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Executive Director

The Fight Against COVID-19 Continues with a New Clinical Trial

Annandale, VA; June 23, 2021 – The leaders of the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) would like to express their extreme gratitude to its volunteer participants in the Pfizer COVID-19 vaccine clinical trial. These volunteers’ contributions of time and consistent attention to detailed follow-ups helped lead to the Emergency Use Authorization (EUA) for one of the three COVID-19 vaccines in record time. The delivery of these vaccines has, in turn, substantially reduced new infections and created a pathway back to more normal lives.

“Our Pfizer vaccine study participants have and continue to assist in creating essential data on the durability and length of antibody protection post-vaccination. This effort is vital to adding to the understanding of how the virus and the vaccine behave over longer periods of time”, stated Executive Director, Steve Poretz. “To this end, we can begin to look at using this data to set out on a new Pfizer vaccine clinical trial to evaluate whether a booster (3rd dose) will be needed.”

Study participants who initially received the active vaccine (not the placebo) will be invited to enroll in the upcoming booster study. This will be conducted on a smaller scale with limits on how many participants can enroll. CARE-ID together with Pfizer are targeting a start date of July 5th to evaluate this third dose (booster). For qualified participants, the booster dose will be administered six to twelve months after a participant’s second dose. “The need for booster shots to existing vaccines has not yet been determined, but studies are running to find out whether it [is] necessary”, said Pfizer CEO and Chairman Albert Bourla. “But based on the data, Pfizer is anticipating people will need a booster shot — essentially a third dose — within eight to 12 months of their second shot”¹. A one-year data point for many clinical trial participants will occur towards the end of the summer or early fall.

“One concern, as we move forward, is sections of the country with low vaccination rates. Low vaccinations rates threaten equitable vaccine distribution intended to reduce the development of new variants. Viral mutations in low vaccination rate areas can create new opportunities for variants to develop and spread”, stated CARE-ID principal investigator, Donald M. Poretz, MD, FACP, FIDSA. “To address this concern, genetic surveillance in low vaccination areas will become increasingly important to decrease the risk of global spread and confirm the need to seek out a booster vaccine dose.”

Since determining the timing for administering a booster vaccine is extremely challenging, participation in clinical trials will help identify the best recommendations and guidelines. Ongoing clinical trial participation, can hopefully close the gaps created by variants.

The smaller scale of the upcoming Pfizer booster study will make participation criteria particularly strict and the participant numbers smaller. CARE-ID staff will contact ongoing participants based on eligibility as determined by Pfizer and the Food & Drug Administration (FDA). “Whether our volunteers participated in the earlier, initial clinical trial or are selected to now participate in the booster study, we hope they have taken great pride in their contribution. Volunteers are imperative to bringing successful preventative and therapeutic medicines and vaccines to the public”, stated Steve Poretz.

“It is also important to remember no COVID-19 vaccine, whether the one CARE-ID studied or other approved vaccines, is 100% effective against contracting the virus. Although vaccines and, most importantly, getting vaccinated are intended to prevent infections, they are equally important in decreasing the severity of illness if infected”, stated Dr. Poretz. “Breakthrough infections in vaccinated individuals are occasionally identified, but the resulting illness is substantially decreased and possibly even asymptomatic.”

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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/>

¹ First published on June 14, 2021 CBS News