



HVTN Fact Sheet, February 2004

The HIV Vaccine Trials Network (HVTN) is an international collaboration of more than 25 research institutions that conducts trials of candidate HIV vaccines in humans. It is the largest clinical trials program devoted to the development and testing of HIV vaccines worldwide. The HVTN was established in 1999 by the National Institute for Allergy and Infectious Diseases at the United States National Institutes of Health, and is headquartered at the Fred Hutchinson Cancer Research Center in Seattle, Washington. Statistical, data management and laboratory expertise are provided by centralized facilities at the Fred Hutchinson Cancer Research Center in Seattle and Duke University in Durham, North Carolina. The HVTN has strong collaborations with inventors of vaccines and a wide variety of scientists working in the areas of HIV virology, immunology and pathogenesis.

The goal of the HVTN is to provide high quality data on the safety, immunogenicity and efficacy of HIV vaccine candidates in humans through a global field trial capacity. HVTN trials evaluate HIV vaccine regimens designed to reduce the frequency of HIV acquisition, progression and transmission to others.

The HVTN integrates clinical trials development and management with state-of-the-art laboratory testing and development of new immunological assays to establish correlates of protection against HIV infection. HVTN protocol development teams assist companies and inventors of candidate HIV vaccines in expediting clinical development. Currently over 25 vaccine trial concepts from laboratories in industry, academic institutions and governments are in progress or in development.

The HVTN is currently conducting eleven clinical trials of HIV vaccine candidates, which are summarized in Table 1. The HVTN is also studying participants from HVTN Phase I and II trials who became HIV-infected during the course of a trial. This study examines the virologic, immunologic and clinical natural history of these infected participants, comparing individuals who received vaccines with those who received placebo.

Table 1: Ongoing HVTN Trials

Developer	Vaccine	Protocol	Enrollment	Sites
Aventis/VaxGen	ALVAC vCP 1452 + AIDSVAX B/B	203	Complete	USA
Aventis	ALVAC vCP 1452 high-dose	039	Complete	USA
GlaxoSmithKline	NefTat fusion protein+ gp120	041	Complete	USA
Aventis	ALVAC vCP 1452 + MN rgp120	026	Complete	International
H Robinson (Emory University)	JS2 DNA	045	Complete	USA
Epimmune	Multi-epitope CTL DNA	048	In progress	USA, Botswana
Alphavax	VEE Gag replicon	040	In progress	USA & S. Africa
Merck	MRK Ad5 Gag	050	In progress	USA, International
Chiron	Env/Gag DNA/PLG B + gp 140 clade B	049	In progress	USA

Table 1: Ongoing HVTN Trials (continued)

Developer	Vaccine	Protocol	Enrollment	Sites
NIH Vaccine Research Center	Multiclade DNA + DNA IL-2/Ig	044	In progress	USA
NIH Vaccine Research Center	Multiclade DNA	052	In progress	USA

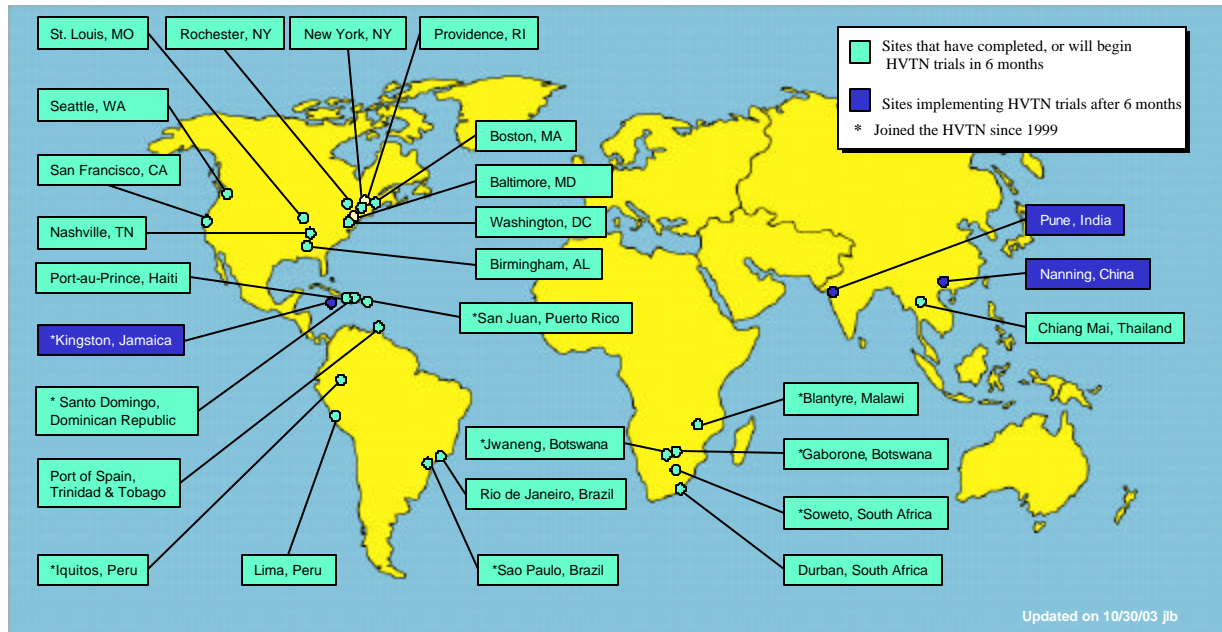
HVTN trials that are currently anticipated to start within 2004 are listed by vaccine type in Table 2 below. Plans for phase IIB and phase III trials of two products are also in progress, contingent upon the results of phase I/II studies.

Table 2: Planned HVTN Trials

Developer	Vaccine	Protocol	Anticipated Start Date	Sites
DNA Vaccines				
GeoVax	JS7 DNA plasmid	058	Q3 2004	TBD
Wyeth	Gag DNA + IL-12 DNA	TBD	Q3 2004	USA
SAAVI	DNA plasmids	TBD	Q4 2004	TBD
Vector Vaccines				
<i>Alphavirus:</i>				
Alphavax	VEE gag replicon	059	Q3 2004	USA & S. Africa
<i>Adenovirus:</i>				
NIH VRC	Multiclade Ad5	054	Q2 2004	USA, International
<i>Poxvirus:</i>				
Therion	MVA + FPV	055	Q1 2004	USA
Geovax	MVA	TBD	Q3 2005	USA
<i>Fungal:</i>				
GlobelImmune	Yeast Gag	053	Q3 2004	USA
Peptides				
Wyeth	Multi-epitope CTL	056	Q1 2004	USA
Combination Approaches				
NIH Vaccine Research Center	Multiclade DNA + multiclade Ad5	057	Q2 2004	USA
NIH Vaccine Research Center	Multiclade DNA + multiclade Ad5	204	Q3 2004	USA, International
ANRS/Aventis	Lipopeptide 5 + ALVAC vCP1452	042	Q1 2004	USA
Wyeth	Multi-epitope CTL + Gag DNA/IL-12 DNA	056 Rollover	Q3 2004	USA
Epimmune	DNA + Multi-epitope HTL Protein	TBD	Q1 2005	USA, International
Epimmune	DNA + MVA	TBD	Q2 2005	USA, International

Led by Dr. Larry Corey, Principal Investigator, and Dr. Judy Wasserheit, Director, the HVTN currently includes trial sites and investigators in 13 countries on four continents. These are shown on the map and list that follow.

HIV Vaccine Trials Network Sites



HVTN GLOBAL TRIAL SITES:

Baltimore, MD

Johns Hopkins University, Drs. Donald Burke, Christopher Beyrer, Clayton Harro
University of Maryland at Baltimore, Drs. William Blattner, Farley Cleghorn

Birmingham, AL

Alabama Vaccine Research Clinic, Dr. Mark Mulligan

Blantyre, Malawi

Kachere Rehabilitation Center, Drs. Newton Kumwenda, Richard Pendame, Taha E. Taha

Boston, MA

Brigham & Women's Hospital – Harvard Medical School, Drs. Raphael Dolin, Lindsay Baden
Fenway Community Health, Dr. Kenneth Mayer

Chiang Mai, Thailand

Research Institute for Health Sciences - Chiang Mai University, Dr. Thira Sirisanthana

Durban, South Africa

Medical Research Council, Drs. Andrew Robinson, Timothy Tucker

Gaborone, Botswana

Botswana-Harvard Partnership for HIV Research & Education, Dr. Myron Essex

Iquitos, Peru

Impacta, Drs. Lourdes Kusunoki, Pedro Goicochea, Annette Ghee

Jwaneng, Botswana

Botswana-Harvard Partnership for HIV Research and Education, Dr. Myron Essex

Updated 2/4/04, lab

Kingston, Jamaica

Jamaica Ministry of Health, *Dr. Peter Figueroa*

Lima, Perú

IMPACTA, *Dr. Jorge Sanchez*

Nanning, China

Guangxi Center for HIV/AIDS Prevention & Control, *Drs. Jie Chen, Zhijun Li, Wei Liu*

Nashville, TN

Vanderbilt University, *Drs. Peter Wright, Paul Spearman*

New York, NY

Project Achieve – Bronx & Union Square, *Dr. Beryl Koblin*
Columbia University, *Dr. Scott Hammer*

Port-au-Prince, Haiti

Cornell-GHESKIO, *Dr. Jean Pape*

Port of Spain, Trinidad & Tobago

Medical Research Foundation of Trinidad & Tobago, *Drs. Noreen Jack, Courtenay Bartholomew*

Providence, RI

Miriam Hospital, *Dr. Michelle Lally*

Pune, India

National AIDS Research Institution, *Drs. Ramesh Paranjape, Sanjay Mehendale*

Rio de Janeiro, Brazil

Hospital Escola Sao Francisco de Assis, *Drs. Mauro Schechter, Paulo Barroso*

Rochester, NY

University of Rochester, *Dr. Michael Keefer*

Sao Paulo, Brazil

Centro de Referencia, *Dr. Artur Kalichman*

San Francisco, CA

San Francisco Department of Public Health, *Dr. Susan Buchbinder*

San Juan, Puerto Rico

University of Puerto Rico School of Medicine, *Dr. Carmen Zorrilla*

Santo Domingo, Dominican Republic

Instituto Dermatologico, *Dr. Ernesto Guerrero*

Saint Louis, MO

St. Louis University, *Drs. Robert Belshe, Sharon Frey, Geoffrey Gorse*

Seattle, WA

Fred Hutchinson Cancer Research Center / University of Washington Vaccine Trials Unit, *Drs. Julie McElrath, Connie Celum*

Soweto, South Africa

Medical Research Council, *Drs. Glenda Grey, James McIntyre*