



HPTN Protocols Snapshot: In Development through Closed to Follow Up

Protocol #	Title	Sites	Study Status	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 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	In development	Antibody mediated prevention	HIV-uninfected adults	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	Antibody mediated prevention	HIV-uninfected adults	TBD	TBD	TBD	TBD	TBD	N/A
HPTN 086	Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (LA CAB) for the Prevention of HIV among Adolescents	TBD	In development	PrEP	HIV-uninfected adolescents	TBD	TBD	TBD	TBD	TBD	N/A
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	Enrolling	Antibody mediated prevention	HIV-uninfected adults	2 Feb 2018	28 Feb 2018	30 Sept 2018	5 May 2021	124	42
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	Enrolling	Antibody mediated prevention	HIV-uninfected MSM and TGW	31 March 2016	6 April 2016	30 June 2018	30 Sept 2020	2700	2580

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	Enrolling	PrEP	HIV-uninfected women	7 Nov 2017	27 Nov 2017	15 July 2019	6 June 2022	3184	164
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	Enrolling	PrEP	HIV-uninfected MSM and TGW	5 Dec 2016	19 Dec 2016	21 June 2019	3 Sept 2021	4500	2088
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	Enrolling	Antibody mediated prevention	HIV-uninfected women	9 May 2016	17 May 2016	31 January 2018	31 March 2020	1900	1721
HPTN 082	Evaluation of Daily Oral PrEP as a Primary Prevention Strategy for Young African Women: A Vanguard Study	INTL	Closed to Accrual	PrEP	HIV-uninfected women	28 Sept 2016	13 Oct 2016	12 Oct 2017	14 Nov 2018	600	451
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 Accrual	Integrated Strategy	HIV-infected virally unsuppressed MSM	17 March 2016	6 June 2016	15 Dec 2017	28 Feb 2019	356	144
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	Closed to Accrual	PrEP	HIV-uninfected men and women	9 Feb 2015	23 Feb 2015	27 May 2016	31 July 2018	194	200
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	Closed to Accrual	TASP	HIV-infected and uninfected men and women	25 Nov 2013	28 Nov 2013	15 July 2017	30 June 2018	120,000	48,548
HPTN 076	Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre-Exposure Prophylaxis (PrEP)	US/INTL	Closed to Follow-Up	PrEP	HIV-uninfected women	6 March 2015	13 April 2015	14 Sept 2015	22 March 2017	132	136
HPTN 075	Feasibility of HIV Prevention Cohort Studies Among MSM in Sub-Saharan Africa	INTL	Closed to Follow-Up	Behavioral	HIV-infected and	12 June 2015	16 July 2015	12 July 2016	25 Aug 2017	400	401

					uninfected MSM						
HPTN 074	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	TASP	HIV-infected people who inject drugs (PWID) and HIV-uninfected injection partners	4 Feb 2015	21 April 2015	10 June 2016	30 June 2017	1250	1314
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	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 073	Pre-Exposure Prophylaxis (PrEP) Initiation and Adherence among Black Men who have Sex with Men (BMSM) in Three U.S. Cities	US	Closed to Follow-Up	PrEP	HIV-uninfected MSM	13 Aug 2013	15 Aug 2013	22 Sept 2014	30 Sept 2015	225	226

Updated: 2 August 2018