STEPS FOR COVID-19 VACCINES TO BE AUTHORIZED FOR 5- TO 11-YEAR-OLDS

Before vaccines can be authorized for use, their safety and effectiveness are thoroughly evaluated by scientists, researchers, medical professionals, the U.S. Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).

DECADES OF RESEARCH

Messenger RNA (mRNA) technology has been studied for decades. Breakthrough on this research allowed two COVID-19 mRNA vaccines to be authorized in the U.S. for emergency use during the public health emergency. One is the Pfizer vaccine.

RESEARCH AND DEVELOPMENT

Scientists study the virus and develop a vaccine. A smaller dose of the Pfizer vaccine was tested in children ages 5-11 beginning in March 2021. More than 245 million adult and adolescent doses have already been administered across the U.S.

TESTING

Healthy volunteers participate in clinical studies to receive the vaccine so it can be tested for safety and possible side effects. Clinical trials in children ages 5-11 years found the vaccine to be 90.7% effective in preventing symptomatic COVID-19. To compare, the flu shot is typically between 40% to 60% effective.

INDEPENDENT REVIEW

Panels of independent experts and medical professionals evaluate the testing data and make recommendations to the CDC and FDA about authorization and use of the vaccine.

The FDA panel is called the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the CDC panel is called the Advisory Committee on Immunization Practices (ACIP).

AUTHORIZATION

The FDA grants authorization for emergency use, and the CDC recommends information about administering the vaccine.

ONGOING SAFETY EVALUATION

Vaccine safety is continuously monitored by many systems and agencies, including the CDC's Vaccine Adverse Event Reporting System (VAERS).

FULL APPROVAL

After vaccine recipients have been followed for at least six months, the manufacturer can apply for full approval. The Pfizer-BioNTech vaccine, the first authorized for emergency use, has now been fully approved for those 16 and older under the brand name "Comirnaty."

Ohio Department of Health

coronavirus.ohio.gov/vaccine
gettheshot.coronavirus.ohio.gov