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 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	*Feb 2023*	*Feb 2023*	*Nov 2023*	*May 2024*	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 2023*	*Mar 2023*	*May 2023*	*Mar 2024*	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	*May 2023*	*May 2023*	*May 2024*	*May 2025*	1000	N/A

Updated: 24 June 2022

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	*Dec 2022*	*Dec 2022*	*Nov 2023*	*Aug 2026*	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	*Dec 2022*	*Dec 2022*	*Dec 2023*	*June 2026*	250	N/A
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	Open to Accrual	N	Antibody Mediated Prevention	HIV-infected MSM and TGW	5 Feb 2020	*TBD*	*TBD*	*TBD*	46	N/A
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	Enrolling	Y	Antibody Mediated Prevention	HIV Uninfected Adults	20 Oct 2021	15 Nov 2021	*Sept 2022*	*July 2023*	95	33
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	May 11, 2022	May 14, 2022	*Sept 2026*	*Sept 2026*	3200	66

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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	184
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	*Dec 2022*	*Dec 2025*	61	11
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	Enrolling	N	Integrated Strategy	Transgender Women	24 Feb 2021	26 Mar 2021	*Dec 2022*	*Sept 2024*	310	198
HPTN 083-02	Factors Influencing Adherence to Injectable PrEP and Retention in an Injectable PrEP Research Study	US/INTL	Enrolling	Y	PrEP	HIV-uninfected MSM and TGW	08 Oct 2019	5 Nov 2019	*Nov 2022*	*Nov 2022*	300	79
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-	US	Closed to Accrual	Y	Antibody Mediated Prevention	HIV-uninfected adults	24 Aug 2020	10 Nov 2020	05 Oct 2021	*Feb 2023*	32	33

	523LS via intravenous infusion or via subcutaneous injections in healthy, HIV-uninfected adult participants											
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 Accrual	Y	PrEP	HIV-uninfected adolescents	4 Nov 2020	3 Dec 2020	6 Aug 2021	*Feb 2023*	55	55
HPTN 084	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	7 Nov 2017	27 Nov 2017	8 Nov 2020	*Sept 2022*	3200	3224
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	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

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