

VAX

AN IAVI REPORT
BULLETIN

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VAX is a monthly bulletin featuring shorter, non-technical versions of articles from the *IAVI Report*, the newsletter on AIDS vaccine research published by the International AIDS Vaccine Initiative. VAX is currently available in English, French, Spanish and Portuguese as a pdf (www.iavi.org/iavireport) or an e-mail bulletin. If you would like to receive VAX by e-mail, please send a request including language preference to: VAX@iavi.org

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SPECIAL ISSUE

2003:
YEAR IN REVIEW

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POSTER

From New York to Nairobi, 2003 was a busy year for AIDS vaccine research. Nineteen new trials were launched at sites in 13 countries and preparation activities got underway in many more. The majority of the trials were small Phase I studies, which are the first step in human trials of AIDS vaccine development. For this special issue of VAX, researchers, community members and trial staff share highlights and lessons learned from last year.

AUSTRALIA

The Australian-Thai HIV Vaccine Consortium initiated the first trial of an exclusively Australian-designed preventive AIDS vaccine candidate.

"One important lesson that we learned in 2003 is that the overwhelming interest initially received from the Australian public following the media campaign to inform and educate about the trial did not actually translate into recruitment of willing and eligible volunteers. Many of the volunteers were recruited by word of mouth or through bulletins distributed within hospital and healthcare networks."

Rebekah Puls, Clinical Project Leader, and Dr. Anthony Kelleher, Principal Investigator, St Vincent's Hospital, Sydney, Australia

BOTSWANA

On 26 June 2003, the Botswana Ministry of Health and the Maiteko a Tshireletso Vaccine Initiative launched a Phase I vaccine trial—the first HIV vaccine trial in southern Africa.

"One important part of our work in 2003 was the continued support for AIDS vaccine research from Botswana's President Festus Mogae. Another highlight of the year was a radio call-in show with a trial participant. 'He [the volunteer] reached out to many people that evening', says Dr. Joe Makhema, co-investigator of the trial. 'We admire his commitment and dedication.'"

Michelle Schaan, Health Communication Officer, Botswana Harvard AIDS Institute, Gaborone, Botswana

BRAZIL

The Rio De Janeiro HIV Vaccine Trials Unit founded the first AIDS vaccine community advisory board in Brazil (see below). It is currently preparing to begin immunizations as part of an ongoing international Phase II trial conducted by the US HIV Vaccine Trials Network (HVTN) and sponsored by the National Institute of Allergy and Infectious Diseases (NIAID).

"The highlight of 2003 was the announcement from several HIV vac-

cine trial sponsors, including the HIV Vaccine Trials Network, that HIV vaccine trial participants in developing countries who become HIV-infected through high-risk contact during the course of a trial will receive long-term antiretroviral therapy. This issue has been debated for years, and the final decision was a result of intense community political pressure combined with strong ethical commitment from many scientists."

Monica Barbosa de Souza, HIV Vaccine Trials Unit Community Education Coordinator, Rio de Janeiro, Brazil

"In 2003 the Rio community advisory board (CAB) did a lot of work to bring down the language barrier we face in evaluating trials. Specifically, we asked for the informed consent form and the trial protocol in Portuguese, and explained to trial sponsors that CAB input is important for both of these documents. It took some time but eventually we obtained both documents. We learned a lot from this experience, including the importance of trust between the CAB and the research staff."

Octavio Valente Junior, CAB Member, President of Grupo Pela Vidda, Rio de Janeiro, Brazil

INDIA

In 2003 IAVI India continued community consultations, outreach and other preparedness activities for Indian AIDS vaccine trials.

"Do we in India really need an AIDS vaccine? Last year, IAVI India frequently faced this question from various sections of the community. Today, this question is hardly ever asked. Instead, people are saying: 'We certainly need an AIDS vaccine, so how can we make sure we get one?' This highly significant shift reveals an acceptance—however tentative—that India, and Indians, will need to be involved in the global quest for an AIDS vaccine. Considering the history of human clinical trials in India, this has been a giant leap in community perception."

Anjali Nayyar, Country Director, IAVI India, New Delhi, India

A PUBLICATION OF THE IAVI REPORT

[The Newsletter of the International AIDS Vaccine Initiative]

KENYA

In 2003 the Kenya AIDS Vaccine Initiative (KAVI) launched its fourth preventive AIDS vaccine trial in collaboration with the International AIDS Vaccine Initiative.

"One highlight of last year was the launch, in January, of a Peer Leader program that brought 16 volunteers from around Nairobi to monthly workshops on AIDS vaccine development at the KAVI site. The Peer Leaders have been incredibly motivated and have done workshops, spoken on radio shows and been informal resources to help bridge the gap between the research team and the communities we're working with on the trials."

Sabina Wakasiaka, Nurse Counselor, Kenya AIDS Vaccine Initiative, Nairobi, Kenya

PERU

IMPACTA is an AIDS vaccine trials unit in Lima, Peru that is currently participating in an international trial conducted by the HVTN.

"In the Peruvian AIDS arena, 2003 will be remembered for the media campaign that IMPACTA launched on World AIDS Day. Television and radio stations and newspapers donated space and airtime worth US\$500,000. This allowed us to talk about how the AIDS epidemic is growing locally and internationally and how Peruvians are fighting against AIDS—including volunteering for and supporting AIDS vaccine trials."

Cesar Bazan, Community Educator, IMPACTA, Lima, Peru

SOUTH AFRICA

In November 2003 South Africa commenced its first two Phase I vaccine trials. The two trials are coordinated by the South African AIDS Vaccine Initiative; one is sponsored by NIAID/HVTN and the other by IAVI.

"In a year of highlights and 'firsts' for vaccines in South Africa, the biggest first was the commencement, within one week, of two Phase I clinical trials at the same two sites. The first injections at the Soweto and Durban sites were met with jubilation, singing, popping champagne corks and praying. Our volunteers shared the joy and underlying solemnity of the occasion. Durban volunteer Joan McCosh said, 'We all know someone affected by AIDS. I have two granddaughters and I hope that a vaccine is available for them when they are adolescents. Where would we all be today if people hadn't tried out the smallpox or polio vaccines?'"

Michelle Galloway, SAAVI Communications Manager, Cape Town, South Africa

SWITZERLAND

In 2003 the Swiss Vaccine and Immunotherapy Center, in collaboration with IAVI, began a Phase I study that is also taking place in South Africa.

"What we appreciated this year is the quality of collaboration among staff at the hospital trial site and with our external partners. Sharing methods and experiences allowed us to be well trained and prepared to face the day-to-day events of a clinical trial. Another highlight is our volunteers who are doing a great job and are a precious help for recruiting new participants."

Séverine Burnet, Study Manager, Swiss Vaccine and Immunotherapy Center, Lausanne University Hospital, Switzerland

THAILAND

On 29 September 2003, the Thai Ministry of Health, the US Military HIV Research Program and other partners officially launched Thailand's second Phase III efficacy trial of a preventive AIDS vaccine.

"The protocol review for the Phase III prime boost trial took nearly 2 years—the most lengthy review process ever for a human trial in Thailand. The preparatory phase was especially challenging because of the Thai national policy that medical research should be integrated into national health care centers that also provide routine care. This policy is designed to strengthen the local health care systems and it helps ensure that the trial is part of the community. We have learned that it is possible to do this and would like to encourage other developing countries to do so as well."

Dr. Supachai Rerks-Ngarm, Principal Investigator, Prime Boost Phase III Trial, Bangkok, Thailand

UGANDA

The Uganda Virus Research Institute (UVRI) and IAVI launched Uganda's second preventive AIDS vaccine trial in 2003.

"One highlight of 2003 was the inauguration of our new vaccine trial unit in Entebbe, including laboratories, clinical and counseling rooms, and offices. The Honorable Mike Mukula, the Minister of State for Health, officiated at the ceremonies and said, 'There are many reasons to be hopeful about these trials.' He also urged Ugandans to remain on guard despite the declining HIV prevalence and the hope that a vaccine would eventually be found. 'The moment we become complacent, we are heading for trouble.'"

Emmanuel Mugisha, Senior Community Development Coordinator, IAVI/UVRI, Entebbe, Uganda

UNITED KINGDOM

The St Thomas' Hospital HIV Vaccine Trials Unit is participating in a Phase I trial that is co-sponsored by IAVI and also includes a

study site in Nairobi, Kenya.

"The year's highlight was achieving enrollment for our Phase I trial within the targeted timeline. We've found so many committed and selfless individuals who were willing to take part. One volunteer's comments sum up the overall spirit: 'If I can do anything to help, I will have a go. And it's not as if someone is asking me to climb Everest. It's not a great burden, but it could turn out to be very important.'"

Dr. Barry Peters, O10 Study Team Lead Investigator, St Thomas' Hospital HIV Vaccine Trials Unit, Oxford, UK

USA

In December 2003 the Aaron Diamond AIDS Research Center (ADARC) and IAVI began a Phase I vaccine trial.

"Throughout the entire planning process for the trial we were very concerned about our ability to recruit low-risk HIV-negative volunteers to participate in the trial. Instead, we have been overwhelmed by the positive response and have been challenged to keep up with the phone calls from people interested in volunteering—which have numbered in the hundreds!"

Dr. Sarah Schlesinger, Trial Physician, ADARC/Rockefeller University, New York, USA

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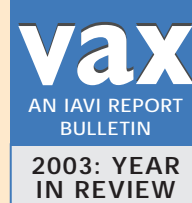
Many thanks to the contributors to this issue of VAX, to Steve Wakefield of the HVTN and to all of the 2003 AIDS vaccine trial volunteers.



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IAVI is a scientific organization founded in 1996 whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. IAVI focuses on four key areas: accelerating scientific progress; education and advocacy; ensuring vaccine access and creating a more supportive environment for industrial involvement in HIV vaccine development.

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AIDS VACCINE TRIALS 2003: YEAR IN REVIEW


The following trials of preventive AIDS vaccines began immunizations in 2003. Additional countries and sites will be added to some of these trials in 2004. For updated information please visit the IAVI Vaccine Trials Database (www.iavi.org/trialsdb). We welcome additions, corrections and comments (e-mail to trialsdb@iavi.org).

•JANUARY - USA
Phase I, 30 volunteers
pGA2/JS2 DNA (B) 
NIAID, HVTN; VICAL

•MAY - USA
Phase I, 273 volunteers
MRKAd5-gag.pol.nef (B) 
MERCK; MERCK

•AUGUST - USA
Phase I, 10 volunteers
EnvPro gp140 (D) 
SJCRRH; SJCRRH


•SEPTEMBER - USA
Phase I, 250 volunteers
ALVAC vCP205 (B), MRKAd5-gag (B)  
AVENTIS PASTEUR, MERCK; AVENTIS PASTEUR, MERCK


•DECEMBER - USA
Phase I, 45 volunteers
ADVAX DNA (C) 
ADARC, IAVI; VICAL



•DECEMBER - USA
Phase I, 168 volunteers
env/gag DNA/PLG B (B), gp140 B (B)  
NIAID, HVTN; CHIRON



•JULY - Switzerland, UK
Phase I, 24 volunteers
NYVAC-HIV C (C) 
IMPERIAL COLLEGE LONDON, EUROVAC; AVENTIS PASTEUR



•SEPTEMBER - France
Phase I, 34 volunteers
gp160MN/LAI-2 (B) 
ANRS; AVENTIS PASTEUR

•NOVEMBER - Italy
Phase I, 32 volunteers
tat DNA (B) 
ISS; PAREXEL


•JULY - Botswana, USA
Phase I, 32 volunteers
EP HIV-1090 DNA (B) 
NIAID, HVTN; EPIMMUNE



•APRIL - Kenya, UK
Phase I, 111 volunteers
HIVA.DNA and/or HIVA.MVA (A)  
IAVI, KAVI, MRC; COBRA, IDT

•MARCH - Kenya
Phase I, 10 volunteers
HIVA.DNA and/or HIVA.MVA (A)  
IAVI, KAVI, MRC; COBRA, IDT

•FEBRUARY - Uganda
Phase I, 50 volunteers
HIVA.DNA and/or HIVA.MVA (A)  
IAVI, UVRI; COBRA, IDT

•NOVEMBER - South Africa, Switzerland, UK
Phase I, 111 volunteers
HIVA.MVA (A) 
IAVI; COBRA, IDT

•NOVEMBER - South Africa, USA
Phase I, 48 volunteers
AVX101 VEE (C) 
NIAID, HVTN; ALPHA Vax

•OCTOBER - Thailand
Phase III, 16,000 volunteers
ALVAC-HIV vCP1521 (E), AIDS VAX B/E gp120 (B/E)  
NIAID, HVTN, THAI MINISTRY OF HEALTH; AVENTIS PASTEUR, VaxGen




•JUNE - Australia
Phase I/II, 24 volunteers
pHIS-HIV-B; rFPV-HIV-B (B)  
NIH, UNSW; ATVC

MAP KEY

TRIAL INFORMATION

•Month - Countries
Phase, No. volunteers
VACCINE (CLADE)
TRIAL SPONSOR; MANUFACTURER

VACCINE TYPE

DNA 
Viral Vector 
Protein Subunit 

Abbreviations: ADARC: Aaron Diamond AIDS Research Center; ANRS: Agence Nationale de Recherche sur le SIDA; ATVC: Australian-Thai HIV Vaccine Consortium; CCRI: Columbus Children's Research Institute; EuroVac: European Vaccine Effort Against HIV/AIDS; HVTN: HIV Vaccine Trials Network; IAVI: International AIDS Vaccine Initiative; IDT: Impfstoffwerk Dessau Tornau GmbH; ISS: Istituto Superiore di Sanita; KAVI: Kenya AIDS Vaccine Initiative; MRC: UK Medical Research Council; NIH: National Institutes of Health; NIAID: National Institute of Allergy and Infectious Diseases; SJCRRH: St Jude Children's Research Hospital; UNSW: University of New South Wales; UVRI: Uganda Virus Research Institute