INTERNATIONAL AIDS VACCINE INITIATIVE
2008 Annual Progress Report
IAVI’s mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.
Evolution

The new AIDS Vaccine Design and Development Laboratory

The new IAVI Neutralizing Antibody Center at The Scripps Research Institute

A fully operational Innovation Fund to promote cutting-edge science
Commitment

Global network of partnerships
Clinical trial center support
Community outreach and social science
Promise

Build scientific and human capacity in the developing world
Sustain local, national and global focus on ending AIDS
Ensure access to vaccines where they’re needed most
Message from the President

Since we were founded in 1996, the International AIDS Vaccine Initiative has undergone constant change as we have pursued our mission of ensuring the development of an AIDS vaccine for the world. Still, 2008 stands out as a particularly eventful period in our history.

As part of our ongoing efforts to address the scientific challenges facing AIDS vaccine designers, IAVI in 2008 significantly expanded our applied research program, aimed at informing the design of improved AIDS vaccine candidates. We opened a new laboratory in New York City and a joint facility with The Scripps Research Institute in California. With the benefit of IAVI-supported clinical research centers in Africa, we stepped up the search for HIV-infected individuals who produce neutralizing antibodies to HIV. And we fully operationalized our Innovation Fund, which finances out-of-the box technologies that could advance AIDS vaccine research and development. Together, these efforts at year’s end produced an advance that may help accelerate the solution of the key problem of how to design a vaccine that elicits neutralizing antibodies to HIV.

But that’s just part of our 2008 story, of course. The full picture is provided in the following report.

IAVI is called an “initiative” for a reason—those of us who work at IAVI are only a part of the endeavor. None of what we achieved last year, or in any of IAVI’s history, would have been possible without the commitment of our many partners and collaborators, including political leaders, policy makers, scientists, members of civil society and multilateral groups. We are continually enlightened by our engagement with partners, and grateful for their generosity. We are especially indebted to the volunteers who graciously participate in clinical trials and studies. They are the greatest heroes of AIDS vaccine R&D. And last but not least, we also are grateful to our many generous donors, whose sustained support for us despite the challenging economic environment is a source of great inspiration.

We thank those of you who have been a part of our mission, and invite the rest of you to join us as we continue to move toward our vision of a world without AIDS.

[Signature]
She arrived tired and weak, but with a hope that had steeled her through the long trip to Entebbe. Her name was Rose, and she presented two granddaughters no older than 10, colorfully outfitted in matching ruffled dresses.

Wiping the perspiration from her brow with a handkerchief, Rose explained to the staffer at the International AIDS Vaccine Initiative’s Uganda office that she already had lost the girls’ mothers and two additional children to AIDS, and now she was raising seven grandchildren left behind. At that moment, more than 1.5 million Ugandans had died of AIDS, leaving behind more than 1 million orphans. Rose had taken that long trip on a very hot day, having read in the newspaper that “the vaccine people” had arrived in Uganda. Now she wanted to get her granddaughters an inoculation that would protect them from the fate of their lost mothers.

Rose imagined a world without AIDS, but she was too early. The IAVI staffer explained the purpose of the organization’s presence in Uganda: to test experimental AIDS vaccines in an effort to one day develop an effective vaccine. She gave Rose and her granddaughters tea and cookies, the best information available on how to prevent HIV infection and a referral to an HIV-prevention education group in Kampala.

Rose’s story, and those of millions of others like Rose, her daughters and her grandchildren, motivate the work we do at IAVI. Individuals like Rose have lost too much. Young people like her grandchildren are in far too grave a danger. We need to be able to offer them more than tea and the same prevention advice that has the world registering 7,400 new HIV infections every single day. We need to offer a revolutionary change.

At IAVI, we believe the development of an AIDS vaccine can be that revolutionary change. This report describes our progress in 2008 toward our mission of ensuring the development of a safe, effective, accessible, preventive AIDS vaccine for use throughout the world. Such a vaccine offers the best hope of ending the AIDS pandemic and returning us to a world without AIDS.
Meeting the challenge

2008 was a year of considerable transition for IAVI. Most notably, it was the year the organization added its own bricks-and-mortar dimension to an expanding, global applied research program, opening two state-of-the-art facilities. IAVI’s applied research program is aimed at expediting the solution of the scientific problems that so far have stymied the design of effective AIDS vaccine candidates.

IAVI was not originally created to address problems of complex science. IAVI was conceived in 1996 as a group that would advocate for the development of an accessible AIDS vaccine, explore public policy reforms that would promote AIDS vaccine research and development, and develop and test AIDS vaccine candidates. But over time, as scientists learned more about HIV and its interactions with the immune system, it became clear that conventional vaccinology would not produce a fully protective AIDS vaccine. Rather, researchers would need to unlock some of the mysteries of HIV and the body’s response to the virus to design novel vaccine concepts that would go beyond the initial approaches.

After a 2001 IAVI-commissioned survey of global efforts to design AIDS vaccine candidates pointed to gaps in the field, IAVI began investing not just in product development of candidates but in the design of novel ones to help fill the identified gaps. These investments led to the establishment of scientific consortia to tackle the major challenges and culminated in the opening in 2008 of a new 36,000-square-foot facility in New York City to house IAVI’s AIDS Vaccine Design and Development Laboratory, which had been incubated at the State University of New York’s Downstate Medical Center in Brooklyn. The Design Lab is an industry-style facility devoted to developing a new generation of more effective AIDS vaccine candidates, and to prioritizing vaccine candidates to ensure that the most promising are accelerated to clinical testing. These efforts complement the vaccine design and development work IAVI is undertaking with partners around the world.

The year also saw the opening of the IAVI Neutralizing Antibody Center at The Scripps Research Institute in La Jolla, California. This facility is dedicated to solving the most difficult problem facing AIDS vaccine designers: how to create a vaccine that elicits antibodies that neutralize the wide variety of HIV types circulating worldwide. And in
another effort to advance breakthroughs, IAVI in 2008 fully operationalized its Innovation Fund, making awards to six entities, mostly biotech companies, working outside HIV vaccine R&D on promising new technologies that could advance the field.

Even as IAVI has enlarged the applied research part of its R&D program to produce discoveries that will lead to novel vaccine candidates, the organization has steadfastly maintained its vaccine development effort to enable rapid progression of novel candidates from design through development, and to ensure the accelerated testing of candidates via a network of partners in the developing world. In that respect, IAVI’s R&D evolution can be seen not as a shift away from development toward applied research, but rather as an expansion of the applied research component. This is in keeping with IAVI’s core principle of addressing key gaps in the field to accelerate the development of an AIDS vaccine for use throughout the world.

Because HIV causes AIDS only in humans, it is imperative to use clinical trials to test the most promising AIDS vaccine candidates in the pipeline. Even if first-generation candidates do not prove fully protective, they still have much to teach investigators, who can then use those results to design better alternatives. The clinical centers and labs within the IAVI network also conduct observational studies—on how the body first responds to HIV infection, for example—that feed vaccine designers with important data that informs their work. And these centers provide the robust network necessary to move vaccine candidates that advance to efficacy testing expeditiously through that process.

At the same time, the reality is that for the immediate
How AIDS Holds the World Back

In 2000, world leaders assembled at the United Nations to identify an action agenda for the new millennium, agreeing on a series of eight visionary goals to be achieved by 2015. These goals reflected key aims for the broad international development agenda, and included a commitment to halt and begin to reverse the AIDS pandemic.

On behalf of UNAIDS and more than 40 partners in the international development and global health field, IAVI in 2008 produced a policy brief documenting the role of the HIV response in achieving not only the HIV-specific goal but the broad range of Millennium Development Goals. In particular, the brief described how an AIDS vaccine and other HIV prevention technologies could dramatically improve global well-being and international development prospects.

Some of the key findings:

■ **HIV deepens poverty and hunger.** The Millennium Development Goals envision a 50% reduction in severe hunger and in the number of people living on less than US$ 1 a day. Yet the AIDS pandemic is impeding efforts to reduce poverty and prevent hunger. In southern Africa, a case of HIV infection results in an average 10% decline in household earnings. Studies show that an AIDS death in a rural Rwanda farm household leads to an 18% drop in the bean harvest on that farm.

■ **HIV threatens children’s potential.** The pandemic is reducing children’s educational opportunities, the focus of the second Millennium Development Goal. The pandemic has orphaned 15 million children worldwide; orphans are 12% less likely to attend school than non-orphans. With nearly 400,000 children becoming infected with HIV each year—primarily by mother-to-child transmission—many vulnerable children never even reach school age.

■ **HIV slows progress for women.** The 2015 goals call for dramatic progress in reducing gender inequalities, empowering women and improving women’s health. Here, too, a vaccine is urgently needed to support progress for women. In the world’s poorest region—sub-Saharan Africa—women account for more than 60% of all HIV infections, and adolescent girls are several times more likely to become infected than boys their age.

■ **HIV worsens other infectious diseases.** HIV is driving a frightening resurgence of tuberculosis in southern Africa and contributing to the spread of malaria. An AIDS vaccine and other new HIV prevention technologies are needed not only to control the spread of HIV but to combat other diseases that cause additional millions of deaths each year.
time frame there is less trial work to be done than originally anticipated, owing to the failure in 2007 of the candidate in the second AIDS vaccine efficacy trial to draw to a close, the Phase Ib STEP trial. This outcome resulted in decisions to cut short the Phambili trial in South Africa of the same candidate and, in 2008, to cancel two trials of a candidate of the U.S. government’s Vaccine Research Center that, like the STEP candidate, was based on a vector made from the common cold virus adenovirus type 5. Six IAVI-supported trial centers in Africa were to have participated in a Phase Ib trial of the Vaccine Research Center’s candidate, which was ultimately reconfigured into a much smaller trial in the Americas only.

To ensure that the capacity, both human and physical, of the global clinical trial network IAVI supports remains well utilized and that investigators and technicians continue to expand their experience and skills, IAVI developed plans in 2008 for additional clinical research studies to both inform HIV vaccine design and to expedite AIDS vaccine development.

Disappointment about the STEP trial results produced concern in some quarters about the AIDS vaccine mission that IAVI’s advocacy, communications and resource mobilization arms worked to dispel over the year. At the same time, the trial outcome produced an opportunity to reset expectations and strategies, underscoring as it did that the timeline to licensure of an AIDS vaccine is likely longer than many, even within the field, had realized.

Just as IAVI in recent years has put more resources into applied science to solve the problems vexing AIDS vaccine designers, so has it adjusted its non-science programs to confront today’s real challenges. That shift was apparent in 2008. IAVI’s public policy work is now focused less on down-the-road matters, such as ensuring access to an eventual vaccine, and more on immediate issues like creating incentives for industry to invest in AIDS vaccine R&D, a priority in 2008. Advocacy efforts have been revised, for instance to emphasize the long-term nature of vaccine development. Given the need for long-term and flexible financing for R&D, IAVI has increasingly worked to diversify its funding sources to include more private and corporate donors. And the organization has initiated efforts to engage a younger generation—of scientists, advocates, policy-makers and potential donors—in the AIDS vaccine effort. It has been said that the development of an AIDS vaccine is a marathon, not a sprint. We now know it is likely to be a relay race as well.

“It is not enough to provide treatment to everyone who becomes infected with HIV. If that is our strategy, we will be struggling against HIV forever … We must strive to defeat HIV decisively. That means giving renewed support for the development for a cure, a vaccine or both.”

—Michel Sidibé, Executive Director, Joint United Nations Programme on HIV/AIDS
New urgency, focus

Since its inception, IAVI’s R&D program has addressed gaps in the field of AIDS vaccine development, bringing together key players, pursuing new ideas to surmount crucial questions, expanding the pipeline of potential products and using rigorous criteria to advance the most promising candidates. In 2008, IAVI took important steps to strengthen vaccine design efforts while continuing its ongoing efforts in vaccine development.

VACCINE DESIGN

In September 2008, the organization established the IAVI Neutralizing Antibody Center in partnership with The Scripps Research Institute on the Scripps campus in La Jolla, California. This new center is the keystone of an expanded international scientific network, the Neutralizing Antibody Consortium (NAC), dedicated to finding ways to design vaccine candidates that generate broadly neutralizing antibodies against HIV.

The Neutralizing Antibody Consortium was formed by IAVI in 2002 after IAVI determined that a major gap in the field was the paucity of work dedicated to solving a key scientific problem impeding AIDS vaccine development—the ability to elicit broadly neutralizing antibodies against HIV by immunization. From 2002 to 2007, the NAC grew from a small scientific consortium to a major global effort and made a number of key scientific advances on the path toward the solution of this problem.

In 2007, an external scientific review of the NAC concluded that the power of the consortium would be magnified if some of its member investigators devoted themselves full-time to AIDS vaccine R&D, and if a critical mass of researchers came together in one facility. The idea was to create a water-cooler effect, the swapping of information and inspiration that takes place when individuals working toward the same goal informally encounter one another on a regular basis. Thus was born the idea for the Neutralizing Antibody Center.

In 2008, IAVI signed an extended partnership agreement with The Scripps Research Institute, one of the world’s largest non-profit biomedical research organizations, and established the center, with a planned initial commitment of US$ 30 million over five years. Dennis Burton, Ph.D.,
a renowned leader in immunology and the director of the NAC, serves as the scientific leader of the center. The new facility will bring together biologists, virologists, chemists, immunologists and experts in other disciplines to work side by side.

In 2008, consortium scientists at Scripps demonstrated that less antibody is likely to be needed for HIV protection than previously believed. These findings generated new optimism that an AIDS vaccine that elicits effective antibodies against HIV can be developed.

Meanwhile, important elements of the Neutralizing Antibody Consortium’s work were underway at other institutions connected to the NAC. Recently, the consortium added to its portfolio a Medicinal Chemistry Program co-funded by IAVI and the Government of India’s Department of Biotechnology. Under this program, Indian investigators are using the tools of medicinal chemistry to design immunogens that would prompt the immune system to produce broadly neutralizing antibodies to HIV. By the end of 2008, the program had produced a number of immunogens that were under evaluation in animal studies. IAVI has begun discussions with the Department of Biotechnology about the possibility of creating a dedicated facility in India for AIDS vaccine design in the near future.

Opened in November 2008, IAVI’s new AIDS Vaccine Design and Development Laboratory in New York City is an integrated, industrial-style facility dedicated solely to expediting AIDS vaccine development. Construction was aided by US$ 12 million in New York City grants that encourage biotech enterprises to locate in the city. The facility is now home to 30 full-time staff collectively focused on the preclinical design and development of AIDS vaccine candidates. The emphases of the Design Lab’s efforts are:

- Developing candidate HIV vaccines based on replicating viral vectors. These are viruses that are engineered to mimic the characteristics of the most effective licensed vaccines, for the purpose of preventing and controlling HIV infection;

- Accelerating NAC efforts to design vaccines that induce the immune system to produce antibodies that neutralize the diverse types of HIV circulating worldwide.

Collectively, the Neutralizing Antibody Center, Design Lab and IAVI’s Human Immunology Lab located at Imperial

![Partners in the Neutralizing Antibody Consortium](image-url)
College London, together with an extensive array of global partners, form the web of IAVI’s vaccine design program.

Within this framework, solving the HIV neutralizing antibody problem is now IAVI’s highest vaccine design priority. One of its major efforts has been to identify and study people who naturally produce broadly effective antibodies against HIV, trying to learn exactly where on the virus those antibodies attach and how this might inform the design of a vaccine. By the end of 2008 this study, known as Protocol G, had screened more than 1,800 people in the clinical research centers IAVI supports in Africa and in other collaborating research centers. More than 150 HIV-positive subjects had been identified whose blood neutralized a wide array of HIV types in circulation today. Of those, some 15 to 20 people had been identified as \textit{elite neutralizers}, people whose blood contains significant amounts of potent antibodies that neutralize multiple types of HIV.

The goal is to find specific antibodies, termed \textit{monoclonal antibodies}, that neutralize a wide array of HIV types in circulation worldwide, to determine where exactly on HIV they attach, and to mimic this portion of HIV in the design of new vaccine candidates. The aim is to induce the body to produce such broadly neutralizing antibodies by immunization. A handful of such antibodies have been identified in the past. In animal experiments, these antibodies, when delivered in sufficient quantities, protected the animals from infection with SHIV, providing a proof of concept for a protective antibody-based AIDS vaccine.

Another of IAVI’s scientific networks, the Control of HIV/SIV Live Attenuated Consortium (LAC), is looking at a different set of issues. The human body, once infected with HIV, can control the infection for a time. Some people—classified as \textit{long-term non-progressors} or \textit{elite controllers}—have been infected with HIV but keep the virus at harmless levels for long periods without any treatment. The LAC is exploring what mechanisms allow that control, and how we can translate those mechanisms into viable vaccine approaches.

In 2008, consortium scientists determined the efficacy of a live attenuated SIV vaccine against two types of SIV challenge, one that exactly matched the vaccine, in which significant protection was observed, and one that did not match the vaccine, in which less protection was observed. These findings reinforced the HIV variability issue as a major scientific challenge in AIDS vaccine development. The findings also provided important clues about why
some animals were protected and others were not. IAVI’s vaccine designers are now using this information to inform the design of multi-component vaccines with the aim of addressing HIV variability.

In parallel, scientists at IAVI’s Human Immunology Lab, in collaboration with IAVI partners, including scientists in the network of clinical research centers IAVI supports in the developing world, are evaluating human HIV infection, comparing individuals who control HIV with those who do not. This has entailed developing new and sensitive laboratory tests to predict whether an HIV-infected individual will control HIV, based on how his or her immune system responds to the virus, as measured by markers in the blood. If valid, these tests would enable vaccine developers to better predict whether a candidate AIDS vaccine might control HIV based on the results of early human trials. Developers could assess in the laboratory whether cells from the blood of vaccinated volunteers could control HIV. That way, researchers could better prioritize candidate vaccines—that is, determine which should be advanced to the next trial stage. IAVI’s Human Immunology Lab has now developed these tests, termed _viral inhibition assays_, for human vaccine trials, and comparable assays are in development for monkey studies conducted by the Design Lab. The human assay is being qualified for use in future trials by an IAVI-supported clinical trial that began in 2008. New assays are important given indications from previous clinical studies that the laboratory tests currently used are not an accurate predictor of whether an AIDS vaccine candidate will be protective.

Most scientists believe that an effective AIDS vaccine will need to stimulate both neutralizing antibodies and cell mediated immunity. Whereas neutralizing antibodies target the virus itself, cellular immune responses attack the cells of the host that have been infected by the virus. The best licensed vaccines (such as the live attenuated vaccines against measles, mumps and chickenpox) stimulate both arms of the immune system. And the best SIV vaccines use a live attenuated construct. Thus, major efforts are underway by IAVI and others to design AIDS vaccine candidates that mimic the efficacy of live attenuated vaccines with candidates that are safe for human use. To facilitate this work, IAVI has established a Vectors Consortium consisting of scientists from the Design Lab and extramural partners.

The Vectors Consortium, supported in part by the Bill & Melinda Gates Foundation, is now focused on the
Exploring New Vectors

Animal experiments using live attenuated SIV as a vaccine suggest that replication of the vaccine virus is an important factor in efficacy. When live attenuated SIV has been crippled so that it can replicate only once, its effectiveness as a vaccine is greatly diminished. This has led IAVI to evaluate persistently replicating viruses as potential vector candidates.

Vectors that elicit mucosal immune responses, which prevent pathogens from penetrating and replicating at mucosal surfaces, are of interest for two reasons. First, HIV most commonly enters the body through mucous membranes, so activated immunity at those sites could be of value. Second, HIV establishes a beachhead early after infection in cells of the immune system located in the gut, where it amplifies and invades immune cells throughout the body. This has led IAVI to focus on viruses that target immune cells of the gut as potential vectors for vaccine development.

In 2008, the Vectors Consortium successfully achieved key milestones toward the development of a novel set of replicating vectors, and soon will begin to evaluate such vectors in preclinical studies, the laboratory and animal research that precedes trials in humans. Prioritization of such vectors by pre-determined criteria eventually will lead to improved candidates entering the clinic.

VACCINE DEVELOPMENT

While IAVI has injected new urgency into vaccine design, the organization remains committed to the development and testing of experimental AIDS vaccines. In 2008, IAVI and its partners collaborated on a diverse array of vaccine approaches, reflecting the imperative to work closely with governmental agencies, non-profits and private industry to expand the pool of promising candidates.

IAVI supported the Aaron Diamond AIDS Research Center in New York in its launch of a Phase I trial of the center’s DNA AIDS vaccine candidate, called ADVAX, using a method of administration called electroporation—sending an electric pulse to create temporary pathways through cell membranes to inject substances. Previous studies have indicated that this method can enhance immune responses. The current trial aims to determine whether this system generates stronger cell-mediated immunity than delivering a vaccine by standard needle and syringe injection. Data from the trial is expected in 2009.

In 2008, IAVI, the Indian Council of Medical Research and India’s National AIDS Control Organization announced the results of a Phase I trial conducted in India of an AIDS vaccine candidate based on a vector constructed from modified vaccinia Ankara, or MVA. The candidate was found to be safe and well-tolerated, and it generated immune responses—albeit modest—in 100% of volunteers who received the high dose. Based on these results, the decision was made to test the candidate in combination with the ADVAX DNA AIDS vaccine candidate in a prime-boost regimen, a strategy of combining two vaccines with the hope of generating immune responses better than those generated.
AIDS Vaccine R&D Provides Ancillary Benefits

Although the ultimate goal of AIDS vaccine R&D is an effective vaccine, this work produces additional benefits, especially in developing countries. In 2008, IAVI detailed those benefits in a paper, The Journey Towards an AIDS Vaccine: Perspectives on Conducting Trials in Developing Countries, which was based on interviews with nearly 100 individuals involved in AIDS vaccine studies in 10 developing countries. Findings included:

- **Trial volunteers reported that their health and well-being improved as a result of their participation in AIDS vaccine studies.** They reported greater self-esteem and increased access to health education and services. Through its trials and HIV studies, IAVI and its partners have provided voluntary HIV testing and counseling to more than 100,000 people in Africa. In many cases, antiretroviral therapy is provided for study participants who become HIV-infected through risky behaviors.

- **Staff at clinical trial centers gained skills and experience,** career enhancement and a greater exposure to social science and non-clinical fields. Their new skills can and have been transferred to other scientific efforts, for example, to develop a malaria vaccine, microbicides to prevent HIV infection, and new drugs to treat AIDS.

- **At the national level, vaccine studies have built scientific capacity, strengthened institutions, enhanced physical infrastructure and laid the groundwork for future access to AIDS vaccines.** By providing employment for national researchers, these studies have helped counteract the brain drain that negatively affects low- and middle-income countries. Equipment and facilities from AIDS vaccine studies remain after research projects end, supporting other research and health-care activities.

- **Studies provide useful data.** For example, because many healthy African volunteers were being excluded from AIDS vaccine trials based on blood levels developed for Western populations, IAVI and its partners conducted breakthrough research to define “normal” values for local populations. These standards now enable researchers in Africa in a variety of fields to more accurately screen for healthy volunteers and monitor the well-being of trial participants.

by either vaccine alone. IAVI and partners in 2008 prepared for two trials using the DNA-MVA regimen, one at two locations in India—the National AIDS Research Institute in Pune and the Tuberculosis Research Centre in Chennai—and another at the St. Stephen’s AIDS Trust at London’s Chelsea and Westminster Hospital. Data from these trials will be available in 2009 and 2010.

IAVI and partners also began preparations in 2008 for a Phase I trial of an HIV vaccine candidate based on adenovirus type 35 (Ad35). Adenoviruses have been popular vectors for AIDS vaccine development. But because many people have been exposed to the common adenoviruses, and
thus have pre-existing immunity to them, IAVI and partners are pursuing a platform based on Ad35, a rare adenovirus type that most people have never encountered. Preparations for the “first in man” Phase I trial of this vaccine candidate, at the University of Rochester in New York, were completed in time for immunizations to begin in early 2009. If the candidate shows satisfactory results in this preliminary trial, IAVI expects to work with collaborators to move it, as a component in a prime-boost regimen, into trials in Africa.

IAVI moved forward on an AIDS vaccine candidate that belongs to a new generation built on replicating vectors. Developed along with the Japanese firm DNA VEC, it is based on the Sendai virus, which infects the respiratory tracts of animals, with the aim of generating mucosal immunity. The candidate would be delivered through a nasal spray. The Sendai candidate is currently early in preclinical development.

One key innovation championed by IAVI is a method of more efficiently testing T-cell vaccine candidates for efficacy. The process, which IAVI dubbed a Screening Test of Concept (STOC) Trial, uses smaller numbers of volunteers to more quickly determine whether a candidate has any efficacy. If it does, then further resources can be devoted to testing it in a larger trial for efficacy or improving it before further testing. These streamlined trials would save time and money, and better inform decisions about which products to accelerate. In the wake of the STEP results, the concept of this type of screening trial gained support in the AIDS vaccine field. The next efficacy trial scheduled after STEP was redesigned from a traditional, large trial to a more efficient, small trial.

One of IAVI’s main goals is to build and support clinical trial capacity in countries most heavily affected by HIV so that vaccine candidates can be tested where they are needed most. In preparation for future STOC trials, and to gain information relevant to vaccine design, IAVI has established a robust clinical research program consisting of several protocols, some of which have already provided scientific benefits. The ongoing Protocol B and related studies explore the incidence of HIV in various populations to plan for future STOC trials and to improve strategies for involving individuals at highest risk of HIV infection in clinical studies. Protocol C assesses acute HIV infection with an eye toward understanding how the human immune system responds to HIV infection. These studies also will provide data on circulating types of HIV that will inform vaccine design. Protocol D established reference ranges for blood test results in a variety of settings in Africa.
These help establish whether volunteers are healthy. Using relevant ranges serves to accelerate recruitment and improve the ability to monitor the health of participants not only in AIDS vaccine trials but also in trials of interventions for other emerging infectious diseases. Protocol F involves the study of the seroepidemiology of certain viruses in the developing world and thus provides information relevant to the selection of vectors for AIDS vaccine candidates. And Protocol G, as noted earlier, identified elite neutralizers, who are key to attacking the HIV neutralizing antibody problem.

In addition, IAVI and partners are helping to study a promising, experimental approach to HIV prevention called pre-exposure prophylaxis, or PrEP—the taking of antiretroviral drugs by uninfected individuals to reduce the risk of acquiring HIV. A number of other ongoing and planned studies are testing or will test the safety and efficacy of daily-administered PrEP. But some individuals may not be able to afford or gain access to PrEP daily and may instead use PrEP on an intermittent basis. In fact, such off-label usage already has been reported in the United States. Studies in animal models have shown efficacy for both daily and intermittent PrEP. With no clinical studies underway to test whether intermittent PrEP is safe, acceptable or effective, or to evaluate what drug levels can be achieved when the drug is taken intermittently, IAVI decided to pursue these questions. In 2008, IAVI made preparations to study the safety and acceptability of taking antiretroviral therapy as pre-exposure prophylaxis on an intermittent basis, in this case twice a week and after sex. These small trials, in different populations, are not designed to evaluate efficacy. This research could yield information about whether people who are at risk for HIV exposure develop immune responses against HIV, and how taking PrEP might influence this process, something that has not been studied in humans to date. Data from animal models suggests that there may be an important interaction between PrEP and immune responses generated by HIV exposure. These findings may provide valuable insights for the development of improved AIDS vaccine candidates.

**SPURRING INNOVATION**

Appreciating the need to bring fresh ideas into AIDS vaccine R&D, in 2007 IAVI, in partnership with the Gates Foundation, initiated a new program, the Innovation Fund, which grants awards to encourage small- and medium-size entities working outside the HIV vaccine field to experiment with promising ideas that could advance AIDS vaccine R&D.

“Whether it takes us 15 years, 20 years, 25 years to get an AIDS vaccine, it is what will break the back of the disease.”

—Melinda French Gates, Co-chair and Trustee, Bill & Melinda Gates Foundation
In 2008, the innovation team evaluated and assessed more than 80 technologies, 30 of which were subjected to a rigorous screening process. In the course of the year, the fund awarded grants to six projects in the United States, Belgium, Britain, India and South Africa. The fund’s focus for the year was on the design of immunogens for improved cell-mediated responses to HIV, the design of immunogens that elicit neutralizing antibodies, and assay development and...

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**Thinking Out of the Box**

IAVI’s Innovation Fund, a partnership with the Gates Foundation, was designed to bring scientific entities, mostly biotech companies, working outside the HIV vaccine field into the fold. The program gives seed money to develop experimental technologies that could advance AIDS vaccine R&D. In 2008, the Fund awarded grants to six projects:

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<tr>
<th>Recipient</th>
<th>Usual focus</th>
<th>Innovation grant purpose</th>
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<tr>
<td><strong>Theraclone</strong></td>
<td>Development of therapeutic antibodies for the treatment of infectious diseases and inflammation using the I-STAR™ Antibody Discovery Platform</td>
<td>To isolate broadly neutralizing antibodies against HIV from the sera of HIV-infected individuals</td>
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<td>Seattle, Washington, U.S.</td>
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<tr>
<td><strong>Dr. Michel Nussenzweig</strong></td>
<td>Combines biochemistry and molecular biology with gene targeting and transgenic technologies to better understand the molecular aspects of adaptive and innate immune responses</td>
<td>To devise a method of purifying and cloning B-cells that can express broadly neutralizing antibodies</td>
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<td><strong>Elevation Biotech</strong></td>
<td>Design and discovery of novel and small peptides to generate neutralizing antibodies against HIV</td>
<td>To produce an antigen that will generate in vaccinees neutralizing antibodies to HIV</td>
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<tr>
<td><strong>Strand Life Sciences</strong></td>
<td>Combines data mining, predictive modeling, bioinformatics and computational chemistry to develop products for drug discovery for pharmaceutical companies worldwide</td>
<td>To apply computer-modeling expertise to design antigens that generate neutralizing antibodies against HIV</td>
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<td><strong>Lipoxen</strong></td>
<td>Biopharmaceutical company providing lipid-based delivery solutions to improve the efficacy and performance of drugs and vaccines</td>
<td>To design a lipid-based HIV vaccine candidate</td>
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<tr>
<td><strong>Algonomics</strong></td>
<td>Provides integrated immunogenicity services to pharmaceutical companies</td>
<td>To apply the Epibase® tool to modify an HIV protein to improve the immune responses elicited by vaccine candidates</td>
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technologies for accelerating the rate at which AIDS vaccine candidates are screened—that is, assessed for promise. [See sidebar, opposite page]

The purpose of the Innovation Fund, which is on schedule to meet its target of granting 15 to 20 awards over three years, is to finance out-of-the box initiatives that would not necessarily attract private investment but would, if successful, pay off significantly in scientific terms. With such high-risk ventures, the expectation is that most will fail. By year’s end, however, an award to the U.S. biotech firm now called Theraclone to test a unique platform for isolating broadly neutralizing antibodies to HIV from serum appeared to pay off, an advance that may help accelerate the effort to solve the neutralizing antibody problem.

**SCIENCE ADVOCACY**

In a series of biannual *AIDS Vaccine Blueprints* starting in 1998, IAVI has offered its suggestions to the field for speeding advances in AIDS vaccine R&D. In its 2008 *Blueprint*, unveiled in August at the International AIDS Conference in Mexico City, IAVI sought to reset both expectations and focus in the search for an AIDS vaccine. The *Blueprint* offered a roadmap for the future—a series of interim goals to bring the field closer to the ultimate goal of a safe, effective and accessible vaccine. It proposed that progress be measured against those shorter-term scientific milestones. In the future, IAVI plans to report the progress of its own R&D programs against those milestones.
PART III WORKING WITH COMMUNITIES

Listening, learning

Kenya. Uganda. Rwanda. Zambia. South Africa. India. IAVI-supported clinical research centers conduct their work where the problem is most urgent. These centers are where the rationality of science meets the human reality of the AIDS crisis. In places like Kangemi, Masaka, Kigali, Lusaka, Nyanga and Pune, people are living every day with the consequences of AIDS. None of the vital R&D toward an AIDS vaccine for the populations that need it most would be possible without the ground-level involvement of these communities, coupled with the political commitments of their local and national governments. Engaging these communities, encouraging them to take ownership of the fight against AIDS, is a bedrock principle at IAVI. This engagement flows two ways: While IAVI and its partners in these countries build and maintain the physical and intellectual capacity for scientific research, they also conduct social research to facilitate that work, and engage surrounding populations to educate, raise awareness and cultivate support. In turn, voices from those communities inform and reshape the contours of the clinical projects and the overall effort.

The nexus of that interaction is a Community Advisory Board—key representatives of area populations—and a trial center’s Community Liaison Officers—staff members responsible for local mobilization. In October 2008 in Johannesburg, IAVI convened community liaison officers from collaborating clinical research centers to update them on developments in AIDS vaccine R&D and to enable them to share their experiences in community outreach. At that meeting, IAVI field-tested a recently developed toolkit for Community Advisory Boards, offering guidelines and practical advice to enhance effectiveness and outreach. In Beijing, IAVI and the Chinese Academy of Medical Sciences held a workshop to discuss the experience of Community Advisory Boards in China so far and how to adapt international guidelines on community involvement to the Chinese context. The meeting provided the basis for a set of guidelines on community boards that are being developed for use throughout China.

IAVI also completed and launched its Vaccine Literacy Toolkit, a compendium of educational and training materials to provide consistent, comprehensive information on AIDS vaccine development. The toolkit has been used in training sessions with Community Advisory Board
members, reporters, government officials and representatives
from non-governmental organizations that support AIDS
vaccine work. The toolkit is available not just to IAVI
and collaborators but to other actors in the AIDS vaccine
field. As part of IAVI’s increasing involvement in China,
components of the kit were translated into Chinese and
distributed at four IAVI-sponsored meetings in Beijing.

To further its educational mission, IAVI, along with the
Nigeria-based Journalists Against AIDS and other partners,
conducted a three-day training workshop in Uganda for
African journalists. The sessions were aimed at equipping
journalists to report accurately on efforts to develop new
prevention tools against AIDS.

IAVI has developed and field-tested a manual on
integrating gender issues into clinical research in Africa. The
program is designed to improve awareness and understanding
of gender issues relevant to AIDS vaccine clinical research.
Over the years, AIDS vaccine researchers have learned that
recruiting sufficient numbers of women into trials often
requires special strategies. For instance, because women bear
the largest burden of domestic responsibilities, follow-up
visits may have to accommodate their schedules and the need
for on-site child care. Gender-sensitivity training has been
conducted for clinical research center workers, Community
Advisory Boards and members of other organizations
working on HIV vaccine R&D in sub-Saharan Africa. At the
International AIDS Conference in August 2008 in Mexico
City, IAVI and partners disseminated a brief and presented
findings on a research project in East Africa, Social and
Gender Impacts of Participation in HIV Vaccine Trials.

At a satellite session at that conference and at a
symposium in advance of the AIDS Vaccine Conference in
Cape Town in October 2008, IAVI focused on the need to
develop female-initiated and -controlled methods of HIV
prevention. In China, in a meeting organized by Tsinghua
University’s AIDS Policy Research Institute, IAVI and other
research organizations and women’s groups came together
to build a joint movement for investment in new prevention
technologies, including vaccines, to protect women from HIV.
As a result, a Gender Advisory Group was formed to provide
ongoing advice related to clinical trial research in China and
to serve as the point of contact for future efforts on this issue.

Social science research is another link in IAVI’s chain
of commitments to developing countries. Some studies
are designed to improve the clinical research process
while others aim to understand communities at high

“HIV infection is more than 25 years old, and
we may spend another 25 years searching for
its vaccine, but we have to keep the faith—the
same faith that scientists kept for 47 years as they
searched and found a vaccine against polio.”

—Madame Jeannette Kagame,
First Lady of Rwanda
New Twists on the AIDS Vaccine Message

In response to widespread disappointment regarding the results of the STEP trial, IAVI in 2008 undertook a comprehensive review, including outreach to key informants, to develop a communications strategy for the post-STEP era. Based on this review, IAVI decided, in addition to arguing that a vaccine remains an urgent priority, to stress the following messages:

- Evidence suggests an AIDS vaccine is possible. There are indications from human observations and animal studies that the immune system can thwart immunodeficiency viruses. This implies that a vaccine against human immunodeficiency virus is possible.

- Patience is needed in vaccine development. It often takes decades to develop a vaccine. For example, the chickenpox vaccine took 42 years to develop. By contrast, HIV was only identified as the causative agent of AIDS in 1983. Yet history indicates that the time required to develop a vaccine is clearly worth it—in the case of chickenpox, incidence of the disease has fallen by 83% in the United States in the vaccine era.

- Work continues unabated on an AIDS vaccine. Although large-scale clinical trials attract the greatest media attention, a full-court effort remains underway, yielding an expanding body of science that is contributing to the development of improved vaccine candidates.

- Focused scientific inquiry can generate extraordinary progress. When HIV was discovered, the antiretroviral drugs now used to treat AIDS were thought to be beyond the reach of science. Yet today we have more drugs to treat HIV than for all other viruses put together. That just demonstrates what is possible when we focus the power of science on a problem.

A HISTORICAL LOOK AT VACCINE DEVELOPMENT

<table>
<thead>
<tr>
<th>Infectious agent (linked disease)</th>
<th>Years elapsed between linking of agent to disease and the licensing of a vaccine in the U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles</td>
<td>10</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>16</td>
</tr>
<tr>
<td>Human papillomavirus (cervical cancer)</td>
<td>12-25</td>
</tr>
<tr>
<td>Rotavirus (diarrheal disease)</td>
<td>33</td>
</tr>
<tr>
<td>Varicella zoster (chickenpox)</td>
<td>42</td>
</tr>
<tr>
<td>Pertussis (whooping cough)</td>
<td>42</td>
</tr>
<tr>
<td>Polio</td>
<td>47</td>
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<tr>
<td>Haemophilus influenza</td>
<td>92</td>
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<tr>
<td>Typhoid</td>
<td>105</td>
</tr>
<tr>
<td>Malaria</td>
<td>116</td>
</tr>
<tr>
<td>Human immunodeficiency virus (AIDS)</td>
<td>26</td>
</tr>
</tbody>
</table>

Risk of HIV infection and thus how best to inform them of and engage them in vaccine research. In 2008, IAVI sponsored or assisted in four studies related to HIV in communities in southern Africa; presented data from a study in India focusing on men who have sex with men and on transgender communities; in collaboration with the Creative Research and Evaluation Centre in Uganda and the Overseas Development Group at the University of East Anglia, initiated a pilot study among fishing communities in Uganda; and continued collaboration on a study in the Indian state of Tamil Nadu concerning political attitudes and perceptions surrounding the introduction of the new vaccine against human papillomavirus.
PART IV SUSTAINING SUPPORT

Shaping the debate

The immense challenges of fighting HIV require not just local mobilization but sustained national and international will. This is all the more so in the wake of the STEP trial results, which in some quarters generated pessimism around prospects for an AIDS vaccine. At the same time, matters including climate change and the economic downturn competed for space with global health issues like AIDS.

Through active media outreach, IAVI worked to influence the post-STEP commentary. IAVI President and CEO Seth Berkley published opinion pieces in media outlets such as the Wall Street Journal and the Guardian, and co-authored commentaries with Rwandan First Lady Jeannette Kagame in the Boston Globe and with Nobel Laureate David Baltimore in the Los Angeles Times. In its outreach, IAVI sought to remind policy-makers and the public at large of the inevitability of failure in the development of new products for health, the learning that results from failure and the continued importance of AIDS vaccine R&D. [See sidebar, opposite page]

IAVI’s own website and publications, including fact sheets, brochures and papers, informed readers about the need for an AIDS vaccine and the progress toward one. IAVI’s India office published the newsletter Sankalp in English, Tamil and Marathi, and the East Africa office inaugurated its own newsletter, Pamoja. IAVI Report, the scientific journal on AIDS vaccine R&D, and its sister publication VAX, for lay readers, got complete makeovers in 2008. [See sidebar, next page]

Across six continents, IAVI worked in 2008 in myriad other ways to strengthen and sustain financial and political support to achieve an effective AIDS vaccine, and to raise the profile of vaccines within larger discussions of HIV prevention and global health. At the U.N. General Assembly Special Session on HIV/AIDS and at high-level U.N. meetings surrounding progress toward the Millennium Development Goals—the humanitarian, environmental and global health goals world leaders aim to achieve by 2015—delegations from developed and developing countries expressed support for continued investment in research and development of new HIV prevention technologies.

The year saw three middle-income countries that are affected by AIDS and possess burgeoning R&D sectors—
India, Brazil and South Africa— all take steps to deepen their commitment to AIDS vaccine work. India for the first time included a commitment to “advancing research and development of HIV vaccines” in its Five-Year Plan, which lays out the central government’s long-term policies. Brazil launched a National AIDS Vaccine Plan, including significant funding for R&D. As part of the rollout, IAVI is providing the government with technical assistance to develop an agenda for investment. For its part, the transitional South African leadership that came into power in September 2008 expressed support for evidence-based approaches toward HIV, including vaccine R&D. IAVI continued to work with the Departments of Science and Technology in these three countries to encourage AIDS vaccine R&D cooperation within the framework of the IBSA (India, Brazil, South Africa) Dialogue Forum, a grouping that promotes collaboration among the three. The declaration that emerged from the fourth IBSA meeting of science and technology ministers, held in 2008, included agreement on developing AIDS vaccine R&D projects.

With support from IAVI and the International Partnership for Microbicides, the U.K.’s Department for International
Development (DFID) organized a high-level meeting on new tools for HIV prevention. DFID Minister of State Gareth Thomas announced that his government would spend £220 million (about US$ 350 million on that date) over five years to support product-development research for new prevention tools, including vaccines, to fight AIDS, malaria, tuberculosis and other diseases. In his remarks, Thomas stressed the importance of long-term support to entities developing new drugs, vaccines and other medical tools.

As a public-private partnership, IAVI is positioned not only to advocate for sustained governmental commitments to AIDS vaccine R&D, but also to promote national strategies to encourage private-sector innovation in biomedical research. This is important because industrial entities have considerable vaccine development know-how but have been reluctant to enter an enterprise in which profits and timelines are so uncertain. For the aids2031 initiative, a consortium seeking ways to take action now to change the course of the epidemic by the year 2031, IAVI prepared a paper on stimulating innovation in research and development. The aids2031 initiative brings together economists, epidemiologists and scientists to question conventional wisdom, stimulate debate and encourage new thinking on HIV and AIDS issues. IAVI's paper, presented in November, explored dedicated funding initiatives such as IAVI’s Innovation Fund; the Gates Foundation’s Grand Challenges Explorations; prizes for biomedical breakthroughs; advance market commitments for new products; and revised intellectual property approaches such as patent extensions or patent buyouts.

In a similar vein, IAVI continued in 2008 to collaborate with the Global Health Technologies Coalition, the Aeras Global TB Vaccine Initiative and the PATH Malaria Vaccine Initiative to explore ways to accelerate the development of new health technologies and to create new financing mechanisms for that work.

IAVI and several AIDS treatment and prevention organizations also urged the U.S. Food and Drug Administration to include HIV in its Priority Review Voucher program, which provides the sponsor of a newly approved drug that treats or prevents an eligible tropical or neglected disease the right to fast-track another product through the approval process, or to sell that right. The FDA is considering comments from IAVI, among others, as it begins to implement the program.

To support the fact-based case for the value of an AIDS vaccine, IAVI continued its work modeling the impact of

“Developing a preventive HIV/AIDS vaccine is going to be much tougher than we originally thought. And we need as many people as possible committed to helping us reach this goal.”

—Dr. Omu Anzala, Associate Professor at the University of Nairobi School of Medicine and Director of the Kenya AIDS Vaccine Initiative
such a vaccine on various countries that have been hit hard by the epidemic. Impact studies highlight the relevance of AIDS vaccines in fighting the pandemic and are intended to help policy makers, vaccine developers and funders make informed decisions about HIV interventions and investments in AIDS vaccine R&D. IAVI’s work on the global impact of a vaccine has found that a vaccine that is 50% effective given to just 30% of the total population could cut the number of new infections in the developing world by one quarter over 15 years. In 2008, IAVI focused on country-level analyses to complement the global estimates. IAVI sponsored a study in Uganda, conducted by the Uganda Institute of Public Health and guided by the Uganda AIDS Commission, and another in Brazil, conducted by the Evandro Chagas Clinical Research Institute with support from the National Program for STDs and AIDS. Results from both studies will be published in 2009. A similar study was begun in Kenya, by the Kenya AIDS Vaccine Initiative in collaboration with IAVI and the Futures Institute, with results also expected in 2009.

Appreciating that considerable work remains to be done, and at considerable expense, to deliver an effective AIDS vaccine, IAVI has increasingly worked to diversify its funding base. Despite the economic recession, IAVI’s existing government donors remained committed to the organization in 2008. Of note was the Spanish government’s decision to triple its 2007 commitment to €3 million (US$ 4.67 million on that date) for the year. In 2008, foundations, corporations and individuals contributed a significant amount of cash and in-kind gifts to IAVI. Of note was a new US$ 10 million multi-year grant from the Starr Foundation in support of the Design Lab and Innovation Fund.

Given what are likely to be the time requirements for developing an effective AIDS vaccine, IAVI’s advocates, researchers and fund-raisers have begun to explore means of engaging potential stakeholders from a younger generation. To help recruit promising young scientists to the field, from developing countries as well as from the West, IAVI began preparations for a scientific fellowship program, set to roll out in the near future. To attract young people who might be interested in the mission in general, IAVI began to look for them where young people, especially in the developed world, can generally be found: on the internet. The organization in 2008 conducted a comprehensive overhaul of its website to increase its user-friendliness and its ability to support new media, began to explore the use of social networking sites and launched, on YouTube, a series of 30-second video testimonials from individuals around the world in support of AIDS vaccine development.

“Those of us who were born into a world without AIDS owe it to future generations to leave behind a world that is again free of AIDS.”

—Dr. David Kihumuro Apuuli, Director General, Uganda AIDS Commission
PART V LOOKING AHEAD

Promises to keep

Eight years ago, world leaders at the United Nations committed themselves to the Millennium Development Goals, an ambitious program of humanitarian, environmental and global health efforts to be accomplished by 2015. One of those targets is to halt and reverse the spread of HIV and AIDS. In 2008—the halfway point of this framework—the rate at which HIV is spreading globally appears to be stable. That’s good news, but it obscures the fact that HIV incidence has stabilized at an atrocious rate, such that 2.7 million people become infected annually. And every year, more people than ever are living with HIV. Although access to AIDS treatments has expanded dramatically in recent years, these life-prolonging drugs still reach barely one-third of those in need. When the drugs are available, they serve to mitigate but not end the pandemic. For every two people who receive antiretroviral treatment, five others become infected with HIV.

AIDS doesn’t just destroy lives, it undermines entire societies. AIDS compromises other development goals such as poverty reduction, improvements in child and maternal health and nutrition, gains in basic education and control of other infectious diseases. And the increasing financial burden of AIDS compromises investments in these other important priorities.

With its focus on solutions for and engagement with the countries in which the AIDS burden is greatest; its fully integrated model incorporating policy work, advocacy and R&D; and its emphasis on speed, flexibility and innovation, IAVI remains well-positioned to continue making contributions to the development of a safe, effective and accessible AIDS vaccine. Such a vaccine remains the surest path to ending the pandemic. That path is longer and more difficult than once believed, but along the way IAVI has planned and executed strategic changes while remaining faithful to its mission. Many of those changes bore fruit in 2008, nourishing IAVI and its partners for the journey ahead. With sustained commitment, the dream of a vaccine can become a reality, not just for Rose’s granddaughters but for the entire world.
A solid foundation

IAVI’s financial position remained strong in 2008, with net assets of more than US$ 126 million. The total revenue for 2008 was US$ 91 million; expenditures totaled US$ 96 million. This revenue was raised despite a challenging environment in the wake of the STEP study results and a serious economic downturn, with many donors re-confirming their commitments to IAVI for 2008.

While the public sector continues to be the most significant source of funding for IAVI, it dropped from 89% of funds in 2007 to 85% in 2008 because of an increase in contributions from foundations, reflecting IAVI’s efforts to diversify its funding base. In keeping with this effort, IAVI has initiated a sponsored research program to raise new dollars for applied research.

Our 2008 strategy strongly emphasized investment in innovation and vaccine design, as well as strengthening work to ensure global commitment to a vaccine. We increased funding for our vaccine design program and our hallmark Neutralizing Antibody Consortium, and 2008 was the first full operational year of our Innovation Fund, developed to finance early-stage breakthrough technologies. We continued building upon IAVI’s solid foundation of global policy research and advocacy work while ensuring our engagement with partners and communities in the countries most affected by the AIDS pandemic.
In 2008, IAVI had 194 employees working in seven countries. Add in the IAVI-funded staffs at partner institutions and organizations and the number of people involved leaps to 724.

Members of the IAVI team represent more than 30 nationalities

The majority of the 724 IAVI-funded positions are at clinical research centers

More than half are women

IAVI staff
Clinical research center staff

“Hello, Lusaka, It’s La Jolla Calling”

The IAVI staff list reads a bit like an atlas. IAVI’s employees are spread across the globe. The entire organization aims to work seamlessly to ensure the development of an AIDS vaccine. But sharing a single goal means IAVI staff must be able to communicate with far-away colleagues in real time, on an ongoing basis. So in 2008 the organization strengthened its internal communications capacity, beginning the roll-out of new technology to facilitate effective communication and information-sharing in real time.

IAVI’s new telephone system includes an instant messaging function, which eventually will allow staff in Nairobi to immediately reach staff in Amsterdam or New York. The system includes a social messaging function, similar to techniques used by Yahoo or Facebook, that informs individuals of the location of colleagues—for example, in a staff meeting, at a departmental retreat, traveling to an IAVI-supported clinical trial center in Zambia.

Apart from facilitating quick communications, the new system will reduce IAVI’s phone bills. When traveling, staffers can use their laptop computers to make international phone calls, bypassing more costly mobile phones, phone cards or hotel lines. By increasing the capacity for high-quality videoconferencing, the improvements also will reduce the need for international travel, helping IAVI maximize the use of every dollar of financial support toward its mission of contributing to the earliest possible emergence of an AIDS vaccine.
Summary of 2008 Achievements

A report like this one can’t possibly encompass the efforts of the hundreds of dedicated people working at and with IAVI toward a world without AIDS. The following pages provide a compendium of accomplishments in 2008, organized by the goals articulated in IAVI’s Strategic Plan 2008-2012. These snapshots provide a quick look at the many ways IAVI reaches across political, corporate and social boundaries to bring together the best minds working to end the AIDS pandemic.
STRATEGY I 2008 OBJECTIVES AND ACCOMPLISHMENTS

Implement a focused and innovative R&D program

1. Identify promising AIDS vaccine candidates for advancement to efficacy trials

- IAVI received verbal approval from the FDA to advance a candidate based on Ad35 to an initial Phase I clinical trial in Rochester, N.Y.

- First immunizations were given in a Phase I trial of a DNA+MVA prime-boost candidate in London; approval was given to test the same candidate in a Phase I trial in India.

- Development continued of a candidate based on a Sendai vector in collaboration with the Japanese firm DNAVEC.

2. Address the major vaccine design challenges impeding the development of a safe and effective AIDS vaccine

Efforts focused on solving the HIV neutralizing antibody problem were expanded:

- In the Protocol G study, of nearly 2,000 subjects screened about 10% were identified as having broadly neutralizing antibodies to HIV and a subset were determined to be elite neutralizers; cells from elite neutralizers were being assessed by various technologies for identification of broadly neutralizing monoclonal antibodies for use by the Neutralizing Antibody Consortium (NAC) to facilitate immunogen design.

- A B cell immunobiology program focused on enhancing B cell memory responses to HIV antigens was established as part of the Neutralizing Antibody Consortium.
  - Gunilla Karlsson of the Karolinska Institute joined the NAC, focused on dissection of B cell responses to guide Env immunogen design.
  - The biotech firm Spaltudaq, of Seattle, and scientist Michel Nussenzweig, of Rockefeller University, received awards through IAVI’s Innovation Fund to probe the B cell repertoire by independent approaches, with the goal of identifying broadly neutralizing monoclonal antibodies against HIV.

- Next generation carbohydrate, protein and peptide-based immunogens for neutralizing antibodies against HIV were screened.
  - Immune complexes demonstrated enhanced breadth and potency compared with antigen alone.
  - First-generation glycan-based immunogens were screened.
  - First-generation computational-biologically designed scaffolds were screened.
  - Peptide mimetic immunogen screening was initiated.

- A plan was developed to focus more commitment of time from NAC principal scientists and a key milestone was achieved through establishment of the IAVI Neutralizing Antibody Center at The Scripps Research Institute in La Jolla, California.
The capacity of IAVI’s AIDS Vaccine Design and Development Laboratory was expanded to accelerate development of replicating viral vectors:

- Construction of the new lab facility was completed.
- Key milestones achieved included supporting work that produced the preliminary assessment of efficacy of the persistently replicating CMV vector; the rescue and initiation of construction of the prototype mucosally targeted Reovirus vector; initial design/construction of mucosally targeted canine distemper and Newcastle disease virus vectors; and construction of control DNA and Ad5 vectors to serve as baseline controls in non-human primate challenge studies. An algorithm for prioritization of replicating viral vectors in the portfolio was developed.

Progress was achieved toward informing the design of next-generation candidates to control HIV infection:

- The next set of studies from the Live Attenuated Consortium (LAC) was completed and how these translated to new vaccine designs was documented.
  - The first large-scale study of live attenuated SIV (delta-nef, 239) vs. homologous and heterologous challenge was completed at the University of Wisconsin. This study elucidated the levels of protection and key cellular immune responses elicited by the vaccine when a high-dose intravenous challenge was employed.
  - The first phase of a two-phase study looking at the very early immune responses and localization of live attenuated SIV was completed by Ashley Haase (University of Minnesota) and Paul Johnson (New England Primate Center). This study already is providing seminal information of where live attenuated SIV is replicating (perifollicular regions of GALT- nodes), suggesting that mucosal targeting may be required to mimic immune responses conferred by live attenuated SIV.

- IAVI’s Human Immunology Lab advanced its Viral Inhibition Assay to the point where HIV controllers, non-progressors and vaccinees are now being assessed. Comparable assay development is proceeding in parallel for assessment of monkeys immunized with SIV vaccines by the LAC, including at IAVI’s Design Lab.

IAVI’s Innovation Fund granted awards in 2008 to six entities working outside the AIDS vaccine field to fund experimental technologies that could advance the field:

- Theraclone (U.S.) has a process for isolating broadly neutralizing antibodies to HIV from the sera of HIV-infected individuals.
- Michel Nussenzweig at Rockefeller University (U.S.) has a different process for isolating broadly neutralizing antibodies to HIV.
- Strand Life Sciences (India) is working toward the same goal using computer-generated designs.
- Lipoxen (U.K.) is designing a lipid-based HIV vaccine candidate.
- Elevation Biotech (South Africa) is working to produce an antigen that will generate in vaccinees neutralizing antibodies to HIV.
- Algonomics (Belgium) aims to modify an HIV protein to improve the immune responses elicited by AIDS vaccine candidates.
STRATEGY II 2008 OBJECTIVES AND ACCOMPLISHMENTS

Secure and sustain global commitment

1. Persuade key political leaders, policy-makers and opinion leaders that sustained, robust financing for AIDS vaccine R&D is a wise and critical investment

With the help of its many partners, IAVI helped organize or participated in multiple events and efforts to enhance support for the AIDS vaccine field, including:

- A high-level conference on new prevention tools against HIV for the U.K.’s Department for International Development, supported by IAVI and the International Partnership for Microbicides, at which the U.K. committed £220 million (about US$ 350 million) on product-development research for neglected diseases.

- The U.N. High-Level Meeting on the Millennium Development Goals, where an IAVI policy brief was widely disseminated and was endorsed by 43 IAVI partner organizations worldwide.

- Two visits to clinical trial research centers in East Africa for European parliamentarians and donors.

- A seminar in Brussels on the role of new E.U. member states in fighting AIDS.

- The Kenya National AIDS Control Council’s Parliamentarian Conference on HIV/AIDS, which called for more government funding of health-care research, including on HIV vaccines.

- The Global Ministerial Forum for Health in Bamako, Mali, which included AIDS vaccines in its final action plan.

- The report of the HIV Vaccines and Microbicides Resource Tracking Working Group, of which IAVI is a part, presented at the 2008 International AIDS Conference in Mexico City.

2. Position AIDS vaccines as a vital component of a comprehensive global AIDS response and international development agenda

With 2008 marking the midpoint of the Millennium Development Goals effort, discussions were held globally about the role of research in improving public health, stimulating development and improving aid. Both the U.N. General Assembly Special Session on HIV/AIDS and country delegations at the U.N. Millennium Development Goals Review meeting expressed strong support for continued investment in these tools.

- IAVI President Seth Berkley spoke at a session of the Mexico City conference titled "Vaccines and Microbicides, Where do we go from here?"

- IAVI and several NGOs sponsored a briefing—hosted by the permanent missions of India and the Netherlands to the U.N.—before the U.N. High-Level Meeting on HIV/AIDS. More than 95 ambassadors and their representatives received an update
3. Further improve communication of the field’s main achievements and challenges

- IAVI’s AIDS Vaccine Blueprint 2008: A Challenge to the Field, a Roadmap for Progress laid out IAVI’s views of specific challenges ahead, as well as a plan for overcoming them.

- IAVI clinical research center network investigators had 43 articles published in scientific journals in 2008.

- IAVI engaged in active outreach to media around the world and responded quickly to media inquiries to maximize accurate coverage of issues. IAVI’s work was covered in some 120 features in global media monitored by the organization; IAVI spokespersons were quoted in 71 of those.

4. Ensure that IAVI serves as a trusted source for scientific, policy and advocacy information and guidance on AIDS vaccines

- IAVI Report, a bimonthly scientific newsletter on AIDS vaccine R&D, was relaunched with an updated, four-color design, enhanced graphics and increased coverage of scientific conferences and meetings, in keeping with the findings of a comprehensive reader survey. Its sister publication, VAX, for lay readers, also was redesigned. The redesigns spurred increased subscription requests.

- IAVI’s India office published six issues of Sankalp, a newsletter on AIDS vaccine R&D issues in India—in English, Tamil and Marathi. IAVI’s East Africa office inaugurated its own newsletter, Pamoja.

- IAVI collaborated with AVAC, the African AIDS Vaccine Programme and other organizations to sponsor a satellite symposium at the International AIDS Vaccine Conference in Cape Town, South Africa, on such topics as basic research literacy; ethics in HIV research; gender, vaccines and HIV prevention; and priorities for the field.

- IAVI co-hosted with AVAC an open forum in Johannesburg to introduce the Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials.

- IAVI and partners sponsored a satellite session in Mexico City highlighting the need to address gender inequalities that exacerbate women’s vulnerabilities to HIV and the need for investment in research on HIV prevention for women.
STRATEGY III  2008 OBJECTIVES AND ACCOMPLISHMENTS

Promote public policies that support vaccine R&D and future access

I. Generate concrete progress with regard to the adoption of policies to accelerate AIDS vaccine R&D and to promote future access to safe and effective vaccines

- To influence debates on global health R&D and financing mechanisms, IAVI took part in the deliberations of the WHO’s Intergovernmental Working Group on Public Health and Innovation.

- IAVI and partners analyzed the potential impact of AIDS vaccines in Brazil, Kenya and Uganda to build the case for a vaccine and to inform policy decisions.

- At the request of the aids2031 initiative, IAVI analyzed incentive mechanisms for stimulating innovation in R&D.

- IAVI and several AIDS treatment and prevention organizations urged the U.S. FDA to include HIV/AIDS in its Priority Review Voucher program.

- IAVI analyzed regulatory, procurement and pricing processes for AIDS vaccines, in part to identify potential barriers to access.

- IAVI, along with the Aeras Global TB Vaccine Foundation and the Malaria Vaccine Initiative, explored the feasibility of a new financing mechanism for PDPs.

- IAVI and partners analyzed opportunities to accelerate vaccine R&D in Brazil.

- IAVI’s public policy department published six policy briefs, three joint publications, one journal article and several other presentations, including:
  - The Journey Toward an AIDS Vaccine: Perspectives on Conducting Trials in Developing Countries
  - Strengthening the Response to HIV and AIDS: Helping Make the MDGs a Reality
  - Unleashing Europe’s Biopharmaceutical Innovation Potential

- IAVI conducted a qualitative research study in the Indian state of Tamil Nadu on the views of Indian policy makers on the introduction of the HPV vaccine, in an effort to identify factors that would influence those views.

- IAVI supported a workshop on female-initiated HIV prevention technologies organized by China’s Tsinghua University’s AIDS Policy Research Institute, and formed a gender advisory group for new HIV prevention technology research in China.

- IAVI supported research and publication from the Rwanda/Zambia HIV Research Group on the effectiveness of couples voluntary counseling and testing as a method for reducing transmission of HIV.

- Among the Public Policy Department’s publications were:
  - WHO’s Key Normative Processes and Institutions for Vaccines: A Primer
  - Sustaining the HIV Prevention Research Agenda: Funding for Research and Development of HIV Vaccines, Microbicides and Other New Prevention Options, 2000 to 2007
  - U.S. FDA Priority Review Vouchers: An effective incentive to develop drugs and vaccines for neglected diseases?
I. Strengthen the capacity to accelerate clinical trials of AIDS vaccines in developing countries

- The IAVI-supported network of clinical and laboratory facilities was expanded to 12 centers capable of conducting clinical research studies to the highest ethical and technical standards, with associated laboratories to analyze safety and some immune response parameters. The centers are in India, Kenya, Rwanda, South Africa, Uganda and Zambia.

- IAVI conducted studies to define at-risk groups and their HIV incidence at clinical research centers in Kenya, Rwanda, Uganda and Zambia, and supported infrastructure and training to prepare for a similar study in a mining community near the IAVI-affiliated research center in Rustenburg, South Africa.

- IAVI developed the document Clinical Guidance: Essential Approaches for IAVI Clinical Research to help partners conduct clinical research and communicate to stakeholders the approach of the IAVI-supported network on such issues as community engagement, informed consent, counseling, referrals for health services, post-exposure prophylaxis, laboratory management and gender issues.

- IAVI upgraded clinical and laboratory facilities, trained staff and installed sophisticated equipment at several clinical research centers in eastern and southern Africa.

- IAVI field-tested a new toolkit for community advisory boards. In East Africa, IAVI held an annual meeting with CAB liaison officers and supported cross-CAB networking in Uganda.

- To aid the recruitment for the planned Phase I trial in India, community outreach tactics were developed jointly with the two host clinical trial centers.

- IAVI entered into a formal agreement with the Ndlela HIV Vaccine Trial Center in Agincourt, South Africa. The grant supported infrastructure development and other work.

- IAVI supported a site exchange between the research center in Rustenburg and the Desmond Tutu HIV Foundation, which has operated in Cape Town for more than five years. Rustenburg staff members observed strategies for community outreach.

- IAVI issued an award to the Tutu Foundation to conduct a follow-up survey to assess changes in knowledge, beliefs, stigma and safe practices in the trial center community. The survey is an effort to measure the effectiveness of an education program initiated in 2003.

- In Rustenburg, IAVI supported research to explore community social mapping; sexual risk behavior of men and women; HIV-related stigma; and the factors influencing the uptake of HIV testing services.

- IAVI and its partners ICRW and the University of Nairobi published a summary of the results of a study on barriers to women’s participation in vaccine research in Kenya. The findings are being used to help research centers build staff capacity to address gender issues and shape recruitment and retention strategies.
IAVI provided financial support to the International Council of AIDS Service Organizations to produce a guide and CD-ROM to improve the involvement of communities in HIV vaccine R&D.

IAVI presented a proposal to the Indian government to establish a vaccine design laboratory in that country.

With IAVI input, the official Five Year Plan (2007-2012) of India included language on "advancing research and development of HIV vaccines."

A workshop on new HIV prevention tools was coordinated by India's National Coalition on Health Initiatives, an IAVI-supported group.

IAVI launched its vaccine literacy toolkit, a set of educational materials designed to disseminate consistent, comprehensive information to civil society partners. The toolkit was introduced in Kenya and Uganda, and materials were translated into Chinese and distributed at IAVI-sponsored meetings in Beijing.

IAVI and partners supported the Nigerian organization Journalists Against AIDS in convening a three-day workshop in Uganda on reporting about new HIV prevention tools.

IAVI conducted training and advocacy initiatives with a network of some 120 organizations in Kenya interested in supporting HIV vaccine research.

IAVI supported the launch of Brazil’s National AIDS Vaccine Plan, which includes a government commitment of US$ 25 million over five years. IAVI is collaborating with Brazil’s National AIDS Program to develop an agenda for investing the money.

IAVI convened several workshops and networking opportunities in China, including a session on gender issues and new prevention tools, a meeting with researchers and a workshop on community advisory boards.

IAVI worked with the Departments of Science and Technology in India, South Africa and Brazil on promoting cooperation. A working group produced a memorandum of understanding and identified priority items for further discussion.

IAVI signed a memorandum of understanding with the South African AIDS Vaccine Initiative to bolster information-sharing and collaboration between the two organizations.

2. Promote national support, capacity and policies to facilitate research and ensure future access to a vaccine

IAVI supported the launch of a national committee of Brazilian NGOs working on vaccines to ensure greater integration of partners on the ground.

IAVI convened a workshop on research incentives in Brazil to identify strategies to boost Brazil’s engagement in AIDS vaccine R&D.

IAVI supported cross-regional training and exchanges for clinical, counseling and laboratory staff and community advisory board members throughout the IAVI clinical research center network.

IAVI participated in the East African Legislative Assembly’s Annual Partnership Forum, which is organized by the assembly and UNAIDS.

3. Ensure learning and collaboration across countries and IAVI programs, and that the global agenda is informed by country-level experience and perspectives
Refine IAVI’s internal operations

1. Ensure proper stewardship of IAVI’s financial assets worldwide and provide timely, accurate and relevant financial information, analysis and planning to IAVI management and external constituencies

   - The organization continued in 2008 to invest net assets in a conservative manner and weathered the economic downturn at year’s end with positive returns.
   
   - All audits were conducted and passed with no material findings.

2. Pursue business processes and strategies that promote speed, flexibility, innovation, partnership and access

   - IAVI entered into several new partnerships and innovative funding programs to advance its AIDS vaccine research and development program.
   
   - A new development collaboration was put in place with the Aeras Global TB Vaccine Foundation to design and test new BCG-based vector designs.
   
   - A workshop was sponsored by IAVI with leading product-development partnership organizations to identify and share best business practices in intellectual property, alliance management and legal issues in PDP research and development.
   
   - IAVI sought to make publicly accessible its research results through numerous presentations and publications.

3. Support and facilitate operations worldwide through best management and human resource practices and state-of-the-art technology

   - The organization developed appropriate data management systems and IT infrastructure for the new Design Lab in New York and the IAVI Neutralizing Antibody Center at The Scripps Research Institute in California.
   
   - IAVI launched a new intranet portal to improve access to corporate content and knowledge.
   
   - IAVI rolled out a new unified voice communication system and video conference system to improve global communications and realize savings in travel and telephone expenditures.
   
   - The organization hired an internal audit firm, RSM McGladrey, to support its own internal efforts in quality assurance and compliance.
   
   - The performance management system was reviewed and upgraded. A pilot study was conducted using the Success Factors platform to benchmark the IAVI system against best practice.

   - Human Resources policies and
4. Mobilize sufficient financial resources to achieve IAVI’s strategic goals in 2008-2012

- Ninety-two headquarters staff took part in training in effective participation in teams and committees.

- Proactive HR risk management resulted in proper tax management for international hires; an audit of health and welfare benefits, resulting in US$ 16,000 of corrections in employee deductions; and establishment of individual pension plans for all international hires and establishment of retirement plans for our London staff.

- Working with partners through the Global Health Technologies Coalition, IAVI ensured that the US$ 48 billion reauthorization of the U.S. President’s Emergency Plan for AIDS Relief included supportive language for advance market commitments for the eventual purchase of new vaccines and for efforts to promote vaccine development. This reauthorization, which also made reference to IAVI’s work, will guide how the U.S. government implements its global AIDS programs over the next five years.

- IAVI maintained its positive relationships with and financial support from its public-sector donors around the world. Funding from USAID and the Canadian International Development Agency remained steady, as did support from European governments, including those of the Netherlands, Sweden, Norway, Ireland, Denmark and the United Kingdom, as well as the European Union. The Spanish government significantly increased its commitment to IAVI. The World Bank renewed its commitment. Efforts continued to solicit new public-sector donors, including Japan and Germany.

- To help fund construction of the IAVI AIDS Vaccine Design and Development Laboratory, IAVI entered into an agreement with the New York Economic Development Corporation, as well as into a series of transactions that qualify under the Federal Historic Preservation Tax Incentives Program and the U.S. Treasury’s New Markets Tax Credit program.

- Foundations, corporations and private individuals contributed a significant amount of cash and in-kind gifts in 2008. Of note was a US$ 10 million grant from the Starr Foundation to support the Design Lab and the Innovation Fund. Corporate support increased.

Note: IAVI’s Strategic Plan 2008-2012 featured an additional objective under Strategy 3: “Define the likely efficacy scenarios for cell-mediated vaccines in 2008-2012 and identify appropriate policy responses to each.” In the aftermath of the STEP trial results, IAVI determined that this was not a high priority for 2008.
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