Questions & Answers

What is IAVI's role in the search for a vaccine to prevent AIDS?

IAVI plays three key roles in global efforts to end the AIDS epidemic. First, IAVI provides financial and technical support to scientific partnerships joining industry, academia and government to accelerate the research and development of promising vaccine concepts for the developing world from preliminary laboratory studies to clinical trials in humans. Additionally, IAVI advocates for public policies that would make vaccine research a political and economic priority – and ensure rapid global access once a vaccine developed. Finally, IAVI is committed to supporting the development and implementation of strategies to increase understanding of the clinical trial process at the community level. As the world moves closer to finding a vaccine, IAVI focuses on identifying, mobilizing and supporting communities to participate in clinical trials.

What is unique about IAVI's research and development programme?

IAVI's vaccine research and development programme is tailored to meet the specific needs of developing countries, where the HIV/AIDS epidemic is most devastating. Candidate vaccines must prove to be safe and effective but also practical in terms of the manufacturing cost, ease of administration (for example, oral versus injection) and ease of storage (for example, room temperature versus refrigeration).

The genetics of both humans and the HIV virus differ geographically, which may affect a vaccine's effectiveness. For this reason, IAVI conducts human trials of vaccine candidates across different regions in the world, particularly in Africa and Asia, regions where a vaccine is needed most urgently. To date, IAVI-sponsored vaccines have been developed based on subtypes of the HIV virus most prevalent in these regions.

What is a public-private partnership?

IAVI is a global not-for-profit, public-private partnership for product development, also known as 'product development public-private partnership' (PDP). PDPs are not-for-profit initiatives created to utilize both the public and private sectors in developing medicines for poverty-related and neglected diseases. The public sector, given its commitment to international public goods for health, such as vaccines, is united with the private sector, which offers its business discipline and expertise in developing medicines. PDPs have been proven to be highly cost-effective and are now responsible for managing three-quarters of all drug development projects for neglected diseases.

As part of its PDP philosophy, IAVI partners with more than 40 academic, biotechnology, pharmaceutical and government institutions to research and develop AIDS vaccines.

Will IAVI make a profit from the sale of any vaccine it successfully develops?
No. In fact, all IAVI research partners must agree that any AIDS vaccine discovered with IAVI sponsorship must be made available in developing countries at reasonable prices, in sufficient quantities and rapidly after it has been licensed as a safe and effective product.

What are some examples of IAVI's advocacy objectives?
IAVI believes that the global challenge of developing and delivering an AIDS vaccine requires a new global coalition that puts a premium on speed, cooperation and equity. In addition to securing adequate funding for research, IAVI advocates innovative global finance mechanisms to proactively close the gap between anticipated demand for a preventive AIDS vaccine in the hardest hit countries and limited purchase and delivery capabilities. IAVI also stimulates an innovative approach to intellectual property (IP) that protects industrial investment in research, yet recognizes an AIDS vaccine as a public good and thus ensures access..

Why is IAVI conducting so many trials and testing so many candidates?
Development of any new vaccine is a long and complicated scientific research process. It usually takes 10 to 15 years and a minimum of US$100 to US$200 million to develop a vaccine, and for every success there are many leads that provide valuable scientific insights but don't make it to the clinical trial stage. Developing a vaccine to prevent HIV/AIDS is particularly challenging in that HIV is one of the most complicated viruses ever identified. It is still unknown whether a single 'universal' vaccine can create immunity against the different sub-strains, or 'clades', of the HIV virus, or if a different vaccine must be developed against each clade.

Given the inherent complexities of any vaccine research – and particularly HIV/AIDS – IAVI's strategy is to move several promising candidates forward into clinical testing simultaneously in an effort to accelerate the discovery of a safe, effective vaccine.

What is the process for IAVI to obtain approval for a clinical trial?
IAVI must submit a comprehensive package of preclinical and manufacturing data, along with a detailed study protocol, outlining everything that will happen in the trial, to the appropriate national regulatory agencies for review. Examples of these agencies are the Food and Drug Administration in the US and the Medicines Control Council in South Africa. Each participating institution or trial center also must obtain study approval from its Institutional Review Board or Ethics Committee.

Even in advance of seeking approval for a clinical trial, IAVI invests in a rigorous review of the potential trial sites – evaluating everything from the credentials of the researchers and scientists who would be

conducting the trial, to a validation of the laboratories and facilities where the trial would take place. IAVI also evaluates the political and social environment in the potential clinical trial community. Does the environment support the ethical recruitment of trial volunteers and provide an appropriate network of outreach for these volunteers?

Typically, IAVI will begin the process of site evaluation and, if needed, support site development, a year or more before seeking approval to begin a trial. In this way, IAVI directly contributes to empowering and building health infrastructure in developing countries, in addition to advancing the search for a preventive AIDS vaccine.

What is a Phase IIb trial?

A Phase IIb trial will determine if our vaccine candidate works – that is, an efficacy trial. It would be a 'proof of principle' trial, demonstrating the product's efficacy, but it would not be sufficiently detailed to gain marketing licensing from a regulatory agency. However, if the product works, we can move into large Phase III trials and expand to other sites. This way we would save time and money and thus speed either the development of that vaccine candidate or the re-routing of resources to more promising candidates more quickly if the product is not successful.

How will IAVI persuade people to participate in its clinical trials?

IAVI is not involved in the active recruitment of volunteers for vaccine trials; this is the responsibility of the clinical research team at each site. What IAVI does do, well in advance of a recruitment campaign, is work to build a political and social environment that supports participation. For example, IAVI will provide training on the vaccine trial process to medical professionals and journalists; brief political leaders, stakeholders and non-governmental organizations on HIV/AIDS vaccine research; and support the development and distribution of educational materials for potential volunteers.

Does IAVI do animal testing?

Yes. The use of animal models in laboratories is mandatory by law and indispensable from a scientific perspective. The research scientists will need to test for safety, immunogenicity and efficacy before a vaccine can be injected into humans during a clinical trial. IAVI adheres to accepted national and international guidelines for the conduct of all animal-based research. IAVI opposes the indiscriminate, careless and unnecessary use of animals in any research. IAVI is committed to keep animal use to a level which is necessary and no more.

Why does IAVI continue to work on new vaccine concepts?

IAVI believes that we must continue to explore new designs in vaccines. We cannot rely on conventional vaccine development methods, as they are not appropriate for HIV. Scientists are currently testing the first generation of AIDS vaccines, which are based on novel vaccine concepts. If one or several of these vaccines prove to be able to protect against HIV infection, experts anticipate that this protection is likely to be partial.

These partially effective vaccines can still save the lives of millions of people. IAVI estimates that a 50% effective vaccine given to just 30% of the population could cut the number of new HIV infections in the developing world by more than half in 15 years. But a highly effective vaccine coupled with broad coverage could come close to stopping AIDS. That is why IAVI believes that scientists must continue to work on improving vaccine design, aiming for a generation of vaccines that are highly effective at blocking HIV infection.