HPTN HIV Prevention Trials Network

HPTN Protocols Snapshot:

Protocol #	Title	Sites	Study Status	IND	Research Area	Study Population	Open to Accrual *(projected)*	1st Participant Enrolled *(projected)*	Closed to Accrual *(projected)*	Closed to Follow Up *(projected)*	Target Accrual	Actual Accrual as of report date
HPTN 119	DoxyPEP Africa	INTL	In Development	TBD	Integrated Strategy	TBD	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	N/A
HPTN 118	Adolescent 3E	TBD	In Development	TBD	Integrated Strategy	Adolescents	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	N/A
HPTN 117	PK and adherence of Doxycycline	US	In Development	TBD	Integrated Strategy	Healthy Adults	*TBD*	*TBD*	*TBD*	*TBD*	16	N/A
DMID 24-0020/HPTN 116	Neurosyphilis Study	TBD	In Development	TBD	STI	TBD	*Aug 2025*	*Aug 2025*	*Dec 2028*	*Dec 2029*	*TBD*	N/A
HPTN 115/ATN 173	Doxycycline Prophylaxis for Prevention of Sexually Transmitted Infections Among Adolescent and Young People Assigned Female at Birth in the United States	US	In Development	N	PEP	Adolescents	*Feb 2025*	*Feb 2025*	*June 2026*	*June 2027*	760	N/A
HPTN 104	To evaluate adherence to a single dual prevention pill, DPP (co-formulated TDF/FTC + ethynyl estradiol/levonorgestrel oral contraceptive pill (OCP), compared with the two tablets with daily oral TDF/FTC + ethynyl estradiol/levonorgestrel oral contraceptive pill for pre-exposure prophylaxis	INTL	In Development	Y	MPT	HIV uninfected cis-women	*Mar 2025*	*Mar 2025*	*June 2026*	*June 2027*	300	N/A

Updated: 31 January 2025

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	and pregnancy prevention in HIV-uninfected women											
HPTN 113	Double Prevention: A Vanguard Study of an Integrated Strategy of HIV PrEP and STI PEP for Young Latino Sexual Minority Men (SMM) in the Americas.	US/INTL	Pending	N	Integrated Strategy	Young Latino Sexual Minority Men (SMM)	*July 2025*	*July 2025*	*July 2026*	*July 2027*	500	N/A
HVTN 141/HPTN 105	A phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics and in vitro neutralization of VRC01.23LS, ePGDM1400v9-LS and ePGT121v1-LS alone and in combination in healthy, HIV-uninfected adult participants	TBD	Pending	Y	PrEP	HIV Uninfected Adults	*Aug 2025*	*Aug 2025*	*Oct 2025*	*Oct 2026*	136	N/A

Updated: 31 January 2025

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HPTN 096 Post Pilot	Getting to Zero among Black MSM in the American South: Testing the Efficacy of an Integrated Intervention Strategy	US	Pending	N	Integrated Strategy	Black MSM	*May 2025*	*May 2025*	*Dec 2027*	*Dec 2027*	N/A	N/A
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.	US/INTL	Open to Accrual	Y	mAb	HIV uninfected adults	14 Jan 2025	*Feb 2025*	*July 2025*	*July 2026*	200	N/A
A5416/HVTN 806/HPTN 108	A Phase I, Open-Label Study of the Safety, Antiviral & Immunomodulatory 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	Enrolling	TBD	Antibody Mediated Prevention	Adult participants living with HIV	26 Apr 2024	28 May 2024	*Mar 2025*	*Mar 2027*	48	31

Updated: 31 January 2025

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HPTN 106	A Phase 2 Crossover Study Of On-Demand Prep Formulations Comparing Rectal And Oral Tenofovir-Based Prep Evaluating Extended Safety, Acceptability, And Pharmacokinetics/Pharmacodynamics	US	Enrolling	Y	PrEP	HIV Uninfected MSM	25 Sept 2024	29 Oct 2024	*Oct 2025*	*Mar 2026*	150	19
HPTN 103	A Phase 2, Open-Label, Multicenter, Randomized Clinical Trial to Evaluate the Feasibility, Safety, and Acceptability of Long-Acting Subcutaneous Lenacapavir vs. Daily Oral Emtricitabine/Tenofovir Disoproxil Fumarate for Pre-Exposure Prophylaxis Among People who Inject Drugs	US	Enrolling	Y	PrEP	HIV Uninfected PWID	4 June 2024	20 Aug 2024	*Aug 2025*	*May 2028*	250	39
HPTN 102	A Phase 2, Open-Label, Multicenter, Randomized Study to Evaluate the Pharmacokinetics, Safety, and Acceptability and Use of Twice Yearly Long-Acting Subcutaneous Lenacapavir for Pre-Exposure Prophylaxis Among Women in the United States	US	Enrolling	Y	PrEP	HIV Uninfected Women	23 Apr 2024	31 May 2024	*May 2025*	*Nov 2027*	250	96
HPTN 084 Pregnancy	A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women.	INTL	Enrolling	Y	PrEP	HIV-uninfected women	1 Jan 2022	1 Jan 2022	*June 2025*	*Apr 2026*	N/A	450

Updated: 31 January 2025

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HTPN 112	Improving HIV prevention among heterosexual men seeking STI services in sub-Saharan Africa: examining the feasibility, acceptability, and associated costs of a systems-navigator-delivered integrated prevention package.	INTL	Closed to Accrual	N	Integrated Strategy	Heterosexual Men	21 Mar 2024	2 Apr 2024	15 Nov 2024	*June 2025*	200	203
HPTN 111	Uptake of HIV Self-testing and Linkage to Prevention and Care among Heterosexual Men attending Barbershops in Uganda: A Cluster Randomized Trial.	INTL	Closed to Accrual	N	Integrated Strategy	Heterosexual Men	10 Mar 2024	13 Mar 2024	27 Jun 2024	*June 2025*	250	249
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.	US	Closed to Accrual	Y	STI	Adults at risk of STI	19 Nov 2020	29 Dec 2020	*TBD*	*Feb 2026*	2200	2606
HPTN 094	INTEGRA: A Vanguard Study of Integrated Strategies for Linking Persons with Opioid Use Disorder to Care and Prevention for Addiction, HIV, HCV and Primary Care	US	Closed to Accrual	N	Integrated Strategy	PWID	7 May 2021	2 June 2021	30 Sept 2023	*Dec 2024*	450	447

Updated: 31 January 2025

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HPTN 083 OLE	A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men	US/INTL	Closed to Accrual	Y	PrEP	HIV-uninfected MSM and TGW	5 Dec 2016	19 Dec 2016	16 Mar 2020	*Feb 2025*	N/A	2278
HPTN 083	A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men	US/INTL	Closed to Accrual	Y	PrEP	HIV-uninfected MSM and TGW	5 Dec 2016	19 Dec 2016	16 Mar 2020	*June 2025*	5000	4570
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/INTL	Closed to Follow Up	Y	Antibody Mediated Prevention	HIV Uninfected Adults	20 Oct 2021	15 Nov 2021	5 Oct 2022	19 July 2023	95	95

Updated: 31 January 2025

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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/INTL	Closed to Follow-Up	N	Antibody Mediated Prevention	HIV-infected MSM and TGW	5 Feb 2020	22 Aug 2022	26 Jun 2023	22 July 2024	46	18
HVTN 805/HPTN 093	Antiretroviral analytical treatment interruption (ATI) to assess immunologic and virologic responses in participants who received VRC01 or placebo and became HIV infected during HVTN 703/HPTN 081	INTL	Closed to Follow-Up	N	Antibody Mediated Prevention	HIV-infected women	02 Apr 2021	28 May 2021	14 Sept 2022	22 July 2024	61	13

Updated: 31 January 2025

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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	Closed to Follow-Up	Y	Antibody Mediated Prevention	HIV-uninfected adults	24 Aug 2020	10 Nov 2020	05 Oct 2021	18 Jan 2023	32	33
HPTN 091	Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation to Prevent HIV Acquisition and HIV Transmission for Transgender Women in the Americas: A Vanguard Feasibility and Acceptability Study	US/INTL	Closed to Follow-Up	N	Integrated Strategy	Transgender Women	24 Feb 2021	26 Mar 2021	16 Dec 2022	16 Aug 2024	310	307
HVTN 130/HPTN 089	A Phase I clinical trial to evaluate the safety, pharmacokinetics, and functional activity of a combination of VRC07-523LS, PGT121, and PGDM1400 in healthy, HIV-1 uninfected adult participants.	US	Closed to Follow-Up	Y	Antibody mediated prevention	HIV-uninfected adults	17 July 2019	31 Jul 2019	17 Dec 2019	25 Mar 2021	27	27
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	Closed to Follow-Up	Y	PrEP	HIV-uninfected adolescents	4 Nov 2020	3 Dec 2020	6 Aug 2021	10 Jan 2023	55	55

Updated: 31 January 2025

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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	Closed to Follow Up	Y	PrEP	HIV-uninfected adolescents	19 Feb 2020	6 July 2020	10 Jan 2022	7 July 2023	55	9
HPTN 084 Blinded	A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women.	INTL	Participants of Study/Primary Analysis Complete	Y	PrEP	HIV-uninfected women	7 Nov 2017	27 Nov 2017	8 Nov 2020	17 Oct 2022	3200	3224

Updated: 31 January 2025