Infectious Diseases Institute Clinical Research Site

MAKERERE UNIVERSITY

01

Background and Unique Resources at the Infectious Diseases Institute (IDI)

The Infectious Diseases Institute (IDI), Makerere University is an internationally recognized Centre of Excellence in HIV management and research located at the Mulago National Referral and Teaching Hospital in Kampala, Uganda. With over 8,000 HIV-positive individuals receiving care, the IDI clinic was inaugurated in 2002; free antiretroviral treatment has been provided since April 2004. The clinic also serves as a referral center for complex patients requiring specialist care attending public clinics in the Kampala-Wakiso region, resulting in a highly treatment-experienced ART cohort.

In 2005, a dedicated research program was started at the IDI Centre of Excellence, which currently hosts over 100 research projects. The range of current and past research includes clinical trials, implementation science, program evaluations for models of care and treatment outcomes, observational studies, and translational research.

Within the Research Program several systems, including electronic automated software to upkeep regulatory functions, have been developed over the years to support studies' research cycle compliance, patients' safety, and studies' implementation.

In addition to strong systems, including institutional SOPs for research and studies and an overarching research policy, other distinctive features of the IDI program are:

- 1) A research translational lab that includes a pharmacokinetic unit with capacity for analyzing several antiretroviral and anti-TB drug levels;
- 2) A core laboratory that is certified by the College of American Pathologists (CAP);
- 3) A RedCap management system supporting clinical trials including multicenter studies
- 4) A clinic site that was adapted to host clinical trials (separate research pharmacy, in-patient ward for phase 2 clinical trials);
- 5) A Centre for Bioinformatics and Data Intensive Sciences with capacity for advanced computing infrastructure and software to enable storage, retrieval, and analysis of data from high-throughput sequencing, microarrays, proteomics, imaging, clinical, epidemiological, and any other data intensive studies.
- 6) Experienced clinical investigators, of which some are members of national and international disease specific committees
- 7) Presence of an inhouse Research Ethics Committee
- 8) Experience study personnel including (coordinators, doctors, nurses, laboratory technologists, pharmacists, data managers, statisticians, regulatory officer, Clinical Research Associates, etc.)
- 9) Served as coordinating center for multi-site and multi-country trials
- 10) Leading on capacity building for conduct of clinical trials initiatives on the continent
- 11) Multiple sites and presence across Uganda: IDI Kalangala, IDI-Kasangati, and supported health facilities across Uganda

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IDI Organizational Structure and Organogram for the Clinical Research Site (CRS)

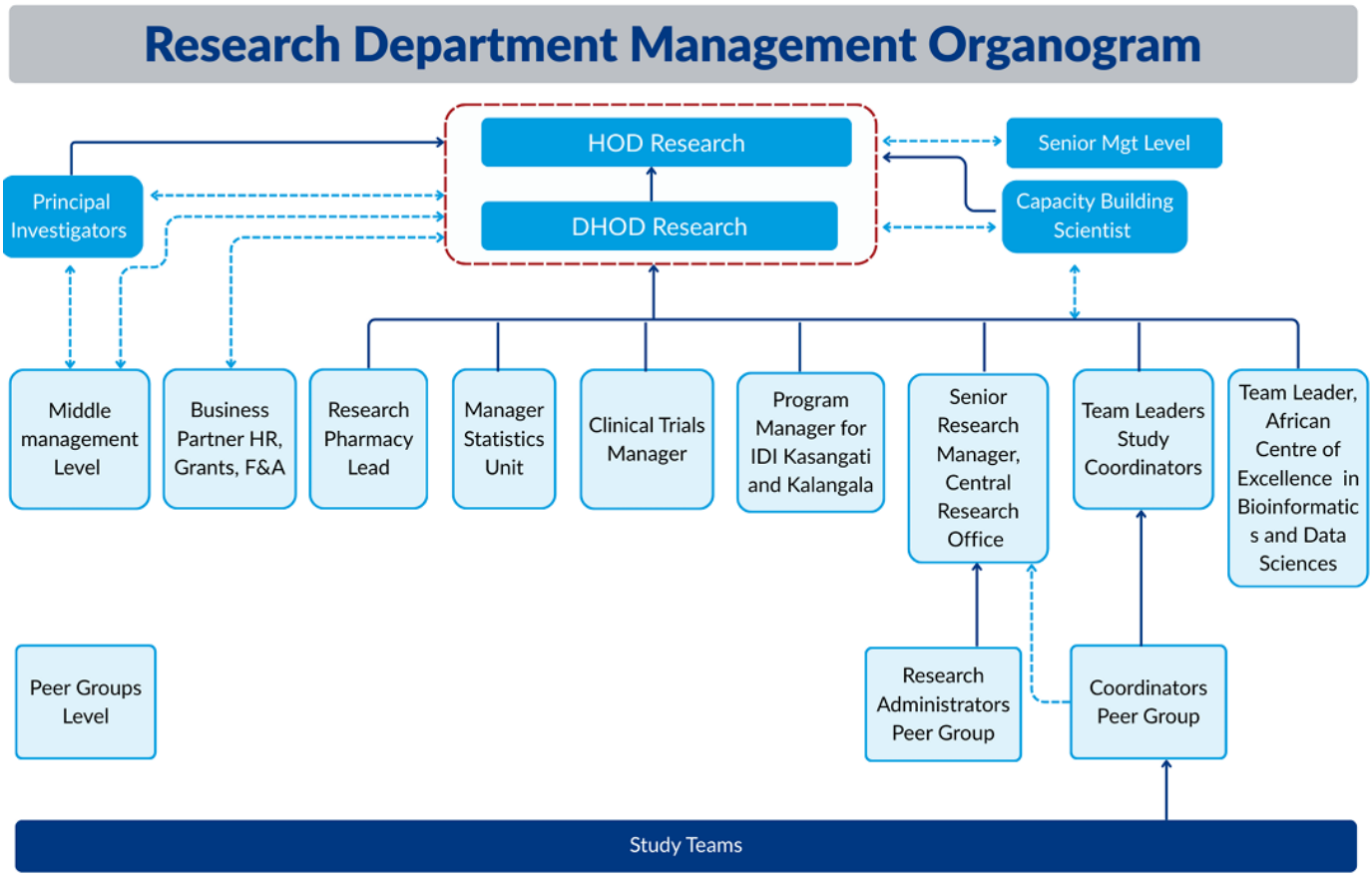

Figure 1. Diagram showing the CRS structure

The organo-structure of the CRS at IDI is shown above.

Generally, the CRS leverages on existing Research Department structures and existing staff. The acting Head of the CRS is **Dr Stephen Okoboi** and provides oversight of the day-to-day CRS activities. Other key staff of the CRS are the Research Department administrator, who provides the administrative oversight, Clinical Trials Manager who oversees the operations of the clinical trials, Research Senior pharmacist who oversees the pharmacy activities, the Research monitoring and regulatory officers who ensure regulatory and protocol compliance. Depending on the clinical trial needs also a lab technician with extensive experience in pharmacokinetic studies and the RedCap manager are available to the support the trial.

1.1. CRS Leadership

Dr. Stephen Okoboi is a clinical research leader with over 15 years of experience in research management, governance, and strategic development. As Acting Head of Research at the IDI, he plays a pivotal role in steering the department's strategy, overseeing research operations, and ensuring compliance with national and international regulatory standards. He provides high-level oversight for IDI's Clinical Trials Unit, leads business development, and fosters sustainable research collaborations across regional networks. A key member of IDI's Senior Management Team, Stephen is recognized for his ability to lead cross-functional teams, support grant acquisition, and mentor emerging researchers.

Dr. Barbara Castelnuovo is the Capacity Building specialist and immediate former Head of the Research program at IDI. She has the day-to-day responsibility for overseeing the capacity building activities for the next generation scientists and supports capacity building initiatives for conduct of clinical trials on the African continent. She has coordinated and implemented several clinical trials at IDI for the last 20 years, including being the PI of a large (268 patients) pharmacokinetic trial in HIV-positive individuals co-infected with TB, and an RCT on second-line ART strategies (ongoing). She set up a number of observational cohorts at IDI that form unique research platforms.

Provia Ainembabazi is the CRS Clinical trial manager and ensures that the various sections of the research department (administration, laboratory, statistical unit, research pharmacy, and regulatory office) support the clinical trials. Additionally, the Coordinator will liaise with other departments at IDI (clinical services, finance (which includes procurement), and grant management) to ensure that all aspects of research studies are well executed. She has over 6 years of experience in research governance and regulation, monitoring, clinical trials management and capacity building across academia and industry across phase I to phase IV clinical trials.

Ms. Eva Laker is the Pharmacist of Record for clinical trials and is assisted by Mr. John Kisembo and Ms. Rhona Muyise. She is a pharmacist with over thirteen years of work in the field of HIV/AIDS including NIH funded studies. She has been a clinical trial pharmacist on several trials at IDI including being a central pharmacy coordinator for multisite, multi country clinical trials at IDI. Her areas of expertise also include development and preparation of SOPs, quality control mechanisms, risk assessment for incoming studies, and pharmacovigilance tools. She is also a research scientist at IDI.

1.2. Additional Site Support Staff

Other staff that support the clinical trials, including the Research Manager (Paul Gonza, procurement, logistic support), the regulatory officer, (Rita Kanyesigye, obtaining protocol approvals), internal monitoring (Rose Diana Naluyima), community coordination (Simon Peter Asiimwe), a grant manager (Stephen Anyijukire), a finance officer (Bernard Musaana, budget management), Statistics and data management (Joseph Musaazi), and the laboratory service leader (Bernard Bagaya)

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1.3. Recruitment strategies

IDI can recruit participants from IDI Clinical Centre located at Mulago Hospital (8,000 people living with HIV), and can get referrals from all the clinics at the Kampala City Council Health Facilities, and nearby Wakiso district, where IDI has presence. The site has experience in working closely with other facilities and train the staff on the eligibility criteria for referral to the site.

3.1 Description of Potential or Existing Community Engagement Plans

IDI has a well-established community advisory board (CAB) and has developed its own patient engagement handbook. The community engagement officer (Simon Peter Asiimwe) coordinates the activities between the CAB and site quarterly and on needs basis.

The IDI also engages patients through a group of elected expert patients called the "Friends Council". The CAB engages in a three-way relationship between researchers, patients, and the targeted community. IDI CAB members include volunteers from activist and patient groups, non-governmental, and government organizations. Through the CAB and the Friends Council, we engage the different communities and patient groups by:

1) Sensitizing all parties involved in health research, including official introduction of the trial team members;

2) Mapping local community organizations to understand the local culture and practices, and relationships with researchers and health authorities;

3) Assessing the willingness of the community to engage in clinical trials research;

4) Engagement workshops with community activists and representatives of people affected by HIV to brainstorm and agree on ways to promote their participation in clinical trials through a model of community engagement, with CABs;

5) Organizing annual basic clinical trials and research literacy workshops and annual training of CAB members;

6) Following up community engagement assessments with regular interactions, and meeting to report and present on clinical trial outcomes. Community representatives will be encouraged to present progress and outcomes in forums such as the Uganda Annual National Research Ethics Conference as an opportunity to publicize community engagement efforts and learn about other community research experiences.

3.2 Administration

3.2.4 Regulatory and Compliance

The CRS leverages on the IDI existing systems for regulatory and compliance. Under the Research Department, a dedicated regulatory officer and internal monitor are assigned to ensure regulatory and ethical compliance. The regulatory officer, and internal monitors are the have experience in local and international regulations and guidelines, including US FDA regulations, ICH GCP, and NIAID Research Rules and Policies. The Regulatory and Compliance staff ensures compliance from the time of protocols submission for regulatory approval, throughout every phase of protocols implementation, from protocol training to study close out. The CRS has developed institutional Standard Operational Procedures to conduct clinical trials. Internal monitoring visits are conducted at study inception through a site activation, after the enrollment of the first few patients and afterwards at regular interval depending on the level of risk associated with specific clinical trials. GCP certificates of all staff involved in human participant research are kept up to date.

3.2.5 Finance, Accounting, and Logistic Systems

The CRS leverages on the IDI existing systems. Over the past 20 years, IDI has established a robust and transparent financial accounting and logistics system that strictly adheres to internationally acceptable accounting principles. Grants and research budgeted are monitored by a designated grant officer, who work with the study PIs, research manager and finance officers to monitor study expenses and keep budgets up to date through the electronic Grants, Expenditure and Management System. Additionally, the grant officers are well knowledgeable about various funders (e.g. NIH, EDCTP) rules and allowable expenses and support the PIs in financial decision making. All expenses have to be approved by the designated grant officer and PI before obtaining approval from the financial officer. Under Finance and administration, a dedicated Operation and Procurement Offices ensure functionality of the current structures and the flow of supplies to support all programs, including the Research program with dedicated officers through the electronic Procurement Management System. IDI has a Gold Good Financial Grant Practice (GFGP) certification since 2025.

3.2.6 Ensuring Compliance with ICH GCP, DAIDS, FDA, NIAID

Multiple mechanisms are in place at IDI to ensure compliance with all regulatory authorities, therefore these mechanisms will also be used by the CRS.

The independent IDI Research Ethic committee (REC) was established in 2020. It comprises fifteen members, including scientists and community representatives. The REC reviews research protocols ranging from clinical trials, observational studies, and diagnostic studies, to behavioral studies and student research. Studies under the CRS are submitted to the IDI REC.

The Regulatory Affairs Information System (RAIS) is a software developed in-house to register and manage the regulatory aspects of all research projects at IDI. All prospective research projects at IDI are registered in RAIS. The CRS Regulatory Officer uses RAIS and uploads essential documents into RAIS; automatic reminders are sent by RAIS two months (and thereafter weekly) before each deadline to the PI, the Study Coordinator, and the IDI Research Manager.

The 60 Research Program standard operating procedures (SOPs) documents were authored by IDI senior research staff and scientists and are revised every three years or when need arises from changing regulations. They describe all the procedures from pre-study activities and implementation of clinical trial activities, to close out activities. Regular trainings on the Research SOPs are conducted for all research staff.

Specific Protocol trainings are conducted prior to inception of each of the CRS research project. All study staff are trained on the specific study protocol before the execution of any study activities, and refresher trainings when amendments occur.

Regular internal monitoring. One of the major oversight activities performed by the IDI Research Office is to monitor research project activities and compliance to the approved protocols. The IDI Research Office has five internal monitors who support development of risk management plans, risk based monitoring plans and monitoring tools. For each CRS based trial a specific monitor is assigned.

Central research regulatory function. Since 2017 all research project regulatory binders are centrally stored and kept under double key and lock. Since 2025, we have adopted use of Veeva Site Vault for managing essential documents. The binders are routinely reviewed by the internal monitors to ensure that all essential documents are available and that they are up to date.

Quarterly research department meetings are conducted within the IDI research department. CRS staff are expected to attend, as important research aspects, like findings from both external and internal monitors, emerging ethical concerns, national and international research guidelines are discussed.

3.3 IDI Clinical Trial Infrastructure

3.5.1 Clinical Trials Environment

Figure 5. Phase 2 trial ward at the site.

I has an HIV clinic at the main IDI site located within Mulago Referral National Hospital; the clinic has registered more than 33,000 patients, of whom 8,000 currently receive care. Special clinics have been established for special HIV-infected populations, such as sero-discordant couples, adolescents, older adults, pregnant mothers, Most-At-Risk Populations (MARPs), and those with non-communicable diseases. As the number of patients requiring second-line and other complex forms of antiretroviral treatment has gradually increased, IDI has evolved into a referral center for more HIV-related complicated cases within the national referral system. The clinic and the research programs have been closely intertwined; since 2008, the IDI clinic has established itself as a solid research platform, with the number of clinic-based research projects steadily rising.

The clinic provides a conducive environment for clinical trials, with clinical rooms that are well equipped to support administration of Investigational medicinal product, participant monitoring and Pharmacokinetic sampling within the clinic and within 10 meters from the urgent care section of the facility, dedicated to the management of severe illnesses and clinical cases requiring urgent management. The clinical rooms and urgent care section are collectively equipped with advanced cardiac life support resuscitation equipment including an automated defibrillator, piped oxygen, wall-mounted oto/ophthalmoscope, Android Blood Pressure machines, patient monitors 8.4" screen, two ECG machines, examination rooms with reclining exam beds, and access to electronic medical records via Integrated Clinic Enterprise application ICEA-NET and others.

3.5.2. Research Pharmacy

Figure 6. The dedicated research pharmacy

A dedicated research pharmacy is adjacent to the Clinical rooms with facilities for storage (including fridges and freezers) and dispensing of investigational medicinal products. The Pharmacy employs two staff with Bachelors in Pharmacy, one logistics officer with a diploma in Pharmacy, and two pharmacy technicians.

Room temperature in the study pharmacy is maintained by central air conditioning controlled by pharmacy staff and supported by municipal power with backup generator and Solar. Refrigerated (2-8°C), -40°Cand -80°C storage is available with a pharmacy grade fridge. Each study has its own cabinets with 2 compartments available for drug storage and 2 for quarantine. The pharmacy is accessed only by pharmacy staff through biometric access. Temperature is monitored daily using the min-max thermometer.

In case of temperature excursions in product storage areas, telephone call and email is sent to the pharmacists within 15 minutes through a sensor phone system; corrective action including product quarantine where applicable, is immediately instated. Primary continuous temperature monitoring of ambient, refrigerated storage space is accomplished via a battery-operated data logger that records temperature every 4 hours. The site pharmacist prints and reviews electronic temperature logs weekly.

3.5.3 Laboratory Capacity

The site will leverage on the existing specialize laboratories at IDI, services will be charge as cost per test.

3.5.3.1 IDI Core Laboratory

The IDI Core Lab, formerly Makerere University-John Hopkins University (MU-JHU), is a Center of Excellence for the provision of research/clinical laboratory services. The Core Laboratory staff consists of an experienced team of 48 Full Time staff members. The Laboratory supports international HIV research networks like HPTN, IMPAACT, and MTN. The lab currently supports more than 18 network clinical studies for laboratory services and 79 other partners/studies.

The Core lab staff process over 16,000 samples per month following internationally recognized Research Ethics, Good Clinical and Laboratory Practices (GCP and GLP), 7 days a week, all year round. The laboratory offers a full range of screening, safety, and monitoring tests. New tests are added as needed by individual studies.

In addition to testing, the Core Lab supports study/project start-ups through training and implementation services. The core lab offers services 7 days a week, all year round. Tests include HIV serology, Western Blot, CD4/CD8 lymphocyte counts, Syphilis RPR and TPHA determination, PBMC storage, buffy coats; Hepatitis B and C serology, HIV DNA PCR (Roche – CAP/CTM), HIV quantitative RNA PCR, (Roche – CAP/CTM), HIV resistance testing, routine chemistries, hematology, parasitology (blood and stool slides), urinalysis, urine pregnancy, INH testing, Cryptococcal antigen, a long list of immunoassays*, and others as needed.

The laboratory maintains several levels of redundancy for electrical power for all of the key equipment (testing instruments, freezers, refrigerators etc.). In addition to the automated voltage regulator to stabilize local electrical power and class II spike protection devices, each key instrument has an internal or external battery (uninterrupted power supply), a panel of batteries for the building, and two electrical power backup generators. We maintain installation, validation, maintenance, calibration, corrective action and service records on all equipment, and perform routine maintenance and calibration according to manufacturer recommendations and/or GCLP & CAP guidelines.

The laboratory is air-conditioned so that instruments and computers/servers are maintained at room temperature and assays are performed at room temperature as required by manufacturers' instructions. Since accreditation 2 decades ago, the laboratory has undergone 12 CAP and 21 Pharmaceutical Product Development-GCLP compliant audits which have cited no critical findings with a few recommendations.

3.5.3.2. IDI Translational Research Laboratory

Figure 7. The LC-MS in the Translational Lab.

Associated with the IDI Core Lab is a very active IDI Translational Research Laboratory with approximately 1500 sq. ft. of laboratory space.

The Translational Laboratory has Mycology, Immunology, Molecular Biology, and Pharmacokinetics (PK) sub-sections. The Microbiology section has a BACTEC machine, incubators, biosafety cabinets, and fluorescent microscopes (iLED Primostar Zeiss and Zeiss mercury vapor lamp).

The Molecular Biology section has an RT-PCR machine (AB 7500), convectional PCR, BioFire machines, and Gene Xpert (Tb diagnostics and STI (NG and chlamydia, HPV)). The Immunology section has the FACS Canto II flow cytometer, MiniMACs cell separator, Luminex MAGPIX, ELISA washer, and plate reader; and the PK section has two HPLC machines and a mass spectrophotometer.

The Translational Lab provides support to all research studies at IDI, including the IDI CRS, with a variety of assays ranging from regular assays like Gene Xpert for TB diagnosis to study specific assays, like LAM, CRAG, antibiotic culture and sensitivity, ELISA, flow cytometry, molecular studies, and pharmacokinetic studies. Real-time PCR is being used for genetic analysis through allelic discrimination and in the quantification of different helminths. Newly acquired equipment includes a Care HPV system for HPV diagnosis, Bio-Spectrometer (Nanodrop), and MAGNA pure for DNA extraction. The lab has -150°C and -80°C repositories for specimens and refrigerators for storage of reagents.

3.5.3.2 Pharmacokinetic (PK) laboratory

The Pharmacokinetic (PK) laboratory is a section of the Translational Research Laboratory specializing in PK assays (determining drug levels in different sample matrices). It is equipped with a Thermo Scientific LCQ fleet liquid chromatography-mass spectrometry (LC-MS) and two high performance liquid chromatography machines (HPLC-UV, LC-2010C HT, Shimadzu Corporation, Japan). Several accessories that aid in sample processing are also available such as the multi-tube vortexer and the refrigerated centrifuge.

The section employs two full-time staff and two other staff have been trained in PK assays. Methods are available for determination of several drugs in different matrices including: anti-TB drugs (rifampicin, desacetyl rifampicin, isoniazid, ethambutol, pyrazinamide, rifabutin, amikacin, and moxifloxacin); antiretroviral drugs (dolutegravir, tenofovir, lopinavir, atazanavir, efavirenz, etravirine, raltegravir, darunavir, and nevirapine); and anti-epileptic drugs (phenytoin and carbamazepine).

The laboratory has the capacity to develop new methods on-site upon request by a new study or the clinic. Several methods have been developed on-site including a method for determination of seven antiretroviral drugs using HPLC-UV. Other methods have been optimized according to the available equipment in the laboratory.

The section subscribes to “Kwaliteitsbewaking Klinische Geneesmiddelanalyse en Toxicologie, KKGT” (Quality Assessment in Therapeutic Drug Monitoring and Clinical Toxicology) for external quality assurance. It also receives continuous technical support from partner PK laboratories (Department of Clinical Chemistry, University of Zurich, Switzerland and Department of Pharmacy, Radboud University, Nijmegen, Netherlands).

The laboratory has analyzed drug levels for over 10 studies since 2015. One of the major studies was “Study on OUtcomes related to Tuberculosis and HIV drug concentrations in Uganda-SOUTH”. In this study, a total of 6,588 samples was analyzed including 6,024 samples for anti-TB drugs (isoniazid, rifampicin, ethambutol, and pyrazinamide) and 564 samples for antiretroviral drugs (efavirenz, lopinavir, and atazanavir). The section also receives samples from the infectious diseases clinic for therapeutic drug monitoring (TDM) from patients with suspected non-adherence, drug related toxicity, and virologic failure

3.5.4 Data Management Capacity

IDI established the IDI Clinical DataFax Data Management Unit in June 2009 through NIH-Uganda ICER and OCICB/NIAID/NIH. The Unit has achieved success in data management of 35 single and multi-site international clinical trials (from phase 1 to phase 4 trials). Since 2020 we have phased out DataFax and build RedCap management unit that is capable of design and manage databases for all studies including clinical trials and multisite studies

The Unit has capacity of designing statistical plans and perform analysis of complex clinical trials. The senior statistician, Joseph Musaazi was the statistician of the CAREs and NADIA trials published in the New England Medical Journal, Nature Medicine and Lancet Infectious Diseases.

3.6 Clinical Trial Experience

3.6.3 Type of Clinical Trials

The IDI has a track record of both industry and investigator-initiated studies including phase I PK through IV studies across various diseases indication such as HIV, HIV co-infection, Tuberculosis, cryptococcal and TB meningitis, COVID-19, malaria, contraceptives, Vaccines and others. Table 2 "Summary of selected clinical trials and studies experience 2010–2025, Infectious Diseases Institute" at the end of this section shows a summary of the selected clinical studies experience at IDI from 2010 through 2025.

3.6.4 Actions to Ensure Regulatory, Safety, and Operations Compliance

These actions are shown in the tale below- and leverage on existing systems and structures at IDI

Self-imposed Internal Monitoring or other actions	Regulatory	Safety	Operations
1. CRS Organogram: overall oversight by the PI and deputy PI with support from the coordinator	✓	✓	✓
2. Standard procedures for grant/study planning/proposal writing, grant submission, budget guidelines, protocol template for clinical trials			✓
3. Regulatory affairs electronic system (RAIS) for tracking essential document-types, versions, and renewal dates	✓		
4. Randomization procedures through randomization software within the DataFax system executed independently by the IDI statistical unit			✓
5. Research Department standard operation procedures (SOPs) for clinical trials (e.g., SOP for consenting patients)		✓	✓
6. Delegation of pharmacovigilance officer (PVO) role to a qualified study team member with strong medical background		✓	
7. Investigational products: pre-submission meetings with regulatory agencies (particularly NDA) to align submission dossier contents	✓		
8. Dedicated Research Pharmacy and pharmacists to procure, store, and dispense investigational products			✓
9. Centralization in a safe environment of all key study documents including the regulatory binders; the regulatory binders are regularly inspected by the IDI internal monitor and the regulatory officer	✓	✓	✓
10. Risk Management Plan (RMP) required for all clinical trials with specific adaptations for ongoing monitoring of risks to trial participants	✓	✓	✓
11. Protocol training and site initiation visit prior to study inception for all study staff with the internal monitor	✓	✓	✓
12. Electronic systems for managing essential documents and e-consenting	✓		✓

3.6.5 Experience with Inspections

Between Jan 2018 and May 2025, the National Drug Authority (NDA) and Uganda National Council for Science and Technology (UNCST) conducted 10 inspections, while RECs conducted 12 monitoring visits for clinical trials. Inspections included site inspection, interviewing key staff, and document review, and focused on suitability of premises, confidentiality, and adequacy for the study procedures; and equipment available for assessing participants and collection of biological specimens. Documents that were reviewed included regulatory binders, study operating procedures, participant source documents, and investigational medicinal accountability records. IDI was commended for maintaining up-to-date and accurate IMP accountability documents, proper informed consent documents and records of the consent process, enrollment of eligible participants without enrollment violations, and adherence to clinical trial protocols. IDI was selected by NDA to serve as a practicum center for NDA of clinical trials training and a sentinel site to pilot roll-out of new drugs in HIV public health programs.

Findings were categorized as critical, major, and minor, based on the observed issues and impact to both study data and participant safety, rights, and welfare. Inspectors reported no critical findings, which would have resulted in trial pauses or discontinuation. No Investigational Medicinal Product trial at IDI has been stopped due to non-compliance with either ethical or regulatory guidelines; rather, trial stoppages were due to futility.

NDA conducts annual regulatory inspections to assess suitability of the IDI pharmacy to serve as a research facility for Investigational Medicinal Products. In 2018, the IDI pharmacy was issued with a certificate of permission to handle Investigational Medicinal Products. The IDI pharmacy was issued with a certificate of suitability of premises, Pharmacy License, and annual Import Permit that allow us to import and manage Investigational Medicinal Products.

Table 2. Summary of selected clinical trials and studies experience 2010–2025, Infectious Diseases Institute

Trial title	Years of Study	Sponsor	Design/ phase	Drug or Vaccine	Indication	Age
Anti-Retroviral for Kaposi's Sarcoma	2007-2012	Infectious Diseases Institute, Makerere University	CT (Phase 4)	Drug	HIV/ Kaposi's Sarcoma	Adults
Lateral Flow Urine LAM Test in Diagnosis of TB	2010 - 2012	Infectious Diseases Institute, Makerere University	Diagnostic	Device	HIV	Adults
Multivitamins, HAART and HIV/AIDS	2010 - 2013	Infectious Diseases Institute, Makerere University	CT (Phase III)	Drug	HIV	Adults
Cryptococcal Optimal ART Timing Trial	2010 - 2015	Infectious Diseases Institute, Makerere University	CT (Phase IV)	Drug	HIV/ Cryptococcal Meningitis	Adults
QUACT Malaria Tororo	2011-2013	Infectious Diseases Institute, Makerere University	CT	Drug	Malaria	Adults
Food Rilpivirine PK	2012-2013	Infectious Diseases Institute, Makerere University	CT(PK)	Drug	HIV	Adults
LNG Implant PK09	2012-2014	Infectious Diseases Institute, Makerere University	CT(PK)	Drug	HIV	Adults
Dose Optimisation of Stavudine	2012-2014	Infectious Diseases Institute, Makerere University	CT (Phase 3)	Drug	HIV	Adults
Sertraline for treatment of HIV Cryptococcal Meningitis (ASTRO)	2012 - 2016	University of Minnesota	CT (Phase III)	Drug	HIV/ Cryptococcal Meningitis	Adults

CT=Clinical Trial; PK=Pharmacokinetics; CDC=Centers for Disease Control and Prevention; NIH=National Institutes of Health; EDCTP=European & Developing Countries Clinical Trials Partnership; WRHI=Wits Reproductive Health & HIV Institute; SSAT=St. Stephen's AIDS Trust; GCC=Grand Challenges Canada; NINDS=National Institute of Neurological Disorders and Stroke; NIAID=National Institute of Allergy and Infectious Diseases; NICHD=National Institute of Child Health and Human Development

Trial title	Years of Study	Sponsor	Design/ phase	Drug or Vaccine	Indication	Age
Pharmacokinetic interactions between artemisinin- and rifampicin- (Artem–TB)	2012 - 2015	EDCTP	CT(PK)	Drug	TB patients	Adults
Pharmacokinetics of Anti TB drugs and Tuberculosis treatment outcomes (SOUTH)	2013-2016	Univ. of Zurich	CT (Phase IV)	Drug	HIV/ Tuberculosis	Adults
Breast Milk PK14	2014	Academy of Medical Sciences Starter	CT(PK)	Drug	HIV	Adults
DolACT1 PK	2014	University of Liverpool	CT(PK)	Drug	HIV	Adults
Etonorgestrel Implant PK11	2015	Infectious Diseases Institute, Makerere University	CT(PK)	Drug	HIV/ Contraception	Adults
Pregnancy PK15	2016	Infectious Diseases Institute, Makerere University	CT(PK)	Drug	HIV	Adults
Breastfeeding Mothers PK16	2016	University of Liverpool	CT(PK)	N/A	HIV	Adults
DolPHIN1 Study	2016	University of Liverpool	CT (Phase III)	Drug	HIV	Adults
Levonorgestrel Implant & ART	2017	Infectious Diseases Institute, Makerere University	CT(PK)	Drug	HIV/ Contraception	Adults
Dolutegravir in Pregnant HIV Mothers and their Neonates (DolPHIN 2)	2017-2021	University of Liverpool	CT (Phase III)	Drug	HIV	Adults
High Dose AMBISOME on a fluconazole backbone for Cryptococcal Meningitis Induction Therapy in sub-Saharan Africa: A Phase 3 Randomized Non-Inferiority Trial (AMBITION-CM).	2017-2021	London School of Hygiene & Tropical Medicine	CT (Phase III)	Drug	HIV/ Cryptococcal meningitis	Adults
Steady-state pharmacokinetics of Efavirenz (Sustiva/Stocrin) 400 mg once daily in the presence of Rifampicin and Isoniazid	2018	St Stephens Aids Trust	CT (Phase IV)	Drug	HIV/ Tuberculosis	Adults
A Pharmacokinetic Evaluation Of Etonogestrel Implant Versus Darunavir- Or Rilpivirine- Drive-I)	2018-2020	Infectious Diseases Institute, Makerere University	CT (Phase IV)	Drug	HIV	Adults

Trial title	Years of Study	Sponsor	Design/ phase	Drug or Vaccine	Indication	Age
A Pharmacokinetic Evaluation Of Levonorgestrel Implant Versus Darunavir-Based Or Rilpivirine-Based ART Ugandan Women (Drive-II)	2018-2020	Infectious Diseases Institute, Makerere University	CT (Phase IV)	Drug	HIV	Adults
Two-month Regimens Using Novel Combinations to Augment Treatment Effectiveness for Drug-Sensitive Tuberculosis (TRUNCATE-TB).	2018-2022	University College, London	CT (Phase II/ III)	Drug	Pulmonary Tuberculosis	Adults
Etonongestrol dose escalation with EFV	2019-2022	University of Pittsburgh	CT(PK)	Drug	HIV	Adults
High-Dose Intravenous Rifampicin to Improve Survival of Tuberculosis Meningitis: A phase II open-label randomized controlled trial (RifT Study).	2019	London School of Hygiene & Tropical Medicine	CT (Phase II, PK)	Drug	HIV/ Tuberculosis Meningitis	Adults
Encochleated Oral Amphotericin for Cryptococcal Meningitis. (EnACT)	2019-2023	Matinas BioPharma Nanotechnologies, Inc	CT (Phase I/II)	Drug	Cryptococcal meningitis	Adults
Immunogenicity of Fractional One-fifth and One-half Doses of Yellow Fever Vaccine Compared to Full Dose in Children 9-23 Months Old in Uganda	2019-2020	U.S. Centers for Disease Control and Prevention (CDC)	CT (Phase IV)	Vaccine	Yellow Fever/ vaccine	Children
A Randomized, Four-arm Open-Label Phase IIb Clinical Trial to Evaluate the Pharmacokinetics, Safety/Tolerability and Efficacy of High Dose Rifampicin in TB-HIV Co-infected patients on Efavirenz-or Dolutegravir based Antiretroviral Therapy. (SAEFRIF)	2019-2021	Infectious Diseases Institute, Makerere University	CT (Phase IIb)	Drug	TB-HIV co-infection	Adults
Single Dose Liposomal Amphotericin for Asymptomatic Cryptococcal Antigenemia. (ACACIA)	2019 -Ongoing	Infectious Diseases Institute, Makerere University	CT (Phase II/ III)	Drug	HIV/ Cryptococcal antigenemia	Adults

Trial title	Years of Study	Sponsor	Design/ phase	Drug or Vaccine	Indication	Age
Nucleosides and Darunavir/Dolutegravir in Africa (The NADIA Trial): A Randomised Controlled Trial of Darunavir versus Dolutegravir and Tenofovir versus Zidovudine in Second-line Antiretroviral Therapy Regimens for the Public Health Approach in Sub-Saharan Africa	2019-2021	Infectious Diseases Institute, Makerere University	CT (Phase III)	Drug	HIV	Children & Adults
High Dose Oral Rifampicin to Improve Survival from Adult Tuberculosis Meningitis: A Double-blinded Randomised Controlled Phase III Trial. (HARVEST)	2019-2025	Infectious Diseases Institute, Makerere University	CT (Phase III)	Drug	TB meningitis	Adults
Safety and Pharmacokinetics of the combination Broadly Neutralizing Antibodies, 3BNC117-LS-J and 10-1074-LS-J, in Healthy American and African Adults	2019-2023	International AIDS Vaccine Initiative	CT (Phase I/II)	Vaccine	HIV	Adults
Trial of faropenem and cefadroxil (in combination with amoxicillin/Clavulanic acid and standard TB drugs) in patients with pulmonary tuberculosis: measurement of early bactericidal activity and effects on novel biomarkers	2019	National University Hospital, Singapore	(CT phase II)	Drug	Pulmonary Tuberculosis	Adults
A Phase II trial to describe the pharmacokinetics, safety and efficacy of pharmacogenetics-guided dosing of isoniazid in patients with HIV-associated TB (PHINX)	2020-2024	Infectious Diseases Institute, Makerere University	CT (Phase II)		HIV/ Tuberculosis	Adults
A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older	2020-2024	Sanofi Pasteur, a Sanofi Company	(CT phase III)	Vaccine	COVID-19	Adults

Trial title	Years of Study	Sponsor	Design/ phase	Drug or Vaccine	Indication	Age
A Phase 3b, Randomized, Multicenter, Open-Label Study Evaluating the Efficacy, Safety and Tolerability of Switching to Long-Acting Cabotegravir Plus Long-Acting Rilpivirine From Current Antiretroviral Regimen in HIV-Infected, Virological Suppressed Adults in Sub-Saharan Africa. (CARES)	2021-2024	Janssen Cilag International NV	(CT Phase III)	Drug	HIV	Adults
The Impact of coprevalent optimistic infections in hospitalised adults with advanced HIV disease and cryptococcal meningitis (IMPROVE)	2021-2024	London School of Hygiene & Tropical Medicine	(CT Phase III)	Drug	HIV/ Cryptococcal Meningitis	Adults
Optimizing Malaria Treatment for HIV-Malaria Co-infected Individuals by addressing Artemether-Lumefantrine and Efavirenz, A randomized Controlled Trial (OPTIMAL)	2021-2024	Infectious Diseases Institute, Makerere University	CT (Phase IV)	Drug	HIV/ Malaria	Adults
An Open-label, randomized, Single intravenous dosing to investigate the effect of fixed dose combinations of tenofovir/lamivudine or atazanavir/ ritonavir on the pharmacokinetics of remdesivir in Ugandan healthy volunteers. (REMTLAR)	2021	Infectious Diseases Institute, Makerere University	CT (Phase II)	Drug	Ebola/HIV	Adults
Drug Interactions between Dolutegravir (DTG) and escalating-doses of Rifampicin (RIF) Study (DORIS Study)	2021-2023	University of Liverpool	(CT Phase IV)	Drug	Tuberculosis	Adults
Efficacy, Safety and Effectiveness of Injectable Cabotegravir/Rilpivirine in Improving HIV-1 Control in Sub-Saharan Africa: A Pragmatic Phase 3b Open-Label Randomized Controlled Trial. (IMPALA)	2022-Ongoing	MRC/UVRI and LSHTM Uganda Research Unit	(CT Phase III)	Drug	HIV	Adults
Exposure-Response Evaluation of IV Artesunate in Children with Severe Malaria (DMID)	2023-2025	University of Maryland	(CT Phase IV)	Drug	Malaria	Children

Trial title	Years of Study	Sponsor	Design/ phase	Drug or Vaccine	Indication	Age
Optimizing the Dose of Flucytosine for the Treatment of Cryptococcal Meningitis (FLOOR)	2024	University of Minnesota	(CT Phase II)	Drug	HIV/ Cryptococcal Meningitis	Adults
Therapeutic Drug Monitoring for Antimicrobial Agents for People Living with HIV (TAP trial)	2024 – On-going	Infectious Diseases Institute, Makerere Uni-versity	(CT Phase IV)	Drug	HIV/ Tuberculosis/ Therapeutic Drug Monitoring	Adults
A Phase 4, Open-Label, Rollover Study to Provide Continued Access to Cabotegravir Long-acting Injection and Rilpivirine Long-acting Injection to Participants Living with Human Immunodeficiency Virus Type 1 (HIV-1) Infection Who Participated in Long acting Combination Therapy Studies	2025 - Ongo-ing	Janssen-Cilag Limited	(CT Phase IV)	Drug	HIV	Adults
A Phase III/IV factorial randomised double-blind trial to compare the addition of dapagliflozin versus placebo, and rosuvastatin/ ezetimibe versus pitavastatin, in patients with HIV on integrase strand transfer inhibitor-based antiretroviral therapy with elevated metabolic risk (OPTIMAR)	2025-Ongo-ing	Kirby Institute	(CT Phase III/ IV)	Drug	HIV	Adults
Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial PLATFORM-CM	2025-Ongo-ing	University of Minnesota	(CT Phase II/ III)	Drug	HIV/ Cryptococcal Meningitis	Adults

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