

Pfizer-BioNTech COVID-19 Vaccine for Children Under 5

 On February 1, 2022 Pfizer-BioNTech initiated a rolling submission to expand the Emergency Use Authorization (EUA) of the Pfizer COVID-19 Vaccine to include children 6 months through 4 years of age (6 months to <5 years of age).

Data were submitted for two 3 µg doses of what is anticipated to be a three-dose series. No significant safety concerns were identified, and two of the 3 µg dose demonstrated a favorable safety profile in children 6 months to under 5 years of age.

 Why did they submit? In response to the public health concerns and a request from the U.S. Food and Drug Administration (FDA).

As of February 3, 2022, in the U.S.:

- Over 12 million child COVID-19 cases have been reported
- Children represented 18.9% (12,042,870/63,819,973) of all cases
- >107,000 children 0-17 have been hospitalized since August 2020 due to COVID-19

And as of January 31, 2022:

- There have been 6,851* total Multisystem Inflammatory Syndrome in Children (MIS-C) cases reported
- 59 MIS-C deaths reported
- 98% of patients had a positive test result for SARS CoV-2. The remaining 2% of patients had contact with someone with COVID-19.

*Additional patients are under investigation. After review of additional clinical data, patients may be excluded if there are alternative diagnoses that explained their illness.

 COVID-19 vaccines prevent deaths in older age groups and a recent report showed that two doses of the Pfizer-BioNTech vaccine were highly effective in preventing MIS-C in persons aged 12-18 years (estimated effectiveness against MIS-C was 91%).

 On February 11, 2022 the FDA postponed the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to discuss the request for authorization of Pfizer-BioNTech COVID-19 vaccine for children under five.

 Why? Based on the FDA preliminary assessment of the data, it is believed additional information regarding the ongoing evaluation of a third dose should be a part of their decision-making for potential authorization.

 The FDA and other regulatory bodies involved in vaccine approval will ensure the data supports effectiveness and safety before authorizing a COVID-19 vaccine for use in our youngest children.

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Details of the Pfizer-BioNTech Clinical Trials for Children Under 5

 The phase 1/2/3 trial initially enrolled **4,500 children ages 6 months to under 12** years of age in the United States, Finland, Poland, and Spain from more than 90 clinical trial sites.

 Additional children have been enrolled in all age groups, currently there are approximately **8,300 children**.

 Study was designed to evaluate the **safety, tolerability, and immunogenicity** of the Pfizer-BioNTech vaccine on a two-dose schedule (approximately 21 days apart) in:

- Ages 5 to under 12 years;
- Ages 2 to under 5 years;
- And ages 6 months to under 2 years

 Children under age 5 received a **3 µg dose for each injection** in the Phase 2/3 study.

 The trial enrolled children with/without prior evidence of SARS-CoV-2 infection.

 Pfizer-BioNTech announced it would test a **third 3 µg dose** given at least two months after the second dose in children under age 5 and a third dose of the 10 µg formulation in children 5 to under 12 years of age.

Data on a third dose given at least 8 weeks after completion of the second dose are expected in the coming months and will be submitted to the FDA to support a potential expansion of this requested EUA.



No safety concerns have been identified.



Moderna COVID-19 Vaccine for Children



On March 23rd, Moderna announced that they were moving forward with global regulatory submissions for mRNA-1273 for primary vaccination of children 6 months to under 6 years of age. Additionally, Moderna has initiated a submission for emergency use authorization of the COVID-19 vaccine in children ages 6 to 11 years old and are updating their submission to the FDA for emergency use authorization in adolescents ages 12 to 17 years with additional follow-up data.

Data were submitted for a two-dose series, with dosage depending on age group.



Moderna announced plans for entering the submission process with the FDA for an emergency use authorization of a 50 µg two-dose primary series for children aged 6 years to under 12 years. This age group has already been authorized in Australia, Canada and the European Union.

Moderna updated its submission to the FDA for the emergency use of a 100 µg two-dose primary series in adolescents aged 12 to under 18 years. The 100 µg two-dose primary series has been authorized in adolescents 12 to 17 years of age in the European Union, UK, Australia, Canada, Switzerland and other countries.



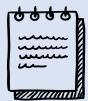
Data on booster doses for all pediatric populations are expected in the coming months and will be submitted to the FDA to support a potential expansion of the requested EUA.

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As of 3/23/22

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Details of the Moderna Clinical Trials for Children Under 18



The KidCOVE trial (for ages 6 months – under 12 years) initially enrolled **11,700 pediatric participants** in the United States and Canada.



Approximately 6,700 participants aged 6 months to under 6 years were enrolled.



Study was designed to evaluate the **safety, tolerability, and immunogenicity** of the Moderna (SpikeVax) vaccine on a two-dose schedule (approximately 28 days apart) in:

- Ages 12 to 17 years;
- Ages 6 to under 12 years;
- And ages 6 months to under 6 years



Dosage was dependent on age:

- Children 6 months through 6 years received two 25 µg doses
- Children 6 to 12 years received two 50 µg doses
- Children 12 to 18 years received two 100 µg doses



Side effects were similar to other pediatric vaccines. Rates of fever greater than 38 C were:

- 17.0% in ages 6 months – under 2 years
- 14.6% in 2 years – under 6 years
- 23.9% in 6 years – under 12 years

Fever greater than 40°C was seen in only a few children (0.2% in each age group). No deaths, no myocarditis or pericarditis, and no multisystem inflammatory syndrome in children (MIS-C) were reported.



No safety concerns have been identified.

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COVID-19 Vaccines for Children Under 5

BE FLEXIBLE – We have not had to “mass vaccinate” little ones before, but you do it all the time (flu shots). Information is going to change; you may find something works and then find that it doesn’t. Do your best to go with it and adapt quickly if needed.

Make it fun – Access to this vaccine is a BIG deal for many parents in this age group. This is something they have been waiting for. Let’s celebrate and congratulate and thank our parents for bringing their children in to be vaccinated! (Think: stickers, balloons, etc.)

Think about logistics, but don’t over-think it! – For example, you might not need additional or new equipment to vaccinate these age groups.

Keep in mind pharmacists cannot vaccinate under 3 - IL state law allows for [pharmacists to vaccinate down to the age of 7](#). During the COVID-19 pandemic the Federal Government lowered the age to 3 years old nationally through an [emergency order](#).

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