



HPTN Protocols Snapshot:

Protocol #	Title	Sites	Study Status	IND	Research Area	Study Population	Open to Accrual (projected)	1 st 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	N	Integrated Strategy	TBD	<i>TBD</i>	<i>TBD</i>	<i>TBD</i>	<i>TBD</i>	<i>TBD</i>	N/A
HPTN 117	PK and adherence of Doxycycline	US	In Development	N	Integrated Strategy	Healthy Adults	<i>March 2026</i>	<i>March 2026</i>	<i>Jan 2027</i>	<i>TBD</i>	16	N/A
DMID 24-0020/HPTN 116	Neurosyphilis Study	TBD	In Development	N	STI	TBD	<i>Aug 2025</i>	<i>Aug 2025</i>	<i>Dec 2028</i>	<i>Dec 2029</i>	<i>TBD</i>	N/A
HPTN 115/ATN 173	Doxycycline Prophylaxis for Prevention of Sexually Transmitted Infections Among Adolescent and Young Women in the United States	US	In Development	N	PEP	Adolescents Women	<i>Feb 2025</i>	<i>Feb 2025</i>	<i>June 2026</i>	<i>June 2027</i>	760	N/A
HPTN 113	Duo: A Phase IIIb Individual-Level Randomized Controlled Trial of an Integrated Strategy of HIV PrEP and STI PEP for Young Men who have Sex with Men in the Americas	US/INTL	Pending	N	Integrated Strategy	Young Men who have Sex with Men	<i>Jan 2026</i>	<i>Jan 2026</i>	<i>June 2027</i>	<i>June 2028</i>	500	N/A

Updated: 3 October 2025

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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	Nov 2025	Nov 2025	May 2026	June 2027	136	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 and pregnancy prevention in HIV-uninfected women	INTL	Pending	Y	MPT	HIV uninfected women	TBD	TBD	TBD	TBD	300	N/A
HPTN 096 Post Pilot	Testing the Efficacy of an Integrated Intervention Strategy in the American South	US	Pending	N	Integrated Strategy	MSM in the Southern US	TBD	TBD	TBD	TBD	N/A	N/A

Updated: 3 October 2025

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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	Enrolling	Y	mAb	HIV uninfected adults	14 Jan 2025	7 Mar 2025	Nov 2025	Nov 2026	200	70
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	Mar 2026	Aug 2026	150	113
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	Closed to Accrual	TBD	Antibody Mediated Prevention	Adult participants living with HIV	26 Apr 2024	28 May 2024	5 Feb 2025	Mar 2026	48	32

Updated: 3 October 2025

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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	Late 2024	Feb 2026	2200	2606
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	1 Aug 2025	May 2028	180	181
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	Closed to Accrual	Y	PrEP	HIV Uninfected Women	23 Apr 2024	31 May 2024	29 July 2025	Jan 2028	250	253

Updated: 3 October 2025

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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	Closed to Accrual	Y	PrEP	HIV-uninfected women	1 Jan 2022	1 Jan 2022	5 Apr 2025	Dec 2025	N/A	462
HPTN 113-01	Focus Group Discussion prior to HPTN 113	US/INTL	Closed to Follow Up	N	Integrated Strategy	Men who have Sex with Men	26 Sept 2024	26 Sept 2024	30 Apr 2025	31 May 2025		63
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 Follow Up	N	Integrated Strategy	Heterosexual Men	21 Mar 2024	2 Apr 2024	15 Nov 2024	1 Sept 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 Follow Up	N	Integrated Strategy	Heterosexual Men	10 Mar 2024	13 Mar 2024	27 Jun 2024	30 June 2025	250	249

Updated: 3 October 2025

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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
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	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	2 Feb 2024	61	13

Updated: 3 October 2025

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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
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

Updated: 3 October 2025

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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/INTL	Closed to Follow Up	Y	PrEP	HIV-uninfected MSM	5 Dec 2016	19 Dec 2016	16 Mar 2020	31 Mar 2025	N/A	2278
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/INTL	Closed to Follow Up	Y	PrEP	HIV-uninfected MSM	5 Dec 2016	19 Dec 2016	16 Mar 2020	31 Mar 2025	5000	4570
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	Participants of Study/Primary Analysis Complete	Y	Antibody Mediated Prevention	HIV-uninfected adults	24 Aug 2020	10 Nov 2020	05 Oct 2021	18 Jan 2023	32	33
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: 3 October 2025