HPTN HIV Prevention Trials Network

Network Overview

FOR BUSINESS DEVELOPMENT

HPTN at a Glance

62 total studies
17 active, 45 completed

56 active sites

13 active countries

850+ publications

Our Mission

The HIV Prevention Trials Network (HPTN) is dedicated to the discovery and development of new products and innovative integrated strategies to reduce the acquisition and transmission of HIV and other sexually transmitted infections (STIs). The HPTN strives to end HIV as a global health threat.

Our Journey

Research has demonstrated that HIV prevention saves lives. While the HIV global epidemic is far from over, prevention strategies, including pre-exposure prophylaxis (PrEP), treatment as prevention (TasP), HIV and STI testing, and condom use, have led to significant declines in HIV-related deaths.

Since its inception in 1999, the HPTN has successfully conceptualized, designed, and implemented complex clinical research studies focusing on biomedical interventions and integrated strategies to prevent HIV acquisition and transmission with more than 65 clinical research sites globally. The HPTN has long-standing partnerships with the U.S. National Institutes of Health, pharmaceutical companies, the Gates Foundation, and many other organizations and academic researchers worldwide. In addition, the HPTN has forged collaborations to develop integrated strategies with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the U.S. Centers for Disease Control and Prevention (CDC), and ministries and departments of health in several countries.

Our Research Agenda

The HPTN research agenda focuses on four strategies:

1. **Long-acting antiretroviral (ARV) and other agents for pre-exposure prophylaxis (PrEP)**
2. **Multipurpose prevention technologies (MPTs)**
3. **Broadly neutralizing antibodies (bnAbs)**
4. **Integrated strategies for HIV prevention**

Our Global Reach

Argentina
- Buenos Aires, Buenos Aires

Botswana
- Gaborone, South-East District

Brazil
- Porto Alegre, Rio Grande do Sul
- Rio de Janeiro, Rio de Janeiro
- São Paulo, São Paulo

Eswatini
- Mbabane, Hhohho Region

Kenya
- Kisumu, Nyanza

Malawi
- Blantyre, Southern Region
- Lilongwe, Central Region

Peru
- Callao, Callao
- Iquitos, Maynas
- Lima, Lima

South Africa
- Johannesburg, Gauteng
- Durban, KwaZulu-Natal
- Cape Town, Western Cape
- Westville, KwaZulu-Natal
- Verulam, KwaZulu-Natal

Thailand
- Chiang Mai, Chiang Mai
- Pathumwan, Bangkok

Uganda
- Kampala, Kampala
- Entebbe, Wakiso District

United States
- Atlanta, GA
- Baltimore, MD

United States cont.
- Birmingham, AL
- Boston, MA
- Bronx, NY
- Chicago, IL
- Decatur, GA
- Houston, TX
- Los Angeles, CA
- Newark, NJ
- New York, NY
- Oakland, CA
- Philadelphia, PA
- Pittsburgh, PA
- Raleigh, NC
- San Francisco, CA
- Washington, DC

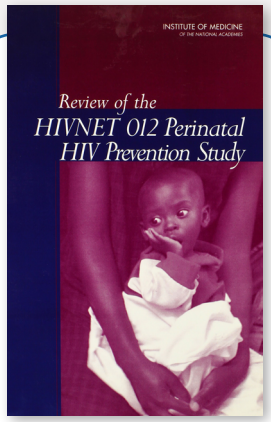
Vietnam
- Hanoi, Ba Dinh District

Zimbabwe
- Harare, Harare
- Chitungwiza, Harare

Our History

The roots of the HPTN are found in the establishment of the HIV Network for Prevention Trials (HIVNET) in 1993. HIVNET was initially designed as a multicenter, multidisciplinary collaborative research network for HIV-prevention efficacy trials, including vaccines, microbicides, and mother-to-child transmission. As research needs expanded, HIVNET evolved into two separate networks in 1999: the HPTN and the HIV Vaccine Trials Network (HVTN). In 2006, the HPTN evolved further with the creation of the separate Microbicides Trials Network (MTN), focusing on topical agents, and the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT), which focused on the prevention of mother-to-child transmission.

The HPTN has collaborated with more than 65 clinical research sites in 13 countries to evaluate new HIV prevention interventions and strategies in populations with a disproportionate HIV burden. The HPTN research agenda – more than 60 trials ongoing or completed with over 175,000 participants enrolled and evaluated – focuses primarily on discovering new HIV prevention tools and evaluating integrated strategies, including biomedical interventions combined with behavioral risk reduction and structural interventions. All phases of the HPTN research agenda are fully supported by three central resource partners – The Leadership and Operations Center (LOC) at FHI 360, the Laboratory Center (LC) at Johns Hopkins University, and the Statistical and Data Management Center (SDMC) at the Fred Hutchinson Cancer Center.



HIVNET 012 provided strong evidence that a simple, single-dose nevirapine regimen could substantially reduce mother-to-child HIV transmission, leading to widespread implementation of this strategy globally.

All phases of the HPTN research agenda are fully supported by three central resource partners:

fhi360

The Leadership and Operations Center (LOC) at FHI 360

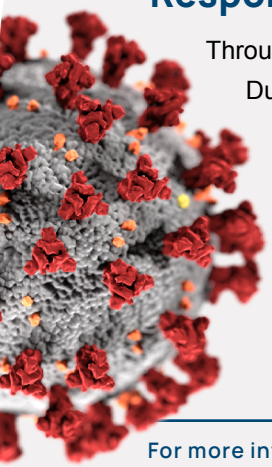
JOHNS HOPKINS UNIVERSITY

The Laboratory Center (LC) at Johns Hopkins University

Fred Hutch Cancer Center

The Statistical and Data Management Center (SDMC) at the Fred Hutchinson Cancer Center

Responding to Emerging Public Health Threats



Through experience and reputation, the HPTN is uniquely poised to respond to emerging public health threats. During the height of the COVID-19 global pandemic, the HPTN was uniquely poised to immediately respond as part of the COVID-19 Prevention Network (CoVPN), funded by the U.S. National Institute of Allergy and Infectious Diseases at the U.S. National Institutes of Health. The HPTN was involved in several registrational trials evaluating monoclonal antibodies to prevent COVID-19. In addition, many of the HPTN sites also participated in the COVID-19 vaccine registration trials. As a CoVPN operations center, the HPTN LOC managed clinical research, fiscal programs, community engagement, and communications outreach for trials evaluating interventions for the prevention of COVID-19.

HPTN Leadership

The Executive Committee (EC), under the direction of the HPTN Principal Investigators (PIs) Dr. Wafaa El-Sadr and Dr. Myron Cohen, sets the HPTN's research priorities and directs its scientific agenda. Effective June 2025, Dr. Sinead Delany-Moretlwe and Dr. Raphael J. Landovitz will assume the Network PI roles. Drs. El-Sadr and Cohen will move to advisory positions.

The EC includes leadership from the LOC, SDMC, LC, and National Institutes of Health (NIH), along with representatives from the community and CRSs.

HPTN Principal Investigators

Dr. Wafaa El-Sadr

Dr. Myron Cohen

Leadership and Operations Center (LOC)

The HPTN LOC staff facilitates and manages HPTN's research and operations, from developing the scientific agenda and protocols to managing study conduct at clinical research sites. The LOC is also responsible for sub-award management, community engagement, communications, and publication and dissemination of study results.

HPTN LOC staff attending the 2024 HPTN Annual Meeting in Washington D.C.

A key component of the Network's success has been the LOC's successful engagement of community members at all stages of science development, from concept generation, protocol development, and study implementation to dissemination of study results, as an integral part of the team and as partners at participating sites.

The HPTN LOC is based at FHI 360 in Durham, North Carolina. FHI 360, a nonprofit 501(c)3 global organization operating in more than 60 countries, is recognized as a worldwide leader in clinical research and service delivery. FHI 360 has diverse research expertise, including the prevention and treatment of HIV and other STIs, other infectious diseases including tuberculosis, malaria, Zika, and Ebola, maternal, adolescent, and child health, substance abuse, epidemiology, and health-related behaviors.

HPTN LC staff attending the 2024 HPTN Annual Meeting in Washington D.C.

Laboratory Center (LC)

The HPTN LC is centralized at the Johns Hopkins University School of Medicine in Baltimore, Maryland. The HPTN LC participates in all phases of protocol development and is responsible for implementing and assessing laboratory procedures at study sites. The LC assists in the quality assessment of clinical research sites (CRSs), including building laboratory expertise and capacity at non-U.S. CRSs, primarily in resource-limited settings. The LC's Quality Assurance/Quality Control (QA/QC) Core performs testing for QA/QC of site HIV test results and oversees laboratory activities at HPTN study sites. The LC scientific cores also evaluate and validate assays for use in HPTN protocols and develop novel assays and laboratory methods to achieve study objectives.

Laboratory Center (LC) cont.

The LC's pharmacology core has been an international leader in understanding the multi-compartment pharmacology of antiretroviral agents, established adherence benchmarks for oral PrEP regimens, and characterized the pharmacology of topical and long-acting PrEP agents. The LC's pharmacology core has also explored contributors to PrEP pharmacologic variability and interrogated pharmacologic causes for PrEP product failure.

The LC's virology core is responsible for designing HIV testing algorithms for study protocols and performing specialized assays related to the virology of HIV and other sexually transmitted viruses. This work has led to the discovery of new mechanisms by which long-acting PrEP agents impact HIV virology and immunology, complicating the detection and confirmation of HIV infection. This core also performs advanced research in HIV drug resistance, phylogenetics, and natural HIV infection control.

Statistical and Data Management Center (SDMC)

HPTN SDMC staff attending the 2024 HPTN Annual Meeting in Washington D.C.

At the forefront of clinical research, the SDMC specializes in comprehensive trial design, data collection, reporting, and statistical analysis for HPTN trials. HPTN biostatisticians collaborate closely with HPTN investigators to develop innovative and practical design strategies to address complex trial questions. We employ a variety of trial designs, including community-randomized, double-anonymized, individually randomized, and quasi-experimental approaches, to ensure the highest quality of research outcomes. In the era of highly effective, long-acting HIV treatment and prevention interventions, the SDMC continues to develop strategies to evaluate new agents and strategies in areas where high transmission rates persist.

SDMC staff is committed to data accuracy and integrity, prioritizing fit-for-purpose data collection incorporating advanced tools and technologies, including clinical trial software, research laboratory assays, mobile applications, and electronic health records (EHR).

Located at the Fred Hutchinson Cancer Center in Seattle, the SDMC is dedicated to advancing scientific discovery and improving health outcomes through rigorous statistical and data management excellence.

Modelling Centre

The HPTN Modelling Centre, part of the SDMC, is an international collaboration between the Imperial College London, the Fred Hutchinson Cancer Center in Seattle, and Massachusetts General Hospital in Boston. The Centre develops and uses various mathematical models and cost-effectiveness analyses to support HPTN research activities, clinical trials, product development, public health decisions, and future HPTN research directions. The Centre works with multiple HPTN study teams to project the population impact of their interventions under various utilization scenarios. Recent results from the Centre's research were used as evidence by the World Health Organization (WHO) Guideline Development Group to formulate recommendations for long-acting PrEP. The Centre also collaborates with other global health agencies and recently assisted UNAIDS in evaluating their annual estimates of the contribution of different risk populations.

Our Studies

Global Impact

The HPTN has made significant contributions to the field of HIV prevention. Research findings have prompted policy changes from organizations such as the WHO and PEPFAR. The HPTN has also managed the development and implementation of registrational studies, resulting in the approval of new drug applications by the U.S. Food and Drug Administration (FDA), European Medical Agency, and other international drug regulatory agencies.

HIVNET 012, a randomized clinical trial to evaluate the efficacy of two short-course antiretroviral drug regimens for the prevention of HIV transmission, demonstrated that the administration of nevirapine is a safe, effective way to prevent vertical transmission of HIV. Nevirapine use by mothers living with HIV has blocked the transmission of HIV and saved tens of thousands of infant lives.

HPTN 052 was a randomized, controlled trial designed to evaluate the effectiveness of antiretroviral therapy (ART) to prevent the sexual transmission of HIV in sero-different couples. The landmark study demonstrated early ART can suppress viral load and prevent HIV transmission. Study results were instrumental for WHO to update its guidelines in 2013 – ARV for all people living with HIV. In addition, the concept of undetectable equals untransmittable (U=U) served as a basis for updated PEPFAR guidelines and other policymakers.

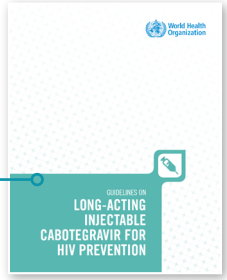
HPTN 052 was named "Breakthrough of the Year by Science magazine in 2011

HPTN 071 (PopART), conducted from 2013 through 2018, involved more than one million people living in 21 communities in South Africa and Zambia. The study was designed to measure the effects of two HIV combination prevention strategies that offered HIV testing to people in their homes annually, with linkage to HIV care and treatment at a local health facility for those living with HIV; both were compared to standard of care. Findings demonstrated that delivery of a combination prevention intervention that included household-based HIV testing, coupled with antiretroviral therapy provided according to local guidelines, resulted in a 20 percent decrease in HIV incidence in the two combination arms compared to the standard of care. The study also showed that combining proven interventions to understand effectiveness can inform how to translate research into implementation.

New HIV Prevention Agents

Developing alternative agents for PrEP may increase uptake, adherence, and ultimately, effectiveness, as more options are able to meet the needs of more individuals. Long-acting injectable agents offer a significant advancement in prevention options, creating the potential to prevent HIV acquisition without relying on adherence to a daily oral regimen.

HPTN 083 and HPTN 084 (The Life Study) demonstrated the superiority of long-acting injectable cabotegravir (CAB-LA) over oral tenofovir disoproxil and emtricitabine (TDF/FTC) among cisgender women, cisgender men who have sex with men, and transgender women who have sex with men. These studies provided pivotal data to support the approval of CAB-LA for the prevention of HIV by the FDA and several international regulatory authorities.



Data from **HPTN 083** and **HPTN 084** helped inform the World Health Organization's guidelines on the use of CAB-LA for HIV Prevention in 2022

HPTN 083-01 and HPTN 084-01 (The LIFT Study) are substudies of HPTN 083 and HPTN 084, and they examined whether CAB-LA for PrEP is safe and acceptable for adolescents. Notably, data from these studies contributed to the approval of CAB-LA for prevention for adolescents who weigh at least 77 pounds (35 kg).

New Indications for Existing Agents

Existing agents have the potential to benefit previously unstudied populations or address completely new indications. HPTN researchers conduct studies to evaluate the expanded use of these agents.

The **HPTN 084 Open-Label Extension** study evaluated the safety and infant outcomes among pregnant participants using CAB-LA and results demonstrated that CAB-LA used as PrEP was generally well tolerated and usually safe for both pregnant cisgender women and their babies.

Lenacapavir is a first-in-class selective HIV capsid inhibitor with subcutaneous injections every six months. The drug was approved by the FDA for the treatment of HIV. Lenacapavir was subsequently studied as an investigational drug to prevent HIV infection. Results demonstrated that twice yearly lenacapavir injections reduced HIV infection by more than 96 percent in two pivotal phase 3 studies. The HPTN and Gilead Sciences are collaborating on two companion HIV prevention studies. **HPTN 102/PURPOSE 3** is evaluating the feasibility, safety, and acceptability of long-acting subcutaneous lenacapavir for PrEP among cisgender women in the U.S. **HPTN 103/PURPOSE 4** will examine the same, but among people who inject drugs.

Our Studies

Integrated Strategies

HPTN researchers employ multidimensional approaches to develop and evaluate integrated strategies to reduce HIV acquisition in communities deemed most vulnerable.

HPTN 091 (The I Am Study), is the first NIH-funded trial focused solely on the needs of transgender women. The study evaluated the feasibility, acceptability, and preliminary impact of a multi-component strategy that provides HIV prevention services, gender-affirming hormone therapy, and peer health navigation to improve PrEP uptake and adherence among transgender women in the U.S. and Brazil. The primary outcome measured at week 26 showed an increase in PrEP uptake and an encouraging level of PrEP adherence; however, PrEP uptake and adherence levels were the same between study arms.

HPTN 094 (INTEGRA), is a vanguard study to determine the efficacy of using mobile health units to provide integrated health services – particularly medication for opioid use disorder (OUD) and medicines for HIV treatment or prevention – to people with OUD who inject drugs in five U.S. cities (Houston, Los Angeles, New York, Philadelphia, and Washington, D.C.).

HPTN 096 (BETA), is a hybrid effectiveness-implementation trial to assess an integrated, HIV status-neutral, population-based approach designed to reduce HIV incidence among cisgender and transgender Black men who have sex with men (MSM) in the U.S. South. The integrated intervention will test strategies focused on increasing HIV testing, PrEP use among Black MSM living without HIV, and viral suppression rates among Black MSM living with HIV.

HPTN 111 (TRIM) aims to determine whether a barbershop-based HIV prevention initiative in Uganda is feasible and acceptable to the barbers who deliver the services and their clients.

HPTN 112 (NJIRA) is evaluating the potential benefit(s), acceptability, and associated costs of a system navigator-delivered HIV prevention intervention in promoting and supporting persistent use of evidence-based HIV PrEP among heterosexual, cisgender men receiving care for STIs at the high-volume urban Bwaila STI Clinic in Lilongwe, Malawi.

Ongoing Biomedical Research

Consistent with the Network's mission to discover and develop new and innovative strategies to reduce the acquisition and transmission of HIV, HPTN researchers are conducting several studies focusing on new PrEP, multipurpose prevention technologies, and antibody-mediated prevention drugs.

HPTN 104 (OWN) will evaluate adherence to a single, dual prevention pill (DPP; co-formulated TDF/FTC for PrEP plus ethynyl estradiol/levonorgestrel for pregnancy prevention), compared with two separate tablets with daily oral TDF/FTC and ethynyl estradiol/levonorgestrel in HIV-uninfected women.

HPTN 106 (REV UP) is a phase 2 crossover study of on-demand PrEP formulations comparing rectal and oral tenofovir-based products.

The HPTN is partnering with the HIV Vaccine Trials Network (HVTN) to evaluate several **monoclonal antibodies**, or mAbs, alone or in combination with multiple mAbs, for HIV prevention. The findings from these studies will help inform future prevention approaches for HIV.

HIV VACCINE TRIALS NETWORK

Sexually Transmitted Infection Studies

Sexually transmitted infections (STIs) continue to impact global populations, with transmission rates increasing among those vulnerable to HIV acquisition and those living with HIV. Historically, research has focused on STI and HIV prevention separately. However, STIs (e.g., chlamydia, gonorrhea, syphilis, and trichomoniasis) have been shown to increase HIV transmission and acquisition. As such, HPTN researchers are evaluating strategies to prevent STIs along with prevention of HIV infection.

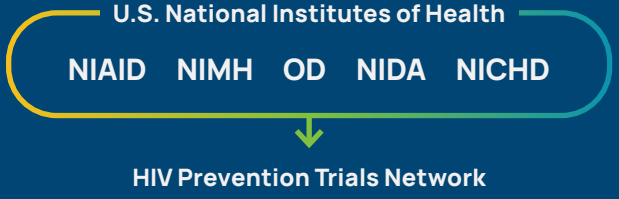
HPTN 107/DMID 19-0004 (The MAGI Study) is a collaboration with the Division of Microbiology and Infectious Diseases (DMID) to assess the efficacy of meningococcal Group B vaccine (Bexsero) in preventing gonococcal infection.

HPTN 115/ATN 173 (Foxxy Doxxy) is a collaboration with the Adolescent Medicine Trials Network (ATN) and will examine doxycycline prophylaxis for prevention of STIs among adolescent and young people assigned female at birth in the U.S. There are other collaborative efforts to evaluate the efficacy of doxycycline in prevention of STIs.

ATN Adolescent Medicine Trials Network for HIV Interventions

Funding

The **U.S. National Institute of Allergy and Infectious Diseases**, the **U.S. National Institute of Mental Health**, the **Office of The Director**, the **U.S. National Institute on Drug Abuse**, and the **Eunice Kennedy Shriver National Institute of Child Health and Human Development**, all part of the **U.S. National Institutes of Health**, co-fund the HPTN.



Partnerships

The HPTN has long-standing partnerships with pharmaceutical companies, academic researchers worldwide, the Gates Foundation, and several other organizations. In addition, the HPTN has forged collaborations to develop integrated strategies with PEPFAR, CDC, and ministries and health departments in several countries. The HPTN continues to build strategic partnerships with other NIH-funded HIV prevention networks and NIH institutes to maximize innovation and meet scientific goals.