

# FAQS: CLINICAL TRIALS FOR COVID-19 TREATMENTS

## THE BASICS

### Q: Why do we need to research new treatments when we have vaccines for COVID-19?

A vaccine is given to try to prevent people from getting a disease and prepare their bodies with antibodies to lessen symptoms if they do get a disease. This gives them a better chance of not getting worse and needing hospital care. Treatments are given to help people who are already sick fight the disease and recover better. We need new treatments for people who are sick with COVID-19 or who can't take the vaccine due to another medical condition.

### Q: Aren't monoclonal antibodies an effective treatment for COVID-19? Why do we need to test other treatments?

Monoclonal antibodies (mAbs) are authorized for emergency use by the U.S. Food and Drug Administration (FDA) to treat people who have had mild or moderate symptoms of COVID-19 for 10 days or less *and* who are at high risk for more serious symptoms. If given to people within the first 10 days of COVID-19 infection, mAbs can reduce the risk of getting more serious symptoms of COVID-19 or needing to stay in the hospital. Not everyone is a good candidate for mAbs. People who are past the 10 day timeframe or are too sick for mAbs may need a different treatment. More treatments are needed to help with the many different symptoms of COVID-19 and to prevent people from getting worse.

The more effective and safe treatments for COVID-19 we have for people at different stages of COVID-19, the more we can help people who do get sick.

### Q: How could I benefit from participating in a clinical trial?

You may get access to a possible new treatment only available to participants. During the clinical trial, you'll receive healthcare that's focused on your specific needs. You could also be paid for your time, depending on the trial. Best of all, you'll have taken action to protect yourself and your loved ones—now and in the future.

## THE PROCESS

### Q: What happens in a clinical trial?

You will be checked on and treated by a highly-trained medical research team. Treatments are offered in what the FDA calls the "gold standard" for research studies: a randomized, double-blind, placebo-controlled clinical trial. In these trials, there are two groups of participants. Some participants are assigned randomly to the group that receives the drug being tested, and some are assigned randomly to a "control" group that receives a placebo. (A placebo looks like the drug being tested but it actually has none of the active drug in it.) It's important to know that everyone who takes part in a clinical trial for possible COVID-19 treatments is treated for COVID-19. Participants who don't receive the drug being tested get another possible treatment currently available for the disease.

### Q: If I decide to participate, can I drop out of the clinical trial before it ends?

Yes. You can leave a clinical trial at any time. Even if you drop out before the study ends, a medical team will continue to check on you to make sure you don't have any negative effects from the trial and that your COVID-19 care continues.

### **Q. Will it cost me anything to participate in a clinical trial?**

All study procedures and medications are provided at no cost to participants. Participants may be responsible for costs related to care outside of the clinical trial itself, such as routine visits with their healthcare provider and transportation to the trial site. The study team will let possible participants know about the details related to a specific clinical trial.

### **Q: If I participate, will I have to show my immigration status?**

No. Your privacy is protected by a federal law known as HIPAA (the Health Insurance Portability and Accountability Act). Your name will not be shared and your privacy is protected. Any personal information that identifies you will not be included in any reports or shared outside of the research care team.

## **GETTING STARTED**

### **Q: Do I need a referral or permission from a healthcare provider to join a clinical trial?**

No, you do not need a referral. But you should discuss the benefits of joining a clinical trial with your healthcare provider. This helps you make sure it is the right choice for you and keeps them informed of your health decisions.

### **Q: Where can I learn more?**

Visit [CombatCOVID.hhs.gov/Clinical-Trials](https://CombatCOVID.hhs.gov/Clinical-Trials) or call 1-877-414-8106 to speak with an information specialist who can answer your questions.

### **Q: I speak Spanish, not English. Can I still participate in a clinical trial?**

Yes! The website [CombateCOVID.hhs.gov](https://CombateCOVID.hhs.gov) has information in Spanish as well as a toll-free number. Call 1-877-414-8106 to speak with an information specialist who can answer your questions in Spanish.