

# NIH HIV/AIDS Clinical Research

The National Institutes of Health (NIH) conducts clinical research studies—biomedical or health-related research studies involving human volunteers—for HIV/AIDS and other diseases and conditions, such as cancer, cardiovascular disease, Alzheimer’s disease, allergy and infectious diseases, and neurological disorders. These studies are conducted both in the United States and at international sites. To search for clinical trials related to other diseases and conditions, you can visit [clinicaltrials.gov](http://clinicaltrials.gov).

## Clinical Trials

Clinical trials are a vital component of NIH HIV/AIDS medical research that investigates new ways to prevent, detect, and/or treat disease. The goal of clinical trials is to determine if a new test, intervention, or treatment works and is safe. Treatments might be

new drugs or combinations of drugs, new surgical procedures or devices, or new ways to use existing therapies. Clinical studies also can look at other aspects of care, such as engagement and maintenance in care, as well as adherence to care.

Clinical trial volunteers play a critical role in enhancing the scientific understanding of HIV/AIDS and in developing new and more effective therapeutic and preventive interventions. Volunteers who participate in clinical trials can play a more active role in their own or others’ health care, gain access to new research treatments before they are widely available, and make a vital contribution to medical research.

General information about clinical trials is available at [www.nih.gov/health-information/nih-clinical-research-trials-you/basics](http://www.nih.gov/health-information/nih-clinical-research-trials-you/basics).

## NIH HIV/AIDS Clinical Trials Networks

**A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 3 Safety and Effectiveness Trial of a Vaginal Matrix Ring Containing Dapivirine for the Prevention of HIV-1 Infection in Women (ASPIRE, Phase III Trial, MTN 020/ASPIRE Study).** First NIH-funded clinical study to demonstrate that a sustained drug delivery product that slowly releases an antiretroviral (ARV) drug over time can offer women partial protection from HIV.

[www.mtnstopshiv.org/studies/3614](http://www.mtnstopshiv.org/studies/3614)

**Strategic Timing of Antiretroviral Treatment (START).** First NIH-funded large-scale randomized clinical trial to establish that earlier ART benefits all HIV-infected individuals. This study provided concrete scientific evidence to support the current [U.S. HIV treatment guidelines](http://www.niaid.nih.gov/news/newsreleases/2015/Pages/START.aspx), which recommend that all HIV-infected individuals, including those who are asymptomatic, take ARVs regardless of their CD4+ cell count and viral load.

[www.niaid.nih.gov/news/newsreleases/2015/Pages/START.aspx](http://www.niaid.nih.gov/news/newsreleases/2015/Pages/START.aspx)

**A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples (HPTN 052).** First randomized clinical trial to show that treating HIV-infected individuals with ART and achieving an undetectable viral load can reduce the risk of sexual transmission of HIV to their uninfected partners.

[www.hptn.org/research\\_studies/hptn052.asp](http://www.hptn.org/research_studies/hptn052.asp)

**A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus TLC-Plus: Treat Approach for HIV Prevention in the United States (HPTN 065).** NIH-funded study evaluating the feasibility of a community-focused strategy to expand HIV testing, diagnose HIV infection, link HIV-positive individuals to medical care, and initiate treatment, providing key information for programs in the United States that aim to decrease the transmission of HIV through such an approach.

[www.hptn.org/research\\_studies/hptn065.asp](http://www.hptn.org/research_studies/hptn065.asp)

**The iPrEx Study: Pre-Exposure Prophylaxis as HIV Prevention Among Men Who Have Sex with Men.** NIH-funded study determining that a daily tablet containing a combination of two antiretroviral drugs decreased HIV risk among men who have sex with men and transgendered women who have sex with men at high risk of HIV. [www.niaid.nih.gov/news/QA/Pages/iPrExQA.aspx](http://www.niaid.nih.gov/news/QA/Pages/iPrExQA.aspx)

**Promoting Maternal-Infant Survival Everywhere (PROMISE).** This study showed that one triple-drug regimen for preventing mother-to-child HIV transmission may be safer than another for women and their babies. These findings provide further support for World Health Organization guidelines for preventing mother-to-child HIV transmission.

[www.niaid.nih.gov/news/newsreleases/archive/2010/Pages/PROMISE.aspx](http://www.niaid.nih.gov/news/newsreleases/archive/2010/Pages/PROMISE.aspx)



## Clinical Trials Protocols and Ethical Conduct

NIH-funded clinical trials are conducted only if preliminary research shows that the intervention appears to be both safe and potentially effective. Scientists develop a plan to test the intervention in human participants, known as the study protocol. This plan is carefully designed with input from the community (e.g., community advisory boards) and extensively reviewed by such independent, external groups such as institutional review boards and ethics review committees. Extensive ethical guidelines are in place to protect clinical trial volunteers and preserve the integrity of the science.

## NIH Intramural HIV/AIDS Clinical Trials

Since the NIH Clinical Center opened in 1953, clinical trials have been a key feature of the Intramural Research Program portfolio. The program excels in the type of basic research needed to advance biomedical knowledge, providing the foundation for health research worldwide, as well as the type of clinical research that culminates in cures and therapies. The National Institute of Allergy and Infectious Diseases (NIAID) conducts early-stage HIV vaccine clinical research through its Dale and Betty Bumpers Vaccine Research Center (VRC). The VRC Clinical Trials Core Laboratory performs Phase I clinical research of HIV vaccines developed at the VRC. More information about the VRC can be found at [www.niaid.nih.gov/about/organization/vrc/Pages/Default.aspx](http://www.niaid.nih.gov/about/organization/vrc/Pages/Default.aspx).

## NIH HIV/AIDS Clinical Trials Networks

The HIV/AIDS Clinical Trials Networks are managed by the NIAID and co-funded by multiple Institutes and Centers (ICs), including the National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Institute of Neurological Disorders and Stroke (NINDS), and National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). In 2010, the NIH HIV/AIDS networks were restructured to increase cross-network collaboration, create transparent mechanisms for network leaders to solicit and support ideas from the research community, and develop a means for external researchers to make use of the networks' clinical trial infrastructure, specimens, and capacity. Each of these networks consists of a leadership group led by principal investigators and includes an operations center, statistical and data management center, and a central laboratory. Networks have one or more clinical trials units (CTUs) and clinical research sites (CRS) located at health maintenance organizations, private physician practices and clinics, community and university academic health centers, hospitals, and outpatient centers, where the clinical trials are performed.

These networks have been designed to address five HIV/AIDS scientific priorities:

- **Therapeutics: AIDS Clinical Trials Group (ACTG)**—Therapeutics for HIV/AIDS and HIV-associated infections in adults (including HIV cure, as well as co-occurring noninfectious and infectious diseases, such as hepatitis and tuberculosis). [www.actgnetwork.org](http://www.actgnetwork.org)
- **Children and Mothers: International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT)**—HIV/AIDS and HIV-associated infections in children and mothers. [www.nichd.nih.gov/research/supported/pages/impaaact.aspx](http://www.nichd.nih.gov/research/supported/pages/impaaact.aspx)
- **HIV Prevention: HIV Prevention Trials Network (HPTN)**—Integrated strategies to prevent HIV infection. [www.hptn.org/index.htm](http://www.hptn.org/index.htm)
- **HIV Vaccines: HIV Vaccine Trials Network (HVTN)**—Vaccines to prevent HIV infection. [www.hvtn.org/en.html](http://www.hvtn.org/en.html)

- **Microbicides: Microbicides Trials Network (MTN)**—Microbicides to prevent HIV infection. [www.mtnstophiv.org/](http://www.mtnstophiv.org/)

For more information about the HIV/AIDS network CTUs and CRS and a complete listing by institution, see [www.niaid.nih.gov/about/organization/daids/Networks/Pages/daidsnetworkunits.aspx](http://www.niaid.nih.gov/about/organization/daids/Networks/Pages/daidsnetworkunits.aspx).

In addition to the networks managed by the NIAID, several clinical trial networks are managed and supported by other key NIH ICs:

- **Adolescents: Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)**—Managed and supported by the NICHD—with additional support from NIAID, NIMH, NIDA, and the National Institute on Minority Health and Health Disparities (NIMHD)—the ATN develops and conducts behavioral, community-based translational, prophylactic, therapeutic, microbicide, and vaccine trials, both independently and in collaboration with existing research networks and individual investigators, in HIV-infected and HIV-at-risk pre-adolescents, adolescents, and young adults up to age 25. [www.nichd.nih.gov/research/supported/pages/atn.aspx](http://www.nichd.nih.gov/research/supported/pages/atn.aspx)
- **AIDS Defining Cancers: AIDS Malignancy Consortium (AMC)**—Managed and supported by the NCI, the AMC supports clinical trials for the treatment and management of AIDS-related cancers. [www.pub.emmes.com/study/amc/public](http://www.pub.emmes.com/study/amc/public)
- **Drug Abuse: National Drug Abuse Treatment (NDAT) Clinical Trials Network (CTN)**—Managed and supported by NIDA, the NDAT CTN conducts studies to develop, validate, refine, and deliver new treatment options for patients in community treatment programs. [www.drugabuse.gov/ctn](http://www.drugabuse.gov/ctn)
- **Global Clinical Research: International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)**—Supported and managed by NIAID, and supported by NIMH and NINDS, INSIGHT defines optimal strategies for the management of HIV and other infectious diseases through a global clinical research network. <http://insight.cabr.umn.edu>

## Major Cohort Studies

Since the earliest days of the HIV/AIDS epidemic, the NIH has been committed to the establishment of long-term cohort studies to address the key scientific questions and challenges in populations at risk:

- The **Multicenter AIDS Cohort Study (MACS)**, sponsored by the NIAID, National Institute on Deafness and Other Communication Disorders (NIDCD), NIDA, NIMH, and NCI, and conducted since 1984, is an ongoing prospective study of the natural and treated histories of HIV infection in homosexual and bisexual men. Data from the MACS have been the basis of more than 1,100 publications in peer-reviewed journals. <https://statepi.jhsph.edu/mac/macs.html>
- The **Women's Interagency HIV Study (WIHS)**, co-funded by the NICHD, NIAID, NCI, NIMH, and NIDA, is the largest and longest ongoing U.S. study to investigate the impact of HIV infection on women in the United States. <http://statepiaps.jhsph.edu/wihs>
- The **Pediatric HIV/AIDS Cohort Study (PHACS)** network, sponsored by the NICHD, with co-funding from the NIAID; NIDA; NIDCD; NIMH; National Heart, Lung, and Blood Institute (NHLBI); National Institute of Dental and Craniofacial Research (NIDCR); NINDS; and National Institute on Alcohol Abuse and Alcoholism (NIAAA), is a longitudinal cohort study established to address two critical pediatric HIV research questions: the long-term safety of fetal and infant exposure to antiretroviral treatment (ART) and the effects of perinatally

acquired HIV infection in adolescents. [www.nichd.nih.gov/research/supported/Pages/phacs.aspx](http://www.nichd.nih.gov/research/supported/Pages/phacs.aspx)

- The **Veterans Aging Cohort Study (VACS)**, supported by NIAAA in collaboration with the Department of Veterans Affairs, is a prospective, observational cohort study of HIV-positive veterans and an age/race/site-matched control group of HIV-negative veterans in care in the United States. Researchers seek to understand the role of comorbid medical and psychiatric disease in determining clinical outcomes of HIV infection. [www.vacohort.org](http://www.vacohort.org)

## Additional Clinical Trials Resources

- For more information about AIDS clinical trials, visit [www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov).
- For information about clinical trials in the NIH Intramural Research Program, visit [www.irp.nih.gov/nih-clinical-center/clinical-trials](http://www.irp.nih.gov/nih-clinical-center/clinical-trials).
- The NIAID sponsors the Legacy Project, which works nationally to increase awareness of and build support for HIV prevention and treatment clinical and behavioral research by addressing factors that influence participation of historically underrepresented communities. [www.hanc.info/legacy/Pages/default.aspx](http://www.hanc.info/legacy/Pages/default.aspx)
- For information about clinical trials in general, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or [www.nih.gov/health/clinicaltrials](http://www.nih.gov/health/clinicaltrials), an NIH resource that catalogs and explains thousands of ongoing clinical studies.

## NIH-Sponsored Research Consortia

The NIH is committed to establishing international research collaborations that address priority areas in HIV research:

- The **D.C. Partnership for HIV/AIDS Progress (DC-PFAP)** was launched in 2010 as a collaboration between the NIH, the District of Columbia Department of Health, and the District of Columbia Center for AIDS Research (DC-CFAR) at George Washington University. Working with the D.C. Department of Health and the DC-CFAR, the NIAID and the NIH Clinical Center co-lead the DC-PFAP with additional funding provided by the NIH Office of AIDS Research (OAR), NIMH, and NIDA. This partnership is laying the groundwork necessary to stem the rate of new HIV infections in the city, improve the health of District residents living with HIV, and strengthen the city's response to the HIV/AIDS epidemic. [www.niaid.nih.gov/news/newsreleases/Archive/2010/Pages/DCHIVpartnership.aspx](http://www.niaid.nih.gov/news/newsreleases/Archive/2010/Pages/DCHIVpartnership.aspx)
- The **Center for HIV/AIDS Vaccine Immunology (CHAVI)** is a consortium of universities and academic medical centers established by the NIAID to solve major problems in HIV vaccine development and design. [www.chavi.org](http://www.chavi.org)
- The **National NeuroAIDS Tissue Consortium (NNTC)**, supported by the NINDS and NIMH, was established to collect, store, and distribute samples of nervous tissue, cerebrospinal fluid, blood, and other tissue from HIV-infected and uninfected individuals to support HIV research related to NeuroAIDS disorders. [www.nntc.org](http://www.nntc.org)
- The **Martin Delaney Collaboratory** is an initiative designed to foster public-private partnerships to accelerate progress toward an HIV cure. Each research team will pursue a unique and complementary approach aimed at eradicating HIV reservoirs. [www.niaid.nih.gov/news/newsreleases/Archive/2011/Pages/DelaneyCollab.aspx](http://www.niaid.nih.gov/news/newsreleases/Archive/2011/Pages/DelaneyCollab.aspx)
- The **International Epidemiologic Databases to Evaluate AIDS (IeDEA)** network is an international research consortium established by the NIAID, with co-funding from the NICHD, NIDA, NIMH, and NCI, to collect and define key variables, harmonize data, and implement methodology to effectively pool data into large data sets to address high-priority research questions and streamline HIV/AIDS research. [www.iedea.org](http://www.iedea.org)
- The **Centers for AIDS Research (CFAR)** program began in 1988 and is co-sponsored by the Fogarty International Center, NIAID, NCI, NICHD, NHLBI, NIDA, NIMH, National Institute on Aging (NIA), National Institute of General Medical Sciences (NIGMS), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and NIMHD. CFAR provides administrative and shared research support to synergistically enhance and coordinate high-quality AIDS research projects. CFAR accomplishes this through core facilities that provide expertise, resources, and services not otherwise readily obtained through more traditional funding mechanisms. <http://www.niaid.nih.gov/labsandresources/resources/cfar/Pages/Default.aspx>
- The **CFAR Network of Integrated Clinical Systems (CNICS)** project is the first electronic medical records-based resource network poised to integrate clinical data from the large and diverse population of HIV-infected persons who are receiving care at one of the NIH-funded CFAR sites. [www.uab.edu/cnics](http://www.uab.edu/cnics)