

Frequently Asked Questions

Global HIV Vaccine Enterprise Scientific Strategic Plan

What is the Global HIV Vaccine Enterprise (the Enterprise)?

The Global HIV Vaccine Enterprise is an unprecedented, international response by the scientific community to HIV/AIDS -- a global alliance of more than 30 independent research, funding, advocacy and stakeholder organizations¹ working together to accelerate the development of a preventive HIV vaccine. The Enterprise promotes collaboration, catalyzes fresh thinking and supports new approaches to address the most pressing scientific and organizational challenges and opportunities in HIV vaccine research and development. While Enterprise partners remain independent, they also commit to align their strategies and activities to realize the shared vision of the Enterprise Scientific Strategic Plan.

Why was the Enterprise created?

Recognizing that the challenge of developing a safe and effective vaccine would require the best collaborative efforts of researchers, funders and advocates worldwide, a group of two-dozen scientific leaders proposed in 2003 the creation of a unique approach to help guide independent research efforts on HIV vaccines— a call that was later supported and endorsed by the leaders of the Group of 8 (G8) nations². Today, that vision is realized in the Global HIV Vaccine Enterprise.

What is the Enterprise Scientific Strategic Plan?

The cornerstone of the Global HIV Vaccine Enterprise is its Scientific Strategic Plan (the Plan), a collaborative framework to accelerate HIV vaccine research and development. The first Enterprise Scientific Strategic Plan was published in 2005.

Developed by the Enterprise Council³ and informed by the input of the Enterprise Science Committee and more than 400 researchers, policy makers, funders and advocates worldwide, the Plan presents a shared vision and strategy to transform recent scientific advancements and the momentum and opportunities of the past five years into faster, smarter and more productive research to develop an HIV vaccine. The Plan defines critical roadblocks, as well as opportunities that would benefit from increased

¹ Enterprise stakeholders are the global leaders in HIV vaccine research: African AIDS Vaccine Partnership (AAVP), AIDS Vaccine for Asia Network (AVAN), The Bill & Melinda Gates Foundation, Brazilian Ministry of Health, Canadian HIV Vaccine Initiative (CHVI), Center for HIV/AIDS Vaccine Immunology (CHAVI)/NIAID, Chinese AIDS Vaccine Initiative (CAVI), Chinese Center for Disease Control and Prevention, Chinese Ministry of Health, Collaborative for AIDS Vaccine Discovery (CAVD)/The Gates Foundation, European Commission (EC), European and Developing Countries Clinical Trials Partnership (EDCTP), Europrise, Eurovacc, French National Agency for Research on AIDS and Viral Hepatitis (ANRS), GlaxoSmithKline, AVAC: Global Advocacy for HIV Prevention (AVAC), the NIAID-funded HIV Vaccine Trials Network (HVTN), International AIDS Vaccine Initiative (IAVI), Joint United Nations Programme on HIV/AIDS (UNAIDS), Merck & Co., Inc., Novartis, sanofi pasteur, South African Medical Research Council, South African AIDS Vaccine Initiative (SAAVI), U.K. Department for International Development (DfID), U.S. Agency for International Development (USAID), U.S. Military HIV Research Program (MHRP), U.S. National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health Office of AIDS Research (OAR), Wellcome Trust, World Health Organization (WHO).

² St. Petersburg: 2006.

³ The governing body of the Enterprise.

global cooperation, and is designed to complement and build on the independent research efforts and discoveries of Enterprise members worldwide. The Plan articulates the commitment of Enterprise partners to work toward aligning their strategies and activities to help realize a shared vision for the field.

How was the Plan developed?

In January 2009, the Enterprise Council initiated a broad consultative process to update the 2005 Plan to reflect the anticipated challenges and opportunities in HIV vaccine research for the next five years. The Enterprise Science Committee identified five key areas of focus for the Plan and Working Groups of leading researchers from around the world came together to develop strategies to address these five areas of challenges and opportunities.

What are the Plan's principle recommendations?

The 2010 Scientific Strategic Plan identifies two main scientific priorities in its recommendations to accelerate HIV vaccine research and development:

Priority 1: Optimize the clinical trials endeavor by fully integrating iterative scientific inquiry with product development.

Priority 2: Harness the full potential of preclinical models and the revolution in biomedical science.

How will the Plan's priorities be achieved?

To achieve the first Priority, the Plan highlights the need to fundamentally alter how clinical trials are designed and conducted. Specifically, the Plan recommends that the field:

- strengthen existing or create new research structures that bring together basic, preclinical and clinical researchers to design, execute and analyze trials;
- implement process improvements and explore novel trial design strategies to increase significantly the number, efficiency and speed of clinical trials;
- implement a robust pipeline of diverse vaccine strategies;
- ensure compatibility of trial data, regardless of sponsor;
- strengthen global, ethical, legal and regulatory frameworks;
- maintain appropriate and flexible research capacity in high-incidence countries;
- strengthen community engagement throughout trial design and implementation.

To achieve the second Priority, the Plan underscores the need for new tools and research approaches, more trials with shorter turnaround times, collaborations with researchers from other disciplines and rapid data sharing. Specifically, the Plan recommends that the field:

- develop and rapidly disseminate novel technologies for HIV vaccine design and testing;
- build multidisciplinary collaborations of HIV investigators and scientists from other fields;

- implement the rapid sharing of research data;
- develop infrastructure for depositing and analyzing a growing body of research data;
- develop collaborative programs to maximize the use of and increase the relevance of the non-human primate (NHP) model: promote research on the earliest events following vaccination and infection in NHP; and standardize protocols, assays and reagents in NHP research.

The 2010 Plan also highlights several challenges and opportunities that cut across these two priorities, including strategies to increase the engagement of the pharmaceutical and biotechnology sector in HIV vaccine research, attract young and early-career investigators to the field and increase and diversify financial support for HIV vaccine research and development. The Plan offers a number of strategies in each area, as well as targets against which to measure progress.

How do the recommendations from the 2005 Plan differ from those in the 2010 Plan?

The HIV vaccine field is rapidly changing. The first Enterprise Scientific Strategic Plan, published in 2005, addressed the challenges and opportunities facing the field at that time. Specifically, the 2005 Plan called for increased collaboration and coordination among HIV vaccine research partners and identified priority areas for action to speed and improve HIV vaccine research.

Action on recommendations in the 2005 Plan led to significant progress in the field and across HIV vaccine research efforts. The 2010 Plan identifies the major opportunities for collaborative efforts to build on these achievements, address current challenges, advance HIV vaccine science and accelerate vaccine development.

What did the 2005 Scientific Strategic Plan achieve?

Since the publication of the original Scientific Strategic Plan, the more than 30 organizations that comprise the Global HIV Vaccine Enterprise have moved to transform the field into the open, nimble, coordinated and collaborative enterprise envisioned by the 2005 Plan. Among their efforts are several research collaborations founded in response to the 2005 Plan that are now taking the field forward:

- The Center for HIV-AIDS Vaccine Immunology (CHAVI), funded by the US National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), unites the efforts of researchers from 43 institutions in nine countries to better understand the critical early events that follow HIV infection.
- The Collaboration for AIDS Vaccine Discovery (CAVD), an initiative of The Bill & Melinda Gates Foundation, has deepened our understanding of immune responses and supports the development of standardized assays and research methodologies for use in HIV vaccine research worldwide.
- Important collaborative research initiatives led by the International AIDS Vaccine Initiative (IAVI), the French National Agency for Research on AIDS (ANRS) and the European Commission (EC) are also promoting the research goals outlined in the 2005 Plan.

An evaluation found that the 2005 Plan was key to encouraging greater dialogue and coordination among HIV vaccine research funders and scientists, and was the impetus for the commitment of new funding to support action on a number of Plan priorities, including:

- increased investment in HIV vaccine research;
- standardization of key assays;
- increasing the quantity and quality of sustainable clinical research facilities and expanding access to well-defined populations at risk of HIV infection;
- increased regulatory capacity building and greater exchange of information;
- development of an intellectual-property framework to stimulate early-stage research;
- establishment of coordinated, dedicated product development and manufacturing capacity to support HIV vaccine trials.

How will the Enterprise ensure that the 2010 Plan recommendations are enacted?

The Scientific Strategic Plan is not the plan for any single organization, but an agreement of Enterprise partners to align their independent strategies and activities to address critical roadblocks and maximize global cooperation in the quest for safe and effective HIV vaccines.

Each stakeholder organization will identify and implement the Plan's goals and targets in which they are best equipped to contribute. The Enterprise Council will review the Plan's goals and targets with stakeholders on a regular basis and will report progress to the global community.

For more information on the Global HIV Vaccine Enterprise and the Scientific Strategic Plan, please visit www.vaccineenterprise.org.

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