



K-IRDO CLINICAL RESEARCH SITE

Creating, Developing and Sustaining Empowered
and Healthy Individuals and Communities

INTRODUCTION - 1/2

- Impact Research and Development Organization (IRDO) is a local non-governmental organization registered in Kenya in January 2003 (#OP.218/051/2002/0159/2403), with headquarters in Kisumu and regional offices in 8 counties
- The mission is to improve public health by designing, implementing and evaluating research and programs that benefit local communities.
- IRDO has 4 divisions: Programs, Research, Business Systems and Business Development, each overseen by a Head of Division.

INTRODUCTION - 2/2

- RDO has been implementing biomedical (including clinical trials), epidemiological and behavioral studies focusing on HIV prevention, care and treatment mostly in western Kenya, but also in Nairobi and Coast regions.
- Most research funding comes from the National Institutes of Health, PEPFAR (through CDC) and the BMGF.
- IRDO runs a clinical research site (K-IRDO CRS) at the Tuungane Hospital, Tom Mboya Estate, Kisumu.
- The key sections of the CRS are Clinical, Laboratory, Pharmacy Community Engagement, and Grants Management

Tuungane Hospital

Services Profile

- General outpatient
- TB integrated services
- General in-patient
- Laboratory
- Pharmacy
- Ultrasound
- Counselling (including HTS)
- Theatre
- Maternal, neonatal and child health

Available Facilities

- Waiting/Reception Area
- General Outpatient clinic
- Triage and Observation rooms
- Consultation rooms
- In-patient Wards: Male, Female, Paediatric
- Fully Equipped theatre
- Ultrasound
- Pharmacy
- Laboratory
- Call Centre
- Electronic Medical Systems (Syhos)

TUUNGANE HOSPITAL (Clinical Services)



HOSPITAL RECEPTION



TRIAGE ROOM



CONSULTATION ROOM



THEATRE



WARD



PROCEDURE ROOM/EMERGENCY ROOM



K-IRDO CRS Laboratory

K-IRDO Research Laboratory - 1/2

- The K-IRDO lab is currently served by 3 laboratory technologists (additional 2 on call from field stations, as needed)
- The lab is ISO 15189:2012, accredited by KENAS
- Laboratory documentation currently in place:
 - Laboratory Quality Manual.
 - Clinical hand book
 - Laboratory Safety manual
 - Specimen Collection Manual
 - Material Safety Data Sheets
 - Standard Operating Procedures (SOPs)
 - Technical SOPs
 - Management SOPs
 - Study Specific SOPs

- Laboratory Facilities;
 - Two Air conditioning units
 - One 80⁰C Freezer
 - One 20⁰C Freezer
 - One 2⁰C-8⁰C Refrigerator
 - Class II A Biosafety Cabinet
 - Hematology Analyzer
 - Biochemistry Analyzer
 - GeneXpert machine for RT-PCR
 - Chemiluminescence Immunoassay Analyzer
 - Electrolytes Analyzer
 - Two Automatic Backup Generators - 30 KVA each
 - Digital min max thermometer for manual room temperature monitoring
 - Lockable cabinets
 - Biometric door system
 - ELTEK data logger for all equipment, inclusive of room temperature and relative humidity monitoring within the laboratory.

K-IRDO Research Laboratory – 1/5



K-IRDO Research Laboratory – 2/5



K-IRDO Research Laboratory – 3/5



K-IRDO Research Laboratory – 4/5.



K-IRDO Research Laboratory – 5/5



K-IRDO CRS Pharmacy

K-IRDO Research Pharmacy - 1/2

- The Pharmacy is currently covered by;
 - 1 Pharmacist of Record (BPharm, MPharm, PhD-Clinical Pharmacy)
 - 2 Associate Pharmacists (both BPharm)
- Pharmacy documentation currently in place:
 - Quality Management Plan
 - Standard Operating Procedures (SOPs);
 - Pharmacy operations and management
 - Cold storage and room temp monitoring
 - Disposal of expired medicines, hazardous waste.
 - Gowning and Degowning
 - Aseptic technique
 - Pharmacy equipment and maintenance

K-IRDO Research Pharmacy - 2/2

- Pharmacy Facilities:
 - Two(2) Air conditioning units
 - Two pcs of -80°C Freezer
 - One pc of -25°C Freezer
 - One pc 2°C-8°C Refrigerator
 - Digital min max thermometer for manual room temperature monitoring.
 - Class IIA Biosafety cabinet
 - Two (2) automatic backup generators
 - Lockable cabinets
 - Biometric door system
 - ELTEK data logger for all equipment in pharmacy that is inclusive of room temperature and relative humidity monitoring

K-IRDO Research Pharmacy - 1/5



K-IRDO Research Pharmacy - 2/5



K-IRDO Research Pharmacy - 3/5



K-IRDO Research Pharmacy - 4/5



K-IRDO Research Pharmacy - 5/5



K-IRDO CRS Team and Areas of Potential Collaboration

Current Research Team: Clinical

- The clinical team on site is composed of;
 - Medical Doctors
 - Pharmacists
 - Nursing Officers
 - Laboratory Technologists
 - Clinical Officers
- The team supports mainly with participants management including:
 - All aspects of investigational products delivery
 - Management and reporting of AEs, SAEs, SUSARs, PDs, etc
 - Coordinating pharmacovigilance
 - Participant enrollment and follow up activities
 -among other roles
- Also supports service provision at the hospital

Current Research Team: Non-clinical & Regulatory



- **Research Assistants:**
 - Main duties are to screen, consent and enroll volunteers; administer questionnaires and take/update locator information
 - Schedule visits and track follow-up appointments
- **Field Team:**
 - The site has field staff
 - Main role is participant recruitment and retention
 - The field staff are linked to CHVs who help with recruitment and tracing of participants who miss visits.
- **Data-cum-IT Team**
 - Responsible for creating participant databases and tracking tools; support electronic data capture and biometrics
- **Regulatory Affairs/QA-QC Team:**
 - There are 3 officers (led by a nurse and supported by a CO and a non-clinical staff)
 - Responsible for all regulatory submissions and approvals, site monitoring visits, and QA/QC activities

K-IRDO CRS Clinical Trial Experience

- A complete list of studies that have been conducted at our site was shared with your team; however, we would like to highlight the following;
 - Solidarity Trial Vaccines (STV): An international randomised trial of candidate vaccines against COVID-19 – this is a phase 3 trial sponsored by WHO through KAVI and MOH. Feb 2022 – March 2024
 - The primary aim is to evaluate safety and efficacy of candidate vaccines for COVID-19
 - Retention rate is currently at 99% of the 500 enrolled.
 - Adaptive Platform Treatment Trial for Outpatients with COVID-19 (Adapt Out COVID Study). A phase II/III trial sponsored by NIH. July 2021 - June, 2022.
 - Aim was to evaluate the safety and efficacy of investigational agents for the treatment of non-hospitalized adults with COVID-19.
 - Phase 3 multi-centre, double randomized, placebo-controlled effectiveness and safety study to assess the role of Truvada in preventing HIV acquisition in women (FEM-PrEP Trial). August 2007 – July 2012
- In addition, four of the current K-IRDO CRS staff have conducted 16 other drug or vaccine trials in their previous work stations, adding to the experience of the site.

K-IRDO CRS Site Interests

- Our site has capacity to conduct studies Phase II and III trials, including IND and devices, in the following areas;
 - Women and Children's Health
 - Infectious Diseases, primarily,
 - HIV
 - Malaria
 - Hepatitis
 - STIs
 - TB, etc
 - NCDs, primarily:
 - Diabetes
 - Cancers
 - Cardiovascular diseases
 - Mental Health:
 - Neurology
 - Psychiatry
 - Others:
 - Allergy
 - Gastroenterology
 - Hematology