HPTN HIV Prevention Trials Network

## HPTN Protocols Snapshot:

| Protocol # | Title | Sites | Study Status | IND | Research Area | Study Population | Open to Accrual *(projected)* | 1st Participant Enrolled *(projected)* | Closed to Accrual *(projected)* | Closed to Follow Up *(projected)* | Target Accrual | Actual Accrual as of report date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **HPTN 104** | To evaluate adherence to a single dual prevention pill, DPP (co-formulated TDF/FTC + ethynyl estradiol/levonorgestrel oral contraceptive pill (OCP), compared with the two tablets with daily oral TDF/FTC + ethynyl estradiol/levonorgestrel oral contraceptive pill for pre-exposure prophylaxis and pregnancy prevention in HIV-uninfected women | US | In Development | Y | MPT | HIV uninfected cis-women | *Nov 2024* | *Dec 2024* | *Oct 2025* | *Oct 2026* | 1000 | N/A |
| **HPTN 113** | Double Prevention: A Vanguard Study of an Integrated Strategy of HIV PrEP and STI PEP for Young Latino Sexual Minority Men (SMM) in the Americas. | US/INTL | Pending | N | Integrated Strategy | Young Latino Sexual Minority Men (SMM) | *Dec 2024* | *Dec 2024* | *Dec 2025* | *Dec 2026* | 500 | N/A |
| **HPTN 106** | A Phase 2 Crossover Study Of On-Demand Prep Formulations Comparing | US | Pending | Y | PrEP | HIV Uninfected MSM | *July 2024* | *July 2024* | *July 2025* | *Nov 2025* | 200 | N/A |

*Updated: 30 June 2024*

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| | Rectal And Oral Tenofovir-Based Prep Evaluating Extended Safety, Acceptability, And Pharmacokinetics/Pharmacodynamics | | | | | | | | | | | |
| **HVTN 141/HPTN 105** | A phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics and in vitro neutralization of VRC01.23LS, ePGDM1400v9-LS and ePGT121v1-LS alone and in combination in healthy, HIV-uninfected adult participants | TBD | Pending | Y | PrEP | HIV Uninfected Adults | *Jan 2025* | *Jan 2025* | *June 2025* | *July 2026* | 136 | N/A |
| **HPTN 096 Post Pilot** | 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 | *Sept 2024* | *Sept 2024* | *TBD* | *2027* | N/A | N/A |
| **HPTN 103** | A Phase 2, Open-Label, Multicenter, Randomized Clinical Trial to Evaluate the Feasibility, Safety, and Acceptability of Long-Acting Subcutaneous Lenacapavir vs. Daily Oral Emtricitabine/Tenofovir Disoproxil Fumarate for Pre-Exposure Prophylaxis Among People who Inject Drugs | US | Open to Accrual | Y | PrEP | HIV Uninfected PWID | 4 June 2024 | *July 2024* | *Feb 2025* | *Jan 2028* | 250 | N/A |

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| **HTPN 112** | Improving HIV prevention among heterosexual men seeking STI services in sub-Saharan Africa: examining the feasibility, acceptability, and associated costs of a systems-navigator-delivered integrated prevention package. | INTL | Enrolling | N | Integrated Strategy | Heterosexual Men | 21 Mar 2024 | 2 Apr 2024 | *May 2025* | *May 2025* | 215 | 61 |
| **A5416/HVTN 806/HPTN 108** | A Phase I, Open-Label Study of the Safety, Antiviral & Immunomodulatory of Broadly Neutralizing Antibodies 3BNC117-LS-J and 10-1074-LS-J in Combination in ART-treated Adults in sub-Saharan Africa Living with HIV during a Monitored Analytical Treatment Interruption | INTL | Enrolling | TBD | Antibody Mediated Prevention | Adult participants living with HIV | 26 Apr 2024 | 28 May 2024 | *Dec 2024* | *Dec 2026* | 48 | 5 |
| **HPTN 107** | A Phase II randomized, observer-blind, placebo-controlled study, to assess efficacy of meningococcal Group B vaccine rMenB+OMV NZ (Bexsero) in preventing gonococcal infection. | US | Enrolling | Y | STI | Adults at risk of STI | 19 Nov 2020 | 29 Dec 2020 | *TBD* | *TBD* | 2200 | 808 |
| **HPTN 102** | A Phase 2, Open-Label, Multicenter, Randomized Study to Evaluate the Pharmacokinetics, Safety, and Acceptability and Use of Twice Yearly Long-Acting Subcutaneous Lenacapavir for Pre-Exposure Prophylaxis | US | Enrolling | Y | PrEP | HIV Uninfected Women | 23 Apr 2024 | 31 May 2024 | *Dec 2024* | *June 2027* | 250 | 1 |

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| | Among Women in the United States | | | | | | | | | | | |
| **HPTN 084 Pregnancy** | 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 | 1 Jan 2022 | 1 Jan 2022 | *Sept 2024* | *Apr 2026* | N/A | 348 |
| **HPTN 111** | Uptake of HIV Self-testing and Linkage to Prevention and Care among Heterosexual Men attending Barbershops in Uganda: A Cluster Randomized Trial. | INTL | Closed to Accrual | N | Integrated Strategy | Heterosexual Men | 10 Mar 2024 | 13 Mar 2024 | 27 Jun 2024 | *Apr 2025* | 250 | 249 |
| **HVTN 804/HPTN 095** | 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 | Closed to Accrual | N | Antibody Mediated Prevention | HIV-infected MSM and TGW | 5 Feb 2020 | 8 Aug 2022 | 27 Jun 2023 | *June 2025* | 46 | 18 |

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| **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 | Closed to Accrual | N | Integrated Strategy | PWID | 7 May 2021 | 2 June 2021 | 30 Sept 2023 | *Sept 2024* | 450 | 447 |
| **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 | Closed to Accrual | N | Antibody Mediated Prevention | HIV-infected women | 02 Apr 2021 | 28 May 2021 | 14 Sept 2022 | *July 2025* | 61 | 13 |
| **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 | Closed to Accrual | N | Integrated Strategy | Transgender Women | 24 Feb 2021 | 26 Mar 2021 | 16 Dec 2022 | *Jun 2024* | 310 | 307 |

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| **HPTN 084 OLE** | 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 | 20 Jan 2022 | 20 Jan 2022 | 1 Oct 2022 | *Jan 2026* | n/a | 2472 |
| **HPTN 083 OLE** | 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 | *Sept 2024* | N/A | 2278 |
| **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 | *June 2025* | 5000 | 4570 |

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| **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 | US/INTL | Closed to Follow Up | Y | Antibody Mediated Prevention | HIV Uninfected Adults | 20 Oct 2021 | 15 Nov 2021 | 5 Oct 2022 | 19 July 2023 | 95 | 95 |
| **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 | Closed to Follow-Up | Y | Antibody Mediated Prevention | HIV-uninfected adults | 24 Aug 2020 | 10 Nov 2020 | 05 Oct 2021 | 18 Jan 2023 | 32 | 33 |
| **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 |

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| **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 | Closed to Follow-Up | Y | PrEP | HIV-uninfected adolescents | 4 Nov 2020 | 3 Dec 2020 | 6 Aug 2021 | 10 Jan 2023 | 55 | 55 |
| **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 | Closed to Follow Up | Y | PrEP | HIV-uninfected adolescents | 19 Feb 2020 | 6 July 2020 | 10 Jan 2022 | 7 July 2023 | 55 | 9 |
| **HPTN 084 Blinded** | 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 | Participants of Study/Primary Analysis Complete | Y | PrEP | HIV-uninfected women | 7 Nov 2017 | 27 Nov 2017 | 8 Nov 2020 | 17 Oct 2022 | 3200 | 3224 |

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