



### HPTN Protocols Snapshot:

Protocol #	Title	Sites	Study Status	IND	Research Area	Study Population	Open to Accrual (projected)	1 <sup>st</sup> 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	Sept 2025	Oct 2025	Aug 2026	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

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<b>HPTN 104</b>	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	In Development	Y	MPT	HIV uninfected cis-women	Mar 2025	Mar 2025	June 2026	June 2027	300	N/A
<b>HPTN 113</b>	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
<b>HVTN 141/HPTN 105</b>	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: 28 February 2025

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<b>HPTN 096 Post Pilot</b>	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
<b>HVTN 206/HPTN 114</b>	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
<b>A5416/HVTN 806/HPTN 108</b>	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	32

Updated: 28 February 2025

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<b>HPTN 106</b>	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	34
<b>HPTN 103</b>	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	45
<b>HPTN 102</b>	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	107
<b>HPTN 084 Pregnancy</b>	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	462

Updated: 28 February 2025

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<b>HTPN 112</b>	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
<b>HTPN 111</b>	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
<b>HPTN 107</b>	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

Updated: 28 February 2025

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<b>HPTN 083 OLE</b>	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
<b>HPTN 083</b>	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
<b>HVTN 140/HPTN 101</b>	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

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<b>HVTN 804/HPTN 095</b>	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
<b>HPTN 094</b>	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 Follow Up	N	Integrated Strategy	PWID	7 May 2021	2 June 2021	30 Sept 2023	17 Dec 2024	450	447
<b>HVTN 805/HPTN 093</b>	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

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<b>HVTN 136/ HPTN 092</b>	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
<b>HPTN 091</b>	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
<b>HVTN 130/HPTN 089</b>	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

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<b>HPTN 084-01</b>	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
<b>HPTN 083-01</b>	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
<b>HPTN 084 Blinded</b>	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