

Dear study participants,

The Pfizer and BioNTech COVID-19 investigational vaccine has started to receive emergency regulatory authorizations from health authorities around the world, including an Emergency Use Authorization (EUA) from the U.S. FDA. This is a truly meaningful and encouraging moment in this study and we are grateful you have chosen to be part of this important research. It is important to note that vaccines authorized for emergency use are still considered investigational and are not yet approved for general use.

Many of you have asked if participants who received the placebo will be offered the investigational vaccine as part of the clinical trial. We are pleased to share that Pfizer and BioNTech have made a change to the clinical trial study design which will give all participants who originally received placebo an option to transition to the active vaccine group of the study, if interested. The option to transition is completely voluntary. Whatever you decide, we encourage you to remain in the study. Your continued participation will provide valuable contributions to the understanding of COVID-19 and the investigational vaccine.

The Vaccine Transition Option

The Vaccine Transition Option is a voluntary process that offers all participants 16 years and older in the placebo group an option to transition to the vaccine group. Interested participants can transition at two time points. To determine the order in which participants can begin the Vaccine Transition Option, Pfizer and BioNTech are following the guidance of the U.S. Centers for Disease Control Advisory Committee for Immunization Practices, which has prioritized currently:

1. Healthcare workers will have the option of transiting to receive a vaccine if they received a placebo.
2. We will offer vaccines Friday, December 18th, and Monday, December 21st to all healthcare workers.
3. At this time, all individuals who are not healthcare workers will have vaccinations at visit 4, unless CDC recommendations allow you to be in a group that qualifies sooner, in which case, will offer as soon as possible.

Available Now

At this time, if you are a healthcare worker or a resident of a long-term facility and wish to take part in the Vaccine Transition Option, please contact us at [REDACTED]

We will be able to confirm:

If you are in the following groups: Healthcare worker or resident of a long-term facility
Whether you have received the placebo or investigational vaccine
How to continue in the clinical trial if you choose to transition from the placebo group to the active vaccine group

At the 4th study visit

If you are not in one of these groups: Healthcare worker or resident of a long-term facility we will discuss an option to transition from the placebo group to the vaccine group at your 4th study visit, approximately 6 months after you originally received your second injection.

We respectfully ask that you wait until Study Visit #4 to discuss the Vaccine Transition Option.

The decision to transition to the vaccine group is up to you

The choice to move from the placebo group to the active vaccine group is completely up to you. Your continued involvement in the clinical trial, whether by following your current schedule or taking part in the Vaccine Transition Option, allows us to continue learning as much information about the vaccine as possible.

Important reminders

Please keep in mind the following guidelines whether you choose the Vaccine Transition Option or continue with your current study plan:

It is important you continue to follow all the instructions given to you by the study nurse or doctor. Please contact us if you experience symptoms that might be COVID-19. You still need to follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use).

This milestone represents the hard work, commitment and courage of so many, especially participants like you, who volunteered to make a difference during this pandemic. We are so proud to be part of this effort together.

Thank you for volunteering!