THE COVID-19 VACCINE PEDIATRIC STUDY

Now Enrolling 12 to 15 Year-Olds

Learn more about this vaccine research study to see if it is right for your child.

Pfizer | BIONTECH

An Important Contribution

Every modern vaccine we have today was first studied in clinical trials involving hundreds to thousands of people before becoming available to the public.

Today, hundreds of millions of people 12 years and older around the world have received the Pfizer BioNTech COVID-19 vaccine because of the over 46 thousand people who volunteered to be a part of our landmark trial. We are profoundly grateful to them and the thousands of children and their families who are already participating in our COVID-19 Vaccine Pediatric Study.

Joining a clinical trial is an important and personal decision for you and your family. By choosing to join, your child will represent children like them—in age, gender, race, ethnicity, and from communities like yours. We hope it is one you will consider.

What To Expect

- All participants will receive the COVID-19 vaccine. There is no placebo (injection with no active ingredient).
- Your child may have a blood sample taken at the beginning of the study and 4 days after vaccine dose 2.
- Over the course of the 6 months, your child will attend 3 in-office study visits and 2 follow-up telephone calls.
- You and your child will be asked to track any side effects your child may have. To make this easier, you will be given an electronic diary.
- Your child's time in the study will last approximately 6 months.

FAQs

What is myocarditis and pericarditis?

Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the thin lining around the heart. Most cases of these conditions resolve with minimal treatment.

What is the blood test being used in the study?

A high level of a protein, called troponin I, which is found in the blood could be an early sign of myocarditis or pericarditis. If troponin I is confirmed to be a sign of potential myocarditis or pericarditis, then the blood samples collected from participants in this study will be tested for troponin I.

We Are Here To Help

We encourage you to talk to your doctor or the study team if you have questions about participating. You can always change your mind and leave the study at any time.

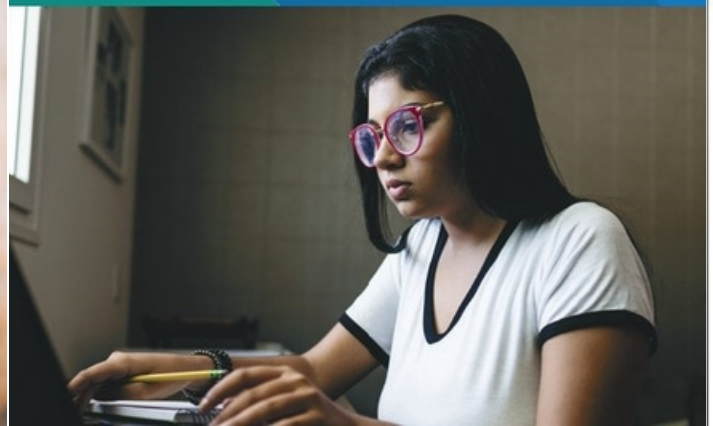
About This Study

On May 10, 2021, the Pfizer & BioNTech COVID-19 vaccine received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for 12-15 year-olds.

We are now starting a study for adolescents 12-15 years old that includes a blood test that could help potentially detect and better understand the risk of developing myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the thin lining around the heart) after receiving the study vaccine.

We are conducting this new study because recent data from adults and adolescents who were vaccinated in the real world show a risk of developing myocarditis/pericarditis. While the chance of having this occur is very low, we want to better understand how to detect this risk in adolescents.

Healthy adolescents between the ages of 12 and 15 may participate. All participants will have the opportunity to receive the COVID-19 vaccine during their time in the study. Participation in the study will last approximately 6 months.



Contact Us

If you have questions or concerns about anything related to this study, please let the study team know. If you do not have questions now, you can always call or email the study team.

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THE COVID-19 VACCINE PEDIATRIC STUDY (C4591007)



PARENTS: YOUR CHILD CAN HELP MAKE A DIFFERENCE IN THE FIGHT AGAINST COVID-19

Every modern vaccine was first tested in clinical trials involving hundreds to thousands of people before becoming available to the public. While progress has been made to develop COVID-19 vaccines for adults, currently there are no approved COVID-19 vaccines available for children. Before they can be approved, COVID-19 vaccines need to be studied in a clinical trial that involves children.

In this pediatric COVID study, we will learn if the COVID-19 study vaccine can produce an immune response against COVID-19, and if it is safe, in children 6 months to 11 years old. All participants will have the opportunity to receive the COVID-19 study vaccine during their time in the trial.

Participation in clinical trials by children of all backgrounds will make a difference by contributing to the development of vaccines for everyone. Joining a clinical trial is an important and personal decision for you and your family. We hope it is one you and your child will consider.

WHAT TO EXPECT

PARTICIPANTS WILL BE
RANDOMLY ASSIGNED
(BY CHANCE) TO RECEIVE THE COVID-19 STUDY VACCINE OR PLACEBO*

PARTICIPANTS WILL RECEIVE THEIR
2 INJECTIONS
3 WEEKS APART

PARTICIPANTS WILL HAVE AT LEAST
4 SCHEDULED FOLLOW-UP VISITS

PARTICIPANTS WILL TRACK THEIR HEALTH AND
REPORT
ANY POTENTIAL COVID-19 SYMPTOMS

TWO THIRDS OF THE PARTICIPANTS WILL RECEIVE THE COVID-19 STUDY VACCINE AND ONE THIRD WILL RECEIVE THE PLACEBO. 6 MONTHS AFTER INJECTION 2, ALL PARTICIPANTS WILL LEARN IF THEY RECEIVED THE COVID-19 STUDY VACCINE OR PLACEBO. PARTICIPANTS WHO RECEIVED THE PLACEBO WILL HAVE THE OPTION TO RECEIVE THE COVID-19 STUDY VACCINE.

[CONTACT A STUDY TEAM MEMBER TO LEARN MORE]

[STUDY CLINIC]

[CONTACT PERSON]

[PHONE NUMBER]

[EMAIL ADDRESS]

[*COVID*VACCINESTUDY1.COM]**

*injection with no active ingredient

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INFORMATION FOR PARENTS

What is a clinical trial?

A clinical trial is a type of research study that collects new information and answers important questions about health and disease. All new medicines, including vaccines, need to be tested in clinical trials before they can be available to the public.

How do vaccines work?

Unlike most medicines, which treat or cure diseases, vaccines prevent them. A vaccine stimulates your immune system to produce antibodies, exactly like it would if you were exposed to the disease. After getting vaccinated, you develop immunity to that disease, without having to get the disease first. This is what makes vaccines such powerful medicine.

Is this a live vaccine being studied?

The study vaccine does not contain any live virus. The placebo is also an injection but it contains saline instead of active ingredients.

Has the COVID-19 study vaccine been studied in older children and adults?

The first trial for the COVID-19 study vaccine enrolled over 46,000 people 12 years and older and included 2,260 children aged 12-15 and 754 children aged 16-17.*

How can I learn more?

If you're interested in learning more about this clinical trial for your child, please visit **COVIDVaccineStudy1.com**.

*The study vaccine has received authorization for emergency use (EUA) by the U.S. FDA and other countries for individuals 16 and older. An EUA allows the investigational vaccine to be used during the current COVID-19 public health emergency. The vaccine has not been approved or licensed by the FDA but has been authorized for emergency use under an EUA to prevent COVID-19 in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the product's emergency use, unless the declaration is terminated, or authorization revoked sooner. Please see EUA Fact Sheet at **http://www.cvdvaccine.com**.