Clinical Alliance for Research and Education - Infectious Diseases

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# COVID-19 Vaccine Booster Shots and Booster Clinical Trial Update

**Annandale, VA; August 23, 2021** – At the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) our researchers are closely following media reports and we appreciate how much information is coming out and recognize how confusing it can be at times.

"To ensure our study participants and their loved ones have the best information possible that CARE-ID can provide, we base all that we do on the science, vaccine experts, and FDA guidance and approvals, in addition to the appropriate CDC recommendations", stated Executive Director, Steve Poretz. "Guided by these principles, we are providing our clinical trial participants the following information on the status of our upcoming booster shots for the original clinical trial that began last August."

What about booster shots?

"We understand the anxiety and concern in wanting to receive a booster, and we are working closely with Pfizer on the exact timing. And we are waiting on an amendment to the clinical trial protocols which must be approved by the FDA", stated CARE-ID principal investigator, Donald M. Poretz, MD, FACP, FIDSA. "The approval timing is anticipated to be soon, but we are unable to provide an exact date. We know the FDA's priority is to move this forward as soon as possible" The boosters are not only designed in consideration of maintaining antibody levels this fall, but also for variants of concern that could circulate later this year and in early 2022. To sustain data integrity and provide future recommendations, longitudinal participation in controlled clinical trials is essential".

It has become increasingly clear the mRNA COVID-19 vaccines will require a booster dose to provide on-going maximum protection. A September 20$^{th}$ date was initially provided as a target for an Emergency Use Authorization (EUA) for booster doses to the general population, but again this will require the FDA's final approval. For the studies at CARE-ID, the start is waiting on final review and approval from Pfizer, the FDA, and the Institutional Review Board (IRB) which also looks at the science and participant safety. Updates are coming in daily and study participants will be contacted as soon as a definite start date for the booster doses can begin. It is anticipated that booster doses through the studies will follow a priority schedule for healthcare workers, age of the participant, and then other health conditions that place someone at higher risk. "We are optimistic the approval will occur very soon, so we are prepared to quickly implement the booster rollout", stated Steve Poretz.

What is the importance of antibody testing?

Many clinical trial participants are asking about checking their vaccine induced antibodies. In routine clinical practice, antibody testing is not currently recommended to assess immunity status to SARS-CoV-2 following COVID-19 vaccination. Based on the science and FDA approvals this application has not yet been clearly defined. Currently, most commercial blood testing labs use antibody tests that identify if someone has been exposed to the actual SARS-CoV-2 infection and its specific variant. Research on the use of tests to determine vaccine-induced protection is ongoing. "Although the Pfizer studies produce a measure of vaccine induced antibodies, CARE-ID does not receive individual participant's levels", stated Steve Poretz. "At the moment, this data is visible to the independent Data Safety Monitoring Board (DSMB) for the studies. The DSMB meets at least monthly and looks at unblinded data to provide their input to the scientific and clinical team overseeing the study". DSMB members are third party specialists engaged to evaluate the safety and effectiveness of the vaccine.

Newer antibody tests on the market under an EUA by the FDA are not recommended for use as an indication of the degree of immunity for making clinical decisions. The DSMB assess an in-depth analysis of specific memory cells of the immune system. Specific T-cell and B-cell analysis provides insight to long-term vaccination protection beyond the currently available antibody testing at commercial labs. These cells provide answers as to why the current mRNA vaccines have been beneficial during the Delta variant surge, despite media reports of waning antibodies. "In consideration of all our vaccine research participants, we have had one participant that tested positive and required a medical evaluation following a high-risk exposure. The outcome did not require hospitalization and only over the counter symptom management was utilized", stated CARE-ID principal investigator, Donald M. Poretz, MD.

How important will booster shots become?

"Obtaining and studying longitudinal data on a booster dose will be essential to assess the need for future boosters or establishing a schedule for a series of immunizations like for polio, tetanus / diphtheria / pertussis, and the Hepatitis B series", stated Steve Poretz. "These vaccinations ultimately provide long-term T-Cell and B-cell immunity that often leads to a lifetime or a significant duration of protection. As we wait for the start of boosters, the leaders and researchers at CARE-ID continue to extend our utmost gratitude for the willingness of our participants to contribute to this essential research process".

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**About CARE-ID**

CARE-ID conducts clinical research trials in the field of infectious diseases with particular focus on the safety and confidentiality of our participants, quality of our data, and integrity of our results. We partner with pharmaceutical and biotechnology companies to develop experimental therapies for both the prevention and treatment of infectious diseases.

**About Pfizer**

Pfizer Inc. is an American multinational pharmaceutical and biotechnology corporation headquartered Manhattan, New York City, New York. The name of the company commemorates its co-founder, Charles Pfizer (1824-1906). Pfizer develops and produces medicines and vaccines for immunology, oncology, cardiology, endocrinology, and neurology.
https://www.pfizer.com/