



In 2005, 13 new trials of preventive AIDS vaccine candidates began in 9 countries around the world. Two of these involved vaccine candidates that entered Phase II trials, an intermediate stage of clinical evaluation. India, China, and Rwanda started their first AIDS vaccine trials last year and South Africa began the country's first Phase II AIDS vaccine trial. Several of these newly initiated trials involved novel vaccination strategies, including prime-boost regimens where two candidates are administered separately to try to improve the immune responses induced. The table below is a list of all ongoing AIDS vaccine trials.

## Ongoing Trials of Preventive AIDS Vaccines

Trial No.	Title	Start Date	Organizer, Sponsor, Manufacturer	Project Site(s)	Vaccine Name	Antigen (Clade)
<b>Phase III (Large trials in high-risk populations; test vaccine efficacy)</b>						
RV 144	A trial of Aventis Pasteur live recombinant ALVAC-HIV (vCP1521) priming with VaxGen gp120 B/E (AIDSVAX® B/E) boosting	Oct-03	WRAIR, Department of Community Disease Control, MOPH, TAVEG, AFRIMS	Thailand (several)	Prime: ALVAC vCP1521 Boost: AIDSVAX B/E	<i>env</i> (E), <i>gag/pol</i> (B), <i>env</i> (B,E)
<b>Phase II (Mid-sized trials in low- and high-risk populations; test vaccine safety, immunogenicity)</b>						
IAVI A002	A placebo-controlled, double-blind trial to evaluate the safety and immunogenicity of tgAAC09, an HIV vaccine containing clade C Gag-PR-ΔRT DNA in an adeno-associated virus (AAV) capsid, administered twice, at three dosage levels and two dosing intervals	Nov-05	IAVI, Targeted Genetics	South Africa (3) Later: Uganda, Zambia	tgAAC09	<i>gag</i> , PR, RT (C)
HVTN 204	A clinical trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine, VRC-HIVDNA016-00-VP, followed by a multiclade recombinant adenoviral vector HIV-1 vaccine boost, VRC-HIVADV014-00-VP	Sep-05	NIAID, VRC, HVTN, Vical, GenVec	USA (7), Brazil (2), South Africa (3) Later: Haiti, Jamaica	Prime: VRC-HIVDNA-016-00-VP Boost: VRC-ADV-014-00-VP	<i>gag</i> , <i>pol</i> , <i>nef</i> (B), <i>env</i> (A,B,C); <i>gag</i> , <i>pol</i> (B), <i>env</i> (A,B,C)
HVTN 502/ Merck 023	A double-blind, randomized, placebo-controlled, proof-of-concept study to evaluate the safety and efficacy of a three-dose regimen of the Merck adenovirus serotype 5 vaccine (MRKAd5 HIV-1 Gag/Pol/Nef)	Dec-04	HVTN, NIAID, Merck	USA (12), Canada, Peru (2), DR, Haiti, Puerto Rico, Australia, Brazil (2), Jamaica	MRKAd5 HIV-1 Gag/Pol/Nef	<i>gag</i> , <i>pol</i> , <i>nef</i> (B)
ANRS VAC 18	A randomized, double-blind vaccine trial to compare the safety and immunogenicity of 3 doses of LIPO-5 versus placebo	Sep-04	ANRS, Aventis Pasteur	France (6)	LIPO-5	5 lipopeptides containing CTL epitopes from Gag, Pol, Nef (B)
<b>Phase I (Small trials in low-risk populations; test vaccine safety, immunogenicity)</b>						
HVTN 064	A clinical trial to evaluate the safety and immunogenicity of recombinant protein vaccine EP-1043 and the DNA vaccine EP HIV-1090 given alone or in combination	Jan-06	HVTN, NIAID, Pharmexa-Epimmune	USA (3), Peru (2)	EP-1043, EP HIV-1090	<i>gag</i> , <i>pol</i> , <i>vpr</i> , <i>nef</i> (B); Protein containing T-helper epitopes from <i>env</i> , <i>gag</i> , <i>pol</i> , <i>vpu</i> (B)
IAVI D001	A randomized, placebo-controlled, dose-escalating, double-blinded study to evaluate the safety and immunogenicity of TBC-M4 (modified vaccinia Ankara (MVA) HIV-1 multigenic subtype C) vaccine	Dec-05	IAVI, Therion	India	TBC-M4	<i>env</i> , <i>gag</i> , <i>tat-rev</i> , <i>nef</i> -RT (C)
IAVI V001	A randomized, placebo-controlled, double-blind trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine followed by recombinant, multiclade HIV-1 adenoviral vector vaccine or the multiclade HIV-1 adenoviral vector vaccine alone	Nov-05	IAVI, NIAID, VRC	Rwanda, Kenya	Prime: VRC-HIVDNA-016-00-VP Boost: VRC-ADV-014-00-VP	<i>gag</i> , <i>pol</i> , <i>env</i> (B); <i>gag</i> , <i>pol</i> , <i>env</i> (A,B,C)
RV 158	A double-blind, randomized, dose escalating, placebo-controlled, study of safety and immunogenicity of WRAIR/NIH live recombinant MVA-CMDR (HIV-CM235 <i>env</i> /CM240 <i>gag/pol</i> ) administered by intramuscular or intradermal route	Nov-05	WRAIR, NIH	USA Later: Thailand	MVA-CMDR	gp160, <i>gag</i> , and <i>pol</i> (Integrase-deleted and reverse transcriptase nonfunctional) (A,E)
HVTN 063	A clinical trial to evaluate the safety and immunogenicity of HIV-1 Gag DNA vaccine alone or with IL-15 DNA, boosted with HIV-1 Gag DNA + IL-15 DNA, HIV CTL multi-epitope peptide vaccine, or HIV-1 Gag DNA + IL-12 DNA	Sep-05	HVTN, NIAID, Wyeth	USA (7), Brazil (2)	Prime: GENEVAX Gag-2692 +/- IL-15 DNA; Boost: Multi-epitope CTL Peptide vaccine or GENEVAX Gag-2692 + IL-15 DNA or GENEVAX Gag-2692 + IL-12 DNA	<i>gag</i> (B); <i>env</i> , <i>gag</i> , <i>nef</i> (B) or <i>gag</i> (B)
HVTN 060	A clinical trial to evaluate the safety and immunogenicity of an HIV-1 Gag DNA vaccine with or without IL-12 DNA adjuvant, boosted with homologous plasmids or with HIV CTL multi-epitope peptide vaccine, RC529-SE, plus GM-CSF	Aug-05	HVTN, NIAID, Wyeth	USA (3), Thailand	Prime: GENEVAX Gag-2692 +/- IL-12 DNA adjuvant Boost: DNA plasmids or RC529-SE and GM-CSF	<i>gag</i> (B); <i>gag</i> (B) or <i>env</i> , <i>gag</i> , <i>nef</i> (B)

## Ongoing Trials of Preventive AIDS Vaccines

Trial No.	Title	Start Date	Organizer, Sponsor, Manufacturer	Project Site(s)	Vaccine Name	Antigen (Clade)
<b>Phase I (Small trials in low-risk populations; test vaccine safety, immunogenicity) • Continued from front page</b>						
HVTN 054	A dose-escalation clinical trial to evaluate the safety and immunogenicity of a multiclade, multivalent recombinant adenoviral vector HIV vaccine, VRC-HIVADV014-00-VP, in participants who have low titers of pre-existing Ad5 neutralizing antibodies	Apr-05	HVTN, NIAID, VRC	USA (4)	VRC-HIVADV014-00-VP	<i>gag, pol</i> (B), <i>env</i> (A,B,C)
N/A	A randomized, placebo-controlled, double-blind trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine	Mar-05	Guangxi CDC	China	DNA vaccine	DNA plasmids (B,C)
N/A	Evaluation of the tolerability and safety of a recombinant HIV-1 multi-envelope DNA plasmid vaccine (EnvDNA)	Feb-05	St. Jude, NIH	USA	EnvDNA	<i>env</i> (A,B,C,D,E)
IAVI C002	A randomized, placebo-controlled, dose-escalating, double-blinded, study to evaluate the safety and immunogenicity of a modified vaccinia Ankara (MVA) expressing HIV-1 clade C <i>env/gag-pol</i> and <i>nef-tat</i> fusion genes (ADMVA) vaccine	Jan-05	IAVI, ADARC	USA (2)	ADMVA	<i>env/gag-pol, nef-tat</i> (C)
VRC 009 (05-I-0081)	A clinical trial to evaluate the safety and immunogenicity of a booster dose of a recombinant multiclade HIV-1 adenoviral vector vaccine, VRC-HIVADV014-00-VP, in volunteers who were previously immunized with VRC-HIVDNA009-00-VP in VRC 004 (03-I-0022)	Jan-05	NIAID, VRC	USA	VRC-HIVADV014-00-VP	<i>gag/pol</i> Polyprotein, <i>env</i> (A,B,C)
HVTN 057	A clinical trial to evaluate the safety of a multiclade recombinant adenoviral vector vaccine administered to participants from HVTN 052	Nov-04	HVTN, NIAID, VRC	USA (14)	VRC-HIVADV014-00-VP	<i>gag/pol</i> Polyprotein, <i>env</i> (A,B,C)
HVTN 059	A study to evaluate the safety of and immune response to an alphavirus replicon, HIV-1 subtype C Gag vaccine, AVX101	Oct-04	HVTN, NIAID, Alphavax	USA (6), South Africa, Botswana	AVX101 (VEE)	<i>gag</i> (C)
HVTN 055	A trial to evaluate the safety and immunogenicity of rMVAHIV and rFPVHIV vaccines, alone or in combination	Sep-04	HVTN, NIAID, Therion	USA (4), Brazil (2)	TBC-M358(MVA); TBC-M335 (MVA); TBC-F357(FPV); TBC-F349(FPV)	<i>env, gag</i> (B); <i>tat, rev, nef, RT</i> (B); <i>env, gag</i> (B); <i>tat, rev, nef, RT</i> (B)
N/A	A clinical trial to assess the safety and immunogenicity of an HIV vaccine based on AVANT's Therapore(R) technology	Jul-04	WRAIR, NIAID	USA	LFN-p24	Anthrax-derived polypeptide LFn <i>gag</i> p24 protein (B)
HVTN 056	A clinical trial to evaluate safety and immunogenicity of a CTL multi-epitope peptide vaccine formulated with RC529-SE, with or without GM-CSF	Apr-04	HVTN, NIAID, Wyeth	USA (7)	Wyeth multiepitope CTL peptide vaccine	CTL epitopes from <i>env</i> or <i>gag</i> (B)
VRC 008 (05-I-0148)	A clinical trial of a prime-boost HIV-1 vaccination schedule: multiclade DNA vaccine, VRC-HIVDNA016-00-VP, followed by multiclade adenoviral vector vaccine, VRC-HIVADV014-00-VP	Apr-04	NIAID, VRC	USA	Prime: VRC-HIVADV014-00-VP Boost: VRC-HIVDNA016-00-VP	<i>gag/pol</i> Polyprotein, <i>env</i> (A,B,C)
HVTN 044	A clinical trial to evaluate safety and immunogenicity of the DNA vaccine VRC-HIVDNA009-00-VP with plasmid cytokine adjuvant VRC-ADJDNA004-IL2-VP	Dec-03	HVTN, NIAID, VRC	USA (7)	VRC-HIVDNA009-00-VP IL-2/Ig DNA adjuvant	<i>gag, pol, nef</i> (B), <i>env</i> (A,B,C)
HVTN 049	A clinical trial to evaluate safety and immunogenicity of a gag DNA/PLG and env DNA/PLG microparticle vaccines and gp140/MF59 adjuvant vaccine	Dec-03	HVTN, NIAID, Chiron	USA (11)	Gag and Env DNA/PLG; Oligomeric gp140/SF-162	<i>gag, env</i> DNA/PLG (B); Oligomeric gp140 (B)
IAVI A001	A randomized, placebo-controlled, double-blind dose-escalation trial to evaluate the safety and immunogenicity of tgAAC09, a gag-PR-ΔRT AAV HIV vaccine	Dec-03	IAVI, Targeted Genetics	Belgium (2), Germany (2), India	tgAAC09	<i>gag, protease, RT</i> (C)
N/A	MRKAd5 HIV-1 as a prime, ALVAC vCP205 as a boost	Sep-03	Merck, Aventis Pasteur	USA (17)	Prime: MRKAd5 HIV-1 Boost: ALVAC vCP205	<i>gag</i> (B); <i>env, gag, pol</i> (B)
HVTN 050/ Merck 018	A dose-escalating study of the safety, tolerability, and immunogenicity of a three-dose regimen of the MRKAd5 HIV-1 Gag vaccine	Jan-03	HVTN, NIAID, Merck	USA (11), Malawi, Haiti, Thailand, Brazil (2), Puerto Rico, South Africa, Peru, DR		MRKAd5 HIV-1 <i>gag</i> (B)
B011/ RV 138	A study of Aventis Pasteur live recombinant ALVAC-HIV (vCP205, HIV-1 Env/Gag/Pol) administered subcutaneously via ex vivo transfected, autologous dendritic cells	Jul-02	WRAIR	USA	ALVAC-HIV vCP205	<i>env, gag, pol</i> (B)

**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; **ANRS:** Agence Nationale de Recherche sur le SIDA; **DR:** Dominican Republic; **Guangxi CDC:** Guangxi Centre for Disease Control and Prevention, China; **HVTN:** HIV Vaccine Trials Network; **IAVI:** International AIDS Vaccine Initiative; **MOPH:** Ministry of Public Health Thailand; **NIAID:** US National Institute Allergy and Infectious Diseases; **NIH:** US National Institutes of Health; **St. Jude:** St. Jude Children's Research Hospital; **TAVEG:** Thai AIDS Vaccine Evaluation Group; **VRC:** Vaccine Research Center at the US National Institutes of Health; **WRAIR:** Walter Reed Army Institute of Research

Sources: IAVI, VRC, HVTN, [clinicaltrials.gov](http://clinicaltrials.gov), <http://chi.ucsf.edu/vaccines>, [www.anrs.fr](http://www.anrs.fr)

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IAVI is a global not-for-profit organization working to speed the search for a vaccine to prevent HIV infection and AIDS. Founded in 1996 and operational in 23 countries, IAVI and its network of partners research and develop vaccine candidates. IAVI also advocates for a vaccine to be a global priority and works to assure that a future vaccine will be accessible to all who need it.



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