

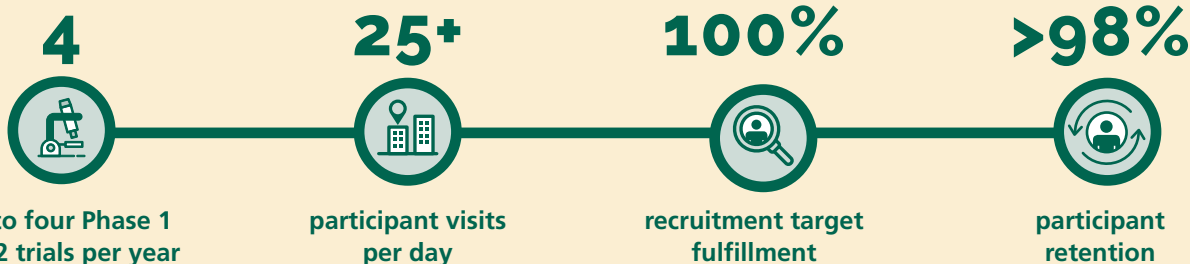
THE MAKERERE UNIVERSITY WALTER REED PROGRAM

MUWRP-Uganda



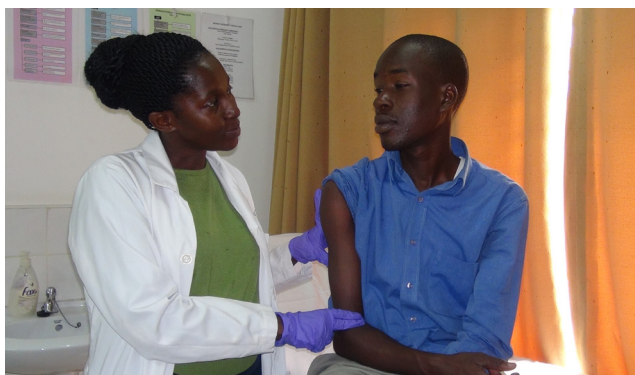
The Makerere University Walter Reed Program (MUWRP) Clinical Research Site (CRS) based in Kampala, Uganda, is part of a robust international medical research initiative focused on combating infectious disease threats. The CRS is able to support Phase 1-3 clinical trials as well as non-clinical research such as prospective cohort studies and program evaluations. The site boasts 16 years of experience in conducting IND clinical trials and a staff with extensive research backgrounds and proven skill with collecting high quality data.

MUWRP CRS BY THE NUMBERS:



EBOLA RESEARCH HIGHLIGHTS

In 2009, MUWRP and the U.S. Military HIV Research Program (MHRP) launched the first Ebola vaccine clinical trial conducted in Africa. Since then the site has been involved with the trials of four more Ebola vaccine candidates at various stages of development.



- First Ebola vaccine clinical trial in Africa in 2009; published in *The Lancet*, December 2014
- Phase 1b clinical trial testing ChAd3 vaccine
- Phase 2 study testing Ad 26/MVA Ebola vaccines
- Phase 1 trial comparing two doses of an Ebola Sudan chimpanzee adenovirus vector vaccine, (cAd3-EBO S)
- Long-term follow up study on Ebola survivors from 2007-08 Bundibugyo ebolavirus outbreak; published in *Lancet ID*

HIV RESEARCH HIGHLIGHTS

MUWRP has successfully completed many HIV cohort and vaccine studies, which have advanced understanding of HIV subtypes and disease progression in the region. By building infrastructure and increasing the capabilities of local public and private partners, MUWRP also helps ensure quality services for communities participating in vaccine research and HIV cohort studies. Recent studies include:

- **A004:** Phase 1/2 clinical trial evaluating the safety and Immunogenicity of a homologous Ad26 Mosaic Vector regimens, or Ad26 Mosaic and MVA Mosaic heterologous vector regimens for HIV prevention
- **RV398:** study testing the safety and virologic effect of a human monoclonal antibody, VRC01, administered intravenously to adults during acute HIV infection
- **RV217** – Early Capture HIV Cohort Study: MHRP's ambitious RV217 study followed a group of high-risk volunteers, tracked their HIV status and characterized progression through the acute stages of HIV infection. This prospective study captured samples from the earliest stages of HIV — in some cases within days of infection.



PEPFAR

MUWRP has been working in Uganda with MHRP to provide HIV care, treatment and prevention services since 2005 with the support of the President's Emergency Plan for AIDS Relief (PEPFAR). MUWRP routinely reviews and conducts in-depth analyses of its PEPFAR-funded programs.

PEPFAR-supported Research:

- **RV329-AFRICOS (ongoing):** Fifteen-year longitudinal study to evaluate the impact of clinical, biological and socio-behavioral issues on HIV infection and disease progression. The CRS has enrolled more than 600 volunteers for this protocol with a 91% retention rate.
- **FISHER FOLK Protocol:** Evaluates a novel design to improve access and retention rates among the fishing communities of Koome Islands
- **PreP demonstration project:** Evaluates feasibility, acceptability and adherence to PreP use among adolescent and young women at high risk for HIV

SITE FEATURES

MUWRP Clinic

The MUWRP main clinic has an outstanding research staff trained in Good Clinical Practice and Human Research Participant Protection. It has advanced management and quality systems in place.

Clinical and Research Laboratory

MUWRP has well trained and highly qualified professionals and is accredited by the College of American Pathologists (CAP). It has state-of-the-art capabilities including diagnostics, flow cytometry, processing and safety laboratories and a well-established liquid nitrogen plant.

DISEASE PREVALENCE

HIV: 6.2%, **Schistosomiasis:** 25.6%, periodic outbreaks of **Ebola**

PARTNERS

Walter Reed Army Institute of Research | Henry M. Jackson Foundation for the Advancement of Military Medicine | U.S. Military HIV Research Program | U.S. Department of Defense's Armed Forces Health Surveillance Branch – Global Emerging Infections Surveillance and Response System (DoD AFHSB-GEIS) | JPEO | NMRC | USAMRIID

EMERGING INFECTIOUS DISEASES

With support from U.S. DoD partners, the Emerging Infectious Diseases Program (EIDP) at MUWRP supports early detection and response to emerging and re-emerging infectious diseases.

- **Influenza Surveillance:** Part of a laboratory-based influenza surveillance global network that detects local influenza outbreaks, provides isolates for the WHO vaccine pool and detects any emerging strains that could have pandemic potential
- **Anti-Microbial Resistance Surveillance:** Strengthens the capacity of hospital laboratories to conduct surveillance for clinically important bacteria
- **Acute Febrile Illness (AFI):** Helps track the occurrence of AFI agents of pandemic potential and establishes capabilities for rapid detection, identification and response to these pathogens

Data Management Centre (DMC)

In addition to specialized training in data management and analysis, all data management personnel have been trained in Good Clinical Practice and Human Research Participants Protection.

Community Advisory Board

MUWRP is committed to actively engaging communities throughout the research process, from trial protocol development/design through implementation to dissemination of research findings.



JOINT MOBILE EMERGING DISEASE INTERVENTION CLINICAL CAPABILITY (JMEDICC)

JMEDICC, at the Fort Portal Regional Referral Hospital, provides a platform for clinical trials during filovirus (Ebola/Marburg) outbreaks, allowing testing of new therapeutics or medical countermeasures. The JMEDICC portfolio is currently being established through the following approaches:

- Improved standard of care support to patients through training of clinical staff.
- Improved laboratory capacity through laboratory renovations, provision of supplies and equipment, and training of laboratory staff.
- Development of clinical research capability through renovations of an isolation research ward, research staff hires and training. The resulting capacity will offer a mechanism to greatly accelerate the development of life saving products for future outbreaks.
- Conduct of an observational study of sepsis management in Uganda as a measure to maintain staff clinical research capability.
- Planning to implement a Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI) protocol of a yet to be approved drug for compassionate use during an Ebola outbreak.