

## COVID-19 Vaccines – Pfizer Vaccine Use in Children

- On September 20, 2021, [Pfizer announced top-line results](#) from a Phase 2/3 trial evaluating the Comirnaty<sup>®</sup> vaccine in children ages 5 to 11 years old. This is the first COVID-19 vaccine data available in children younger than 12 years.
- Children ages 5 to 11 years, with or without prior evidence of infection, were given two 10 mcg doses of vaccine 21 days apart. This dose is lower than the 30 mcg dose used in individuals 12 years and older.
  - The trial enrolled 2,268 individuals
  - Immune response was measured by SARS-CoV-2 neutralizing antibody geometric mean titer (GMT) measured one month after the second dose of vaccine. The GMT was 1,197.6 for the 5 to 11 year-old population and this was considered to be similar (not inferior) to the immune response observed in individuals 16 to 25 years old (GMT = 1,146.5), which was used as the control group for this study.
  - The side effects were considered comparable to those observed in the 16 to 25 year-old group.
  - Further details are not yet available, but Pfizer plans to publish the data in a scientific peer-reviewed journal soon.
- Pfizer plans to share this information with the Food and Drug Administration to be included in the Emergency Use Authorization (EUA) for Comirnaty.
- Comirnaty has a mix of FDA approved and EUA indications
  - Approved:
    - As a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
  - EUA:
    - To prevent COVID-19 in individuals 12 through 15 years,
    - provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
  - Pending:
    - Administration of a 3<sup>rd</sup> dose (booster) at least 6 months after completion of the primary series for use in individuals 65 years of age and older and individuals at high risk of severe COVID-19, including healthcare workers and others at high risk for occupational exposure.
- Studies are ongoing in two cohorts of younger children, ages 2 to 5 years, and ages 6 months to 2 years. Data on the use of COVID-19 vaccines in these ages is expected later in 2021.
- Before COVID-19 vaccines can be given to children younger than 12 years old, the FDA must authorize this use and the CDC's ACIP panel will review the evidence and issue recommendations as they have done throughout the COVID-19 pandemic. The FDA has not yet revised the EUA for use in children younger than 12 years of age, but the OptumRx Pipeline Team continues to monitor for updated data and recommendations on COVID-19 vaccine use.