

Ongoing and Planned Trials of Preventive HIV/AIDS Vaccines, January 2012



Trial	Phase	Start Date	Sponsor/Funder/ Developer ***	Trial Site ***	Number of Participants *	Vaccine(s) **	Clade	Status / Expected Completion Date
Phase IIb (safety and efficacy)								
HVTN 505	Phase IIb	June 2009	HVTN, NIAID, VRC	US (Nashville, TN; Birmingham, AL; Los Angeles, CA; San Francisco, CA; Denver, CO; Orlando, FL; Atlanta, GA; Chicago, IL; Bethesda, MD; Boston, MA; New York, NY; Rochester, NY; Cleveland, OH; Philadelphia, PA; Dallas, TX; Houston, TX; Annandale, VA; Seattle, WA)	2,200	VRC-HIVDNA016-00-VP; VRC-HIVADV014-00-VP Prime: VRC-HIVDNA016-00-VP	A,B,C	Ongoing / Expected 2013
Phase II (safety, adherence, acceptability, feasibility)								
GeoVax Preventative Vaccine (HVTN 205)	Phase IIa	February 2009	DAIDS, GeoVax Labs Inc., HVTN	Peru (Lima), US (Birmingham, AL; San Francisco, CA; New York, NY; Seattle, WA)	299	JS7 plasmid DNA and MVA62B vaccine administered as (1) DNA at months 0 and 2 and MVA at months 4 and 6 or (2) MVA at months 0, 2 and 6	B	Ongoing, fully enrolled / August 2012, long-term follow-up Aug 2014
Phase I/II (safety, adherence, acceptability, feasibility)								
HIVIS 06	Phase I/II	January 2012	Karolinska Institutet, SMI, WRAIR	Tanzania	20	Modified Vaccinia Ankara		Planned / September 2012
TaMoVac I	Phase I/II	June 2010	EDTCP, Imperial College, INS, MHRP, Muhimbili University of Health and Allied Sciences, SMI, University of Munich	Mozambique (Maputo), Tanzania (Dar es Salaam and Mbeya)	120	Prime: HIVIS-DNA Boost: MVA- CMDR	DNA Env ABC, gag AB, Rtmut B, rev B; MVA Env E, gag A, pol A	Ongoing
HVTN 078	Phase I/II	October 2009	EuroVacc, HVTN, NIAID, VRC	Switzerland (Lausanne)	80	NYVAC-B; VRC-HIVADV038-00-VP	A,B,C	Ongoing
Phase I (safety, adherence, acceptability, feasibility)								
GeoVax Preventative Vaccine (HVTN 094)	Phase I	Targeted start date of Q1 2012	DAIDS, HVTN, GeoVax Labs Inc.	HVTN clinical research sites in US	48	GEO-D03 plasmid DNA and MVA62B vaccine administered as DNA at months 0 and 2 and MVA at months 4, 6, and 8	B, DNA co-expresses GM-CSF adjuvant	Planned / Q4 2013, long-term follow up Q4 2015
IAVI B004	Phase I	December 2011	IAVI, Ichor, Profectus and three clinical research partners in Africa	Rwanda (Kigali); Kenya and Uganda sites in early 2012 pending approvals	75	Multiantigen HIV (HIV-MAG) Plasmid DNA (pDNA) Vaccine Co-administered With Recombinant Human IL-12 pDNA (GENEVAX® IL-12) Followed or Preceded by Recombinant Ad35-GRIN/ENV HIV Vaccine		Ongoing / April 2013

HVTN 086	Phase I	November 2011	DAIDS, NIAID, Novartis, SAAVI	South Africa (Klerksdorp; Soweto; Cape Town)	184	SAAVI DNA-C2 prime and SAAVI MVA-C boost, with and without concurrent Novartis subtype C gp140/MF59 boost; SAAVI MVA-C with concurrent or subsequent Novartis subtype C gp140/MF59 vaccine.	C	Ongoing
Mucovac2	Phase I	November 2011	SGUL	United Kingdom (London, York)	36	CN54gp140	C	Ongoing / November 2012
HVTN 073E	Phase I	October 2011	DAIDS, NIAID, SAAVI	US (Boston, NY; Rochester, NY), South Africa (Cape Town, Soweto)	36	Novartis Sub C gp140 with MF59	C	Ongoing
HVTN 090	Phase I	October 2011	DAIDS, NIAID	US (Atlanta, GA; Nashville, TN; Philadelphia, PA; San Francisco, CA)	60	VSV IN HIV gag vaccine (rVSVN4CT1gag1)	B	Ongoing
ISS P-002	Phase I	September 2011	Istituto Superiore di Sanita in cooperation with Novartis Vaccines & Diagnostics	Italy (Modena, Monza, Rome)	50	HIV-1 Tat/delta-V2 Env combined vaccine HIV-1 delta-V2 Env vaccine HIV-1 Tat vaccine	Clade B HIV-1 Tat protein; clade C HIV-1 delta-V2 Env protein	Recruiting / February 2014
HVTN 088	Phase I	August 2011	DAIDS, NIAID	US (Birmingham, AL; Nashville, TN; Rochester, NY; Seattle, WA)	40	Novartis Sub C gp140 with MF59	C	Ongoing
Extention HVTN 073E / SAAVI 102	Phase I	August 2011	HVTN, NIAID	US (Massachusetts)	36	Sub C gp140 Vaccine With MF59 Adjuvant, as a Boost Following SAAVI DNA-C2 Vaccine and SAAVI MVA-C Vaccine	C	Ongoing
CN54gp140-hsp70 Conjugate Vaccine (TL01)	Phase I	July 2011	EU, SGUL	UK (London)	8	CN54gp140 glycoprotein-hsp70 conjugate vaccine	C	Ongoing / February 2012
VRC 016	Phase I	June 2011	NIAID, VRC	US (Bethesda, MD)	24	VRC-HIVADV014-00-VP and VRC-HIVDNA016-00-VP	A, B, C	Ongoing / July 2014
HVTN 091	Phase I	May 2011	IAVI	South Africa (Klerksdorp; Soweto; Cape Town)	80 for HVTN (SA) sites; 212 for entire study	Ad26.ENVA.01 and AD35ENV (adenoviral vectors) given in heterologous or homologous prime-boost doses inserts: Clade A env gp140	A	Ongoing
HVTN 076	Phase Ib	May 2011	DAIDS, NIAID, VRC	US (Seattle)	45	VRC-HIVDNA016-00-VP clade B gag, pol, and nef, clade A env, clade B env, clade C env VRC-HIVADV014-00-VP clade B gag-pol, clade A env, clade B env, clade C env	A, B, C	Ongoing
IAVI B002	Phase I	February 2011	GSK, IAVI	Kenya, Uganda, Zambia	140	Ad35 investigational HIV vaccine		Ongoing / November 2012
HVTN 084	Phase I	January 2011	HVTN, DAIDS, VRC	Brazil (Sao Paulo), Peru (Iquitos, Barranco), Switzerland (Lausanne), US (Boston, MA; New York, NY and Chicago, IL)	100	Single dose: VRC-HIVADV014-00-VP or VRC-HIVADV054-00-VP (adenoviral vectors) Inserts: ADV014:clade B gag-pol; clades A, B, C env; ADV054: clade B gag-pol	A,B,C	Ongoing
HVTN 083	Phase I	October 2010	DAIDS, NIAID, VRC	US (Birmingham, AL; San Francisco, CA; Atlanta, GA; Boston, MA; New York, NY; Rochester, NY; Nashville, TN)	180	rAd35:(VRC-HIVADV027-00-VP); rAd5: (VRC-HIVADV038-00-VP); rAd5: (VRC-HIVADV052-00-VP) Inserts: rAd35: env clade A; rAD5(038); env clade A; rAD5(052) env clade B	A, B	Ongoing

IAVI B003 (IPCAVD 004)	Phase I	October 2010	Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Crucell, IAVI, IPCAVD, HVTN, NIAID, Ragon Institute	Kenya (Kangemi), Rwanda (Kigali), South Africa (Cape Town, Johannesburg, & Klerksdorp), US (Boston, MA)	217 (52 at BWH)	Recombinant Adenovirus HIV-1 Vaccine, Ad26.ENVA.01 AND Ad35-ENV	A	Ongoing, not recruiting / September 2012
MV1-F4-CT1	Phase I	October 2010	Consortium EU: Gent U, GSK, Institut Pasteur, NIBSC, SGUL	Belgium	24	Recombinant HIV I Clade B Measles Vaccine Vector	B	October 2011
Ad26.ENVA.01 (IPCAVD 003)	Phase I	September 2010	Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Crucell, IPCAVD, NIAID	US (Boston, MA)	24	Recombinant Adenovirus HIV-1 Vaccine, Ad26.ENVA.01	A	Ongoing, not recruiting / November 2012
RV 262	Phase I	September 2010, will start in Africa in January/ February 2012	MHRP, NIAID	Kenya (Kericho), Uganda (Kampala), Tanzania (Mbeya)	92	Prime: PENNVAX-G DNA (ENV & GAG) Administered by Intramuscular Biojector 2000 or CELLECTRA Intramuscular Electroporation Device Boost: MVA-CMDR (HIV-1 CM235 ENV/CM240 GAG/POL)	A,B,C,D,E	Ongoing - not yet open to recruitment at African sites. U.S. fully enrolled
GeoVax Therapeutic Vaccine (GV-TH-01)	Phase I	June 2010	GeoVax Labs, Inc.	US (Atlanta, GA; Birmingham, AL; Los Angeles, CA)	10	J57 plasmid DNA and MVA62B vaccine administered as DNA at months 0 and 2 and MVA at months 4 and 6	B	Ongoing, recruiting/ May 2014
DCVax-001 (SSC-0710)	Phase I	May 2010	Rockefeller University	US (New York)	45	Anti-DEC-205 Monoclonal Antibody (Mab) Targeted HIV Gag p24 Vaccine (DCVax-001) With Poly ICLC (Hiltonol) as Adjuvant	B	Ongoing / May 2013
HVTN 082	Phase I	January 2010	HVTN, NIAID, VRC	US (Boston, MA; Seattle, WA; San Francisco, CA)	8	Prime: VRC-HIVDNA016-00-VP (DNA vaccine) ; Boost VRC-HIVADV014-00-VP (adenoviral vector) Inserts: ADV014:clade B gag-pol; clades A, B, C env; ADV016: clade B gag, pol, and nef, clades A, B and C env	A, B, C	Closed to enrollment
HIVIS 05	Phase I	March 2009	MHRP, SIDA, SMI	Sweden (Stockholm)	24	MVA-CMDR	MVA Env E, gag A, pol A	Ongoing
Ad5HVR48.ENVA.01 (IPCAVD 002)	Phase I	February 2009	Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Crucell, IPCAVD, NIAID	US (Boston, MA)	48	Recombinant Adenovirus HIV-1 Vaccine, Ad5HVR48.ENVA.01	A	Ongoing, not recruiting / December 2012
Tiantan vaccinia HIV Vaccine	Phase I	November 2007	China CDC, National Center for AIDS/STD Control and Prevention	China (Beijing)	48	DNA and replicating vaccinia Tiantan (rTV) expressing HIV CN54 gag, pol and env genes	B, C	Ongoing
HVTN 077	Phase I	January 2007	DAIDS, NIAID, VRC	US (Birmingham, AL; San Francisco, CA; Atlanta, GA; Boston, MA; New York, NY; Rochester, NY; Seattle, WA)	192	Recombinant Adenoviral Subtype 35 (rAd35) and Subtype 5 (rAd5) HIV-1 Vaccines When Given as a Heterologous Prime-Boost Regimen or as Boosts to a	A	Ongoing

						Recombinant DNA Vaccine in Healthy, Ad5-Naïve and Ad5-Exposed (VRC-HIVDNA044-00-VP;VRC-HIVADV027-00-VP;VRC-HIVADV038-00-VP)	
HVTN 085	Phase I	TBD	HVTN, NIAID, VRC	TBD	90	VRC rAd5 HIV vaccine	Planned
<p>Aaron Diamond AIDS Research Center (ADARC); Agence Nationale de Recherches sur le Sida (ANRS); United States Division of AIDS (DAIDS); The European and Developing Countries Clinical Trials Partnership (EDCTP); European Union (EU); HIV Vaccine Trials Network (HVTN); GlaxoSmithKline (GSK); International AIDS Vaccine Initiative (IAVI); Instituto Nacional de Saúde (INS); National Center in HIV Epidemiology and Clinical Research (NCHECR); United States National Institute of Allergy and Infectious Disease (NIAID); The National Institute for Biological Standards and Control (NIBSC); United States National Institutes of Health (NIH); Quarters 1 – 4 (Q1, Q2, Q3, Q4); South African AIDS Vaccine Initiative (SAAVI); St. George’s University of London (SGUL); Swedish Institute of Infectious Disease Control (SMI); Swedish International Development Cooperation Agency (SIDA); United Kingdom Medical Research Council (UK MRC); United States Military HIV Research Program (MHRP); Vaccine Research Center (VRC); Walter Reed Army Institute of Research (WRAIR)</p> <p><i>*The studies listed in this table are HIV prevention trials and thus are looking at whether the experimental intervention reduces the risk of HIV infection—trial participants are HIV-negative, unless otherwise noted.</i></p> <p><i>**In addition to the assigned intervention, all trial participants receive a standard HIV prevention package, possibly including but not limited to: risk reduction counseling, condom provision and behavioral interventions.</i></p> <p><i>***Countries, sponsors, funders and developers are listed alphabetically.</i></p>							