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	Rectal douche	US	In Development	Y	PrEP	HIV Uninfected MSM	*TBD*	*TBD*	*TBD*	*TBD*	TBD	N/A
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	*TBD*	*TBD*	*TBD*	*TBD*	TBD	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	*TBD*	*TBD*	*TBD*	*TBD*	TBD	N/A
HPTN 103	A Randomized, Open-Label Study of Acceptability and Use of Lenacapavir vs TDF/FTC Among PWID in US	US	In Development	Y	PrEP	HIV Uninfected PWID	*TBD*	*TBD*	*TBD*	*TBD*	TBD	N/A

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HPTN 102	A Randomized, Open-Label Study of Acceptability and Use of Lenacapavir vs TDF/FTC Among US Women	US	In Development	Y	PrEP	HIV Uninfected Women	*TBD*	*TBD*	*TBD*	*TBD*	TBD	N/A
HVTN 138/ HPTN 098	A phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of the monoclonal antibody CAP256V2LS administered alone and in combination with VRC07-523LS via intravenous or subcutaneous infusions in healthy, HIV-1 uninfected adult participants	TBD	In Development	TBD	Antibody Mediated Prevention	HIV Uninfected Adults	*TBD*	*TBD*	*TBD*	*TBD*	125	N/A
HPTN 097	HPTN 074 Plus: A Phase III Randomized Clinical Trial to Optimize HIV Viral Suppression Comparing the HPTN 074 Intervention and immediate ART as the Standard of Care with an Integrated Intervention of Immediate MAT plus Enhanced Social Support among HIV-infected PWID	TBD	In Development	TBD	Integrated Strategy	PWID	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	N/A
HVTN 129/ HPTN 088	A Phase I clinical trial to evaluate the safety, pharmacokinetics, and functional activity of a trispecific antibody, SAR441236, in healthy, HIV-1 uninfected adult participants	US	In Development	Y	Antibody Mediated Prevention	HIV-uninfected adults	*TBD*	*TBD*	*TBD*	*TBD*	87	N/A
HPTN 096	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	*July 2022*	*July 2022*	*Sept 2026*	*Sept 2026*	3200	N/A

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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	*June 2022*	*Apr 2023*	95	15
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	*Sept 2023*	*Sept 2024*	860	137
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	*March 2022*	*June 2024*	61	8
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	*July 2022*	*Apr 2024*	310	109

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 VRC07-523LS via intravenous infusion or via subcutaneous injections in healthy, HIV-uninfected adult participants	US	Closed to Accrual	Y	Antibody Mediated Prevention	HIV-uninfected adults	24 Aug 2020	10 Nov 2020	05 Oct 2021	*June 2022*	32	33
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	*July 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	*Mar 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	*Apr 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
HVTN 127/HPTN 087	A multicenter, randomized phase 1 clinical trial to evaluate the safety and serum concentrations of a human monoclonal antibody, VRC-HIVMAB075-00-AB (VRC07-523LS), administered in multiple doses, routes, and dosing schedules to healthy, HIV-uninfected adults.	US/INTL	Closed to Follow-Up	Y	Antibody mediated prevention	HIV-uninfected adults	2 Feb 2018	28 Feb 2018	9 Oct 2018	07 Dec 2020	124	124

HVTN 704/HPTN 085	A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection among men and transgender persons who have sex with men.	US/INTL	Concluded	Y	Antibody mediated prevention	HIV-uninfected MSM and TGW	31 March 2016	6 April 2016	5 Oct 2018	29 Jan 2021	2700	2701
HVTN 703/HPTN 081	A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection in women in sub-Saharan Africa.	INTL	Concluded	Y	Antibody mediated prevention	HIV-uninfected women	9 May 2016	17 May 2016	20 Sept 2018	03 Mar 2021	1900	1924