

HPTN Protocols Snapshot

Protocol #	Title	Sites	Study Status	IND	Research Area	Study Population	Open to Accrual	1st Participant Enrolled	Closed to Accrual	Closed to Follow Up	Target Accrual	Actual Accrual
HPTN 120	PRISM Feasibility Study		In Development		Integrated Strategy		Jan 2028	Jan 2028	Jan 2029	Jan 2031		N/A
HPTN 119	Weekly Doxycycline Prophylaxis for Prevention of Sexually Transmitted Infections among Young African Women	INTL	In Development		STI	TBD	Nov 2026	Nov 2026	Sep 2027	Sep 2028	580	N/A
HPTN 113	A Phase IIb Individual-Level Randomized Controlled Trial of an Integrated Strategy of HIV PrEP and STI PEP for Young Men.	US/INTL	Pending		Integrated Strategy	Young MSM	Nov 2026	Nov 2026	Sep 2028	Sep 2028	500	N/A
HPTN 104	A multisite, open-label, randomized crossover study comparing adherence to a single daily dual prevention pill (DPP) versus FTC/TDF and Combined Oral Contraception separate pill dosing (2PR), given for pre-exposure prophylaxis and pregnancy prevention in women	INTL	Pending		MPT	HIV-uninfected Women	Nov 2026	Nov 2026	Sep 2027	Sep 2028	300	N/A
HPTN 117	Characterization of Doxycycline Pharmacokinetics and Adherence Post-Single and Repeat Dosing Schemas	US	Open to Accrual		Integrated Strategy	Healthy Adults	16 Jul 2026	Sep 2026	Aug 2027	Jul 2027	16	N/A
ATN 173/HPTN 115	Doxycycline Prophylaxis for Prevention of Sexually Transmitted Infections Among Adolescent and Young Adult Females in the United States	TBD	Open to Accrual		Integrated Strategy	Adolescent and Young Adult Females	18 Jun 2026	18 Jun 2026	Dec 2027	Dec 2028	760	N/A
HPTN 096 Post-Pilot	Getting to Zero among Highest HIV Incidence (HHI) Men who have Sex with Men (MSM) in the American South: Testing an Integrated Strategy	US	Open to Accrual	Y	Integrated Strategy	MSM (Southern US)	7 Nov 2025	5 Nov 2025	Jan 2029	Jan 2029	900	N/A
HVTN 141/HPTN 105	A phase 1 clinical trial to evaluate the safety, pharmacokinetics, and in vitro neutralization of ePGT121v1-LS, PGDM1400LS, and VRC07-523LS administered in multiple doses and routes to adult participants without HIV-1	TBD	Enrolling	Y	Antibody Mediated Prevention	HIV-uninfected Adults	9 Mar 2026	19 Mar 2026	Sep 2026	Sep 2027	83	21
HVTN 206/HPTN 114	A phase 2 clinical trial to evaluate the safety, tolerability, pharmacokinetics and neutralization of VRC07-523LS, PGT121.414.LS and PGDM1400LS broadly neutralizing monoclonal antibodies in adult participants without HIV and in overall good health	TBD	Closed to Accrual	Y	Antibody Mediated Prevention	HIV-uninfected Adults	14 Jan 2025	7 Mar 2025	15 May 2026	May 2027	200	186
DMID 19-0004/HPTN 107	A Phase II randomized, observer-blind, placebo-controlled study, to assess efficacy of meningococcal Group B vaccine rMenB+OMV NZ (Bexsero) in preventing gonococcal infection.	TBD	Closed to Accrual		STI	Adults at STI Risk	19 Nov 2020	29 Dec 2020	21 Nov 2024	Nov 2025	2200	2606
HPTN 103	A Phase 2 Single Arm Trial to Assess the Safety, Acceptability and Pharmacokinetics of Injectable Lenacapavir (LEN) as a Pre-Risk Exposure Prophylaxis (PrEP) Agent among People who Inject Drugs (PWID)	US	Closed to Accrual		PrEP	HIV-uninfected PWID	4 Jun 2024	20 Aug 2024	1 Aug 2025	Aug 2027	180	181
HPTN 102	A Randomized, Open-Label Study of Acceptability and Use of Lenacapavir vs TDF/FTC Among US Women	TBD	Closed to Accrual		PrEP	HIV-uninfected Women	23 Apr 2024	31 May 2024	29 Jul 2025	Jan 2028	250	253
HPTN 084	A Phase 3 Double Blind Safety and Efficacy Study of Long-	INTL	Closed to Accrual	Y	PrEP	HIV-uninfected	20 Jan 2022	21 Jan 2022	6 Apr 2025	Jan 2026	3200	N/A

OLE/Pregnancy	Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women.					Women						
HPTN 083	Phase 3 study of Cabotegravir LA vs daily oral TDF/FTC for PrEP in HIV uninfected men who have sex with men	US/IN TL	Closed to Accrual	Y	PrEP	HIV-uninfected MSM	5 Dec 2016	19 Dec 2016	16 Mar 2020		4500	4570
HPTN 113-01	Focus Group Discussion prior to HPTN 113	US/IN TL	Closed to Follow Up		Integrated Strategy	MSM	26 Sep 2024	26 Sep 2024	30 Apr 2025	31 May 2025		63
HPTN 112	Improving HIV prevention among heterosexual men seeking STI services in Malawi: examining the benefits, acceptability, and associated costs of a systems-navigator-delivered integrated prevention package.	INTL	Closed to Follow Up		Integrated Strategy	Heterosexual Men	21 Mar 2024	2 Apr 2024	15 Nov 2024	1 Sep 2025	200	203
HPTN 111	Feasibility and Acceptability of a Barbershop Based HIV Prevention Initiative Among Heterosexual Men in Kalangala Islands, Uganda: A Cluster Randomized Trial	INTL	Closed to Follow Up		Integrated Strategy	Heterosexual Men	10 Mar 2024	13 Mar 2024	27 Jun 2024	30 Jun 2025	250	249
A5416/HVTN 806/HPTN 108	A Phase I, Randomized, Placebo-Controlled Study of the Safety, Antiviral & Immunomodulatory Activity of Broadly Neutralizing Antibodies 3BNC117-LS-J and 10-1074-LS-J in Combination in ART-treated Adults in sub-Saharan Africa Living with HIV during a Monitored Analytical Treatment Interruption	INTL	Closed to Follow Up		Antibody Mediated Prevention	Adults Living with HIV	26 Apr 2024	28 May 2024	5 Feb 2025	25 Jun 2026	32	32
HPTN 106	A Phase 2 Crossover Study of On Demand PrEP Formulations Comparing Rectal and Oral TFV-Based PrEP Evaluating Extended Safety, Acceptability, and PK/PD	TBD	Closed to Follow Up	Y	PrEP	HIV-uninfected MSM	25 Sep 2024	29 Oct 2024	15 Jan 2026	16 Jun 2026	150	150
HVTN 804/HPTN 095	Antiretroviral analytical treatment interruption (ATI) to assess immunologic and virologic responses in participants who received VRC01 or placebo and became HIV-infected during HVTN 704/HPTN 085	US/IN TL	Closed to Follow Up	Y	Other	HIV-positive MSM	5 Feb 2020	22 Aug 2022	26 Jun 2023	22 Jul 2024	16	18
HPTN 091	Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation to Prevent HIV Acquisition and HIV Transmission for TGW in the Americas: A Vanguard Feasibility and Acceptability Study	US/IN TL	Closed to Follow Up		Integrated Strategy	Transgender Women	24 Feb 2021	26 Mar 2021	16 Dec 2022		310	307
HVTN 140/HPTN 101	A phase 1 dose-escalation clinical trial to evaluate the safety, tolerability, and pharmacokinetics of PGDM1400LS alone and in combination with VRC07-523LS and PGT121.414.LS in healthy, HIV-uninfected adult participants	US/IN TL	Participants Off Study & Primary Analysis Completed		Antibody Mediated Prevention	HIV-uninfected Adults	20 Oct 2021	15 Nov 2021	5 Oct 2022	19 Jul 2023	95	95
HPTN 094	INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for Addiction, HIV, HCV and Primary Care.	US	Participants Off Study & Primary Analysis Completed		Integrated Strategy	PWID	6 May 2021	2 Jun 2021	30 Sep 2023		860	447
HVTN 805/HPTN 093	Antiretroviral analytical treatment interruption (ATI) to assess immunologic and virologic responses in participants who initiated ART in early HIV infection after having received VRC01 or placebo in HVTN 703/HPTN 081	INTL	Participants Off Study & Primary Analysis Completed	Y	Other	HIV-positive Women	2 Apr 2021	28 May 2021	14 Sep 2022	4 Feb 2025	16	13
HVTN 127/HPTN 087	A multicenter, randomized, partially blinded phase 1 clinical trial to evaluate the safety and serum concentrations of a human monoclonal antibody, VRC-HIVMAB075-00-AB (VRC07-523LS), administered in multiple doses and routes to healthy, HIV-uninfected adults.	US/IN TL	Participants Off Study & Primary Analysis Completed	Y	Antibody Mediated Prevention	HIV-uninfected Adults	2 Feb 2018	28 Feb 2018	10 Oct 2018	7 Dec 2020	124	N/A
HPTN 084-01	Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females – A Sub-study of HPTN 084	INTL	Participants Off Study & Primary Analysis Completed	Y	PrEP	HIV-uninfected Adolescents	4 Nov 2020	3 Dec 2020	6 Aug 2021	10 Jan 2023	50	55
HPTN 083 OLE	Phase 3 study of Cabotegravir LA vs daily oral TDF/FTC for PrEP in HIV uninfected men who have sex with men	US/IN TL	Participants Off Study & Primary Analysis Completed	Y	PrEP	HIV-uninfected MSM				31 Mar 2025	4500	2278

HPTN 083-01	Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Males – A sub-study of HPTN 083	US/IN TL	Participants Off Study & Primary Analysis Completed	Y	PrEP	HIV-uninfected Adolescents	1 Jun 2020	6 Jul 2020	10 Jan 2022	7 Jul 2023	50	9
HVTN 136/HPTN 092	A phase 1 dose-escalation clinical trial to evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of the monoclonal antibody PGT121.414.LS administered alone and in combination with VRC07-523LS via intravenous infusion or via subcutaneous injections in healthy, HIV-uninfected adult participants.	US	Concluded	Y	Antibody Mediated Prevention	HIV-uninfected Adults	24 Aug 2020	10 Nov 2020	5 Oct 2021	18 Jan 2023	32	33
HVTN 130/HPTN 089	A phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of combinations of monoclonal antibodies PGT121, PGDM1400, 10-1074, and VRC07-523LS administered via intravenous infusion in healthy, HIV-uninfected adult participants	US	Concluded	Y	Antibody Mediated Prevention	HIV-uninfected Adults	17 Jul 2019	31 Jul 2019	17 Dec 2019	25 Mar 2021	27	27
HVTN 704/HPTN 085	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.	US/IN TL	Concluded	Y	Antibody Mediated Prevention	HIV-uninfected MSM/TG	31 Mar 2016	6 Apr 2016	5 Oct 2018	1 Dec 2020	2700	N/A
HVTN 703/HPTN 081	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.	INTL	Concluded		Antibody Mediated Prevention	Women at HIV Risk (sub-Saharan Africa)	9 May 2016	17 May 2016	20 Sep 2018	3 Mar 2021	1268	N/A