



IAVI in India

IAVI is a global not-for-profit organization working to accelerate the development of a vaccine to prevent HIV infection and AIDS. Founded in 1996, IAVI researches and develops vaccine candidates, conducts policy analyses, and serves as an advocate for the field. IAVI also works to ensure that AIDS vaccines are a global priority and that a future vaccine will be accessible to all who need it.

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In India, IAVI partners with the Ministry of Health and Family Welfare through the National AIDS Control Organization (NACO) and the Indian Council of Medical Research (ICMR) to implement the AIDS vaccine program. IAVI also collaborates with the Ministry of Science and Technology, through the Department of Biotechnology (DBT) and the Council of Scientific and Industrial Research (CSIR), to advance research on the design and development of new AIDS vaccines.



Photo courtesy of the President of India's office

Dr. JL Excler, Senior Medical Director, IAVI India; Dr. Seth Berkley, IAVI President and CEO; The Honorable President of India, APJ Abdul Kalam; Ms. Sweta Das, Country Operations Manager, IAVI India; Professor NK Ganguly, Director General, Indian Council of Medical Research (ICMR)

Research and Development (R&D)

India's political leadership has encouraged research and technical exchange and emphasized the need to pursue multiple vaccine candidates simultaneously to speed vaccine development. The country's first clinical trial of a preventive AIDS vaccine candidate began in February 2005 with an evaluation of safety and immunogenicity of tgAAC09 (an adeno-associated virus vaccine). The National AIDS Research Institute (NARI) in Pune, Maharashtra; IAVI; and Targeted Genetics Corporation—a Seattle, Washington-based biotechnology company—collaborated on the trial.

In February 2006, researchers at the Tuberculosis Research Centre (TRC) in Chennai, Tamil Nadu, launched a Phase I trial of a second vaccine candidate, TBC-M4 (a modified vaccinia Ankara vaccine). IAVI partnered with Therion Biologics Corporation—a Cambridge, Massachusetts-based biotechnology company—to develop TBC-M4. An Indian scientist from the National Institute of Cholera and Enteric Diseases (NICED) in Kolkata assisted Therion in the candidate's design.

Building Infrastructure for Vaccine Trials

In preparation for multiple Phase I trials, IAVI has established two centers of excellence for AIDS vaccine clinical evaluation in India. The vaccine trial centers at NARI and TRC each have a data management unit and an immunology laboratory dedicated entirely to clinical trial activities. Clinical trial staff members at both sites have been trained in Good Clinical Practice and Good Clinical Laboratory Practice. They have also been sensitized to gender and ethical issues prior to initiation of the AIDS vaccine trials. Additionally, IAVI has established a community center in Pune, Maharashtra, to facilitate the recruitment of potential volunteers.

Mobilizing Community, Political, and Private Sector Support for AIDS Vaccine Research

To speed the development of an AIDS vaccine, IAVI solicits the support of policy planners, medical practitioners, research organizations, NGOs, women's groups, and the media. As part of the AIDS vaccine program, NACO, ICMR, and IAVI organize consultative and orientation meetings with these key stakeholders to increase community involvement in vaccine research and development.

Early efforts to guide the design of the AIDS vaccine community program included state-wide and one-on-one consultations with experts and community leaders. Meetings were held in Andhra Pradesh, Maharashtra, Tamil Nadu, Assam (including participation from Manipur and Nagaland), and Karnataka to address community concerns about AIDS vaccine research. Since then IAVI has continued to engage civil society as both a partner with and advisor to the AIDS vaccine program.

The program receives strong support from India's top political leadership. India's President, the Prime Minister, the Leader of the Opposition, and a number of Chief Ministers of states with high HIV prevalence have publicly expressed their resolute support for India's AIDS vaccine initiatives. Since the program's initiation, Indian partners and IAVI have been organizing policy workshops, individual consultations, and regular briefings with parliamentarians at the national level and legislators at the regional level in an effort to engage both national and local policy makers in AIDS vaccine development.

The AIDS vaccine program also receives tremendous encouragement from prominent industrialists in the country. IAVI is committed to working with the private sector to mobilize Indian business in broader



Mr. Jayaraj

Vaccine trial center counselor, Angelene Samuel, simulates a counseling session at the Tuberculosis Research Centre in Chennai, Tamil Nadu

HIV/AIDS education and prevention efforts. In addition to collaborating with India's pharmaceutical and biotechnology sectors to advance AIDS vaccine research and development, IAVI and partners work with institutional bodies such as Federation of Indian Chambers of Commerce and Industry (FICCI) and Confederation of Indian Industry (CII) to increase awareness about preventive AIDS vaccines and ongoing research in India.

Expert Panels

IAVI's work in India is guided by several advisory groups that provide strategic direction and counsel:

- **National Advisory Board:** This distinguished group comprises senior members of government, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO), national and international NGOs, human-rights activists, ethicists, lawyers, and health and gender experts. The board is divided into four sub-groups focusing on communications, science, vaccine access, and social issues.
- **Informed Consent Group:** This ad-hoc group of senior scientists, lawyers, ethicists, human-rights experts, and community leaders ensures that all those who volunteer for trials have full understanding of any risks and/or benefits. They also review the process and materials for communicating medical details and procedures to volunteers.
- **NGO Working Group:** This board consists of NGO leaders from states with high HIV prevalence and ensures that trials are conducted safely and ethically, with adequate community involvement and representation. The group is examining ways to mobilize support for AIDS vaccines

in the states of Tamil Nadu and Maharashtra—the sites for the Phase I trials—by involving NGOs at the grassroots level.

- **Gender Advisory Board:** Composed of a small group of experts, this board oversees and guides the program’s efforts to incorporate gender concerns into AIDS vaccine trials. The board has assisted in developing training modules and guidelines for implementing gender-sensitivity training for trial staff at NARI and TRC. The group aims to encourage recruitment and retention of women in AIDS vaccine trials conducted by NACO-ICMR-IAVI, setting standards for other vaccine trials in the process.
- **Informal Committee on Standards of HIV Care and Treatment for AIDS Vaccine Clinical Trial Participants:** This informal committee comprises policy makers, researchers, community stakeholders, healthcare providers, clinical trial investigators, members of NGOs and CBOs, and people living with AIDS. The members helped to clarify the responsibilities of research sponsors and the host country government in providing appropriate care and treatment for trial participants and host communities. Their recommendations were endorsed by the government and included in the Phase I trial informed consent documents.
- **Sankalp Editorial Advisory Board:** This small group comprises experts from the United Nations, NACO, and NGOs working in the HIV/AIDS field. The board provides strategic direction on the information needs of the community. Sankalp, a regional publication on AIDS vaccines, relies on the board’s expertise for the technical content of the newsletter.

IAVI’s Donors

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