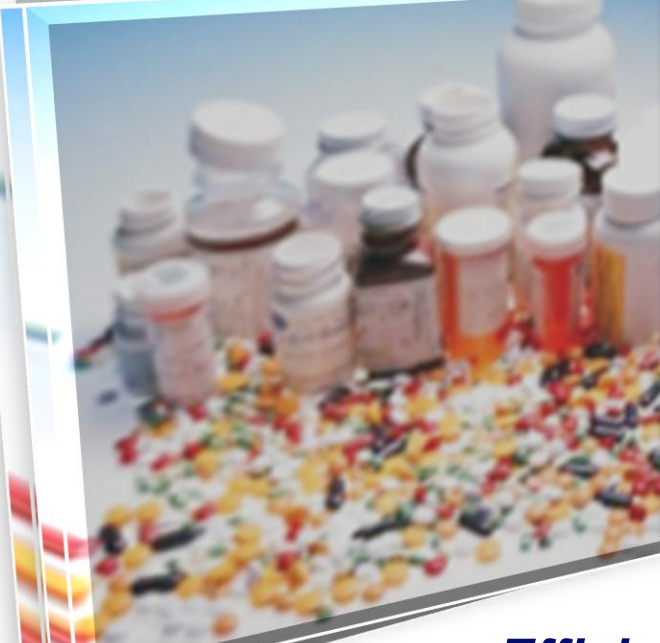


# ClinWin Research Services



**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

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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.

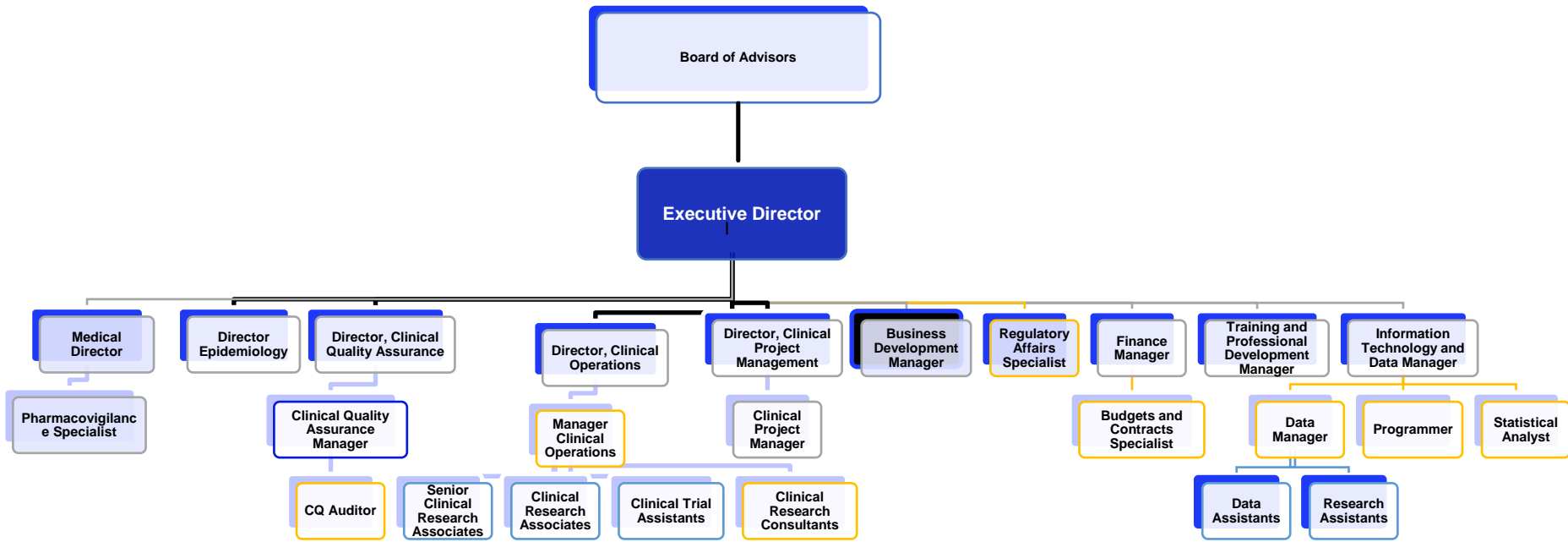
**2012**  
First 4 employees.  
2 CRAs, Data Manager and Project Manager.

**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.

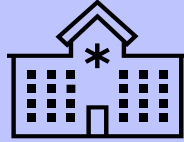
**2019- to date**  
In consortium with Pharmalys CRO, awarded contract to manage RTT,S Malaria vaccine trial in Kenya, Ghana and Malawi.

**2021 -**  
Expanded operations into Tanzania.



# 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, program Monitoring and Evaluation



# Therapeutic Expertise



- Infectious diseases and vaccines
- Dermatology
- Endocrinology
- Hematology
- Immunity
- Psychiatry
- Neglected Tropical Diseases
- Cardiovascular
- Reproductive Health
- Medical Devices
- Diagnostics
- Antimicrobial resistance
- Oncology
- Respiratory
- Herbal Medicine
- SARS-COV-19

# Vaccines Clinical Trials Experience



Shigella

Varicella Zoster

HIV

Hookworm

Ebola

Respiratory Syncytial  
virus

TB

Human Papilloma Virus

Malaria

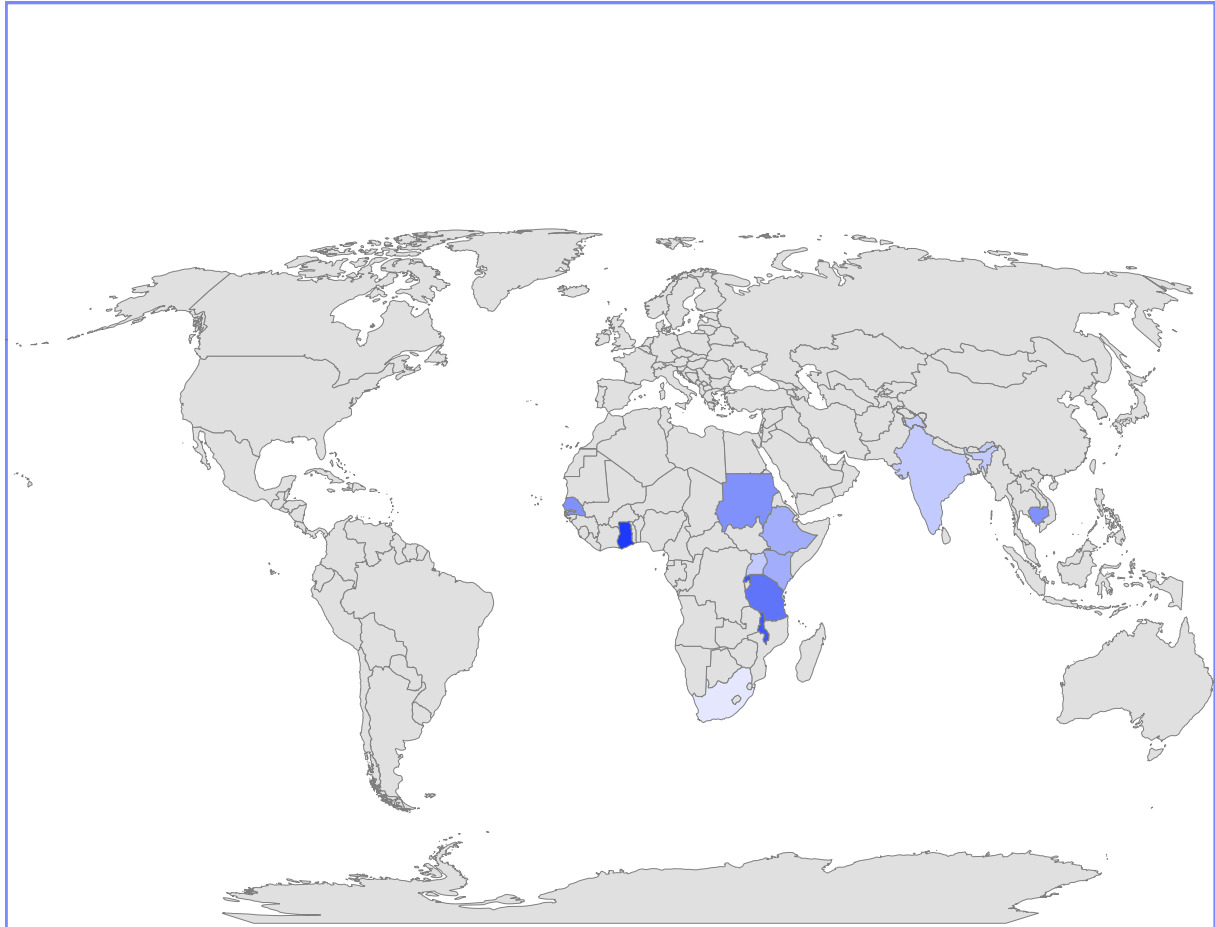
SARS-COV-19

Leishmaniasis

# Geographical Experience



Kenya  
Uganda  
Tanzania  
Rwanda  
South Sudan  
Malawi  
South Africa  
Mozambique  
Senegal  
Ivory Coast  
Mali  
Ghana  
Egypt  
Tunisia  
Morocco  
Ethiopia  
Sudan  
Zambia  
Zimbabwe  
Nigeria  
India  
Cambodia



# Technology Experience



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

- Medidata RAVE
- Oracle,
- Clinical Trial Management Systems
- Inform
- R
- RedCap,
- OpenClinica
- ODK
- KAMOLO EDC
- Medrio
- Castor
- e-PRO
- e-Consent



# 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

- Mycetoma Research Centre

- Global and regional CROs, e.g. POSEIDON CRO (Morocco and Tunisia), REMEDY&Co Japan, Integral Health Ltd, OnQ Clinical S.A, Pharmalys. Phoenix Clinical Research (Egypt), FieldPro Research (Ivory Coast) and ClinGroup (MENA), Angel Michaels Research (Kenya/Nigeria), ORCI trials.



# 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**

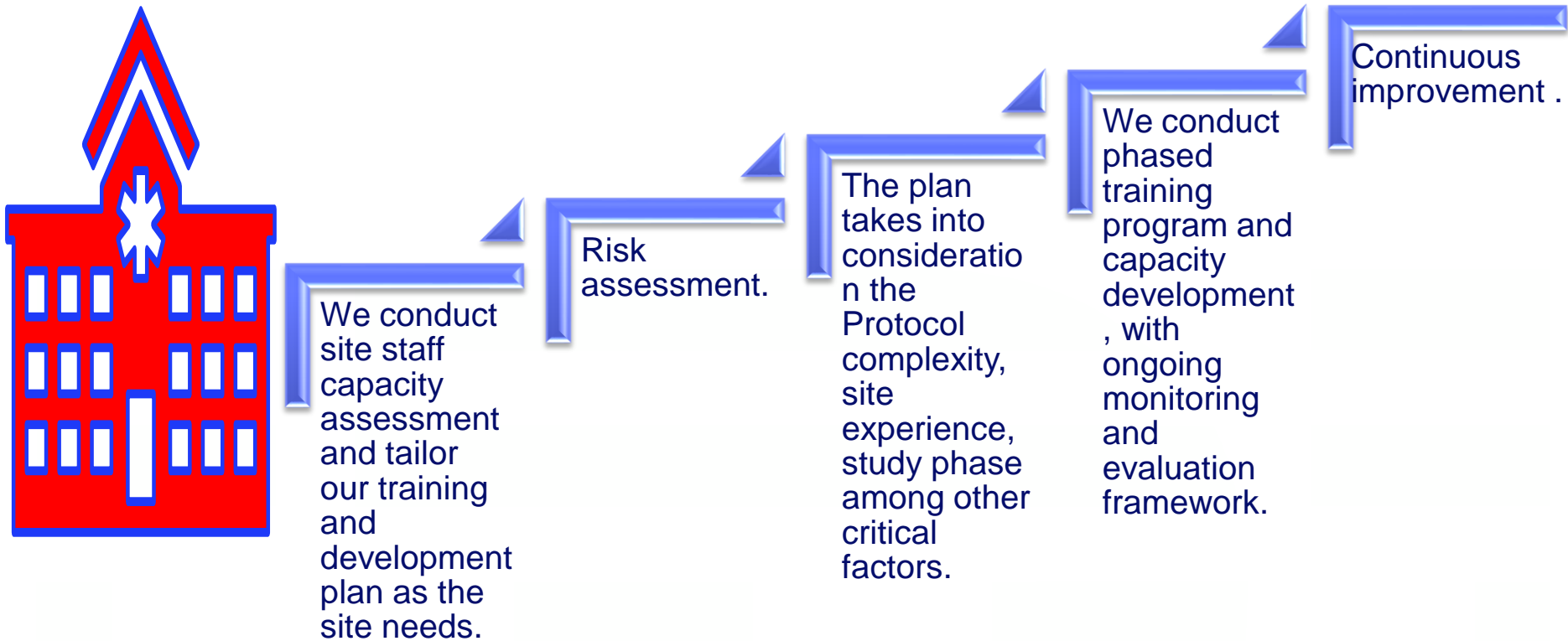
**Good Clinical Laboratory Practice**

**Vaccinology**

# Clinical Trials Monitoring Training History



# Clinical Trial Site Staff Capacity Development process



# Clinical Trials Site Development

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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
- Staff training

# 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**

**Clinical Laboratory Scientists**

# STRATEGIC MANAGEMENT CONSULTING



## Case Studies



HIV, Gender and  
Human Rights  
Assessment  
Survey

AFRICA MARKET  
LABORATORIES SURVEY  
*(Kenya, Nigeria, Ivory Coast  
And Egypt)*

NATIONAL AIDS  
CONTROL COUNCIL,  
STRATEGIC PLAN 2020  
-2024

POINT PREVALENCE  
SURVEY FOR  
ANTIMICROBIAL  
PRESCRIPTION  
PATTERNS

COUNTY INTERGRATED  
DEVELOPMENT PLAN –  
2018 -2022 FOR KITUI  
COUNTRY

Short Acting Beta-2 Agonist  
(SABA) and its potential  
effects on asthma control: A  
cross-sectional survey



ClinWin DataTrix  
Data Driven Decisions



# 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

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

Free to use software:-



# Our Current and Past Clients

- Institute Pasteur
- University of Virginia
- 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
- National Institute of Medical Research
- Pharmalys CRO
- OnQ CRO
- Remedy & Co CRO Japan
- FIND
- National Syndemic Diseases Control Council
- Integral Health Limited



# References and Testimonials -1



13<sup>th</sup> August 2024

To Whom it May Concern

**Re: ClinWin Research Services**

We have contracted ClinWin Research Services from 5<sup>th</sup> April 2024 to the 9<sup>th</sup> August 2024 to monitor the field evaluation of a schistosomiasis rapid diagnostic test prototype conducted at 3 different sites in Kenya.

ClinWin performed activities related to ensuring the study protocol and related standard operating procedures were followed as per Good Clinical Practice guidelines, declaration of Helsinki and local regulatory and ethical requirements.

These activities included:

- Support of Site Initiation Visits and writing of SIV reports
- Daily site monitoring as per Monitoring Plan
- Review of sample collection, processing and storage procedures
- Review of test results and reporting
- Source data review and verification
- Support OpenClinica data queries clarification
- Completion of daily monitoring sheets for reporting to FIND
- Support in set-up and maintenance, as well as review of the Investigator Site File

The ClinWin team were a great asset to the project team. Their expertise, flexibility, diligence and hardworking nature contributed to the success of the project within a tight timeline. We definitely recommend them for the abovementioned services.

Yours sincerely,

Rossella Baldan  
Clinical Trial Manager, FIND

Sarah Hingel  
Principal Scientist, FIND

FIND  
Global Health Campus  
Chemin du Pommier 40  
1218 Geneva  
Switzerland

T: +41 (0)22 710 27 88

[www.findds.org](http://www.findds.org)



5<sup>th</sup> September 2023

**TO WHO IT MAY CONCERN**

Dear Sir/Madam,

**REFREERNCE: CLINWIN RESEARCH SERVICES**

This is to confirm that we engaged ClinWin Research Services between year 2020 -2022 to provide study management and monitoring services for the following projects:

1. The Global Point Prevalence Survey among private and public health facilities in Kenya to provide quantifiable measures to assess and compare quantity and quality of antimicrobial prescribing and resistance in hospitalized adults, children and neonates, as part of ongoing worldwide survey.
2. Market research project on the use of microbiology products across clinical laboratories in Kenya, Cote d'Ivoire, Nigeria and Egypt using a structured questionnaire.

ClinWin provided the following services:

1. Obtaining Protocol ethical approval as well as hospitals and County department of health approvals.
2. Data collection, entry and cleaning.
3. Biostatistical analysis and reporting.

ClinWin was open and collaborative in understanding our needs and ensured deadlines were met. I would definitely work with them again and therefore strongly recommend them for future opportunities.

Please do not hesitate to contact me if you do need further information.

Thank you.

Best regards,

**Dr. Kiplangat Sigei**

Medical Affairs Manager, Anglophone Africa

[kiplangat.sigei@biomerieux.com](mailto:kiplangat.sigei@biomerieux.com) | [www.biomerieux.com](http://www.biomerieux.com)

# References and Testimonials -2

Downloaded from <http://gh.bmj.com/> on April 19, 2017 - Published by group.bmj.com

## 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

Updated information and services can be found at:  
[http://gh.bmj.com/content/2/Suppl\\_2/A52.2](http://gh.bmj.com/content/2/Suppl_2/A52.2)

### These include:

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**Topic Collections** Articles on similar topics can be found in the following collections  
[Open access \(357\)](#)

### Notes

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](http://www.nature.com/mtm)

## ARTICLE

### Broad HIV-1 inhibition *in vitro* by vaccine-elicited CD8<sup>+</sup> T cells in African adults

Gaudensia Mutua<sup>1</sup>, Bashir Farah<sup>1</sup>, Robert Langat<sup>1</sup>, Jackton Indangasi<sup>1</sup>, Simon Ogola<sup>1</sup>, Brian Onsembe<sup>1</sup>, Jakub T Kopczynski<sup>2</sup>, Peter Hayes<sup>2</sup>, Nicola J Borthwick<sup>1</sup>, Ambreen Ashraf<sup>1</sup>, Len Dally<sup>1</sup>, Burc Barin<sup>1</sup>, Annika Tillander<sup>1</sup>, Jill Gilmour<sup>1</sup>, Jan De Bont<sup>1</sup>, Alison Crook<sup>1</sup>, Drew Hannaman<sup>1</sup>, Josephine H Cox<sup>1</sup>, Omu Anzala<sup>1</sup>, Patricia E Fast<sup>1</sup>, Marie Reilly<sup>1</sup>, Kundai Chinyenze<sup>1</sup>, Walter Jaoko<sup>1</sup>, Tomáš Hanke<sup>1\*</sup>; 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<sup>+</sup> 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,<sup>1</sup> 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<sup>+</sup> T cells.<sup>2</sup> While induction of appropriate B-cells to produce bnAbs currently holds promise, CD8<sup>+</sup> T cells are important to limit and remove HIV-1-infected cells.<sup>3,4</sup> Broadly specific CD8<sup>+</sup> 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<sup>5–11</sup> in humans, the first appearance of human leukocytes antigen (HLA) class Ia-restricted CD8<sup>+</sup> T cells forces extensive virus escape in targeted epitopes during acute HIV-1 infection<sup>12</sup> and correlates with a decrease in acute viremia,<sup>13</sup> however, T cells eventually fail to prevent AIDS.<sup>14</sup> Also genome-wide association studies showed protective effects of certain HLA class I allotypes.<sup>15</sup> 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,<sup>12</sup> rapid expansion following exposure to cognate antigens,<sup>13,14</sup> efficient killing of infected cells,<sup>15–19</sup> production of soluble antiviral factors<sup>13,16,18</sup> and the use of shared T-cell receptors (public clonotypes),<sup>17</sup> we believe CD8<sup>+</sup> T-cell specificity<sup>20–24</sup> and breadth<sup>25,26</sup> of epitope recognition are key to a successful control of extremely variable pathogens such as HIV-1. The most relevant evaluation of the CD8<sup>+</sup> T-cell effector functionality prior to efficacy trials in humans is the *in vitro* viral inhibition assay (VIA).<sup>27–29</sup> VIA collectively measures T-cell functions by quantifying reduction in HIV-1 replication in cultured autologous CD4<sup>+</sup> T cells, and does so in the context of immune response-evasive mechanisms.<sup>26</sup> Furthermore, VIA permits functional identification of inhibitory epitopes<sup>27</sup> 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.<sup>27,31,34</sup>

## 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 5<sup>th</sup> 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

# References and Testimonials - 3

## THE JENNER INSTITUTE

Old Road Campus Research Building  
Roosevelt Drive, Oxford OX3 7DQ

Tel: +44 (0)1865 617630 Fax: +44 (0)1865 617608

Email: tomas.hanke@ndm.ox.ac.uk

Website: www.jenner.ac.uk

Professor Tomáš Hanke  
Head of The HIV-1 Vaccine Programme



February 20, 2018

To Whom It May Concern

### RE: CLINWIN RESEARCH SERVICES

This is to confirm that CLINWIN Research Services, a Contract Research Organization was engaged between 2013-2015 to provide clinical trial monitoring services and site management on behalf of the University of Oxford-sponsored clinical trial. This was a phase I/IIa clinical trial testing candidate HIV-1 vaccines conducted at KAVI-Institute of Clinical Research, University of Nairobi, Kenya.

CLINWIN performed Site Initiation, interim clinical trial monitoring and close-out visits, and other operational activities related to study management. These activities were conducted as per University of Oxford Standard Operating Procedures, Good Clinical Practice guidelines, declaration of Helsinki and applicable regulatory requirements.

The team was pleasant to work with, cooperative, hardworking, diligent and are well acquitted with requisite knowledge and experience to manage clinical research projects.

Do not hesitate to contact me if you do need further information.

Yours sincerely,



THE JENNER INSTITUTE - DEVELOPING INNOVATIVE VACCINES  
A Partnership between Oxford University and the Pirbright Institute



## To Whom it May Concern

Nairobi, October 24, 2019

### Re: ClinWin Research Services

We have contracted ClinWin Research Services to monitor and manage some of our clinical trials. These include a Phase II and III clinical studies on Visceral Leishmaniasis, Post Dermal Kalazar Leishmaniasis and Mycetoma in Sudan, Kenya and Uganda; and antimicrobial resistance drug trial in Kenya.

ClinWin performs activities related to study conduct and evaluation in accordance with DNDi Standard Operating Procedures, Good Clinical Practice guidelines, declaration of Helsinki and local regulatory and ethical requirements.

These activities include:

- Sites monitoring and management
- Source data verification
- Laboratory review of samples storage, tests results and reporting
- Data queries clarification and case report forms review
- Training of CRAs

The ClinWin is team player, cooperative, hardworking, diligent and are well equipped with requisite knowledge and experience to manage clinical research and health systems evaluation programs.

We highly recommend them for similar services. Should you require any further information, kindly do not hesitate to contact the undersigned.

Sincerely,

Simon Bolo  
Regional Operations Leader  
DNDi Africa Regional Office

AFRICA REGIONAL OFFICE

Tetezi Towers, 3rd Floor, George Padmore Road, Kilimani  
P. O. Box 21936 - 00505 Nairobi, Kenya  
Tel: +254 020 399 50 00  
Email: info@ndi.org | Website: www.ndi.org

HEADQUARTERS

15 Chemin Louis-Dunant 1202 Geneva Switzerland  
Tel: +41 (0) 22 906 9230 Fax: +41 (0) 22 906 9231  
Email: dndi@dndi.org

DNDi Africa is ISO 9001:2008 certified



# References and Testimonials - 4



Page 1 of 1



16<sup>th</sup> August 2024

## TO WHOM IT MAY CONCERN

Dear Sir/Madam

This letter confirms that our organization engaged ClinWin Research Services between 2023 and 2024 to provide monitoring services for a study conducted in neonate population at one site in Kenya. This study aimed at obtaining pharmacokinetic data and confirming neonatal dosing for a new antibiotic combination.

ClinWin's role encompassed conducting on-site monitoring visits to ensure data quality and integrity throughout the study. Their commitment to understanding our project objectives and adherence to timelines was exemplary. In addition, ClinWin demonstrated flexibility and capability in navigating through a complex study management structure. The collaborative nature of our partnership contributed significantly to the study's success.

Based on our positive experience, we wholeheartedly recommend ClinWin Research Services for their monitoring expertise.

**Christophe Escot – Clinical Operation Leader / GARDP**

11th November 2019,

## TO WHO IT MAY CONCERN

Dear Sir/Madam,

REF: CLINWIN RESEARCH SERVICES

This is to confirm that we have engaged ClinWin Research Services to provide study monitoring services for a real world non-interventional study on Asthma in Kenya.

The study is ongoing and has been implemented in twenty hospitals and clinics in Kenya.

Yours Sincerely,

DocuSigned by:  
*Kennedy Njau*  
C35149661744410...

Dr Kennedy Njau

Medical Director Sub Sahara Africa

**AstraZeneca Pharmaceuticals Limited**  
Reg. No. CPB/2015/21739  
1st Floor Avenue 5 / Rose Avenue,  
Kilimani, Nairobi

TEL: +254 (20) 5135800  
e-mail address:  
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Campus, Cambridge, CB2 0AA, England

Executive Directors:  
Claire Kagambi (Kenyan); Jeroen Commissaris (Dutch)

# Thank you



# OUR CONTACT



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Email: [info@clinwinresearch.com](mailto:info@clinwinresearch.com)

Website: [www.clinwinresearch.com](http://www.clinwinresearch.com)