



**U.S. Agency for International Development and U.S. Global AIDS
Coordinator
Report to Congress
Capabilities and Capacity for Vaccines in Low- and Middle-Income Countries**

The U.S. Agency for International Development (USAID) and the U.S. Department of State submit this report pursuant to Section 7019(e) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2024 (Div. F, P.L. 118-47) and House Report 118-146, which states:

"Not later than 120 days after the date of the enactment of this Act, the Secretary of State and Administrator of USAID, in consultation with other relevant Federal departments and agencies, shall submit a report to the appropriate congressional committees detailing capabilities and capacity for vaccine design, testing, review, distribution, and manufacturing in low- and middle-income countries, including in Africa."

USAID and the U.S. Department of State, in collaboration with other Federal departments and agencies, provide support to augment and maximize utilization of capacity in low- and middle-income countries (LMIC) to design, test, review, and distribute vaccines against priority infections. The resulting strengthened capabilities in these countries will provide a return on investment many times over as they enable quality-assured vaccines to be manufactured more cost-effectively, reviewed more expeditiously, and distributed more efficiently and equitably to populations where they are needed most.

USAID expands access to vaccines by strategically building manufacturing capacity for quality-assured vaccines; strengthening regulatory systems, supply chains, and service delivery; and leveraging its global procurement volumes to encourage private sector investment and partnerships and improve global markets. For two decades, USAID has invested in increasing the global supply of quality-assured medicine and vaccines for priority disease areas, including through technical assistance to manufacturers in Africa and through its partnership with Gavi, the Vaccine Alliance across LMICs. USAID, in collaboration with the State Department, is also supporting a landscape analysis to investigate potential policy and investment pathways to increase the responsiveness of Latin American vaccine development and manufacturing capacities to outbreaks. In addition, USAID invests in strengthening regulatory authorities at the national and regional level, supply chain management, and pharmacy management systems to accelerate access to and appropriate use of quality-assured vaccine products that are safe and effective, facilitating a viable marketplace for manufacturers of quality health commodities, while removing falsified and substandard products from the market.

USAID works with Gavi and its Alliance partners, which include the World Health Organization (WHO), to strengthen the WHO pre-qualification processes that will support market authorization of African-manufactured vaccines. In December 2023, the Gavi Board approved up to \$1 billion for Gavi to establish the [African Vaccine Manufacturing Accelerator \(AVMA\)](#)¹, which would make the funds available for the next ten years to support the sustainable growth of Africa's manufacturing base. This will have the potential to not only contribute to healthy global vaccine markets, but also to benefit outbreak and pandemic prevention, preparedness, response, and resilience. The creation of new markets for vaccines produced in Africa hinges significantly on continued investments in health systems strengthening, introducing, and scaling up new vaccines, improving the sustainability of immunization programs, and ensuring healthy vaccine markets on the African continent. Gavi plays a critical role in facilitating vaccine access to lower-income countries and investing in health systems, including support for service delivery and cold chain logistics. USAID complements Gavi's efforts by investing in national immunization systems to support equitable vaccine distribution, service delivery, demand generation, data systems, and technical assistance across the supply chain, including vaccine regulation and delivery systems.

One specific example of a Gavi program that has strengthened the capacity for vaccine distribution and delivery in LMICs is Gavi's Innovation for Uptake, Scale, and Equity in Immunisation (INFUSE) program. This program helps improve vaccine delivery systems by connecting high-impact, proven innovators (known as Pacesetters) and innovations with the countries that need them most. It then "infuses" them with capital and expertise to help take those innovations to scale. In collaboration with USAID's Project Last Mile (PLM) Initiative, INFUSE supports the testing and scale of innovations from INFUSE's cohort of current and prospective Pacesetters to increase availability, demand for, and access to life-saving immunizations in Africa. It provides technical assistance and catalytic grant funding to Pacesetters to help test and scale applications of the innovation in an African context.

USAID has also played an active role in the development and deployment of new malaria vaccines. USAID funded critical research that contributed to the development of the first generation of malaria vaccines for distribution to children in Africa. Several additional vaccine candidates that were developed with USAID support moved forward to clinical testing in Africa with non-USG funding. Following WHO prequalification of the second malaria vaccine in December 2023, global supply is no longer constrained, and Gavi has developed an expedited review process for countries applying to receive the vaccine.

Through robust engagement with Gavi, WHO, and many other collaborators, the USAID-led U.S. President's Malaria Initiative (PMI) and USAID maternal and child health teams have assisted in the deployment of the malaria vaccines by supporting the design of global and national malaria vaccine programs. USAID has also supported the development of guidance and tools for use by

1

https://www.gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important?ad_source=1&gclid=CjwKCAjw9layBhBJEiwAVuc3fjUcFxpqr4sHjqmWJuBiskIm-_oetYB4d2JTr5Fs5dx2EzC18KKcBoCljiQAvD_BwE

partner countries to facilitate national malaria vaccine introduction and worked with over 18 host country governments in Africa to support vaccine introduction planning and deployment-related activities as part of a comprehensive malaria control program. In coordination with broader U.S. government efforts, USAID is helping countries develop quality and accelerated introduction plans and is leveraging bilateral relationships to ensure that host country governments have the information, technical assistance, and resources they need. For example, USAID/PMI supports health worker training, the development and implementation of social and behavior change strategies, including communication plans and materials, and cold chain capacities, all critical to a country's successful introduction of a vaccine.

USAID also funds the Coalition for Epidemic Preparedness Innovations (CEPI) through a contribution that supports CEPI's overall mission to accelerate the development of vaccines and therapeutics against emerging infectious diseases and enable access to these vaccines and therapeutics during outbreaks. CEPI's efforts include work to build capacity and capability in LMICs through investments in laboratory testing, clinical site readiness, regulatory strengthening, and support for manufacturing. CEPI is supporting capability strengthening activities of selected vaccine manufacturers in Global South countries, near areas at high risk of disease outbreaks, with a particular focus on regions where CEPI's priority pathogens are endemic. CEPI created and funds *Enable*, the world's largest-ever study of Lassa fever. Over 23,000 participants have taken part across West Africa. Data from this study will give researchers a better picture of the true disease burden and the number of people who are at risk of Lassa virus infection and who might benefit from Lassa fever vaccination, once developed. Findings from the study will also guide the design of future vaccine trials and could help define future vaccination strategies when a Lassa fever vaccine has been approved for use.

In addition to supporting CEPI's mission to develop new vaccines for viruses such as Lassa fever, USAID continues to support HIV vaccine development, strategically focused on strengthening and utilizing capacity in African countries to lead these efforts. Through its longstanding partnership with the nongovernmental organization IAVI, USAID provides assistance to augment the capacity of research centers in Kenya, South Africa, Rwanda, Zambia, and Uganda to test HIV vaccine immunogens. This includes the capacity to develop and implement clinical protocols, as well as the ability to lead complex laboratory immunological analyses needed for these trials. For example, USAID collaborated with the Bill and Melinda Gates Foundation (BMGF), Moderna, and IAVI to support the G003 trial, the first-ever trial of an RNA-delivered HIV vaccine immunogen in African countries. The trial enrolled participants in South Africa and Rwanda and conducted a set of complex laboratory analyses in Kenya. The African institutions demonstrated capabilities equivalent to counterparts in the United States, thus laying the groundwork for complex lab analyses for other future trials of HIV immunogens to be undertaken within Africa, potentially saving time and reducing costs. Other HIV vaccine trials are planned for initiation in 2024, which will be entirely led from the inception of protocol design by African scientists. The first trial of a USAID-supported and African-led consortium called BRILLIANT (**BR**inging Innovation to **c**linical and **L**aboratory Research to End HIV/AIDS In Africa through **N**ew Vaccine **T**echnology) will explore combinations of antigens to stimulate precursors of broadly neutralizing antibodies (bnAbs) against HIV.

In terms of HIV vaccine design in African countries, USAID supports African scientists in screening specific envelope trimers from circulating HIV viruses in order to identify those with characteristics that are particularly favorable for use as immunogens to induce bNAbs. This research has identified a number of promising HIV envelopes that researchers will incorporate into mRNA constructs for preclinical testing in animals to determine which merit further testing in clinical trials in humans. Moreover, through the partnership with the BRILLIANT Consortium, USAID is supporting the South African Medical Research Council to collaborate with the South African company, Afrigen Biologics, which is currently developing its capabilities for manufacturing mRNA vaccines for clinical trials. The ultimate goal of this research is to support African researchers to design, manufacture and test an mRNA-delivered HIV envelope construct for a phase I clinical trial fully in Africa.

In addition, USAID supports key systems for collaboration within Africa that enable more efficient and productive HIV vaccine research. USAID is supporting: (1) A new biorepository in South Africa that will store and share samples from many HIV vaccine and epidemiological research sites in Africa, and (2) The transfer of a cloud-based Trusted Research Environment to Africa that will securely store and share data from HIV vaccine and epidemiological studies in a manner that is jointly governed by a group of scientists from several African countries. Lastly, through the Coalition to Accelerate and Support Prevention Research (CASPR), USAID supports a locally-led network of African organizations to engage communities, policymakers, and other key stakeholders in the research and development of HIV vaccines and other biomedical products from the initial period of study design to results dissemination. CASPR also develops webinars, trainings, courses, and other resources aimed at building the capacity of researchers and other relevant stakeholders to engage in Good Participatory Practice, which includes ethical and effective stakeholder engagement throughout clinical trials.