

In 2004, fifteen new trials to test AIDS vaccine candidates were initiated in seven different countries. The most advanced of the newly-launched trials is a Phase IIb study, which is a proof of concept trial to see if this type of vaccine is effective in preventing infection with HIV. Eleven new Phase I trials, the first stage of testing vaccine candidates in humans, also began in 2004. The world map inside this special issue of VAX highlights the trials that began in 2004 and, along with the table below, provides a rundown of all the ongoing clinical trials of preventive AIDS vaccines around the world.

#### Ongoing Trials of Preventive HIV Vaccines

Trial No.	Sponsor; Manufacturer	Start Date	Sites (No.)	Vaccine Name	Antigen	Clade	Comment
<b>Phase III (Large trials in high-risk populations; test vaccine efficacy)</b>							
N/A	WRAIR, AFRIMS, MoH; Aventis, VaxGen	October 2003	Thailand (several)	ALVAC vCP1521 AIDSVAX B/E	<i>env</i> (E), <i>gag/pol</i> (B) <i>env</i> (B, E)	B, E B, E	16,000 healthy HIV-negative adult volunteers
<b>Phase II (Mid-sized trials in low- &amp; high-risk populations; test vaccine safety, immunogenicity)</b>							
HVTN 502/ Merck 023	HVTN, Merck; Merck	December 2004	US (12), Canada (1), Peru (2), Dominican Republic (1), Haiti (1), Puerto Rico (1), Australia (1)	MRKAd5 HIV-1 <i>gag/pol/nef</i>	<i>gag, pol, nef</i>	B	To test whether the cellular immune response generated by Merck's vaccine is potent enough to impact infection with HIV in 1,500 at-risk volunteers
ANRS VAC 18	ANRS; Aventis	September 2004	France (6)	LIPO-5	5 lipopeptides containing CTL epitopes (from Gag, Pol, Nef)	B	Compare CD8 response of 3 doses of LIPO-5 versus placebo
IAVI 010	IAVI, KAVI; Cobra, IDT	February 2003	UK, Kenya	DNA.HIVA MVA.HIVA	<i>gag</i> + 25 CTL epitopes <i>gag</i> + 25 CTL epitopes	A A	HIV-DNA +/-MVA boost
<b>Phase I/II (Mid-sized trials in low-risk populations; test vaccine safety, immunogenicity)</b>							
HVTN 042/ ANRS VAC 19	HVTN, ANRS; Aventis	June 2004	US (13)	LIPO-5 ALVAC-HIV (vCP1452)	See above <i>env, gag, pol, nef</i>	B B	To evaluate safety and immunogenicity of LIPO-5 alone, vCP1452 alone, and ALVAC prime/LIPO-5 boost
GTU-MultiHIV	FIT Biotech	February 2004	Finland	GTU-MultiHIV B clade	<i>nef, rev, tat, gag, pol, env</i> , CTL epitopes	B	Immunogenicity of GTU-MultiHIV clade B DNA after intradermal and intramuscular injection
HVTN 052	HVTN; Vical	December 2003	US (10)	VRC-HIVDNA-009- 00-VP	<i>gag, pol, nef, env</i>	B A,B,C	Phase Ib, safety, immunogenicity of multiclade DNA vaccine
N/A	UNSW; AVC	June 2003	Australia	pHIS-HIV-B rFPV-HIV-B	<i>gag, RT, rev, tat, vpu, env</i> <i>gag, RT, rev, tat, vpu, env</i>	B B	DNA vaccine + fowlpox boost
<b>Phase I (Small trials in low-risk populations; test vaccine safety, immunogenicity)</b>							
IAVI C002	IAVI; IDT	January 2005	US (2)	ADMVA	<i>env/gag-pol, nef-tat</i>	C	Safety, immunogenicity of an MVA vector vaccine
HVTN 057	NIAID/VRC; Vical	November 2004	US (12)	VRC-HIVADV014- 00-VP	<i>gag/pol</i> polyprotein <i>env</i>	B A,B,C	Safety, immune response to VRC-HIVADV014-00-VP, when given as a booster to already vaccinated adults (HVTN 052)
HVTN 059	NIAID; AlphaVax	October 2004	US (5)	AVX101 (VEE)	<i>gag</i>	C	Safety, immunogenicity of an alphavirus replicon
VRC 007 (04-I-0254)	NIAID/VRC; Vical	August 2004	US (1)	VRC-HIVDNA016- 00-VP	<i>gag, pol, nef, env</i>	B A, B, C	Safety, immunogenicity of a 6-plasmid multiclade HIV-1 DNA vaccine
HVTN 055	NIAID; Therion	July 2004	US (6)	TBC-M358 (MVA) TBC-M335 (MVA) TBC-F357 (FPV) TBC-F349 (FPV)	<i>env, gag, tat, rev, nef, RT, env, gag, tat, rev, nef, RT</i>	B B B B	Safety, immunogenicity of MVA-HIV and rFPV-HIV alone or in combination
ANRS VAC 16	ANRS; Biovector SA	July 2004	France (6)	LIPO-4T (LPHIV-1)	4 lipopeptides containing CTL epitopes (from Gag, Pol-RT, Pol, Nef)	B	Safety and immunogenicity of lipopeptides LIPO-4T, by two administration routes
VRC 006 (04-I-0172)	NIAID; GenVec	May 2004	US	VRC-HIVADV014- 00-VP	<i>gag/pol</i> polyprotein <i>env</i>	B A,B,C	Safety, tolerability, immune response of a multiclade HIV adenoviral vector vaccine in uninfected adults
N/A	NIAID, WRAIR; AVANT	May 2004	US	LFn-p24	Anthrax-derived polypeptide LFn <i>gag</i> p24 protein	B	18 healthy volunteers. Aim: inducing strong and persistent HIV-1 Gag specific CD8 T cell responses

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## Ongoing Trials of Preventive HIV Vaccines

Trial No.	Sponsor; Manufacturer	Start Date	Sites (No.)	Vaccine Name	Antigen	Clade	Comment
<b>Phase I (Small trials in low-risk populations; test vaccine safety, immunogenicity) • Continued from front page</b>							
HVTN 056	NIAID; Wyeth	April 2004	US (7)	HIV CTL MEP	CTL epitopes from <i>env</i> or <i>gag</i>	B	Safety and immunogenicity of HIV CTL MEP
N/A	UMMS; ABL	April 2004	US	DNA Proteins	<i>gag</i> + 5 <i>env</i> 5 recombinant gp120	A,B,C,E A,B,C,E	DNA prime: 1 <i>gag</i> gene (C) + 5 <i>env</i> genes (A, 2 B, C, E). Boost: 5 gp120 (same isolates as DNA). Adjuvant: QS21.
HVTN 050/ Merck 018	NIAID; Merck	January 2004	Thailand, Brazil, Haiti, Puerto Rico	MRKAd5 HIV-1	<i>gag</i>	B	Replication defective Ad-5 vector
IAVI A001	IAVI; Targeted Genetics	December 2003	Belgium (2), Germany (2), India	tgAAC09 AAV	<i>gag</i> , protease, RT	C	Recombinant AAV vector; single shot
IAVI C001	IAVI, ADARC; Vical	December 2003	US (2)	ADVAX DNA	<i>gag</i> , <i>env</i> , <i>pol</i> , <i>nef</i> , <i>tat</i>	C	Multi-gene approach
HVTN 049	HVTN; Chiron	December 2003	US (8)	Gag and Env DNA/PLG Oligomeric gp140/MF59	<i>gag</i> , <i>env</i> DNA/PLG; Oligomeric gp140	B B	Safety, immunogenicity of DNA/PLG and <i>env</i> DNA/PLG prime, oligomeric gp140/MF59 boost
HVTN 044	HVTN; Vical	December 2003	US (3)	VRC-HIVDNA-009-00-VP	<i>gag</i> , <i>pol</i> , <i>nef</i> <i>env</i>	B A,B,C	Safety, immunogenicity of multiclade DNA vaccine with IL-2/Ig DNA adjuvant
IAVI 011	IAVI, SAAVI; IDT	November 2003	South Africa (2), UK (1), Switzerland (1)	MVA-HIVA	<i>gag</i> + 25 CTL epitopes	A	Dose response
EnvPro	St Jude's	September 2003	US	EnvPro protein	gp140	D	Purified Env protein
ISS P-001	ISS; Excell	September 2003	Italy (4)	HIV-1 Tat protein	<i>tat</i>	B	Safety, immunogenicity of the recombinant HIV-1 Tat protein in healthy HIV-negative volunteers
N/A	Merck; Aventis	2003	US (17)	MRKAd5 HIV-1; ALVAC vCP205	<i>gag</i> <i>env</i> , <i>gag</i> , <i>pol</i>	B	MRKAd5 HIV-1 prime, ALVAC vCP205 boost
HVTN 040	NIAID, SAAVI; AlphaVax	July 2003	US (4), South Africa (2)	AVX101 VEE	<i>gag</i>	C	Safety and immunogenicity of VEE vector
ANRS VAC 14	ANRS; Aventis	June 2003	France (2)	gp160MN/LAI-2	gp120 (MN strain), gp41 (LAI strain)	B	Safety and immunogenicity, using several routes
HVTN 048	NIAID; Epimmune	April 2003	US (2), Botswana	EP HIV-1090 DNA	21 CTL epitopes from <i>gag</i> , <i>pol</i> , <i>env</i> , <i>nef</i> , <i>rev</i> , <i>vpr</i>	All	Safety and immunogenicity
VRC 004 (03-I-0022)	NIAID/VRC; Vical	November 2002	US	VRC-HIVDNA009-00-VP	<i>gag</i> , <i>pol</i> , <i>nef</i> (clade B); <i>env</i> (clades A, B, C)	A,B,C	Safety and immunogenicity of a multiclade vaccine
B011; RV 138	WRAIR; Aventis	July 2002	US	ALVAC-HIV vCP205	<i>env</i> , <i>gag</i> , <i>pol</i>	B	Response to vaccine subcutaneously (via dendritic cells), intradermally, or intramuscularly
N/A	Merck	2002	US	<i>gag</i> DNA	<i>gag</i>	B	Dose response
01-I-0079	NIAID/VRC; Vical	January 2001	US	VRC4302 DNA	<i>gag</i> , <i>pol</i>	B	Dose and immune response
N/A	Merck	2001	US	<i>gag</i> DNA Ad5 <i>gag</i>	<i>gag</i> <i>gag</i>	B B	Evaluation of DNA vs. Ad5 prime + Ad5 boost

**ABL:** Advanced BioScience Laboratories, Inc.; **ADARC:** Aaron Diamond AIDS Research Center; **AFRIMS:** Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand, is a joint U.S.-Royal Thai Army Command; **AlphaVax:** AlphaVax Human Vaccines Inc.; **ANRS:** Agence Nationale de Recherche sur le SIDA; **AVANT:** AVANT Immunotherapeutics, Inc.; **AVC:** Australian Vaccine Consortium; **Aventis:** Aventis Pasteur; **Excell:** Excell Biotech; **HVTN:** HIV Vaccine Trials Network; **IAVI:** International AIDS Vaccine Initiative; **IDT:** Impfstoffwerk Dessau Tornau GmbH; **ISS:** Istituto Superiore di Sanità; **KAVI:** Kenyan AIDS Vaccine Initiative; **MoH:** Ministry of Health (Thailand); **NIAID:** US National Institute Allergy and Infectious Diseases; **PACTG:** Pediatric AIDS Clinical Trials Group; **SAAVI:** South African AIDS Vaccine Initiative; **St Jude's:** St Jude's Children's Research Hospital; **Therion:** Therion Biologics Corporation; **UMMS:** University of Massachusetts Medical School; **UNSW:** University of New South Wales; **VRC:** Vaccine Research Center; **WRAIR:** Walter Reed Army Institute of Research

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