



### 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 095</b>	Intensively Monitored Antiretroviral Pause to Assess Immunologic and Virologic Responses in Participants Who Received VRC01 or Placebo and Became HIV Infected During the AMP Studies in the Americas	US/INTL	In Development	TBD	Antibody Mediated Prevention	HIV-infected MSM and TGW	TBD	TBD	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	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	N/A
<b>HPTN 093</b>	Intensively Monitored Antiretroviral Pause to Assess Immunologic and Virologic Responses in Participants Who Received VRC01 or Placebo and Became HIV Infected During the AMP Studies in Africa	INTL	In Development	TBD	Antibody Mediated Prevention	HIV-infected women	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, 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 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 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>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,	US	Pending	TBD	Antibody mediated prevention	HIV-uninfected adults	TBD	TBD	TBD	TBD	27	N/A

	HIV-1 uninfected adult participants.											
<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	1342
<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	3780
<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 (VRC07-523LS), administered in multiple doses, routes, and dosing schedules to healthy, HIV-uninfected adults.	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
<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	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

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	infection in women in sub-Saharan Africa.											
<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	600	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 un-suppressed MSM	17 March 2016	6 June 2016	15 Dec 2017	8 Feb 2019	356	144
<b>HPTN 076</b>	Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre-Exposure Prophylaxis (PrEP)	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
<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	US	Closed to Follow-Up	N	PrEP	HIV-uninfected MSM	13 Aug 2013	15 Aug 2013	22 Sept 2014	30 Sept 2015	225	226

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	Men who have Sex with Men (BMSM) in Three U.S. Cities											
<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 Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)	US/INTL	Closed to Follow-Up	Y	PrEP	HIV-uninfected MSM/TGW, WSM at high risk of acquiring HIV infection	29 Aug 2011	12 Sep 2011	6 May 2014	18 Dec 2014	540	622
<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
<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