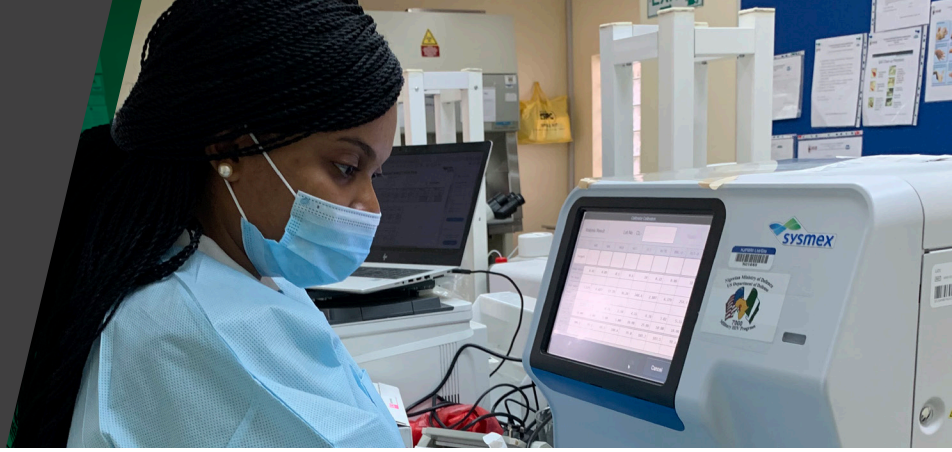
CLINICAL RESEARCH CENTRE (CRC)

Abuja, Nigeria



A regional leader in clinical research, the CRC is dedicated to generating the knowledge necessary to develop innovative solutions to medical challenges and providing a conducive environment for the training of future generations of scientists.

The mission of the CRC is to conduct high quality clinical research to support the development of countermeasures against infectious disease threats of public health importance. The CRC has past experience with, and is currently participating in, clinical and epidemiologic research related to several endemic and emerging infectious diseases.

COVID-19

SARS-CoV-2 Vaccine Trial

- A Phase 3, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety and immunogenicity of SARS-CoV-2 adjuvanted recombinant protein vaccines (bivalent) for prevention of COVID-19 in adults.

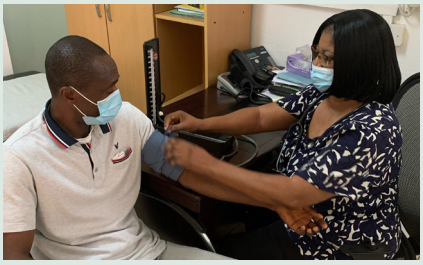
Africa CDC Cohort Study

- Sample collection and biobanking for SARS-CoV-2 characterization and future immune response studies among individuals with natural infections, vaccinees and breakthrough infections in six African countries.

LASSA FEVER

- **Seroprevalence and Risk Factors of Lassa Virus Infection in Nigeria:** This cross-sectional study will determine the prevalence of Lassa virus-specific antibodies among 630 adults in rural and semi-urban regional locations. It will also identify socio-demographic, travel patterns, environmental and vector exposure factors that are predictive of Lassa diagnosis and will inform future Lassa vaccine trials.
- **Characterizing Incidence, Seroprevalence, Risk Factors, and Transmission of Lassa Virus Infection in Southern Nigeria:** In partnership with the Africa Center of Excellence for Genomics of infectious Diseases (ACEGID), this study is designed to capture acute cases of Lassa virus infection to better understand the mechanism of infection and host immune response, and define risk factors for symptomatic disease and clinical outcomes.
- **Lassa Vaccine Phase 2a/2b:** As part of the Lassa Fever Vaccine Efficacy and Prevention for West Africa (LEAP4WA) consortium, the CRC will participate in Phase 2 clinical trials to evaluate the safety, tolerability and immunogenicity of a new candidate Lassa virus vaccine. Target enrollment for the 2a trial is 384 adults and children, and the Phase 2b trial will enroll about 4,950 participants. This work is funded by the Coalition for Epidemic Preparedness Innovations and European and Developing Countries Clinical Trials Partnership through an award to the International AIDS Vaccine Initiative.

About the CRC



The CRC was established in 2014 through a U.S.-Nigeria military-to-military partnership. The Centre has over 20 staff, an on-site clinical laboratory and receives additional support from the Defence Reference Laboratory (ISO 15189:2012-accredited by the American Association for Laboratory Accreditation). Activities include clinical trials, cohort studies, and public health intervention programs, with capacity to enroll 20 vaccine trial participants per day.

The CRC works with the Emerging Infectious Diseases Branch (EIDB), U.S. Military HIV Research Program (MHRP), and Diagnostics and Countermeasures Branch (DCB) at the Walter Reed Army Institute of Research (WRAIR), as well as several international collaborators. The CRC is supported by HJF Medical Research International and the Nigerian Ministry of Defence (NMOD).

Community Engagement

The CRC community engagement team helps ensure successful implementation of studies and enables excellent participant retention (~ 94.5%). Community Advisory Board (CAB) highlights include:

- Study-specific stakeholders' meetings
- Tiered introductions of new research studies
- Study-specific CAB constitution and board empowerment to function autonomously
- Connecting researchers with community gatekeepers, chiefs and councils
- Periodic check-ins and outreach to research communities

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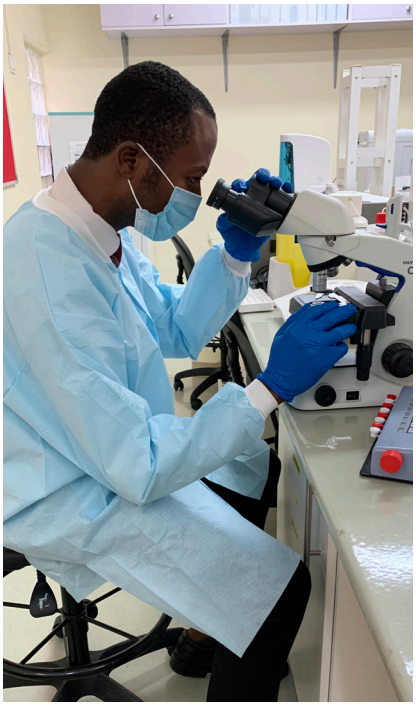
EBOLA

- **Ebola Vaccine: ChAd3-EBO-Z:** This was the first Ebola vaccine trial in Nigeria, conducted between August 2015 and November 2016. The CRC enrolled 330 participants for this study of a GlaxoSmithKline experimental vaccine, exceeding the original sample size expectation for Nigeria by over 100%.
- **Ebola Vaccine: Ad26.ZEBOV/MVA-BN-Filo:** The CRC enrolled 38 participants for this study, including 16 adults with HIV, with retention of 89.5% of participants at 12 months. This was an early trial for Johnson & Johnson's emergency use authorized Ebola vaccine (Zabdeno), which was deployed for the outbreak in Guinea in 2021.

HIV

- **Recent Infection Epidemiology:** Surveillance to establish recency of infection among persons newly diagnosed with HIV in Nigeria.
- **African Cohort Study (AFRICOS):** Large, long-term cohort study at multiple African sites that evaluates HIV prevention and treatment services and HIV comorbidities supported through local facilities, funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).
- **TRUST Cohort Study:** Prospective study characterizing HIV and STI prevalence, incidence and risk behaviors among sexual and gender minority populations.
- **Vaccine Development Feasibility**: Assessment of potential field sites and target populations for HIV vaccine cohort development in Nigeria.



MONKEYPOX

- **Monkeypox Public Outreach and Sample Collection Training:** A Defense Threat Reduction Agency (DTRA)-funded project designed to support trainings for 120 veterinary and healthcare workers in Nigeria.

SEVERE INFECTIOUS DISEASE

- **Surveillance, Detection, Risks and Consequences of Severe Infectious Disease in West Africa:** Study of acute fever or other severe infectious illness at health facilities in Nigeria, Ghana and Liberia.
- **Ultrasound Platform Study:** A sub-study to the above, this research will determine the value of the ultrasound platform in diagnosing respiratory illnesses. This study is implemented in collaboration with Defense Advanced Research Projects Agency (DARPA).
- **Malaria Slide Bank Study:** This project will develop geographically and genetically diverse malaria parasite master cell banks to use for controlled human malaria infection studies. This sub-study is funded in part by the Bill & Melinda Gates Foundation and completed in partnership with ACEGID and NMOD.

WRAIR | USAMRD-A
U.S. ARMY MEDICAL RESEARCH DIRECTORATE-AFRICA

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