



To our Incredible Patients and Residents, their Families and Loved Ones, and our Dedicated Team Members,

We've all been encouraged by news of the development, successful testing, and approval of the effective vaccines & Boosters against COVID-19. We are pleased that our state has placed a top priority on distributing and administering the vaccine to skilled nursing centers.

We are very excited of this opportunity, as the health, safety, and wellness of our residents, patients, and staff is our top priority. In an effort of full transparency, we are doing everything we can to help facilitate the vaccination process.

We are grateful for our partnership with Pharmscript Pharmacy, as this vaccination process will be both convenient and efficient for our residents, patients, and team members. An immunization clinic will be on-site at our community, where a team of pharmacy representatives will help us manage the immunization process. As always, we will continue to maintain our COVID-19 precautionary measures throughout this process.

Our incredible clinical team and frontline heroes continue to go above and beyond to ensure the safety and well-being of those that we care for and serve each and every day.

By receiving the COVID-19 vaccinations and Boosters, we will be protecting not only our own health and safety, but also the health, safety, and wellness of our loved ones, those who we serve, and our fellow neighbors in our local community.

As shared by the CDC (Centers for Disease Control and Prevention), here are several key facts regarding the COVID-19 vaccinations and Boosters:

- Getting vaccinated & remaining Up-To-Date with Boosters can help prevent you and others from getting sick with COVID-19. If you get sick, you may spread the disease to friends, family, and others around you while you're sick, but a COVID-19 vaccination helps protect you by creating an antibody response without having to experience sickness.
- COVID-19 vaccines & Boosters will not give you COVID-19.
- COVID-19 vaccines & Boosters will not cause you to test positive on COVID-19 viral tests.
- People who have gotten sick with COVID-19 may still benefit from getting vaccinated & Boosted- experts aren't sure how long someone who has recovered from COVID-19 is protected from getting sick again.

Next Vaccination Clinic Date: Wednesday, January 4th, 2023 – Start time scheduled for 10:00 AM starting with the patient Vaccinations first

We've all been in this together since the pandemic erupted in March 2020, and it has forced us to consistently consider how to best protect ourselves and each other COVID-19 vaccines & Boosters provide us all with a great chance to continue to move forward and stop the spread of the virus. Let's come together again and continue to look out for one another by getting vaccinated as soon as possible.

Sincerely,
Administration



A nuestros increíbles pacientes y residentes, sus familias y seres queridos, y a nuestros dedicados miembros del equipo,

Todos nos sentimos alentados por las noticias del desarrollo, las pruebas exitosas y la aprobación de vacunas y refuerzos efectivos contra COVID-19. Nos complace que nuestro estado haya dado máxima prioridad a la distribución y administración de la vacuna a los centros de enfermería especializada.

Estamos muy entusiasmados con esta oportunidad, ya que la salud, la seguridad y el bienestar de nuestros residentes, pacientes y personal es nuestra principal prioridad. En un esfuerzo de total transparencia, estamos haciendo todo lo posible para ayudar a facilitar el proceso de vacunación.

Estamos agradecidos por nuestra asociación con Pharmscript Pharmacy, ya que este proceso de vacunación será conveniente y eficiente para nuestros residentes, pacientes y miembros del equipo. Habrá una clínica de inmunización en nuestra comunidad, donde un equipo de representantes farmacéuticos nos ayudará a administrar el proceso de inmunización. Como siempre, continuaremos manteniendo nuestras medidas de precaución COVID-19 durante todo este proceso.

Nuestro increíble equipo clínico y héroes de primera línea continúan yendo más allá para garantizar la seguridad y el bienestar de aquellos a quienes cuidamos y servimos todos los días.

Al recibir las vacunas y refuerzos de COVID-19, estaremos protegiendo no solo nuestra propia salud y seguridad, sino también la salud, la seguridad y el bienestar de nuestros seres queridos, aquellos a quienes servimos y nuestros vecinos en nuestra comunidad local.

Según lo compartido por los CDC (Centros para el Control y la Prevención de Enfermedades), aquí hay varios datos clave sobre las vacunas y refuerzos contra el COVID-19:

- Vacunarse y mantenerse actualizado con Boosters puede ayudar a evitar que usted y otras personas se enfermen de COVID-19. Si se enferma, puede contagiar la enfermedad a amigos, familiares y otras personas a su alrededor mientras está enfermo, pero una vacuna contra el COVID-19 ayuda a protegerlo al crear una respuesta de anticuerpos sin tener que experimentar la enfermedad.
- Las vacunas y refuerzos de COVID-19 no le darán COVID-19.
- Las vacunas y refuerzos de COVID-19 no harán que usted dé positivo en las pruebas virales de COVID-19.
- Las personas que se enfermaron con COVID-19 aún pueden beneficiarse de vacunarse y reforzarse. Los expertos no están seguros de cuánto tiempo una persona que se recuperó de COVID-19 está protegida de volver a enfermarse.

La próxima fecha de la clínica de vacunación: **Miércoles, 4 de Enero de 2023** - Hora de inicio programada para las 10:00 a. m. comenzando con los pacientes primero.

Todos hemos estado juntos en esto desde que estalló la pandemia en marzo de 2020, y nos ha obligado a considerar constantemente cómo protegernos mejor a nosotros mismos y a los demás, y detener la propagación del virus. Reunámonos de nuevo y sigamos cuidándonos unos a otros vacunándonos lo antes posible.

Atentamente,
Administración



COVID-19 Vaccines for Long-term Care Residents

Updated Nov. 18, 2022

What You Need to Know

- CDC recommends everyone stay up to date with COVID-19 vaccines for their age group:
 - [Children and teens ages 6 months-17 years](#)
 - [Adults ages 18 years and older](#)
- People who are moderately or severely immunocompromised have [different recommendations for COVID-19 vaccines](#).
- COVID-19 vaccines, including boosters, are effective at protecting people from getting seriously ill, being hospitalized, and dying.
- Updated (bivalent) boosters are the best protection from current COVID-19 variants.

If you live or work in a Long-term Care (LTC) setting, you can help protect yourself and the people around you by staying up to date with a your COVID-19 vaccines, including boosters as soon as possible.

- COVID-19 vaccines are [safe](#) and [effective](#)—especially against becoming seriously ill, being hospitalized and dying—and very important for older adults.
- [Older adults and people with certain health conditions](#) are more likely to get very sick from COVID-19.
- COVID-19 vaccines can help keep you from getting seriously ill if you do get COVID-19.
- Use the [COVID-19 booster tool](#) to learn when you can get an updated (bivalent) booster to [stay up to date with all recommended COVID-19 vaccines](#).



Residents and their families can ask a LTC provider about the current COVID-19 vaccination rate among their staff and residents.

- Nursing homes are required by the Centers for Medicare and Medicaid Services (CMS) to monitor weekly COVID-19 vaccination data for residents and healthcare personnel through [CDC's National Healthcare Safety Network](#). CMS posts updated information about individual nursing homes, including resident and staff vaccination rates, on the [CMS COVID-19 Nursing Home Data](#) [↗](#).
- Resident and staff vaccination data from assisted living and other LTC settings may be monitored by your state.

If your loved one is not able to ask questions or otherwise communicate with the LTC staff, here's what to know about consent for getting a COVID-19 vaccine:

- Consent or assent for a COVID-19 vaccine is given by LTC residents (or people appointed to make medical decisions on their behalf called a medical proxy) and documented in their charts per the provider's standard practice.
- Residents who receive a COVID-19 vaccine (or their medical proxy) also receive a fact sheet before vaccination. The fact sheet explains the risks and [benefits of COVID-19 vaccination](#).
- Some COVID-19 vaccination providers may require written, email, or verbal consent from recipients before getting vaccinated. This is at the provider's discretion; written consent is not required by federal law for COVID-19 vaccination in the United States (U.S.).
- Residents (or their medical proxies) get a [vaccination card](#) or printout that tells them which COVID-19 vaccine they received and the date they received it. If their vaccine card is full, the vaccine provider can give them another card. This should also be recorded in their medical chart.

Safe, Easy, Free, and Nearby COVID-19 Vaccination

COVID-19 vaccines are **free of charge** to all people living in the U.S., regardless of their immigration or health insurance status.

COVID-19 Vaccines Are Free

How to Get a COVID-19 Vaccine



Take these steps to get a COVID-19 vaccine for you or your family member:

- Talk with the LTC staff about getting vaccinated on site.
- Ask a family member or friend to help you schedule a vaccination appointment if you can't get vaccinated on site. Visit [vaccines.gov](#) to find providers near you.
- If you have additional questions about how to get a COVID-19 vaccine, talk with your healthcare provider.

To find COVID-19 vaccine locations near you: Search [vaccines.gov](#), text your ZIP code to 438829, or call 1-800-232-0233.

Related Pages

- › [Myths and Facts about COVID-19 Vaccines](#)
- › [What to Expect after Your COVID-19 Vaccine](#)
- › [Frequently Asked Questions about COVID-19 Vaccination](#)
- › [COVID-19 Vaccine Boosters](#)
- › [Information about Medicare and COVID-19 Vaccine](#) 
- › [Talking with Patients about COVID-19 Vaccination](#)



For Healthcare Workers

[Post-Vaccination Considerations for Residents](#)

Last Updated Nov. 18, 2022



Stay Up to Date with COVID-19 Vaccines Including Boosters

Updated Dec. 9, 2022

On December 9th, 2022, CDC expanded the use of updated (bivalent) COVID-19 vaccines for children ages 6 months-5 years. Please see the [CDC](#) and [FDA](#) media statements for additional information.

What You Need to Know

- Updated (bivalent) boosters became available on:
 - **September 2, 2022**, for people 12 years of age and older
 - **October 12, 2022**, for people aged 5–11
- CDC recommends everyone stay up to date with COVID-19 vaccines for their age group:
 - [Children and teens ages 6 months–17 years](#)
 - [Adults ages 18 years and older](#)
- Getting a COVID-19 vaccine after you recover from COVID-19 infection provides added protection against COVID-19.
- If you recently had COVID-19, you **may** consider [delaying your next vaccine dose \(primary dose or booster\)](#) by 3 months from when your symptoms started or, if you had no symptoms, when you first received a positive test.
- People who are moderately or severely immunocompromised have [different recommendations for COVID-19 vaccines](#).
- COVID-19 vaccine and booster recommendations may be updated as CDC continues to monitor the latest COVID-19 data.



Updated Boosters Are Recommended for Some People

CDC recommends that **people ages 5 years and older** receive one updated (bivalent) booster if it has been at least 2 months since their last COVID-19 vaccine dose, whether that was:

- Their final primary series dose, or
- An original (monovalent) booster

People who have gotten more than one original (monovalent) booster are also recommended to get an updated (bivalent) booster.

Find Out When You Can Get Your Booster



Boosters are an important part of protecting yourself or your child from getting seriously ill or dying from COVID-19. People ages 5 years and older should receive one updated (bivalent) booster, including those who are moderately or severely immunocompromised.

[Find Out When to Get a Booster >](#)

People who did not receive Pfizer-BioNTech, Moderna, Novavax, or Johnson & Johnson's Janssen, like [people who were vaccinated abroad](#), have specific recommendations.

This tool is intended to help you make decisions about getting COVID-19 vaccinations. It should not be used to diagnose or treat COVID-19.

About COVID-19 Vaccines

COVID-19 vaccines available in the United States are effective at protecting people from getting seriously ill, being hospitalized, and dying. As with other vaccine-preventable diseases, you are protected best from COVID-19 when you stay up to date with the recommended vaccinations, including recommended boosters.

Four COVID-19 vaccines are approved or authorized in the United States:

- Pfizer-BioNTech
- Moderna
- Novavax
- Johnson & Johnson's Janssen (J&J/Janssen) (However, CDC recommends that the J&J/Janssen COVID-19 vaccine only be [considered in certain situations](#), due to safety concerns.)

Updated (Bivalent) Boosters

The updated (bivalent) boosters are called "bivalent" because they protect against **both** the original virus that causes COVID-19 **and** the Omicron variant BA.4 and BA.5.

Previous boosters are called "monovalent" because they were designed to protect against the original virus that causes COVID-19. They also provide some protection against Omicron, but not as much as the updated (bivalent) boosters.

The virus that causes COVID-19 has changed over time. The different versions of the virus that have developed over time are called variants. Learn more about [variants of the COVID-19 virus](#).

Two COVID-19 vaccine manufacturers, Pfizer and Moderna, have developed updated (bivalent) COVID-19 boosters.

When Are You Up to Date?

You are **up to date** with your COVID-19 vaccines if you have completed a COVID-19 vaccine primary series and received the most recent booster dose recommended for you by CDC.

COVID-19 vaccine recommendations are based on three things:

1. Your age

2. The vaccine you first received, and
3. The length of time since your last dose

People who are moderately or severely immunocompromised have [different recommendations for COVID-19 vaccines](#).

You are still up to date if you receive all COVID-19 vaccine doses recommended for you and then become ill with COVID-19. You do not need to be immediately revaccinated or receive an additional booster.



For Healthcare Workers: Learn more about [COVID-19 vaccine schedules](#).

Getting Vaccines If You Had or Currently Have COVID-19

If you recently had COVID-19, you **may** consider delaying your next vaccine dose (whether a primary dose or booster) by 3 months from when your symptoms started or, if you had no symptoms, when you first received a positive test.

Reinfection is less likely in the weeks to months after infection. However, certain factors, such as personal risk of severe disease, or risk of disease in a loved one or close contact, local [COVID-19 Community Level](#), and the most common [COVID-19 variant](#) currently causing illness, could be reasons to get a vaccine sooner rather than later.

Children and teens ages 6 months–17 years

COVID-19 vaccine dosage is based on age on the day of vaccination, not on size or weight. Children get a smaller dose of COVID-19 vaccine than teens and adults based on their age group.

Pfizer-BioNTech



AGE GROUP

6 MONTHS–4 YEARS

1st Dose
Pfizer-BioNTech
PRIMARY SERIES

2nd Dose
Pfizer-BioNTech
PRIMARY SERIES
3–8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech
PRIMARY SERIES
At least 8 weeks after 2nd dose

Up to Date: 2 weeks after 3rd dose, since a booster is not recommended for this age group at this time

More details: [Staying up to date](#)

AGE GROUP

5–11 YEARS

1st Dose
Pfizer-BioNTech
PRIMARY SERIES

2nd Dose
Pfizer-BioNTech
PRIMARY SERIES
3–8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech
UPDATED (BIVALENT) BOOSTER

At least 2 months after 2nd dose or last booster, children age 5 years can only get a Pfizer-BioNTech booster, and children ages 6–11 years can get a Pfizer-BioNTech or Moderna booster.

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

AGE GROUP

12–17 YEARS

1st Dose
Pfizer-BioNTech
 PRIMARY SERIES

2nd Dose
Pfizer-BioNTech
 PRIMARY SERIES
 3–8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech or Moderna
 UPDATED (BIVALENT) BOOSTER
 At least 2 months after 2nd dose or last booster

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

[Pfizer-BioNTech Vaccine Overview](#)

Moderna

AGE GROUP

6 MONTHS–5 YEARS

1st Dose
Moderna
 PRIMARY SERIES

2nd Dose
Moderna
 PRIMARY SERIES
 4–8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech
 UPDATED (BIVALENT) BOOSTER
 Children 5 years of age can get a Pfizer-BioNTech booster at least 2 months after their 2nd dose. (Children 6 months to 4 years are not recommended for a booster.)

Up to Date: Children 6 months to 4 years of age are up to date two weeks after completing the 2nd dose of their primary series. Children 5 years of age who received a Moderna primary series are up to date immediately after they have received the most recent booster recommended for them.
More details: [Staying up to date](#)

AGE GROUP

6-17 YEARS

1st Dose
Moderna
PRIMARY SERIES

2nd Dose
Moderna
PRIMARY SERIES
4-8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech or Moderna
UPDATED (BIVALENT) BOOSTER
At least 2 months after 2nd primary series dose

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

[Moderna Vaccine Overview](#)

Novavax

AGE GROUP

12-17 YEARS

Novavax is not authorized as a booster dose at this time.

1st Dose
Novavax
PRIMARY SERIES

2nd Dose
Novavax
PRIMARY SERIES
3-8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech or Moderna
UPDATED (BIVALENT) BOOSTER
At least 2 months after 2nd primary series dose

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

[Novavax Vaccine Overview](#)

Adults ages 18 years and older

Pfizer-BioNTech

AGE GROUP

18 YEARS AND OLDER

1st Dose
Pfizer-BioNTech
PRIMARY SERIES

2nd Dose
Pfizer-BioNTech
PRIMARY SERIES
3-8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech or Moderna
UPDATED (BIVALENT) BOOSTER

At least 2 months after 2nd primary series dose or last booster

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

[Pfizer-BioNTech Vaccine Overview](#)

Moderna

AGE GROUP

18 YEARS AND OLDER

1st Dose
Moderna
PRIMARY SERIES

2nd Dose
Moderna
PRIMARY SERIES
4–8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech or Moderna
UPDATED (BIVALENT) BOOSTER
At least 2 months after 2nd primary series dose or last booster

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

[Moderna Vaccine Overview](#)

Novavax

AGE GROUP

18 YEARS AND OLDER

1st Dose
Novavax
PRIMARY SERIES

2nd Dose
Novavax
PRIMARY SERIES
3–8 weeks after 1st dose
More details: [Getting your 2nd dose](#)

3rd Dose
Pfizer-BioNTech or Moderna
UPDATED (BIVALENT) BOOSTER
At least 2 months after 2nd primary series dose

A monovalent Novavax booster is available in limited situations
More details: [Novavax booster](#)

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

[Novavax Vaccine Overview](#)

Johnson and Johnson's Janssen



AGE GROUP

18 YEARS AND OLDER

1st Dose
J&J/Janssen
PRIMARY SERIES

2nd Dose
Pfizer-BioNTech or Moderna
UPDATED (BIVALENT) BOOSTER
At least 2 months after 2nd
primary series dose

A monovalent J&J/Janssen
booster is available in limited
situations.
More details: [J&J/Janssen booster](#)

Up to Date: Immediately after you have received the most recent booster recommended for you
More details: [Staying up to date](#)

[J&J/Janssen Vaccine Overview](#)

Getting your 2nd dose: Talk to your healthcare or vaccine provider about the timing for the 2nd dose in your primary series.

- **People ages 6 months through 64 years, and especially males ages 12 through 39 years,** may consider getting the 2nd primary Pfizer-BioNTech, Moderna, or Novavax 8 weeks after the 1st dose.
 - A longer time between the 1st and 2nd primary doses may increase how much protection the vaccines offer, and further minimize the rare risk of [myocarditis and pericarditis](#).
- **Anyone wanting protection due to high levels of community transmission, people ages 65 years and older, or people who are more likely to get very sick from COVID-19,** should get the second dose of:
 - **Pfizer-BioNTech** COVID-19 vaccine **3 weeks (or 21 days)** after the first dose.
 - **Moderna** COVID-19 vaccine **4 weeks (or 28 days)** after the first dose.
 - **Novavax** COVID-19 vaccine **3 weeks (or 21 days)** after the first dose.

Staying up to date: If you have completed your primary series, but are not yet eligible for a booster, you are also considered up to date.

Novavax booster: You may get a monovalent Novavax booster **if** you are unable or unwilling to receive a Pfizer or Moderna updated (bivalent) COVID-19 booster **and** you meet the following requirements:

- You are 18 years of age or older
- You completed a COVID-19 vaccine primary series at least 6 months ago
- You have **not** gotten any other booster dose

Mixing COVID-19 Vaccine Products

Do Not Mix Primary Series

CDC does not recommend mixing products for your primary series doses. If you received Pfizer-BioNTech, Moderna, or Novavax for the first dose of your primary series, you should get the same product for all following primary series doses.

Mixing Boosters

The following information applies to boosters for people ages 5 and older. Children under age 5 years are not recommended to receive a booster at this time.

Children age 5 years old

Children age 5 years old are only currently recommended to receive the updated (bivalent) Pfizer-BioNTech booster, and they can get this booster whether they received the Pfizer-BioNTech or Moderna primary series.

Children age 5 years old can no longer get an original (monovalent) mRNA (Pfizer-BioNTech or Moderna) booster.

People ages 6 years and older

People ages 6 years and older can get a different product for their updated (bivalent) booster than they received for their primary series or last booster. People ages 6 years and older can no longer get an original (monovalent) mRNA (Pfizer-BioNTech or Moderna) booster.

To find COVID-19 vaccine locations near you: Search [vaccines.gov](https://www.vaccines.gov), text your ZIP code to 438829, or call 1-800-232-0233.



Learn About Getting Your Vaccine

- Do you need to wait to get vaccinated after getting COVID-19 or getting treatment for COVID-19?
- How can you prepare for vaccination?
- What can you expect during and after your vaccination?

[Getting Your COVID-19 Vaccine](#)

Vaccination Received Outside the United States

Specific recommendations for people vaccinated outside the United States depend on whether:


- The vaccine(s) received are accepted in the United States as valid vaccinations
- The primary series was completed and, if eligible, a booster dose was received







These recommendations apply only to people who are **not** moderately or severely immunocompromised.

COVID-19 vaccines available abroad that are accepted in the United States as valid vaccinations

Vaccines approved or authorized by the U.S. Food and Drug Administration (FDA) currently include:

- Pfizer-BioNTech
- Moderna
- Novavax
- Johnson & Johnson's Janssen

Vaccines listed for emergency use by the [World Health Organization \(WHO\)](#)  currently include those that are listed above and the following:

- [AstraZeneca/Oxford vaccine](#) 
- [Sinopharm](#) 
- [Sinovac](#) 
- [COVAXIN](#) 
- [Covovax](#) 
- [CanSino](#) 

If You Receive a Vaccine That is Not in the U.S. Accepted List Above

- Wait at least 28 days after the last dose you received of that vaccine then start COVID-19 vaccination over with a COVID-19 vaccine that has been approved or authorized by the FDA.
- If the FDA has not approved or authorized a vaccine there may be limited data available or reviewed on the safety or effectiveness of the COVID-19 vaccine.

How to Complete a Primary Series

- Receive 1 dose of a single-dose accepted COVID-19 vaccine
- Receive 2 doses of a 2-dose accepted COVID-19 vaccine

CDC does not recommend mixing different COVID-19 vaccines for the primary series, but CDC is aware that mixing COVID-19 vaccines for the primary series is increasingly common in many countries outside the United States. Therefore, people who receive a mixed primary series, meaning two different COVID-19 vaccines, have completed the series.

If You Started But Didn't Complete a Primary Series

- You will need to complete the primary series. If you got 1 dose of Moderna, Novavax, or Pfizer-BioNTech, it is best to get the same vaccine again to complete the primary series.

After Completing a Primary Series

If you are not yet eligible for a booster, you are considered up to date. Otherwise, stay up to date by getting the booster recommended for you as soon as a booster is recommended for you based on your age and the appropriate time has passed since completing the primary series.

Proof of vaccination card in the United States

The white CDC [COVID-19 vaccination cards](#) are issued only to people vaccinated in the United States. CDC recommends that people vaccinated outside of the United States keep their documentation of being vaccinated in another country as proof of vaccination. CDC does not keep vaccination records nor determine how vaccination records are used. People can update their records with vaccines they received while outside of the United States by:

- Contacting the [immunization information system \(IIS\)](#) in their state.

- Contacting their healthcare provider or local or state immunization program through their [state's health department](#).

Learn more about [COVID-19 vaccination cards](#).

For Healthcare Workers: Learn more about the recommendations for [people vaccinated outside of the United States](#).



For Healthcare and Public Health

[Use of COVID-19 Vaccines in the United States: Interim Clinical Considerations](#)

Last Updated Dec. 9, 2022

**FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE
(VACCINATION PROVIDERS)**

EMERGENCY USE AUTHORIZATION (EUA)

**PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT
(ORIGINAL ANDOMICRON BA.4/BA.5)**

**BOOSTER DOSE FOR 12 YEARS OF AGE AND OLDER
DO NOT DILUTE**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) for active immunization to prevent COVID-19 in individuals 12 years of age and older.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent. It is supplied in single dose and multiple dose vials with gray caps and labels with gray borders.

DO NOT DILUTE PRIOR TO USE.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use in individuals 12 years of age and older as a single booster dose administered at least 2 months after either:

- completion of primary vaccination with any authorized or approved COVID-19 vaccine, or
- receipt of the most recent booster dose with any authorized or approved monovalent¹ COVID-19 vaccine.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in a single dose and multiple dose vial with a gray cap and a label with a gray border, which **MUST NOT BE DILUTED PRIOR TO USE.**

Pfizer-BioNTech COVID-19 Vaccine, Bivalent, which is supplied in a single dose and multiple dose vial with a gray cap and a label with a gray border, should not be used in individuals 6 months through 11 years of age.²

¹ Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

² Different presentations of Pfizer-BioNTech COVID-19 Vaccine, Bivalent are available. Pfizer-BioNTech COVID-19 Vaccine, Bivalent, supplied in multiple dose vials with maroon caps and labels with maroon borders, is available for use as a third dose of the primary series in individuals 6 months through 4 years of age. Pfizer-BioNTech COVID-19 Vaccine, Bivalent, supplied in multiple dose vials with orange caps and labels with orange borders, is available for use as a single booster dose in individuals 5 through 11 years of age.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of myocarditis, cases of pericarditis, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent. See “MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for active immunization to prevent COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

The storage, preparation, and administration information in this Fact Sheet apply to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in:

- single dose vials with gray caps and labels with gray borders, and
- multiple dose vials with gray caps and labels with gray borders.

DO NOT DILUTE PRIOR TO USE.

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Vial Storage Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may arrive frozen at ultra-cold conditions in thermal containers with dry ice.

Once received, frozen vials may be immediately transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 single dose vials may take up to 2 hours to thaw at this temperature. A carton of 10 multiple dose vials may take up to 6 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) for up to 18 months from the date of manufacture. Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.

If cartons of Pfizer-BioNTech COVID-19 Vaccine, Bivalent are received at 2°C to 8°C (35°F to 46°F), they should be stored at 2°C to 8°C (35°F to 46°F). Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

Regardless of storage condition, the vaccine should not be used after 18 months from the date of manufacture printed on the vial and cartons.

Vial Storage During Use

If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to the first puncture. After first puncture, the multiple dose vial should be held between 2°C to 25°C (35°F to 77°F). Multiple dose vials should be discarded 12 hours after first puncture.

Transportation of Vials

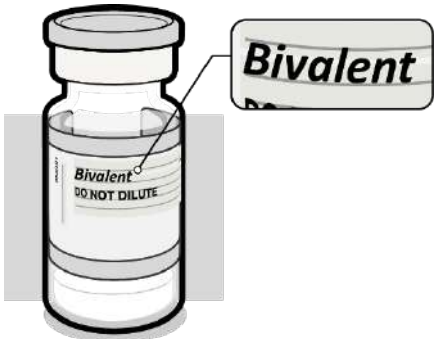
If local redistribution is needed, vials may be transported at -90°C to -60°C (-130°F to -76°F) or at 2°C to 8°C (35°F to 46°F).

Dosing and Schedule

A single booster dose (0.3 mL) of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months after completion of primary vaccination with any authorized or approved COVID-19 vaccine or after receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

Dose Preparation

- Pfizer-BioNTech COVID-19 Vaccine, Bivalent vials contain a frozen suspension without preservative. Each vial must be thawed prior to administration. **DO NOT DILUTE** prior to use.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)].
- Refer to thawing and preparation instructions in the panels below.

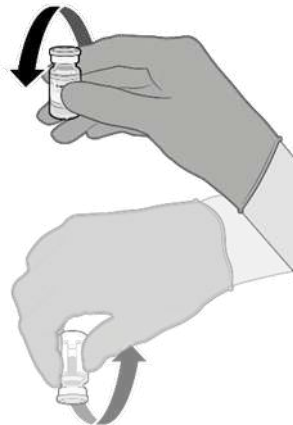
| Preparation Instructions | |
|--|--|
| Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial with Gray Cap and Label with Gray Border – VIAL VERIFICATION | |
|  <p>✓ Gray cap and label with gray border.</p> | <ul style="list-style-type: none">• Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine, Bivalent:<ul style="list-style-type: none">○ has a gray cap and a label with a gray border○ states Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). |

THAWING PRIOR TO USE



Store in the refrigerator for up to 10 weeks prior to use.

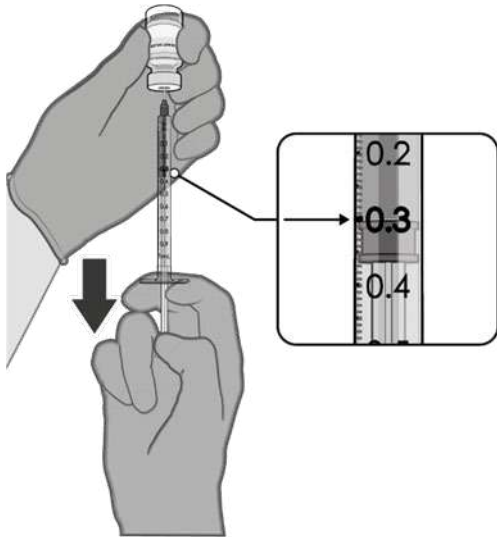
- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine, Bivalent before use either by:
 - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)].
 - A carton of 10 single dose vials may take up to 2 hours to thaw.
 - A carton of 10 multiple dose vials may take up to 6 hours to thaw.
 - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Thawed vials can be stored in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 10 weeks prior to use.
- Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.



Gently × 10

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discolored or if particles are observed after mixing.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES



Withdraw 0.3 mL dose of vaccine.

Single Dose Vial

- Withdraw a single 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Administer immediately.
- Discard vial and any excess volume.

Multiple Dose Vial

- Multiple dose vials contain 6 doses of 0.3 mL each.
- Withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent preferentially using low dead-volume syringes and/or needles. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.
- Administer immediately.
- If the amount of vaccine remaining in a multiple dose vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.

Multiple Dose Vial – Record Date and Time of First Puncture



**Record the date and time of first puncture.
Use within 12 hours after first puncture.**

- Record the date and time of first vial puncture on the Pfizer-BioNTech COVID-19 Vaccine, Bivalent multiple dose vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after first puncture.

Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The vaccine will be a white to off-white suspension. Do not administer if vaccine is discolored or contains particulate matter.

After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (*see Full EUA Prescribing Information*).

Warnings

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Monitor Pfizer-BioNTech COVID-19 Vaccine, Bivalent recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

Myocarditis and Pericarditis

Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for

vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Adverse Reactions

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on:

- safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved, hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
- safety data from clinical trials which evaluated primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, and
- post marketing safety data with Pfizer-BioNTech COVID-19 Vaccine.

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process. The bivalent vaccine (Original and Omicron BA.1) contained 15 mcg of nucleoside-modified messenger RNA (modRNA) encoding the S-glycoprotein of SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 15 mcg of modRNA encoding the S-glycoprotein of SARS-CoV-2 Omicron variant lineage BA.1, for a total of 30 mcg modRNA per dose. This is the same total quantity of modRNA per dose as a dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent and as a dose of Pfizer-BioNTech COVID-19 Vaccine authorized for primary vaccination in individuals 12 years of age and older (and previously, but no longer, authorized for booster vaccination in individuals 12 years of age and older).

Adverse Reactions in Clinical Trials

Adverse reactions following administration of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine or the bivalent vaccine (Original and Omicron BA.1) that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, injection site swelling, fever, injection site redness, lymphadenopathy, nausea, malaise, pain in extremity, rash, and decreased appetite (*see Full EUA Prescribing Information*).

Adverse Reactions Identified in Post Authorization Experience

Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), syncope, and dizziness have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

Additional adverse reactions, some of which may be serious, may become apparent with post-authorization use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Vaccine Information Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Vaccine Information Fact Sheet for Recipients and Caregivers) prior to the individual receiving each dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent which is not an FDA-approved vaccine.
- There is an option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- The significant known and potential risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION³

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, Bivalent the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine, Bivalent for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use in individuals 12 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine, Bivalent or their caregiver, information consistent with the “Vaccine Information Fact Sheet for Recipients and Caregivers” prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.

³ Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine must adhere to the same reporting requirements.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events* (irrespective of attribution to vaccination),
 - cases of myocarditis,
 - cases of pericarditis,
 - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
 - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of myocarditis, cases of pericarditis, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent to recipients.

* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent 1 of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.


To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

| Website | Fax number | Telephone number |
|--|----------------|------------------|
| www.pfizersafetyreporting.com | 1-866-635-8337 | 1-800-438-1985 |

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine, Bivalent Fact Sheets, please scan the QR code provided below.

| Global website | Telephone number |
|---|---|
| <p data-bbox="363 571 670 604">www.cvdvaccine.com</p>  | <p data-bbox="997 617 1211 646">1-877-829-2619</p> <p data-bbox="976 667 1232 697">(1-877-VAX-CO19)</p> |

AVAILABLE ALTERNATIVES

There may be clinical trials or availability under EUA of other COVID-19 vaccines for use as a booster dose, including bivalent vaccines that contain or encode the spike protein of the Omicron variant of SARS-CoV-2.

FEDERAL COVID-19 VACCINATION PROGRAM

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see <https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html>.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved

product, Pfizer-BioNTech COVID-19 Vaccine, Bivalent for active immunization to prevent COVID-19.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

For the authorized uses, although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany



Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1537-4.0

Revised: 8 December 2022

Revised: 8 December 2022

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

**FULL EMERGENCY USE
AUTHORIZATION (EUA) PRESCRIBING
INFORMATION**

**PFIZER-BIONTECH COVID-19 VACCINE,
BIVALENT (ORIGINAL ANDOMICRON
BA.4/BA.5)**

**FULL EMERGENCY USE AUTHORIZATION PRESCRIBING
INFORMATION: CONTENTS***

- 1 AUTHORIZED USE**
 - 2 DOSAGE AND ADMINISTRATION**
 - 2.1 Preparation for Administration
 - 2.2 Administration Information
 - 2.3 Vaccination Schedule
 - 3 DOSAGE FORMS AND STRENGTHS**
 - 4 CONTRAINDICATIONS**
 - 5 WARNINGS AND PRECAUTIONS**
 - 5.1 Management of Acute Allergic Reactions
 - 5.2 Myocarditis and Pericarditis
 - 5.3 Syncope
 - 5.4 Altered Immunocompetence
 - 5.5 Limitation of Effectiveness
 - 6 OVERALL SAFETY SUMMARY**
 - 6.1 Clinical Trials Experience
 - 6.2 Post Authorization Experience
 - 8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING
ADVERSE EVENTS AND VACCINE ADMINISTRATION
ERRORS**
 - 10 DRUG INTERACTIONS**
 - 11 USE IN SPECIFIC POPULATIONS**
 - 11.1 Pregnancy
 - 11.2 Lactation
 - 11.3 Pediatric Use
 - 11.4 Geriatric Use
 - 13 DESCRIPTION**
 - 14 CLINICAL PHARMACOLOGY**
 - 14.1 Mechanism of Action
 - 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR
EUA**
 - 18.1 Efficacy of Primary Series of Pfizer-BioNTech COVID-19 Vaccine in Participants 16 Years of Age and Older
 - 18.2 Efficacy of Primary Series of Pfizer-BioNTech COVID-19 Vaccine in Participants 12 Through 15 Years of Age
 - 18.3 Immunogenicity of Primary Series of Pfizer-BioNTech COVID-19 Vaccine in Participants 12 Through 15 Years of Age
 - 18.4 Immunogenicity of the Bivalent Vaccine (Original and Omicron BA.1) Administered as a Second Booster Dose
 - 18.5 Immunogenicity of a First Booster Dose With a Pfizer-BioNTech COVID-19 Vaccine Primary Series in Participants 18 Through 55 Years of Age
 - 18.6 Immunogenicity of a First Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine
 - 19 HOW SUPPLIED/STORAGE AND HANDLING**
 - 20 PATIENT COUNSELING INFORMATION**
 - 21 CONTACT INFORMATION**
- * Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

This EUA Prescribing Information pertains only to Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

2 DOSAGE AND ADMINISTRATION

The storage, preparation, and administration information in this Prescribing Information apply to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in:

- single dose vials with gray caps and labels with gray borders, and
- multiple dose vials with gray caps and labels with gray borders.

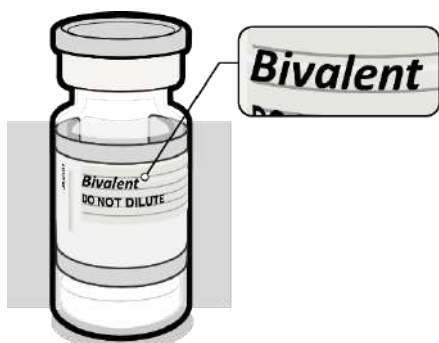
DO NOT DILUTE PRIOR TO USE.

2.1 Preparation for Administration

- Pfizer-BioNTech COVID-19 Vaccine, Bivalent vials contain a frozen suspension without preservative. Each vial must be thawed prior to administration. **DO NOT DILUTE** prior to use.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] [*see How Supplied/Storage and Handling (19)*].
- Refer to thawing and preparation instructions in the panels below.

Preparation Instructions

Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial with Gray Cap and Label with Gray Border – VIAL VERIFICATION



✓ Gray cap and label with gray border.

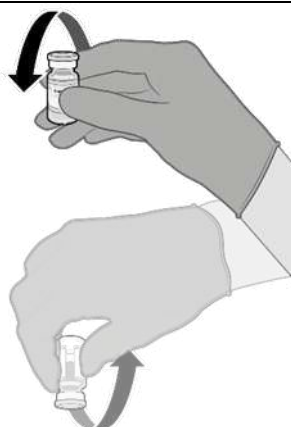
- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine, Bivalent:
 - has a gray cap and a label with a gray border
 - states Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).

THAWING PRIOR TO USE



Store in the refrigerator for up to 10 weeks prior to use.

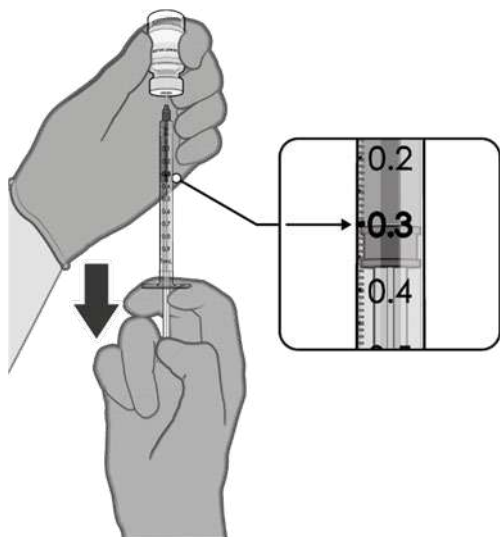
- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine, Bivalent before use either by:
 - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)].
 - A carton of 10 single dose vials may take up to 2 hours to thaw.
 - A carton of 10 multiple dose vials may take up to 6 hours to thaw.
 - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Thawed vials can be stored in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 10 weeks prior to use.
- Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.



Gently × 10

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discolored or if particles are observed after mixing.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES



Withdraw 0.3 mL dose of vaccine.

Single Dose Vial

- Withdraw a single 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Administer immediately.
- Discard vial and any excess volume.

Multiple Dose Vial

- Multiple dose vials contain 6 doses of 0.3 mL each.
- Withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent preferentially using low dead-volume syringes and/or needles. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.
- Administer immediately.
- If the amount of vaccine remaining in a multiple dose vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.

Multiple Dose Vial – Record Date and Time of First Puncture



**Record the date and time of first puncture.
Use within 12 hours after first puncture.**

- Record the date and time of first vial puncture on the Pfizer-BioNTech COVID-19 Vaccine, Bivalent multiple dose vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after first puncture.

2.2 Administration Information

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The vaccine will be a white to off-white suspension. Do not administer if vaccine is discolored or contains particulate matter.

After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately.

2.3 Vaccination Schedule

A single booster dose (0.3 mL) of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months after completion of primary vaccination with any authorized or approved COVID-19 vaccine or after receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for injection.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent is 0.3 mL [*see Dosage and Administration (2.1)*].

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent [*see Description (13)*].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Monitor Pfizer-BioNTech COVID-19 Vaccine, Bivalent recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

5.2 Myocarditis and Pericarditis

Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

5.5 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of myocarditis, cases of pericarditis, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.⁴ To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on:

- safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved, hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
- safety data from clinical trials which evaluated primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, and
- post marketing safety data with Pfizer-BioNTech COVID-19 Vaccine.

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process. The bivalent vaccine (Original and Omicron BA.1) contained 15 mcg of nucleoside-modified messenger RNA (modRNA) encoding the S-glycoprotein of SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 15 mcg of modRNA encoding the S-glycoprotein of SARS-CoV-2 Omicron variant lineage BA.1, for a total of 30 mcg modRNA per dose. This is the same total quantity of modRNA per dose as a dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent and as a dose of Pfizer-BioNTech COVID-19 Vaccine authorized for primary vaccination in individuals 12 years of age and older (and previously, but no longer, authorized for booster vaccination in individuals 12 years of age and older).

The clinical study that evaluated a booster dose of the bivalent vaccine (Original and Omicron BA.1) included participants greater than 55 years of age. Adverse reactions following administration of the bivalent vaccine (Original and Omicron BA.1) as a second booster dose included pain at the injection site (58.1%), fatigue (49.2%), headache (33.6%), muscle pain (22.3%), chills (13.0%), joint pain (11.3%), injection site redness

⁴ Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine must adhere to the same reporting requirements.

(7.0%), injection site swelling (6.6%), fever (5.0%), lymphadenopathy (0.3%), nausea (0.3%), and malaise (0.3%).

In a clinical study of participants 18 through 55 years of age, adverse reactions following administration of a first booster dose of Pfizer-BioNTech COVID-19 Vaccine were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%). Severe allergic reactions (including anaphylaxis), myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Overall 3,013 participants 6 months through 4 years of age and 3,109 participants 5 through 11 years of age in Study 3 (NCT04816643) and 22,851 participants 12 years of age and older in Study 1 (NCT04380701) and Study 2 (NCT04368728) have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine during the Phase 2/3 blinded placebo-controlled follow-up period. In a subset of Study 4 (NCT04955626), 305 participants greater than 55 years of age received a second booster dose with the bivalent vaccine (Original and Omicron BA.1).

Bivalent Vaccine (Original and Omicron BA.1) Administered as a Second Booster Dose

In Study 4, a total of 610 participants greater than 55 years of age previously vaccinated with a 2-dose primary series and 1 booster dose of Pfizer-BioNTech COVID-19 Vaccine went on to receive a second booster dose with either Pfizer-BioNTech COVID-19 Vaccine or the bivalent vaccine (Original and Omicron BA.1).

The 305 participants greater than 55 years who received a second booster dose with Pfizer-BioNTech COVID-19 received it 5.3 to 13.1 months after receiving the first booster dose and had a median follow-up time of 1.8 months up to a data cut-off date of May 16, 2022. Their median age was 66 years (range 56 through 87 years of age), 47.5% were male and 52.5% were female, 87.9% were White, 18.7% were Hispanic/Latino, 4.3% were Asian, and 6.2% were Black or African American.

The 305 participants greater than 55 years who received a second booster dose with the bivalent vaccine (Original and Omicron BA.1) received it 4.7 to 11.5 months after receiving the first booster dose and had a median follow-up time of 1.7 months up to a data cut-off date of May 16, 2022. Their median age was 67 years (range 56 through 85 years of age), 53.1% were male and 46.9% were female, 89.8% were White, 14.8% were Hispanic/Latino, 5.2% were Asian, and 4.3% were Black or African American.

Solicited Local and Systemic Adverse Reactions

Table 1 and Table 2 present the frequency and severity of reported solicited local reactions and systemic reactions, respectively, within 7 days of a second booster dose of Pfizer-BioNTech COVID-19 Vaccine or bivalent vaccine (Original and Omicron BA.1).

In participants who received the bivalent vaccine (Original and Omicron BA.1), the mean duration of injection site pain, redness, and swelling was 2.2 days (range 1 to 12 days), 2.9 days (range 1 to 10 days), and 1.9 days (range 1 to 4 days), respectively.

Table 1: Local Adverse Reactions, by Maximum Severity, Within 7 Days After a Second Booster Dose – Participants Greater Than 55 Years of Age – Safety Population

| | Pfizer-BioNTech COVID-19 Vaccine N ^a =298 n ^b (%) | Bivalent Vaccine (Original and Omicron BA.1) N ^a =301 n ^b (%) |
|---|--|--|
| Redness^c | | |
| Any (>2 cm) | 19 (6.4) | 21 (7.0) |
| Mild | 12 (4.0) | 13 (4.3) |
| Moderate | 6 (2.0) | 8 (2.7) |
| Severe | 1 (0.3) | 0 |
| Swelling^c | | |
| Any (>2 cm) | 18 (6.0) | 20 (6.6) |
| Mild | 10 (3.4) | 14 (4.7) |
| Moderate | 8 (2.7) | 6 (2.0) |
| Severe | 0 | 0 |
| Pain at the injection site^d | | |
| Any | 179 (60.1) | 175 (58.1) |
| Mild | 154 (51.7) | 159 (52.8) |
| Moderate | 24 (8.1) | 15 (5.0) |
| Severe | 1 (0.3) | 1 (0.3) |

Note: Adverse Reactions were collected in the electronic diary (e-diary) from day of vaccination (Day 1) through Day 7 after the study vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the study vaccination.

b. n = Number of participants with the specified adverse reaction.

c. Mild: >2.0 to 5.0 cm; Moderate: >5.0 to 10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Table 2: Systemic Adverse Reactions, by Maximum Severity, Within 7 Days After the Second Booster Dose – Participants Greater Than 55 Years of Age – Safety Population

| | Pfizer-BioNTech COVID-19 Vaccine N ^a =298 n ^b (%) | Bivalent Vaccine (Original and Omicron BA.1) N ^a =301 n ^b (%) |
|----------------------------|--|--|
| Fever | | |
| ≥38.0°C | 11 (3.7) | 15 (5.0) |
| ≥38.0°C to 38.4°C | 6 (2.0) | 11 (3.7) |
| >38.4°C to 38.9°C | 5 (1.7) | 0 |
| >38.9°C to 40.0°C | 0 | 4 (1.3) |
| >40.0°C | 0 | 0 |
| Fatigue^c | | |
| Any | 135 (45.3) | 148 (49.2) |
| Mild | 70 (23.5) | 88 (29.2) |
| Moderate | 64 (21.5) | 55 (18.3) |
| Severe | 1 (0.3) | 5 (1.7) |

| | Pfizer-BioNTech COVID-19 Vaccine N ^a =298 n ^b (%) | Bivalent Vaccine (Original and Omicron BA.1) N ^a =301 n ^b (%) |
|--|--|--|
| Headache^c | | |
| Any | 79 (26.5) | 101 (33.6) |
| Mild | 47 (15.8) | 71 (23.6) |
| Moderate | 31 (10.4) | 29 (9.6) |
| Severe | 1 (0.3) | 1 (0.3) |
| Chills^c | | |
| Any | 49 (16.4) | 39 (13.0) |
| Mild | 32 (10.7) | 25 (8.3) |
| Moderate | 17 (5.7) | 14 (4.7) |
| Severe | 0 | 0 |
| Vomiting^d | | |
| Any | 4 (1.3) | 5 (1.7) |
| Mild | 2 (0.7) | 5 (1.7) |
| Moderate | 2 (0.7) | 0 |
| Severe | 0 | 0 |
| Diarrhea^e | | |
| Any | 13 (4.4) | 27 (9.0) |
| Mild | 10 (3.4) | 18 (6.0) |
| Moderate | 3 (1.0) | 5 (1.7) |
| Severe | 0 | 4 (1.3) |
| New or worsened muscle pain^c | | |
| Any | 59 (19.8) | 67 (22.3) |
| Mild | 35 (11.7) | 40 (13.3) |
| Moderate | 24 (8.1) | 27 (9.0) |
| Severe | 0 | 0 |
| New or worsened joint pain^c | | |
| Any | 27 (9.1) | 34 (11.3) |
| Mild | 16 (5.4) | 23 (7.6) |
| Moderate | 11 (3.7) | 11 (3.7) |
| Severe | 0 | 0 |
| Use of antipyretic or pain medication^f | | |
| | 80 (26.8) | 88 (29.2) |

Note: Adverse reactions and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from day of vaccination (Day 1) through Day 7 after the study vaccination.

- N = Number of participants reporting at least 1 yes or no response for the specified adverse reaction after the study vaccination.
- n = Number of participants with the specified adverse reaction.
- Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
- Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
- Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
- Severity was not collected for use of antipyretic or pain medication.

Unsolicited Adverse Events

Overall, the participants who received a second booster dose with the bivalent vaccine (Original and Omicron BA.1) had a median follow-up time of 1.7 months (range 1.0 to 2.0 months) to the cut-off date (May 16, 2022).

In an analysis of all unsolicited adverse events reported following the second booster dose, through 1 month after the booster dose, those assessed as adverse reactions not already captured by solicited local and systemic reactions were lymphadenopathy (n = 1, 0.3%) for the Pfizer-BioNTech COVID-19 Vaccine and (n = 1, 0.3%) for the bivalent vaccine (Original and Omicron BA.1), nausea (n = 1, 0.3%) for the Pfizer-BioNTech COVID-19 Vaccine and (n = 1, 0.3%) for the bivalent vaccine (Original and Omicron BA.1), and malaise (n = 0) for the Pfizer-BioNTech COVID-19 Vaccine and (n = 1, 0.3%) for the bivalent vaccine (Original and Omicron BA.1).

Serious Adverse Events

Serious adverse events up to 1 month after the second booster dose in ongoing follow up were reported by no Pfizer-BioNTech COVID-19 Vaccine recipients and by 1 bivalent vaccine (Original and Omicron BA.1) recipient (1 serious adverse event considered unrelated to the vaccine).

Pfizer-BioNTech COVID-19 Vaccine

Primary Series

The safety of the primary series Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) was evaluated in participants 12 years of age and older in 2 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.

Study BNT162-01 (Study 1) was a Phase 1/2, 2-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 46,000 participants, 12 years of age or older. Of these, approximately 43,448 participants [21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo] in Phase 2/3 are 16 years of age or older (including 138 and 145 participants 16 and 17 years of age in the vaccine and placebo groups, respectively) and 2,260 participants are 12 through 15 years of age (1,131 and 1,129 in the vaccine and placebo groups, respectively).

In Study 2, Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Participants 16 Years of Age and Older

At the time of the analysis of Study 2 for the EUA, 37,586 [18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo] participants 16 years of age or older had been followed for a median of 2 months after the second dose.

The safety evaluation in Study 2 is ongoing. The safety population includes participants 16 years of age and older enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 through 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7,960, placebo = 7,934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

In Study 2 in which 10,841 participants 16 through 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

The higher frequency of reported unsolicited non-serious adverse events among Pfizer-BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by 4 participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Participants 12 Through 15 Years of Age

In an analysis of Study 2, based on data up to the cutoff date of March 13, 2021, 2,260 participants (1,131 Pfizer-BioNTech COVID-19 Vaccine; 1,129 placebo) were 12 through 15 years of age. Of these,

1,308 (660 Pfizer-BioNTech COVID-19 Vaccine and 648 placebo) participants have been followed for at least 2 months after the second dose. The safety evaluation in Study 2 is ongoing.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the participants who received the Pfizer-BioNTech COVID-19 Vaccine, 50.1% were male and 49.9% were female, 85.9% were White, 4.6% were Black or African American, 11.7% were Hispanic/Latino, 6.4% were Asian, and 0.4% were American Indian/Alaska Native.

Unsolicited Adverse Events

In the following analyses of Study 2 in participants 12 through 15 years of age (1,131 of whom received Pfizer-BioNTech COVID-19 Vaccine and 1,129 of whom received placebo), 98.3% of study participants had at least 30 days of follow-up after Dose 2.

Serious Adverse Events

Serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.1% of placebo recipients. There were no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 5.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 5.8% of placebo recipients. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy plausibly related to the study intervention were imbalanced, with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (7) vs. the placebo group (1). There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Participants 5 Through 11 Years of Age

In an analysis of Study 3 Phase 2/3, based on data up to the cutoff date of September 06, 2021, 2,268 participants [1,518 Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA); 750 placebo] were 5 through 11 years of age. Of these, 2,158 (95.1%) [1,444 Pfizer-BioNTech COVID-19 Vaccine and 714 placebo] participants have been followed for at least 2 months after the second dose. An analysis of Study 3 Phase 2/3 adverse event data also included another 2,379 participants [1,591 Pfizer-BioNTech COVID-19 Vaccine and 788 placebo], of whom 71.2% had a follow-up period for at least 2 weeks after Dose 2 up to the cutoff date of October 8, 2021. The safety evaluation in Study 3 is ongoing.

Demographic characteristics in Study 3 were generally similar with regard to age, gender, race, and ethnicity among participants 5 through 11 years of age who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Among the 4,647 participants 5 through 11 years of age who received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine or placebo, 51.8% were male and 48.2% were female, 77.3% were White, 5.8% were Black or African American, 16.9% were Hispanic/Latino, 8.3% were Asian, and 0.4% were American Indian/Alaska Native.

Unsolicited Adverse Events

In the following analyses of Study 3 in participants 5 through 11 years of age (1,518 of whom received Pfizer-BioNTech COVID-19 Vaccine and 750 of whom received placebo), 99.5% of participants had at least 30 days of follow-up after Dose 2.

Serious Adverse Events

In 1 group of participants (initial enrollment cohort) with a median of 2.3 months follow-up post Dose 2, no serious adverse events were reported that were considered related to vaccination. In a second group of participants (expansion cohort) with a median of 2.4 weeks follow-up post Dose 2, no serious adverse events were reported that were considered related to vaccination.

Non-Serious Adverse Events

In 1 group of participants (initial enrollment cohort), non-serious adverse events from Dose 1 through up to 30 days after Dose 2 up to the cutoff date of September 06, 2021, in ongoing follow-up were reported by 10.9% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 9.1% of placebo recipients. In this group of participants, >99% had follow-up 30 days post Dose 2. In a second group of participants (expansion cohort) for which the median follow-up was 2.4 weeks (range 0 to 3.7 weeks), non-serious adverse events from Dose 1 through the cutoff date of October 8, 2021, were reported by 7.1% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 6.3% of placebo recipients.

In the initial enrollment cohort, from Dose 1 through 30 days after Dose 2, lymphadenopathy was reported in 13 (0.9%) participants in the Pfizer-BioNTech COVID-19 Vaccine group vs. 1 (0.1%) in the placebo group. In the expansion cohort from Dose 1 through the cutoff date, lymphadenopathy was reported in 6 (0.4%) participants in the Pfizer-BioNTech COVID-19 Vaccine group vs. 3 (0.4%) in the placebo group. There were no other notable patterns between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Participants 2 Through 4 Years of Age

In an analysis of Study 3 (Phase 2/3), based on data in the blinded placebo-controlled follow-up period up to the cutoff date of April 29, 2022, 886 participants 2 through 4 years of age who received a 3-dose primary series [606 Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA); 280 placebo] were have been followed a median of 1.4 months after the third dose.

Demographic characteristics in Study 3 were generally similar with regard to age, gender, race, and ethnicity among participants 2 through 4 years of age who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Among the 1,835 participants 2 through 4 years of age who received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine, 49.1% were male and 50.9% were female, 80.1% were White, 14.4% were Hispanic/Latino, 7.1% were multi-racial, 6.9% were Asian, 5.1% were Black or African American, and 0.2% were American Indian/Alaska Native.

Unsolicited Adverse Events

In the following analyses of Study 3 in participants 2 through 4 years of age (606 of whom received Pfizer-BioNTech COVID-19 Vaccine and 280 of whom received placebo), 76.6% of participants had at least 30 days of follow-up after Dose 3.

Serious Adverse Events

Serious adverse events from Dose 1 through 1 month after Dose 3, with an overall median of 1.4 months follow-up after Dose 3 were reported by 0.7% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.9% of placebo recipients. One serious adverse event of fever (maximum temperature 40.3°C) on Day 3 after Dose 2 in a 4-year-old was considered possibly related to vaccination.

Non-Serious Adverse Events

Non-serious adverse events from Dose 1 through up to 30 days after Dose 3, in ongoing follow-up were reported by 18.5% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 18.5% of placebo recipients.

From Dose 1 through 30 days after Dose 3, lymphadenopathy was reported in 1 (0.1%) participant in the Pfizer-BioNTech COVID-19 Vaccine group vs. 0 (0.0%) in the placebo group. There were no other notable patterns between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Participants 6 Through 23 Months of Age

In an analysis of Study 3 (Phase 2/3), based on data in the blinded placebo-controlled follow-up period up to the cutoff date of April 29, 2022, 570 participants 6 through 23 months of age who received a 3-dose primary series [386 Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA); 184 placebo] have been followed for a median of 1.3 months after the third dose.

Demographic characteristics in Study 3 were generally similar with regard to age, gender, race, and ethnicity among participants 6 through 23 months of age who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Among the 1,178 participants 6 through 23 months of age who received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine, 50.0% were male and 50.0% were female, 78.3% were White, 9.9% were multi-racial, 13.7% were Hispanic/Latino, 7.7% were Asian, 3.6% were Black or African American, and 0.3% were American Indian/Alaska Native.

Unsolicited Adverse Events

In the following analyses of Study 3 in participants 6 through 23 months of age (386 of whom received Pfizer-BioNTech COVID-19 Vaccine and 184 of whom received placebo), 83.7% of participants had at least 30 days of follow-up after Dose 3.

Serious Adverse Events

Serious adverse events from Dose 1 through 1 month after Dose 3, with an overall median of 1.3 months follow-up after Dose 3 were reported by 1.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 2.3% of placebo recipients. No serious adverse events were reported that were considered related to vaccination.

Non-Serious Adverse Events

Non-serious adverse events from Dose 1 through up to 1 month after Dose 3, in ongoing follow-up were reported by 29.1% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 26.3% of placebo recipients.

From Dose 1 through 30 days after Dose 3, lymphadenopathy was reported in 2 (0.2%) participants in the Pfizer-BioNTech COVID-19 Vaccine group vs. 0 (0%) in the placebo group. There were no other notable patterns between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

First Booster Dose Following a Primary Series of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) in Participants 18 through 55 Years of Age

A subset of Study 2 Phase 2/3 participants of 306 participants 18 through 55 years of age received a first booster dose of Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) approximately 6 months (range of 4.8 to 8.0 months) after completing the primary series. Additionally, a total of 23 Study 2 (Phase 1) participants (11 participants 18 through 55 years of age and 12 participants 65 through 85 years of age) received a first booster dose of Pfizer-BioNTech COVID-19 Vaccine approximately 8 months (range 7.9 to 8.8 months) after completing the primary series. Participants were monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events through 1 month after vaccination and for serious adverse events for 6 months after the last vaccination.

Among the 306 Phase 2/3 participants, the median age was 42 years (range 19 through 55 years of age), 45.8% were male and 54.2% were female, 81.4% were White, 27.8% were Hispanic/Latino, 9.2% were Black or African American, 5.2% were Asian, and 0.7% were American Indian/Alaska Native. Among the 12 Phase 1 participants 65 through 85 years of age, the median age was 69 years (range 65 through 75 years of age), 6 were male and all were White and Not Hispanic/Latino. Following the booster dose, the median follow-up time was 2.6 months (range 2.1 to 2.9 months) for Phase 1 participants and 2.6 months (range 1.1 to 2.8 months) for Phase 2/3 participants.

Solicited Local and Systemic Adverse Reactions

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of a first booster dose with Pfizer-BioNTech COVID-19 Vaccine for Phase 2/3 participants 18 through 55 years of age.

In participants who received a first booster dose, the mean duration of pain at the injection site was 2.6 days (range 1 to 8 days), for redness 2.2 days (range 1 to 15 days), and for swelling 2.2 days (range 1 to 8 days).

Table 3: Study 2 – Frequency and Percentages of Participants With Solicited Local Adverse Reactions, By Maximum Severity, Within 7 Days After a First Booster Dose of Pfizer-BioNTech COVID-19 Vaccine – Participants 18 through 55 Years of Age*

| Solicited Local Adverse Reaction | Pfizer-BioNTech COVID-19 Vaccine [±] First Booster Dose N ^a = 289 n ^b (%) |
|----------------------------------|---|
| | Redness ^c |
| Any (>2 cm) | 17 (5.9) |
| Mild | 10 (3.5) |
| Moderate | 7 (2.4) |
| Severe | 0 |
| Swelling ^c | |
| Any (>2 cm) | 23 (8.0) |
| Mild | 13 (4.5) |
| Moderate | 9 (3.1) |
| Severe | 1 (0.3) |

| | Pfizer-BioNTech COVID-19 Vaccine[±] First Booster Dose N^a = 289 n^b (%) |
|---|--|
| Solicited Local Adverse Reaction | |
| Pain at the injection site^d | |
| Any | 240 (83.0) |
| Mild | 174 (60.2) |
| Moderate | 65 (22.5) |
| Severe | 1 (0.3) |

Note: Adverse Reactions were collected in the electronic diary (e-diary) from day of vaccination (Day 1) to Day 7 after the booster dose.

Note: No Grade 4 solicited local adverse reactions were reported.

* A subset of Phase 2/3 participants 18 through 55 years of age who received a booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) approximately 6 months after completing the primary series.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to 5.0 cm; Moderate: >5.0 to 10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

± Pfizer-BioNTech COVID-19 Vaccine .

Table 4: Study 2 – Frequency and Percentages of Participants With Solicited Systemic Adverse Reactions, by Maximum Severity, Within 7 Days After a First Booster Dose with Pfizer-BioNTech COVID-19 Vaccine – Participants 18 through 55 Years of Age*

| | Pfizer-BioNTech COVID-19 Vaccine[±] First Booster Dose N^a = 289 n^b (%) |
|--|--|
| Solicited Systemic Adverse Reaction | |
| Fever | |
| ≥38.0°C | 25 (8.7) |
| ≥38.0°C to 38.4°C | 12 (4.2) |
| >38.4°C to 38.9°C | 12 (4.2) |
| >38.9°C to 40.0°C | 1 (0.3) |
| >40.0°C | 0 |
| Fatigue^c | |
| Any | 184 (63.7) |
| Mild | 68 (23.5) |
| Moderate | 103 (35.6) |
| Severe | 13 (4.5) |
| Headache^c | |
| Any | 140 (48.4) |
| Mild | 83 (28.7) |
| Moderate | 54 (18.7) |
| Severe | 3 (1.0) |
| Chills^c | |
| Any | 84 (29.1) |
| Mild | 37 (12.8) |
| Moderate | 44 (15.2) |
| Severe | 3 (1.0) |

| Solicited Systemic Adverse Reaction | Pfizer-BioNTech COVID-19 Vaccine[±] |
|--|---|
| | First Booster Dose N^a = 289 n^b (%) |
| Vomiting^d | |
| Any | 5 (1.7) |
| Mild | 5 (1.7) |
| Moderate | 0 |
| Severe | 0 |
| Diarrhea^c | |
| Any | 25 (8.7) |
| Mild | 21 (7.3) |
| Moderate | 4 (1.4) |
| Severe | 0 |
| New or worsened muscle pain^c | |
| Any | 113 (39.1) |
| Mild | 52 (18.0) |
| Moderate | 57 (19.7) |
| Severe | 4 (1.4) |
| New or worsened joint pain^c | |
| Any | 73 (25.3) |
| Mild | 36 (12.5) |
| Moderate | 36 (12.5) |
| Severe | 1 (0.3) |
| Use of antipyretic or pain medication^f | 135 (46.7) |

Note: Adverse reactions and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from day of vaccination (Day 1) to Day 7 after the booster dose.

Note: No Grade 4 solicited systemic adverse reactions were reported.

* A subset of Phase 2/3 participants 18 through 55 years of age who received a booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) approximately 6 months after completing the primary series.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

± Pfizer-BioNTech COVID-19 Vaccine .

In Phase 1 participants ≥ 65 years of age (n = 12), local reaction pain at the injection site (n = 8, 66.7%) and systemic reactions fatigue (n = 5, 41.7%), headache (n = 5, 41.7%), chills (n = 2, 16.7%), muscle pain (n = 4, 33.3%), and joint pain (n = 2, 16.7%) were reported after the booster dose. No participant in this age group reported a severe systemic event or fever after the booster dose.

Unsolicited Adverse Events

Overall, the 306 participants who received a first booster dose, had a median follow-up time of 2.6 months after the booster dose to the cut-off date (June 17, 2021).

In an analysis of all unsolicited adverse events reported following the first booster dose, through 1 month after the booster dose, in participants 18 through 55 years of age (N = 306), those assessed as adverse reactions not

already captured by solicited local and systemic reactions were lymphadenopathy (n = 16, 5.2%), nausea (n = 2, 0.7%), decreased appetite (n = 1, 0.3%), rash (n = 1, 0.3%), and pain in extremity (n = 1, 0.3%).

Serious Adverse Events

Of the 306 participants who received a first booster dose of Pfizer-BioNTech COVID-19 Vaccine, there were no serious adverse events reported from the booster dose through 30 days after the booster dose. One participant reported a serious adverse event 61 days after the booster dose that was assessed as unrelated to vaccination.

First Booster Dose Following a Primary Series of Pfizer-BioNTech COVID-19 in Participants 5 Through 11 Years of Age

A subset of Phase 2/3 participants 5 through 11 years of age received a first booster dose of Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA) at least 5 months after completing the primary series (range 5 to 9 months, 86.8% of participants received a booster dose at least 8 months after Dose 2). Those participants vaccinated prior to February 22, 2022 provided the safety database (n=401), and had a median safety follow-up of 1.3 months from vaccination through the data cut-off date of March 22, 2022.

The median age of these 401 participants was 8.0 years (range 5 through 11 years of age), 52.4% were male and 47.6% were female, 70.1% were White, 7.2% were Black or African American, 22.9% were Hispanic/Latino, 7.7% were Asian, and 2.0% were American Indian/Alaska Native.

Unsolicited Adverse Events

Overall, the 401 participants who received a first booster dose of Pfizer-BioNTech COVID-19 Vaccine had a median follow-up time of 1.3 months after the booster dose through the cutoff date.

In an analysis of all unsolicited adverse events reported in participants 5 through 11 years of age (N = 401) through up to 1 month after a first booster dose, lymphadenopathy (n = 10, 2.5%) was an adverse reaction not already captured by solicited local and systemic reactions.

Serious Adverse Events

No serious adverse events were reported after the first booster dose through the cutoff date.

First Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine

The safety of a Pfizer-BioNTech COVID-19 Vaccine booster dose in individuals who completed primary vaccination with another authorized or approved COVID-19 Vaccine (heterologous booster dose) is inferred from the safety of a Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) booster dose administered following completion of Pfizer-BioNTech COVID-19 Vaccine primary series (homologous booster dose) and from data from an independent National Institutes of Health (NIH) study Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine. In this study, participants who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of 1 of 3 vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported in the study following the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose

did not identify any new safety concerns, as compared with adverse reactions reported following a Pfizer-BioNTech COVID-19 Vaccine primary series doses or homologous booster dose.

Second Booster Dose Following Primary Series and First Booster Vaccination

Safety surveillance data from the Ministry of Health of Israel on the administration of approximately 700,000 fourth doses of the Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) given at least 4 months after the third dose in participants 18 years of age and older (approximately 600,000 of whom were 60 years of age and older) revealed no new safety concerns.

6.2 Post Authorization Experience

The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis

Gastrointestinal Disorders: diarrhea, vomiting

Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)

Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

Nervous System Disorders: syncope, dizziness

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following administration of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of myocarditis
- Cases of pericarditis
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent 1 of the outcomes listed above

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using 1 of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine, Bivalent and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within 1 month prior.
2. In Box 18, description of the event:
 - a. Write “Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA” as the first line.
 - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
 - a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
 - b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
 - c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

| Website | Fax number | Telephone number |
|--|-------------------|-------------------------|
| www.pfizersafetyreporting.com | 1-866-635-8337 | 1-800-438-1985 |

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

No data are available regarding the use of Pfizer-BioNTech COVID-19 Vaccine, Bivalent during pregnancy.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (modRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the intramuscular route on 4 occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Bivalent for use as a booster dose in individuals 5 through 17 years of age is based on the safety and effectiveness of Pfizer-BioNTech COVID-19 Vaccine in individuals 6 months of age and older and safety and immunogenicity data with the bivalent vaccine (Original and Omicron BA.1) in individuals greater than 55 years of age.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent is not authorized for use in individuals younger than 5 years of age as a booster dose.

11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older who received the primary series and their data contributes to the overall assessment of safety and effectiveness of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent [*see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)*]. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

A clinical study with the bivalent vaccine (Original and Omicron BA.1) included 197 individuals 65 years of age and older and their data contribute to the overall assessment of safety and effectiveness of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is supplied as a sterile, frozen suspension in single dose and multiple dose vials with gray caps and labels with gray borders.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent is formulated to contain 15 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 15 mcg of modRNA encoding the S glycoprotein of SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 (Omicron BA.4/BA.5). The S-proteins of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 are identical. Each dose contains 30 mcg modRNA.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in single dose and multiple dose vials also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.

The Pfizer-BioNTech COVID-19 Vaccine, Bivalent does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine, Bivalent is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

The effectiveness of a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is based on effectiveness of primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine and immunogenicity of a second booster dose with the bivalent vaccine (Original and Omicron BA.1).

18.1 Efficacy of Primary Series of Pfizer-BioNTech COVID-19 Vaccine in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥ 56 -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion of Study 2, based on data accrued through November 14, 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 5 presents the specific demographic characteristics in the studied population.

Table 5: Demographics (population for the primary efficacy endpoint)^a

| | Pfizer-BioNTech COVID-19 Vaccine* (N=18,242) n (%) | Placebo (N=18,379) n (%) |
|---|---|---------------------------------------|
| Sex | | |
| Male | 9318 (51.1) | 9225 (50.2) |
| Female | 8924 (48.9) | 9154 (49.8) |
| Age (years) | | |
| Mean (SD) | 50.6 (15.70) | 50.4 (15.81) |
| Median | 52.0 | 52.0 |
| Min, max | (12, 89) | (12, 91) |
| Age group | | |
| ≥ 12 through 15 years ^b | 46 (0.3) | 42 (0.2) |
| ≥ 16 through 17 years | 66 (0.4) | 68 (0.4) |
| ≥ 16 through 64 years | 14,216 (77.9) | 14,299 (77.8) |
| ≥ 65 through 74 years | 3176 (17.4) | 3226 (17.6) |
| ≥ 75 years | 804 (4.4) | 812 (4.4) |
| Race | | |
| White | 15,110 (82.8) | 15,301 (83.3) |
| Black or African American | 1617 (8.9) | 1617 (8.8) |
| American Indian or Alaska Native | 118 (0.6) | 106 (0.6) |
| Asian | 815 (4.5) | 810 (4.4) |
| Native Hawaiian or other Pacific Islander | 48 (0.3) | 29 (0.2) |
| Other ^c | 534 (2.9) | 516 (2.8) |

| | Pfizer-BioNTech COVID-19 Vaccine* (N=18,242) n (%) | Placebo (N=18,379) n (%) |
|----------------------------------|---|---------------------------------------|
| Ethnicity | | |
| Hispanic or Latino | 4886 (26.8) | 4857 (26.4) |
| Not Hispanic or Latino | 13,253 (72.7) | 13,412 (73.0) |
| Not reported | 103 (0.6) | 110 (0.6) |
| Comorbidities^d | | |
| Yes | 8432 (46.2) | 8450 (46.0) |
| No | 9810 (53.8) | 9929 (54.0) |

* Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

- a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.
- b. 100 participants 12 through 15 years of age with limited follow-up in the randomized population received at least 1 dose (49 in the vaccine group and 51 in the placebo group). Some of these participants were included in the efficacy evaluation depending on the population analyzed. They contributed to exposure information but with no confirmed COVID-19 cases, and did not affect efficacy conclusions.
- c. Includes multiracial and not reported.
- d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
 - Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
 - Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
 - Obesity (body mass index ≥ 30 kg/m²)
 - Diabetes (Type 1, Type 2 or gestational)
 - Liver disease
 - Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 through 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 through 17 years of age began enrollment from September 16, 2020, and 12 through 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 6.

Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

| First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection* | | | |
|--|--|---|--|
| Subgroup | Pfizer-BioNTech COVID-19 Vaccine[±] N^a=18,198 Cases n1^b Surveillance Time^c (n2^d) | Placebo N^a=18,325 Cases n1^b Surveillance Time^c (n2^d) | Vaccine Efficacy % (95% CI) |
| All subjects ^e | 8 2.214 (17,411) | 162 2.222 (17,511) | 95.0 (90.3, 97.6) ^f |
| 16 through 64 years | 7 1.706 (13,549) | 143 1.710 (13,618) | 95.1 (89.6, 98.1) ^g |
| 65 years and older | 1 0.508 (3848) | 19 0.511 (3880) | 94.7 (66.7, 99.9) ^g |
| First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection | | | |
| Subgroup | Pfizer-BioNTech COVID-19 Vaccine[±] N^a=19,965 Cases n1^b Surveillance Time^c (n2^d) | Placebo N^a=20,172 Cases n1^b Surveillance Time^c (n2^d) | Vaccine Efficacy % (95% CI) |
| All subjects ^e | 9 2.332 (18,559) | 169 2.345 (18,708) | 94.6 (89.9, 97.3) ^f |
| 16 through 64 years | 8 1.802 (14,501) | 150 1.814 (14,627) | 94.6 (89.1, 97.7) ^g |
| 65 years and older | 1 0.530 (4044) | 19 0.532 (4067) | 94.7 (66.8, 99.9) ^g |

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

± Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. No confirmed cases were identified in participants 12 through 15 years of age.

f. Credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta=r(1-VE)/(1+r(1-VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.

g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

18.2 Efficacy of Primary Series of Pfizer-BioNTech COVID-19 Vaccine in Participants 12 Through 15 Years of Age

A descriptive efficacy analysis of Study 2 has been performed in approximately 2,200 participants 12 through 15 years of age evaluating confirmed COVID-19 cases accrued up to a data cutoff date of March 13, 2021.

The efficacy information in participants 12 through 15 years of age is presented in Table 7.

Table 7: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Participants 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population

| First COVID-19 occurrence from 7 days after Dose 2 in participants 12 through 15 years of age without evidence of prior SARS-CoV-2 infection* | | | |
|---|--|---|--|
| | Pfizer-BioNTech COVID-19 Vaccine[±] N^a=1005 Cases n^{1b} Surveillance Time^c (n^{2d}) | Placebo N^a=978 Cases n^{1b} Surveillance Time^c (n^{2d}) | Vaccine Efficacy % (95% CI^e) |
| Participants 12 through 15 years of age | 0 0.154 (1001) | 16 0.147 (972) | 100.0 (75.3, 100.0) |
| First COVID-19 occurrence from 7 days after Dose 2 in participants 12 through 15 years of age with or without evidence of prior SARS-CoV-2 infection | | | |
| | Pfizer-BioNTech COVID-19 Vaccine[±] N^a=1119 Cases n^{1b} Surveillance Time^c (n^{2d}) | Placebo N^a=1110 Cases n^{1b} Surveillance Time^c (n^{2d}) | Vaccine Efficacy % (95% CI^e) |
| Participants 12 through 15 years of age | 0 0.170 (1109) | 18 0.163 (1094) | 100.0 (78.1, 100.0) |

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

± Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

18.3 Immunogenicity of Primary Series of Pfizer-BioNTech COVID-19 Vaccine in Participants 12 Through 15 Years of Age

In Study 2, an analysis of SARS-CoV-2 50% neutralizing titers (NT50) 1 month after Dose 2 in a randomly selected subset of participants demonstrated non-inferior immune responses (within 1.5-fold) comparing

participants 12 through 15 years of age to participants 16 through 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2 (Table 8).

Table 8: Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Participants 12 Through 15 Years of Age to Participants 16 Through 25 Years of Age (Immunogenicity Subset) –Participants Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

| | | Pfizer-BioNTech COVID-19 Vaccine* | | | |
|---|-------------------------|--|--|---|--|
| | | 12 Through 15 Years n ^a =190 | 16 Through 25 Years n ^a =170 | 12 Through 15 Years/ 16 Through 25 Years | |
| Assay | Time Point ^b | GMT ^c (95% CI ^c) | GMT ^c (95% CI ^c) | GMR ^d (95% CI ^d) | Met Noninferiority Objective ^e (Y/N) |
| SARS-CoV-2 neutralization assay - NT50 (titer) ^f | 1 month after Dose 2 | 1239.5 (1095.5, 1402.5) | 705.1 (621.4, 800.2) | 1.76 (1.47, 2.10) | Y |

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic-acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (up to 1 month after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 were included in the analysis.

* Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

- n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
- Protocol-specified timing for blood sample collection.
- GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to $0.5 \times \text{LLOQ}$.
- GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (12 through 15 years of age minus 16 through 25 years of age) and the corresponding CI (based on the Student t distribution).
- Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.
- SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

18.4 Immunogenicity of the Bivalent Vaccine (Original and Omicron BA.1) Administered as a Second Booster Dose

In an analysis of a subset from Study 4, a total of 610 participants greater than 55 years of age who had previously received a 2-dose primary series and 1 booster dose with Pfizer-BioNTech COVID-19 Vaccine received 1 of the following as a second booster dose: Pfizer-BioNTech COVID-19 Vaccine or bivalent vaccine (Original and Omicron BA.1). GMRs and seroresponse rates were evaluated at 1 month after vaccination with the bivalent vaccine (Original and Omicron BA.1). The bivalent vaccine (Original and Omicron BA.1) booster dose was administered 4.7 to 11.5 months (median 6.3 months) after the first booster dose. The Pfizer-BioNTech COVID-19 Vaccine booster dose was administered 5.3 to 13.1 months (median 6.3 months) after the first booster dose.

The primary objective of the study was to assess superiority with respect to level of 50% neutralizing titer (NT50) and noninferiority with respect to seroresponse rate of the anti-Omicron BA.1 immune response induced by a dose of the bivalent vaccine (Original and Omicron BA.1) relative to the response elicited by a

dose of Pfizer-BioNTech COVID-19 Vaccine given as a second booster dose in participants greater than 55 years of age.

A secondary objective of the study was to assess noninferiority with respect to level of NT50 to the Original SARS-CoV-2 strain induced by a dose of the bivalent vaccine (Original and Omicron BA.1) relative to the response elicited by a dose of Pfizer-BioNTech COVID-19 Vaccine given as a second booster dose. A comparison of seroresponse rates to the Original strain was descriptive.

Superiority of the anti-Omicron BA.1 NT50 for the bivalent vaccine (Original and Omicron BA.1) relative to Pfizer-BioNTech COVID-19 Vaccine was met, as the lower bound of the 2-sided 95% CI for GMR was >1. Noninferiority of the anti-Original NT50 for the bivalent vaccine (Original and Omicron BA.1) relative to Pfizer-BioNTech COVID-19 Vaccine was met, as the lower bound of the 2-sided 95% CI for GMR was >0.67 and the point estimate of the GMR was ≥ 0.8 (Table 9).

Non-inferiority of the seroresponse rate to the Omicron BA.1 variant for the bivalent vaccine (Original and Omicron BA.1) relative to Pfizer-BioNTech COVID-19 Vaccine was met as the lower limit of the 2-sided 95% CI for the difference in percentages of participants with seroresponse is >-5% (Table 10). A descriptive summary of seroresponse to the Original strain is also included in Table 10.

Table 9: Study 4 - Geometric Mean Ratios – Participants Without Evidence of Infection Up to 1 Month After the Second Booster Dose – Immunogenicity Subset – Participants Greater Than 55 Years of Age – Evaluable Immunogenicity Population

| Assay | Vaccine Group (as randomized) | Sampling Time Point ^a | N ^b | GMT (95% CI) ^c | GMR (95% CI) ^d |
|---|--|----------------------------------|----------------|---------------------------|---------------------------|
| SARS-CoV-2 neutralization assay - Omicron BA.1 - NT50 (titer) ^e | Pfizer-BioNTech COVID-19 Vaccine | 1 month | 163 | 455.8 (365.9, 567.6) | |
| | Bivalent Vaccine (Original and Omicron BA.1) | 1 month | 178 | 711.0 (588.3, 859.2) | 1.56 (1.17, 2.08) |
| SARS-CoV-2 neutralization assay - Original strain - NT50 (titer) ^e | Pfizer-BioNTech COVID-19 Vaccine | 1 month | 182 | 5998.1 (5223.6, 6887.4) | |
| | Bivalent Vaccine (Original and Omicron BA.1) | 1 month | 186 | 5933.2 (5188.2, 6785.2) | 0.99 (0.82, 1.20) |

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Immunogenicity subset = a random sample of 230 participants in each vaccine group.

Note: Participants who had no serological or virological evidence (prior to the 1-month post-study vaccination blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] result negative at the study vaccination and the 1-month post-study vaccination visits, negative NAAT [nasal swab] result at the study vaccination visit, and any unscheduled visit prior to the 1-month post-study vaccination blood sample collection) and had no medical history of COVID-19 were included in the analysis.

- Protocol-specified timing for blood sample collection.
- n = number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
- GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to $0.5 \times \text{LLOQ}$.
- GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (vaccine group in the corresponding row - Pfizer-BioNTech COVID-19 Vaccine) and the corresponding CI (based on the Student t distribution). Superiority for anti-Omicron BA.1 immune response is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 1 after satisfying multiplicity adjustment. Noninferiority for anti-Original strain is declared if the lower limit of the 2-sided 95% CI for the GMR is greater than 0.67 (1.5-fold criterion) and the point estimate of the GMR is ≥ 0.8 , after satisfying multiplicity adjustment.
- SARS-CoV-2 NT50 were determined using a validated 384-well assay platform (original strain [USA-WA1/2020, isolated in January 2020] and Omicron B.1.1.529 subvariant BA.1).

Table 10: Study 4 - Number (%) of Participants Achieving Seroresponse – Participants Without Evidence of Infection Up to 1 Month After the Second Booster Dose – Immunogenicity Subset – Participants Greater Than 55 Years of Age – Evaluable Immunogenicity Population

| Assay | Vaccine Group (as randomized) | Sampling Time Point ^a | N ^b | n ^c (%) (95% CI ^d) | Difference % ^e (95% CI ^f) |
|---|--|----------------------------------|----------------|---|--|
| SARS-CoV-2 neutralization assay - Omicron BA.1 - NT50 (titer) ^g | Pfizer-BioNTech COVID-19 Vaccine | 1 month | 149 | 85 (57.0) (48.7, 65.1) | |
| | Bivalent Vaccine (Original and Omicron BA.1) | 1 month | 169 | 121 (71.6) (64.2, 78.3) | 14.6 (4.0, 24.9) |
| SARS-CoV-2 neutralization assay - Original strain - NT50 (titer) ^g | Pfizer-BioNTech COVID-19 Vaccine | 1 month | 179 | 88 (49.2) (41.6, 56.7) | |
| | Bivalent Vaccine (Original and Omicron BA.1) | 1 month | 186 | 93 (50.0) (42.6, 57.4) | |

Abbreviations: LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Immunogenicity subset = a random sample of 230 participants in each vaccine group.

Note: Seroresponse is defined as achieving ≥ 4 -fold rise from baseline (before the second booster dose). If the baseline measurement is below the LLOQ, the postvaccination measure of $\geq 4 \times$ LLOQ is considered a seroresponse.

Note: Participants who had no serological or virological evidence (prior to the 1-month post-study vaccination blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] result negative at the study vaccination and the 1-month post-study vaccination visits, negative NAAT [nasal swab] result at the study vaccination visit, and any unscheduled visit prior to the 1-month post-study vaccination blood sample collection) and had no medical history of COVID-19 were included in the analysis.

- Protocol-specified timing for blood sample collection.
- N = Number of participants with valid and determinate assay results for the specified assay at both the pre-vaccination time point and the given sampling time point. This value is the denominator for the percentage calculation.
- n = Number of participants with seroresponse at 1 month after vaccination for the given assay.
- Exact 2-sided CI based on the Clopper and Pearson method.
- Difference in proportions, expressed as a percentage (vaccine group in the corresponding row - Pfizer-BioNTech COVID-19 Vaccine).
- 2-sided CI based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage. Noninferiority for anti-Omicron BA.1 seroresponse is declared if the lower bound of the 2-sided 95% CI for the difference is greater than -5% after satisfying multiplicity adjustment.
- SARS-CoV-2 NT50 were determined using a validated 384-well assay platform (original strain [USA-WA1/2020, isolated in January 2020] and Omicron B.1.1.529 subvariant BA.1).

18.5 Immunogenicity of a First Booster Dose With a Pfizer-BioNTech COVID-19 Vaccine Primary Series in Participants 18 Through 55 Years of Age

Effectiveness of a booster dose of Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) was based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). In Study 2, analyses of NT50 1 month after the booster dose compared to 1 month after the primary series in individuals 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster vaccination demonstrated noninferiority for both geometric mean ratio (GMR) and difference in seroresponse rates. Seroresponse for a participant was defined as achieving a ≥ 4 -fold rise in NT50 from baseline (before primary series). These analyses are summarized in Table 11 and Table 12.

Table 11: Geometric Mean 50% Neutralizing Titer (SARS-CoV-2 USA_WA1/2020) – Comparison of 1 Month After Booster Dose to 1 Month After Primary Series – Participants 18 Through 55 Years of Age Without Evidence of Infection up to 1 Month After Booster Dose* – Booster Dose Evaluable Immunogenicity Population[±]

| Assay | n^a | 1 Month After Booster Dose GMT^b (95% CI^b) | 1 Month After Primary Series GMT^b (95% CI^b) | 1 Month After Booster Dose/ 1 Month After Primary Series GMR^c (97.5% CI^c) | Met Noninferiority Objective^d (Y/N) |
|---|----------------------|--|--|--|---|
| SARS-CoV-2 neutralization assay - NT50 (titer) ^e | 212 | 2466.0 (2202.6, 2760.8) | 750.6 (656.2, 858.6) | 3.29 (2.77, 3.90) | Y |

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

Note: Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

- * Participants who had no serological or virological evidence (up to 1 month after receipt of a booster dose of Pfizer-BioNTech COVID-19 Vaccine) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after the booster dose were included in the analysis.
- ± All eligible participants who had received 2 doses of Pfizer-BioNTech COVID-19 Vaccine as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.
 - a. n = Number of participants with valid and determinate assay results at both sampling time points within specified window.
 - b. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to $0.5 \times \text{LLOQ}$.
 - c. GMRs and 2-sided 97.5% CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution).
 - d. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the GMR is >0.67 and the point estimate of the GMR is ≥ 0.80 .
 - e. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Table 12: Seroreponse Rate for 50% Neutralizing Titer (SARS-CoV-2 USA_WA1/2020) – Comparison of 1 Month After Booster Dose to 1 Month After Primary Series – Participants 18 Through 55 Years of Age Without Evidence of Infection up to 1 Month After Booster Dose* – Booster Dose Evaluable Immunogenicity Population[±]

| Assay | N ^a | 1 Month After Booster Dose n ^b % (95% CI ^c) | 1 Month After Primary Series n ^b % (95% CI ^c) | Difference (1 Month After Booster Dose - 1 Month After Primary Series) % ^d (97.5% CI ^e) | Met Noninferiority Objective ^f (Y/N) |
|---|----------------|---|---|--|--|
| SARS-CoV-2 neutralization assay - NT50 (titer) ^g | 200 | 199 99.5 (97.2, 100.0) | 196 98.0 (95.0, 99.5) | 1.5 (-0.7, 3.7) | Y |

Abbreviations: CI = confidence interval; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

Note: Seroreponse is defined as achieving a ≥ 4 -fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result $\geq 4 \times$ LLOQ is considered a seroreponse.

Note: Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

- * Participants who had no serological or virological evidence (up to 1 month after receipt of booster vaccination) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster vaccination were included in the analysis.
- ± All eligible participants who had received 2 doses of Pfizer-BioNTech COVID-19 Vaccine as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.
- a. N = number of participants with valid and determinate assay results for the specified assay at baseline, 1 month after Dose 2 and 1 month after the booster dose within specified window. These values are the denominators for the percentage calculations.
- b. n = Number of participants with seroreponse for the given assay at the given dose/sampling time point.
- c. Exact 2-sided CI based on the Clopper and Pearson method.
- d. Difference in proportions, expressed as a percentage (1 month after booster dose – 1 month after Dose 2).
- e. Adjusted Wald 2-sided CI for the difference in proportions, expressed as a percentage.
- f. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the percentage difference is $> -10\%$.
- g. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

18.6 Immunogenicity of a First Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine

Effectiveness of a Pfizer-BioNTech COVID-19 Vaccine booster dose (30 mcg modRNA) in individuals who completed primary vaccination with another authorized or approved COVID-19 Vaccine (heterologous booster dose) is inferred from immunogenicity data supporting effectiveness of a Pfizer-BioNTech COVID-19 Vaccine booster dose administered following completion of Pfizer-BioNTech COVID-19 Vaccine primary series and from immunogenicity data from an independent NIH study Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine. In this study, participants who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of 1 of 3 vaccines: Moderna

COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA). Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Pfizer-BioNTech COVID-19 Vaccine was demonstrated regardless of the vaccine used for primary vaccination.

19 HOW SUPPLIED/STORAGE AND HANDLING

Single Dose Vials: Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection. Single dose vials with gray caps and labels with gray borders are supplied in a carton containing 10 single dose vials. One vial contains 1 dose of 0.3 mL.

- Carton of 10 single dose vials: NDC 59267-1404-2
- Single dose vial: NDC 59267-1404-1

Multiple Dose Vials: Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection. Multiple dose vials with gray caps and labels with gray borders are supplied in a carton containing 10 multiple dose vials. One vial contains 6 doses of 0.3 mL.

- Carton of 10 multiple dose vials: NDC 59267-0304-2
- Multiple dose vial: NDC 59267-0304-1

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Vial Storage Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may arrive frozen at ultra-cold conditions in thermal containers with dry ice.

Once received, frozen vials may be immediately transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 single dose vials may take up to 2 hours to thaw at this temperature. A carton of 10 multiple dose vials may take up to 6 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) for up to 18 months from the date of manufacture. Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.

If cartons of Pfizer-BioNTech COVID-19 Vaccine, Bivalent are received at 2°C to 8°C (35°F to 46°F), they should be stored at 2°C to 8°C (35°F to 46°F). Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

Regardless of storage condition, the vaccine should not be used after 18 months from the date of manufacture printed on the vial and cartons.

Vial Storage During Use

If not previously thawed at 2°C to 8°C (35°F to 46°F), allow Pfizer-BioNTech COVID-19 Vaccine, Bivalent single dose vials or multiple dose vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to the first puncture. After first puncture, the multiple dose vials should be held between 2°C to 25°C (35°F to 77°F). Multiple dose vials should be discarded 12 hours after first puncture.

Transportation of Vials

If local redistribution is needed, single dose vials and multiple dose vials may be transported at -90°C to -60°C (-130°F to -76°F) or 2°C to 8°C (35°F to 46°F).


20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Vaccine Information Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

| Website | Telephone number |
|---|--|
| <p data-bbox="310 1121 594 1150">www.cvdvaccine.com</p>  | <p data-bbox="1036 1199 1300 1272">1-877-829-2619 (1-877-VAX-CO19)</p> |

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.

BIONTECH

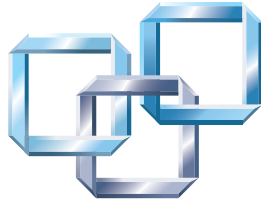
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany



Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1536-4.0

Revised: 8 December 2022



PALMETTO

SUBACUTE CARE CENTER

**For More Information about COVID-19,
please click on the resources below:**

[Our Masking Policy](#)

[Infection Control Protocols](#)