



### HPTN Protocols Snapshot:

| Protocol #               | Title   | Sites   | Study Status   | IND | Research Area       | Study Population                       | Open to Accrual<br><i>(projected)</i> | 1 <sup>st</sup> Participant Enrolled<br><i>(projected)</i> | Closed to Accrual<br><i>(projected)</i> | Closed to Follow Up<br><i>(projected)</i> | Target Accrual | Actual Accrual as of report date |
|--------------------------|---|---------|----------------|-----|---------------------|--|---------------------------------------|--|---|---|----------------|----------------------------------|
| <b>HPTN 113</b>          | 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 | In Development | N   | Integrated Strategy | Young Latino Sexual Minority Men (SMM) | Mar 2024                              | Mar 2024   | Mar 2025                                | Mar 2026                                  | TBD            | N/A                              |
| <b>HPTN 106</b>          | A Phase 2 Crossover Study Of On Demand Prep Formulations Comparing Rectal And Oral Tenofovir-Based Prep Evaluating Extended Safety, Acceptability, And Pharmacokinetics/Pharmacodynamics  | US      | In Development | Y   | PrEP                | HIV Uninfected MSM                     | Mar 2024                              | Mar 2024   | Mar 2025                                | Aug 2025                                  | 200            | N/A                              |
| <b>HVTN 141/HPTN 105</b> | 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     | In Development | Y   | PrEP                | HIV Uninfected Adults                  | Aug 2024                              | Aug 2024   | Oct 2024                                | Aug 2025                                  | 136            | N/A                              |

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| <b>HPTN 104</b> | 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                    | Nov 2024   | Oct 2025                      | Oct 2026                        | 1000           | N/A                              |
| <b>HPTN 112</b> | 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  | Pending        | N   | Integrated Strategy | Heterosexual Men         | Feb 2024                    | Feb 2024   | Oct 2024                      | Nov 2024                        | 315            | N/A                              |
| <b>HPTN 111</b> | Uptake of HIV Self-testing and Linkage to Prevention and Care among Heterosexual Men attending Barbershops in Uganda: A Cluster Randomized Trial.   | INTL  | Pending        | N   | Integrated Strategy | Heterosexual Men         | Jan 2024                    | Jan 2024   | June 2024                     | Mar 2025                        | 200            | N/A                              |

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| <b>A5416/HVTN 806/HPTN 108</b> | 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  | Pending      | TBD | Antibody Mediated Prevention | Adult participants living with HIV | Oct 2023                       | Oct 2023  | May 2024                         | May 2025                           | 48             | N/A                              |
| <b>HPTN 103</b>                | 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    | Pending      | Y   | PrEP                         | HIV Uninfected PWID                | Feb 2024                       | Feb 2024  | July 2024                        | June 2027                          | 250            | N/A                              |
| <b>HPTN 102</b>                | 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 Among Women in the United States  | US    | Pending      | Y   | PrEP                         | HIV Uninfected Women               | Feb 2024                       | Feb 2024  | Oct 2024                         | Apr 2027                           | 250            | N/A                              |

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| <b>HPTN 096 Post Pilot</b> | 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             | 2024                           | 2024  | TBD                              | 2027                               | N/A            | N/A                              |
| <b>HVTN 143/HPTN 109</b>   | A phase 1- clinical trial to evaluate the safety, tolerability, pharmacokinetics and tolerability of combinations of monoclonal antibodies VRC01.23LS, PGT121.414.LS, and PGDM1400LS administered via intravenous infusion in adults without HIV | INTL  | Open to Accrual | TBD | Antibody Mediated Prevention | Adults without HIV    | 10 Oct 2023                    | Nov 2023  | May 2024                         | Feb 2025                           | 77             | N/A                              |
| <b>HPTN 107</b>            | 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                              |

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| <b>HPTN 084 Pregnancy</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     | 1 Jan 2022                     | 1 Jan 2022  | Sept 2024                        | Apr 2026                           | N/A            | 151                              |
| <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 | Closed to Accrual | N   | Antibody Mediated Prevention | HIV-infected MSM and TGW | 5 Feb 2020                     | 8 Aug 2022  | 27 Jun 2023                      | June 2026                          | 46             | 18                               |
| <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                                     | US      | Enrolling         | N   | Integrated Strategy          | PWID                     | 7 May 2021                     | 2 June 2021   | 30 Sept 2023                     | Mar 2024                           | 450            | 447                              |

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| <b>HVTN 805/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    | Closed to Accrual | N   | Antibody Mediated Prevention | HIV-infected women         | 02 Apr 2021                    | 28 May 2021   | 14 Sept 2022                     | Nov 2025                           | 61             | 13                               |
| <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 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                      | 9 Sept 2023                        | 310            | 307                              |
| <b>HPTN 084 OLE</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    | Closed to Accrual | Y   | PrEP                         | HIV-uninfected women       | 20 Jan 2022                    | 20 Jan 2022   | 1 Oct 2022                       | Aug 2025                           | n/a            | 2472                             |
| <b>HPTN 083 OLE</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 | Closed to Accrual | Y   | PrEP                         | HIV-uninfected MSM and TGW | 5 Dec 2016                     | 19 Dec 2016   | 16 Mar 2020                      | Mar 2024                           | N/A            | 2278                             |

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| <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 | Closed to Accrual   | Y   | PrEP                         | HIV-uninfected MSM and TGW | 5 Dec 2016                     | 19 Dec 2016   | 16 Mar 2020                      | Jan 2024                           | 5000           | 4570                             |
| <b>HVTN 140/HPTN 101</b> | 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                               |
| <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      | 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                               |

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| <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    | 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                               |
| <b>HPTN 084-01</b>       | 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                               |
| <b>HPTN 083-01</b>       | 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                                |

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| <b>HPTN 084 Blinded</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  | 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                             |