



## HPTN Protocols Snapshot: In Development through Closed to Follow Up

Protocol #	Title	Sites	Study Status	IND	Research Area	Study Population	Open to Accrual (projected)	1 <sup>st</sup> Participant Enrolled (projected)	Closed to Accrual (projected)	Closed to Follow Up (projected)	Target Accrual	Actual Accrual as of report date
<b>HVTN 136/HPTN 092</b>	A phase 1 dose-escalation clinical trial to evaluate the safety, tolerability, and pharmacokinetics of PGT121LS alone and in combination with VRC07-523LS in healthy, HIV-uninfected adult participants	US	In Development	TBD	Antibody Mediated Prevention	HIV-uninfected adults	TBD	TBD	TBD	TBD	32	N/A
<b>HPTN 091</b>	Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation to Prevent HIV Acquisition and HIV Transmission for Transgender Women: A Vanguard Feasibility and Acceptability Study	TBD	In development	TBD	Integrated Strategy	Transgender Women	TBD	TBD	TBD	TBD	448	N/A
<b>HVTN 131/HPTN 090</b>	A phase 1 multi-site randomized clinical trial to evaluate the safety, tolerability, and pharmacokinetics of anti-HIV monoclonal antibodies VRC07-523LS and 10E8VLS administered SC and IV in healthy, HIV-1-uninfected adult participants.	US	In development	TBD	Antibody mediated prevention	HIV-uninfected adults	TBD	TBD	TBD	TBD	95	N/A
<b>HVTN 130/HPTN 089</b>	A Phase I clinical trial to evaluate the safety, pharmacokinetics, and functional activity of a combination of VRC07-523LS, PGT121, and	US	In development	TBD	Antibody mediated prevention	HIV-uninfected adults	TBD	TBD	TBD	TBD	27	N/A

	PGDM1400 in healthy, HIV-1 uninfected adult participants.												
<b>HVTN 129/ HPTN 088</b>	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	TBD	Antibody mediated prevention	HIV-uninfected adults	TBD	TBD	TBD	TBD	78	N/A	
<b>HPTN 083-01</b>	Safety, Tolerability, Usability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescents – A sub-study of HPTN 083	US	In development	TBD	PrEP	HIV-uninfected adolescents	TBD	TBD	TBD	TBD	50	N/A	
<b>HPTN 084-01</b>	Safety, Tolerability, Usability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescents – A Sub-study of HPTN 084	INTL	In development	TBD	PrEP	HIV-uninfected adolescents	TBD	TBD	TBD	TBD	50	N/A	
<b>HPTN 084</b>	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	7 Nov 2017	27 Nov 2017	15 Jul 2019	6 June 2022	3200	1151	
<b>HPTN 083</b>	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	Y	PrEP	HIV-uninfected MSM and TGW	5 Dec 2016	19 Dec 2016	1 May 2020	30 Sept 2022	4500	3618	
<b>HVTN 127/HPTN 087</b>	A multicenter, randomized phase 1 clinical trial to evaluate the safety and serum concentrations of a	US/INTL	Closed to Accrual	Y	Antibody mediated prevention	HIV-uninfected adults	2 Feb 2018	28 Feb 2018	9 Oct 2018	31 Dec 2020	124	124	

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	human monoclonal antibody, VRC-HIVMAB075-00-AB (VRC07-523LS), administered in multiple doses, routes, and dosing schedules to healthy, HIV-uninfected adults.											
<b>HVTN 704/HPTN 085</b>	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	Closed to Accrual	Y	Antibody mediated prevention	HIV-uninfected MSM and TGW	31 March 2016	6 April 2016	5 Oct 2018	30 Sept 2020	2700	2701
<b>HPTN 082</b>	Evaluation of Daily Oral PrEP as a Primary Prevention Strategy for Young African Women: A Vanguard Study	INTL	Closed to Accrual	N	PrEP	HIV-uninfected women	28 Sept 2016	13 Oct 2016	12 Oct 2017	26 Oct 2018	600	451
<b>HVTN 703/HPTN 081</b>	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 Accrual	N	Antibody mediated prevention	HIV-uninfected women	9 May 2016	17 May 2016	20 Sept 2018	31 Mar 2020	1900	1924
<b>HPTN 078</b>	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	N	Integrated Strategy	HIV-infected virally unsuppressed MSM	17 March 2016	6 June 2016	15 Dec 2017	8 Feb 2019	356	144
<b>HPTN 077</b>	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 Follow-Up	Y	PrEP	HIV-uninfected men and women	9 Feb 2015	23 Feb 2015	27 May 2016	31 July 2018	194	200
<b>HPTN 076</b>	Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for	US/INTL	Closed to Follow-Up	Y	PrEP	HIV-uninfected women	6 March 2015	13 April 2015	14 Sept 2015	22 Mar 2017	132	136

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	Pre-Exposure Prophylaxis (PrEP)											
<b>HPTN 075</b>	Feasibility of HIV Prevention Cohort Studies Among MSM in Sub-Saharan Africa	INTL	Closed to Follow-Up	N	Behavioral	HIV-infected and uninfected MSM	12 June 2015	16 July 2015	12 July 2016	25 Aug 2017	400	401
<b>HPTN 074</b>	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) and HIV-uninfected injection partners	4 Feb 2015	21 April 2015	10 June 2016	30 June 2017	1250	1314
<b>HPTN 074 Extension</b>	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
<b>HPTN 073</b>	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	N	PrEP	HIV-uninfected MSM	13 Aug 2013	15 Aug 2013	22 Sept 2014	30 Sept 2015	225	226
<b>HPTN 071</b>	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 Follow-Up	N	TASP	HIV-infected and uninfected men and women	25 Nov 2013	28 Nov 2013	15 July 2017	30 June 2018	120,000	48,548
<b>HPTN 067</b>	A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the	US/INTL	Closed to Follow-Up	Y	PrEP	HIV-uninfected MSM/TGW, WSM at high	29 Aug 2011	12 Sep 2011	6 May 2014	18 Dec 2014	540	622

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	Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)					risk of acquiring HIV infection						
<b>HPTN 065</b>	TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States	US	Closed to Follow-Up	N	Integrated Strategy	HIV-infected individuals	28 Sep 2010	29 Sep 2010	31 Dec 2013	31 Dec 2014	520	423
<b>HPTN 063</b>	Preparing for international prevention trials involving HIV-infected individuals in care settings	INTL	Closed to Follow-Up	N	Behavioral	HIV-infected men and women	25 Mar 2010	26 Mar 2010	19 Apr 2012	4 Jun 2013	800	751