



Danish Organisation Strategy
for
International AIDS Vaccine
Initiative (IAVI)

2014-2018

September 2014

1. Objective

1.1. Objective of strategy

This strategy for the cooperation between Denmark and the International AIDS Vaccine Initiative (IAVI) forms the basis for the Danish contributions to IAVI and is the central platform for dialogue and partnership with the organisation. It follows the guidelines for short organisation strategies for organisations receiving less than DKK 35 million in annual contribution from Denmark. It follows and outlines the Danish priorities for IAVI's performance within the framework established by IAVI's own *Strategic Plan 2011-2015*¹. The Danish strategy for IAVI follows the duration of the Danish organisation strategy for the 'sister' initiative, the International Partnership for Microbicides (IPM) covering 2014-2018. The present organisation strategy will be revised, if warranted by IAVI's strategy covering 2016 onwards.

1.2. Objectives of the organisation

IAVI was established in 1996 as a non-profit Product Development Partnership (PDP) and has since then grown to become a respected and effective partner in the global HIV/AIDS response. The organisation provides leadership within the field of research and development of AIDS vaccines with a special focus on the virus strains which are prevalent in developing countries. The objectives of IAVI are to accelerate the development of AIDS vaccines by identifying opportunities and gaps in the field and ensure that IAVI invests its resources in areas that add most value; to harness partnerships to expand the diversity and number of novel AIDS vaccine candidates; and to build support for AIDS vaccine development.

IAVI works with its partners in developed and developing countries to identify gaps in existing research and to design, prioritise and prepare infrastructure for clinical testing of AIDS vaccine candidates. Its niche within the broader field of research and development is translational work taking scientific results through the chain of development of a pharmaceutical product and preparing roll-out of the product to end users. The organisation is also concerned with capacity development – creating research infrastructure in the South – and advocacy efforts to mobilise awareness about AIDS vaccine research.

2. The organisation

2.1. Basic data and management structure

IAVI is a partnership of five types of collaborators: i) Bio-tech industry (such as GlaxoSmithKline, Crucell and Algonomics; ii) Academic institutions and government laboratories (incl. Imperial College, University of Oxford, Aarhus University and Statens Serum Institut; iii) African research institutions (incl. Kenya AIDS Vaccine Initiative/University of Nairobi, Wellcome Trust-KEMRI, Uganda Virus Research Institute; iv) Multilateral and Civil Society Organisations (WHO, UNAIDS, AIDS Fondet, Kenya AIDS NGO Consortium; and v) other Project Development Partnerships, including the International Partnership for Microbicides.

Headquartered in New York, IAVI is a global organisation with regional offices in Amsterdam, Nairobi, Johannesburg and New Delhi. It is organised to work with 100 key collaborators including researchers, policy makers and civil society organisations representing key populations and affected communities in 23 countries.

¹ IAVI has recently commenced initial development of a new strategy covering 2016 onwards.

Organisational background facts	
Established	1996
Headquarters	New York, USA
Regional offices	Amsterdam, The Netherlands; Nairobi, Kenya; Johannesburg, South Africa; New Delhi, India
Collaborations (academia, industry, governments)	More than 100 in Europe, Japan, India, Africa and the US
CEO	Margaret G. McGlynn
Human resources	155 employees located in the US, Europe, Africa, and India locations.
Previous Danish funding	2012-2014: 15 M DKK 2012-13: 7.5 M DKK 2010: 10 M DKK 2001-2008: 65 M DKK

The governing body of IAVI is organised around the Board of Directors which is responsible for overseeing management and strategic direction. The Board has 13 members, each elected for staggered three-year terms. The directors are recruited based on academic and organisational merit within the fields of experience in government, industry,

private foundations and non-governmental organisations. The members of the Board are not paid or remunerated for their services to the organisation. Two advisory committees (Scientific and Policy Advisory Committee, respectively) provide strategic advice on governance and policy to the senior leaders.

2.2. Mission and mandate

IAVI's mission is to create the conditions for a world without AIDS through the discovery of an AIDS vaccine which can be effective throughout the world. It is a leading organisation in the field of AIDS vaccine research and development working to expedite the identification of a preventive AIDS vaccine through public-private partnerships.

The core of the organisation's mandate is to ensure that a future preventive AIDS vaccine will be effective and available throughout the world, thus also for people in the South who are not a priority for the for-profit pharmaceutical industry. The organisation works with key populations such as male and female sex workers, men who have sex with men, and other vulnerable groups to ensure their participation in a plan for the distribution and uptake of a future vaccine.

2.3. Achievements and mode of operation

Achievements

IAVI has made substantial achievements within its prime areas of work: to conduct AIDS vaccine trials and related epidemiological research, to develop research and technical capacity in developing countries, and to build support for AIDS vaccines.

Regarding the first area of work, IAVI has achieved a robust and promising scientific track record. Since 2000, the organisation has tested 15 new vaccine candidates in 26 clinical trials and has built strong clinical and laboratory consortia in Sub-Saharan Africa and India. In 2009, the AIDS vaccine field had a significant year, achieving results that prove that making a preventive, effective vaccine is possible. The evidence included positive results from the first human AIDS vaccine trial where a vaccine candidate protected 30% of volunteers

from HIV infection²; the discovery of new broadly neutralising antibodies that can prevent HIV infection from the major HIV virus types circulating globally; and results from a study in monkeys in which a vaccine was shown to clear infection from 50% of the population. In 2013, IAVI and partners demonstrated cutting-edge progress in two priority areas of AIDS vaccine science³. The new scientific knowledge generated from the testing of IAVI candidates will be used in vaccine design and creates a space for optimism. Researchers globally are now turning these discoveries into the next generation of powerful new vaccine candidates. The next set of efficacy trials to test these concepts is anticipated to begin in 2016/2017. The work of IAVI has a positive “add-on effect“, beyond the immediate scope of IAVI. IAVI makes its research findings and results available to other research groups, thereby contributing to potentially faster development of a vaccine.

Over the last two years, IAVI has taken the strategic decision to diversify its product pipeline to include four different vaccine strategies, each with multiple different candidates, with a goal of ensuring it continues to support and/or fund the best opportunities in the field, and therefore contributes to finding an AIDS vaccine in the fastest possible time.

IAVI has built clinical research capacity across Africa through the establishment of a network of Clinical Research Centres with highly skilled staff. These centres are learning environments for the national partners through the establishment of tests and processes to permit valid comparison of clinical data. More than 1,600 clinicians and laboratory staff have received training in good clinical practice, and South-based junior investigators are increasingly being promoted to principal investigators or trial directors. This contributes to the retention of talented African researchers and clinicians. The creation of local academic opportunities is in line with Danish wishes to strengthen South-driven research.

Mode of Operation

IAVI works through a diverse range of institutional, strategic and ad-hoc partnerships. These partnerships harness expertise and resources, improve the quality and impact of IAVI’s work, build and share knowledge between developed and developing countries, and raise the visibility and influence of those most affected by the AIDS pandemic.

With the aim of increasing the engagement in and ownership of the national health response in regions most affected by the pandemic, IAVI and its partners have developed a well-established programme for research capacity building work in Eastern and Southern Africa, with a focus on research and related activities that will benefit the most vulnerable populations. This programme includes continued investment in skills transfer, training and mentoring of African researchers and research technicians. This helps build southern based research capacity and works to ensure that the highest scientific and ethical standards are applied in conducting vaccine trials and related epidemiological studies.

IAVI takes a comprehensive public health approach to engaging communities in AIDS vaccine research and is committed to a response that requires within its work approach a range of prevention interventions including,

² The trial is commonly referred to as ‘the Thai trial’ (or RV-144) as it was conducted in Thailand, involving more than 16,000 volunteers.

³ Those areas being ‘broadly neutralising antibodies’ and ‘replicating viral vectors’.

for example, increasing access to sexual and reproductive health education and services, particularly for women, young people and vulnerable populations such as men who have sex with men (MSM), and voluntary HIV counselling and testing, with referrals for appropriate treatment, care and support for all volunteers in IAVI's clinical trial programmes.

2.4. Effectiveness of the Organisation

IAVI has been subject to several independent evaluations and reviews over the past years. In the *Irish Aid Review of Support to Product Development Partnerships* and the *Review of Denmark's Support to the Response to HIV/AIDS* (both 2011) the organisation has been characterised as a relevant partner because of its unique focus on HIV vaccine research and development and for its ability to foster clinical and research capacity with its collaborating research consortia in the South. The Danish review was in favour of the PDP modality and noted *"that vaccine development is a high-risk but high-return investment which only public sector institutions are willing to finance"* and recommended that the Ministry of Foreign Affairs considered increasing its funding to this purpose⁴. The Irish review noted that *"IAVI continues to provide value for money. IAVI is contributing to building scientific and regulatory capacity and infrastructure in developing countries which should foster economic growth"*.

In an independent Evaluation of the International AIDS Vaccine Initiative 2003-2009, initiated by the World Bank, the conclusion was also positive acknowledging that *"IAVI has been a leader in developing capacity in the developing world for clinical trials, and for helping to enable trials to be carried out effectively, efficiently, and to high ethical standards"*. The evaluation noted, however, that there was room for improvement with regard to benchmarks to measure how IAVI compares to other organisations and to the relatively high turnover among key personnel.

Due to a general downturn in funding, the budget of IAVI shrank and IAVI was downsized to become a smaller, more cost-effective organisation. Measures taken to overcome a more than 20% cut in budget included a reduction in senior management; overall organisational structure/staffing across all departments; placing greater emphasis on improving operational and business practices and efficiencies; prioritising research and development where IAVI would have the greatest impact on the field without compromising projects that could advance the most promising work in the portfolio.

The organisational reform addressed the issues raised by the World Bank evaluation by establishing measurable benchmarks and by developing and investing in standardised recruitment policies and retention strategies. The downsizing process naturally influenced IAVI's research and development portfolio and the organisation is actively working to attract further funding. Increased funding would among other enable accelerated design and development of a broadly neutralising antibody vaccine candidate, thereby increasing the likelihood of finding a universally effective vaccine faster.

Following the organisational restructuring process, IAVI adopted a centralised monitoring and evaluation system that includes a performance framework with targets which are mapped to IAVI's strategic goals and

⁴ This was done through an extraordinary grant of 7.5 million DKK in 2012.

annual work plans. The adjunct indicators were revised in order to measure annual organisational achievements as well as broader impact against the strategic plan. IAVI collects project progress data on a quarterly basis and reports to donors on an annual basis.

3. Key strategic opportunities and challenges

Opportunities

There is a solid concord between Danish priorities and IAVI's objectives. As expressed in *The Right to a Better Life: Strategy for Denmark's Development Cooperation* (2012), Denmark is determined to be at the forefront of international efforts to promote sexual and reproductive health and rights and in the response to HIV/AIDS. In the *Strategy for Denmark's Support to the International Fight against HIV/AIDS* (2005) emphasis is put on a comprehensive, evidence-based and balanced prevention-treatment response. An effective vaccine is the optimal way to provide protection to people at risk of being infected with an incurable disease and thereby prevent a huge amount of human suffering and reduce the costs and burden on health systems and budgets.

Another advantage of a vaccine is that it would free women (and men) from the difficulty of negotiating consistent condom use with a sex partner⁵. A vaccine could protect them without exposing them to the risk of gender-based violence that often follows such intimate talks. This is particularly relevant for the most vulnerable population groups including sex workers and MSM. The *Review of Denmark's Support to the Response to HIV/AIDS* (2011) assessed IAVI positively and concluded that investment in vaccines was a strategically sound way for Denmark to contribute to preventing HIV and AIDS.

Another priority of the Danish strategy is to reach vulnerable population groups through a rights-based approach. While first and foremost a research and advocacy organisation, IAVI also provides health services to the volunteering trial participants (more than 16,000 individuals since 2004). In line with the ethical standards that such bio-medical trials must adhere to, the participants are offered counselling, health information, HIV testing and referral to national treatment programmes in case of a positive test result. In addition, IAVI supported projects have tested more than 300,000 individuals for HIV. IAVI is engaged in identifying and reaching out to under-served population groups providing services and advocating for their right to health care. These efforts are in direct alignment with the priority that Denmark assigns to gender equality and human rights in its development corporation within the *Strategic Framework for Gender Equality, Rights and Diversity* (2014).

Denmark prioritises the need to address stigma and discrimination of vulnerable groups such as MSM, male and female sex workers and injecting drug users. IAVI's open and evidence-based work with these groups is of strong symbolic, political and health related value. This is exemplified through a new consortium to develop a network of research centres in Kenya and South Africa aiming to identify, follow and treat MSM. Furthermore, IAVI's research centre in Uganda covers a large cohort from the fishing communities; a group identified as highly underserved by HIV/AIDS and broader health care services in the 2013 evaluation of Danish, Irish and USAID support to HIV/AIDS in Uganda.

⁵ Acknowledging that a condom provides protection against a wider range of sexually transmitted diseases.

Challenges

With an estimated 35.5 million people living with HIV (2013), the AIDS pandemic remains a global health challenge in spite of remarkable increase in access to treatment, unprecedented international political commitment, resource mobilisation and civil society engagement. Every day 6,300 people become infected, and the daily death toll of AIDS is estimated at 4,300. With the advent of antiretroviral therapy (ARVs), an AIDS diagnosis is no longer a death sentence but rather a chronic condition. However, in a situation where more people become infected with HIV than the number of people eligible (and able) to access medicines, it is not possible to ‘treat our way out of the pandemic’. Current estimates show that even with the full scale-up of existing HIV prevention tools, which include not only access to ARVs but also education, condom provision and adult circumcision, it would still not be feasible to truly end the pandemic. Only with a vaccine, will it be possible to “Get to Zero”, with even a modestly effective vaccine having a significant impact on the number of HIV infections over time⁶.

The greatest challenge in developing an effective AIDS vaccine is that the HIV virus rapidly mutates which has led to great regional diversity. Consequently, a vaccine developed for one region, for example North America and Europe, may not prove to be effective in Africa where the burden of disease is highest. Currently, industry research into an AIDS vaccine is limited due to perceived uncertain return on investment compared to research and development cost. IAVI’s research focuses on a new generation of vaccine candidates that would be effective against all types of HIV circulating globally, with a focus on vaccines suitable for developing countries and at a cost that is affordable in resource-constrained settings.

Many of the challenges that the field of product development faces are of relevance for IAVI – as it is the case with its ‘sister organisation’ IPM. It is particular challenging to sustain momentum for investment in scientific discovery of an AIDS vaccine rather than allocating funds to already existing health technologies. However, comparative analysis conducted on behalf of the Copenhagen Consensus Centre (2011) has demonstrated that vaccine development is estimated to be a much more cost-effective investment compared to expanding already existing technologies. According to conservative projections, an AIDS vaccine with only 50% efficacy, which would reach as few as 30% of the population, would still avert 5.6 million new infections in low and middle income countries between 2015 and 2030.

Failure is always a risk in research, and roll-out of an effective vaccine to the end users is not around the corner. But it is closer than it has ever been and significant scientific progress has been made over the past couple of years. Denmark believes in the need to invest and engage on this matter with a long-term and risk willing perspective in an effort to sustain momentum for investment in AIDS vaccines. Denmark’s partnership with IAVI takes point of departure in the recognition that identifying an AIDS vaccine is a long and risky haul. Denmark will remain a partner in this journey and support the on-going efforts of IAVI and other partners to advocate for sustained resource flows, including by facilitating communication to/with a broader, non-technical audience.

⁶ Modeling project – UNAIDS, Futures Institute, IAVI, AVAC.

4. Priority results to be achieved

The priority results defined for Denmark's assistance to IAVI are determined by *The Right to a Better Life: Strategy for Denmark's Development Cooperation* as well as in *Strategy for Denmark's Support to the International Fight against HIV/AIDS*. Denmark's assistance to IAVI will be part of the ambition to control the AIDS pandemic and to promote a human rights-based approach towards groups who are most vulnerable to HIV infection.

In IAVI's strategic plan covering 2011-2015 three objectives are outlined:

- Accelerating the development of HIV/AIDS vaccines by identifying opportunities and gaps in the field and ensuring that IAVI invests its resources in areas that add most value;
- Harness partnerships to expand the diversity and number of novel AIDS vaccine candidates; and
- Building support for AIDS vaccine development.

In support of these objectives, the three Danish priority areas for IAVI are:

- **Support the research in and development of AIDS vaccine candidates to be used in developing countries.** The objectives include contributing to the continued progress in the clinical pipeline of AIDS vaccines relevant for parts of the world with the highest burden of HIV and strengthening of research capacity in developing countries and of South-driven research capacity.
- **Continued institutional reform process.** In line with the already ongoing efforts to improve the efficiency, effectiveness and added value of IAVI, the objectives include to promote the optimisation of IAVI's systems and resources; to support IAVI's own capacity to respond timely to and to continue to work in partnership with academia, industry, civil society as well as a diversified group of donors.
- **Sustained efforts to combat corruption and misuse of funds.** Objectives include: To ensure increased rigour and transparency in the management of funds through the consistent implementation of the quality management system and standard operating procedures in accordance with the organisation's Code of Conduct, Conflict of Interest Policy and Whistle-blower Policy.

5. Budget

The budget for the Danish contribution to IAVI for the coming five years is shown in the table below:

	2014	2015 ⁷	2016	2017	2018
Commitment in DKK million		15			15
Annual releases in DKK million	5 ⁸	5	5	5	5

Denmark provides un-earmarked, core funding to IAVI. IAVI currently has a strong and diversified donor base, but most of the donors offer earmarked funding. Only 25% of funding is un-earmarked. It is the un-earmarked,

⁷ The numbers for 2015/18 are preliminary and subject to parliamentary approval.

⁸ Committed in 2012 (15 million DKK for 2012-2014).

core support which provides flexibility, enabling IAVI to make data-based decisions and to follow science quickly in new directions.

IAVI receives financial support from 12 government and multilateral agencies, including Denmark, the Netherlands, Norway, United States, United Kingdom, Ireland, Japan as well as private foundations, particularly the Bill & Melinda Gates Foundation. In-kind support is received from private sector companies including GlaxoSmithKline, Google, and Bristol-Myers Squibb.

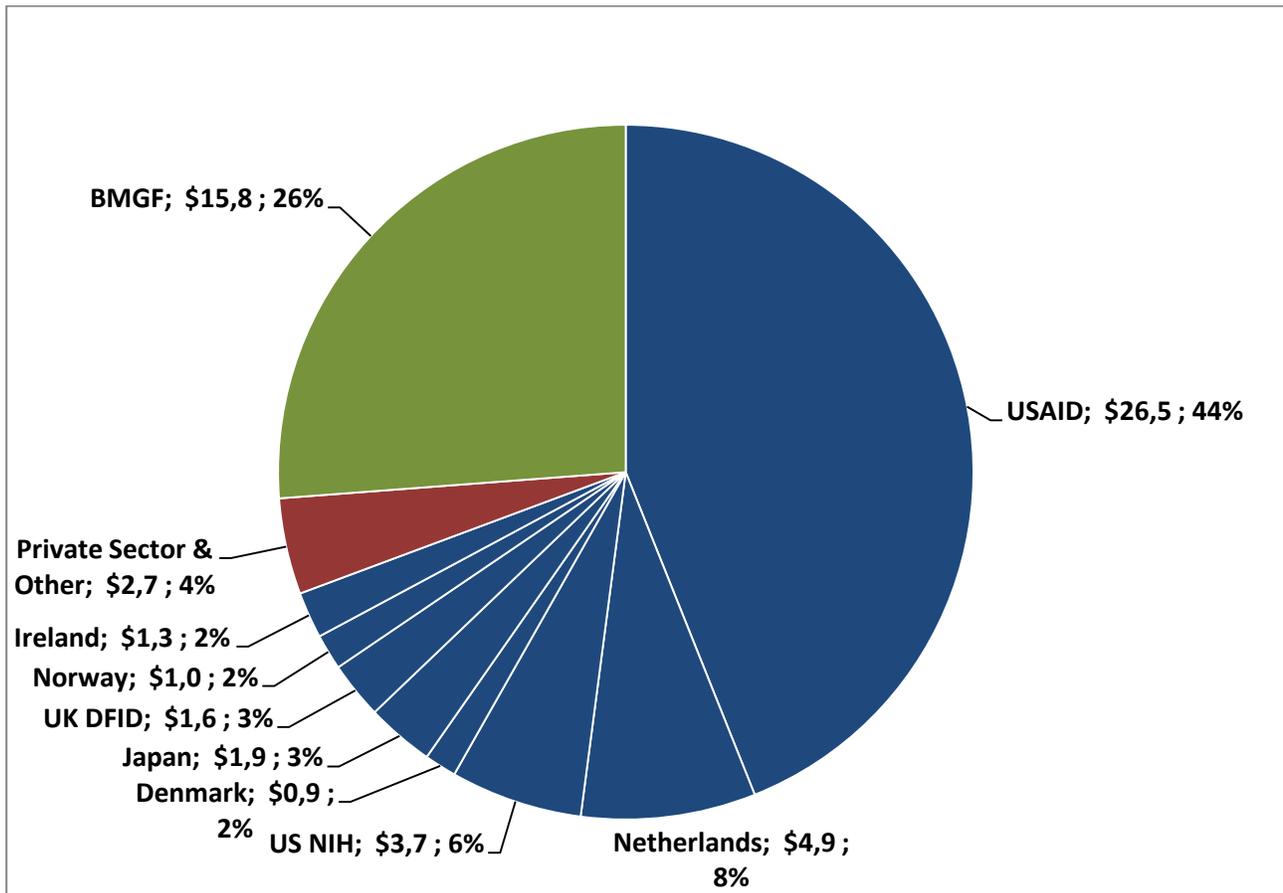
6. Summary results matrix

The below framework based on IAVI’s own monitoring and evaluation system forms the basis of monitoring of Denmark’s support to IAVI. The support will be monitored through the annual PDP Funders report and annual audited accounts submitted to the donors by IAVI. In addition, the annual donor meeting enables dialogue with IAVI management and with other donors to the organisation.

	Intended Results (selected from IAVI’s own monitoring framework)	Indicators (selected from IAVI’s own monitoring framework)	Baseline
Goal	To develop AIDS vaccine(s) meeting the needs of the most vulnerable to HIV and AIDS, with partners across the world		
Priority Area 1: Support the research in and development of AIDS vaccine candidates to be used in developing countries			
Objective 1: To expand the pipeline of AIDS vaccine candidates	Clinical pipeline of AIDS vaccine candidates expanded	1) Number of active Phase I and II clinical trials; 2) Number of active AIDS vaccine efficacy trials	1) IAVI has 3 active Phase I / II clinical trials ongoing; 2) IAVI is currently conducting no AIDS vaccine efficacy trials
Objective 2: To strengthen the research capacity in developing countries and of South-driven research capacity	Clinical and behavioural science research capacity in developing countries sustained and strengthened	1) % of clinical research centres and key staff meet necessary qualification standards to conduct clinical trials and relevant behavioural studies among key populations; 2) Number of active epidemiology, clinical research studies and relevant behavioural studies	1) 80% of CRCs & key staff meet necessary qualification standards to conduct clinical trials 2) IAVI is currently conducting 7 epidemiology studies with 1 clinical research study to be initiated in 2014

Objective 3: Ensure that momentum remains high for financial support to investing in AIDS vaccines	Global investment in AIDS vaccines research and development, and in the future, accessibility of key populations to these vaccines is sustained	1) Number of documented instances, including national and international commitments, for which stakeholders publicly endorse efforts to develop AIDS vaccines and to ensure access to them; 2) Number of documented instances in which stakeholders utilise IAVI policy outputs or policy outputs to which IAVI has contributed	1) At least 30 documented instances per year publicly endorsing efforts to develop AIDS vaccine R&D and ensure access to them; 2) At least 20 documented instances per year in which stakeholders utilise IAVI policy outputs or policy outputs to which IAVI has contributed
Priority Area 2: Efficiency, effectiveness and added value of IAVI including institution reform process			
Objective 4: To assist IAVI in its efforts of adopting a leaner organisation structure	IAVI's systems and resources optimised with regards to efficiency, effectiveness and added value	1) Number of business improvements implemented to optimise IAVI's performance; 2) % of spending on general and administrative expenses of IAVI's annual expenses; 3) % of staff turnover on an annual basis; 4) IAVI maintains stable funding	1) At least 1 business improvement identified & implemented annually 2) Max. 12.5% spent by IAVI on G&A expenses annually 3) Maintain max. 15% level staff turnover 4) IAVI generates at least US\$ 60m p.a.
Priority Area 3: Effort to combat corruption and misuse of funds			
Objective 5: Continued improvement with regards to preventing financial fraud and to ensure that funds are appropriately utilised for their defined purposes	To ensure increased rigour and transparency in the management of funds through the consistent implementation of the quality management system & standard operating procedures under the direction of the Global Quality Assurance Unit	1) Results of internal controls conducted; 2) Results of quarterly reviews of clinical trial centre spending and on-site audits; 3) Results of annual financial audits	

Annex 1: IAVI's projected funding 2014



BMGF: Bill and Melinda Gates Foundation

US NIH: National Institutes of Health

Annex 2: Overview of IAVI Financial expenses in USD⁹

	2012 Research and Development Expenses	2012 Expenses	As % of total
Applied research	24,525,940		
Preclinical development	8,833,142		
Clinical trials	14,942,097		
Cohort and site development	4,153,763		
Research and Development	52,454,942	52,454,942	73
Fundraising		2,878,942	
Vaccine advocacy, education and policy/access		6,766,992	
General and administrative*		9,825,676	
Other Expenses		19,470,718	27
Total Expenses		71,925,660	100

* 13% of total expenses. G&A costs cover indirect costs applied to support the entire organisation i.e. expenditures incurred in the day-to-day operations of IAVI which are not directly related to specific projects or programmes. This includes contributions to rent, utilities, insurance, office supplies, legal and management costs.

⁹ 2012 represents the latest audited financial accounts for IAVI.