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 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	In Development	N	Integrated Strategy	Young Latino Sexual Minority Men (SMM)	*TBD*	*TBD*	*TBD*	*TBD*	TBD	N/A
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	In Development	N	Integrated Strategy	Heterosexual Men	*TBD*	*TBD*	*TBD*	*TBD*	TBD	N/A
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	In Development	N	Integrated Strategy	Heterosexual Men	*Nov 2023*	*Nov 2023*	*Feb 2024*	*Mar 2025*	200	N/A

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HVTN 143/HPTN 109	A phase 1- clinical trial to evaluate the safety, tolerability, pharmacokinetics and tolerability of combinations of monoclonal antibodies VRC01.23LS, PGT121.414.LS, and PGDM1400LS administered via intravenous infusion in adults without HIV	TBD	In Development	TBD	Antibody Mediated Prevention	Adults without HIV	*Oct 2023*	*Oct 2023*	*May 2024*	*Feb 2025*	89	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	In Development	TBD	Antibody Mediated Prevention	Adult participants living with HIV	*Sept 2023*	*Sept 2023*	*June 2024*	*Nov 2025*	30	N/A

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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	In Development	Y	PrEP	HIV Uninfected MSM	*Sept 2023*	*Sept 2023*	*Sept 2024*	*Feb 2025*	200	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	In Development	Y	PrEP	HIV Uninfected Adults	*Mar 2024*	*Mar 2024*	*May 2024*	*Mar 2025*	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	US	In Development	Y	MPT	HIV uninfected cis-women	*Nov 2023*	*Nov 2023*	*Nov 2024*	*Nov 2025*	1000	N/A

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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	In Development	Y	PrEP	HIV Uninfected PWID	*Aug 2023*	*Aug 2023*	*July 2024*	*Apr 2027*	250	N/A
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	In Development	Y	PrEP	HIV Uninfected Women	*June 2023*	*June 2023*	*June 2024*	*Dec 2026*	250	N/A
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	Enrolling	Y	STI	Adults at risk of STI	19 Nov 2020	29 Dec 2020	*Sept 2023*	*Jan 2024*	2200	808

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HPTN 096	Getting to Zero among Black MSM in the American South: Testing the Efficacy of an Integrated Intervention Strategy	US	Enrolling	N	Integrated Strategy	Black MSM	11 May 2022	14 May 2022	*Sept 2026*	*Sept 2026*	3200	452
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	Enrolling	N	Antibody Mediated Prevention	HIV-infected MSM and TGW	5 Feb 2020	8 Aug 2022	*June 2023*	*June 2026*	46	17
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	Enrolling	N	Integrated Strategy	PWID	7 May 2021	2 June 2021	*July 2023*	*July 2024*	860	334
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	Enrolling	N	Antibody Mediated Prevention	HIV-infected women	02 Apr 2021	28 May 2021	08 Nov 2022	*Nov 2025*	61	13

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HPTN 084 OLE 2	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	24 Jan 2023	10 Feb 2023	*July 2023*	*Feb 2026*	N/A	5
HPTN 084 OLE 1	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	17 Oct 2022	*Sept 2023*	n/a	2472
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 Accrual	N	Integrated Strategy	Transgender Women	24 Feb 2021	26 Mar 2021	16 Dec 2022	*Sept 2024*	310	307
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 Accrual	Y	Antibody Mediated Prevention	HIV Uninfected Adults	20 Oct 2021	15 Nov 2021	Oct 05 2022	*Sept 2023*	95	95

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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 Accrual	Y	PrEP	HIV-uninfected adolescents	19 Feb 2020	6 July 2020	10 Jan 2022	*Aug 2023*	55	9
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	*June 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	*Jan 2024*	5000	4570

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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
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

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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