



Clinical Research at the Infectious Diseases Institute

The Infectious Diseases Institute is a center of excellence for patient care, treatment and research in infectious disease. Since 2004, IDI has participated in large international trials in HIV treatment and prevention, tuberculosis, malaria and other infectious disease, and has authored over 180 scientific publications.



Centrally located facility

IDI is located in Kampala, Uganda, 45 minutes drive from Entebbe International Airport. The Institute is situated between Mulago National Referral Hospital and Makerere University College of Health Sciences.



Site features include:

- 1084m² purpose built out patients clinic facility serving over 10,000 HIV & TB patients per year
- Cohort of 850 patients receiving second-line antiretroviral therapy (ART)
- Access to an additional 9000 patients through Kampala City clinics
- Outreach clinics serving an additional 42,000 patients per year
- Adjacent to Mulago National Referral Hospital; access to emergency care and in patient wards
- Relationships with eight Regional Referral Hospitals
- On-site Pharmacy
- On-site College of American Pathologists certified Core Laboratory
- On-site translational laboratory



State-of-the-art equipment

- Translational lab with ELISA, HPLC, fluorescence microscopy, GeneXpert and flow cytometry capabilities
- PBMC isolation and storage, PBMC stimulation and incubation
- Laboratory processing, repository creation with Freezer works software-80°C freezer storage
- Core Lab with state of-the art equipment for critical diagnosis and monitoring tests in Chemistry, Hematology, Microscopy, Serology, Flow Cytometry, Urinalysis and Molecular Pathology
- Coulter *Act 5diff* Autoloaders for hematology testing
- Roche PCR fully automated instruments for HIV RNA Viral Load testing and Pediatrics DNA PCR HIV early detection
- Standby generator for continual power supply

Infectious Diseases Institute. Mulago Hospital Complex P. O. Box: 22418 Kampala, Uganda

Tel: +256-41-4307000; or +256-31-2307000 Fax: +256-41-4307290; +256-31-2307290 Email: office@idi.co.ug

A breadth of capabilities

IDI Clinical Trials Unit offers a wide spectrum of study capabilities from Phase II, III, IV of drug development.

The unit has human pharmacology experience conducting:

- Pharmacokinetics / Pharmacodynamics (PK/PD) studies
- Drug-Drug interaction studies
- Food effect studies
- Pharmacokinetic studies in pregnancy

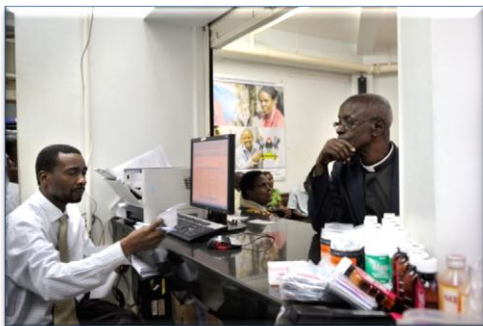


Effective recruitment

IDI focuses on defined patient populations:

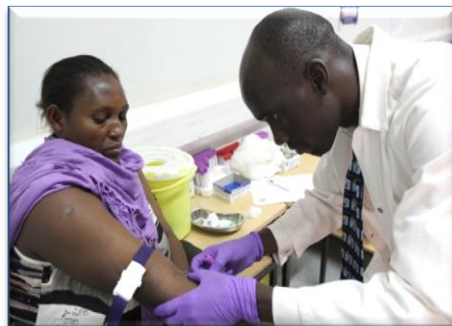
- HIV, for which IDI has its own specialist clinic in Kampala and 10 Outreach clinics in rural areas of Uganda
- Tuberculosis via IDI's clinic in Kampala and our relationship with the Gulu Regional Referral Hospital clinic
- Malaria, via relationships with Regional Referral Hospitals

We are located by, and have excellent relationships with departments at Mulago Hospital, Uganda's national referral hospital for access to and care for patients with a variety of serious infectious and cardiovascular diseases and malignancies.



Staff

Through intensive research capacity building, IDI has established an experienced cadre of research staff well trained in clinical trial management that have worked on several large, international clinical trials in HIV and infectious diseases.



Research Expertise

IDI operates to ICH-GCP and has a full suite of in-house SOPs in place. Internal QA/QC and monitoring teams ensure the collection of high quality data. Our research expertise includes:

- Support, guidance and scientific input to trial design
- Regulatory support, internal monitoring and quality management
- Pharmacokinetic and translational medicine
- Immunology, microbiology, hepatology and epidemiology
- Project management and trial coordination
- Grants and financial administration
- Data management
- Fully electronic medical records via Integrated Clinic Enterprise application ICEA-NET
- Robust DataFax system well-suited to regional studies
- Biostatistics
- Clinical study report writing

***To learn more about IDI and our clinical research capabilities, please visit
<http://idi.mak.ac.ug/> or contact Allen Mukhwana,
Senior Research Administrator at +256 414 307 242, email amukhwana@idi.co.ug***

Key Projects

Phase II trials

- Efficacy and safety of TMC278 in antiretroviral-naïve HIV-1 patients: A phase IIb randomized trial *with Tibotec pharmaceuticals*

Phase III trials

- Randomized Placebo-Controlled Trial of HSV-2 Suppression to Prevent HIV Transmission among HIV-Discordant Couples *with University of Washington*
- Use of Atorvastatin as Adjuvant Therapy Among Suboptimal Responders to Antiretroviral Therapy in an African Cohort of HAART-treated Adults
- Randomized, blinded, placebo-controlled trial to demonstrate if pre-exposure prophylaxis decreases HIV-1 acquisition among HIV-1 uninfected individuals within HIV-1 discordant couples (**PrEP**) *with University of Washington*. Switching at low HIV-1 RNA into fixed dose combinations (**SALIF – TMC278IFD3002**).
- A 48-week non-inferiority study comparing rilpivirine, tenofovir disoproxil fumarate plus emtricitabine to efavirenz, tenofovir disoproxil fumarate plus emtricitabine *with Janssen Pharmaceuticals*

Phase IV Randomized Trials/Strategy Trials

- Development of Anti-Retroviral Therapy in Africa (**DART**) with UK Medical Research Council (MRC)
- Europe - Africa Research Network for Evaluation of Second-line Therapy (**EARNEST**) *with European and Developing Countries Clinical Trials Programme (EDCTP)*.
- Anti-retroviral therapy for AIDS-related Kaposi's Sarcoma in Africa (**ARKS**) *with UCSF*
- Comparison of treatment outcomes between intravenous artesunate and intravenous quinine followed by artemisinin combination therapy for severe malaria in Tororo, Uganda (**EPQUACT**) *with EDCTP*
- Cryptococcal Optimal ART Timing (**COAT**) *with University of Minnesota*
- Prevention of early mortality in patients initiating antiretroviral therapy by presumptive TB treatment (**PROMPT**) *with EDCTP*

Pharmacokinetic studies

- Evaluation of the effect of food on the pharmacokinetics of rilpivirine *with Janssen Pharmaceuticals*
- Drug interactions between artemisinin therapies and rifampicin-based TB treatment (**ARTEM-TB**) *with EDCTP*
- Pharmacokinetic evaluation of levonorgestrel implant and antiretroviral therapy *with Northwestern University*
- Evaluation of the pharmacokinetics of artemether-lumefantrine versus efavirenz, nevirapine or rifampicin *with Trinity College Dublin*
- Evaluation of the effect of food on the pharmacokinetics of lopinavir/ritonavir, tenofovir, emtricitabine and efavirenz *with Trinity College Dublin*
- Drug interaction study between lopinavir/ritonavir and artemether-lumefantrine *with University of Liverpool*
- Drug interaction study between nevirapine and rifampicin-based tuberculosis treatment *with University of Liverpool*
- Effect of pregnancy on the steady-state pharmacokinetics of nevirapine in Ugandan women *with Northwestern University*