The George Washington University (GW) is playing an important role in a historic global effort to rapidly develop and test vaccines that protect against the novel coronavirus and its disease, COVID-19. Based on its long track record in conducting vaccine research and clinical vaccine trials, as well as its extensive community partnerships, GW was one of nearly 100 clinical research sites in the U.S. selected to test investigational vaccines as part of the COVID-19 Prevention Network, established by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH).

In July 2020, GW began its participation in a late-stage (Phase 3) study of Moderna’s mRNA vaccine. In November 2020, Moderna reported that the vaccine’s efficacy against COVID-19 was 94.1% and filed with the U.S. Food and Drug Administration for Emergency Use Authorization.

### Moderna Clinical Vaccine Trial at the George Washington University

- **349 volunteers** enrolled in GW’s clinical trial to test the Moderna vaccine.
- **50%** of GW’s trial volunteers came from communities of color.
- **26%** of trial volunteers over the age of 65.
- **>25%** of trial volunteers had at least one comorbidity such as heart disease, severe obesity, HIV or diabetes.
- **2 yrs** GW’s vaccine research team will monitor trial volunteers for symptoms, side effects and COVID-19.

### Lead Investigators

**Dr. David Diemert**
Lead Investigator for the clinical vaccine trial and a professor of medicine at GW’s School of Medicine and Health Sciences and a physician in the Division of Infectious Diseases at the GW Medical Faculty Associates. Dr. Diemert is the clinical director of the GW Vaccine Research Unit.

**Dr. Marc Siegel**
Co-Investigator and associate professor of medicine at GW’s School of Medicine and Health Sciences and a physician in the Division of Infectious Diseases at the GW Medical Faculty Associates.

**Dr. Elissa Malkin**
Co-Investigator and assistant research professor of medicine at GW’s School of Medicine and Health Sciences. Dr. Malkin is a member of GW’s Vaccine Research Unit.

**Dr. Manya Magnus**
Co-Investigator and a professor in the Department of Epidemiology at GW’s Milken Institute School of Public Health. Dr. Magnus is the Clinical Research Site lead for GW’s HIV Prevention Trials Network site.

In addition to the trial’s lead investigators, numerous individuals support GW’s clinical research site, from infectious disease experts and clinicians to nurses, lab and pharmacy technicians and data entry assistants.
VACCINE TRIAL VOLUNTEER RECRUITMENT

GW recruited volunteers to take part in its clinical trial of the Moderna vaccine from the Washington, D.C. community and beyond. Extensive community partnerships forged through GW’s HIV Prevention Trials Network Clinical Research Site and Its Vaccine Research Unit, in addition to word-of-mouth and widespread local news coverage, helped GW’s vaccine research team quickly get the word out to the DC-area community about the trial and the need for volunteers. The team worked closely with its many partners to listen and respond to the community’s questions and concerns about participating in the trial.

TESTING AND OBSERVATION

A total of 349 volunteers came to either the Foggy Bottom clinic or a trailer provided by the U.S. Department of Defense for the study to serve as additional clinical space. There, the volunteers provided informed consent, had their medical history recorded, and underwent a physical examination. A computer program randomly assigned the volunteer to either the vaccine or the placebo group and two unblinded team members administered the first injection. As a double-blind study, neither the volunteer nor the research team knew which injection the volunteer received. Approximately 4 weeks later, the volunteer returned to receive their second injection. Volunteers were encouraged to continue the safety precautions they were already taking, and were instructed to keep an electronic diary to track their symptoms. The team monitored volunteers for symptoms and side effects through notifications from the electronic diary and telephone check-ins.

SAMPLE PROCESSING

Blood and nasal swab samples collected from volunteers throughout the trial were brought back to the laboratory of Dr Jeanne Jordan in GW’s Science & Engineering Hall. The blood was spun down in a centrifuge to separate the red and white blood cells from the blood serum. The serum was then divided into smaller sample sizes and sent to another central lab for antibody testing that looks for signs of an immune response. The team also froze the nasal swabs and shipped them to a separate laboratory that performed a polymerase chain reaction (PCR) test to look for presence of the virus through acute or active infection.

ABOUT VACCINE RESEARCH AT GW

Researchers at GW have long been involved in vaccine development and conducting vaccine trials for investigational products. The GW Vaccine Research Unit, for example, conducts clinical trials of experimental vaccines and products that are designed to prevent infectious diseases such as HIV and the Zika virus, and neglected tropical diseases such as hookworm infection and schistosomiasis. GW also runs an HIV Prevention Trials Network Clinical Research Site, led by GW’s Milken Institute School of Public Health, which is part of a network of sites worldwide supported by the National Institutes of Health that develop and test the safety and efficacy of experimental HIV treatments.

The experience and infrastructure of the GW Vaccine Research Unit and the HPTN site, in addition to Dr. Jordan’s lab and the university’s deep ties to the community, allowed GW to pivot in a moment of crisis to serve as a COVID-19 clinical vaccine site.

TIMELINE

July 27, 2020
GW announces participation in a clinical trial for an investigational COVID-19 vaccine co-developed by Moderna and NIH scientists. Begins enrolling trial volunteers.

August 12, 2020
GW’s clinical vaccine research team enrolls its first volunteer.

Oct. 21, 2020
Operation Warp Speed’s Dr. Moncef Slaoui tours GW’s vaccine trial site. ABC News airs exclusive coverage of Dr. Slaoui’s visit to GW’s Vaccine Research Center.

Nov. 16, 2020
Moderna releases an interim analysis of late-stage study results showing close to 95% vaccine efficacy.

Nov. 23, 2020
GW's clinical vaccine research team administers its final vaccination to a volunteer.

Nov. 30, 2020
Moderna files with the U.S. Food and Drug Administration for Emergency Use Authorization for its vaccine.