



UMB News

UMB Begins Phase 3 of Novavax COVID-19 Vaccine Trial

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Researchers at the **University of Maryland School of Medicine (UMSOM)** will participate in a Phase 3 clinical trial of an investigational COVID-19 vaccine to protect against SARS-CoV-2, the coronavirus causing COVID-19 that continues to impact millions of people around the world. The clinical trial will test the safety and effectiveness of NVX-CoV2373, being developed by U.S. biotechnology company Novavax, Inc., based in Gaithersburg, MD.

The vaccine trial is being conducted by researchers in UMSOM's **Center for Vaccine Development and Global Health (CVD)** as part of their National Institute of Allergy and Infectious Diseases (NIAID)-funded Vaccine Treatment and Evaluation Unit (VTEU), and the COVID-19 Prevention Network (CoVPN). It adds to the extensive COVID-19 vaccine research that has been underway on campus since early spring.

The principal investigator for this vaccine trial at UMSOM is **Monica McArthur, MD, PhD**, assistant professor of pediatrics. **Karen Kotloff, MD**, professor of pediatrics, is co-chair for the trial protocol, which will be implemented at multiple sites across the country and Mexico, and plans to enroll up to 30,000 adults. The UMSOM site is expected to recruit up to 500 participants.

The clinical trial at CVD aims to enroll the diverse populations most impacted by COVID-19. They will include people who have increased risk of exposure because of location or circumstance, such as occupation. Individuals 65 and older, African Americans and LatinX populations, as well as individuals at risk of severe COVID-19, will be represented.

"This virus has not been democratic. We have seen that it has impacted minorities, the elderly, and people with certain medical conditions the hardest, and so an important goal of this research is to learn about the safety and effectiveness of the vaccine in these groups," said Kotloff, who is associate director for clinical research in CVD and principal investigator of the VTEU.

A key component of this research includes UMSOM's efforts to enroll participants in Maryland's communities most impacted by the coronavirus, including Langley Park and Baltimore.

"We know this virus disproportionately affects older adults, those with unstable medical conditions, and racial and ethnic minorities, which makes it all the more imperative that the vaccine works well in those who need it most," said McArthur.

The Novavax trial is part of Operation Warp Speed, a multi-agency collaboration led by the U.S. Department of Health and Human Services (HHS), which aims to accelerate the development, manufacturing, and distribution of medical countermeasures for COVID-19. Under Operation Warp Speed, thousands of



Clockwise from top left: Monica McArthur, Karen Kotloff, E. Albert Reece, and Kathleen Neuzil.

volunteers are enrolled in various large-scale clinical trials, testing a variety of investigational vaccines intended to protect people from COVID-19.

“Our CVD team is contributing to the advancement of several promising COVID vaccine candidates. Our researchers are working to ensure that the safety and performance of these vaccines is meticulously assessed,” said **Kathleen Neuzil, MD, MPH, FIDSA**, the Myron M. Levine, MD, DTPH Professor of Vaccinology and director, CVD. Neuzil is a co-director of the COVID-19 Prevention Trials

Network, which brings together experts from existing NIAID-supported clinical research networks to fight COVID-19.

About the Vaccine

The Novavax vaccine candidate, NVX-CoV2373, is a stable, prefusion protein antigen derived from the genetic sequence of the SARS-CoV-2 coronavirus spike (S) protein and is adjuvanted with Novavax’s proprietary MatrixM™. NVX-CoV2373 contains purified protein antigen and can neither replicate nor can it cause COVID-19.

The vaccine is already in Phase 3 trials in the U.K., with more than 15,000 participants enrolled. Interim data in this event-driven trial are expected as soon as early first quarter of 2021, although the timing depends on the overall COVID-19 rate in the region.

“Our COVID-19 experts at the University of Maryland School of Medicine have been at the forefront of vaccine research. This research — which builds upon extensive COVID-19 vaccine and therapy research that has been underway for several months — will lead us a step closer to licensure and impact millions of people,” said UMSOM Dean **E. Albert Reece, MD, PhD, MBA**, executive vice president for medical affairs, [University of Maryland, Baltimore](#), and the John Z. and Akiko K. Bowers Distinguished Professor.

About the Phase 3 Trial

The Phase 3 clinical trial is a randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety, and immunogenicity of the vaccine in participants ages 18 and older. Two-thirds of the participants will receive two intramuscular injections of the vaccine administered 21 days apart and the other third will receive a placebo.

The trial is designed to enroll at least 25 percent of participants ages 65 and older, as well as to prioritize groups who are most affected by COVID-19, including racial and ethnic minorities.

Participants will be followed carefully to assess the safety of the vaccine and its ability to prevent COVID-19 with frequent telephone calls and completion of smartphone diaries. They will be asked to provide a nasal swab and a blood sample at an initial screening visit, as well as at several time points after each vaccination and over the next two years after the second vaccination. Scientists will examine blood samples in the laboratory to better understand the immune responses to SARS-CoV-2 that provide protection.



Volunteer for a COVID-19 Vaccine Clinical Trial

Make a difference! Take part in research investigating a vaccine for COVID-19.

Adults 18 and older may qualify for this study. Compensation up to \$1,750 may be provided. If interested, you must be willing to go to the University of Maryland, Baltimore campus, or CASA de Maryland, Hyattsville, to enroll in the study.

Learn more:

VISIT: [CVDTrials.org](https://www.cvdtrials.org)

TEXT: COVIDRESEARCH to 52855

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