



HPTN Protocols Snapshot:

Protocol #	Title	Sites	Study Status	IND	Research Area	Study Population	Open to Accrual (projected)	1 st Participant Enrolled (projected)	Closed to Accrual (projected)	Closed to Follow Up (projected)	Target Accrual	Actual Accrual as of report date
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	TBD	In Development	TBD	Antibody Mediated Prevention	HIV Uninfected Adults	TBD	TBD	TBD	TBD	95	N/A
HPTN 099	A Phase I Double Blind Study of Cabotegravir (CAB)-eluting Implants for HIV-1 Pre-Exposure Prophylaxis in Adults	TBD	In Development	TBD	PrEP	TBD	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	TBD	In Development	TBD	Integrated Strategy	PWID	TBD	TBD	TBD	TBD	TBD	N/A

	Integrated Intervention of Immediate MAT plus Enhanced Social Support among HIV-infected PWID												
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	June 2025	Dec 2025	3200	N/A	
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	Pending	N	Integrated Strategy	PWID	May 2021	May 2021	Oct 2023	Oct 2024	860	N/A	
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	Open to Accrual	N	Antibody Mediated Prevention	HIV-infected women	02 Apr 2021	May 2021	Jan 2022	April 2024	61	N/A	
HVTN 804/ HPTN 095	Antiretroviral analytical treatment interruption (ATI) to assess immunologic and virologic responses in participants who received	US/INTL	Open to Accrual	N	Antibody Mediated Prevention	HIV-infected MSM and TGW	5 Feb 2020	TBD	TBD	TBD	46	N/A	

Updated: 06 May 2021

	VRC01 or placebo and became HIV-infected during HVTN 704/HPTN 085												
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	Enrolling	Y	Antibody Mediated Prevention	HIV-uninfected adults	24 Aug 2020	10 Nov 2020	July 2021	Nov 2022	32	9	
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	April 2022	Feb 2024	310	2	
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	Enrolling	Y	PrEP	HIV-uninfected adolescents	4 Nov 2020	3 Dec 2020	Oct 2022	Apr 2023	50	19	
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	40	
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	Enrolling	Y	PrEP	HIV-uninfected adolescents	19 Feb 2020	6 July 2020	June 2021	June 2022	50	3	

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	Nov 2022	3200	3224
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	31 Dec 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	US/INTL	Closed to Follow-Up	Y	Antibody mediated prevention	HIV-uninfected MSM and TGW	31 March 2016	6 April 2016	5 Oct 2018	29 Jan 2021	2700	2701

	transgender persons who have sex with men.											
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	Closed to Follow Up	Y	Antibody mediated prevention	HIV-uninfected women	9 May 2016	17 May 2016	20 Sept 2018	03 Mar 2021	1900	1924
HPTN 078	Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected Men Who Have Sex with Men (MSM) in the United States	US	Closed to Follow-up	N	Integrated Strategy	HIV-infected virally un-suppressed MSM	17 March 2016	6 June 2016	15 Dec 2017	8 Feb 2019	356	144
HPTN 074 Extension	Extension: Integrated treatment and prevention for people who inject drugs: A vanguard study for a network-based randomized HIV prevention trial comparing an integrated intervention including supported antiretroviral therapy to the standard of care	INTL	Closed to Follow up	N	TASP	HIV-infected people who inject drugs (PWID) originally enrolled in HPTN 074	24 Aug 2017	11 Sept 2017	30 June 2018	5 July 2018	504	328
HPTN 082	Evaluation of Daily Oral PrEP as a Primary Prevention Strategy for Young African Women: A Vanguard Study	INTL	Participants Off Study and Primary Analysis Completed	N	PrEP	HIV-uninfected women	28 Sept 2016	13 Oct 2016	12 Oct 2017	26 Oct 2018	400	451
HPTN 077	A Phase IIa Safety, Tolerability and Acceptability Study of an Investigational Injectable HIV Integrase Inhibitor, GSK1265744, for PrEP in HIV Uninfected Men and Women	US/INTL	Participants Off Study and Primary Analysis Completed	Y	PrEP	HIV-uninfected men and women	9 Feb 2015	23 Feb 2015	27 May 2016	31 July 2018	194	200
HPTN 076	Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre-Exposure Prophylaxis (PrEP)	US/INTL	Participants Off Study and Primary Analysis Completed	Y	PrEP	HIV-uninfected women	6 March 2015	13 April 2015	14 Sept 2015	22 Mar 2017	132	136
HPTN 075	Feasibility of HIV Prevention Cohort Studies	INTL	Participants Off Study and	N	Behavioral	HIV-infected and	12 June 2015	16 July 2015	12 July 2016	25 Aug 2017	400	401

	Among MSM in Sub-Saharan Africa		Primary Analysis Completed			uninfected MSM						
HPTN 073	Pre-Exposure Prophylaxis (PrEP) Initiation and Adherence among Black Men who have Sex with Men (BMSM) in Three U.S. Cities	US	Participants Off Study and Primary Analysis Completed	N	PrEP	HIV-uninfected MSM	13 Aug 2013	15 Aug 2013	22 Sept 2014	30 Sept 2015	225	226
HPTN 071	Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART): A cluster-randomized trial of the impact of a combination prevention package on population-level HIV incidence in Zambia and South Africa	INTL	Participants Off Study and Primary Analysis Completed	N	TASP	HIV-infected and uninfected men and women	25 Nov 2013	28 Nov 2013	15 July 2017	06 July 2018	52,500	48,548