

Questions and answers: The Global HIV/AIDS Vaccine Enterprise

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The Global HIV/AIDS Vaccine Enterprise is an alliance of organizations that are involved in researching and developing a vaccine to prevent AIDS. Enterprise members, which include both organizations that undertake R&D and those that support it, are committed to accelerating progress toward a safe and effective vaccine by promoting greater international scientific cooperation and collaboration and mobilizing new resources.

The Enterprise was proposed and initially convened by the Bill & Melinda Gates Foundation. Founding members include IAVI, the US government's National Institutes of Health (NIH), the French government's National Agency for Research on AIDS (ANRS), UNAIDS, the World Health Organization and the Wellcome Trust, among others.

How is the Enterprise intended to help progress toward a vaccine?

The Enterprise was proposed in a June 2003 position paper published in the journal *Science*. The paper argued that an AIDS vaccine is one of the most difficult challenges facing biomedical science today, and while important progress has been made, there is a critical limitation in the way vaccine R&D is currently conducted: Most of the work is undertaken by small groups of investigators—academic laboratories and biotechnology companies—who typically operate independently of each other, and the scale of their projects is often too small to adequately address major scientific questions. The pace of progress could be increased through greater cooperation and collaboration, and more funding

targeted to large projects that tackle major questions.

Enterprise members agree to reach consensus on scientific priorities (see below), voluntarily divide responsibility for addressing them and establish joint ventures that pool expertise, infrastructure and resources. They agree to iteratively apply each other's advances so that the best science emerges as quickly as possible and unnecessary duplication is avoided.

Enterprise members will develop systems for more openly exchanging information as well as share research protocols so that the work of one group is compatible with others. In these ways, the Enterprise is patterned after the Human Genome Project, a scientific alliance that is widely credited with speeding the successful identification of all of the genes in human DNA.

The *Science* paper argued for additional resources, given that total global spending to develop a vaccine is just a fraction of spending to combat the epidemic, and more resources would better position vaccine efforts for success. Enterprise members will mobilize new resources and see that they are targeted to priority areas. The Enterprise received the endorsement of leaders of G8 nations at their summit in 2004, and the G8 pledged to take up the issue of additional resources for vaccine R&D at future summits.

What is the Enterprise doing?

The Enterprise is in the initial stages of taking shape. To date, its principal activity has been to publish a strategic scientific plan for the global AIDS vaccine field. This is a consensus statement

of priorities—the most significant scientific hurdles and an exploration of some of the potentially promising avenues for solving them. The plan does not prescribe specific activities, as at this stage the intent is to stimulate dialogue. Among the issues addressed:

Vaccine discovery: There are new insights into HIV and the immune system that should be applied to the design of novel vaccine candidates.

Laboratory methods: Researchers should standardize laboratory techniques and benchmarks for determining which candidates are most promising and should be prioritized.

Manufacturing: As more vaccine candidates advance to testing, additional manufacturing capacity is needed to produce vaccine doses for trials. This includes expertise in engineering manufacturing processes.

Clinical trials and regulation: There is an acute need to build capacity for conducting trials in the developing countries hardest hit by the epidemic. This includes training personnel and addressing gaps in developing countries' ability to review and approve plans for trials in a timely fashion.

Intellectual property: Greater cooperation and collaboration among institutions may require new legal agreements that facilitate information sharing while protecting intellectual property rights that stimulate innovation.

The full plan appears in the February 2005 issue of the journal *PLoS Medicine*, which is free at www.plosmedicine.org.¹

How is the Enterprise structured?

The Enterprise is led by a Coordinating Committee of representatives of member organizations. The committee seeks technical guidance from ad hoc expert working groups. The committee is assisted administratively by an interim secretariat at the Gates Foundation until a permanent secretariat is established.

¹ For additional background on these and other issues, see the IAVI publications *Scientific Blueprint 2004* and *Speeding the manufacture of an HIV vaccine: policy issues and options*.

Who funds the Enterprise? Does the Enterprise fund others?

The Enterprise's activities to date have been primarily supported by the member organizations, who lend staff time. The Gates Foundation has provided start-up funding to assist with meeting expenses and other administrative costs.

The Enterprise is an alliance that will provide a global forum to advocate for new investments in AIDS vaccine R&D. The Enterprise is not a fund or a funding agency. Members that themselves are funding agencies will provide support for R&D through their own mechanisms, using Enterprise principles as a guide. For example, both the Gates Foundation and the US NIH have announced competitive bidding processes to support projects that will help discover new vaccine candidates, in line with the priorities outlined in the Enterprise strategic scientific plan.

What is IAVI's involvement?

As a founding member, IAVI is actively involved in helping the Enterprise take shape. IAVI was a co-signer of the *Science* paper that proposed the Enterprise and serves on the Coordinating Committee. A number of IAVI scientists have served on the expert working groups that have provided technical guidance. IAVI is also involved in the advisory group that has been set up to explore the location and structure of the permanent secretariat.

The R&D priorities outlined in the Enterprise's strategic scientific plan emphasize many of the same themes as IAVI's organizational Strategic Plan for 2005–2007, which IAVI is implementing through its global partnerships.

IAVI's unique approach is to integrate R&D with public policy and advocacy, working in partnership with the public and private sectors of both industrialized and developing countries. IAVI is helping to build high-level political support for vaccines; promote public policies that facilitate accelerated R&D and prepare for access to a successful vaccine; and educate and engage communities where vaccine trials take place.