IAVI’S MISSION is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.
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ACRONYMS

€ ................................................................. Euro
Ad5 ........................................................... adenovirus serotype-5
Ad35 .......................................................... adenovirus serotype 35
ADARC ...................................................... Aaron Diamond AIDS Research Center
AIDS ........................................................ acquired immunodeficiency syndrome
AMC .......................................................... advance market commitment
ANRS ........................................................... Agence National de Recherche sur le Sida et les Hépatites Virales
AVC ........................................................... AIDS Vaccine Consortium
BCG .......................................................... Bacille Calmette-Guérin
BD .............................................................. Becton, Dickinson and Company
CAB ........................................................... community advisory board
CAD ........................................................... Canadian dollar
CHAIVI ...................................................... Center for HIV/AIDS Vaccine Immunology
DBT .......................................................... Department of Biotechnology (India)
DNA .......................................................... deoxyribonucleic acid
EU ............................................................. European Union
G8 .............................................................. Group of Eight industrialized nations
HIV ............................................................ human immunodeficiency virus
HPV ........................................................... human papillomavirus
IAVI ........................................................... International AIDS Vaccine Initiative
IFFIm ........................................................ International Financing Facility for Immunization
IFMSA ........................................................ International Federation of Medical Students Associations
KAVI ........................................................... Kenya AIDS Vaccine Initiative
LAC ........................................................... Live Attenuated Consortium
MSM ........................................................ men who have sex with men
MVA .......................................................... modified vaccinia Ankara
NAC ........................................................... Neutralizing Antibody Consortium
NGO ........................................................ nongovernmental organization
NIAID ......................................................... National Institute of Allergy and Infectious Diseases
NIH .......................................................... National Institutes of Health
OECD ........................................................ Organization for Economic Cooperation and Development
PATH ........................................................ Program for Appropriate Technology in Health
PAVE ........................................................ Partners for AIDS Vaccine Development
PDP ............................................................ Product development public-private partnership
PPP ........................................................... Public-private partnership
R&D .......................................................... research and development
SAAVI ........................................................ South Africa AIDS Vaccine Initiative
SEK ........................................................... Swedish krona
SIV ............................................................ simian immunodeficiency virus
STOC ........................................................ screening test of concept
TB ............................................................. tuberculosis
UK ............................................................ United Kingdom
UNAIDS .................................................... Joint United Nations Programme on HIV/AIDS
US ............................................................ United States
USAID ......................................................... US Agency for International Development
UVRI ........................................................ Uganda Virus Research Center
WHO ........................................................ World Health Organization
When the International AIDS Vaccine Initiative (IAVI) was launched in 1996, an estimated 7 million people had died of AIDS. Now, 12 years later, more than 25 million people have died in modern history’s worst pandemic. By the end of 2007, an estimated 33 million people were living with HIV infection worldwide, with new infections on the rise in some of the world’s most populous countries. More than ever before, an AIDS vaccine is urgently needed to curb the spread of HIV infection.

The year 2007 was an important one in the global search for an AIDS vaccine. Although disappointing results were reported from trials of what was thought to be the world’s most promising vaccine candidate—an adenovirus-based vaccine developed by Merck & Co.—the early termination of the trials due to a lack of efficacy actually served to clarify a scientific challenge facing the AIDS vaccine field. The Merck results strongly suggest that a preventive vaccine will likely need to produce neutralizing antibodies and perhaps cell-mediated immunity to HIV as well.

IAVI’s scientific program is well placed to respond to this challenge. Research consortia created by IAVI earlier this decade are making important progress towards answering some of the key scientific questions surrounding AIDS vaccines, including how to generate the neutralizing antibody responses that are likely needed to confer strong and long-lasting immunity to HIV. At the same time, IAVI is pursuing new vaccine approaches to elicit more robust cellular immunity. To support these efforts, IAVI’s new Innovation Fund strengthens IAVI’s capacity to expedite research in important unexamined areas and to engage scientific experts who are not yet involved in the search for an AIDS vaccine.

Setbacks are inevitable in developing a vaccine against a foe as complicated as HIV. IAVI in conjunction with our partners has worked overtime this year in its communication efforts to ensure that this is understood. In fact, IAVI has been reinvigorated by the challenges posed by the Merck trial results. Our AIDS Vaccine Development Laboratory, now fully functional, gives IAVI the capacity to rapidly translate new scientific insights and innovations into rationally designed vaccine candidates. Last year, IAVI’s worldwide network of clinical research centers was strengthened to accelerate testing on promising candidates as soon as they emerge. And progress in implementing sustainable financing mechanisms for new vaccines will increase the likelihood that future AIDS vaccines can be rapidly put to use to save lives.

A unique organization in the AIDS vaccine world, IAVI pursues a fully integrated approach to vaccine development, combining its research and development program with advocacy, policy analysis, and country-level programs. We are pleased to present this latest summary of IAVI’s activities and achievements, covering the year 2007. This report aims to reflect transparency in our work, which is among our core values, and attempts to put this year’s activities into context over the final year of IAVI’s 2005-2007 Strategic Plan.

While I am immensely proud of the work of IAVI’s talented global staff, I would be remiss if I failed to acknowledge the many partners who make our work possible. Everything IAVI does is done in partnership with others, and genuine, respectful, and productive partnerships will remain a bedrock operating principle for IAVI.

IAVI remains inspired by its founding vision of a world without AIDS. Each year will bring new advances and challenges. But by remaining committed to long-term goals, we will build upon our advances and learn from our failures as we work toward the development of a safe and effective AIDS vaccine for use throughout the world.

Josh Bethesda
The International AIDS Vaccine Initiative (IAVI) has long advocated for a multi-component approach to HIV vaccination and has developed a research program that pursues diverse approaches to AIDS vaccine research and development (R&D). The benefits of a multi-component approach became particularly apparent in September 2007, when human clinical trials of an advanced vaccine candidate developed by the pharmaceutical company Merck were halted when no evidence of efficacy was found. This candidate, like most of those currently in the AIDS vaccine development pipeline, was based on a single theory—that a strong cellular response could protect and/or control against HIV infection.

IAVI is well positioned to help the field accelerate AIDS vaccine research at this stage of the vaccine effort. IAVI’s research consortia, established earlier this decade, are already generating important research advances, helping point the way toward more promising product development strategies. A new grant-making arm enables IAVI to expedite research on innovative new scientific directions, while IAVI’s AIDS Vaccine Development Laboratory in the Brooklyn borough of New York City provides the capacity to rapidly translate scientific advances into rationally designed candidates for human testing. And IAVI’s global clinical trial network—consisting of 15 fully equipped partner research centers in five countries—is ready to expedite human testing on promising vaccine candidates as soon as they emerge.

This report summarizes the achievements in 2007 of IAVI’s integrated approach to the AIDS vaccine challenge, linking scientific efforts with advocacy, policy reform, and extensive work in low- and middle-income countries. As in prior years, IAVI’s wide range of activities was undertaken in close collaboration with a host of partners in many countries and from multiple disciplines.

Over the last three years, IAVI was guided by its 2005-2007 Strategic Plan, which identified five priority action areas:

- **ACCELERATE** research and development of AIDS vaccines
- **MOBILIZE** strong and sustained global commitment
- **ADVOCATE** for public policies that support vaccine research and development and future access
- **PARTNER** with countries where the epidemic is, or is likely to be, most severe
- **OPERATE** an optimally efficient and effective organization to advance IAVI’s mission

IAVI issued progress reports in both 2005 and 2006. This progress report, covering 2007, is the last for the period covered by the 2005-2007 Strategic Plan.

During the period covered by this Strategic Plan, the urgent need for an AIDS vaccine has only become more apparent. At the end of 2007, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) estimated that approximately 33 million people worldwide were living with HIV, including 2.5 million people (nearly 400,000 of them children) who became newly infected in 2007. A preventive vaccine remains the world’s best hope for ending the global HIV epidemic.

### 1. ACCELERATE Research and Development of AIDS Vaccines

In 2007, IAVI expanded and diversified the AIDS vaccine pipeline, taking advantage of the enhanced research capacity that the AIDS Vaccine Development Laboratory brings to the organization. IAVI made progress in developing and evaluating a range of promising preclinical vaccine candidates, including some that used diverse approaches in anticipation of the possible failure of the Merck candidate.

With the aim of obtaining answers to critical scientific challenges, in 2007 IAVI and its scientific collaborators intensified efforts in three different research consortia:

- The **Neutralizing Antibody Consortium (NAC)**, with 18 investigators from premier academic institutions worldwide, continued working to design immunogens that evoke broadly neutralizing antibodies against HIV.
- In response to the urgent need to characterize the correlates of immunity in humans to facilitate rational vaccine design, IAVI continued to scale up its **Control of HIV/SIV Consortium** (also known as the **Live Attenuated Consortium**, or LAC).
The Vectors Consortium, supported in part by the Bill & Melinda Gates Foundation, actively explored potential vectors, including ones that elicit persistent immune responses and immune responses at mucosal surfaces, as well as novel chimeric viruses that are morphologically indistinguishable from HIV particles but are safe because they are produced using a completely unrelated, non-pathogenic virus.

In 2007, the IAVI Innovation Fund was established to bring promising technologies from other fields into the AIDS vaccine arena in an effort to break through scientific barriers and bring together early-stage ideas and products from innovative scientists and companies. With US$ 10 million in financing, of which the initial US$ 5 million was provided by the Bill & Melinda Gates Foundation, IAVI expects to provide innovation funding to between 15 and 20 biotech companies over the next three years. IAVI innovation funding is expected to extend into a broad range of fields, including virology, immunology, and bioengineering.

Under the 2005-2007 Strategic Plan, IAVI strengthened and expanded its worldwide network of state-of-the-art clinical research sites to accelerate high-quality trials of early promising candidates as soon as they emerge. IAVI conducted five different research protocols to expand the evidence base for the rational design and evaluation of vaccine candidates. IAVI also advocates for use of the Screening Test of Concept (STOC) trial, which can help identify superior vaccine candidates much sooner than more expensive, time-consuming traditional efficacy trials and thus facilitate rational prioritization of competing candidates for limited clinical trial capacity and resources.

II. MOBILIZE Strong and Sustained Global Commitment

IAVI continued to build and sustain political commitment and support for AIDS vaccines at global, regional, and national levels. A few examples:

• IAVI's advocacy efforts with Palaniappan Chidambaram, the Indian finance minister, resulted in a meeting of finance ministers and their representatives in Washington, DC, in October 2007 that focused on innovative financing instruments for AIDS vaccine R&D.

• On behalf of the Joaquim Chissano Foundation, former Mozambican President Joaquim Chissano signed a partnership agreement with IAVI to speed development of an AIDS vaccine, including plans to catalyze greater governmental action on AIDS vaccines in southern Africa and in other regions.

• IAVI met with leading parliamentarians in India and with scientific and political leaders in China.

• IAVI met with a broad array of senior leaders from Europe, with particular focus on Germany, given its leadership of both the Group of Eight industrialized countries (G8) and the European Union (EU).

IAVI continued in 2007 to build support for AIDS vaccines by collaborating closely with a wide range of sectors, including diverse civil society groups, women’s organizations, and the scientific community.

IAVI continued to urge enhanced public sector, philanthropic, and private industry financing for AIDS vaccine R&D. As part of the HIV Vaccines and Microbicides Resource Tracking Working Group, IAVI reported that public sector and philanthropic financing for AIDS vaccine R&D more than doubled between 2000 and 2006.
In 2007, IAVI strengthened its capacity to deliver relevant, accurate information on AIDS vaccines. IAVI capitalized on key events, such as World AIDS Vaccine Day and the World Economic Forum, to obtain high-profile media coverage of AIDS vaccines. IAVI worked with many reporters to help ensure accurate and balanced reporting of the Merck vaccine trial results and offered broad-based assistance to reporters in the form of a new communications toolkit and numerous media training opportunities focused on AIDS vaccines. Key IAVI publications, such as IAVI Report and Sankalp (IAVI’s India newsletter), increased their reach in 2007.

III. ADVOCATE for Public Policies that Support Vaccine R&D and Future Access

IAVI and its partners continued to advocate in 2007 for the translation of political commitment into sound policies to accelerate the era of AIDS vaccination.

In light of the long-term nature of the search for an AIDS vaccine, IAVI and its advocacy partners focused extensive attention on developing and implementing sustainable financing mechanisms for research, development, introduction, and scale-up of vaccines and HIV prevention interventions. In particular, IAVI was an early advocate of advance market commitments (AMCs) for future health technologies; leading donor countries have identified pneumococcal vaccines as the first pilot for AMCs, and future pilots will likely focus on malaria and AIDS vaccines.

An analysis commissioned by IAVI determined that carefully designed structural changes and improved targeting of funding could provide a substantial impetus to scientific innovation and private sector involvement in AIDS vaccine research. IAVI entered into discussions with the global investment firm Goldman Sachs, which engineered the financial structure of the International Financing Facility for Immunization (IFFIm), to explore innovative strategies to secure strong sustainable financing for AIDS vaccine research. IAVI hopes to ascertain donor interest in this effort in 2008.

IAVI directed significant public policy research and advocacy in 2007 toward strategies to ensure expedited uptake of future AIDS vaccines. IAVI has been an active participant in a process sponsored by the WHO and the Global HIV Vaccine Enterprise to consider potential scenarios in the AIDS vaccine field in 2008-2010, with the goal of anticipating and responding to problems and identifying important opportunities to accelerate development and use of AIDS vaccines. IAVI also provided financial, technical, and planning support for a four-day meeting in September 2007 of the African regulators in Ouagadougou, Burkina Faso, to improve regional collaboration on drug regulatory issues and promote strategies to avoid potential regulatory delays for vaccine clinical trials and future introduction of AIDS vaccines.

IAVI also made progress on convincing policymakers of the potential impact of an AIDS vaccine and on gauging future demand for such products. Plans were formalized to pilot IAVI’s model of the future impact of AIDS vaccine uptake in Uganda and Brazil. IAVI analyses, published in two research papers and presented at various conferences and policy workshops in India and Europe, suggest that policy changes, such as strengthening regulatory processes or boosting health system capacity to deliver vaccines, could have a considerable impact on demand and uptake of future vaccines.

To expedite uptake of future AIDS vaccines, IAVI seeks to learn from national experiences with other health technologies, as reflected in its human papillomavirus (HPV) project. Financed mostly by special targeted funds and anchored by a working collaboration with PATH, IAVI is contributing to efforts to ensure rapid introduction and uptake of HPV vaccines, working to ensure that lessons learned in the process inform planning for introduction of future AIDS vaccines.

IV. PARTNER with Countries Where the Epidemic Is, or Is Likely to Be, Most Severe

Since its creation more than a decade ago, IAVI has functioned as a unique partnership between low- and high-income countries. IAVI has an ongoing presence in 24 countries on five continents, including six countries that host IAVI-supported clinical trial centers. In 2007, IAVI continued its efforts to build strong national support for AIDS vaccines, meeting with senior political leaders in China, India, South Africa, Zambia, and other low- and middle-income countries.

Work also continued to ensure the preparedness of IAVI-sponsored facilities in low- and middle-income countries to expedite needed research, including future clinical trials of promising vaccine candidates. IAVI worked in 2007 to strengthen services required for vaccine trials, including treatment and care referrals for trial
volunteers and for individuals excluded from trials after testing HIV-positive. IAVI continues to work with clinical trial centers to address adult male circumcision, ensuring access to essential health information, counseling, and referrals. IAVI completed quality assurance and counseling supervision programs at two sites in Kenya and began programs at additional Kenya sites and in Uganda.

IAVI documented the structure, function, and support needs of community advisory boards (CABs) at IAVI-sponsored trial centers in East Africa, India, and southern Africa. Information derived from these exercises informed development of an action plan to increase support to CABs. Under development are CAB-focused tools and guidance documents. In addition, two international CAB meetings were held to support the preparedness of IAVI-sponsored sites, one with community liaison officers (research center staff members responsible for community mobilization and CAB activities), and the second with CAB members from facilities in different regions. IAVI also supported visits by the Chinese Academy of Medical Sciences at four clinical research centers for a CAB assessment project in China.

While the overriding purpose of IAVI's work in low- and middle-income countries is to expedite R&D of AIDS vaccines, the countries and communities that host IAVI-supported trials also obtain important benefits. For example, IAVI is helping promote knowledge of HIV serostatus by offering voluntary HIV counseling and testing in IAVI-supported facilities; to date, more than 48,000 people have received these services.

V. OPERATE an Optimally Efficient and Effective Organization to Advance IAVI’s Mission

Envisioning IAVI's continued growth, the 2005-2007 Strategic Plan provided for a thorough, ongoing assessment and strengthening of IAVI's internal procedures, with the aim of ensuring the organization's ability to pursue the search for an AIDS vaccine with the necessary speed, flexibility, and willingness to take informed risks.

IAVI developed a monitoring and evaluation system for use by the IAVI board of directors, senior management, and donors. IAVI is collaborating with fellow product development public-private partnerships (PDPs) and other nongovernmental organizations (NGOs) to harmonize evaluation systems, including sharing IAVI's online system for collecting and reporting evaluation data.

IAVI's Johannesburg office became fully operational in 2007. Extensive support from IAVI's finance, information technology, and human resource staff helped bring the new office up to speed and in alignment with IAVI policies and practices.

In the human resource arena, IAVI filled 55 positions in 2007, benefiting from expanded in-house recruiting, selective use of search firms, and outreach to key professional networks. IAVI embarked on new initiatives to improve retention and support professional development, including content development for its internal leadership development program and significant progress toward the establishment of IAVI University, which aims to stimulate career growth and increase professional capacity at all staffing levels by offering employees direct job application development tools.

The organization increased resources mobilized from key private sector sources and from small donors while maintaining robust support from public sector and philanthropic donors. Eleven governments, with the addition in 2007 of Spain, accounted for 87% of IAVI's 2007 revenue. To help implement the AIDS Vaccine Development Laboratory, IAVI received a generous capital grant of US$12 million from the New York City Economic Development Corporation, as well as additional new markets tax incentives totaling US$3 million to support capital building expenses. IAVI received generous support from numerous foundations, including a US$5 million grant from the Bill & Melinda Gates Foundation, which, with a US$100,000 matching grant from the John D. Evans Foundation, helped launch the IAVI Innovation Fund. In 2007, total cash donations and in-kind contributions to IAVI disbursed in 2007 were valued at almost US$800,000.

Despite a year of disappointing trial results and scientific introspection in the field, IAVI worked to strengthen its capacity to address current challenges and to plan proactively for the future. As in prior years, IAVI's achievements in 2007 could not have occurred without the continuing support of the organization's donors and without energetic collaboration with its many partners. In 2008, IAVI remains as committed as ever to its animating vision—a world without AIDS.
INTRODUCTION

When the history of the global search for an AIDS vaccine is written, 2007 may be seen as a turning point.

Clinical trials of a promising vaccine candidate developed by the pharmaceutical company Merck yielded disappointing results, as vaccinations in humans were terminated in September when no evidence of efficacy was found. Like most other vaccine candidates in the research and development (R&D) pipeline, the Merck candidate aimed to generate cellular immunity to HIV. The results produced a major shift in the AIDS vaccine field, with experts widely recognizing that one-dimensional approaches to HIV vaccination are unlikely to confer the level of protection needed to alter the global epidemic’s course. Instead, long-term control of the HIV pandemic will likely require multi-component vaccines that generate both strong cellular immunity and broadly neutralizing antibody responses.

The International AIDS Vaccine Initiative (IAVI) has long advocated for a multi-component approach to HIV vaccination and has developed its research program to pursue diverse approaches to AIDS vaccine R&D. IAVI is well positioned to help accelerate AIDS vaccine research at this stage of the vaccine effort.

Earlier this decade, IAVI established consortia of leading researchers to address the key challenges confronting the field, including the development of broadly neutralizing antibodies. IAVI’s research consortia are generating important research advances, helping point the way toward more promising product development strategies. A new grant-making arm enables IAVI to expedite research on innovative new scientific directions, and the AIDS Vaccine Development Laboratory in the Brooklyn borough of New York City now equips the organization with the capacity to rapidly translate scientific advances into rationally designed candidates for human testing. And IAVI’s global clinical trial network—consisting of 15 fully equipped partner facilities in six countries—is ready to expedite human testing on promising vaccine candidates as soon as they emerge.

The need for a safe and effective AIDS vaccine remains as urgent as ever. At the end of 2007, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) estimated that approximately 33 million people worldwide were living with HIV. An estimated 2.5 million people became infected with HIV in 2007, including more than 400,000 children. Few promising signs are evident in some of the most heavily affected countries, including South Africa, where the rate of new HIV infections has yet to decline. Infection rates continue to climb in China, Indonesia, Russia, and a number of other countries. A preventive vaccine remains the world’s best hope for ending the global HIV epidemic.

Over the last three years, IAVI has been guided by the 2005-2007 Strategic Plan, which identified five priority action areas:

- **ACCELERATE** research and development of AIDS vaccines
- **MOBILIZE** strong and sustained global commitment
- **ADVOCATE** for public policies that support vaccine research and development and future access
- **PARTNER** with countries where the epidemic is, or is likely to be, most severe
- **OPERATE** an optimally efficient and effective organization to advance IAVI’s mission

IAVI issued progress reports in both 2005 and 2006. This progress report, covering 2007, is the last for the period covered by the 2005-2007 Strategic Plan.

In 2007, key IAVI achievements included the following:

- Launching the IAVI Innovation Fund. This program will provide US$ 10 million in targeted funding over the next three years to between 15 and 20 biotech companies to explore promising but insufficiently addressed research avenues in such fields as virology, immunology, and bioengineering.

- Pursuing a broad range of potential vaccine products, both through the vaccine development partnerships and IAVI’s Vaccine Development Laboratory.

- Securing a capital grant of US$ 12 million from the New York City Economic Development Corporation and an additional US$ 3 million in anticipated tax incentives to expedite operationalization of the AIDS...
Vaccine Development Laboratory in the Brooklyn Army Terminal in New York City.

- Strengthening and expanding research consortia of leading global scientists focused on key scientific challenges, and enrolling and monitoring trial volunteers in five different clinical research protocols.
- Helping Indian Minister of Finance Palaniappan Chidambaram organize an unprecedented meeting of finance ministers and their representatives to explore sustainable financing options for AIDS vaccine research.
- Working collaboratively with research partners to update estimates of available financing for AIDS vaccine research and to significantly improve the capacity to estimate future demand for, and the potential public health impact of, an AIDS vaccine.
- Securing high-level media coverage of AIDS vaccine research in leading global media outlets and key regional publications in Africa, Asia, Europe, and North America; developing a communications toolkit to help and motivate journalists to cover AIDS vaccine issues; and significantly expanding the circulation of IAVI Report and VAX.
- Implementing quality assurance and capacity-building activities to maintain state-of-the-art readiness at IAVI-sponsored clinical trial centers in low- and middle-income countries.
- Launching IAVI’s office in Johannesburg to support five vaccine trial centers in southern Africa.
- Attracting the first financial contribution from the government of Spain, bringing to 11 the number of national governments that financially support IAVI’s work.
Our research and development work seeks to expand the product development pipeline and pursue innovative approaches to accelerate progress in the field.
The 2005-2007 Strategic Plan recognized that these would be challenging years in the global quest to develop a safe and effective AIDS vaccine. The Strategic Plan called for expanding the product development pipeline and pursuing innovative approaches to address obstacles that have slowed progress in the field. To expedite testing of promising vaccine candidates, the Strategic Plan provided for the creation and maintenance of a robust, ready global network of clinical trial centers.

The primary objective of a preventive vaccine is to prevent the establishment of persistent HIV infection. A secondary objective is to control HIV infection and delay progression to AIDS by reducing viral load. IAVI’s R&D program advocates for a research pipeline that includes a multiplicity of approaches to address these objectives. IAVI bases its research approach on the likelihood that an optimally effective AIDS vaccine will likely need to generate both cellular immunity and broadly neutralizing antibodies.

In 2002, IAVI established a research consortium to explore strategies for generating broadly neutralizing antibodies. Other consortia are actively working to address other scientific challenges in AIDS vaccine development.

**Objective:**
Significantly improve the product development pipeline with candidates that have greater potential for success than those in the current pipeline

In recent years, the vaccine development pipeline has been overwhelmingly oriented toward a single approach: cell-mediated immunity to HIV infection. The need for a multi-faceted approach was reconfirmed when the Merck candidate demonstrated a lack of efficacy.

IAVI believes that an optimally successful AIDS vaccine will likely require both strong cellular immunity and broadly neutralizing antibodies. Because of the need for multiple approaches to HIV immunity, IAVI advocates for a development pipeline that includes a portfolio of diverse vaccine candidates, with later-generation candidates building on insights gleaned from the testing of earlier products.

In 2007, IAVI expanded and diversified the AIDS vaccine pipeline, taking advantage of the expanded research capacity that the AIDS Vaccine Development Laboratory brings to the organization. IAVI made progress in developing and evaluating a range of promising preclinical vaccine candidates, including candidates that used diverse approaches in anticipation of the possible failure of the Merck candidate.

**SeV Vector.** In 2007, IAVI worked on its first-ever replicating viral vector, which is also IAVI’s first vector to target mucosal surfaces. In July 2007, IAVI entered into a partnership with DNAVEC, a Japanese biotech, for joint development of a vaccine using DNAVEC’s Sendai virus (SeV) vector technology. The partnership is IAVI’s first in Japan. The candidate to be developed through this partnership is intended to be administered intranasally to stimulate immune responses in both blood and mucosal tissues. DNAVEC and the Japanese National Institute for Infectious Diseases have demonstrated that intranasal administration of a recombinant SeV vaccine can protect monkeys from simian immunodeficiency virus (SIV), a virus that causes AIDS-like illnesses in non-human primates. Under the agreement, IAVI and DNAVEC will each contribute scientific and technical expertise to develop the SeV vector-based vaccine, with the goal of advancing a candidate for clinical testing in the next three years.

**MVA.** In Phase I clinical trials conducted in collaboration with the Tuberculosis Research Centre in Chennai, India in 2006, a candidate based on modified vaccinia Ankara (MVA) yielded broad-based, multi-genic immune responses that represent an improvement over other pox-based vectors. This candidate will now be assessed in prime boost trials in which a deoxyribonucleic acid (DNA) vaccine will precede the MVA immunization with the goal of increasing the magnitude and breadth of HIV-specific immune responses. In addition, process development work on the MVA vector
candidate will continue in parallel with the clinical trials to expedite decisions on potential further development.

**Low-seroprevalent Adenoviruses.** In 2007, IAVI continued pre-clinical development of low-seroprevalent adenovirus-based candidates, remaining on track to initiate a Phase I clinical trial in the US and East Africa in the third quarter of 2008. (Adenoviruses are a group of viruses that infect tissue linings and typically cause respiratory diseases ranging from the common cold to pneumonia.) Various adenoviruses have been used to develop existing AIDS vaccine candidates, although the high-background prevalence of the adenovirus strains on which these early candidates are based has led to concerns that the candidates might not be optimally effective in the real world. The Merck candidate was a Type 5 adenovirus. In 2004, in anticipation of these potential problems, IAVI, working with the Netherlands-based biotechnology company Crucell, initiated pre-clinical development of candidates based on adenovirus strains that are uncommon in the general population. Based on serologic and non-human primate immunogenetic testing, IAVI selected adenovirus serotype 35 (Ad35), an uncommon human adenovirus, as its leading candidate in this area.

**BCG.** IAVI is working closely with the Aeras Global TB Vaccine Foundation to evaluate a Bacille Calmette-Guérin (BCG)-based vaccine vector. Discussions about establishing a formal business agreement between Aeras and IAVI are ongoing, with closure expected in 2008. The BCG initiative aims to enhance the efficacy of the Ad35 platform. In partnership with Crucell, Aeras established the BCG/Ad35 vaccination regimen for tuberculosis (TB), generating impressive immunogenicity data.

**New Delivery Technologies.** In partnership with the Aaron Diamond AIDS Research Center (ADARC), IAVI initiated a Phase I trial of a DNA-based AIDS vaccine that uses electroporation, a vaccine delivery approach that applies an electric current to open channels through which DNA may pass. Pre-clinical studies have found that this approach significantly enhances immune responses and may help improve the immunogenicity of DNA-based AIDS vaccines.

**DNA + Ad5.** As an affiliate of the Partners for AIDS Vaccine Development (PAVE) sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID), IAVI conducted a safety and immunogenicity trial in a number of African trial centers of a DNA prime plus adenovirus serotype-5 (Ad5) boost candidate sponsored by the National Institutes of Health (NIH) Vaccine Research Center. Large-scale efficacy testing of this candidate, based on a cell line belonging to Crucell, was placed on hold in light of the Merck Ad5 candidate trial results, given the increased rates of HIV infection in trial subjects with pre-existing immunity to Ad5. NIAID is currently reviewing options for clinical advancement of the DNA + Ad5 candidate, and IAVI has placed on hold its plans for additional clinical research on this candidate in Africa.

**AIDS Vaccine Development Laboratory.** The IAVI AIDS Vaccine Development Laboratory aims to accelerate the development of promising vaccine candidates that industry usually does not support, primarily because the approaches are deemed to have a low probability of financial return. IAVI seeks to use the laboratory to rapidly translate advancements in antigen delivery and immunogen design into optimally promising vaccine candidates ready for testing. The laboratory is focusing its work in three areas:

- **Novel viral vectors** for use in humans as well as for the delivery of SIV genes for non-human primate head-to-head comparisons, in conjunction with the Vectors Consortium.

- **Design, production, and characterization of immunogens** to evoke broadly neutralizing HIV antibodies (to support the work of IAVI’s Neutralizing Antibody Consortium [NAC]).

- **Operation of a comprehensive non-human primate facility** providing the in vivo model to test candidate vaccines for efficacy.

**objectives:**

**Address the major scientific obstacles that impede global efforts to develop superior product candidates**

IAVI’s science strategy places increased emphasis on vaccine discovery efforts to support and guide the rational design of optimally effective vaccines. By prioritizing vaccine discovery efforts, IAVI aims to answer key outstanding scientific questions and brings together leading scientists in targeted research consortia to collaboratively focus on the scientific challenges that have slowed progress in the search for a preventive vaccine.

**Scale up the Neutralizing Antibody Consortium and establish the Live Attenuated Consortium to form the AIDS Vaccine Consortium**

Although highly effective vaccines against many other diseases are based on creating immunity through the
production of antibodies, extensive scientific research has yet to identify optimal strategies for generating broadly neutralizing antibodies against HIV. In April 2002, IAVI created the NAC to bring some of the world’s leading scientific researchers together in a common, coordinated research effort to solve one of the most important global scientific challenges.

In 2007, the NAC, with 18 investigators from premier academic institutions worldwide, continued to work to design immunogens that evoke broadly neutralizing antibodies against HIV. Using such innovative tools as high-throughput robots, centralized antibody panels, and reagent repositories, researchers attempted to create a high-throughput mechanism for broadly neutralizing antibody development that would achieve interim steps toward the design of antibody vaccines. IAVI-supported researchers have solved the structures of four broadly neutralizing antibodies to HIV, along with their binding sites, leading to the commencement of immunogen design efforts.

NAC achievements in 2007 included implementing a high-throughput antigen screening program with Indian academic and biotechnology institutions, undertaken in partnership with the Indian Department of Biotechnology (DBT). This advance is expected to facilitate the design of novel HIV antigens, complementing the immunogen design efforts of NAC members.

An external five-year review of the NAC concluded that IAVI’s investment in the endeavor had a major impact on the field, helping to expand immunization strategies research beyond cell-mediated immunity, the singular focus of vaccine research in recent years. As the NAC Review Committee observed, the rational design of immunogens, based on a detailed knowledge of the structure of broadly neutralizing antibodies, had never been attempted and was considered a high-risk undertaking. The committee determined that the NAC team is “without exception, world class and well equipped to address the complex problems inherent in identifying and synthesizing antigens capable of inducing broadly neutralizing antibodies.” The scientific output of the NAC was found to be impressive, as measured by the important new knowledge generated, the impact on the field, and publications in leading scientific journals. Based on this review, IAVI intends to significantly expand resources for NAC research beginning in 2008, with the aim of generating concrete progress toward meeting the neutralizing antibody challenge.

Forge a new R&D paradigm that significantly enhances and improves efforts to solve key scientific challenges

In addition to the NAC, IAVI has formed other research networks to tackle important obstacles impeding AIDS vaccine development.

Prior to 2007, IAVI’s R&D program largely involved partnerships with investigators on clinical trials and clinical research protocols. This year, IAVI expanded its work further upstream in collaboration with the DBT. Working with the Indian Institute of Science in Bangalore and the International Centre for Genetic Engineering and Biotechnology in Delhi and Chembiotek, a medicinal chemistry contract research organization in Kolkata, the IAVI-DBT effort focuses on high-throughput design and screening of novel vaccine candidates to complement IAVI’s NAC projects.

Identifying Correlates of Immunity. Nearly three decades after HIV/AIDS first appeared, the biological components of immunity to HIV remain unclear. Without a clear understanding of the correlates of immune protection in humans, vaccine researchers have used imperfect animal models to inform the development and early testing of AIDS vaccine candidates. In response to the urgent need to characterize the correlates of immunity in humans, IAVI established the Control of HIV/SIV Consortium (also known as the Live Attenuated Consortium, or LAC), which IAVI continued to scale up in 2007.

The Control of the HIV/SIV Consortium consists of three primary components:

- **Large-scale systematic non-human primate studies** (of live-attenuated SIV) to assess leading scientific hypotheses on the correlate of protection against SIV.
- **Development of assays** to assess cell-mediated immune responses and evaluate subjects who control HIV.
- **A centralized core pre-clinical immunobiology laboratory and a core human immunobiology laboratory** to provide standard reagents, procedures, and assays across non-human primate protocols and clinical trials.

The assay development program seeks to enhance the ability to predict efficacious immunogenicity of vaccine candidates beyond the capabilities of currently used Elispot tests. (An assay determines the presence, absence, or quantity of a particular component, such
as an antibody or cell.) The program is conducted in collaboration with leading cellular immunology groups, such as those at Harvard and Oxford universities, as well as through active participation in other consortia (e.g., PAVE, the NIAID-sponsored Center for HIV/AIDS Vaccine Immunology [CHAVI], and the Gates-funded Vaccine Immune Monitoring Core). Assays developed through the program will be assessed within IAVI’s clinical research program.

In 2007, IAVI began a partnership with CHAVI to share data, samples, laboratory capacity, methods, and reagents needed to assess factors responsible for controlling HIV. Key aims of the collaboration include defining functional immune responses that help control the virus and identifying host genetic factors that contribute to HIV control.

**Vectors.** The Vectors Consortium, supported in part by the Bill & Melinda Gates Foundation, seeks to improve the evidence base for prioritizing vectors, with the ultimate aim of expanding the product pipeline. Vectors currently being explored include those that elicit persistent immune responses at mucosal surfaces, as well as novel chimeric viruses that are morphologically indistinguishable from HIV particles but are still safe because they are produced using a completely unrelated non-pathogenic virus. Consistent with recent evidence pointing to the importance of vector replication in protecting against infection using live-attenuated SIV, the majority of vectors under study by the consortium are replicating viral vectors.

**Enhance global surveillance efforts to produce new and better concepts entering the vaccine design arena**

IAVI continues to search the world for promising new technologies to improve the product pipeline and to anticipate potential strategies for producing next-generation candidates. In 2007, IAVI acquired access to technologies primarily from large and mid-size biotech companies, including VaxInnate (Flagellin), BioVex (HSV vector), Inovio (electroporation), Juravax (adjuvant), SSI (adjuvant), and Becton, Dickinson and Company (intranasal delivery device).

**Innovation Fund.** In September 2007, the IAVI Innovation Fund was launched at a meeting of the Clinton Global Initiative (CGI), where it was cited as a “Commitment in Action.” Its purpose is to bring promising technologies from other fields into the AIDS vaccine arena to break through scientific barriers and bring together early-stage ideas and products from innovative scientists and companies. The Fund adheres to a strategy to proactively identify novel technologies and accelerate the most promising through IAVI’s public-private partnership (PPP) model. Venture capital firms and selected corporate partners will help identify opportunities for innovation, including technologies that lack proof of concept in the HIV system.

With US$ 10 million in financing, the initial US$ 5 million of which was provided by the Bill & Melinda Gates Foundation, IAVI expects to provide innovation funding to 15 to 20 biotech companies over the next three years in a broad range of fields, including virology, immunology, and bioengineering.

The Innovation Fund’s Venture Capitalist Advisory Committee held its first meeting in November 2007, and the first innovation grant was awarded to VaxDesign, a company that has developed a simulated human immune system with the potential for predicting how humans will respond to new vaccines much earlier in the vaccine development cycle. VaxDesign is initially testing its technology with established vaccines and plans to subsequently move forward with testing AIDS vaccines.

**objective:**

**Strengthen the infrastructure to expedite clinical testing of the most promising candidates in low- and middle-income countries**

Because future AIDS vaccines will primarily be used in low- and middle-income countries, where 95% of the world’s HIV infections occur, it is critical to test vaccine candidates in such settings. Under the 2005-2007 Strategic Plan, IAVI strengthened and expanded its worldwide network of state-of-the-art clinical research facilities and established a structure to expedite the delivery of promising vaccine and immunization candidates to clinical trials in low- and middle-income countries.
centers to accelerate high-quality trials of early promising candidates as soon as they emerge.

In 2007, IAVI further bolstered its research capacity at core clinical trial centers in East Africa, southern Africa, and India to prepare for future efficacy trials. IAVI-supported trial centers were prepared and ready for efficacy testing of NIH’s DNA + Ad5 candidate in 900 subjects in East and southern Africa before trials were placed on hold in light of the Merck Ad5 results. The Human Core Laboratory in London continued its central role analyzing samples drawn from IAVI’s numerous clinical trials. The Core Laboratory ensures international accreditation in Good Clinical Laboratory Practices (GCLP) for its various field laboratories.

IAVI conducted considerable clinical research at IAVI-supported facilities to inform vaccine design efforts.

- **Protocol A** (evaluating prevalence of HIV infection), which involved 6,532 subjects at four sites in Kenya and Uganda, has been completed. More than half (53%) of the subjects enrolled were women, and 695 HIV-infected individuals were identified during screening and referred for care. Data from the study played a useful role in evaluating whether the “BED” diagnostic assay (representing the viral clades B, E, and D) provided an efficient means of assessing HIV seroincidence. The IAVI Africa team reported in the peer-reviewed journal *AIDS* on the poor performance of the assay, and UNAIDS has recommended against its use.

- **Protocol B** (evaluating incidence of new HIV infection) is now enrolling at five research centers in Kenya, South Africa, and Uganda, with three additional centers in Rwanda and Zambia enrolling for site-specific studies of heterosexual transmission in HIV-serodiscordant couples. Cohorts include sexually active couples with discordant HIV status, sex workers, men who have sex with men (MSM), and other groups at higher risk of HIV infection. In 2007, 4,647 at-risk volunteers enrolled in Protocol B research centers. Seroincidence to date has ranged from under 1% to more than 10%. Data derived from Protocol B are expected to aid in the selection of future locations for screening test of concept (STOC) trials and for reallocating resources from low-incidence to high-incidence sites.

- **Protocol C** (evaluating clinical, host, and viral outcomes in early infections) enrolls newly infected volunteers from Protocol B and other sources at the eight Protocol B research centers. By the end of 2007, the study had enrolled 291 volunteers, nearly half of whom enrolled within three months of infection. IAVI is collaborating with CHAVI on analyses of acute HIV infection derived from Protocol C.

- **Protocol D** (determining reference ranges for laboratory safety parameters) has completed enrollment at seven locations in Africa (in Kenya, Rwanda, Uganda, and Zambia), with results presented at the AIDS Vaccine Conference 2007 in Seattle. These trials set up local reference ranges that represent a significant step towards understanding both gender and regional differences in African laboratory intervals and will help accelerate enrollment for future trials of AIDS vaccines, as well as for clinical trials of other prevention tools (such as microbicides for the prevention of HIV and vaccines for TB or malaria) by helping to inform screening and adverse effects (AE) reporting criteria for clinical trials in regions of Africa.

- **Protocol G** (the search for broadly neutralizing antibodies) aims to screen sera from healthy HIV-positive subjects at IAVI-sponsored centers to identify those with broadly neutralizing antibodies against HIV. Identifying new broadly neutralizing antibodies may allow identification of additional targets for the immune system, as well as provide clues for immunogen design. Individuals with the antibodies will serve as sources of blood cells for future studies to inform the design of next-generation vaccine candidates. By the end of 2007, 933 samples had been collected, and a subset of volunteers with broadly cross-reactive neutralizing antibodies provided blood for production of monoclonal antibodies.

IAVI searched for strategies to speed the ability of the vaccine field to obtain early signs of promise from novel candidates. One such approach—the STOC trial—enrolls a limited number of candidates for preliminary efficacy testing of new vaccine candidates. While these smaller trials may lack sufficient statistical power to detect incremental improvements over existing candidates, they would enable the field to identify candidates that represent a significant advance over previous approaches, permitting prioritization of potential breakthrough candidates for expedited, large-scale efficacy trials. STOC trials are much shorter than traditional Phase IIb efficacy trials, require many fewer volunteers, and are significantly less costly and complex. In November 2007, an IAVI paper on STOC trials was published in the journal *AIDS*. 

IAVI – 2007 Annual Progress Report
We promote working globally with an array of stakeholders to further the commitment to and development of an AIDS vaccine.
An AIDS vaccine has the potential to save tens of millions of lives and avert many billions of dollars in future treatment costs. Building on IAVI’s proven success in elevating global awareness of and support for AIDS vaccines, the 2005-2007 Strategic Plan called for the organization to pursue multiple strategies to build and sustain the decades-long commitment that will be needed to end the global HIV epidemic.

**Objective:**
Enhance global public and political commitment to accelerate the development of a safe and effective AIDS vaccine and ensure that, once it is developed, it is available, acceptable, affordable, and effectively used, particularly in low- and middle-income countries

**Expand political commitment and leadership by building on existing relationships and forging new relationships at national and international levels**

**Global Political Leadership.** At the 2007 Commonwealth Heads of Governments Meeting in Uganda, leaders of low- and middle-income countries helped ensure that vaccines and microbicides were cited in the official communiqué as key elements of a comprehensive AIDS response. With support from IAVI, at the outset of the Commonwealth meeting Ugandan First Lady Janet Museveni authored an op-ed that included supportive language on vaccines in *The Monitor*, a leading Ugandan newspaper. IAVI’s president and CEO spoke at an international Group of Eight parliamentary conference in Berlin dedicated to HIV prevention and health, underscoring the central role of vaccines to a comprehensive and effective response to AIDS. At the European Union (EU) AIDS conference in Bremen, Germany, IAVI secured support for AIDS vaccines in the meeting’s final declaration.

IAVI’s advocacy efforts with Palaniappan Chidambaram, the Indian minister of finance, resulted in a meeting of finance ministers and their representatives in Washington, DC, in October 2007 that focused on innovative financing instruments for AIDS vaccine R&D.

This initiative was supported by UK Finance Minister Alistair Darling. An IAVI background paper informed a joint statement by the finance ministers of India, South Africa, and the United Kingdom (UK) that made a commitment to establishing a working group on sustainable financing options for vaccine research.

**Political Leadership in Low- and Middle-Income Countries.** IAVI worked with regional and national actors in low- and middle-income countries to increase political commitment and action on AIDS vaccines.

- *Africa.* On behalf of the Joaquim Chissano Foundation, former Mozambican President Joaquim Chissano signed a partnership agreement with IAVI to speed development of an AIDS vaccine, including working to catalyze greater governmental action on AIDS vaccines in southern Africa and in other regions. Senior IAVI representatives met with Zambian Vice President Rupiah Banda, who pledged to work with IAVI as an advocate for AIDS vaccines and to support IAVI-sponsored clinical research in Zambia. With logistical and financial support from IAVI, the Uganda National Council for Science and Technology launched the revised “National Guidelines for Research Involving Humans and Participants,” the first revision of national research guidelines in 10 years. IAVI participated in a meeting of African and EU parliamentarians in November 2007 in Kigali, Rwanda, which resulted in strong expressions of support for AIDS vaccines from parliamentary leaders and a formal resolution recognizing vaccines as a component of a comprehensive HIV response.

- *Asia.* IAVI met with the Indian Medical Parliamentarians Forum, during which parliamentarians signed a declaration pledging to support AIDS vaccine research in India. In China, IAVI supported the second AIDS Vaccine Network Meeting, convened by the Chinese Academy of Medical Sciences and the Guangxi Center for Disease Control.
Excerpted from the
DECLARATION ON SUSTAINING EFFORTS AND FORGING PARTNERSHIP TOWARDS THE FIGHT AGAINST HIV/AIDS

We, the Members of Parliament of India, along with the National Council on HIV/AIDS, global partners and civil society in the areas of HIV/AIDS,

…Commit ourselves to

Increase commitment and convince the Government and other sectors to take efforts in research and development for new technologies that better meet the prevention needs of people living with HIV/AIDS and those who are most vulnerable to HIV transmission and thus increase public sector investment in AIDS vaccines and microbicides to prevent HIV infection, as pledged in the Declaration of Commitment on HIV/AIDS at The UN General Assembly in August 2001 and the Delhi Declaration in May 2002.

In light of Germany’s joint leadership of the EU and the G8, IAVI increased its outreach to leaders and partners in Germany, including a high-level meeting on AIDS vaccines (co-sponsored with the German research ministry, the Robert Koch Institute, and the German AIDS Foundation) attended by 70 leaders from national ministries, research institutes, private industry, universities, and NGOs. IAVI arranged visits to two IAVI-supported clinical sites in Africa for European parliamentarians, policymakers, and NGO leaders, including representatives from Ireland, the Netherlands, Spain, Sweden, and the UK.

Build a strong set of influential constituencies (e.g., civil society, media, science, the private sector) that actively advocate for AIDS vaccine R&D and future access

The 2005-2007 Strategic Plan recognized that efforts to strengthen and sustain commitment to AIDS vaccine research would benefit from broad-based ownership. Under the Strategic Plan, IAVI has forged advocacy partnerships with a broad array of constituencies, including women’s health advocates, civil society groups, and the scientific community.

Civil Society. IAVI continued working with NGOs in Kenya through such avenues as the Vaccine Support Network, a national network of more than 100 civil society organizations. In India, IAVI convened training and skills-building workshops in Pune for leaders and staff from 42 NGOs in partnership with the National Coalition on Health Initiatives. IAVI supported three Brazilian NGOs — Grupo de Incentivo à Vida in São Paulo, Grupo de Apoio a Prevenção da AIDS in Porto Alegre, and Grupo Pela Vida in Rio de Janeiro — to disseminate AIDS vaccine information countrywide, as

• Latin America. IAVI staff met in Brasilia and São Paulo with Brazilian policymakers and stakeholders, including the leadership of the National AIDS Program, representatives of the Ministry of Science and Technology, and parliamentarians. Brazilian health and science officials pledged to increase Brazil’s engagement in the India-Brazil-South Africa trilateral collaboration on AIDS vaccine research.

Political Leadership in High-Income Countries. As elections ushered in new governments across Europe, IAVI intensified its outreach to key political leaders in the region. IAVI met with newly appointed ministers in Sweden, Denmark, and the UK, as well as with key ministers in Germany, the Netherlands, Portugal, and Spain, to raise awareness of the importance of AIDS vaccines and IAVI’s role in the field. IAVI established relationships with multi-party parliamentary groups in the EU, the Netherlands, and the UK. At a high-level seminar in Madrid co-hosted by IAVI and nongovernmental organization (NGO) partner Grupo de Trabajo sobre Tratamientos des VIH, the Spanish government announced its first contribution of €1 million toward IAVI’s work.

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well as a fourth NGO, GTP+, to organize a two-day workshop for NGOs.

In Europe, IAVI’s civil society partners continued to play an important role in AIDS vaccine advocacy and education. For example, IAVI’s German partner Deutsche AIDS Stiftung helped secure placement of a four-page newspaper article in the Frankfurter Rundschau on AIDS vaccine development, including content from IAVI’s AIDS Vaccine Blueprint 2006: Actions to Strengthen Global Research and Development.

To inform future skills-building and advocacy efforts with NGOs in India, IAVI collaborated with the National Coalition on Health Initiatives to survey 80 NGOs in six states with high HIV prevalence on vaccine literacy and other issues. Preliminary results indicate good understanding of AIDS vaccine research and a strong association of AIDS vaccines with IAVI. IAVI and the International Partnership for Microbicides participated in seminars hosted by national NGO partners in Finland, the Netherlands, Sweden, and the UK, updating parliamentarians, civil society partners, and other stakeholders on recent developments in the field of new prevention tools.

Vaccines as a Women’s Issue. AIDS vaccines would play a critical role in protecting women from HIV transmission, as their use can be initiated by women themselves without their partner’s knowledge. IAVI worked in 2007 to ensure that AIDS vaccines are part of the global discourse on women’s health. IAVI helped develop and place an op-ed in Le Figaro authored by First Lady Jeannette Kagame of Rwanda, focusing on the importance of an AIDS vaccine for women and girls. IAVI actively promoted vaccines at key international meetings, including the World YWCA Council and International Women’s Summit in Nairobi in July 2007, the 4th Asia Pacific Conference on Reproductive and Sexual Health and Rights in India, and the Women Deliver conference in London. IAVI also participated in the gender and youth forum of the South Africa AIDS Vaccine Initiative (SAAVI), where SAAVI cited IAVI as a great model for integrating gender sensitivity into clinical trials.

Youth Organizations. Youth organizations have been a main focus of IAVI’s partnership development work, with the goal of helping young people recognize the importance of an AIDS vaccine to the world’s future health and well-being. In March 2007, IAVI and PATH/Kenya jointly sponsored a vaccine literacy workshop for organizations working with young people. To support IAVI’s partnership with the International Federation of Medical Student Associations (IFMSA), IAVI participated in IFMSA’s 56th General Assembly, presenting on vaccine issues and hosting visitors at IAVI’s Human Core Immunology Laboratory in London.

Science Community. In addition to IAVI’s many interactions with leading scientists at major conferences or in connection with the organization’s collaborative scientific projects, IAVI provided AIDS vaccine updates to key European research institutes, such as the Robert Koch Institute in Germany, the Agence National de Recherche sur le Sida et les Hépatites Virales (ANRS) in France, and the Danish Serum Staten Institute. IAVI also made data presentations at AIDS conferences in Germany, the Netherlands, and Spain; co-organized a symposium on new prevention tools at the 8th International Congress on AIDS in Asia and the Pacific; and provided input on the development of research strategies in the UK and the EU.
Between 2000 and 2006, public sector and philanthropic financing for R&D relating to AIDS vaccines more than doubled, according to global estimates by the HIV Vaccines and Microbicides Resource Tracking Working Group, which includes IAVI and other partners. While the increase in resources reflects major progress in giving AIDS vaccine research the priority it merits, available financing nevertheless falls short of amounts needed to follow through on all promising scientific leads. Moreover, because the search for a vaccine is a long-term undertaking, high-level financing for vaccine research will need to be sustained over decades, underscoring the importance of ensuring strong and durable global commitment to adequate financing.

IAVI helped ensure inclusion of a call for increased support for product development public-private partnerships (PDP) in the outcome document adopted by member states of the Organization for Economic Cooperation and Development (OECD) at their high-level forum on neglected and emerging diseases, held in the Netherlands. The outcome document also called for adoption of policies to provide incentives for private sector investment in research on health conditions that primarily affect low- and middle-income countries. In preparation for the meeting, IAVI worked with fellow PDPs to prepare a briefing document for attendees.

In 2007, IAVI’s senior vice president for public policy was asked to chair a meeting of the advisory board for UNAIDS’ efforts on global resource needs estimation, which helps UNAIDS and other agencies establish global targets for AIDS financing. IAVI emphasized the need to develop new tools to prevent HIV transmission, noting projections of rapidly escalating future treatment costs in the absence of greater progress in lowering the rate of new HIV infections. Separately, IAVI hosted and facilitated a meeting, sponsored by the Bill & Melinda Gates Foundation, to explore the modeling of treatment costs through 2030, a key component of efforts to gauge the potential economic impact of an effective vaccine.

IAVI aims to serve as a critical source of information on AIDS vaccines—for scientific specialists, for stakeholders across the vaccine and AIDS fields, and for the layperson. In 2007, IAVI strengthened its capacity to deliver relevant, accurate information on AIDS vaccines.

**Interpreting Emerging Issues.** IAVI proactively provided background materials and interviews to reporters following the announcement of the Merck trial results. Much of the immediate coverage was well balanced and noted that the disappointing trial results were not grounds for despair. In op-ed commentaries in the Los Angeles Times and South Africa’s Star, IAVI’s President and CEO Seth Berkley argued that an AIDS vaccine is possible, urgent, and essential. In subsequent op-eds in the Washington Post and the Indian Express, Berkley warned against complacency in the fight against AIDS after UNAIDS and WHO lowered their official estimate of the number of people living with HIV.

**Capitalizing on Key Events.** IAVI developed media strategies, secured media coverage, and produced materials for a variety of important scientific and international events:

- **World Economic Forum.** CNN interviewed Berkley and a Reuters article covered the state of research on AIDS vaccines and new prevention tools.
- **International Women’s Day.** IAVI helped develop and place an op-ed by First Lady Jeannette Kagame
of Rwanda that focused on the importance of an AIDS vaccine for women and girls.

- **World AIDS Vaccine Day.** IAVI issued a press statement and collaborated on statements by partners, attracting coverage that included radio broadcasts on New York’s WWOR News, Voice of America, and Dutch BNR News Radio, as well as op-eds by Seth Berkley and head of UNAIDS Peter Piot, Dutch AIDS Ambassador Paul Bekkers, and Kenya AIDS Vaccine Initiative (KAVI) investigators Omu Anzala and Walter Jaoko.

- **Finance Ministers Meeting.** IAVI facilitated coverage of the previously noted meeting of finance ministers in Washington, DC, in the *Press Trust of India* and the *Times of India*.

- **World AIDS Day.** In press statements and key messages, IAVI focused World AIDS Day media outreach on the need for perseverance and innovation in the wake of the disappointing results from the Merck AIDS vaccine trial. IAVI helped develop an op-ed piece by a scientist formerly with the Robert Koch Institute, Professor Reinhard Kurth, in the German national daily *Frankfurter Rundschau*. IAVI supported a Congressional briefing on World AIDS Day, and IAVI’s vice president for country and regional programs served as keynote speaker at the Canadian AIDS Society’s annual breakfast.

**Media Toolkit.** IAVI developed a Communications Toolkit to assist reporters covering AIDS vaccines. The toolkit provides information on how an AIDS vaccine works, why it is so challenging to develop one, basic principles of R&D, and the latest figures on AIDS vaccine research funding. It aims to motivate journalists to cover vaccine-related issues and is also a useful tool for communications staff and spokespeople in the AIDS vaccine community. IAVI also conducted media briefings or workshops for journalists in China, Uganda, and the UK.

**Publications.** Among the publications IAVI produced in 2007 were the 2006 *Annual Progress Report* and *Learning from the Past, Building for the Future: 2008-2012 Strategic Plan*. Efforts to develop a new IAVI website were initiated in 2007, including interviews with stakeholders to inform website re-design.

IAVI launched an extensive reader survey of *IAVI Report* with Harris Interactive that garnered information about how subscribers view the publication. The majority of readers surveyed (71%) use *IAVI Report* as their primary source of information about AIDS vaccines. Feedback was overwhelmingly positive, but also opened some avenues of opportunity for the publication to continue improving. The survey results will also inform future distribution and design efforts, as well as help hone future content and focus.

In 2007, *IAVI Report* produced two special bulletins that covered the sobering Merck results and provided comprehensive coverage of all major scientific conferences in 2007 related to AIDS vaccine development. Bulk subscriptions to *IAVI Report* increased by 87% in 2007, while overall subscriptions rose by 31%. A new subscription database was launched to streamline the subscription process, and new distribution initiatives targeted current subscribers to five scientific journals and the American Society for Virology.

VAX saw its overall distribution increase by 85% in 2007, including substantial numbers of new subscribers.
in low- and middle-income countries. Translated versions of VAX were distributed at several conferences and meetings, including Chinese versions disseminated in partnership with the Chinese Academy of Medical Science.

*Sankalp,* IAVI's India newsletter, published six issues, while the *Uganda AIDS Vaccine Update* published three. IAVI's East Africa regional office launched a regional newsletter, *Pamoja,* to provide updates to key audiences in the region on AIDS vaccines and new prevention tools.

IAVI supported translations and publications on AIDS vaccines in Chinese, made available on CAVAX, a website on AIDS vaccines maintained by the Chinese Academy of Medicine that was receiving roughly 10,000 hits a month in late 2007.

**Multimedia Initiatives.** IAVI increased its use of multimedia formats to communicate the importance of AIDS vaccines to a wide range of audiences. IAVI began developing a video and photography library system that will catalogue images of IAVI and its partners for internal and external use.

Communications staff helped BBC World News produce an AIDS vaccine documentary as part of the *Kill or Cure* series broadcast to millions of households in over 200 countries. The documentary was repackaged into a four-minute video for viewing on iavi.org, at international meetings and YouTube. It was also broadcast on Itunes and Podcast Alley and reached an estimated 13 million viewers in its various formats in 2007.

**Scientific Advocacy.** Consistent with the *AIDS Vaccine Blueprint 2006,* IAVI developed and began implementing a scientific advocacy and communications plan to increase scientific awareness of AIDS vaccine issues and develop effective research-related advocacy messages.

IAVI developed new communications strategies to explain IAVI’s science program and to expand its coverage in scientific publications. IAVI promoted the AIDS Vaccine Development Laboratory in Brooklyn, the launch of new international partnerships to accelerate development of the next generation of vaccine candidates, and the launch of the Innovation Fund (see p. 14). Media outreach led to appearances in such leading publications as the *Financial Times, Globe and Mail* (Canada), *India Express, Kenya Times, Medical News Today, New York Times, Science Daily,* Seattle Times, Times of India, and Japan’s *Yomirui Shimbun and Nikkei Shimbun.* Reviews of a new book on AIDS vaccines titled *AIDS Vaccine Development: Challenges and Opportunities,* co-edited by IAVI and IAVI-affiliated scientists Wayne Koff, Patricia Kahn, and Ian Gust, appeared in the *Journal of Clinical Investigation, Clinical Infectious Diseases, Current Issues in Molecular Biology, Archives of Virology,* and *Emerging Infectious Diseases.* A peer-reviewed article co-authored by Seth Berkley, president and chief executive officer, and Wayne Koff, senior vice president for research and development, appeared in the *Lancet.* IAVI scientists also authored over a dozen articles in peer-reviewed journals such as *Nature, Immunology, Vaccine, AIDS, Journal of Infectious Diseases, Expert Reviews of Vaccines,* and the *Journal of Acquired Immune Deficiency Syndromes.*

**Communications for Advocacy.** Communications activities provided strategic support to the organization’s advocacy initiatives. An article in *Health Affairs* by IAVI staffers on partially effective vaccines generated coverage by United Press International. In a special editorial package in the May/June 2007 issue of *Foreign Policy,* Seth Berkley argued that a more efficient approach to clinical trials could potentially shave years off the time needed to develop an effective AIDS vaccine.

**Supporting New Prevention Tools.** IAVI has long worked in collaboration with PDPs and other organizations to address common issues in the field of new prevention tools. At the request of the Bill & Melinda
Gates Foundation and the UK government, IAVI hosted a meeting of a dozen of the major PDPs and leading donors to explore implementing a common set of performance metrics to evaluate PDPs. A working group was created to promote performance monitoring and improvement and to facilitate the exchange of monitoring and evaluation data.

IAVI also shared its modeling expertise with other groups working on new prevention tools. IAVI served on a working group to identify constraints in making accurate demand forecasts for new prevention tools, which led to publication of a report by the Center for Global Development. IAVI worked with the International Partnership for Microbicides on microbicide introduction strategies, helped PATH create an investment case for vaccines for human papillomavirus (HPV), and worked in concert with UNAIDS, the AIDS Vaccine Advocacy Coalition, and the Alliance for Microbicide Development to track spending on new prevention tools.

IAVI helped develop a joint 2008 advocacy agenda for 10 grantees of the Bill & Melinda Gates Foundation. Joint advocacy by these organizations will focus on increasing funding and financial incentives from the US government for AIDS research, coordinating AIDS prevention research in key low- and middle-income countries, and preparing for likely trial results in 2008 on microbicides, pre-exposure antiretroviral prophylaxis, and suppression therapy for herpes simplex virus type 2.

Communicating the importance, challenges, and collaborative efforts needed for AIDS vaccine R&D are a central focus to IAVI's communications and advocacy activities.
Our policy and advocacy activities seek to achieve changes in policy, laws, and funding that will help bring an AIDS vaccine to all in need.
The 2005-2007 Strategic Plan recognized that financing alone will not ensure that a safe and effective vaccine is available for use throughout the world. To expedite the global search for an AIDS vaccine, policy reforms are needed to create an environment that supports and facilitates AIDS vaccine R&D and ensures that countries, donors, and other stakeholders are prepared to make future vaccines widely accessible as soon as they emerge.

**Objective:**
Make the case for increased/improved public sector investment in an AIDS vaccine

To this end, the 2005-2007 Strategic Plan called on IAVI to mobilize the best available economic and humanitarian arguments to convince policymakers of the wisdom of investing in AIDS vaccine R&D and of making needed policy reforms.

**Effectively advocate for an appropriate level of financing to drive an accelerated R&D program**

Reliable tracking of resources for vaccine research is central to the capacity of IAVI and other advocates to encourage appropriate funding levels. The HIV Vaccine and Microbicides Resource Tracking Working Group, which includes IAVI, estimated that US$ 933 million was spent on AIDS vaccine research in 2006, with the public sector accounting for 80% of funding.

An analysis undertaken by IAVI of vaccines licensed over the last 60 years indicates that both the public and private sectors have played important roles in advancing new vaccines. IAVI’s historical review found that research initiatives characterized by centralized decision making and a narrow focus have been most successful when there is a clear path forward and when the need for a large-scale effort exists.

**Convince key decision makers of the favorable cost-benefit rationale for investing in AIDS vaccine R&D and future access**

To inform future clinical research, IAVI interviewed nearly 100 individuals involved in AIDS vaccine studies in low- and middle-income countries to document the impact including the benefits, challenges, and concerns of trials on individuals, communities, countries, and the world. As outlined in a policy research working paper published in December 2007, some benefits included improved health and well-being, career enhancement and professional development, enhanced health education and service access, and capacity development and institutional strengthening. These findings have the potential to buttress AIDS vaccine advocacy by persuading policymakers of the many ancillary benefits of vaccine research.
facilitate implementation of needed “push” and “pull” mechanisms to increase private sector engagement in AIDS vaccine R&D

The 2005-2007 Strategic Plan called for IAVI to pursue concerted advocacy and collaboration to encourage greater industry involvement, including the establishment and nurturing of meaningful partnerships between public and private sector entities.

Pursue initiatives to increase and accelerate R&D by the private sector or by public-private partnerships (PPPs)

No single private company is likely to have a financial incentive to shoulder the burden of financing the search for a vaccine on its own. Not only is vaccine research risky, expensive, and complicated, but the fact that an AIDS vaccine would be used primarily in low-income countries has led some companies to doubt that a viable market will exist for such a product. Because the history of vaccine research indicates that private industry is often pivotal to the development, introduction, and marketing of new prevention tools, the 2005-2007 Strategic Plan provided that IAVI would advocate for policies to increase financial incentives for the private sector to become engaged in AIDS vaccine research. Such policies include “push” mechanisms that provide direct financial incentives for industry investment in vaccine research, as well as “pull” mechanisms that encourage investment by ensuring that a profitable market will exist for a vaccine when one becomes available for use.

IAVI commissioned a research team from the George Institute to evaluate the feasibility and potential effectiveness of different policies to increase private sector engagement in AIDS, TB, and malaria vaccine research in Europe. IAVI’s analysis suggests that carefully designed structural changes and improved targeting of funding could provide a substantial impetus to scientific innovation and private sector involvement in AIDS vaccine research. These potential policy options were reviewed at a EuropaBio conference in Germany and at a workshop hosted by OECD. OECD plans to share the workshop summary with its permanent delegates, and IAVI intends to continue working with national governments to translate findings into national-level policy proposals.

In addition to policy reforms to enhance financial incentives for industry, IAVI continued in 2007 to evaluate and advocate for novel mechanisms to finance AIDS vaccine research. IAVI entered into discussions
with the global investment firm Goldman Sachs, which engineered the financial structure of the International Financing Facility for Immunization (IFFIm), to explore innovative strategies to secure strong sustainable financing for AIDS vaccine research. IAVI hopes to ascertain donor interest in this effort in 2008.

In 2007, the governments of Canada, Italy, Norway, Russia, and the UK, in addition to the Bill & Melinda Gates Foundation, launched a pilot advance market commitment (AMC) for pneumococcal vaccines. By establishing a firm commitment to finance the purchase and distribution of a future pneumococcal vaccine, the pilot creates an incentive for companies to design an improved vaccine and to manufacture it for low- and middle-income countries. IAVI, which is monitoring the pilot, was among the first organizations actively engaged in investigating the feasibility of AMCs for new health technologies. Leading donor governments have suggested that malaria or AIDS vaccines could be the next products in line for AMCs if the pneumococcal vaccine pilot proves to be effective.

objective:
Ensure that manufacturing capacity and regulatory processes facilitate R&D and rapid access to an AIDS vaccine

For many vaccines that have been introduced in low- and middle-income countries, slow scale-up of manufacturing capacity and bottlenecks in the approval of products by national regulatory authorities have delayed uptake of life-saving products. The 2005-2007 Strategic Plan called for IAVI to develop and implement an advocacy strategy for manufacturing issues and to support efforts to expedite regulatory processes for clinical trials and licensure in both lower-income and high-income countries.

In March 2007, IAVI participated in a meeting sponsored by the WHO and the Global HIV Vaccine Enterprise to consider potential scenarios in the AIDS vaccine field in 2008-2010. The goals were to anticipate and respond to problems and to identify important opportunities to accelerate development and use of AIDS vaccines. IAVI has participated in working groups that resulted from the meeting. IAVI collaborated with partners on interpretation of the Merck trial results and on the development of informed, balanced messages regarding the results.

IAVI provided financial, technical, and planning support for the four-day meeting of the African Vaccine Regulatory Forum in Ouagadougou, Burkina Faso, in September 2007. The forum sponsors periodic regional meetings to provide expert guidance on vaccine evalua-
focusing on national application of the impact modeling tool developed by IAVI in 2006. At the request of the national AIDS agencies of Brazil and Uganda, efforts to model the impact of an AIDS vaccine were launched in each country. IAVI and its research partner, the Futures Institute, entered into partnerships with the Institute of Public Health at Makerere University in Uganda and the Oswaldo Cruz Foundation in Brazil to collect secondary behavioral, epidemiological, and demographic data for improving existing estimates. Data collection has been completed in each country, and national epidemic models have been formulated. Sample vaccine scenarios are now available based on each country’s individual needs. In these scenarios, Uganda will pursue vaccination for the general population, and Brazil is likely to focus on specific subpopulations at higher risk.

**Identify and increase understanding of the factors that will affect AIDS vaccine acceptability, public and private demand, and uptake**

The 2005-2007 Strategic Plan directed IAVI to develop tools for estimating need and demand, with the aim of generating estimates globally and in individual countries. As envisaged in the Strategic Plan, IAVI has made important progress in understanding future demand for an AIDS vaccine, and this work continued in 2007. Based on studies to date, vaccine characteristics (e.g., efficacy, duration, price) are crucial determinants of demand. Efficacy thresholds of 30% to 70% appear...
to be critical to convince national policymakers to support introduction of a future vaccine. Available evidence suggests that revenues from vaccine sales could be considerable in both developed and developing countries, potentially reaching several billion dollars annually. IAVI’s analyses, published in two research papers and presented in various conferences and policy workshops in India and Europe, also suggest that policy changes, such as strengthening regulatory processes or boosting health system capacity to deliver vaccines, could have a considerable impact on demand and uptake of future vaccines.

**Work with other stakeholders and advocacy partners to facilitate preparation of delivery systems for distribution of future vaccines**

The 2005-2007 Strategic Plan also stipulated that IAVI would improve understanding of how countries adopt new health technologies and of the factors that influence adoption, demand, and use, with the aim of putting such lessons into planning for future AIDS vaccines uptake (see figure on p. 28). In 2007, IAVI published a research paper analyzing the launch of new health technologies in India, such as universal immunization, hepatitis B vaccination, no-scalpel vasectomy, voluntary HIV testing and counseling, and antiretroviral therapy. Based on India’s prior experience with new health tools, IAVI recommended several steps to accelerate adoption of future AIDS vaccines, including improving information systems to inform decision making and to build political support, clarifying roles among various governmental and nongovernmental stakeholders to facilitate access to future vaccines, assessing infrastructure needs for vaccine delivery, and securing sufficient and sustainable financial and political commitment for AIDS vaccination efforts.

A major component of IAVI’s efforts to learn from national experiences with other health technologies is its HPV project. Financed mostly by special funds for this work, IAVI is contributing to efforts to rapidly introduce and promote uptake of HPV vaccines, while working to ensure that lessons learned are taken into account in planning for introduction of future AIDS vaccines. A centerpiece of this project is a strategic partnership with PATH on global-level policy research and analysis, financing, and advocacy, with country-level collaboration in Uganda and India. In 2007, IAVI and PATH also worked to prepare an investment case for an HPV vaccine and to forecast HPV vaccine demand.

In addition to its collaboration with PATH, IAVI has engaged in HPV-related advocacy at global and country levels. IAVI participated in the “Global Call to Stop Cervical Cancer,” an advocacy document created by a group of civil society and global health organizations that attracted signatures from more than 1,800 organizations and individuals. IAVI recently joined several organizations in forming “Cervical Cancer Action: A Global Coalition to Stop Cervical Cancer,” which was launched at the Women Deliver conference in London in October 2007. IAVI was also invited to organize and participate in a panel discussion of the board meeting of the Global Alliance for Vaccines and Immunization on the linkages between HPV and AIDS vaccines and on policy reforms to accelerate uptake of new technologies.
We work in partnership. By doing so, we enhance the impact of our efforts and help achieve what could not be accomplished on our own.
Home to 95% of the world’s HIV infections, low- and middle-income countries have the biggest stake in the global search for an AIDS vaccine. Low- and middle-income countries continue to play a central role in AIDS vaccine R&D, particularly in the clinical testing of candidate vaccines in the settings where they are most likely to be used. Since its creation more than a decade ago, IAVI has functioned as a unique partnership between low- and middle-income countries and high-income countries. IAVI has an ongoing presence in 24 countries on five continents, including six countries that host IAVI-supported clinical trial centers.

objective:
Ensure national and site preparedness is in place to accelerate all stages of AIDS vaccine trials, especially in countries where the epidemic is most severe and incidence is high.

IAVI devoted substantial effort to strengthening country-level support for vaccine research, with particular attention to countries and communities in which trials are occurring or are likely to take place in the near future.

Building National Support. IAVI has worked with policymakers and political leaders in diverse regions to galvanize greater national support for AIDS vaccine research. In South Africa and Zambia, IAVI has developed active working relationships with senior political leaders and national ministries. IAVI briefed parliamentarians and political leaders in East Africa on the status of AIDS vaccine research in the region and also briefed the Indian prime minister’s office and local elected political representatives in the Indian states of Maharashtra and Tamil Nadu. In China, IAVI supported the second AIDS Vaccine Network Meeting, convened by the Chinese Academy of Medical Sciences and the Guangxi Center for Disease Control. At the meeting, IAVI highlighted discussions of future directions for vaccine research, regulatory and ethical issues pertaining to vaccine trials, the work of community advisory boards (CABs), and key elements of vaccine preparedness.

Cohort Development and Site Preparedness. IAVI worked in 2007 to strengthen services required for vaccine trials, including treatment and care referrals for trial volunteers and for individuals excluded from trials after testing HIV-positive. IAVI continues to work with clinical trial centers to address adult male circumcision, as well as ensuring access to essential health information, counseling, and referrals.

Quality assurance and counseling supervision programs aim to ensure the highest quality of services to volunteers at study centers. Such initiatives were completed at two locations in Kenya and commenced in additional Kenya and Uganda facilities. In southern Africa, initial quality assurance assessments were made to determine site capacity for voluntary counseling and testing. In partnership with the Research Triangle Institute, IAVI developed an informed consent flip chart for use as a visual aid by research center staff.

IAVI collaborated with the Uganda Virus Research Institute (UVRI) to implement a three-year project designed to strengthen long-term clinical trial and laboratory research capacity and cohort development in Uganda and Malawi. Supported by the European and Developing Countries Clinical Trials Partnership with supplemental backing from IAVI and other partner institutes, this North-South collaboration is intended to bolster country-level capacity for future vaccine trials.

IAVI initiated a social science research project in Uganda to examine strategies for engaging fishing communities, which have emerged in recent epidemiological data as a group at exceptionally high risk of HIV infection. Additional research efforts, undertaken in partnership with the Population Council and local organizations, are studying potential avenues for engaging MSM and transgendered persons in vaccine research in India. A study in Kenya, undertaken in partnership with the International Center for Research on Women and the University of Nairobi, explored gender barriers and potential social effects of participation in vaccine trials.
IAVI provided training for numerous groups to support clinical research. In 2007, IAVI trained 55 counselors who work with MSM in Tamil Nadu and Pune, India. For trial center staff in Africa, IAVI drafted a gender training manual and has begun piloting the training at locations in East Africa. Community educators and organizers received vaccine literacy training at all IAVI-supported centers in southern Africa in December 2007.

**Community Engagement.** In May 2007, IAVI marked the 10th World AIDS Vaccine Day with events around the world to build awareness and support for AIDS vaccine research. World AIDS Day events were held at each of the three IAVI-supported trial centers in Uganda, and events were also conducted in Cape Town, South Africa, and in three different Kenyan provinces in partnership with the Kenya AIDS NGO Consortium, KAVI, and the Vaccine Support Network. In India, a briefing on the completion of the country’s first AIDS vaccine trial took place on World AIDS Vaccine Day, and World AIDS Day events also occurred at two IAVI-supported trial centers in India.

**Community Advisory Boards.** IAVI documented the structure, function, and support needs of CABs at IAVI-supported trial centers in East Africa, India, and southern Africa. Information derived from these exercises informed development of an action plan to increase support to CABs, which calls for a series of CAB-focused tools and guidance documents. IAVI facilitated visits by the Chinese Academy of Medical Sciences to four clinical research centers for a CAB assessment project in China.

IAVI conducted two international CAB meetings, one with community liaison officers (the site staff members responsible for community mobilization and CAB activities), and the second with CAB members from sites in different regions. These meetings updated key staff and CAB members on results from recent vaccine trials and facilitated the exchange of experiences among different CABs. The Southern Africa regional office followed up these meetings with a regional CAB meeting in Johannesburg.
IAVI supported the Desmond Tutu Health Center (DTHC) Adolescent CAB Camp in Cape Town in July 2007. An important outcome of the meeting was a clear indication that capacity building efforts for CABs should address important issues for young people, including personal growth, governance, and sexual and reproductive health, as well as vaccine literacy.

**Ancillary Benefits.** While the overriding purpose of IAVI’s work in low- and middle-income countries is to expedite R&D of AIDS vaccines, the countries and communities that host IAVI-supported trials also attain important benefits. For example, IAVI is helping promote knowledge of HIV serostatus by offering voluntary HIV counseling and testing in IAVI-supported centers; more than 48,000 people have received these services.

Enlisting the support of political leaders, nongovernmental organizations (NGOs), community groups, and strategic coalitions is central to all of IAVI’s activities.
As the world’s only public-private partnership dedicated to the search for an AIDS vaccine, we aim to use every tool available to maximize our impact.
Envisioning IAVI’s continued growth, the 2005-2007 Strategic Plan provided for a thorough, ongoing assessment and strengthening of IAVI’s internal procedures, with the aim of ensuring the organization’s ability to pursue the search for an AIDS vaccine with the necessary speed, flexibility, and willingness to take informed risks.

Organizational structure and management

IAVI is committed to ensuring that each dollar spent achieves maximum impact in support of IAVI’s mission.

Financial Audit. For the sixth year, Ernst & Young LLP completed a financial audit of IAVI, which yielded no material adjustments and produced a clean audit opinion that IAVI’s financial statements fairly convey the organization’s financial position. A separate A-133 audit of IAVI (required for all recipients of US government funds) determined that proper financial control is exercised over US government funds. All project audits for the EU similarly received clean opinions.

Monitoring and Evaluation. IAVI developed a monitoring and evaluation system for use by the IAVI board of directors, senior management, and donors. IAVI is collaborating with fellow PDPs and other NGOs to harmonize evaluation systems, including sharing IAVI’s online system for collecting and reporting evaluation data.

Ensuring Financial Compliance. IAVI finance staff conducted their annual financial and compliance training seminar in Uganda in July 2007, with the aim of promoting universal knowledge of, and compliance with, applicable donor policies and reporting requirements. Attendees included representatives from all IAVI-supported clinical research centers in Africa and India. Topics covered included IAVI’s financial policy, reporting standards, and compliance requirements for US Agency for International Development (USAID) and the EU. In addition, IAVI compliance staff have made routine visits and audits of field offices and trial centers.

Business model and intellectual property

Under the 2005-2007 Strategic Plan, IAVI sharpened and improved its business development efforts, with the aim of ensuring the organization’s ability to forge fruitful research collaborations with partners and to identify promising technologies of potential value in the development of an AIDS vaccine.

As summarized in Section I, IAVI completed a number of new partnership agreements for R&D. These include:

- A new collaboration and license agreement with DNAVEC, a Japanese biotech company to develop a vaccine using a Sendai viral vector and IAVI transgenes.
- Numerous enhancements (as described in Section I) to IAVI’s research consortia.
- A cooperative R&D agreement with the National Cancer Institute for gene optimization for viral vector activities at the AIDS Vaccine Development Laboratory.
- Establishment of a collaborative R&D program with Aeras for a recombinant BCG-based AIDS vaccine candidate.
- A research collaboration with CHAVI.

GlaxoSmithKline and IAVI terminated their project to develop a chimp adenovirus candidate, with plans to modify their collaborative work to explore other vaccine development strategies.

Human resources

In November 2007, a new vice president for human resources, Anthony Musyoka, joined IAVI, with the charge of continuing and strengthening IAVI’s commitment to a satisfied, productive, and qualified work force.

Staffing. IAVI filled 55 positions in 2007 (compared to 23 in 2006), benefiting from expanded in-house recruiting, selective use of search firms, and outreach to key
IAVI began the first phase of systems development for the network to facilitate the transmission and sharing of pre-clinical data across IAVI's own clinical program, as well as across the AVC. A working prototype is expected before the end of 2008.

**Internal communications**

In 2007, IAVI implemented an internal communications plan that includes such activities as periodic “brown bag” lunches featuring programmatic presentations by different departments. An internal newsletter, *IAVI Connection*, was re-launched, and IAVI initiated a quarterly “AIDS Vaccine 101” seminar series on IAVI activities in vaccine science for all IAVI staff members.

**Resource mobilization**

The 2005-2007 Strategic Plan called for expanding and diversifying IAVI’s funding base to ensure that adequate resources are available to support the organization’s strategic and operational objectives. In 2007, the organization made important strides toward these goals, increasing resources mobilized from key private sector sources and from small donors while maintaining robust support from public sector and philanthropic donors.

**Public Sector.** Governments accounted for 87% of IAVI’s 2007 revenue, with the total number of governments providing financial support to IAVI reaching 11. European governments accounted for € 27 million; Spain became IAVI’s newest government donor with a € 1 million commitment. Several of IAVI’s longstanding donors—the Netherlands, the UK, Ireland, and Denmark—continued multi-year funding for the organization, while Norway and Sweden renewed their commitments (in the latter case with an increase to SEK 20 million or approximately US$ 3.3 million). The US government, through the USAID, remained IAVI’s single largest government donor, with total support in 2007 exceeding US$ 28 million. The Canadian government committed CAD$ 20 million for 2007-2008, while the World Bank renewed its support for IAVI with US$ 1 million in 2007 and an additional US$ 1 million in 2008.

**Private Sector.** Several private sector sources increased their support for IAVI in 2007, while important groundwork was established for future growth from other sources. In connection with the implementation of the AIDS Vaccine Development Laboratory, IAVI received a...
generous capital grant of US$ 12 million from the New York City Economic Development Corporation, as well as additional new market tax incentives totaling US$ 3 million to support capital building expenses.

For the sixth consecutive year, Charity Navigator, a leading independent charity evaluator, awarded IAVI its highest rating of four stars, placing the organization among the top 1% of 5,000 charities evaluated nationwide.

**Foundations.** A US$ 5 million grant from the Bill & Melinda Gates Foundation, complemented with a US$ 100,000 matching grant from the John D. Evans Foundation, helped launch the Innovation Fund (see p. 14). Until There’s a Cure Foundation, one of IAVI’s founding donors, renewed its support in 2007, while IAVI completed the second year of its US$ 575,000 grant from the New York Community Trust to support IAVI’s first scientific venture in New York City, the AIDS Vaccine Development Laboratory. The Haas Trusts and Broadway Cares/Equity Fights AIDS renewed their generous annual support for IAVI, while the James B. Pendleton Trust, which originally supported the launch of IAVI’s NAC, provided new funding for key laboratory equipment. With the aim of generating knowledge relevant to introducing a future AIDS vaccine, the William and Flora Hewlett Foundation and the Rockefeller Foundation provided critical support to launch an innovative new project to learn from the introduction of HPV vaccines in low- and middle-income countries.

**Corporate.** In 2007, total cash donations and in-kind contributions to IAVI disbursed in 2007 were valued at almost US$ 800,000.

- Becton, Dickinson and Company (BD), a global medical technology company and IAVI’s first major corporate partner, awarded US$ 900,000 in cash, equipment, and supplies over a three-year period, increasing its level of support by 50%.
- Bristol-Myers Squibb (BMS) made its first grant to IAVI, awarding the organization US$ 75,000 to support the Innovation Fund.
- Continental Airlines donated domestic and international flights for IAVI-related travel.
- Henry Schein Inc., a leading provider of health care products and services, made its first major gift of US$ 50,000 in clinical supplies to IAVI’s Core Laboratory in London.
- Merck & Co. awarded US$ 40,000 to IAVI’s Core Lab to support Good Clinical Laboratory Practice training.
- Pfizer placed a Global Health Fellow to support vaccine preparedness work at IAVI’s trial site in Mtwapa, Kenya, representing a total contribution valued at US$ 115,000.
- Yahoo! and Google provided free advertising, and IAVI received substantial pro bono legal services from Shearman & Sterling, Frommer Lawrence, and White & Case.

**Individual Giving.** Small gifts to IAVI increased by approximately 20%, generating more than US$ 130,000 in support. Roughly half of all individual gifts were made online. IAVI was again part of the Combined Federal Campaign and ran a petition for support on the website Care2.org, generating 2,300 new entries on IAVI’s mailing list. A quarterly newsletter by IAVI’s Resource Development unit, now in its third year, more than tripled its distribution in 2007, with each issue now reaching more than 3,000 current and prospective individual and institutional donors. Through the continued grant from Google AdWords, IAVI attracted more than 60,000 additional visits to its website. A Yahoo!-produced link on its home page for World AIDS Day generated more than 360,000 unique visitors as well as individual contributions from five new countries.
FINANCIAL ABSTRACT

A 2007 review of IAVI's financial position showed an organization that rests on a firm financial foundation, with US$ 100 million in revenue and US$ 87 million in expenditures. IAVI's financial strength is driven by four key elements: a well-diversified and growing donor base, a strong balance sheet, management prioritization of key programs, and effective management of financial resources. In 2007, a significant number of renewals and new grants established a new baseline of support for the organization.

In 2007, public sector grants—largely through official development assistance—contributed 89% of IAVI's revenue (Figure 1). This level of government support reflects the widespread recognition that an AIDS vaccine can blunt and ultimately end the pandemic and is essential to achieving international development goals to lower poverty rates, ensure that all children complete primary education, reduce child mortality, improve maternal health, and curb the global TB epidemic in countries where the AIDS epidemic has taken a terrible toll.

Consistent with the urgency to accelerate AIDS vaccine development, R&D activities accounted for 71% of expenditures (Figure 2), similar to earlier IAVI trends, with the balance going to collateral programs, including vaccine education and advocacy, public policy research, and analysis. IAVI also has consistently kept administrative costs at around 11%, which has helped it win acclaim from Charity Navigator as a four-star charity.

Looking forward, IAVI projects expenses of US$ 90.5 million in 2008, rising to an estimated US$ 111 million in 2012 to meet strategic objectives, which increasingly focus on solving the fundamental challenges that have impeded AIDS vaccine R&D for decades. Based on revenue forecasts for the period 2008-2012, IAVI expects a funding gap of approximately US$ 295 million by 2012 in the absence of new and renewal income to meet programmatic needs.

CONCLUSION

In a year of disappointing trial results and scientific introspection in the field, IAVI nevertheless continued to strengthen its capacity to address current challenges and to plan proactively for the future. As in prior years, IAVI’s achievements in 2007 could not have occurred without the continuing support of the organization’s donors and without energetic collaboration with its multiple partners.

Since its creation, IAVI has been animated by a vision of a world without AIDS. In 2008, IAVI remains as firmly committed to this vision as ever. As recent years have shown, developing preventive vaccines capable of overcoming AIDS will be neither quick nor easy. However, IAVI and its many partners remain convinced that the era of AIDS vaccination is achievable, and that with sufficient commitment, collaboration, and strategic focus, the world can accelerate progress against the greatest of all global health threats.
IAVI – 2007 Annual Progress Report

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