



## 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
<b>HPTN 119</b>	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
<b>HPTN 118</b>	Adolescent 3E	TBD	In Development	N	Integrated Strategy	Adolescents	<i>TBD</i>	<i>TBD</i>	<i>TBD</i>	<i>TBD</i>	<i>TBD</i>	N/A
<b>HPTN 117</b>	PK and adherence of Doxycycline	US	In Development	N	Integrated Strategy	Healthy Adults	<i>Sept 2025</i>	<i>Oct 2025</i>	<i>Aug 2026</i>	<i>TBD</i>	16	N/A
<b>DMID 24-0020/HPTN 116</b>	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
<b>HPTN 115/ATN 173</b>	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

Updated: 29 April 2025

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 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	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
HPTN 104	To evaluate adherence to a single dual prevention pill, DPP (co-formulated TDF/FTC + ethinyl estradiol/levonorgestrel oral contraceptive pill (OCP), compared with the two tablets with daily oral TDF/FTC + ethinyl estradiol/levonorgestrel oral contraceptive pill for pre-exposure prophylaxis and pregnancy prevention in HIV-uninfected women	INTL	Pending	Y	MPT	HIV uninfected women	Mar 2025	Mar 2025	June 2026	June 2027	300	N/A

Updated: 29 April 2025

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
<b>HPTN 096 Post Pilot</b>	Testing the Efficacy of an Integrated Intervention Strategy in the American South	US	Temporarily Closed (Paused) to Accrual	N	Integrated Strategy	MSM in the Southern US	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	Enrolling	Y	mAb	HIV uninfected adults	14 Jan 2025	7 Mar 2025	Sept 2025	Sept 2026	200	10
<b>HPTN 113-01</b>	Focus Group Discussion prior to HPTN 113	US/INTL	Enrolling	N	Integrated Strategy	Men who have Sex with Men	26 Sept 2024	26 Sept 2024	May 2025	June 2025		63
<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	US	Enrolling	Y	PrEP	HIV Uninfected MSM	25 Sept 2024	29 Oct 2024	Oct 2025	Mar 2026	150	63

Updated: 29 April 2025

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
	Pharmacokinetics/Pharmacodynamics											
<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	180	100
<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	Dec 2025	Dec 2028	250	180
<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	Oct 2026	N/A	462
<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	INTL	Closed to Accrual	N	Integrated Strategy	Heterosexual Men	21 Mar 2024	2 Apr 2024	15 Nov 2024	Sept 2025	200	203

Updated: 29 April 2025

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
	systems-navigator-delivered integrated prevention package.											
<b>HPTN 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>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	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
<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	Late 2024	Feb 2026	2200	2606

Updated: 29 April 2025

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
<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
<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	5 Feb 2020	22 Aug 2022	26 Jun 2023	22 July 2024	46	18
<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	2 Feb 2024	61	13

Updated: 29 April 2025

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
<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

Updated: 29 April 2025

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
<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 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 Follow Up	Y	PrEP	HIV-uninfected MSM	5 Dec 2016	19 Dec 2016	16 Mar 2020	31 Mar 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	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

Updated: 29 April 2025



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
	Women who have Sex with Men											
<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