Clinical Alliance for Research and Education - Infectious Diseases

Steve Poretz, RN, MSHA
Executive Director

Important Update in the Fight Against COVID-19

Annandale, VA; January 6, 2021 – On December 11, 2020 the FDA gave its official EUA (Emergency Use Authorization) for the Pfizer COVID-19 vaccine. Together with the November EUA of the Lilly neutralizing antibody bamlanivimab, CARE-ID has made a notable contribution together with its corporate partners in the fight against COVID-19. During July of last year, the leaders of CARE-ID made the important decision to focus their clinical research capabilities to help expand the number of volunteers needed to achieve reportable study results in an unprecedented timeframe. The CARE-ID principal investigators, Drs. Wheeler and Poretz and the group's Executive Director, Steve Poretz, have expressed practically every day of the initial phase of the studies, "We are most grateful to all the members of our northern Virginia community who volunteered and became invaluable collaborators in this fight".

It is important to keep in mind the fight doesn't end with the EUA's. Months of ongoing monitoring and study of volunteers' medical status is essential to understanding the full range of effectiveness for the treatment and vaccine. This on-going nature is a normal part of virtually every clinical research study. In the case of the Pfizer COVID-19 vaccine, this is particularly crucial as virologists, epidemiologists and laboratory researchers are continuing to learn more about the virus, it's behavior and the term of effective protection every day. Especially over the next 6 to 18 months, as new information that might change any part of the study's scope or its expected outcome is uncovered, volunteers will be notified.

Very recently, On December 31, 2020, a senior director in Pfizer's vaccine clinical research and development group indicated, "We recognize that our clinical trial participants are selfless volunteers who have made the important choice to make a difference and fight this pandemic. While the study continues to be blinded to answer important public health questions such as persistence of protection, longer term safety and protection from asymptomatic infections, we are committed to ensuring that our trial participants are recognized for their contributions and that placebo recipients who wish can receive BNT162b2 within the study."

“As a result of the Pfizer decision, our volunteers who may have received "placebo" injections as part of the Pfizer SARS-CoV-2 RNA Vaccine study will receive a specific notification letter from CARE-ID and a follow-up phone call prior to January 22, 2021”, stated Steve Poretz. “We are working very closely with Pfizer on the exact details of the process so that volunteers can now receive the approved vaccine, if desired, as soon as appointments can be scheduled. Our letter will provide the details of the process.”

For this COVID-19 vaccine study, Pfizer established a very large team of clinical researchers in 120 clinical investigational sites around the world, including many states across the United States to accelerate enrolling and managing over 44,000 volunteers who participated in this study.

In medicine, the most dependable results about potential treatments and preventatives come from double-blind placebo-controlled studies. In these trials, participants are randomly assigned to receive either the treatment, in this case a vaccine, or a placebo. Neither they nor their doctors know what they have received. In many trials, it’s simply assumed that patients who received a placebo will get the treatment once the study is completed and unblinded. This step is known as “crossover”.

But as reported by Matthew Harper of Statnews.com, “…the matter of how placebo crossover should be handled during a pandemic was left open by both the FDA and the U.S. government’s Operation Warp Speed effort when the studies began in July”. Crossover is now being addressed based on rising attention and questions posed by some study volunteers. For specifics on the guidelines issued by the CDC, please visit https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html

CARE-ID is located and can be contacted at:
3289 Woodburn Rd. Suite 250
Annandale, Virginia 22003
info@careidresearch.com
703-560-4821 (phone)
703-641-8654 (fax)
http://www.careidresearch.com/

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.