



# IAVI Research and Development (R&D)

IAVI's research and development team designs, develops, and clinically evaluates AIDS vaccine candidates applicable for use in the developing world through a range of partnerships and agreements with more than 40 academic, biotechnology, pharmaceutical, and government institutions around the globe. IAVI has placed an emphasis on applied research, product development, and capacity building and targets the gaps that will advance the entire global AIDS vaccine field. R&D management, drawn largely from the vaccine industry, uses an industrial approach to manage a portfolio of projects, prioritizing the most promising candidates and moving them swiftly through the vaccine development pipeline.

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Jean-Marc Ciboux/Getty Images

Josephine Birungi and Ssemaganda Aloysious at the Uganda Virus Research Institute/IAVI in Entebbe, Uganda

## Applied Vaccine Research

The **Neutralizing Antibody Consortium (NAC)** was established by IAVI to address one of the field's most critical scientific challenges: designing vaccines to induce broadly neutralizing antibodies against HIV, which would be capable of blocking infection by a wide range of HIV isolates circulating worldwide. The NAC comprises several internationally recognized scientific laboratories, complemented by core resources to enable high-throughput screening of leading vaccine designs.

Member institutions comprising the NAC currently include: The Scripps Research Institute; University of Pennsylvania; Cornell University; Dana-Farber Cancer Institute; Harvard University; University of Wisconsin; Institute of Research in Biomedicine; University of Washington; and Global Vaccines Inc.

**IAVI's Live Attenuated Consortium (LAC)** seeks to understand the mechanism for the strong protection of live attenuated SIV vaccination in non-human primates and to translate this knowledge into designing better AIDS vaccine candidates. The LAC is currently composed of five leading HIV scientific laboratories at the following institutions: University of Minnesota; Oregon Health & Science University; Harvard University; Children's Hospital of Philadelphia; and University of Wisconsin.

In 2005 IAVI established the **AIDS Vaccine Development Laboratory** (the Lab), aligned with the State University of New York (SUNY) Downstate Medical Center, to support and complement its research activities. The Lab takes IAVI a step further in fully integrating its R&D efforts, as well as developing common preclinical standards for the AIDS vaccine field. The Lab examines novel AIDS vaccine platforms and immunogens, standardizes pre-clinical testing of AIDS vaccine candidates, and develops candidates for use in clinical products. In addition, the Lab supports the activities of IAVI's research consortia (the NAC and LAC).

## IAVI Product Development Portfolio

In the last six years IAVI and its network of partners have translated innovative technologies into six vaccine candidates that have entered human trials in 11 countries in Asia, Africa, Europe, and North America. IAVI follows the management principles of PMI (Project Management Institute), using project teams with expertise in manufacturing, preclinical, clinical, and regulatory affairs to lead vaccine development. This process ensures rapid development of promising vaccine candidates according to international standards. The current portfolio is noted below:

Vaccine Candidate	Partner	Phase of Development
tgAC009 (adeno-associated virus vaccine, AAV)	Targeted Genetics Corporation	Phase I trial A001 in Germany and Belgium completed India (Pune) initiated Feb 2005* Phase II trial A002 in South Africa initiated Nov 2005 Uganda initiated Feb 2006 Zambia initiated in Apr 2006*
AAV-2	Targeted Genetics Corporation	Preclinical safety and toxicity studies ongoing
ADVAX / ADMVA	Aaron Diamond AIDS Research Center	Phase I trial of ADMVA in US initiated in Jan 2005 Phase I trial of ADVAX in US initiated in Dec 2003
TBC-M4 (modified vaccinia Ankara vaccine)	Therion Biologics	Phase I trial D001 in India (Chennai) initiated in Jan 2006
Adenovirus 35 / 11	Crucell N.V.	Preclinical development ongoing
Non-human Primate Adenovirus	GSK Biologicals	Preclinical development ongoing
DNA + Adenovirus 5	National Institutes of Health/Vaccine Research Center	Phase I trial V001 in Rwanda initiated Nov 2005* Kenya initiated Jan 2006

\*Country's first AIDS vaccine trial

## IAVI Feasibility and Clinical Trial Sites in the Developing World

IAVI's feasibility studies and AIDS vaccine clinical trials are conducted in collaboration with local scientists and clinicians. These sites are located primarily in sub-Saharan Africa and India, regions of the world most severely impacted by the AIDS pandemic.



NARI: National AIDS Research Institute, TRC: Tuberculosis Research Centre, KNH: Kenyatta National Hospital, KAVI: Kenya AIDS Vaccine Initiative, MRC: Medical Research Council, PSF: Projet San Francisco, CGMRC: Centre for Geographic Medicine Research-Coast, ZEHRP: Zambia Emory HIV Research Program, PHRU: Perinatal HIV Research Unit, DTHC: Desmond Tutu HIV Centre.

## Clinical Research Infrastructure

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IAVI has established a number of collaborations with clinical trial sites in the developing world in order to accelerate the testing of candidate vaccines (see previous section). The clinical research infrastructure includes trial sites to conduct clinical research and field laboratories to assess the safety and immunogenicity of vaccines. In these settings, IAVI builds or upgrades clinics, laboratories, and information technology systems and trains staff in Good Clinical Practice (GCP). IAVI's clinical research feasibility studies obtain critical data for conducting vaccine trials and for informing next-generation vaccine design, while Phase I and Phase II trials examine vaccine candidate safety and immunogenicity. IAVI's goal in developing clinical research infrastructure is to conduct the large-scale efficacy trials of AIDS vaccines in developing countries where HIV is most prevalent and where a vaccine is most urgently needed, so that researchers can determine whether AIDS vaccine candidates will work in the communities most affected by the epidemic.

IAVI's Human Core Immunology Laboratory (Core Lab), housed at Imperial College London, is the hub that links IAVI's network of HIV/AIDS vaccine immunology laboratories worldwide. This network of field laboratories enables on-site evaluation of immune responses to candidate AIDS vaccines and allows the Core Lab to serve as a central resource to compare and prioritize candidate AIDS vaccines based on validated immunological assays. The Core Lab also provides comprehensive training and support to field laboratory and clinical staff involved in IAVI-sponsored trials and was the first laboratory in the world accredited to the Good Clinical Laboratory Practice (GCLP).

## IAVI's Donors

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