



Steve Poretz, RN, MSHA, MBA  
Executive Director

## **COVID-19 Vaccine Clinical Trial Update**

**Annandale, VA; February 22, 2022** – At the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) our researchers are closely following media reports as the Omicron variant surge appears to be on the decline. We appreciate how much information is coming out and recognize that the general public is likely to relax its vigilance and recognition that the COVID virus can still cause serious illness for those who don't take full advantage of the protections offered by the vaccines.

“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 provide our Pfizer vaccine clinical trial participants updated information on the status of our on-going trials as well as information on new trials that Pfizer is considering. What we can share today is outlined in the following.”

### Booster shots for younger individuals?

Pfizer is currently considering a booster study for its COVID-19 vaccine for ages 12 to 30 with a special focus on ages 12 to 18. Although an Emergency Use Authorization (EUA) is in place for boosters in the 12 and up group, capturing additional data will be essential in providing guidelines and recommendations. Planning is underway that suggests such a trial could begin in March of this year. While a study isn't certain until all the processes are approved, the prospects for such study look very good at this point in time.

“We understand the anxiety and concern in wanting to receive a booster, and we are working closely with Pfizer on the exact timing. We are waiting on final clinical trial protocols which must be approved by Pfizer and 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, but also for variants of concern. Of particular interest is the Pfizer Omicron specific booster which is ongoing at select centers. We are waiting on guidance from the operations team to confirm if a wider participation will be needed to fully assess an Omicron specific vaccine.”

“It has become increasingly clear the mRNA COVID-19 vaccines require a booster dose to provide on-going, maximum protection. For the studies at CARE-ID, the start is waiting on final review and approval by 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 candidates will be contacted as soon as a definite start date for the younger age group and potential for an Omicron specific clinical trial. We are optimistic the approval will occur very soon, so we are prepared to quickly implement the booster rollout as well as the Omicron specific vaccine as additional information becomes available”, stated Steve Poretz.

#### How important will booster shots become?

“Obtaining and studying longitudinal data on booster doses is essential to assess the need for future boosters or establishing a schedule for a series of immunizations such as those 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. For ongoing participants, in the event you develop respiratory symptoms or other concerns suggesting a coronavirus infection, we ask that you let us know as soon as possible so we can collect specimens for ongoing data collection.”

#### Pfizer’s connection with its vaccine community

Pfizer wishes to communicate to its vaccine trial participants how much it values their efforts with the following message:

“Your participation meant the world. And it could change the world, too.”

The Pfizer Link

With this message, Pfizer is reminding study participants of its online destination for clinical trials information. It is inviting all its vaccine trial participants to explore and to discover additional valuable information and resources that may be useful. Past participants can access this information through an opt-in, online Clinical Trials Alumni Portal at: <https://www.pfizerlink.com/home>

“This is a terrific resource being offered by Pfizer. It demonstrates a continuing commitment to the health and well-being of its clinical trial participants while being transparent with sharable data. We encourage all of our CARE-ID patients and study participants to take full advantage of the information being made available”, stated Steve Poretz.

#### **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.

### **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/>