

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 085	90	HVTN VRC DAIDS	rAd5 multiclade	02/2012	Boston - Brigham; Chicago; Nashville; New York - NYBC; New York - Physicians & Surgeons; NYBC - Bronx; Philadelphia; Rochester; San Francisco; Union Square;	A phase 1b randomized double-blind clinical trial to examine whether polytopic administration of VRC rAd5 gag-pol/env A/B/C vaccine enhances HIV-specific cellular immune responses in humans.	Long Term Follow-up
HVTN 092	143	HVTN BMGF IPPOX EuroVacc DAIDS	DNA clade C NYVAC clade C	04/2013	Atlanta - Hope Clinic; Birmingham; Boston - Brigham; Chicago; Lausanne; Philadelphia; San Francisco; Seattle;	A phase 1 clinical trial to evaluate safety and to compare the immunogenicity of 3 DNA vaccine prime schedules followed by a NYVAC vaccine boost in healthy, HIV-1 uninfected adult participants. The primary objectives are to: 1) evaluate the safety and tolerability of DNA alone and DNA prime followed by NYVAC boost in HIV-uninfected healthy adults; and 2) compare the effect of each of 2 different accelerated priming schedules to the historical schedule on the T-cell responses following the NYVAC boost.	Long Term Follow-up
HVTN 096	96	HVTN BMGF IPPOX EuroVacc GSID USMHRP DAIDS	AIDSVAX® B/E DNA clade C NYVAC clade C	08/2012	Lausanne;	A phase 1 double blind placebo-controlled clinical trial to evaluate the safety and to compare the priming ability of NYVAC alone versus NYVAC + AIDSVAX B/E, and DNA alone versus DNA + AIDSVAX B/E when followed by NYVAC + AIDSVAX B/E boosts in healthy, HIV-1 uninfected adult participants	Long Term Follow-up

* Date first participant enrolled

As of January 9, 2018

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 098	94	HVTN DAIDS Inovio	PENNVAX-GP IL-12 DNA adjuvant	09/2015	Atlanta - Hope Clinic; Nashville; Rochester; Seattle;	A phase 1 clinical trial to evaluate the safety and immunogenicity of PENNVAX®-GP (gag, pol, env) DNA vaccine and IL-12 plasmid, delivered via intradermal or intramuscular electroporation in healthy, HIV-uninfected adult participants	Long Term Follow-up
HVTN 100	252	HVTN BMGF GSK (formerly Novartis) SanofiPasteur DAIDS	ALVAC-HIV (vCP2438) clade C Env; multiclade Bivalent Subtype C gp120/MF59	02/2015	Cape Town - Emavundleni; Durban - eThekweni; Durban - Isipingo; Klerksdorp; Soshanguve; Soweto - Bara;	HVTN 100 tests a regimen similar to the RV144 regimen. It is a phase 1-2 randomized, double-blind, placebo-controlled clinical trial of clade C ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120/MF59® in HIV-uninfected adults at low risk of HIV infection	Enrolling
HVTN 106	105	HVTN CHAVI-ID DAIDS EuroVacc LANL USMHRP	DNA consensus S Env DNA trivalent mosaic Env DNA Clade B T/F natural sequence Env MVA-CMDR	01/2015	Atlanta - Hope Clinic; Birmingham; Boston - Brigham; Boston - Fenway; Lausanne; San Francisco; Seattle;	This phase 1 study aims to rank and select from 3 DNA primes with respect to response rate, total magnitude, and breadth of CD4+ and CD8+ T-cell responses following the DNA primes, and again following the MVA boost	Long Term Follow-up
HVTN 107	132	HVTN DAIDS GSK SanofiPasteur	ALVAC-HIV (vCP2438) Bivalent Subtype C gp120 with MF59 (2 schedules), or with Alum, or unadjuvanted	06/2017	Cape Town - Emavundleni; Durban - eThekweni; ; Soweto - Bara; Tembisa; Maputo; Harare - Seke South;	A Phase 1/2a partially double-blinded, randomized clinical trial to characterize the safety and immunogenicity of clade C ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120 alone, with MF59® adjuvant, and with alum adjuvant in healthy, HIV-uninfected adult participants	Enrolling

* Date first participant enrolled

As of January 9, 2018

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 108	334	HVTN DAIDS BMGF GSK (formerly Novartis) IPPOX	DNA Clade C Bivalent Subtype C gp120/MF59 Bivalent Subtype C gp120/AS01B	12/2016	Birmingham; Boston - Brigham; Boston - Fenway; Cape Town - Emavundleni; Durban - eThekweni; Durban - Verulam; Klerksdorp; Ladysmith; Nashville; New York - NYBC; New York - Physicians & Surgeons; Rochester; Seattle; Soshanguve; Soweto - Bara; Soweto - Kliptown; Tembisa;	A phase 1/2a clinical trial to evaluate the safety and immunogenicity of HIV clade C DNA, and of MF59®- or AS01B-adjuvanted clade C Env protein in various combinations, in healthy, HIV-uninfected adult participants	Enrolling
HVTN 110	60	HVTN PaxVax GSID USMHRP DAIDS	Ad4 multiclade AIDSVAX® B/E (Subtypes B, E gp120)	03/2015	Atlanta - Hope Clinic; Birmingham; Boston - Brigham; Boston - Fenway; Cleveland; Nashville; New York - NYBC; New York - Physicians & Surgeons; Philadelphia; Rochester; San Francisco; Seattle;	A phase 1 clinical trial to evaluate the safety and immunogenicity of orally-administered replication-competent Adenovirus type-4 HIV vaccine regimens in combination with an AIDSVAX® B/E boost, administered intramuscularly (IM) in healthy, HIV-uninfected adult participants	Long Term Follow-up
HVTN 111	132	HVTN DAIDS BMGF GSK (formerly Novartis) IPPOX	DNA Clade C Bivalent Subtype C gp120/MF59	06/2016	Durban - Isipingo; Klerksdorp; Lusaka - Matero; Mbeya; Tembisa;	A phase 1 clinical trial to evaluate the safety and immunogenicity of HIV clade C DNA and of MF59-adjuvanted clade C Env protein, in healthy, HIV-uninfected adult participants	In Follow-up

* Date first participant enrolled

As of January 9, 2018

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 112	14	HVTN DAIDS Profectus Ichor	DNA VSV envC	04/2016	Cleveland; Philadelphia;	A phase 1 trial to evaluate the safety, tolerability, and immunogenicity of HIV-1 nef/tat/vif, env) pDNA, delivered intramuscularly with electroporation, followed by HIV-1 rVSV envC vaccine boosts, in healthy HIV-uninfected adult participants	Long Term Follow-up
HVTN 114	30	HVTN DAIDS GeoVax GSID	AIDSVAX B/E MVA/HIV62B	02/2017	Atlanta - Hope Clinic; Birmingham; Boston - Brigham; Iquitos; Lima - Barranco; Nashville; New York - NYBC; New York - Physicians & Surgeons; Rochester; San Francisco; Seattle;	A phase I clinical trial to evaluate the immunogenicity of AIDSVAX® B/E bivalent gp120 vaccine and MVA/HIV62B in healthy, HIV-1 uninfected adult participants who previously received MVA/HIV62B in DNA/MVA or MVA/MVA regimens in HVTN 205	In Follow-up
HVTN 115	132	HVTN DAIDS CHAVI IDRI	EnvSeq T/F gp120 EnvSeq 53 gp120 EnvSeq 78 gp120 EnvSeq 100 gp120 DNA mosaic gp120 GLA-SE adjuvant	10/2017	Birmingham; New York - NYBC; New York - Physicians & Surgeons; Rochester;	A Phase I clinical trial to evaluate the safety and immunogenicity of CH505 sequential Envs with the adjuvant GLA-SE, administered alone or with DNA mosaic Env, in healthy, HIV-uninfected adult participants	Enrolling
HVTN 116	101	HVTN VRC DAIDS	VRC01 mAb VRC01LS mAb	03/2017	Cape Town - Groote Schuur; Cleveland; Philadelphia; San Francisco; Seattle;	A phase 1 clinical trial to evaluate the safety, pharmacokinetics, and anti-viral activity of VRC-HIVMAB060-00-AB (VRC01) and VRC-HIVMAB080-00-AB (VRC01LS) in the serum and mucosa of healthy, HIV-uninfected adult participants	Enrolling

* Date first participant enrolled

As of January 9, 2018

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 117/ HPX2004 Janssen phase 1	198	HVTN Janssen DAIDS IAVI MHRP BIDMC	Ad26.Mos.HIV Ad26. Mos4.HIV Clade C gp140	07/2016	Atlanta - Hope Clinic; Birmingham; Boston - Brigham; Boston - Fenway; Kigali; New York - NYBC; New York - Physicians & Surgeons; Philadelphia; Rochester; San Francisco; Seattle; Silver Spring;	A randomized, parallel-group, placebo-controlled, double-blind Phase 1/2a study in healthy HIV uninfected adults to assess the safety/tolerability and immunogenicity of 2 different prime/boost regimens; priming with trivalent Ad26.Mos.HIV and boosting with trivalent Ad26.Mos.HIV and Clade C gp140 plus adjuvant OR priming with tetravalent Ad26.Mos4.HIV and boosting with tetravalent Ad26.Mos4.HIV and Clade C gp140 plus adjuvant	In Follow-up
HVTN 118/ HPX2003	150	HVTN Janssen DAIDS IAVI MHRP BIDMC	Ad26.Mos4.HIV Clade C gp140 Mosaic gp140	04/2017	Atlanta - Hope Clinic; Birmingham; Boston - BIDMC; Boston - Brigham; Boston - Fenway; Kericho; Kigali; New York - NYBC; New York - Physicians & Surgeons; Philadelphia; Rochester; San Francisco; Seattle;	A randomized, parallel-group, placebo-controlled, double-blind Phase 1/2a study in healthy HIV-uninfected adults to assess safety/tolerability and immunogenicity of 2 different prime/boost regimens: priming with tetravalent Ad26.Mos4.HIV and boosting with tetravalent Ad26.Mos4.HIV and either Clade C gp140 plus adjuvant OR a combination of Mosaic and Clade C gp140 plus adjuvant	In Follow-up
HVTN 119	56	HVTN DAIDS Profectus University of Washington Ichor NCI	p24CE 1/2 DNA with IL-12 DNA adjuvant p55 Gag with IL-12 DNA adjuvant	11/2017	Cleveland; Atlanta - Hope Clinic; San Francisco;	A phase 1 clinical trial to evaluate the safety and immunogenicity of pDNA vaccines expressing HIV M Group p24Gag conserved elements and/or p55Gag, administered with IL-12 pDNA by intramuscular electroporation, in healthy, HIV-uninfected adult participants	Enrolling

* Date first participant enrolled

As of January 9, 2018

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 122	24	HVTN USMHRP DAIDS	gp145	01/2018	New York - Physicians and Surgeons; New York - NYBC; Philadelphia	A Phase 1 double-blind, randomized clinical trial to evaluate the safety and immunogenicity of recombinant trimeric gp145 Env in healthy, HIV-1 uninfected adult participants	Enrolling
HVTN 702	5400	HVTN GSK (formerly Novartis) DAIDS Sanofi Pasteur BMGF MRC	ALVAC-HIV (vCP2438) Bivalent Subtype C gp120/MF59	10/2016	Cape Town - Emavundleni; Cape Town - Khayelitsha; Durban - eThekweni; Durban - Isipingo; Durban - Verulam; Klerksdorp; Ladysmith; Medunsa; Mthatha; Rustenburg; Soshanguve; Soweto - Bara; Soweto - Kliptown; Tembisa; Botha's Hill	A pivotal phase 2b/3 multi-site, randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120/MF59 in preventing HIV-1 infection in adults in South Africa	Enrolling
HVTN 703/HPTN 081	1500	HVTN HPTN DAIDS VRC	VRC01 mAb	05/2016	Blantyre; Cape Town - Groote Schuur; Durban - Botha's Hill; Durban - Chatsworth; Durban - eThekweni; Gaborone; Harare - Parirenyatwa; Harare - Seke South; Harare - Spilhaus; Hillbrow; Kisumu; Klerksdorp; Lilongwe; Mamelodi; Maputo; Mbeya; Rustenburg; Soweto - Bara; Tembisa;	A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection in women in sub-Saharan Africa	Enrolling

* Date first participant enrolled

As of January 9, 2018

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 704/HPTN 085	2700	HVTN HPTN DAIDS VRC	VRC01 mAb	04/2016	Atlanta - Hope Clinic; Atlanta - Ponce de Leon; Birmingham; Boston - Brigham; Boston - Fenway; Chapel Hill; Cleveland; Iquitos; Lausanne; Lima - Barranco; Lima - San Marcos; Lima - San Miguel; Lima - Via Libre; Los Angeles - Vine Street; Nashville; New York - Bronx Prevention; New York - Harlem Prevention; New York - NYBC; New York - Physicians & Surgeons; Newark; Philadelphia; Rio de Janeiro; Rochester; San Francisco; Seattle; Washington - DC	A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection among men and transgender persons who have sex with men	Enrolling

* Date first participant enrolled

As of January 9, 2018

Ongoing HVTN Trials (Enrolling, In Follow-up, and in Long Term Follow-up)

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description	Stage
HVTN 705	2600	HVTN Janssen DAIDS BMGF	Ad26.Mos4.HIV Clade C gp140	11/2017	Bloemfontein; Cape Town - Emavundleni; Cape Town - Khayelitsha; Durban - Chatsworth; Durban - eThekweni; Durban - Isipingo; Durban - Tongaat; Durban - Verulam; Elandsdoorn; Harare - Seke South; Klerksdorp; Ladysmith; Lilongwe; Lusaka - Matero; Mamelodi; Maputo; Masiphumelele; Medunsa; Mthatha; Ndola; Rustenburg; Soshanguve; Soweto - Bara; Soweto - Kliptown; Tembisa;	A multicenter, randomized, double-blind, placebo-controlled phase 2b efficacy study of a heterologous prime/boost vaccine regimen of Ad26.Mos4.HIV and aluminum phosphate- adjuvanted Clade C gp140 in preventing HIV-1 infection in adult women	Enrolling
HVTN 910	Open	HVTN DAIDS	N/A	12/2011	All sites	This protocol assesses the persistence of HIV vaccine-induced seropositivity in participants who received study vaccines in DAIDS-funded preventive HIV vaccine trials. The primary purpose is to describe how long vaccine-induced antibodies to HIV, detectable on commercially available HIV antibody test kits, persist.	Enrolling

* Date first participant enrolled

As of January 9, 2018