



## HPTN Protocols Snapshot:

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>HPTN 096</b>	Getting to Zero among Black MSM in the American South: An Implementation Science Effectiveness Study	US	In Development	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	N/A
<b>HVTN 804/HPTN 095</b>	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	In Development	TBD	Antibody Mediated Prevention	HIV-infected MSM and TGW	February 2020	February 2020	TBD	TBD	TBD	N/A
<b>HPTN 094</b>	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	TBD	In Development	No	Integrated Strategy	PWID	TBD	TBD	TBD	TBD	TBD	N/A

<b>HVTN xxx/HPTN 093</b>	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	In Development	TBD	Antibody Mediated Prevention	HIV-infected women	TBD	TBD	TBD	TBD	TBD	TBD	N/A
<b>HVTN 136/HPTN 092</b>	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	In Development	TBD	Antibody Mediated Prevention	HIV-uninfected adults	February 2020	February 2020	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	TBD	TBD	N/A
<b>HVTN 129/HPTN 088</b>	A Phase I clinical trial to evaluate the safety, pharmacokinetics, and functional activity of a trispesific 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	US	In development	Y	PrEP	HIV-uninfected adolescents	Nov 2019	Nov 2019	Nov 2020	Nov 2021	50	N/A	

	Cabotegravir (CAB LA) for the Prevention of HIV among Adolescents – A sub-study of HPTN 083											
<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	Y	PrEP	HIV-uninfected adolescents	<i>April 2020</i>	<i>April 2020</i>	<i>April 2021</i>	<i>April 2022</i>	50	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 PGDM1400 in healthy, HIV-1 uninfected adult participants.	US	Enrolling	Y	Antibody mediated prevention	HIV-uninfected adults	17 Jul 2019	31 Jul 2019	<i>October 2019</i>	<i>15 Dec 2020</i>	27	4
<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	<i>April 2020</i>	<i>November 2022</i>	3200	2140
<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	<i>03 Feb 2020</i>	<i>30 Jun 2022</i>	4500	4325
<b>HVTN 127/HPTN 087</b>	A multicenter, randomized phase 1 clinical trial to evaluate the safety and serum concentrations of a human monoclonal antibody, VRC-HIVMAB075-00-AB	US/INTL	Closed to Accrual	Y	Antibody mediated prevention	HIV-uninfected adults	2 Feb 2018	28 Feb 2018	9 Oct 2018	<i>31 Dec 2020</i>	124	124

Updated: 3 September 2019

	(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>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 082</b>	Evaluation of Daily Oral PrEP as a Primary Prevention Strategy for Young African Women: A Vanguard Study	INTL	Closed to Follow-up	N	PrEP	HIV-uninfected women	28 Sept 2016	13 Oct 2016	12 Oct 2017	26 Oct 2018	400	451	
<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 Follow-up	N	Integrated Strategy	HIV-infected virally unsuppressed MSM	17 March 2016	6 June 2016	15 Dec 2017	8 Feb 2019	356	144	
<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 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	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	

	antiretroviral therapy to the standard of care											
<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	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
<b>HPTN 076</b>	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
<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	Participants Off Study and Primary Analysis Completed	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 073</b>	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
<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	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