Trial Participation Overview

The Importance of Participation

The COVID-19 pandemic is like nothing we've seen in more than a century, and it has changed each and every one of our lives. Now, you or your child could be a part of important research on a new COVID-19 vaccine.

By enrolling in the NextCOVE Study, you or your child will be contributing to a potential solution to the evolving COVID-19 pandemic, which has affected the entire world.

Purpose of the Trial

The purpose of the NextCOVE Study is to evaluate an investigational bivalent vaccine that may protect people from getting sick if they come into contact with the virus that causes COVID-19 and multiple variants, including the Omicron variant. The NextCOVE Study is evaluating:

- The safety of the investigational vaccine (called mRNA-1283.222), which is given as 1 booster dose
- The effectiveness of the investigational vaccine at preventing illness after exposure to SARS-CoV-2 compared to another bivalent COVID-19 vaccine
- The occurrence of COVID-19 infection after vaccination with the investigational vaccine

Eligibility Criteria

In order to participate, you or your child must:

- Be at least 12 years old
- Have received a COVID-19 vaccine and at least 1 booster dose of a COVID-19 vaccine

  The booster doses are not required for participants younger than 18 years of age. All trial participants will receive medical care from the trial doctor while in the NextCOVE Study.
- Not have a positive COVID-19 test within 3 months prior to the screening visit
- Be free from exposure to someone with SARS-CoV-2 infection or COVID-19 within 2 weeks prior to receiving the first vaccination
- Not have received a COVID-19 vaccine within 3 months prior to the screening visit
- Be willing and able to comply with all trial requirements

There are additional eligibility requirements, which the trial doctor can explain to you.

About the NextCOVE Study

This trial lasts approximately 13 months and includes up to 6 trial site visits and 3 safety phone calls.

There is 1 injection visit. You or your child will be chosen at random to receive either the investigational booster dose of mRNA-1283.222 or mRNA-1273.222.

You or your child will be asked to return to the trial site 4 times following vaccination. These visits will occur 28 days, 3 months, 6 months, and 12 months after the injection.

You or your child will have 3 safety phone calls — 1 week, 3 weeks, and 9 months after the injection — during which the trial team will check how you or your child is feeling and discuss safety-related information.

About the NextCOVE Study (cont'd)

You or your child will also be asked to complete electronic diary (eDiary) entries for the duration of the trial to report any COVID-19 symptoms that may occur.

You or your child will be closely monitored by the trial team if any symptoms of COVID-19 are reported at any time throughout participation.

Participation in the NextCOVE Study is completely voluntary. You or your child may withdraw from the trial at any time for any reason.

About the Investigational Vaccine

The NextCOVE Study is testing mRNA-1283.222, one of Moderna's bivalent (addressing multiple viral strains at the same time) COVID-19 investigational vaccines that may protect people from getting sick if they come into contact with the virus that causes COVID-19 and multiple variants, including the Omicron variant. Moderna will be evaluating this investigational vaccine as a booster dose in children and adults to learn more about how it works in the body.

Normally, vaccines for viruses are made from a weakened or inactive (not live) virus, but the mRNA-1283.222 investigational vaccine is different. It is made from messenger RNA (mRNA), an instructional molecule that naturally occurs in the body and tells cells how to make protein. The goal of this vaccine is for the protein to trigger the body's immune system to create the antibodies it needs to fight the real SARS-CoV-2 virus, which causes COVID-19.

You or your child, along with up to 8,471 other individuals, will be helping researchers learn more about Moderna's investigational vaccine that may help protect people from getting sick if they come into contact with the virus that causes COVID-19, including its Omicron variant. Your participation could contribute to a potential solution to the evolving COVID-19 pandemic, which has affected the entire world.

How You or Your Child Will Feel after the Vaccination

All vaccines have some side effects for some people, and you or your child may experience side effects in this trial that range from mild to moderate in severity. In other studies of people receiving vaccines similar to mRNA-1283.222, the most common side effects were fever, headache, muscle aches or pain, joint aches or pain, tiredness, nausea/vomiting, and chills. These side effects have been reported more often after the later doses of the investigational vaccine and typically last between 2 and 3 days.

After the injection, you or your child may have pain or redness and hardness of the skin at the injection site. Underarm gland swelling may also occur on the arm where the trial vaccination was given.

Not everyone has side effects, and most side effects go away within a few days after the injection.

We know that decisions regarding your or your child's health are never taken lightly, and we appreciate your consideration of the NextCOVE Study. Your or your child's participation could make a difference that helps change the world.

To learn more, visit NextCOVEStudy.com or contact the participating site listed here: