

IMAGINE A WORLD WITHOUT AIDS



Imagine a world where two million people each year are **spared the heartbreak** of an HIV diagnosis. Imagine a world where 34 million people would live **healthier** more productive lives. Imagine a world where affected communities, would be **thriving**. Imagine a world where healthy, young girls could **thrive**.

This vision drives the U.S. Agency for International Development (USAID) HIV and AIDS program's 15-year partnership with the International AIDS Vaccine Initiative (IAVI) that began with a directive to USAID from the United States Congress. This shared endeavor is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world while strengthening clinical research capacity in regions most devastated by the epidemic. USAID, on the forefront of the global AIDS crisis for more than 30 years and a key implementing agency of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), invests in the science that will deliver results and translate them from research to practice for populations at risk. Like many other authorities, USAID and IAVI believe the most critically important tool to control the HIV epidemic will be a safe and effective HIV vaccine. USAID is proud to highlight IAVI and partner accomplishments by emphasizing their role in supporting elegant science and meaningful research capacity throughout Africa, with the support of the American people.

THE NEXT GENERATION OF HIV VACCINE RESEARCH FOR AFRICA WITH AFRICA

USAID recently awarded IAVI and its partners with a competed five year cooperative agreement provided through PEPFAR. Building on long-standing partnerships with IAVI and African research centers, this new program ADVANCE (Accelerate the Development of Vaccines and New Technologies to Combat the AIDS Epidemic) focuses on the design and development of HIV vaccines and biomedical prevention tools while ensuring they are effective and accessible for all in need. The Africa-centered global partnership will advance pre-clinical and clinical HIV vaccine research, strengthen local capacity and ownership and support sustainable development of African countries. "The design and testing of improved candidates, guided by African scientific leadership, will move the world closer to a globally-effective HIV vaccine," says Benny Kottiri, Research Division Chief at the Office of HIV/AIDS, at USAID.

IAVI, a nonprofit organization established in 1996, works to accelerate the development of broadly effective HIV vaccines accessible to all. IAVI works with partners in 25 countries to research, design and develop promising vaccine candidates. IAVI collaborates with governments, pharmaceutical and bio-tech companies, universities, hospitals and civil society organizations, and conducts and supports research in North America, Europe, Africa, and India. IAVI strengthens the expertise and infrastructure to fight HIV/AIDS in sub-Saharan Africa, the epicenter of today's epidemic. IAVI advocates for policies, financing and environments that drive the fastest possible development of HIV vaccines.



A VACCINE IS NEEDED FOR A DEFINITIVE AND DURABLE END TO HIV/AIDS

The AIDS pandemic continues to be a major global health issue. Despite significantly accelerated implementation of effective prevention and treatment tools to address HIV and AIDS, in 2015 alone, HIV infected more than two million people and killed more than one million. Sub-Saharan Africa remains the region most severely affected with 25 million adults and children living with HIV. Given the scope of the epidemic, new biomedical tools to prevent HIV are essential. The most promising of these is a safe and effective HIV vaccine that provides durable protection, thus providing a realistic and cost-effective means of reversing the AIDS pandemic on a population level.

Although treatment rates have doubled in the past five years, annual new infections with HIV have not decreased substantially. Access and adherence to available prevention and treatment remain challenging for many. Recent modeling results show that even in the face of the massively expanded use of current treatment and prevention options, hundreds of thousands of people in low- and middle-income countries will be newly infected with HIV and die from AIDS for decades to come. An effective, well-adopted vaccine, however, could prevent the majority of new annual HIV infections thereby averting millions of infections and savings countless lives.

HIV VACCINE RESEARCH AND DEVELOPMENT MAKES GREAT STRIDES THROUGH PARTNERSHIP

- **32** HIV vaccine candidates developed, advancing **26** into early-stage clinical trials, including the first HIV vaccine trials in Kenya, India, Zambia and Rwanda
- **97%** clinical trial study volunteer retention rate
- **21** epidemiological studies with **41,542** volunteers
- **8** African clinical research center partners in **5** sub-Saharan African countries with capacity to enroll a trial of **3500** high-risk volunteers in one year
- More than **700** peer reviewed publications
- More than **650,000** individuals in Africa received voluntary HIV testing and counseling
- More than **50** local investigators have gone on to lead clinical trials and epidemiology protocols, and contribute to local/regional health systems
- Support for **8** PhD and **27** Master's degree students selected from African clinical research centers (**45%** women)
- **24** investigator initiated research proposals approved for funding
- More than **1,000** clinicians, nurses and counselors trained in Good Clinical Practices
- More than **1,000** scientists/technicians accredited labs under Good Clinical Laboratory Practices

It is unlikely that a global, sustainable solution to the AIDS pandemic will be economically or logistically feasible in the absence of a safe and effective HIV vaccine.

– Margaret McCluskey, RN, MPH Senior Technical Advisor for HIV Vaccines, USAID Office of HIV & AIDS

It is imperative that we redouble and sustain efforts to ensure access to treatment for all HIV-infected people and to effective prevention services and technologies for all people at risk of HIV infection. However, the world will need an effective HIV vaccine as an essential complement to all other treatment and prevention innovations if we are to end the AIDS pandemic.

– Mark Feinberg, MD, PhD, CEO, IAVI

The development of new vaccines needs to become a top political priority. It is the best hope we have to end the public health threat of diseases like HIV, Ebola and Zika, and to be better prepared for the new ones to come. Without a vaccine, it will be impossible to end AIDS.

– Seth Berkley, MD, IAVI Founder, CEO GAVI, the Vaccine Alliance



USAID's David Stanton and Margaret McCluskey with Dr. Omu Anzala at the Kenya AIDS Vaccine Initiative for World AIDS Vaccine Day.

A 15-YEAR JOURNEY OF GROWTH — FROM SEED POD TO ACACIA TREE

Rooted in USAID support, like Africa's iconic Acacia tree, work by IAVI and partners continues to grow.

- 2016**– Project ADVANCE first competed USAID new funding opportunity for HIV biomedical prevention project
- 2015**– Men who have Sex with Men (MSM) Respect Protect Fulfill Report published
- 2014**– USAID Expert Consultation on African HIV Vaccine Research and Development
 - Vaccine Immunology Science and Technology for Africa (VISTA) Consortium launched
 - International Training Program launched
 - Fisherfolk Roadmap for Prevention published
- 2013**– Sendai Vaccine Study – a first in humans in Africa begins
 - Kenya Prevention Revolution published
 - Lake Victoria Consortium for Health Research to understand the HIV epidemic in this region begins
- 2012**– IAVI-Translational Health Science and Technology Institute HIV Vaccine Design Program (HVTR lab) launched in India
 - FRESH study to identify/enroll volunteers with acute HIV infection in KwaZulu-Natal begins
 - Rural Research Initiative in Maharashtra (NARRIM), by Government of India, begins
- 2011**– Three low sero-prevalence Ad vector trials launched
- 2010**– Partnership with University of KwaZulu-Natal begins
- 2009**– First fishing community HIV incidence studies
 - Investigator initiated research support begins
 - First HIV vaccine trial in Zambia
 - First Pre-exposure prophylaxis trials in Uganda and Kenya to test daily versus intermittent PrEP in MSM (Kenya) and HIV sero-discordant couples begins
 - Isolation of broadly neutralizing antibodies from Africa
- 2008**– Partnership with Aurum Institute begins
- 2007**– First volunteers enrolled in IAVI Protocol G, cross-sectional study with 2,000 to identify new broadly neutralizing antibodies
- 2006**– Protocol C, largest prospective study of early HIV infection in African adults begins
 - First HIV vaccine clinical trial in India
- 2005**– First HIV vaccine trial in Rwanda
 - Enrollment of first MSM cohort in Kilifi, Kenya, a first in Africa, begins
 - Kenya Guidelines for HIV vaccine development
- 2004**– Support Begins for KAVI Kangemi Site
 - Protocol A, HIV prevalence study begins
 - IAVI's epidemiology for vaccine advancement, capacity and science observational epidemiology to continually track and engage high incidence populations in a shifting HIV epidemic in Africa for over a decade begins
 - Prospective cohorts to study volunteer retention, HIV incidence and willingness to participate in future HIV prevention trials begins.
- 2003**– Support to Projet San Francisco, Zambia Emory HIV Research Project, CGMR-C and Medical Research Council/Uganda Virus Research Institute on AIDS begins
- 2002**– Develop Uganda Virus Research Institute — IAVI HIV vaccine program in Uganda
- 2001**– First HIV vaccine trial in Kenya
 - IAVI partnership with the Government of Uganda begins
 - IAVI India program begins
 - Human Immunology Laboratory launched at Imperial College London

Sowing More Seeds

Centers of Research Excellence (CORE) is a network of eight African Clinical Research Centers and laboratories led by highly skilled, in-country researchers. This network, ADVANCE Centers of Research Excellence (CORE), drive regional collaboration, capacity-building and research to test promising HIV vaccine candidates and to better understand the epidemic in Africa.

Human Immunology Laboratory (HIL), established in 2001 at Imperial College London, serves as an external quality control and central reference laboratory to generate validated standardized clinical immunogenicity data from a portfolio of HIV vaccine candidates. The HIL runs a comprehensive training and technology transfer program to continually develop and support IAVI's network of accredited clinical laboratories.

Neutralizing Antibody Consortium (NAC) established at The Scripps Research Institute in La Jolla, CA, is the world's first center dedicated to solving what is perhaps the most pressing problem in the field of HIV vaccine research: eliciting antibodies that neutralize a broad range of HIV strains, known as broadly neutralizing antibodies.

HIV Vaccine Translational Research Laboratory (HVTR) is a research facility at the Government of India's Translational Health Science and Technology Institute (THSTI) in the National Capital Region of New Delhi, India focused on designing vaccines to prevent HIV infection.

Vaccine Immunology Science and Technology for Africa (VISTA) is an African consortium aimed at increasing involvement of African scientists at all stages of vaccine research and development, including design and assessment of next-generation HIV vaccine candidates.

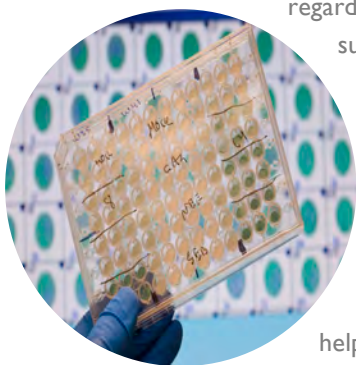
International Training Program provides advanced degree support to PhD and Master's degree candidates competitively selected from the CORE network.

The roots of progress: USAID Grants (2001-2006) & USAID Cooperative Agreements (2006-2011, 2011-2016, & 2016-2021)

IAVI AND PARTNERS LEAD A MULTI-DIMENSIONAL FIGHT AGAINST THE EPIDEMIC

IAVI pushes the envelope toward new and improved vaccine technologies while unraveling the complexities of HIV infection and AIDS progression.

HIV vaccine researchers are facing a number of common challenges regardless of their individual approaches, such as inducing strong and lasting immune responses, optimizing and selecting candidates for further development, manufacturing them in quantity and quality required for clinical testing, regulatory and ethical approval of such studies, and engaging local communities. IAVI helps overcome these bottlenecks by providing product development expertise and validating new technologies while facilitating broad engagement of and strategic collaboration with leading HIV vaccine researchers and centers of excellence. Key scientific advances in defining how the human immune system may protect itself against HIV are driving the discovery of an effective vaccine.



IAVI works with policy makers, scientists, activists, civil society organizations and community representatives to ensure sustained local, regional and global enabling environments that support the development of promising candidates into actual vaccines.

HIV vaccines are now listed as national health research priorities in many countries where IAVI is currently working. This demonstrated national commitment translates into increased domestic support for strengthening research and regulatory facilities. As African researchers become increasingly involved in a wider range of vaccine design and development work there is an opportunity for increasing domestic financing. With developing country leadership and commitment, together USAID and IAVI significantly strengthen the global environment for HIV vaccine research and development enabling future access.



IAVI engages future HIV vaccine users and helps ensure they benefit from research efforts even before vaccines become available.

A better understanding of the social, cultural and economic challenges of vulnerable populations informs the design of vaccines and other new prevention interventions that can be adopted broadly and rapidly. This work also ensures the development of inclusive and effective health policies. With USAID support, IAVI focuses on engaging adolescent girls and young women, men who have sex with men, sero-discordant couples and fishing communities on the shores and islands of Lake Victoria. In addition, the focus on these populations has helped improve their access to counseling and healthcare services.



IAVI builds research capacity in the most affected countries and regions at an individual, institutional and regional level.

Successful HIV prevention requires increased contribution to and ownership of the research effort by those countries and regions that are hit the hardest by the epidemic. IAVI facilitates collaboration around the world to empower next-generation researchers and clinicians to lead the fight to halt this epidemic that devastates their families and communities. These efforts also build research capacity in sub-Saharan Africa and India, and strengthen North-South and South-South knowledge and technology transfer. Such investments advance HIV vaccine research and development, strengthen local health research and support the overall sustainable development of these societies and countries.



These contributions would not have been possible without the tireless commitment of our dedicated partners, researchers, clinicians, advocates, host country governments and community workers. The deepest gratitude goes to all those volunteers around the world who participate in this research despite their often very challenging lives. Our volunteers continue to empower and inspire us.