Frequently Asked Questions (FAQ) for the Imagine Trial

Looking for answers about participation in the Imagine Trial? Read on to learn more about what the clinical trial journey may look like for your child or teen.

Who is sponsoring the Imagine Trial?

This trial is sponsored by Moderna. Moderna is committed to researching investigational vaccines and therapies to see if they are safe and effective and can bring better health and living to people of all ages, sexes, and backgrounds.

How will the clinical trial results be used?

If the results are positive, mRNA-1345 can be submitted to health authorities, such as the U.S. Food and Drug Administration (FDA), to look at whether the investigational vaccine has met certain standards of effectiveness and safety. If the investigational vaccine is approved, it can be made available to the general population. If the trial results are published (e.g., in a medical journal) or presented at medical conferences, individual participants won't be identifiable.

Is the Imagine Trial safe for my child?

Clinical trials must meet specific standards and are closely overseen to help protect participants. But all trials and investigational vaccines have potential risks and discomforts, such as side effects. Safety is our top priority, and your child will be monitored for side effects throughout their participation.

How does the Imagine Trial investigational vaccine work?

The investigational vaccine being studied is a messenger RNA (mRNA) vaccine. mRNA vaccines aim to teach the body how to make a specific protein that may potentially help the immune system prevent certain diseases. The hope is that the investigational vaccine will train the cells of the immune system to "remember" these proteins and help the body quickly protect against the strain of infection if exposed in the future.

The investigational vaccine in this clinical trial, mRNA-1345, aims to protect against respiratory syncytial virus (RSV). Moderna has been researching mRNA-1345 in multiple age populations and is dedicated to advancing research in how we deliver protection against RSV.

Why is the investigational vaccine being evaluated in children and teens 2 to 17 years of age?

Certain people are especially vulnerable to RSV. Globally in 2019, RSV caused 33 million respiratory infections in children 5 years of age or younger.[1] RSV infection may also be severe in children with a variety of medical or chronic conditions, including cystic fibrosis, congenital heart disease, Down syndrome, neuromuscular disease (such as cerebral palsy), lung disease,

asthma, and sickle cell disease.[2-4] Children with these conditions who get RSV may have a higher likelihood for hospitalization, a longer hospital stay, or a need for oxygen therapy.[2]

That's why it's important to research investigational vaccines to see if they can help reduce the disease burden in children and teens.

Can my child get RSV from the investigational vaccine?

Your child cannot become infected with RSV from receiving the investigational vaccine. The investigational vaccine does not include any live virus.

What are the possible side effects of the investigational vaccine?

The most common side effects that were noticed in clinical trials of people who received similar investigational vaccines were pain, redness, and swelling/hardness of the skin at the injection site, underarm swelling, headache, muscle aches, joint pain, feeling tired/unwell, nausea/vomiting, fever, and chills. Most side effects occurred within the first days after injection and went away within a few days.

May we complete any trial visits remotely or at home?

You and your child may have the option for some trial visits to be completed in your home. The clinical trial doctor can discuss these options with you if you'd like.

Can my child continue taking their current medications during the trial?

Talk to the clinical trial doctor about which medications your child is currently taking, and they will let you know if any are not allowed. If you do not tell the doctor about all of your child's current medications, you may be putting your child's health at risk.

Can we continue to see my child's usual doctor during the trial?

You should continue to see your child's usual doctor. Ask them to help you monitor and report any symptoms of respiratory illness during the trial.

Take some time and talk to your family and your child's doctor about participation in the Imagine Trial. Please refer to the Informed Consent Form for more FAQ, and then review any questions with the clinical trial doctor or site listed below.

References:

1. Li Y, Wang X, Blau DM, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. *Lancet*. 2022;399(10340):2047-2064. doi:10.1016/S0140-6736(22)00478-0 **2.** Manzoni P, Figueras-Aloy J, Simões EAF, et al. Defining the incidence and associated morbidity and mortality of severe respiratory syncytial virus infection among children with chronic diseases. *Infect Dis Ther*. 2017;6(3):383-411. doi:10.1007/s40121-017-0160-3 **3.** Respiratory syncytial virus (RSV). Asthma and Allergy Foundation of America. Updated January 2023. Accessed September 12, 2023. https://aafa.org/asthma/asthma-triggers-causes/respiratory-infections-flu-cold-asthma/respiratory-syncytial-virus-rsv/ **4.** Sadreameli SC, Reller ME, Bundy DG, Casella JF, Strouse JJ. Respiratory syncytial virus and seasonal influenza cause similar illnesses in children with sickle cell disease. *Pediatr Blood Cancer*. 2014;61(5):875-878. doi:10.1002/pbc.24887

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