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'Capital of public health': Atlanta is a leader Covid-19 vaccine research

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The eyes of the nation have been on Atlanta since before COVID-19 even made its way into the United States.

The Centers of Disease Control and Prevention (CDC) began monitoring the virus in January and with the race to develop a vaccine underway, the National Institute of Health (NIH) also turned to the city, which is the home of the largest university-based vaccine research center in the world at Emory University.



GETTY IMAGES/ MALTE MUELLER Emory's Hope Clinic was one of just three sites in the U.S. that launched a phase one trial of the Moderna vaccine in spring 2020.

"Atlanta is the capital of public health," said Dr. Nadine Rouphael, associate professor at the

Emory University School of Medicine and principal investigator for the Moderna phase three vaccine trial at the Hope Clinic, the clinical arm of the Emory Vaccine Center. "It made the perfect environment to be able to support this research related to COVID-19, particularly vaccine research."

'In the thick of it'

Emory's Hope Clinic was one of just three sites in the U.S. that launched a phase one

trial of the Moderna vaccine in March 2020. This was due in part to the fact that Emory is home to a Vaccine Trial Evaluation Unit (VTEU) — one of 10 NIH-funded sites across the country engaged in cutting-edge vaccine research and prepared to rapidly conduct large-scale trials.

"We've been really right in the thick of it," said Dr. <u>Rafi Ahmed</u>, director of the Emory Vaccine Center and world-renowned immunologist. "Having the school of public health, having the school of medicine, having the vaccine center and having a major focus on the human immunology program, it really positions us very well for anything that comes up."

Years of investments in research facilities and recruitment of experts in the field, funded both by the university and the Georgia Research Alliance (GRA), prepared Emory to play a pivotal role in conducting human trials of COVID-19 vaccine candidates.

Ahmed was one of the first eminent scholars brought to the state's universities by the GRA, a public-private partnership that works with the University System of Georgia and the Department of Economic Development to expand research capabilities at the state's universities.

"The GRA has been our biggest backer. Without the GRA there would have been no vaccine center. That's the bottom line. Of course the Emory leadership has provided extraordinary support, but I think the GRA was really the catalyst," he said.

GRA spent more than \$30 million to support talent and laboratory equipment at Emory between 1996 and 2018.

"When the pandemic hit, [the GRA] provided additional freezers and centrifuges which were actually quite critical to conducting the clinical trials and increasing our bandwidth from an infrastructure standpoint," said Dr. <u>Evan Anderson</u>, principal investigator for the phase three Moderna vaccine trial at Emory Children's Clinic and an associate professor of medicine and pediatrics at Emory University School of Medicine and Children's Healthcare of Atlanta

While Emory has been conducting clinical trials of vaccines for more than 30 years, the ongoing support from the GRA and the university has been crucial to making the current COVID-19 vaccine research feasible, he said.

Strength in diversity

Along with the reputation and infrastructure of Atlanta's public health ecosystem, Georgia's diverse population has made it a critical center for COVID-29 vaccine research.

"Historically in clinical trials, diversity wasn't really looked at that closely," said Dr. <u>Paul Bradley</u>, principal investigator at the clinical trial site in Savannah operated by Omaha, Neb.-based Meridian Clinical Research LLC, "but just in the last handful of years, there's been an increasing recognition that it's really important to make sure all the ethnic groups are included."

Bradley said that in his more than 30 years as a practicing physician and principal investigator, his office's ability to recruit volunteers from diverse backgrounds has been a "selling point" of the research site. In recruiting for the COVID-19 vaccine studies, he found significant resistance from African American and Latino patients in participating, due to mistrust that stems from historical events such as the Tuskegee syphilis study and ongoing discrimination in the medical field.

Savannah reporter Dawn Baker was the first person in the U.S. to receive a dose of the Moderna vaccine in the phase three trial. Bradley chose Baker, a Black woman, as the initial patient in part because of her reputation and connections in the city.

"You've got to be heroic to participate in any kind of trial and especially one that has as much additional worry and controversy as this one," Bradley said. "So it helps to have a history in the community and the relationships."

Emory hired Spanish speakers to work on community outreach and collaborated with the Grady Health System to enroll Black and Latino patients, said Dr. <u>Colleen Kelley</u>, principal investigator for the phase three Moderna vaccine trial at Grady Health's Ponce de Leon Center and associate professor at Emory.

With a background in HIV research, she and her team were able to apply their knowledge about disparate health outcomes across racial and ethnic lines, and experience with community engagement and education, to ensure the volunteers in the COVID-19 vaccine study reflected the makeup of Atlanta.

"The need to do this was not something new to us," Kelley said. "At the Grady site we

enrolled 70% underrepresented minorities in our trial."

The task ahead

Although both the Pfizer and Moderna vaccines have received Emergency Use Authorization from the Food and Drug Administration and are in the process of being distributed, the work of researchers continues.

The Morehouse School of Medicine (MSM) is one of the institutions leading the national effort to educate the public about the COVID-19 vaccines, designing strategies to reach the communities hardest hit by the pandemic.

Dr. Valerie Montgomery Rice, president and dean of MSM, serves on a panel of African American scientists — one of five the NIH has established for experts from atrisk populations — where she has analyzed the policies and the results of the vaccine clinical trials.

"We have had the opportunity to review every one of the protocols and we've had the opportunity to comment on the consent forms. We help them to develop different recruitment materials...ensuring that there were culturally and linguistically appropriate materials being used to recruit subjects, ensure that subjects knew it was voluntary and also the value proposition of them participating," she said.

The school has also received a \$40 million grant from the Department of Health and Human Services to provide educational materials aimed at informing vulnerable communities about COVID-19 testing, safety measures, and the risks and benefits of taking the vaccine.

But even with Americans willing to be vaccinated, the country and the world will need additional vaccines in order to inoculate a sufficient number of people against the virus.

MSM and Emory University are already enrolling patients for phase three trials of the Novavax vaccine.

Researchers at the University of Georgia (UGA), as well as Atlanta-based biomedical company GeoVax, are developing their own vaccine candidates.

Emory is also enrolling volunteers in a phase three trial for a vaccine created by New

Jersey-based Janssen Pharmaceutical Companies of Johnson & Johnson, the first candidate that may be able to protect people against the virus with a single injection.

As scientists continue to learn more about the virus, its ability to mutate and the efficacy of vaccines, the Emory Vaccine Center and the Center for Vaccines and Immunology at UGA, led by GRA Eminent Scholar Dr. Ted Ross, are conducting studies on the longevity of immune responses to COVID-19.

"One of the key questions now is that people who have been infected and have recovered, we know that they have antibody responses, but the question is for how long do the antibodies stay?" Ahmed said. "Is it just for a few months? What about a year later, what about two years later? Will they need a booster shot? Will they need to get [re]vaccinated? This is a major study that the vaccine center is doing."

Nearly 600,000 Georgians have received a COVID-19 vaccine as of Jan. 21, but long after the virus ceases to be an eminent public health threat, researchers in the state will still be playing a key role in helping the nation to understand the longterm implications of this pandemic.

Vaccine trials conducted in the state

MODERNA

Emory's Vaccine and Treatment Evaluation Unit (VTEU) began a phase one clinical trial of the Moderna vaccine in March. The trial enrolled 45 participants and was one of just two testing sites in the country.

Phase two trials for the Moderna vaccine began enrollment in May. Meridian Clinical Research in Savannah was one of 10 sites in the nation.

Phase three trials launched in late July. Emory ran three trials at the Hope Clinic of Emory Vaccine Center, Grady Health's Ponce de Leon Center and Emory Children's Clinic. Meridian Clinical Research in Savannah and Clinical Research Atlanta, located in Stockbridge, were also among the 100 testing sites nationwide.

PFIZER

A phase three trial for the Pfizer vaccine is being conducted at Meridian Clinical

Research in Savannah, where the first patient received the vaccine. Clinical Research Atlanta, Atlanta Center for Medical Research and IACT Health in Columbus were also among the 155 testing sites around the country.

NOVAVAX

A phase two trial for the Novavax vaccine is being conducted at Meridian Clinical Research, which is one of 18 sites nationwide.

Phase three trials are being conducted at Emory's Ponce Clinical research sites, Morehouse School of Medicine, Synexus Clinical Research US, Inc., Atlanta Center for Medical Research, Clinical Research Atlanta and IACT Health. They are among 122 study locations nationwide.

JOHNSON & JOHNSON

Emory University, Atlanta VA Medical Center, Infectious Disease Specialists of Atlanta and Meridian Clinical Research in Savannah are among the more than 250 sites enrolling patients for a phase three trial of a vaccine candidate developed by Johnson & Johnson's Janssen Pharmaceutical Companies.

Big Numbers

About 30,000 total Moderna patients in phase 3 trial

700 patients in the phase 3 Moderna trials through Emory's sites

\$3.3 billion added to Georgia GDP in 2019 by <u>organizations working in global health</u>, according to Georgia Global Health Alliance

\$4.1 billion in federal funding for Moderna vaccine

\$1.95 billion in federal funding for Pfizer vaccine manufacturing

Grace Donnelly

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