ADVANCING AIDS VACCINE DEVELOPMENT

Pioneering strategies for the design and evaluation of novel vaccine candidates
Credits

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Contact

Arne Nåveke, PhD
Executive Director for Advocacy, Policy, and Communications
International AIDS Vaccine Initiative, IAVI
125 Broad Street, 9th Floor
New York, NY 10004 USA

T: + 1. 212.847.1055
F: + 1. 212.847.1112
ANaeveke@iavi.org
www.iavi.org
IAVI’s mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.
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Year in Review

Microbicides Advance in Development, PrEP Goes Mainstream, Modeling Illustrates the Potential of HIV Vaccines

The International AIDS Vaccine Initiative advocates a comprehensive response to the AIDS pandemic that expands existing HIV prevention, treatment and care and supports the swift development and rollout of new preventive tools and strategies. These include vaccines, treatment as a means of prevention, pre-exposure prophylaxis (PrEP) with antiretroviral drugs and microbicides.

In 2012, we worked with our partners to conduct several preclinical studies and Phase I trials in multiple countries, built a stronger case for AIDS vaccine development through our international networks, shared our findings from ongoing research at medical conferences, expanded our network of academic and private sector partners and continued building research capacity in countries hardest hit by the AIDS pandemic.

Researchers and policymakers are today increasingly convinced that an AIDS vaccine is possible and could help significantly slow the spread of HIV. We are proud of the many steps we took with our partners in 2012 to advance progress toward such vaccines.
Highlights in HIV Prevention in General and for IAVI and its Partners Specifically

Discoveries made in the field of HIV vaccine research set the stage for potentially dramatic progress toward broadly effective AIDS vaccines and other preventive tools. Researchers also made preparations for a number of landmark trials starting in 2013.

HIV Prevention in 2012: The Field

- **APR**
  - The International Partnership for Microbicides launches The Ring Study, a Phase III trial in Uganda and South Africa evaluating whether a vaginal ring containing the antiretroviral drug dapivirine can prevent HIV
  - Researchers publish an analysis of immune responses in the Phase Ib RV144 trial in Thailand, associating one type of antibody response with protection from HIV and another with increased risk in vaccinated participants

- **JUL**
  - The US Food and Drug Administration (FDA) approves the anti-retroviral drug Truvada for pre-exposure prophylaxis (PrEP) of HIV, the first new preventive tool to have won such approval in 19 years
  - The US National Institute of Allergy and Infectious Diseases (NIAID) establishes two new Centers for HIV/AIDS Vaccine Immunology & Immunogen Discovery, one at The Scripps Research Institute in California and another at Duke University in North Carolina

- **AUG**
  - The Microbicide Trials Network launches ASPIRE, another Phase III trial of the dapivirine vaginal ring in Malawi, Zimbabwe, South Africa and Uganda
  - The World Health Organization (WHO) issues new recommendations for the use of PrEP among transgendered women and men who have sex with men at high risk for HIV, and for couples in which only one partner is infected with HIV

- **NOV**
  - The US President’s Emergency Plan for AIDS Relief’s (PEPFAR) strategic blueprint for achieving an “AIDS-free generation” emphasizes the development of new biomedical tools for HIV prevention, including vaccines
Advancing AIDS Vaccine Development

IAVI and Partners in 2012

**APR**
IAVI and partners host a session on building research capacity in developing countries at the Global Forum for Health Research 2012 in Cape Town

**MAR**
Advocacy by IAVI and civil society partners promotes the need for global health R&D, including HIV vaccine development, for inclusion in the European Union’s Horizon 2020 budgetary framework for research and innovation

**MAY**
In partnership with the Bill & Melinda Gates Foundation, IAVI launches a pilot Central Services Facility to assist researchers supported by the Gates Foundation-sponsored Collaboration for AIDS Vaccine Discovery (CAVD) in translational research and product development

**AUG**
Modeling studies with Futures Institute show that an HIV vaccine of 50% efficacy given to 30% of people in low and middle-income countries could avert 5.2 million infections and save roughly $46 billion in therapy costs in the first decade after introduction

**AUG**
IAVI hosts a symposium on Innovation for Global Health in Norway; and IAVI, Imperial College London and Wellcome Trust host a symposium on Innovations in Vaccine R&D

IAVI and Indian government agencies host the nation’s first international symposium on HIV vaccine development and inaugurate a laboratory to support vaccine design

The PATH Malaria Vaccine Initiative (MVI) selects IAVI’s Human Immunology Lab at Imperial College London as a reference lab for evaluating immune responses to malaria vaccine candidates

IAVI and Partners in 2012
Advocacy by IAVI and civil society partners promotes the need for global health R&D, including HIV vaccine development, for inclusion in the European Union’s Horizon 2020 budgetary framework for research and innovation.

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IAVI and Indian government agencies host the nation’s first international symposium on HIV vaccine development and inaugurate a laboratory to support vaccine design.

IAVI and affiliated researchers present results at the AIDS Vaccine 2012 Conference establishing that structures targeted by potent antibodies can be synthetically recreated and potentially used in vaccines to elicit similar antibodies.

Study shows that the injection of PGT121, a potent broadly neutralizing antibody isolated by IAVI-supported researchers, can protect monkeys from a virus analogous to HIV—establishing proof-of-concept for vaccine strategies that seek to elicit such antibodies.

AIDS research partners and IAVI support the inclusion of language promoting the development of new tools for HIV prevention in the strategic blueprint issued by PEPFAR.

An IAVI pilot study in monkeys demonstrates that a replicating vector vaccine candidate derived from the canine distemper virus (CDV) safely induces immune responses that target the simian version of HIV.

IAVI and partners host a session on building research capacity in developing countries at the Global Forum for Health Research 2012 in Cape Town.

The PATH Malaria Vaccine Initiative (MVI) selects IAVI’s Human Immunology Lab at Imperial College London as a reference lab for evaluating immune responses to malaria vaccine candidates.
IAVI has worked with partners to establish a state-of-the-art research and development program to design and evaluate new HIV vaccine candidates, and a variety of policy, advocacy and communication initiatives to sustain global support for AIDS vaccine research. IAVI continued in 2012 to make significant advances toward the development of safe and effective HIV vaccines, expanding the clinical pipeline and accelerating vaccine design and screening.

In vaccine discovery, we work with a global network of research institutions, academic and public laboratories, and bioscience companies (page 20). Our network includes IAVI’s AIDS Vaccine Design and Development Laboratory in New York, and the IAVI Neutralizing Antibody Center in La Jolla, California, which also serves as the headquarters of the Neutralizing Antibody Consortium (NAC) overseen by IAVI. The recently established HIV Vaccine Design Program at the HIV Vaccine Translational Research (HVTR) Laboratory in India contributes to these efforts. IAVI’s Human Immunology Laboratory in London, meanwhile, works with our medical affairs team and a global network of clinical research centers, most notably in sub-Saharan Africa, to conduct clinical research studies aimed at improving the pipeline of HIV vaccine candidates.

In 2012, IAVI continued to refine its portfolio to support the most promising strategies of vaccine design. IAVI and its partners have over the past decade designed 22 novel HIV vaccine candidates, of which 13 have been assessed in 25 clinical trials conducted...
IAVI continued in 2012 to make significant advances toward the development of safe and effective HIV vaccines, expanding the clinical pipeline and accelerating vaccine design and screening in Belgium, Germany, India, Kenya, Rwanda, South Africa, Switzerland, Uganda, United Kingdom, United States and Zambia. In recent years, IAVI’s research and development networks have advanced some of the field’s most exciting new vaccine concepts—pioneering strategies to elicit broadly neutralizing antibodies (bNAbs) against HIV and targeting immune responses in tissues where HIV first establishes itself.

In 2012, based on seminal discoveries made by NAC researchers, we shifted our focus to the preclinical development of vaccine candidates to elicit bNAbs, evaluating more than 60 candidate immunogens of this kind, and selecting two to advance into preclinical development. Researchers at and affiliated with IAVI also completed two early stage vaccine trials and reached the final stages of a third evaluating IAVI’s Ad35 vector in combined regimens with a variety of other candidates.

To prepare for upcoming trials of novel HIV vaccine candidates, two IAVI-affiliated research centers refined their expertise in assessing immune responses in mucosal tissues, which line inner body cavities. The clinical network supported by IAVI made significant progress in identifying key populations at risk of HIV and determining the incidence and risk factors for HIV infection, identifying the types of infecting virus and the immune responses they induce.

IAVI’s global advocacy, policy and communications program, conducted in partnership with AVAC and other advocacy and civil society organizations, seeks to ensure that AIDS vaccine development remains high on the global health agenda as part of a comprehensive approach to HIV prevention. In 2012, our joint efforts helped give prominence to developing new tools for HIV prevention in a number of national and international strategic plans and forums addressing the AIDS crisis and related global health issues.
19 COUNTRIES
where IAVI has HIV vaccine research and development

PARTNERSHIPS

8 COMMUNITY
ADVISORY BOARDS
& similar mechanisms in place at IAVI-sponsored clinical research centers

100 civil society partners working with IAVI to sustain support for HIV prevention & address related global health issues
800+ scientists trained in Good Clinical Practice & Good Clinical Laboratory Practice in the past 9 years, helping build research & development capacity in East & southern Africa.

58 articles based on IAVI-supported research published in peer-reviewed scientific journals in 2012, contributing to HIV research & vaccine development.

60+ candidate immunogens devised to elicit broadly neutralizing antibodies screened in preclinical studies, with 2 advanced to preclinical development in 2012.

300,000+ people reached through voluntary testing and HIV counseling since 2004.
Harnessing cells and antibodies—a two-pronged assault on HIV

In 2012, our researchers and partners advanced the design and evaluation of vaccine candidates that target HIV in two important ways: by eliciting neutralizing antibodies that can stop HIV from invading target cells, and inducing specialized cells of the immune system to destroy cells that become infected.

HIV has evolved multiple mechanisms to evade recognition and destruction by the immune system but the RV144 clinical trial, completed in Thailand in 2009, established the feasibility of an AIDS vaccine. In pursuit of the goal to develop a vaccine capable of preventing infection by a wide variety of the HIV subtypes that circulate in different regions of the world, researchers at IAVI and elsewhere have, among other things, isolated and analyzed scores of antibodies that appear to be able to stop a broad spectrum of HIV variants from infecting cells in the laboratory. They are now racing to apply what they have learned from these antibodies to develop a new generation of vaccines.

IAVI’s R&D program covers a number of activities essential to the development of HIV vaccines, including:

• The design and preclinical development of HIV vaccine candidates to elicit effective antibody and cell-mediated immune responses against HIV, and to target those responses to appropriate tissues
In 2012, researchers at and affiliated with IAVI stepped up their efforts to devise vaccines that might elicit bNAbs against HIV.

- The clinical evaluation of novel HIV vaccine candidates
- Epidemiological research to prepare for such trials, especially in key populations

Validating a new strategy for vaccine design

In 2012, researchers at and affiliated with IAVI stepped up their efforts to devise vaccines that might elicit bNAbs against HIV, and established that the molecular targets of antibodies can be synthetically reconstructed to make immunogens—the active ingredients of vaccines (see box on page 16).

Scientists have long been aware that a minority of HIV-infected people make bNAbs to the virus. These antibodies do not appear to arrest an existing infection, but they may be able to prevent infection if they are present when HIV enters the body for the first time.

In 2012, the quest to develop vaccines based on bNAbs was expanded into India in partnership with the government’s Translational Health Sciences and Technology Institute of the Indian Government’s Department of Biotechnology, which is working with IAVI on increasing the speed and scale of such immunogen design. Meanwhile, NAC researchers screened more than 60 potential immunogens designed on the basis of bNAb studies, and selected two to advance into preclinical development.

Further, IAVI and affiliated researchers showed in 2012 that it is possible to create synthetic immunogens based on a close study of the mechanisms by which antibodies neutralize viruses. One of the approaches NAC researchers have employed to do this applies sophisticated computational and protein engineering techniques to recreate complex molecular structures found on HIV that are uniquely targeted by bNAbs. The hope is that, if given as part of a vaccine, such immunogens might elicit bNAbs. To prove that this novel approach to vaccine design is viable, NAC researchers and their partners reconstructed a molecular structure found on the respiratory syncytial virus (RSV)—which causes respiratory disease in infants—that is effectively targeted by a known
antibody. They then demonstrated that this structure could elicit similar antibodies when it was injected into animals. This proof of concept also has implications for the design of vaccines against other variable viruses, such as hepatitis C and influenza.

Sharing our expertise in antibodies and product development

IAVI is also contributing to studies that will investigate whether bNAb can prevent HIV infection in humans using an approach known as gene transfer, in which a gene that encodes a useful protein is transiently expressed in people. In a Phase I trial that will be sponsored by IAVI and is being supported by the US Agency for International Development (USAID), the Bill & Melinda Gates Foundation and NIAID, researchers will use a harmless viral vector (adeno-associated virus, or AAV) to deliver the gene that encodes a bNAb against HIV, named PG9, which was isolated by IAVI and affiliated researchers in 2009. Researchers will examine whether the antibody is safe, produced at acceptable levels, and how long it persists. Manufacturing of the vector carrying PG9 was completed in 2012.

In partnership with the Gates Foundation, a pilot program was launched in 2012 to assess the feasibility and impact of a Vaccine Product Development Center, Central Services Facility (CSF), to help principal investigators (PIs) supported through the Gates Foundation-funded CAVD to advance vaccine concepts into human trials and to prepare for such studies. For example, the CSF worked with a CAVD PI at Rockefeller University to devise a clinical development plan to assess a new, highly potent, broadly neutralizing antibody as a possible therapeutic agent for HIV infection. Similarly, another CAVD PI and his team at the Harvard Medical School worked with the CSF to fashion a preclinical and clinical development plan for an adenoviral replicating vector bearing a novel mosaic HIV antigen—which is computationally designed and engineered to elicit immune responses against a broad range of circulating HIV subtypes. The pilot CSF, which began as a contract with four participating PIs, was later expanded to a total of six and is now being reviewed by the Gates Foundation for long-term support.

In 2012, IAVI supported a project led by the Global HIV Vaccine Enterprise, along with a number of other product development experts, to develop a web-based tool, From Bench to Clinic, to help researchers efficiently move candidate vaccines into clinical trials in the US, Canada and the European Union. The guide acquaints researchers, funders and advocates with the practical steps, processes, costs and timelines typical to biomedical product development.

Phase I trials completed in Africa and the US

In 2012, IAVI and its partners completed two Phase I clinical trials to test the safety of a candidate vaccine vector based on a respiratory virus, Ad35. One trial in...
Uganda, Zambia and Kenya evaluated a prime-boost regimen of the IAVI candidate, and a protein candidate developed by GlaxoSmithKline. (In a typical prime-boost regimen, two vaccine candidates are given a few months apart to improve immune responses to the immunogens; importantly, in this study it was shown that they can be given at the same time as well.) The second trial, in the US, Kenya, Rwanda and South Africa, evaluated a prime-boost regimen of the Ad35 vector carrying a different HIV immunogen and a non-replicating vector derived from the Ad26 virus and developed at the Beth Israel Deaconess Medical Center in Boston. Both regimens were found to be safe and to elicit immune responses.

IAVI and its partners also continued a third Phase I trial evaluating the Ad35 vaccine candidates given in a prime-boost regimen with a DNA vaccine candidate made by Profectus. The DNA vaccine was given with a novel adjuvant—a substance that enhances the immune response—and delivered by electroporation, in which a small voltage is applied to improve uptake of DNA by cells.

**Improving data integrity and the safety of volunteers**

In 2012, IAVI piloted the use of a fingerprint-reading technology to better identify participants in clinical trials and HIV research. Such technology can help protect both the safety of volunteers and the integrity of data collected in clinical research by enhancing the ability to follow study participants and prevent enrollment of individuals in multiple studies. This technology is also being used to explore whether volunteers can be followed in a “virtual cohort.”

IAVI and partners have developed an improved assessment of understanding (AoU) tool through the application of social science studies supported by IAVI. The new tool is designed to better measure volunteers’ understanding of their risks, rights and responsibilities, which is essential to the ethical conduct of clinical research. It was employed in multiple IAVI studies in 2012.
IAVI also worked with the Global HIV Vaccine Enterprise and other partners to convene dozens of representatives from academia, civil society, government, industry and NGOs from around the world for a consultation on the challenges associated with vaccine-induced sero-positivity—the presence of antibodies against HIV in participants from AIDS vaccine clinical trials, which can result in false positives in future HIV tests. As a result, the WHO’s Vaccine Advisory Committee unanimously agreed to develop formal guidelines to support volunteers.

**Replicating vectors in Africa**

In 2012, IAVI and partners prepared for the clinical evaluation of a novel vector-born HIV vaccine candidate based on a measles-like Sendai virus, which does not cause illness in humans. Unlike most HIV vaccine vectors, this vector can replicate inside the human body, and so might elicit more durable and vigorous immune responses. Further, the vector targets mucosal tissues—the lining of inner body cavities—where HIV establishes a foothold in the earliest stages of infection, and where effective immune responses could thwart HIV as it enters the body. IAVI also advanced another replicating viral vector, derived from the canine distemper virus (CDV) vaccine, into preclinical evaluation in primates. Like the Sendai virus, CDV does not cause illness in humans but does infect immune cells in the gut, eliciting a mucosal response. This might be helpful, as HIV too establishes infection in immune cells found in the gut.

**Domino effects of technical capacity**

In preparation for the Sendai trial, IAVI partners in Rwanda and Kenya, such as the Kenya AIDS Vaccine Initiative (KAVI) refined techniques and assessed mucosal immune responses in volunteers, including some who are currently participating in trials. KAVI in Nairobi has become a regional center of excellence for
mucosal immunology, a capability that will contribute to its efforts to become a hub for clinical research in Africa.

IAVI continued to help partners to build technical capacity for research and ensure that their data are of the consistency and quality required to pass regulatory review. With support from USAID, for example, clinical researchers working with IAVI in Africa have over the years been trained in Good Clinical Practices (GCP). The HIL and partner labs in Africa have also received accreditation in Good Clinical Laboratory Practices (GCLP). By the end of 2012, IAVI and its partners had trained more than 800 people in GCLP since the training started nine years ago. In 2012, IAVI also joined a Gates Foundation initiative to provide GCP and GCLP training to 142 researchers from 17 countries. Some of IAVI’s research partners have, further, extended such training to laboratories across the region, participating in major efforts funded by the European & Developing Countries Clinical Trials Partnership (EDCTP) and others to develop research capacity in Africa.

**Parsing HIV dynamics in severe epidemics and preparing for vaccine trials**

Throughout 2012, IAVI evaluated the incidence of new HIV infections in regional epidemics, focusing mainly on groups in Africa at high risk for HIV. IAVI’s incidence studies, which provide information essential to both vaccine trials and public health policy, have enrolled 16,000 volunteers since 2004. They have extended HIV testing and counseling services to more than 300,000 people. Thanks to support and funding from EDCTP and USAID, IAVI’s partners at the Uganda Virus Research Institute have conducted groundbreaking epidemiological, virological and social science studies with Uganda’s Lake Victoria fishing communities. This work has brought into focus a high-risk population with an HIV prevalence up to five times higher than that of the general population in Uganda and HIV incidence rates that are among the highest in the region.

A subset of volunteers in IAVI’s incidence studies who were previously found to have acquired HIV have been followed from the earliest stages of infection in a study named Protocol C. Access to such a group is of great value to studying a variety of issues related to HIV infection, diagnosis, and transmission. In 2012 alone, IAVI’s Protocol C cohort contributed to more than two dozen other HIV research projects around the world.

In 2012, IAVI stepped up its focus on populations particularly vulnerable to HIV infection in South Africa, Kenya and Uganda, in some cases testing novel approaches to tracking new infections. Such studies are essential to selecting populations for future large-scale trials. At the same time, participation in research can help explain why certain populations are particularly vulnerable to HIV and provide information to people as to how to reduce their risk for HIV infection. In 2012, IAVI and partners provided support to two government clinics in Uganda to improve provision of health services and HIV counseling and testing in fishing communities and helped a hospital that refers people to IAVI studies to improve its services for HIV testing and voluntary male circumcision, an important preventive measure.

In the coastal Kenyan cities of Kilifi and Mtwapa, IAVI and partners have supported public health workers in their effort to tailor their care and counseling outreach to men who have sex with men. Our focused advocacy has encouraged Kenyan public health agencies to improve their HIV prevention outreach to this typically marginalized and stigmatized group.

In Uganda, IAVI provided in-kind support for a mock vaccine trial using a licensed hepatitis B vaccine. The study determined that volunteers from fishing communities along Lake Victoria, whose members tend to be highly mobile, can be recruited and retained in such studies.
Partnerships in Action in 2012

Americas
- USA
- Canada

Europe
- Denmark
- Netherlands
- Norway
- Germany
- Sweden
- Belgium

- Ireland
- Spain
- France
- United Kingdom
- Switzerland
Africa
- Rwanda
- South Africa
- Uganda
- Kenya
- Zambia

Asia
- India
- China
- Japan
- Taiwan
- Australia
Partnerships for Advocacy

Expanding support for HIV prevention and engaging emerging economies

From the day IAVI was established in 1996, it advocated for sustained support for AIDS vaccine development. We continued to do so in 2012, participating in a variety of initiatives to shape global health and HIV policies around the world (see introduction and timeline), model the potential impact of HIV vaccines and boost support for HIV prevention research.

IAVI and other product development partnerships (PDPs) helped convince the German Parliament in 2012 to issue a resolution “to reinforce German commitment in the field of global health and continue to take on responsibility in the field of product development for neglected and poverty-related diseases.” IAVI also provided an update on HIV vaccines to the South African Development Community (SADC) HIV Prevention Working Group Meeting, to ensure vaccine R&D remains a priority in the policies of member countries.

Similarly, IAVI worked with African civil society organizations, UNAIDS and others to ensure new tools like HIV vaccines are included in Kenya’s National Prevention Revolution Plan and Prevention Summit. We also helped convene a meeting of East African researchers in Uganda to share data on HIV epidemiology in fishing communities around Uganda’s portion of Lake Victoria and discuss the establishment of a research consortium focused on such populations, which are often at high risk of HIV.

As part of our ongoing effort to increase the engagement of emerging economies in HIV prevention research, we helped to host the first HIV vaccine research symposium held in India, an event that attracted many political leaders, including a former president. The event coincided with the inauguration.
of the HVTR Laboratory established near New Delhi as part of IAVI’s partnership for vaccine design with the Indian Government’s Translational Health Sciences and Technology Institute. IAVI’s advocacy has also been key to a budding partnership for AIDS vaccine development between Indian and South African researchers. In 2012, scientists from the two countries held a workshop to discuss issues in this area of relevance to both countries, and to begin a long-term research partnership.

IAVI supported and advocated for research on new biomedical tools for HIV prevention by engaging rural communities and enhancing rural research preparedness in regions of India where HIV occurs with relatively high prevalence. These efforts resulted in the establishment, with IAVI’s support, of rural research centers and programs in Maharashtra led by the Government of India.

Providing further evidence for the impact of vaccines

In 2012, IAVI published studies with the Futures Institute examining the impact of HIV on women and girls, finding that even at moderate levels of coverage and 70% efficacy, a vaccine would prevent almost 5 million infections in this group over a decade. Other studies show that an HIV vaccine of 70% efficacy given to 40% of people in low- and middle-income countries could avert almost nine million infections and save almost US$80 billion in therapy costs in the first decade. Another Futures Institute-IAVI model generated in partnership with Chinese researchers shows that a vaccine deployed in Sichuan province would be similarly cost-saving and lead to a 60% decline in new infections in a decade of use. More effective vaccines, if widely used, would have a far deeper impact. To provide advocates around the world access to our modeling, we also launched an online, interactive tool—available on IAVI.org—to assess a vaccine’s impact based on a variety of parameters and regional settings.

Whatever those parameters might be, one message emerges consistently from the projections: the world needs an AIDS vaccine.
## IAVI Financial Snapshot

<table>
<thead>
<tr>
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<th>2012 R&amp;D Program Expenses (US $)</th>
<th>2012 Expenses (US $)</th>
</tr>
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<tbody>
<tr>
<td>Applied research</td>
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<tr>
<td>Preclinical development</td>
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<tr>
<td>Clinical trials</td>
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<td>Cohort and site development</td>
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<td><strong>Research and development</strong></td>
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<td><strong>52,454,942</strong></td>
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<tr>
<td>Fundraising</td>
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<tr>
<td>Vaccine advocacy, education and policy/access</td>
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<tr>
<td>General and administrative</td>
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<tr>
<td>Other Expenses</td>
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<tr>
<td><strong>Total Expenses (US $)</strong></td>
<td></td>
<td>71,925,660</td>
</tr>
</tbody>
</table>
2012 Research & Development Program Expenses

- 47% Applied Research
- 28% Clinical Trials
- 17% Preclinical Development
- 8% Cohort and Site Development
- 14% General & Administrative
- 9% Vaccine Advocacy, Education & Policy
- 4% Fundraising
- 73% Research & Development

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Applying a New Strategy to Better Serve Our Mission

In 2012, we implemented a new strategy that reshaped our research programs and advocacy to focus on areas of AIDS vaccine development and advocacy where we have the most to contribute. As part of this effort, IAVI sought to become a stronger partner to other organizations in the field. It is only by working together that we will overcome the formidable challenges posed by HIV. In consultation with donors, stakeholders and partners, we zeroed in on filling key gaps in HIV vaccine development, and becoming a leading voice in advocacy and policy for the field. We also took deliberate steps to ensure that both our organization and its programs are transparent and accountable to donors and stakeholders, and demonstrate that we deliver value for money.

An uncertain global economic climate lent urgency to our efforts to achieve greater focus and efficiency, which led us to restructure the organization, streamline our programs and reduce our spending by more than 20% to match what we believe are sustainable levels of funding in the future. I believe these changes have brought IAVI’s programs fully in line with its new strategy, and have made us a more focused, efficient and effective organization.

As a consequence, 2012 was a challenging but productive year for IAVI. Much of the credit for that goes to our hardworking partners and staff, who persevered through a period of change in an uncertain economic environment. With our partners in Africa, we completed two Phase I vaccine trials, continued a third, and prepared for one that is today evaluating a new kind of HIV vaccine candidate. Researchers at and affiliated with IAVI designed and assessed scores of novel immunogens to elicit broadly effective antibodies against HIV, and we opened a laboratory with partners in India to support these efforts. Our advocacy, policy and communications teams helped raise the profile of HIV vaccine development in the policies of major organizations and governments, such as PEPFAR and the government of Kenya.

We were also happy to welcome the Global HIV Vaccine Enterprise to our new headquarters at 125 Broad Street in New York. We look forward to continue working with the Enterprise on a variety of AIDS vaccine advocacy and research support projects. Our contributions to HIV vaccine development depended, as always, on the support of a global corps of volunteers who participate in vaccine-related research or advocate for such work in their communities. On behalf of IAVI and its partners, I would like to thank these unsung champions of the campaign against HIV. Their steady support is invaluable to our shared cause. The accomplishments recorded in this report are theirs as much as ours.

I have no doubt that if we keep working together as we did last year, we will continue to make strides toward the development of an AIDS vaccine that will ultimately help stem the tide of the HIV pandemic.

Sincerely,

Margie McGlynn

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As of October 2013