There has never been a more exciting time to be involved in AIDS vaccine development. In just the past three years, we have witnessed the first demonstration that a vaccine may prevent HIV infection and a series of scientific breakthroughs that could revolutionize HIV vaccine design. These advances have inspired researchers and advocates alike, and have contributed greatly to a growing optimism about the prospects of a future vaccine against HIV. Yet they have occurred in the context of an extended economic downturn that has taken a toll on donor nations, threatening funding for many global health initiatives, including AIDS vaccine development.

In response to this reality, IAVI began in 2011 a process of internal assessment and stakeholder engagement to establish the foundation for a new strategy, one better suited to the changed environment. As a board member, I was aware of this strategic review and regularly updated on its progress. But after I became CEO, in July last year, I truly began to appreciate the complexity of the endeavor. Joining the effort has been at once bracing and educational. In shaping the new strategy, I have learned about the many facets of this organization and how it is perceived, the talents of its people and the value created in its long-standing research and advocacy partnerships across the globe. I have benefitted from input from multiple external stakeholders who appreciate IAVI’s contributions and encourage us to contribute to the field even more, focusing on the unique contributions we can make.

The plan that follows seeks to do just that. In its substance, it is an amalgam of the insights and advice shared by IAVI’s leaders, friends, advisors, donors and partners about how IAVI can best serve the field of AIDS vaccine development. The plan also presents a roadmap for improving the effectiveness of the organization and ensuring the effective and efficient application of its resources and assets in partnership with other organizations.

We hope this summary will clarify our new strategy. Though the specific goals and priorities it describes have been carefully formulated and refined, they are not written in stone. Like any effective organization, IAVI must change tack and redirect its resources and energies to respond to changing data and circumstances. What will not change, however, is our commitment to ensuring the development of effective and accessible AIDS vaccines to truly end this pandemic.

Sincerely,

Margaret McGlynn
There have been profound changes in the context in which IAVI operates over the past few years. This includes breakthroughs in AIDS vaccine research and development, progress of other novel HIV-prevention strategies as well as a continued global economic downturn that today threatens the long-term sustainability of all such research. These changes have prompted IAVI to evaluate its existing strategic plan and develop one that reflects the changed environment in which it operates, provides a more compelling vision of the role IAVI can play to advance AIDS vaccine development and aligns employees, partners and donors with that vision to speed progress toward our shared goal of ending the AIDS pandemic.

As part of its strategic review, IAVI conducted an analysis of the AIDS vaccine field; a series of consultations with partners, donors and its own leaders; and an assessment of the organization’s current strengths and weaknesses to determine how and where it can add the most value to the field. Over the next four years, IAVI will help advance the development of an AIDS vaccine by:

**EXECUTIVE SUMMARY**

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
<th>IAVI will:</th>
</tr>
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<tbody>
<tr>
<td>1 Accelerating the development of AIDS vaccines by identifying opportunities and gaps in the field and ensuring that IAVI invests its resources in areas that add most value</td>
<td>• Implement a formalized process to gain input from global stakeholders on opportunities and gaps where IAVI can add the greatest value to the field</td>
</tr>
<tr>
<td>2 Harness partnerships to expand the diversity and number of novel AIDS vaccine candidates</td>
<td>• Focus on selected discovery programs with key external partners to yield novel HIV vaccine candidates • Build on the discovery of new and potent broadly neutralizing antibodies to design immunogens capable of preventing infection by the diverse variants of HIV circulating worldwide • Advance a select number of replicating vectors into clinical trials to create a new generation of AIDS vaccine candidates that elicit more potent and enduring immune responses • Become a product-development resource for the field to help external partners translate product concepts into vaccine candidates by leveraging IAVI’s internal capabilities, expertise and extensive network of external partners • Contribute to the conduct of clinical studies by leveraging clinical trial centers where IAVI has long-standing relationships and capitalizing on clinical capacity established by other available networks</td>
</tr>
<tr>
<td>3 Building support for AIDS vaccine development</td>
<td>• Seek R&amp;D collaborations globally to capitalize on the innovation and existing scientific capabilities of emerging economies and developing countries and to access a broader range of international funding opportunities • Stimulate support for AIDS vaccine R&amp;D by supporting capacity for clinical trials in developing countries and fostering voices of the global South in AIDS vaccine-related advocacy • Ensure that investment in HIV prevention and AIDS vaccine R&amp;D remains central to public policy and international health and development agendas by working closely with other stakeholders and donors to serve as a voice for the field</td>
</tr>
</tbody>
</table>
Mission and vision

**Mission:** To ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.

**Vision:** A world without AIDS

IAVI’s mission unifies employees and resonates as deeply with partners and donors as it does with policymakers and communities in developing countries. The mission and vision remain unchanged.

What the current strategy does reconsider is how IAVI might best ensure the development of an AIDS vaccine—through what it does in its own programs, how it partners with others, and how it applies the resources at its disposal and the talent of its employees and partners to the broader benefit of the field. To guide that change, IAVI has formulated an organizational vision statement that enunciates how it aspires to be regarded by stakeholders and partners. That statement is as follows:

IAVI will be a respected and effective product development partnership that works with other stakeholders to play a key role in accelerating the development of an AIDS vaccine accessible to all.

- A prominent advocate for global support and sustained funding for AIDS vaccine development
- A promoter of policies to ensure prompt global access to future HIV vaccines

IAVI will become an organization that relevant stakeholders seek out as a partner. It will equate its success with the success of the AIDS vaccine field, emphasizing urgency and speed in advancing the most promising candidates, whether they have been developed internally or externally. Similarly, IAVI’s advocacy and policy programs will be conducted in collaboration with others. IAVI will also enhance internal efficiencies and business practices to improve the quality of its partnerships. By establishing priorities and making decisions in a consultative and transparent fashion, IAVI will clarify its role in the field, enhancing its effectiveness in pursuit of its mission.

Specifically, IAVI seeks to be known across the field as:

- A partner of choice for stakeholders involved in AIDS vaccine research and development
- A driver and facilitator of selected discovery research for the benefit of the field
- A collaborator supporting the development and clinical evaluation of AIDS vaccine candidates of relevance to developing countries

In order to develop its strategic framework, IAVI conducted an analysis of the AIDS vaccine field; a series of consultations with partners, donors and its own leaders; and an assessment of the organization’s current strengths and weaknesses to determine how and where it can add the most value to the field.
The International AIDS Vaccine Initiative (IAVI) was founded in 1996 to raise global awareness about the unmet need for AIDS vaccines and to promote their development. From the outset, the organization emphasized the need for AIDS vaccines of relevance to developing countries, where the HIV pandemic has hit hardest. That emphasis was, in fact, woven into its mission: To ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.

As IAVI marks its 15th anniversary, that mission remains as relevant as ever. AIDS still claims nearly 2 million lives every year, taking a disproportionate toll on the most vulnerable and impoverished in developing countries. Antiretroviral drugs have transformed prognoses for HIV-positive people in many places, yet the provision of such treatment has not yet kept pace with the pandemic, despite a remarkable scale-up in the past decade. Significant scientific advances in the last two years indicate that ending the pandemic is truly within reach. However, an AIDS vaccine remains an essential part of the combination prevention efforts that will effectively, and sustainably, do just that.

**Breakthroughs in HIV vaccine research**

Applied research for HIV vaccine design has also proceeded apace. Dozens of novel broadly neutralizing antibodies have been identified by researchers working with IAVI as part of the Neutralizing Antibody Consortium and, independently, by colleagues at the Vaccine Research Center of the US National Institute of Allergy and Infectious Diseases (NIAID), among others. If they can be elicited through vaccination, such antibodies may be able to overcome HIV’s extreme mutability, which has long frustrated attempts to devise preventive HIV vaccines. Structural analysis of the newly isolated broadly neutralizing antibodies has revealed common vulnerabilities on the viral surface that might be targeted by candidate vaccines. The antibodies variously target four distinct regions of the HIV spike, proteins on HIV’s surface that the virus uses to gain entry to its target cells. Structural, biochemical and genetic analysis of some of the new antibodies and their targets—or epitopes—have also yielded significant scientific insights, setting the stage for a new era of rational vaccine design that promises...
to yield more broadly effective vaccines than was previously thought possible. These advances have implications that reach beyond HIV vaccine research. The technologies and approaches that made them possible are now being used to identify vulnerabilities on other pathogens, such as the influenza and hepatitis C viruses. While potentially game-changing, success in devising HIV immunogens on the basis of these studies will take time, sustained investment and considerable effort.

Several preclinical studies of novel vectors for HIV vaccines have produced promising results as well, far exceeding the performance in similar studies of candidates that are today in clinical trials. We expect that these vectors will prove capable of provoking stronger, better sustained responses against HIV. Such responses could markedly improve the outcome of vaccination, by either blocking HIV infection or boosting the body’s ability to suppress the virus following infection. Some of these candidates, such as those based on replicating vectors, face several product-development challenges and, given their novelty, significant regulatory hurdles. Researchers have thus far advanced three HIV vaccine candidates built on replicating vectors into clinical trials, and many more will enter clinical evaluation over the next few years.

Other advances in HIV prevention

Other strategies for HIV prevention have registered impressive successes as well. These include voluntary male circumcision—which can be as much as 60% effective in preventing HIV infection in men—and the therapeutic prevention of mother-to-child transmission. On the research side, assessments of HIV treatment as a means of prevention have provided remarkably encouraging results, fueling calls for more aggressive and expanded treatment of HIV-positive people. One recent study revealed, for example, that ARVs diminish viral transmission by 96% when used as early treatment by an HIV-positive person whose partner is HIV negative. Several intriguing results have also emerged from studies examining the use of ARVs as prophylaxis by HIV-negative people who are at high risk of infection. These findings have fueled calls for greater access to ARVs, even as national governments and donor nations struggle to meet their existing commitments to providing universal access to such drugs under current treatment guidelines. These discoveries herald a profoundly changed landscape for HIV-prevention research, not least due to the impact they’re likely to have on the size and design of future AIDS vaccine trials. Impact modeling suggests that a comprehensive prevention response to HIV will be essential to “get to zero,” and that any such approach must include an AIDS vaccine.

The political and economic environment

The incredible gains in the science are, unfortunately, playing out against a dramatically altered political and fiscal environment. The sustained downturn in the global economy has limited the growth of funds available for global health generally, and AIDS specifically, at a time when increasing funds are required to implement interventions and advance research. With the potential impact of an AIDS vaccine so far in the future, there remains a need to help policymakers appreciate the value such a vaccine might have in the context of treatment and other prevention options.
IAVI’s existing assets

IAVI has identified unique organizational assets that can be leveraged over the next several years for the benefit of the field.

1. Capacity for vaccine development

Over the last decade, IAVI has worked with its nonprofit, public- and private-sector partners to design 22 AIDS vaccine candidates, evaluating 13 of them in early-stage human trials in 11 countries in Asia, Africa, Europe and North America. IAVI’s many long-standing partnerships with academia, biotech, government institutions, contract manufacturing organizations and pharmaceutical companies worldwide have been instrumental to these efforts. They have given IAVI access to innovative technologies, expertise and laboratory capacity that is complemented by its own research infrastructure and staff.

2. Scientific collaborations in the developing world

The engagement of developing countries, where the AIDS pandemic has taken the greatest toll, is central to IAVI’s operational model. Most notably, IAVI has forged productive partnerships with research centers in Africa to evaluate AIDS vaccine candidates and conduct related epidemiological research. It has also established programs for AIDS vaccine design and development with the Government of India.

3. Applied and translational research

Since it launched the Neutralizing Antibody Consortium in 2002, IAVI has been one of the principal drivers in the discovery of broad and potent neutralizing antibodies to support the rational design of immunogens. IAVI and its partners in academia and industry, along with the Vaccine Research Center of the NIAID, have identified dozens of novel broadly neutralizing antibodies since 2009. This analysis is yielding clues to the design of a new generation of AIDS vaccines. With funding from the Coalition for AIDS Vaccine Discovery of the Bill & Melinda Gates Foundation (BMGF), IAVI also established the Replicating Vectors Consortium in 2005 to develop better strategies for harnessing cell-mediated immunity. IAVI has also taken deliberate steps to help bridge the gap between basic research and product development. It has established an AIDS Vaccine Design and Development Laboratory in New York, led by scientists who have considerable expertise in such translational research.

4. Global advocacy for AIDS vaccine R&D

IAVI has, since 1996, forged close relationships with advocates and policymakers in the countries that have been hit hardest by the HIV pandemic and, at the global level, with political leaders, donors, civil society organizations and other key stakeholders. It remains a trusted voice on issues related to AIDS vaccine research and development.

How IAVI has filled gaps in the field of AIDS vaccine development, 2000-present

<table>
<thead>
<tr>
<th>Gap</th>
<th>IAVI approach</th>
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<tr>
<td>Lack of infrastructure to test clinical vaccine candidates in the developing world</td>
<td>Established Clinical Research Center (CRC) network in Africa</td>
</tr>
<tr>
<td>Need for validated clinical immunology assays and processes to permit valid comparison of clinical data across space and time</td>
<td>Established Human Immunology Laboratory; built capabilities of CRCs</td>
</tr>
<tr>
<td>Absence of a coordinated effort to solve the neutralizing antibody problem</td>
<td>Launched the Neutralizing Antibody Consortium</td>
</tr>
<tr>
<td>Lack of investment in novel vaccine approaches as a hedge against the potential failure of existing approaches harnessing cell-mediated immunity</td>
<td>Launched the Replicating Vectors Consortium</td>
</tr>
<tr>
<td>Limited range of biomedical technologies applied to HIV research</td>
<td>Established the Innovation Fund with BMGF to tap technologies from outside the field, particularly those developed by biotechs</td>
</tr>
<tr>
<td>Need for a greater variety of broadly neutralizing antibodies to HIV to expand repertoire of potential vaccine targets</td>
<td>Launched Protocol G, a search for such antibodies involving research centers in 11 countries</td>
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Essential elements for success

To accomplish its mission, IAVI must ensure that it:

1. **Clarifies its role in the field of HIV vaccine development**
   IAVI will work in partnership with key stakeholders and leverage its capabilities and programs together with those of the field. It will clarify its role in upstream research by focusing on opportunities where it can add unique value. IAVI will make its assets available to other researchers to help move their programs forward.

2. **Promotes collaboration to accelerate AIDS vaccine development**
   To create synergy and expedite AIDS vaccine research in a time of constrained resources, it is essential that IAVI be highly effective in collaborating with others in the field. IAVI will engage in a CEO-sponsored process of cultural change over the next year, with a goal of improving how we collaborate with partners.

3. **Embraces transparency**
   To maximize its value to the field and improve donor and stakeholder engagement, IAVI must be more consultative when establishing its priorities and transparent regarding the decisions reached and the rationale behind them. IAVI is taking measures to ensure transparency and has committed itself to an open and consultative process for engaging partners and stakeholders. IAVI has developed a formalized process to seek stakeholder input and better communicate where along the continuum of vaccine design and development it intends to invest the bulk of its monetary, professional and institutional resources.

4. **Promotes advocacy and policy for the field**
   IAVI is in a unique position to serve as a voice for AIDS vaccines. IAVI will focus its efforts on advocating for the field, and will work in partnership with organizations globally, at every level, in its advocacy and policy programs.

5. **Instills an organizational culture that is conducive to partnership**
   IAVI cannot execute this ambitious strategic plan without the strong contributions of other partners. To be successful, IAVI will improve its relationship-management practices to broaden and strengthen its ties with other organizations. We will engage partners in a manner that improves our understanding of their goals, needs and concerns, and employ best practices to ensure our business processes best support our partnerships.
Strategic Framework

**OBJECTIVE 1**
Accelerate the development of AIDS vaccines by identifying opportunities and gaps in the field and ensuring that IAVI invests its resources in areas that add most value.

**OBJECTIVE 2**
Harness partnerships to expand the diversity and number of novel AIDS vaccine candidates.

**OBJECTIVE 3**
Build global support for AIDS vaccine development.
OBJECTIVE 1

Accelerate the development of AIDS vaccines by identifying opportunities and gaps in the field and ensuring that IAVI invests its resources in areas that add most value

IAVI believes that to accelerate AIDS vaccine research and development it must work collaboratively with the field and identify opportunities and gaps where it can best leverage its capabilities and skills.

IAVI will become an organization that relevant stakeholders seek out as a partner. It will equate its success with the success of the AIDS vaccine field, emphasizing urgency and speed in advancing the most promising candidates, whether they have been developed internally or externally.

Similarly, IAVI’s advocacy and policy programs will be conducted in collaboration with others. IAVI will also enhance internal efficiencies and business practices to improve the quality of its partnerships. By establishing priorities and making decisions in a consultative and transparent fashion, IAVI will clarify its role in the field, enhancing its effectiveness in pursuit of its mission.

IAVI will identify opportunities and gaps in the field to determine how it can best add value to AIDS vaccine development, either by its own efforts or by contributing to the programs and projects of other researchers and organizations. IAVI will partner with stakeholders to ensure an accurate assessment of the state of the field and its needs.

Impact 2015

By 2015, IAVI will have maximized the impact of its expertise, infrastructure and funding while leveraging the work and investments of others in the field to accelerate the development of AIDS vaccine candidates.

Deliverables 2011-2015

- Define IAVI’s strategy and priorities in the context of the HIV vaccine field through an ongoing, formalized and transparent process that is inclusive of donors, major research partners and IAVI’s Scientific Advisory Committee
- Accelerate AIDS vaccine research by leveraging IAVI’s resources together with those of the field to increase the number of AIDS vaccine candidates in the clinical pipeline

As opportunities arise, IAVI will selectively invest in the vaccine design programs considered most promising. In doing so, it will consult and coordinate with partners to avoid duplication of effort. IAVI will also ensure that its investments have an additive or synergistic effect on the pace and quality of AIDS vaccine development across the field. It will build on the work done by others and optimize the use of IAVI’s infrastructure and expertise.
OBJECTIVE 2

Harness partnerships to expand the diversity and number of novel AIDS vaccine candidates

Program Priority 1

Immunogens that elicit broadly neutralizing antibodies

This program is currently IAVI’s top R&D priority. If successful, it could transform the AIDS vaccine field by generating vaccine candidates capable of inducing “sterilizing immunity,” of preventing, not merely controlling, HIV infection—a goal that had seemed impossible just five years ago. Over the past decade, IAVI assembled a critical mass of infrastructure, know-how and partnerships in the field of rational immunogen design to support this ambitious program. The investments of IAVI and others have driven the discovery and analysis of multiple broadly neutralizing antibodies, an effort that has yielded novel insights on HIV’s vulnerabilities and how they are targeted by antibodies. Current and future investments will increasingly support the design of immunogens that might elicit such antibodies and so confer protection from a broad range of circulating HIV variants. In pursuit of that objective, IAVI will expand efforts to forge product development partnerships with industry and explore new models for collaboration between the private and nonprofit sectors.

Impact 2015

By 2015, this program will have advanced to preclinical development one or more vaccine candidates capable of neutralizing diverse isolates of HIV circulating worldwide.

Deliverables 2011-2015

- Continue to build partnerships with academia, industry and NIAID to successfully advance immunogen design and screening
- Pursue partnerships with industry to access innovative technologies and capabilities and to secure funding and capacity for development
- Select a first-generation immunogen candidate for pre-clinical development in 2012 to assess rules of immunogenicity for future reference
- Advance one new HIV envelope candidate to product development
Program Priority 2
Replicating viral vectors

IAVI will advance a select number of replicating vectors to clinical trials to create a new generation of AIDS vaccine candidates that elicit more potent and enduring immune responses. In particular, IAVI’s aim is to advance the Sendai vector into early stage clinical trials by 2013, and quickly determine whether emerging data merit further development of two other candidate replicating vectors. The achievement of predetermined milestones will govern the progression of each of these candidates along the vaccine development pipeline.

Impact 2015

By 2015, IAVI will have expanded the number of replicating vector-based vaccine candidates in the pipeline that have the potential to prevent or control HIV infection.

Deliverables 2011-2015

- Assess the field of replicating vectors with key stakeholders to map current investments, assess new opportunities and determine optimal investments to maximize IAVI’s support for the field
- Advance Sendai vector to clinical development
- Select CDV or VSV vector to advance to product development on the basis of data and the needs of the field
- Make lead vector platforms available to others in the field to help optimize their vaccine candidates
Program Priority 3
Accelerating product development across the field

There is a sense across the HIV vaccine research community—one supported by a recent review conducted by the Bill & Melinda Gates Foundation—that many researchers with original and potentially valuable HIV vaccine candidates lack access to the expertise required to translate their concepts into products that can be consistently manufactured on a large scale and evaluated in humans.

IAVI believes that by sharing its product-development expertise with others in the field it can help advance a broader variety of vaccine candidates into clinical development. The product-development expertise of its staff, its partnerships with external providers and vaccine manufacturers and its investments in standing clinical and laboratory infrastructure in Africa put it in a unique position to lend support at every stage of the vaccine-development process. IAVI can thus serve as a product-development engine for the field to help advance novel concepts emerging from academic, pharmaceutical and biotechnology laboratories worldwide.

### Impact 2015

By 2015 IAVI will have accelerated the development of AIDS vaccines by sharing its capabilities in product development with the field. In so doing, IAVI will have helped increase the number, quality and diversity of AIDS vaccine candidates in the pipeline.

### Deliverables 2011-2015

- Build additional partnerships to advance promising vaccine candidates in the field
- Assess overall need, capabilities, available funding and timing for increased investment in a Central Services Facility to provide translational research support to the field
- Establish flexible partnering model with appropriate organizational approach and culture to enable IAVI to work as a collaborator or service provider
Program Priority 4

Sustaining capacity for clinical trials in developing countries

IAVI will contribute to the conduct of efficacy trials of vaccine candidates by forging partnerships with research networks that have established clinical research capacity, and by building unique cohorts in regions where the organization has longstanding relationships and can add value to the field. IAVI will continue to support a comprehensive and sustainable approach to AIDS vaccine research and development through ongoing training at research facilities, by gathering socio-behavioral data on volunteer populations and by engaging and educating communities and stakeholders.

In addition to sustaining capacity for the conduct of clinical trials, IAVI will help advance development of vaccine candidates toward clinical efficacy studies. One of IAVI’s leading priorities in clinical development is the advancement of heterologous vectors to efficacy trials. IAVI has worked with partners to develop the Adenovirus 35 platform, through a range of prime-boost studies examining the Ad35 vector in combination with other protein, DNA and vector-based candidates. IAVI’s intent is to work with partners to advance at least one candidate to Phase IIb trials in Africa by 2015 as a member of the Adenovirus Critical Efficacy Path Partnership (ACEPP).

Impact 2015

By 2015, adequate clinical trial capacity will be available to support HIV vaccine trials for IAVI’s and its partners’ vaccine candidates through IAVI’s clinical research network and collaborations with partner networks.

Deliverables 2011-2015

• In partnership with key stakeholders, conduct an analysis of planned clinical trials and clinical capacity across Africa to identify gaps, seek out partnering opportunities and ensure optimal investments

• Maintain a core of proven partnerships for the conduct of Phase I clinical trials

• Support the availability of clinical infrastructure and appropriate high-risk cohorts in light of geographical variances and recent treatment-as-prevention data to enable Phase IIb efficacy testing of AIDS vaccine candidates

• Advance with partners at least one vaccine candidate to Phase IIb trials in Africa by 2015
OBJECTIVE 3

Build global support for AIDS vaccine development

Program Priority 1

Global collaborations for R&D

IAVI will seek to expand the number and types of collaborations it engages in globally to capitalize on the existing scientific capabilities of a greater number of nations and to leverage international funding opportunities. Over the past 15 years, IAVI has collaborated with scores of researchers around the world, most notably in Africa and India. Most recently, it has announced a program in immunogen design with the Government of India and facilitated the establishment of an HIV vaccine design and development partnership between India and South Africa. IAVI is now working to identify potential collaborations with researchers in China. These kinds of partnerships broaden the base of global support for AIDS vaccine research and development while leveraging the burgeoning technical capacity of emerging economies. To that end, and to ensure the development of vaccines of relevance to the developing world, IAVI will take every opportunity to facilitate the establishment of additional partnerships between governments and researchers of emerging economies as well as developing countries.

Impact 2015

By 2015, IAVI will have helped expand the scope and scale of AIDS vaccine R&D by increasing the number of AIDS vaccine research programs around the world.

Deliverables 2011-2015

- Evaluate opportunities globally to identify promising collaborations for AIDS vaccine research between academic labs, government labs and the private sector

- Develop a joint program for immunogen design and discovery with the Government of India that capitalizes on existing research capacity in India, leverages funding from that government and is integrated with the Neutralizing Antibody Consortium

- Catalyze establishment of transnational AIDS vaccine R&D networks to enhance the productivity of such efforts in India, Brazil, China, South Africa and other countries
IAVI will continue to pursue collaborations with a variety of entities in the regions hit hardest by the AIDS pandemic. Such collaborations will help bolster government and community support for clinical trials and add voices from the South to the call for increased investment in AIDS vaccine R&D. To amplify and build the credibility of such messages, IAVI will expand its partnerships with advocacy networks in Africa and Asia. Mutually supportive relationships with civil society and nongovernmental organizations whose objectives overlap with those of the AIDS vaccine field will help disseminate messages more widely and persuasively. IAVI will continue to support clinical and laboratory research capacity in developing countries, as these partnerships ensure that the candidates under development today will be tested and adopted in the communities that need them most.

**Program Priority 2**

**Collaborations with countries most affected by AIDS**

**Impact 2015**

By 2015, voices from regions most affected by HIV will, with IAVI’s support, feature more prominently in global advocacy for AIDS vaccine development.

**Deliverables 2011-2015**

- Broaden government and community support for clinical trials and the eventual introduction of an AIDS vaccine
- Leverage advocacy networks in India, Africa and other regions to champion investment in AIDS vaccine R&D
- Establish capacity for local resource mobilization and long-term sustainability
Program Priority 3

Securing investment in AIDS vaccine R&D

IAVI will work with partners to advocate for the field and make focused contributions through policy research to make the case for sustained investment in AIDS vaccine R&D. It will thus continue to evaluate and calibrate its communications, advocacy and policy programs in terms of their ability to benefit the field. IAVI’s historic roots as an advocacy organization, its capabilities in policy research and its relationships with policymakers, donors and civil-society organizations around the world will enable unique contributions to global advocacy for AIDS vaccine research and development. Credible modeling of the potential economic impacts and savings from AIDS vaccines, for example, can help make the case to policymakers for long-term investments in AIDS vaccine research.

Impact 2015

By 2015, IAVI and its partners will ensure that the value of AIDS vaccine investment is understood by key stakeholders to support sustained funding for AIDS vaccine R&D and policies that accelerate vaccine development and ensure global access to a future vaccine.

Deliverables 2011-2015

• Develop a focused and integrated policy and advocacy agenda to maximize the synergy and impact of such efforts, identifying key strategic relationships necessary to execute the mission

• Increase the profile of AIDS vaccine R&D by nurturing champions both locally and globally

• Demonstrate potential impact and economic benefits of future AIDS vaccines in the context of the HIV investment framework

• Develop a policy access blueprint for the field to define critical access issues and solutions
Ensuring delivery

We have shaped our strategy to fit the new context of AIDS vaccine research and advocacy, and to reflect the financially constrained environment in which we now operate. The shift in emphasis will gradually alter the operational focus of the organization and its patterns of investment in a number of notable ways.

Over the next five years, IAVI will maximize its investment in R&D. The total percentage spent on each phase of the development continuum may, however, change significantly over time. IAVI anticipates a gradual, data-driven transition in its investments that will ultimately place emphasis on product development as the products in its portfolio, and those of its partners, advance along the development continuum. IAVI fully expects that investment in vaccine discovery programs will yield promising vaccine candidates. Those that meet predetermined milestones will be prioritized for advancement, while those that do not will be dropped. This will allow IAVI to narrow and refine the portfolio of products earmarked for clinical development and so apply resources more efficiently in service to its mission.

Additionally, IAVI will strive to achieve greater efficiency and effectiveness across the organization by minimizing fixed overhead and administrative expenses, implementing best practices and benchmarking against comparable organizations. This plan also stresses the establishment of formalized and transparent decision-making processes that do more to include donors, major research partners, board members and the Scientific Advisory Committee in setting priorities for the organization.

The success of the new strategy also rests on the organization’s ability to change not just

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<th>IAVI will conduct all of its activities around a set of organizational principles tied to its core values</th>
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<tr>
<td>Principle</td>
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<tr>
<td>Leadership and collaboration</td>
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<td>Prioritization and focus</td>
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<td>Flexibility and speed</td>
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<td>Innovation</td>
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<td>Fiscal discipline</td>
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what it does, but how it works. In other words, IAVI must continue to evolve its organizational culture to ensure highly effective partnerships for the benefit of the field. It will have to proactively ensure that the current strategy and its execution remains consistent with the interests of donors, and establish indicators that allow stakeholders to assess the progress of prioritized programs and activities.

Given current constraints on resources, IAVI will have to do much more to coordinate its investments with those of other AIDS vaccine research organizations to ensure its efforts complement rather than duplicate those of others to advance the field. IAVI is also committed to further diversifying its donor base to limit risk, guarantee the sustainability of research and development programs and protect assets that are of value to the field. In addition, IAVI must more deliberately engender a greater involvement of vaccine manufacturers in AIDS vaccine research. They bring to the endeavor unique experience in development, large-scale production, testing and distribution of vaccines. Similar efforts to boost the engagement of the biotech industry, which is responsible for much of the innovation in vaccines today, will also bring benefit to the field. Beyond that, IAVI believes there exists a largely untapped opportunity to partner with the biomedical research programs of emerging economies. These partnerships could maximize their investments and reserves of scientific talent to advance AIDS vaccine development and ensure that those nations are well integrated into the global effort, which should facilitate the future adoption and distribution of AIDS vaccines.

Finally, IAVI is developing an implementation plan to support the effective execution of its strategic plan over the next five years.

IAVI’s implementation plan will include:

- A change-management plan to instill an organizational culture that excels in partnering and is supportive of the new strategic plan
- A formalized process for setting strategy and priorities that includes consultation with donors, partners, the Scientific Advisory Committee and other key stakeholders
- Specific milestones for evaluating both R&D and non-R&D programs
- Improved business processes to increase efficiency and accountability
- A revised resource mobilization strategy that demonstrates how we will fund the new strategic plan, including a donor-engagement plan to build and nurture relationships
- Monitoring and evaluation to demonstrate value of investments and measure success against the goals of the strategic plan
- A contingency plan based on alternative financial scenarios that incorporates input from donors and key stakeholders

IAVI’s implementation plan will include:
In many ways, this new strategy seeks not to change what IAVI is, but to make it better at being what it is supposed to be: a product development partnership. IAVI has forged productive partnerships with dozens of organizations around the world, and it now seeks to become more collaborative and consultative in its management of such relationships. Similarly, having launched the Neutralizing Antibody Consortium and helped pioneer the large-scale discovery and structural analysis of broadly neutralizing antibodies, it is now preparing to apply what it has learned through those efforts to promote diversity in the kinds of vaccine candidates undergoing clinical evaluation. IAVI will likewise continue to support cohorts for HIV research in Africa, but ensure that they are appropriate in the context of a changed landscape of HIV prevention and that capacity is balanced with expected need. In all of this, IAVI will pay more attention to being transparent in its decision-making and rigorous in evaluating its own performance against the objectives laid out in the strategy.

This strategic plan encapsulates the organization’s current views about how it can best serve the field. It is, in other words, a living document. IAVI will modify the strategy if emerging data and other major changes in the global environment warrant such adjustment. The ultimate objective of this strategy, after all, is the advancement of the field as a whole. As such, it must retain the flexibility essential to serving the shifting needs of a rapidly evolving science.

In the coming years, we can be certain that this strategy will need fine-tuning. HIV vaccine development has always been a scientifically challenging andlogistically complex endeavor. That, at least, has not changed. IAVI expects that, in the main, the changes it is now initiating in its own programs and methods of operation will go far in helping the field achieve its objective: the development and worldwide distribution of safe and effective vaccines to reverse the tide of the AIDS pandemic.

**Conclusion**

*What has changed since IAVI’s last strategic plan*

- A cultural shift that increases collaboration and consultation with other researchers and organizations
- A formalized process to identify opportunities and gaps in the field, where the application of IAVI’s resources and capabilities will add most value
- A gradual transition of focus downstream in the product-development continuum, with greater emphasis on the preclinical development of vaccine candidates, including support for those of others in the field, and the evaluation of candidates in clinical trials
- An explicit strategy to increase industry engagement and funding
- A continued commitment to working in partnership with developing countries, with a focus on balancing the scale of clinical capacity with expected needs
- A commitment to systematically pursuing selected opportunities to leverage research expertise and funding opportunities in developing countries and emerging economies
- A unified and focused agenda for policy and advocacy that is formulated and implemented with key partners to help make IAVI a voice for the field
- A commitment to instilling best-practice business processes across the organization to maximize efficiency and effectiveness
- An enhanced donor-engagement strategy to demonstrate increased transparency, accountability and value-for-money
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IAVI’s mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.