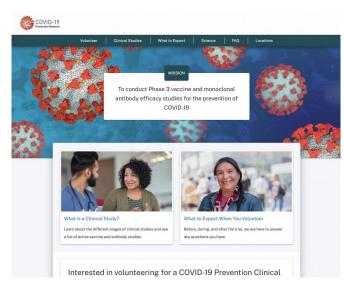


NIH launches clinical trials network to test COVID-19 vaccines and other prevention tools

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COVPN homepage Credit: NIAID

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has established a new clinical trials network that aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines and monoclonal antibodies intended to protect people from COVID-19.

The COVID-19 Prevention Trials Network (COVPN) was established by merging four existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network (HVTN), based in Seattle; the HIV Prevention Trials Network (HPTN), based in Durham, N.C.; the Infectious Diseases Clinical Research Consortium (IDCRC) based in Atlanta; and the AIDS Clinical Trials Group based in Los Angeles. Those individual networks will continue to perform clinical trials for HIV vaccine and prevention and other infectious diseases in addition to their new COVID roles.

"Establishing a unified clinical trial network is a key element of President Trump's Operation Warp Speed, which aims to deliver substantial quantities of a safe, effective vaccine by January 2021," said HHS Secretary Alex Azar. "Starting this summer, this new network will leverage existing infrastructure and engage communities to secure the thousands of volunteers needed for late-stage clinical trials of promising vaccines."

"Having a safe and effective medical countermeasure to prevent COVID-19 would enable us to not only save lives but also help end the global pandemic," said NIAID Director Anthony S. Fauci, M.D. "Centralizing our clinical research efforts into a single trials network will expand the resources and expertise needed to efficiently identify safe and effective vaccines and other prevention strategies against COVID-19."

The network's vaccine testing will be led by Larry Corey, M.D., of the Fred Hutchinson Cancer Research Center in Seattle, and Kathleen M. Neuzil, M.D., M.P.H., of the University of Maryland, Baltimore. The network's monoclonal antibody clinical testing efforts will be led by Myron S. Cohen, M.D., of the University of North Carolina, Chapel Hill, and David S. Stephens, M.D., of Emory University in Atlanta. The HVTN, which is based at the Fred Hutchinson Cancer Research Center, will serve as the COVPN's operational center.

The COVPN is a functional unit of "Operation Warp Speed," a partnership led by the U.S. Department of Health and Human Services (HHS) to invest in and coordinate the development, manufacturing and distribution of COVID-19 diagnostics, therapeutics and vaccines. The network will use a harmonized vaccine protocol developed by the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership.



This will enable analyses of correlates of protection across multiple vaccine trials. The network is expected to operate more than 100 clinical trial sites across the United States and internationally.

The network has developed an extensive community engagement framework to reach out to potential research volunteers and explain the specific details involved in participating in a vaccine or monoclonal antibody clinical study.

"Each of the Phase 3 clinical trials that the COVPN will conduct will require thousands of volunteers," said NIH Director Francis Collins, M.D. "Community engagement, particularly with the communities most vulnerable to COVID-19's severe outcomes, will be critical to the success of this research endeavor."

People also can learn more about the different stages of vaccine research and the new network's COVID-19 vaccine and monoclonal antibody studies by visiting the COVPN's website, at: www.coronaviruspreventionnetwork.org. The COVPN website features a customized data collection platform, which Oracle (Redwood Shores, CA) built and donated, to securely identify potential trial participants. Interested individuals can sign up for a rolling clinical trial participant registry on the website, which features security-enhanced protections. Clinical study staff will use the registry to contact and screen potential study volunteers.

The first Phase 3 clinical trial that the COVPN is expected to conduct will involve testing the investigational mRNA-1273 <u>vaccine</u>, developed by NIAID scientists and their collaborators at the biotechnology company Moderna, Inc., based in Cambridge, Massachusetts. That study is expected to begin this summer.

Provided by NIH/National Institute of Allergy and Infectious Diseases

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