



### 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 116	Neurosyphilis Study	TBD	In Development	TBD	STI	TBD	TBD	TBD	TBD	TBD	TBD	
HPTN 115	Doxy PEP for US Adolescents	TBD	In Development	N	PEP	Adolescents	TBD	TBD	TBD	TBD	TBD	
HVTN 2XX/HPTN 114	Phase 2 mAb Combo	TBD	In Development	Y	mAb	TBD	TBD	TBD	TBD	TBD	TBD	

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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	US	In Development	Y	MPT	HIV uninfected cis-women	Feb 2025	Feb 2025	Jan 2027	Nov 2027	1000	N/A
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)	Dec 2024	Dec 2024	Dec 2025	Dec 2026	500	N/A
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	Pending	Y	PrEP	HIV Uninfected MSM	Aug 2024	Aug 2024	Aug 2025	Jan 2026	200	N/A

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<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	Dec 2024	Jan 2025	Mar 2025	Mar 2026	136	N/A
<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	Sept 2024	Sept 2024	TBD	2027	N/A	N/A
<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	Open to Accrual	Y	PrEP	HIV Uninfected PWID	4 June 2024	July 2024	Feb 2025	Jan 2028	250	N/A

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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	Enrolling	N	Integrated Strategy	Heterosexual Men	21 Mar 2024	2 Apr 2024	Dec 2024	July 2025	215	91
<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	Dec 2024	Dec 2026	48	9
<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	Enrolling	Y	STI	Adults at risk of STI	19 Nov 2020	29 Dec 2020	TBD	TBD	2200	808
<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	US	Enrolling	Y	PrEP	HIV Uninfected Women	23 Apr 2024	31 May 2024	Dec 2025	June 2027	250	3

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	Among Women in the United States											
<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	Sept 2024	Apr 2026	N/A	348
<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	Apr 2025	250	249
<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 Accrual	N	Antibody Mediated Prevention	HIV-infected MSM and TGW	5 Feb 2020	8 Aug 2022	27 Jun 2023	June 2025	46	18

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<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 Accrual	N	Integrated Strategy	PWID	7 May 2021	2 June 2021	30 Sept 2023	Sept 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 Accrual	N	Antibody Mediated Prevention	HIV-infected women	02 Apr 2021	28 May 2021	14 Sept 2022	July 2025	61	13
<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 Accrual	N	Integrated Strategy	Transgender Women	24 Feb 2021	26 Mar 2021	16 Dec 2022	Sept 2024	310	307

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<b>HPTN 084 OLE</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	Closed to Accrual	Y	PrEP	HIV-uninfected women	20 Jan 2022	20 Jan 2022	1 Oct 2022	Jan 2026	n/a	2472
<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	June 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

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<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 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>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

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