

NEWS FROM THE U.S. MILITARY HIV RESEARCH PROGRAM
AT THE WALTER REED ARMY INSTITUTE OF RESEARCH

Accelerating HIV Countermeasure Innovation Through mRNA Manufacturing Capabilities

MHRP is partnering with the Walter Reed Army Institute of Research (WRAIR) Pilot Bioproduction Facility (PFB) to strengthen mRNA vaccine manufacturing capabilities and advance HIV vaccine candidates. This collaboration expands WRAIR's unique capacity within the Department of War to translate scientific discoveries into medical countermeasures that directly support defense health priorities.

WRAIR's PBF is a current Good Manufacturing Practice (cGMP)-compliant facility specializing in the production of vaccines and biologics for use in early-stage clinical trials, and establishing mRNA production technology in-house means WRAIR researchers can more rapidly move vaccine concepts from design to manufacture. Close integration of research and manufacturing enables cross-disciplinary teams to address complex challenges, such as scalability, quality control, and regulatory readiness, early and iteratively in the development process. This coordination accelerates the transition from laboratory discovery to clinical evaluation while minimizing reliance on external manufacturing, reducing costs and shortening countermeasure research and development timelines.

Leveraging these advantages, the PBF is working towards manufacturing an HIV vaccine candidate based on MHRP's multiple founder variant (MFV) design. This novel approach reflects the genetic diversity of HIV-1 soon after acquisition of multiple founder infection and incorporates several envelope sequences into mRNA constructs encapsulated in a single formulation. The goal is to elicit broad, durable antibody neutralizing responses capable of addressing the evasive variability of the HIV virus.

This project represents a highly integrated, cross-institutional effort across WRAIR. In MHRP's viral genetics section, Drs. Morgane Rolland, Eric Lewitus and Hongjun Bai developed the MFV concept and designed promising

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Photo by Mike Walters/WRAIR



MOCHI Study Reaches Full Enrollment in the Philippines

MHRP's Multinational Observational Cohort of HIV and Other Infections (MOCHI) study has reached full enrollment at its Philippines site, marking a milestone achievement in the effort to better understand the fast-growing HIV epidemic in this region of importance to the National Defense Strategy.

MOCHI is a prospective observational cohort study conducted in the Philippines in partnership with the Armed Forces of the Philippines, nongovernmental organization LoveYourself, Inc., and other community stakeholders. The site has now enrolled 400 participants, reflecting strong local engagement efforts.

MOCHI facilitates preparedness for future HIV and STI prevention studies by estimating HIV and STI incidence in populations at risk, tracking the evolution of risk and healthcare-seeking behaviors, building site capacity, evaluating recruitment and retention capacity at participating sites, and maintaining relationships with communities affected by HIV and other STIs. The MOCHI study is also underway at sites in Kenya and Uganda.

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Accelerating HIV Vaccine Innovation Through Enhanced mRNA Manufacturing Capabilities

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antigens in collaboration with Mohamed-Gabriel Alameh at the University of Pennsylvania and WRAIR's structural biology team. The MHRP Product Quality team is working with the PBF to manufacture the MFV vaccine for HIV subtype B, developing processes and assays to ensure product concentration, quality and stability.

Dr. Mangala Rao and Dr. Diane Bolton collaborated on preclinical studies, with Dr. Shelly Krebs' B cell biology team conducting additional analyses. The preclinical work was funded under a MIDRP proposal led by Dr. Rolland. In parallel, Dr. Rolland's team developed MFV antigens for HIV subtype C through a project funded by the NIH and led by Dr. Sandhya Vasan. Looking forward, the program aims to manufacture enough vaccine for pharmacology and toxicology studies and for Phase 1 clinical trials conducted at MHRP's international network of partner sites.

Researchers Share Preliminary Findings from Bispecific Antibody Trial

An ongoing Phase 1 human trial in Tanzania is evaluating the safety and antiviral activity of a novel bispecific antibody, alone and in combination with another potent monoclonal antibody, to combat HIV. Enrollment was completed last Fall, and follow-up visits will continue into Spring 2026. MHRP investigators delivered early findings from the trial during an oral presentation at the 2026 Conference on Retroviruses and Opportunistic Infections.

MHRP's research partners at Tanzania's National Institute for Medical Research - Mbeya Medical Research Center are conducting the study called RV584. WRAIR has been working in Tanzania on countermeasure development for infectious diseases since 2001, and its research is conducted in close collaboration with the Ludwig Maximilian University of Munich and the Mbeya Zonal Referral Hospital.

Bispecific antibodies are lab-engineered antibodies designed to target two distinct binding sites on immune cells or virus envelopes. These molecules can neutralize HIV with improved breadth and potency, and they can be used as both preventive and therapeutic countermeasures.

The trial is also exploring fixed dosing and the safety of intramuscular injection to deliver these mAbs, important advantages for future potential use in remote settings where medical infrastructure may be limited.

DELIVER Workshop: Strengthening International Capacity for HIV Remission Research

MHRP and a global network of partners gathered for a workshop under the Developing Leadership and Innovation in Viral Eradication Research (DELIVER) initiative; an ambitious initiative to advance and harmonize HIV cure research around the world. The workshop, hosted by the SEARCH Foundation and WRAIR-AFRIMS in Bangkok, brought together researchers, clinicians, and community representatives to share insights, align on next steps and create connections to drive research capabilities and innovation.

The DELIVER program focuses on developing laboratory and clinical site infrastructure to build capacity to conduct long-term HIV remission studies in countries most impacted by HIV and to foster collaboration between international and local

experts to encourage knowledge transfer and sharing of best practices. It is being implemented in Kenya, Mozambique, Nigeria, Tanzania, Uganda, Thailand, the Philippines, and Brazil.

Two trials under the initiative, DELIVER-01 and DELIVER-02, have already begun. DELIVER-01 is evaluating broadly neutralizing antibodies with or without a therapeutic vaccine in Thailand, and DELIVER-02 examines the combination of Dual-Affinity Re-Targeting (DART®) bispecific antibodies and latency reversal agents at sites in the U.S. and Kenya. A third DELIVER-03 trial is in advanced stages of planning. This initiative is funded by the Division of AIDS of the National Institute of Allergy and Infectious Diseases, one of the National Institutes of Health.



Motorcycle Couriers Improve HIV Testing Access in Remote Regions of Tanzania

Efficient sample transportation is critical in delivering quality HIV services to ensure timely diagnoses and prompt access to care and treatment. Muze village in the Sumbawanga District of Tanzania's Rukwa Region faces multiple challenges in transporting samples to labs due to its infrastructure: rough roads, limited mobile health services, and minimal public transport options. These obstacles limited access to essential HIV monitoring/diagnostic services, particularly viral load (VL) testing, CD4 testing and HIV Early Infant Diagnosis.

For years, residents of the village have relied on a simple but powerful solution to overcome these obstacles: using local bodaboda (motorcycle) drivers to transport medical samples. This grassroots solution has become a critical resource for people living with HIV (PLHIV) in remote areas, ensuring that no one is left behind.

In 2021, with funding from PEPFAR, MHRP launched a community-based and cost-effective integrated sample referral system. At the heart of this system are trained, locally based motorcycle drivers who transport samples from peripheral health facilities (spokes) to central storage hubs, and from there to the Regional Referral Laboratory. This "spoke-to-hub" model has proven to be transformative.

One of the local heroes of this initiative is Simon Kazule, a dedicated bodaboda driver from Muze village. Each day, Simon travels over 140 kilometers, collecting samples from six health facilities and delivering them to Muze Health Centre. His work ensures blood samples reach testing labs on time, and that results are swiftly returned to clients, improving patient management and outcomes.

Victor Simon, a local laboratory lead, sees this as a game-changer for HIV care in the region. "This model solves one of the biggest challenges in rural HIV care because it provides reliable, fast transport and is very cost effective. We've improved sample integrity and reduced turnaround time from 20–30 days to just 10–14 days. It aligns with national benchmarks and is a scalable solution with real, measurable impact."



MHRP Marks 40th Anniversary

In 1986, Congress directed the Department of Defense to create a dedicated HIV research effort to protect troops from a growing epidemic. The U.S. Military HIV Research Program at WRAIR has become a world leader in HIV countermeasure innovation, and to this day has led the only HIV vaccine study to demonstrate modest infection, the RV144 Thai trial. Today, MHRP continues to ensure force readiness, protect the battlefield blood supply, and reduce the global impact of HIV.

Pictured: An early photo of the Department of Retrovirology team at the original WRAIR building in Bethesda, Maryland.

WRAIR Marks 20 Years of Military-to-Military Health Partnership in Nigeria

In September 2025, WRAIR and the Nigeria Ministry of Defence Health Implementation Programme (MOD-HIP) marked 20 years of groundbreaking military-to-military health partnership. Over the years, this collaboration has provided HIV services to military and civilian communities in the region and conducted research to counter HIV, Ebola, malaria, Lassa fever, and more. Major General Paula Lodi, Commanding General of the U.S. Army Medical Research and Development Command, joined WRAIR Commander COL Brianna Perata in a visit to Nigeria in September 2025 for a commemoration of the partnership.

For the last 20 years, MHRP and MOD-HIP have partnered to implement HIV prevention, care, and treatment with funding from PEPFAR, transforming health outcomes for thousands in the region. More than 41,000 adults and children are currently on treatment and HIV testing services have reached 1.6 million clients. The partnership has also strengthened Nigeria's health system by training more than 2,000 healthcare workers in HIV and TB management and upgrading over 50 laboratories nationwide.



Award-Winning MHRP Research

Congratulations to the MHRP researchers and collaborators who have been recognized at recent conferences for their outstanding work:



MHRP's chief of Animal Models and Viral Persistence Dr. Diane Bolton won a third-place award for her poster, "Defining the Window of Opportunity for HIV Peri-exposure Immunoprophylaxis with Biospecific Monoclonal Antibody 10E8.4/iMAB against High-dose Intravenous SHIV Challenge in Rhesus Macaques," at the 2025 Military Health System Research Symposium.



Alfred Lutaaya, a public health specialist with the Walter Reed Army Institute of Research-Africa team in Uganda, won the Van Tongeren prize for Young Investigators Award at the 2025 International AIDS Society IAS Conference on HIV Science in Kigali, Rwanda, for his work on geospatial and hotspot analysis of HIV-infection in infants.



Dr. Vamsi Vasireddy, Philippines Country Director at Walter Reed Army Institute of Research-AFRIMS, won the Outstanding Presenter Award at the 2025 Indo-Pacific Military Health Exchange for his talk, "Substance use among males eligible for military enlistment in the Philippines who also have behavioral vulnerability to HIV."



Photo by Tyra Breaux/WRAIR

AFRICOS Tracks HIV Drug Resistance

A recent analysis from MHRP's African Cohort Study (AFRICOS) sheds light on how effective the medicine combo of enofovir, lamivudine and dolutegravir (TLD) remains as a first-line antiretroviral treatment (ART) in sub-Saharan Africa. TLD has been established as a safe, reliable therapy to control viral load in people living with HIV, but it can become less effective over time as HIV mutates and develops resistance.

AFRICOS is a large long-term observational cohort study in Kenya, Nigeria, Tanzania, and Uganda that tracks the impact of clinical practices, biological factors and socio-behavioral issues on HIV and disease progression. For this analysis, MHRP researchers focused on participants who had been taking TLD for at least three months but still had a high amount of HIV in their blood, meaning the virus was not fully controlled. Samples were tested to see whether the virus had developed genetic resistance to the ART regimen.

Data showed that among 2,513 participants on TLD, 7.4 percent had uncontrolled viral loads (defined as VL \geq 1000 copies/mL). Resistance to dolutegravir was rare, but emergence of dolutegravir resistance mutations increased over time in Kenya and Tanzania. There was substantial underlying drug resistance to nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs), classes of drugs which include lamivudine and efavirenz.

Researchers concluded that for those without confirmed resistance to dolutegravir, timely adherence support may lead to viral suppression without need for regimen change. However, surveillance for HIV drug resistance remains critical in sub-Saharan Africa to protect the effectiveness of treatment options.

WRAIR Leverages Cryo EM to Deliver Near-Atomic Visualization and Speed HIV Countermeasure Development

MHRP is working closely with WRAIR's structural biology lab to harness cutting-edge cryo-electron microscopy (cryo-EM) to gain detailed insight into how HIV vaccines and antibodies work in the body to inform how next-generation preventive and therapeutic countermeasures are designed, refined and evaluated.

Cryo-EM capabilities, housed within WRAIR's Viral Diseases Program, involve flash-freezing fragile biological samples to enable imaging in a transmission electron microscope. This allows biological samples less than 0.5 micron in diameter to be preserved and imaged. The results are three-dimensional views of molecules at near-atomic resolution, revealing how antibodies bind to viruses, how vaccines assemble and how the immune response takes shape. For MHRP's research and development efforts, this means scientists can see where antibodies bind on the HIV envelope and which parts of the virus are most susceptible to immune neutralization.

"Before, when we made a new product, it was a clear liquid in a clear tube. We could know that it worked, but we couldn't see exactly how it worked at the molecular level," said Dr. Paul Thomas, a research associate who was instrumental in setting up WRAIR's cryo-EM infrastructure. "Now, we can see what the product looks like at various stages, identify key features and problems, and make informed improvements."

Cryo-EM supported work by Dr. Shelly Krebs' B cell biology team to identify promising broadly neutralizing antibodies (bNAbs) in samples from MHRP study cohorts of people living with HIV. Structural analyses showed one bNAb recognized more infected cells than many existing antibodies, "a difference that comes down to where and how it binds on the envelope," explained Dr. Gordon Joyce, chief of structural biology at WRAIR. "Cryo-EM allows us to see that clearly."

Cryo-EM is also playing a key role in MHRP's work on multiple founder variant vaccine design, led by Dr. Morgane Rolland. The high-resolution structural images allow researchers to visualize vaccine antigen designs, confirming how these complex molecules assemble and how their surfaces are presented to the immune system. This approach allows researchers to compare immune responses across candidate vaccines, providing faster feedback on what is and isn't working.

Since cryo-EM's early pioneers won the Nobel Prize in chemistry in 2017, the transformative impact of the technique has been globally recognized; but cryo-EM labs remain a rare asset in the U.S., mostly scattered across universities and government labs. WRAIR's cryo-EM lab is currently the only one in the U.S. Department of War, and is supporting collaborations across HIV, SARS-CoV-2, malaria, Shigella and other infectious disease portfolios.

Building HIV Cure Research Capability Through Technology Transfer

Under the DELIVER initiative, MHRP researchers are conducting targeted technology transfer to expand HIV cure research capacity. Early efforts focus on transferring neutralization, pharmacokinetic (PK), and anti-drug antibody (ADA) assays to DELIVER partner sites, beginning in Tanzania and Thailand. By decentralizing these processes, DELIVER is strengthening local research infrastructure and advancing HIV research capabilities at a network of sites through Africa, Asia and South America.

MHRP scientists launched this effort by engaging partners at the National Institute for Medical Research-Mbeya Medical Research Centre (NIMR-MMRC) in Tanzania to train them on neutralization assays. They began with a comprehensive remote introduction to more than 19 standard operating procedures, augmented with thorough documentation and detailed training videos. In late 2025, an MHRP team traveled to Mbeya to provide hands-on training to NIMR-MMRC laboratory technicians, ensuring consistent assay performance and reinforcing best practices.

Critically, this in-person visit allowed the researchers to tailor protocols to site-specific equipment, workflows and operational challenges. To validate the transfer of these skills, MHRP labs will perform neutralization assays in parallel with the Tanzania team to directly compare results and confirm alignment between sites. Once equivalency is established, NIMR-MMRC will be able to independently conduct neutralization assays to support regional HIV countermeasure trials and other research.

Building on this progress, MHRP scientists will next train colleagues in Thailand on PK and ADA assays to support ongoing an ongoing cure trial in Bangkok. Dr. David Leggat's cellular immunology section has also successfully



tech transferred a multi-parameter flow cytometry assay for immune cytokine staining to AFRIMS Retrovirology in Thailand. In Kericho, Kenya, Dr. Morgane Rolland has worked closely with partner scientists to enhance viral sequence analysis skills as well as to improve laboratory capabilities for genomic research. Upgraded facilities will house next-generation sequencing platforms, advanced bioinformatics, ultrasensitive PCR technology, and sophisticated automation systems, among other capabilities.

Eventually, MHRP will transfer additional technology including HIV reservoir quantification, HLA typing, DNA/RNA scope, and immunohistochemistry to various partner sites. Beyond current studies, these assays are broadly applicable to future research and development involving broadly neutralizing antibodies and other HIV countermeasures, further extending DELIVER's impact.



Dr. Sandhya Vasan Announced as Plenary Speaker at AIDS 2026 Conference

Dr. Sandhya Vasan, Director of the HJF Component of MHRP, has been invited to be a featured plenary speaker on HIV vaccines at the International AIDS Society AIDS 2026 meeting in Rio de Janeiro in July.

Meeting speakers will spotlight cutting-edge science, innovations in service delivery, and forward thinking strategy to end HIV.



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