



HIV + Aging Research Project | PS

NEWSLETTER

VOLUME MMXXIV - ISSUE 11

OCTOBER - NOVEMBER 2024



Bringing HIV Study Protocols to Life with Representative, High-Quality Research

September 4, 2024 • By National Institute of Allergy and Infectious Diseases (republished from POZ Magazine)

Since the start of the 2020 research network grant cycle, HIV clinical research sites have enrolled about 93,000 participants across 78 clinical trials in 25 countries.

The impact of clinical research is often measured by its outcomes. From trials that provide groundbreaking evidence of efficacy to those stopped early for futility, the end results of clinical trials shape practice and future research priorities.

However, years of effort from scientists, study teams and study participants while a trial is underway are sometimes overshadowed by final study outcomes. In this regard, trial implementation requires clinical research sites' operational excellence for the duration of a study. Access to relevant populations depends on the location of each clinical research site as well as investigators' and clinical care providers' engagement with the local community and understanding of their needs and preferences. A high-functioning clinical research site anchored in the communities it works in and comprised of cohesive, well-integrated components is essential to producing high-quality outputs.

Currently, NIAID supports four research networks as part of its HIV clinical research enterprise. The networks are made up of more than 100 clinical research sites, each with local experts, robust research infrastructure, and well-trained, cross-functional staff who maintain standardized procedures and quality controls aligned with their network.

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Upcoming Events & Resource Links

Every seven years, NIAID engages research partners, community representatives, and other public health stakeholders in a multidisciplinary evaluation of network progress toward short- and long-term scientific goals. This process takes account of knowledge gained since the networks were last funded and identifies essential course corrections based on the latest scientific and public health evidence. Subsequent NIAID HIV research investments build on the conclusions of these discussions. This process includes examining the networks' infrastructure model, which the Institute updates and refines to stay aligned with its scientific priorities.

The HIV clinical trials network sites have made tremendous contributions to NIH's scientific priorities by offering direct access to and consultation with populations most affected by HIV globally, and by delivering high-quality clinical research with strong connections to trusted community outreach platforms. Their approach to community engagement anchors clinical research sites beyond the scope of any individual study, and when possible, aligns scientific questions and study protocols based on local context.

Since the start of the 2020 research network grant cycle, HIV clinical research sites have enrolled about 93,000 participants across 78 clinical trials in 25 countries. The networks were able to quickly pivot to support NIAID's emerging infectious disease priority areas, including COVID-19 and mpox. Of the 93,000 participants since 2020, approximately 78,000 were enrolled into COVID-19 clinical trials sponsored by NIAID's Division of AIDS.

Clinical trials sites currently operate with a hub-and-spoke model, with each hub providing centralized support to their linked clinical research sites. This model leverages shared resources where possible and practical, and ensures robust oversight to promote high-quality clinical trial operations. Hubs provide infrastructure and services including laboratory, pharmacy, regulatory, data management, and training to support execution of NIAID-sponsored clinical research.

Future networks will need to maintain core strengths of current models while expanding capacity in areas vital to further scientific progress. These include operations that inform pandemic responses and extending our reach within communities impacted by HIV, including populations historically underrepresented in clinical research. Additionally, there may be opportunities for clinical research sites and other partners to conduct implementation science research based on their capacity and access to relevant populations in the context of specific scientific questions.

Make seamless progress on established and emerging scientific priorities

Our goals include maintaining the strength and flexibility of our current network model and infrastructure to support established scientific priorities that improve the practice of medicine, including high-impact registrational trials to identify new biomedical interventions and support changes to product labelling. The networks also must remain capable of directing operations to generate evidence on interventions for pandemic responses.

Engage underserved populations for more representative studies

Building on its current reach, NIAID and its partners have identified opportunities to expand or strengthen our connections to medically underserved populations affected by HIV, and to increase representation of geographic areas with limited access to current clinical trials sites. We also are seeking clinical research sites with longstanding community relationships and experience conducting randomized clinical trials that include Black gay, bisexual, and other men who have sex with men, transgender people, people who sell sex, people who use drugs, and adolescent girls and young women, as well as populations in African countries with a high HIV prevalence.

Integrate implementation science within clinical research practice

Implementation science is the scientific study of methods and strategies that facilitate the uptake of evidence-based practice and research into regular use by practitioners and policymakers. As biomedical HIV prevention, treatment, and diagnostic options expand, our scientific questions must expand to address not only whether an intervention works, but how it can be delivered to offer health care choices that people need, want and are able to use.

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Steve Rosetti

HARP-PS Board Member

Challenging Times for The LGBTQ+ Community

In light of the recent surge in anti-queer legislation in the United States, many individuals in the LGBTQ+ community are facing heightened levels of concern and anxiety. With new laws being proposed and enacted almost daily, it's crucial to consider where this is all heading and how to manage our well-being amid such changes.

Anxiety, a prevalent mental health issue in the U.S., according to the Anxiety and Depression Association of America, can significantly impact daily life. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5) defines Generalized Anxiety Disorder (GAD) with the following criteria:

- **Excessive Worry:** Persistent anxiety and worry occurring more days than not for at least six months about multiple events or activities, such as work or school performance.
- **Difficulty Controlling Worry:** The individual struggles to manage their anxiety.
- **Symptoms:** The anxiety is accompanied by at least three of the following symptoms (with some present more days than not for the past six months): restlessness or feeling on edge, easy fatigue, difficulty concentrating or blank mind, irritability, sleep disturbances (trouble falling or staying asleep, or restless, unsatisfactory sleep).
- **Significant Impact:** The anxiety, worry, or physical symptoms cause significant distress or impair functioning in social, occupational, or other important areas.
- **Exclusion of Other Causes:** The disturbance is not due to the effects of a substance or another medical condition.

Cognitive Behavioral Therapy (CBT) is an effective short-term treatment for anxiety. CBT helps individuals develop skills to challenge and modify their emotional responses. The fundamental principle of CBT is that thoughts precede feelings, which then lead to actions. By altering negative thought patterns, individuals can alleviate negative emotions and undesired behaviors. Here are some CBT techniques to manage and challenge anxiety:

- **Identify Negative Thoughts:** Understanding how your thoughts influence your feelings is the first step in CBT. Recognize negative thought patterns and their effects on your mental and physical well-being. Common negative thought patterns include: Overgeneralizing, expecting the worst and focusing excessively on minor details

Reflect on whether you view situations optimistically, pessimistically, or realistically. Ask yourself if you see your cup as half full, half empty, or somewhere in between. Identifying these patterns helps in reframing thoughts to be more positive and productive.

- **Challenge Negative Thoughts:** Thought challenging involves questioning and re-evaluating your negative thoughts using evidence from your own experiences. Aim to view situations from an objective perspective. Avoid emotional reasoning ("I feel it, so it must be true") and consider both sides of an argument. Testing your thoughts against reality can help mitigate negativity.
- **Replace Negative Thoughts with Positive or Realistic Ones:** When feeling anxious, it might be unclear what is causing these emotions. Journaling can be a useful tool to bring awareness to your thoughts and feelings. Writing them down can clarify their sources and help replace negative thoughts with more realistic or positive ones.

Addressing anxiety is crucial, especially given the current social climate. Seeking support through therapy, group sessions, or support groups can be beneficial. Building a strong network of family and friends to discuss the challenges faced by the LGBTQ+ community can also provide significant support during these uncertain times.

2024 Vaccine Season

Vaccinations are a critical component of managing health for individuals with HIV. Staying current with recommended seasonal vaccines can help prevent serious illnesses and contribute to better overall health. Consult with your healthcare provider to ensure you're up-to-date on your vaccinations and to address any specific health needs or concerns. By taking these proactive steps, you can protect yourself and improve your quality of life in the coming year.

1. Influenza Vaccine

Why It's Important: Individuals with HIV are at a higher risk for complications from influenza, including severe illness and hospitalization. The flu vaccine helps protect against seasonal flu strains and can reduce the risk of flu-related complications.

2. COVID-19 Vaccine

Why It's Important: People with HIV are at increased risk of severe outcomes from COVID-19. The COVID-19 vaccine significantly reduces the risk of severe illness, hospitalization, and death.

3. Mpox Vaccine

Why It's Important: Mpox, previously known as monkeypox, is a viral infection that has gained attention due to its potential to cause significant health issues. The emergence of mpox as a public health concern underscores the importance of vaccination in preventing and controlling outbreaks.

- **Severity:** Mpox can lead to a range of symptoms from mild to severe, including fever, rash, and swollen lymph nodes. In some cases, it can cause severe complications such as skin infections, eye infections, and even long-term scarring.
- **Vaccine Role:** The mpox vaccine helps prevent the onset of severe illness by stimulating the immune system to recognize and fight the virus. This reduces the likelihood of developing severe symptoms or complications.

Vaccines are also vital tool in preventing disease and maintaining public health. Addressing concerns and misconceptions with empathy, evidence-based information, and open dialogue can help bridge gaps in understanding. For individuals who remain skeptical, seeking guidance from trusted healthcare professionals and considering the broader benefits of vaccination can lead to informed decisions and contribute to better community health.

Patient's Guide to Mpox Treatment with TPOXX (tecovirimat)

Oral TPOXX (tecovirimat) for treatment of mpox is primarily available through the [Study of Tecovirimat for Mpox \(STOMP\)](#). Healthcare providers should see CDC's TPOXX Expanded Access IND Information page for more details.

What You Need to Know

- TPOXX is FDA-approved only for treatment of smallpox.
- Animal studies show TPOXX may potentially help to treat the type of virus that causes mpox, and we are learning more about how it works and whether it helps to treat mpox in people.
- TPOXX is an experimental (investigational) drug that is still being tested in people with mpox to find out if it is safe and effective.
- TPOXX is only available through the Study of Tecovirimat for Mpox (STOMP) clinical trial or CDC's expanded access (compassionate use) program.
- If you have mpox symptoms, visit a healthcare provider, even if you've [had the mpox vaccine](#). You can also contact the STOMP trial for more information about enrolling by calling 1-855-876-9997.
- You can enroll in-person at a study site. If you're not near a study site or unable to attend in-person visits, you can enroll remotely (available Monday through Friday only).
- Oral TPOXX for treatment of mpox is primarily available through STOMP.

2024 PALM SPRING PRIDE

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Bringing HIV Study Protocols to Life with Representative High-Quality Research

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This expanded scientific scope calls for research sites to have a diverse reach and skill sets, including experience and capacity for conducting implementation science research and fostering and maintaining partnerships with organizations that conduct implementation science research on key topics and interventions on which implementers seek stronger evidence.

The research community plays an essential role in shaping NIAID's scientific direction and research enterprise operations. We want to hear from you. Please share your questions and comments at NextNIAIDHIVNetworks@mail.nih.gov.

About NIAID's HIV Clinical Trials Networks

The clinical trials networks are supported through grants from NIAID, with co-funding from and scientific partnerships with NIH's National Institute of Mental Health, National Institute on Drug Abuse, National Institute on Aging, and other NIH institutes and centers. There are four networks—Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections, the HIV Vaccine Trials Network, the HIV Prevention Trials Network, and the International Maternal Pediatric Adolescent AIDS Clinical Trials Network.

This NIAID News blog post was published by the National Institute of Allergy and Infectious Diseases on September 3, 2024.

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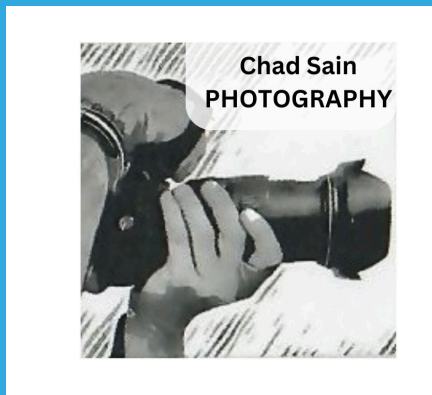
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Upcoming Events



SEPTEMBER 21, 2024
9:00 AM - 3:00 PM
Mizell Center
Palm Springs



OCTOBER 1, 2024
6:00 PM
Medicare and ACA Plans
Speaker: Cesar Perez



November 1, 2024
6:00 PM
TBD



DECEMBER 1, 2024
6:00 PM
WORLD AIDS DAY
Timothy Ray Brown Symposium



Resources

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Housing Assistance
In Home Care



Utility Assistance Programs
Water Energy



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Main Dishes
Salads & More



A Very Special Thank You To Our Volunteers!

Jim Ferguson – Program Director - HIV+ Village PS, and Layout of Newsletter
Christopher Christensen - Program Director RID and Positive Life Series Volunteer
Ken Vergonet – Volunteer Social Media Manager
Chad Sain – Volunteer Photographer (Chad Sain Photography)
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Mike Hartley - Events Volunteer