, with one staff.

2012

First 4 employees.

2 CRAs, Data Manager and Project Manager.

2018 Incorporated in Kenya as Limited Liability Company .

Medical Director,

11 CRAs, 2 COM, 2 CPM, 6 Data Assistants.

4 Clinical Monitors/CRAs Khartoum, Sudan.

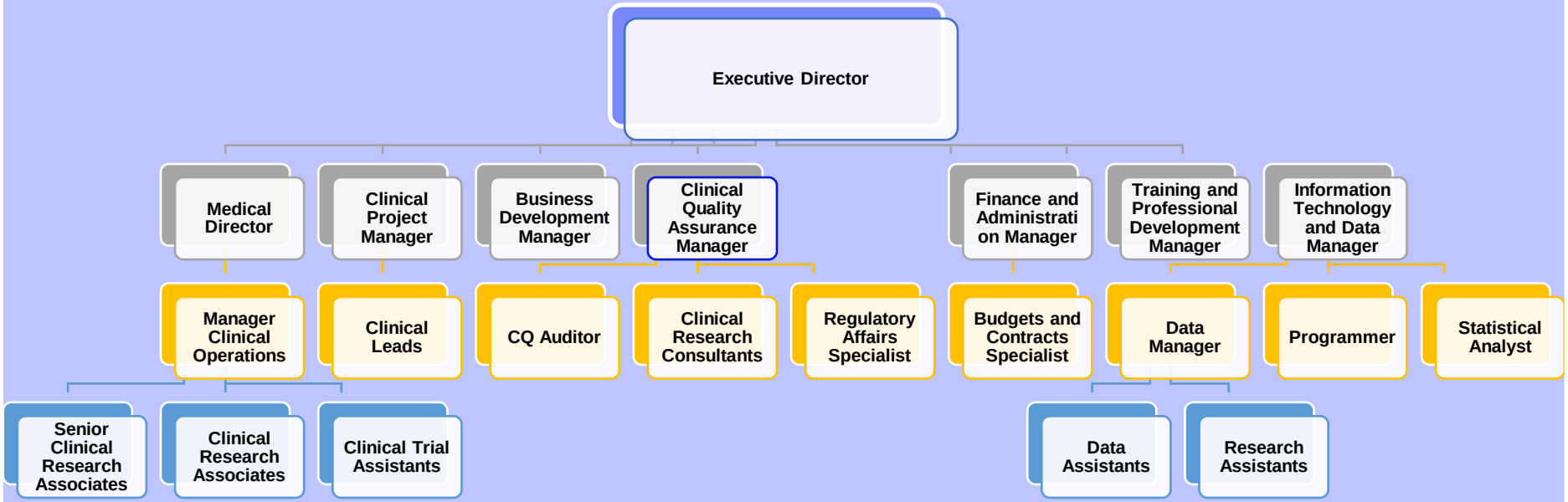
2019 Incorporated in Uganda and Rwanda, with Local staff.

1 Clinical Operations Manager and Country Representative, 3 CRAs.

2019- to date
In consortium with Pharmalys CRO, awarded contract to mange RTT,S Malaria vaccine trial in Kenya, Ghana and Malawi.

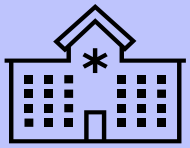
2021 - Expanded operations into Tanzania

ClinWin Organogram



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

- Training and Capacity Development .
- Regulatory affairs consulting
- Functional Services Provision
- Health Outcomes studies
- Surveys, Monitoring and Evaluation

Therapeutic Expertise

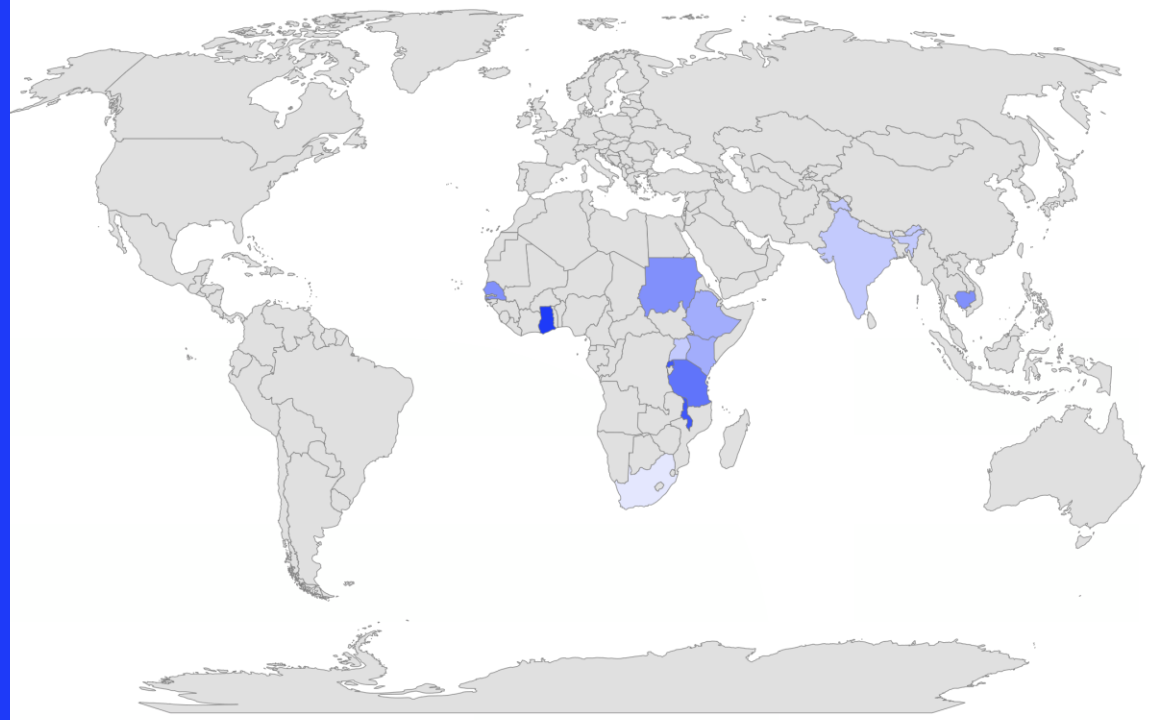
- Infectious diseases
- Neglected Tropical Diseases
  - *Leishmaniasis,,*
  - *Mycetoma,*
  - *Hookworm*
  - *Tungiasis*
- Endocrinology
- Hematology
- Reproductive Health
- Medical Devices
- Antimicrobial resistance
- Oncology
- Respiratory
- Herbal Medicine
- SARS-COV-19

Vaccines Clinical Trials Experience

- Shigella
- HIV
- Ebola
- TB
- Malaria
- Leishmaniasis
- Varicella Zoster
- Hookworm
- Respiratory Synctial virus
- HPV
- SARS-COV-19

Geographical Experience

Kenya
Uganda
Tanzania
Rwanda
Malawi
South Africa
Mozambique
Senegal
Ghana
Ethiopia
Sudan
Zambia
Zimbabwe
Nigeria
India
Cambodia



Technology Experience

Our team is experienced and proficient in Electronic CRFs, mobile data collection, Ele Data Capture systems, these including:

- Meditata RAVE
- Oracle,
- Clinical Trial Management Systems (CTM
- Inform
- R
- RedCap,
- OpenClinica
- ODK
- KAMOLO EDC
- Medrio
- Castor

Partnership and Collaborations

- ClinWin is a member of Alliance for Excellence Consortium https://www.i3consult.com/2443-2/

(*This group of handpicked CROs allows us to take advantage of geographical or indication-related specialization, without the disadvantages of big full-service CROs.*)

- *ALAMERA Consortium*

- Five years Memorandum of Understanding with University of Nairobi, through KAVI Institute of Clinical Research http://kaviuon.org/training for joint development of training and research programmes

- University of Khartoum through The Institute of Endemic Diseases

- Global and regional CROs, e.g. Pharmalys. Phoenix Clinical Research (Egypt), FieldPro Research (Ivory Coast) and ClinGroup (MENA), Angel Michaels Research (Kenya/Nigeria)

CLINICAL RESEARCH TRAINING AND CAPACITY DEVELOPMENT

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:

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

Training History

Sep 2017
Signed MOU Between University of Nairobi and ClinWin Research. To conduct collaborative research and training

October2019
Entry Level Clinical Monitoring training.

20 participants

November 2020
Entry Level Clinical Monitoring training.

15 participants

March 2022
Entry Level Clinical Monitoring training.

23 participants

KAVI ICR/UON – ClinWin Research Clinical Monitoring Course

May 2018
Advanced CRA Course for EACTRC conducted in Nairobi.

10 Participants

February 2019
Drugs for Neglected Diseases Initiative, Clinical Operations team Advanced Monitoring training .

8 participants

August 2019
Drugs for Neglected Diseases Initiative, Leishmaniasis Monitoring team training .

8 participants

August 2021
Entry Level Clinical Monitoring training.

17 participants

October 2022
Entry Level Clinical Monitoring training.

13 participants

Clinical Trials Site Development

We support our clients in:

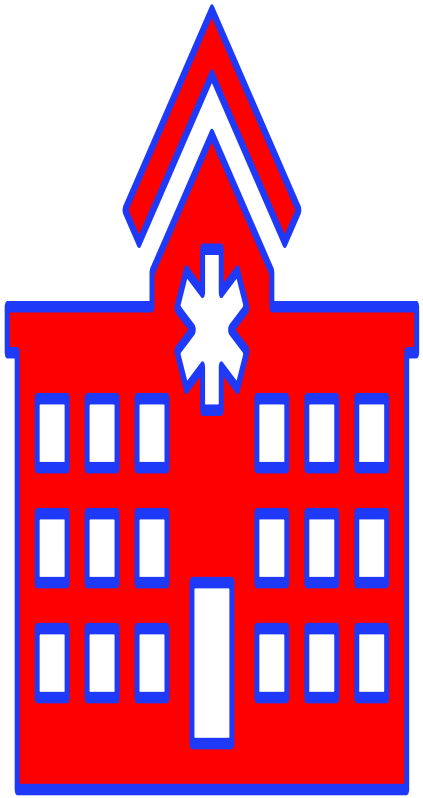
- ❑ Project Management and Site Operations
- ❑ Clinical Research Training and Professional Development
- ❑ Quality Assurance *(trials site QMS development)*
- ❑ Physical infrastructure assessments *(Labs, Pharmacy, patient reception areas, samples storage)*
- ❑ Data Management
- ❑ Study Management

Functional Services Provision

We offer insourced services as extension of the client's team in the following areas:

- Clinical Research Associates/Trial Monitors
- Data Management Managers and Assistants
- Clinical Trial Assistants
- Statisticians
- Patient Recruitment
- Project Manager
- SAS Programmers

Trial Site Staff Capacity Development process



- We conduct site staff capacity assessment and tailor our training and development plan as the site needs.
- The plan takes into consideration the Protocol complexity, site experience, study phase among other critical factors.
- We conduct phased training program and capacity development, with ongoing monitoring and evaluation framework

STRATEGIC MANAGEMENT CONSULTING

Case Studies

COUNTY INTERGRATED DEVELOPMENT PLAN – 2018 -2022 FOR KITUI COUNTRY

AFRICA MARKET LABOARTORIES *SURVEY*

(Kenya, Nigeria, Ivory Coast And Egypt)

NATIONAL AIDS CONTROL COUNCIL, STRATEGIC PLAN 2020 -2024

POINT PREVALENCE SURVEY FOR ANTIMICROBIAL PRESCRIPTION PATTERNS

CLINICAL DATA MANAGEMENT AND BIOSTATISTICS

Our Services

Our team comprises of experienced Data Managers, Biostatisticians, SAS Programmers, Medical Writers, and Information Managements specialists.
The services offered include:

- Design of the study, case report forms (CRFs).
- SAS programming.
- Desk user support.
- Electronic Data Capture training and deployment.
- Remote monitoring modules.
- Operational and regulatory reporting.
- Data Management and plan development.
- Statistical analysis and scientific reporting.
- SQL system set up and training.
- Database development.
- Development of ICH GCP compliant Data Management Plan, SOPs
- Data entry manual and training of data entry clerks on its use.

Clinical Data Management Services Delivery

Start-up Phase

- Designing CRFs
- Writing the Database Management Plan (DMP)
- Database design and validation
  - Edit checks
  - Quality checks
- Writing Validation and error checking plan
- Data SOP's for operations

Conduct Phase

- Real-time data monitoring - via R shiny dashboard
  - Discrepancy management
- Database maintenance and updating
- Continuous and real-time data processing
  - Quality checks and control
  - Custom reporting

Close-out Phase

- Database Quality control and audit
- Database lock and data archiving

CDM systems and software solutions

Leveraging open source and free to use technology to provide the most efficient, reliable and interactive data management system

Free to use software:-

OpenClinica
Open Source for Clinical Research

REDCap
Research Electronic Data Capture

RStudio®

Shiny
by RStudio

Our Current and Past Clients

- Institute Pasteur
- University of Virginia
- National Institutes of Health
- BioMérieux - Africa Medical Affairs
- Astra Zeneca
- World Health Organization, Department of Reproductive Health
- World Health Organization, Global Malaria Programme
- Global Alliance for Veterinary Medicines
- AURUM Institute, South Africa
- Drugs for Neglected Diseases Initiative (DNDi)
- Emerging Infectious Diseases Institute, University of Khartoum
- Global Antibiotic Research and Development programme/DNDi
- Janssen, Global Clinical Development Operations
- International Centre for Insect Physiology and Ecology
- University of Oxford/University of Nairobi collaboration
- Infectious Diseases Institute, Makerere University
- BIORITHM Singapore
- The Clinical Trial Company, United Kingdom
- National Institute of Medical Research
- Pharmalys CRO
- OnQ CRO
- Remedy&Co CRO Japan

THE ROLE OF LOCAL CONTRACT RESEARCH ORGANISATIONS IN BUILDING GCP-COMPLIANT CLINICAL RESEARCH IN POVERTY-RELATED DISEASES IN AFRICA: A CASE OF CLINWIN RESEARCH SERVICES

Peter Onyango

BMJ Glob Health 2017 2: A52
doi: 10.1136/bmjgh-2016-000260.139

Citation: Molecular Therapy — Methods & Clinical Development (2016) **3**, 16061; doi:10.1038/mtm.2016.61
Official journal of the American Society of Gene & Cell Therapy

www.nature.com/mtm

ARTICLE

Broad HIV-1 inhibition *in vitro* by vaccine-elicited CD8+ T cells in African adults

Gaudensia Mutua[1], Bashir Farah[1], Robert Langat[1], Jackton Indangasi[1], Simon Ogola[1], Brian Onsembe[1], Jakub T Kopycinski[2], Peter Hayes[2], Nicola J Borthwick[3], Ambreen Ashraf[2], Lan Dally[4], Burc Barin[4], Annika Tillander[2], Jill Gilmour[2], Jan De Bont[5], Alison Crook[3], Drew Hannaman[6], Josephine H Cox[2], Omu Anzala[1], Patricia E Fast[5], Marie Reilly[7], Kundai Chinyenze[5], Walter Jaoko[1], Tomáš Hanke[3,8]; the HIV-CORE 004 study group

We are developing a pan-clade HIV-1 T-cell vaccine HIVconsv, which could complement Env vaccines for prophylaxis and be a key to HIV cure. Our strategy focuses vaccine-elicited effector T-cells on functionally and structurally conserved regions (not full-length proteins and not only epitopes) of the HIV-1 proteome, which are common to most global variants and which, if mutated, cause a replicative fitness loss. Our first clinical trial in low risk HIV-1-negative adults in Oxford demonstrated the principle that naturally mostly subdominant epitopes, when taken out of the context of full-length proteins/virus and delivered by potent regimens involving combinations of simian adenovirus and poxvirus modified vaccinia virus Ankara, can induce robust CD8+ T cells of broad specificities and functions capable of inhibiting *in vitro* HIV-1 replication. Here and for the first time, we tested this strategy in low risk HIV-1-negative adults in Africa. We showed that the vaccines were well tolerated and induced high frequencies of broadly HIVconsv-specific plurifunctional T cells, which inhibited *in vitro* viruses from four major clades A, B, C, and D. Because sub-Saharan Africa is globally the region most affected by HIV-1/AIDS, trial HIV-CORE 004 represents an important stage in the path toward efficacy evaluation of this highly rational and promising vaccine strategy.

Molecular Therapy — Methods & Clinical Development (2016) **3**, 16061; doi:10.1038/mtm.2016.61; published online 31 August 2016

Despite remarkable progress in decreasing human immunodeficiency virus type 1 (HIV-1) transmission and AIDS-related deaths by antiretroviral drugs,[1] an effective, prophylactic HIV-1 vaccine will be the best strategy for realistically ending the AIDS epidemic. For the most efficient control of HIV-1, a vaccine will likely have to induce both functional binding or broadly neutralizing antibodies (bnAbs) and effective cytotoxic CD8+ T cells.[2] While induction of appropriate B-cells to produce bnAbs currently holds promise, CD8+ T cells are important to limit and remove HIV-1-infected cells.[3,4] Broadly specific CD8+ T cells of a noncanonical type (restricted by Mamu tissue antigens of classes Ib/E and II) were associated with control and clearance of pathogenic simian immunodeficiency virus infection in 54% of about 100 experimentally challenged rhesus macaques.[5–8] In humans, the first appearance of human leukocytes antigen (HLA) class Ia-restricted CD8+ T cells forces extensive virus escape in targeted epitopes during acute HIV-1 infection[9,10] and correlates with a decrease in acute viremia,[10] however, T cells eventually fail to prevent AIDS.[3] Also genome-wide association studies showed protective effects of certain HLA class I allotypes.[11] Our aim is to understand and induce protective T-cell responses, which will complement vaccine-elicited binding or broadly neutralizing antibodies in prevention as well as assist HIV-1 cure.

Functional correlates of T-cell control of HIV-1 replication are likely to be a combination of several qualities, many of which are critically important. Thus, in addition to the efficient recognition of peptide-loaded HLA molecules,[12] rapid expansion following exposure to cognate antigens,[13,14] efficient killing of infected cells,[13–15] production of soluble antiviral factors[13,14,16] and the use of shared T-cell receptors (public clonotypes),[17] we believe CD8+ T-cell specificity[18–24] and breadth[2,25,26] of epitope recognition are key to a successful control of extremely variable pathogens such as HIV-1. The most relevant evaluation of the CD8+ T-cell effector functionality prior to efficacy trials in humans is the *in vitro* viral inhibition assay (VIA).[27–36] VIA collectively measures T-cell functions by quantifying reduction in HIV-1 replication in cultured autologous CD4+ T cells, and does so in the context of immune response-evasive mechanisms.[36] Furthermore, VIA permits functional identification of inhibitory epitopes[27] and the use of a number of HIV-1 isolates, including transmitted/founder viruses, to assess the breadth of the T-cell response inhibition over diverse HIV-1 isolates.[27–31,34]

MEMORANDUM OF UNDERSTANDING

BETWEEN

CLINWIN RESEARCH SERVICES
P O BOX 3289, NAIROBI 00200, KENYA

AND

UNIVERSITY OF NAIROBI
PO BOX 30197-00100
NAIROBI

IN WITNESS WHEREOF, the Parties hereto have executed this Memorandum of Understanding this 5th Day of September 2017

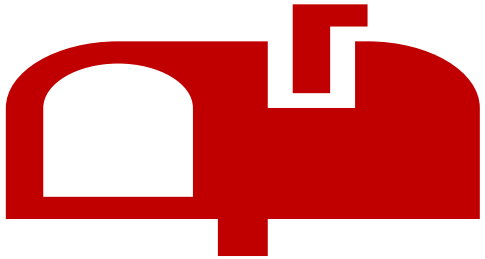
SIGNED for and on behalf of the **UNIVERSITY OF NAIROBI:**

Professor Peter M. F. Mbithi
THE VICE-CHANCELLOR
UNIVERSITY OF NAIROBI

SIGNED for and on behalf of the **ClinWin Research Services, Kenya:**

Mr. Nick Kisengese
DIRECTOR
CLINWIN RESEARCH SERVICES, KENYA

OUR CONTACT



ClinWin Research Services

Landmark Plaza, 13th Floor Argwings Kodhek Road

P O. Box 856 00606,Nairobi Kenya

Tel. Mobile +254 (0)721 515 009/0790089440

Office +254 20 3673526/0703041526 /0730173526

Email: info@clinwinresearch.com

Website: www.clinwinresearch.com

Thank you