

Developing AIDS vaccines for the world: the role of Europe



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Foreword

IAVI's mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.

Scientific endeavours require diligence and intelligence, urgency balanced with patience and good judgement – and a measure of good fortune. The International AIDS Vaccine Initiative (IAVI) also believes that scientific progress benefits from collaboration and partnership, and from using innovative approaches and taking informed risks. And if there was ever a problem in desperate need of progress and better solutions, it is the search for an AIDS vaccine, the best hope to ultimately bring the HIV epidemic to an end.

IAVI's mission is this very goal – but with a twist. IAVI is working towards an AIDS vaccine, but we also advocate and collaborate to optimize the scientific, clinical and policy environment for research and development. At the base of this philosophy is the recognition that the millions of lives at stake demand the attention and efforts of as many people as possible, as efficiently and effectively as possible.

Europe can significantly contribute to this vital quest in the future, as it has in the past. Through research, funding and policy decisions, the European Union and Member States have a range of diverse roles to play in the fight against AIDS. The commitment to a better use of tools for prevention, treatment and care currently available must be matched by a dedication to the development of better tools for use by those in greatest need. Future generations depend on it.



Seth Berkley
President and CEO



Frans van den Boom
Executive Director, Europe



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CHAPTER 1

Imagine a world without AIDS

Human Immunodeficiency Virus (HIV) is one of the greatest challenges of our time.

It undermines economic development, weakens social fabric and causes profound human suffering. IAVI is working towards the vision of a world without Acquired Immunodeficiency Syndrome (AIDS), one in which a safe, effective preventive vaccine will bring the epidemic to an end.



Jean-Marc Giboux/Getty Images

The HIV/AIDS epidemic – a global threat

HIV/AIDS transcends all borders and knows no limitations. It is relentless in its global spread, infecting over 450 people every hour – totalling more than 4 million people per year.¹

In 2005, 40.3 million people were living with HIV, approximately 95% of them in developing countries. Women make up almost half of the total number of people infected with HIV. Sub-Saharan Africa remains the region most affected and is home to approximately two-thirds of all people infected with HIV. India has the largest number of people living with HIV – an estimated 5.7 million at the end of 2005.¹

HIV/AIDS is threatening the attainment of many of the Millennium Development Goals.*

Not just the one specifically relating to HIV/AIDS, but also the others ranging from the eradication of extreme poverty and hunger to the reduction of child mortality.² At current rates, it is calculated that by 2026 in a

** The United Nations Millennium Development Goals are eight goals that all 191 UN Member States have agreed to try to achieve by the year 2015, signed in September 2000.*



Jean-Marc Giboux/Getty Images

‘The development of an AIDS vaccine is the single most important quest on the planet.’

Stephen Lewis, United Nations Special Envoy to Africa at the XVI International Aids Conference, Toronto 2006

typical sub-Saharan country, an HIV prevalence rate of 20% will lower the country's GDP by 67%. Globally, a number of countries are experiencing a reversal in development progress due to the impact of the disease.³

AIDS also affects Europe

HIV/AIDS is advancing at alarming rates in Eastern Europe and Central Asia. In these regions, about 1.3 million people are living with HIV, with 360,000 persons newly infected each year. Within Eastern Europe, Estonia, Latvia, the Russian Federation and Ukraine have the highest infection rates.¹

The epidemic continues in Western Europe as well. In 2004, there were about 23,250 newly reported cases, with an adult (age 15-49) HIV prevalence of 0.5%. Increased migration, including between Eastern and Western Europe, contributes to the spread of HIV, as does the reduced sense of threat among high-risk groups and the difficulties in ensuring adequate and accessible services.⁴

Why we need an AIDS vaccine

Existing AIDS interventions require sustained efforts, with an ever-increasing level of resources. UNAIDS estimates that about €43 billion are needed for all relevant HIV/AIDS programmes until 2008.⁵ While there is an evidence base for many prevention interventions – including condom promotion as well as harm reduction programmes, prevention of mother-to-child transmission programmes and ensuring safe blood supplies – many countries still struggle with implementation.

But even as we work towards better use of the interventions for prevention, treatment and care, we need better tools for the future. Circumcision, better barrier methods for women and microbicides each have potentially important roles to play. But ultimately, a vaccine is needed to end the AIDS epidemic; we know that vaccines are able to control and even eradicate (as in the case of smallpox) viral epidemics.

An AIDS vaccine is possible

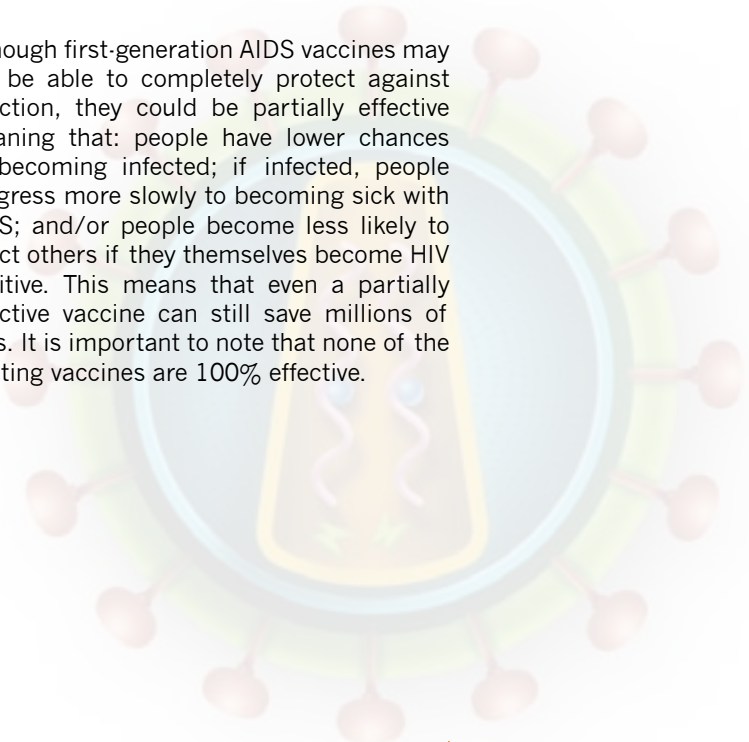
Although a challenging task, scientists believe that the development of an AIDS vaccine is possible. Studies show that existing vaccine candidates are safe and can stimulate immune responses, though we do not know yet if these are sufficient to protect against infection. We do know that there are people who are repeatedly exposed to HIV and who do not become infected. Also, some people, once infected, have immune responses that control HIV for many years. Finally, experimental vaccines against Simian Immunodeficiency Virus (SIV), a close cousin of HIV found in monkeys, have been shown to prevent infection or progression of disease.

How an AIDS vaccine works

HIV is one of the most complicated viruses ever identified. It attacks the immune system that vaccines rely on to fight infections, and it changes and mutates, making it especially difficult for the immune system to target the virus. HIV inserts copies of its genetic material into cells of the immune system and other parts of the body, essentially hiding for years. The body loses its protection mechanisms, leading to AIDS, which is characterized by susceptibility to a range of potentially life-threatening 'opportunistic' infections and cancers.

A preventive vaccine teaches the immune system, before the body is exposed to the virus, how to defend against the virus by creating an immune response. If the vaccinated person is later exposed to the virus, the immune system responds quickly to neutralize and clear the virus.

Although first-generation AIDS vaccines may not be able to completely protect against infection, they could be partially effective meaning that: people have lower chances of becoming infected; if infected, people progress more slowly to becoming sick with AIDS; and/or people become less likely to infect others if they themselves become HIV positive. This means that even a partially effective vaccine can still save millions of lives. It is important to note that none of the existing vaccines are 100% effective.



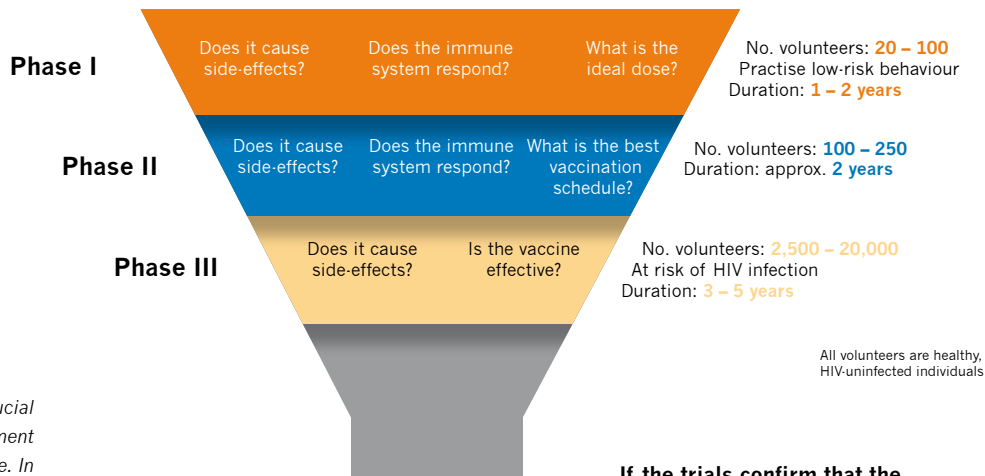
Researching an AIDS vaccine

Scientists use their extensive knowledge of HIV, vaccines and the immune system to develop candidate vaccines in laboratories. Those that show promise need eventually to be tested in human trials to show whether they are safe and effective (this is true for any vaccine or indeed any medical product). There are 3 phases of clinical trials.

Generally it takes **10 to 15 years to develop and fully test each vaccine candidate**. There are currently two vaccines in advanced

clinical trials and information about their effectiveness will become available in 2008-2009. These data will provide considerable insight into the promise of the more than 30 other vaccine candidates currently in early stages of clinical development.

All human clinical trials are carefully reviewed and regulated by international guidelines and international and local scientific, regulatory and ethical committees. This ensures that they are ethical, are conducted safely, and are scientifically sound.



Clinical trials are a crucial part in the development of an AIDS vaccine. In these trials, the vaccine candidates are tested in humans for their safety, ability to cause immune responses and, ultimately, the ability to protect against HIV infection or slow progression to disease.



If the trials confirm that the vaccine candidate is safe and effective, it may be licensed for widespread public use.



Jean-Marc Gboux/Getty Images

CHAPTER 2

About IAVI

IAVI

IAVI is the only organization in the world that focuses solely on developing an AIDS vaccine.

It was founded in 1996 as a non-governmental organization to ensure the development of an AIDS vaccine. It is a product development public-private partnership that combines the strengths of both public funding and social goals with private sector know-how and management approaches.

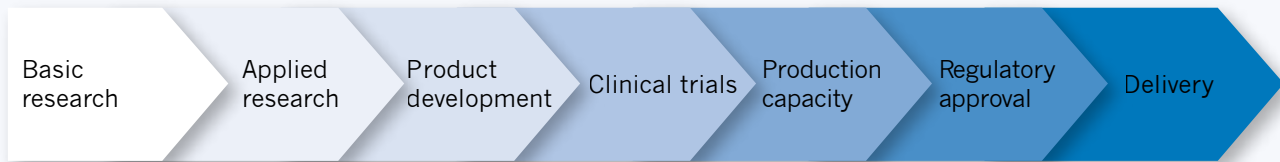
IAVI's staff of approximately 200 people and its partners are active in 24 countries (Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, India, Italy, Ireland, Japan, Kenya, Netherlands, Norway, Rwanda, South Africa, Spain, Sweden, Switzerland, Uganda, UK, USA and Zambia). IAVI has headquarters in New York, the European office in Amsterdam, and offices in Delhi, Johannesburg and Nairobi.

Research and development

The organization has a strong **research and product development team** that partners with scientists in academic, biotechnological, pharmaceutical and governmental institutions in Europe, Japan, the USA, and in a number of low- and middle-income countries.

IAVI's approach to AIDS vaccine research and development relies on disciplined portfolio management typical of pharmaceutical and biotechnological companies. IAVI does not conduct basic research. Rather, it draws on applied research by IAVI and others,





The product development pipeline

Product development public-private partnerships (PDPs) have formed over the past decade to unite public sector’s commitment to international public goods for health with private industry’s business discipline and expertise in product development and marketing. PDPs have proven to be highly cost-effective and are now responsible for three-quarters of all drug development and research for ‘neglected diseases’.⁶

prioritizes the most promising vaccine candidates and moves them through the development pipeline.

IAVI’s R&D efforts have focused on an AIDS vaccine for use in those countries most affected by the HIV/AIDS epidemic. Over the past seven years, IAVI and its partners have advanced **six vaccine candidates*** to testing in human trials in 11 countries in Africa, Asia, Europe and North America.

To target scientific gaps that will advance the entire global AIDS vaccine field, IAVI created two applied research consortia, in which internationally recognized scientists from across the world participate: the Neutralizing Antibody Consortium (NAC) and the Live Attenuated Consortium (LAC). In addition, IAVI recently established an AIDS Vaccine Development Laboratory to accelerate the production of novel AIDS vaccine candidates.

IAVI is a founding member of the Global HIV Vaccine Enterprise, an alliance of independent organizations dedicated to accelerating the development of an AIDS vaccine.

* DNA Oxford, MVA Oxford, DNA-ADARC, MVA-ADARC, MVA-Therion, AAV2



IAVI team with the President of India

Policy research and advocacy

IAVI's public policy work identifies gaps in knowledge or existing policy mechanisms and suggests means to correct these in order to create an enabling environment for HIV vaccine R&D. This includes sufficient provision of investments in vaccine R&D and preparations for future access. IAVI's approach is to work collaboratively with governments, multilateral agencies, NGOs and public-private partnerships. It seeks to catalyze policy reform through policy analysis, dissemination of results and recommendations to decision-makers in developed and developing countries, and evidence-based advocacy. In addition, IAVI cultivates advocacy partnerships to ensure adoption of relevant policies.



Partner

Partnerships in developing countries

IAVI's country programmes work with communities, researchers, academic institutions, media, governments and other partners to create an enabling environment for conducting research in-country and to pave the path for future access and use. Through its approach, IAVI contributes to sustainable development of research and health infrastructures.

IAVI conducts clinical studies across the world, including India, Africa (Kenya, Rwanda, South Africa, Uganda, Zambia), Europe (Belgium, Germany, Switzerland, UK) and the USA. In low- and middle-income countries, this includes the establishment of clinical sites and training of local scientists and healthcare workers. In areas of current and potential trial sites, local communities are involved through Community Advisory Boards (CAB) and Gender Advisory Boards. These form an important bridge between researchers and communities, providing valuable input for clinical trials – ensuring cultural appropriateness and raising awareness about AIDS vaccines.





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Uganda: an example of partnership

In Uganda, IAVI formed a partnership with the Uganda Virus Research Institute (UVRI) in 2001. Achievements of the UVRI-IAVI HIV Vaccine Programme include:

- Establishing the UVRI-IAVI laboratory and clinic;
- Training staff on procedures for laboratory and clinical assessments;
- Organizing workshops on gender and ethical issues related to AIDS vaccine trials;
- Launching Community Advisory Boards and Gender Advisory Boards to provide input on trials and to mobilize and involve communities;
- Supporting the development of a national AIDS vaccine plan;
- Strengthening healthcare and Voluntary Counselling and Testing (VCT) services around trial sites;
- Initiating two clinical trials to test three AIDS vaccine candidates and developing additional infrastructure and staff capacity for future trials.



UVRI/IAVI laboratory in Entebbe, Uganda



Jean-Marc Giboux/Getty Images

Emmanuel Mugisha of UVRI/IAVI in Uganda talking with local fishermen in Ggaba as part of a community outreach programme to prepare for future trials

Europe

Examples of R&D partnerships in Europe:
in the Netherlands, IAVI and Crucell are developing a vaccine based on Crucell's AdVac™ adenovirus vector technology. In Belgium, GSK Biologicals is collaborating with IAVI to evaluate the potential of chimpanzee adenovirus vectors as human vaccines;

Transgene in France is responsible for the manufacturing of the AIDS vaccine pilot lots for this programme.



IAVI's Core Laboratory at Imperial College London, UK

IAVI in Europe

Through its office in Amsterdam, IAVI is mobilizing forces in Europe to support the development of an AIDS vaccine. IAVI works with governments, think tanks, researchers, policy-makers and civil society.

Advancing AIDS Vaccine Science

IAVI remains one of the most important sponsors of AIDS vaccine R&D in Europe. European scientists contribute to both the NAC and LAC. Additionally, IAVI has created partnerships with universities, as well as pharmaceutical and biotechnology companies, to spur vaccine development. These include: Oxford University (UK), GSK Biologicals (Belgium), FIT Biotech (Finland), Crucell (The Netherlands), Bioption (Sweden), Transgene (France), IDT (Germany), Berna (Switzerland) and Cobra (UK).

IAVI's Core Laboratory at Imperial College, London, plays a crucial role in supporting and ensuring the performance of laboratories involved in IAVI's trials. The Core Lab also trains staff in the developing world to such high standards that four IAVI-affiliated laboratories – in Kenya, India, South Africa and

Glenys Kinnock, MEP and Seth Berkley, CEO IAVI



Uganda – have already been certified for ‘Good Clinical Laboratory Practice’ (GCLP), an international standard recognizing quality.

Stimulating Political Action

IAVI collaborates with regional and national governments, the European Commission and Members of the European Parliament to stress the urgency of supporting prevention technologies to fight AIDS. For example, working with the Governments of Ireland, The Netherlands and the United Kingdom during their consecutive European Union Presidencies has resulted in increased attention for new preventive technologies in important declarations, including the Dublin and Vilnius Declarations.



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Engaging Civil Society

IAVI’s advocacy and communications work is supported by the efforts of many European AIDS organizations, listed at the end of this brochure. These partners raise the profile of the issue, stressing the importance of community involvement and generating stakeholder interest in AIDS vaccines in their countries.



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CHAPTER 3

Financing

Financing the AIDS vaccine effort

It takes between €150 million and €400 million to develop and fully test each vaccine candidate.

In 2005, the total global investment in AIDS vaccine R&D was approximately €600 million. Although funding for an AIDS vaccine has increased in recent years, the Global HIV Vaccine Enterprise estimates that the best chance to accelerate R&D efforts requires funding levels closer to €1 billion.⁷

Government funding has consistently predominated in total AIDS vaccine R&D spending. The United States has committed about 85% of the total funds invested by the public sector, with European national governments and the European Commission collectively accounting for just over 10%. Of the European countries, Ireland invested the most relative to its national wealth, followed by the Netherlands.



18 May is HIV Vaccine Awareness Day; awareness campaign in Uganda

Annual average percentage GDP invested by national governments in preventive AIDS vaccine R&D between 2000-2005 ⁸	
0.004 - 0.005 %	United States
0.002 - 0.003 %	Ireland
0.001 - 0.002 %	Canada, South Africa, The Netherlands
0.0005 - 0.001 %	Denmark, Norway, Sweden, United Kingdom
< 0.0005%	Australia, Brazil, China, Finland, France, Germany, India, Italy, Japan, Russia, Thailand

⁸Note: includes only countries for which investment was calculated. The EU as a supra-national body is not listed.

Private-sector funding

In general, private-sector spending on an AIDS vaccine is low. This is due to a combination of scientific, political and financial risks. The five biggest pharmaceutical companies that produce vaccines: Glaxo-SmithKline, Merck, Novartis, sanofi-aventis and Wyeth, along with a number of biotechnology companies, invested approximately €60 million in AIDS vaccine research in 2005. This represents about 10% of the total global spend.

In order to increase the engagement of industry, financial investment risk needs to be reduced – whether by actions that reduce costs or increase potential future revenues.

A number of innovative finance mechanisms have been proposed and discussed to enhance the attractiveness of markets. A few are even partially implemented by national governments and institutions: the airline levy administered by UNITAID; the international finance facility that uses the issuing of governmental bonds on the money markets to finance health technologies and

Unless there is an adequate investment in R&D, there will be continued delay in achieving an AIDS vaccine.



Within the global resource needs, IAVI projects that it will require approximately €255 million in additional financing for the period 2006 to 2010 to pursue its R&D, policy advocacy and capacity-building activities, and prepare for later-phase clinical trials with the speed that the scale of the global pandemic demands.

PUSH Mechanisms

- Subsidies for research
- R&D tax credits
- Liability protection



Reduce costs

PULL Mechanisms

- Market guarantee mechanism
- Tax credits on sales
- Intellectual property incentives



Increase revenues

distribution; and advanced market commitments, a system whereby donor countries contractually agree to finance the purchase of a suitable vaccine, thereby providing the private sector with a market for vaccine development.

It should be noted that none of these new pull mechanisms have included the financing of AIDS vaccine R&D, nor the financing of other earlier stage vaccine development efforts, although they could have significant benefits.

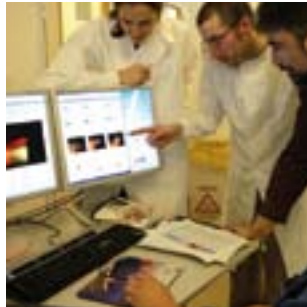


CHAPTER 4

European Union

The European Union can help speed up AIDS vaccine development

The European Union and its Member States are well placed to play a central role in the fight against AIDS.



EU action in support of HIV/AIDS-related research over the period 2002-2006 includes:

- Allocating approximately €78 million to HIV/AIDS-related research within the Sixth Framework Programme. So far, about €27 million of this research expenditure has been used for AIDS vaccine R&D.⁹
- Establishing and supporting the European Developing Countries Clinical Trials Partnership (EDCTP) among 14 EU countries, Norway, Switzerland and African countries. Of the €200 million that have been committed to the EDCTP so far, approximately 5% of funds have been spent on poverty-related disease R&D; about 1/5 of this 5% has been directed at HIV/AIDS-related projects. The first call for proposals for AIDS vaccine R&D will be made in December 2006.
- Supporting Community Preparedness Programmes in developing countries through IAVI (€6 million from 2004-2008) and SAAVI (South African Aids Vaccine Initiative).

How the European Union and its Member States can contribute to discovery of an AIDS vaccine

The world has made ambitious commitments in the fight against HIV/AIDS. With the vision of a world without AIDS, the European Union and its Member States could take the following actions:

- **Increase the contribution to global AIDS vaccine R&D.** Given Europe's limited financial contribution to date, more Member States and the EU should actively support or expand their current support for AIDS vaccine R&D. The EU and its Member States could pursue clear targets for spending and establish an equitable burden-sharing formula for contributions to the global AIDS vaccine R&D effort that governments of developed and developing nations can agree upon. Such commitments should be closely linked to sustained investment in new technologies that enhance the implementation of commitment to universal access for prevention, treatment and care, including drugs, diagnostics and other prevention technologies and services.
- **Increase flexibility in the use of funds designated for AIDS vaccine R&D:** EC research funding mechanisms have often focused on investigator-led research consortia that link numerous institutions and countries. While such an approach suits basic research, it is not sufficiently flexible to support a portfolio management approach and product development efforts. These need to be able to adapt activities as candidates are prioritized for clinical testing and have the flexibility to contract with partners based on needs that emerge during the development process.



'...new efforts should also be directed towards research on preventive technologies. The Commission is ready to support industry-led research on AIDS vaccines and microbicides...'

José Manuel Barroso,
President of the European Commission,
London, 22 May 2006

- **Increase support for international product development public-private partnerships (PDPs).** Despite European support to date, global PDPs fall into a ‘funding gap’ as Directorate General (DG) Development does not fund research activities while DG Research has focused on European research consortia. In addition to ongoing support of basic research, more funding should be made specifically available for the innovative and cost-effective approach that PDPs represent, either via new or existing funding mechanisms for poverty-related and neglected diseases.

- **Create and sustain incentives to increase industry’s engagement.** The EU and its Member States can play a role in creating incentive policies with a ‘push’ and ‘pull’ effect that lower the cost of R&D and ensure viable markets for future AIDS vaccines. Current proposals have so far not included the financing of AIDS vaccine R&D specifically nor the financing of earlier stage vaccine development efforts generally. In future, such mechanisms or others should be further explored for potential application to accelerate AIDS vaccine R&D.

- **Establish an enabling political and legal environment and strengthen research in those countries in which a vaccine is most needed.** It is essential to prepare for rapid vaccine approval and access, so that no time is lost once a vaccine is discovered. Priority should be given to strengthening the regulatory systems in low- and middle-income countries. Likewise, as other development investments are made to reach the UN Millennium Development Goals, priority should also be given to strengthening sustainable research and development capacity in these countries.

Support amongst EU citizens for more collaboration within the European Union is overwhelming: 9 out of 10 want the EU to fund additional research into an AIDS vaccine.¹⁰



With each day lost, the consequences will result in thousands of new infections. Governments, institutions and organizations will be judged by their response to the AIDS epidemic.



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