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COVID-19 Vaccination in the Pediatric Practice

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Dear Colleagues,

The onset of the COVID-19 pandemic brought unprecedented times for pediatric providers and the children and families they serve, and we thank you for your tireless and enduring commitment to providing the best care for your patients. We are reaching out to you now to emphasize the importance of COVID vaccination for your patients in your primary care practice setting and to offer technical and consultant support.

We know that vaccination is vital for protecting our children and adolescents from serious COVID-related illness, hospitalization, and MIS-C. The COVID-19 vaccine is now available to all children ages 6 months and older. With younger children becoming eligible, establishing COVID-19 vaccination in the primary care setting is imperative as our region moves away from the large vaccination clinics held in previous stages of COVID-19 pandemic. This further emphasizes the critical and timely role of primary care teams caring for children in COVID-19 vaccination efforts.

At Accountable Health Partners, we understand the complexity surrounding vaccinating against COVID-19 in the office, including registering to vaccinate, ordering vaccines, storing vaccines, and the various reporting needs. The accompanying *COVID-19 Vaccination in the Pediatric Practice* toolkit compiles relevant information from multiple sources. It is designed to assist pediatric providers not yet vaccinating against COVID-19 in the office through the process of implementing this critical service. Resources to help educate patients through vaccine hesitancy are also included. It is our hope that an element of complexity is removed by using the *COVID-19 Vaccination in the Pediatric Practice* toolkit, and providers are able to implement COVID-19 vaccination in their offices.

It is through strong collaboration and the continued efforts by you, our partners in pediatric care, that we can help protect our region's children and their families against COVID-19. We welcome your questions and partnership.

Laura J. Shipley, M.D.

Associate Medical Director for Maternal-Child Health
Accountable Health Partners

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New York State Vaccine Guidance for Pediatric Populations

Guidance for New York State Providers – Last Updated June 22, 2022

Beginning June 18, 2022 children ages 6 months through 4 years old became eligible to receive the COVID-19 vaccine. A two-dose series by Moderna and a three-dose series manufactured by Pfizer-BioNTech are available in the under 5 years old population. The most current version of the guidance document can be found **here**.

Parents and guardians are encouraged to speak with their child(ren)'s healthcare providers regarding any questions or concerns about the vaccine and their child(ren).

About the research

In some children, COVID-19 cases can cause hospitalization, death, multisystem inflammatory syndrome (MIS-C), and other long-term complications. Vaccination and the use of other mitigation measures can protect children against COVID-19. In clinical trials, side effects were mild and self-limiting with the most common side effect being a sore arm.

Myocarditis and/or pericarditis have occurred rarely in some individuals following the administration of mRNA COVID-19 vaccines. The group most at risk for myocarditis and/or pericarditis after COVID-19 vaccination are males aged 12-29 years. The risk of myocarditis or pericarditis after an mRNA COVID-19 vaccine are lower than the risk of myocarditis associated with SARS-CoV-2 infection in both adolescents and adults.

For children with a history of MIS-C, the pediatric vaccine may be considered after careful consideration of risks and benefits. The benefits of COVID-19 vaccination likely outweigh a theoretical risk for MIS-C for people who; 1) achieved clinical recovery, including normal cardiac function; 2) there have been more than 90 days since their MIS-C diagnosis; 3) are in an area with high or substantial SARS-CoV-2; 4) had the onset of MIS-C before any COVID-19 vaccination.

Clinical trials indicate that the Pfizer-BioNTech vaccine can be given safely to children previously infected with SARS-CoV-2.

Children who have received passive antibody products (monoclonal antibodies or convalescent plasma) as treatment for COVID-19 or as post-exposure prophylaxis should be temporarily deferred for receipt of an mRNA COVID-19 vaccine to avoid potential interference of the antibody treatment with the vaccine-induced response.

- Prophylaxis: defer vaccination for 30 days
- Treatment: defer vaccination for 90 days

Become a COVID-19 Vaccinator in New York State

Providers must enroll in the NYSDOH COVID-19 Vaccination Program and become familiar with the program's requirements to administer vaccine in their offices. Access to the Health Commerce System (HCS) is required to access the application needed to enroll as a vaccinator. For information about registering or accessing HCS, please view **Appendix A**.

Enroll as a COVID-19 Vaccinator

In the Health Commerce System:

- Find "My Content" at the top of the page, and select "All Applications"
- Browse the letter "C" until you find "COVID-19 Vaccine Program Provider Enrollment."
- Select the green "+" to the right of the option.

The application is now available to complete in your "My Applications" panel. Once started, the application can be saved if you provide, at minimum, the healthcare organization name.

New York State Vaccine Program Application

Enrollment into the program requires the completion of a two-section application.

Section A: *COVID-19 Vaccination Program Provider Requirements and Legal Agreement.* This section specifies the conditions of participation for vaccination provider organizations and their constituent facilities in the federal COVID-19 vaccination program. The medical (or equivalent role) and chief executive officer (or chief fiduciary) signing this agreement must be the individuals who is held accountable for and responsible for compliance with the conditions outlined in the agreement. (Note: In the online tool signatures are obtained using an attestation check box.)

> *The CMO/Equivalent (must hold a valid license). Independent practices may list the same individual in both the medical and fiduciary fields.*
> *Because the online form is an attestation, the signatures from both parties should be collected on a hard copy version of the form and stored.*

Section B: *CDC COVID-19 Vaccination Program Provider Profile and Addendum.* This section outlines key minimum data elements required by CDC to be collected from every vaccination provider location[1] receiving COVID-19 vaccine and constituent products, such as receiving site address information, practice type, and patient population size and volume. An addendum includes questions required by NYSDOH.

There are two ways to enroll in the COVID-19 Vaccination Program:

1) Completing Section A, and adding each facility that will receive and administer vaccine on one application by completing Section B for each.
2) Have each facility location enroll independently, requiring Section A and Section B to be filled out for each.[2]

New York State Department of Health provides a detailed, step-by-step guide of each section of the application **here**, and a helpful video guide to completing the application **here**.

[1] Only provider locations that will receive (through shipments) and administer vaccine should be included in Section B. Do not include point-of-dispensing sites (i.e. sites where an enrolled vaccination provider will bring vaccine for administering to a targeted population on the same day).

[2] Locations that are part of a larger organization should check with the parent organization on whether they plan to enroll the sites under their application. If multiple sites are being enrolled, Section B should have different site contacts for each location.

Vaccine Formulation and Storage

Formulation and Packaging

Pfizer-BioNTech:

The Pfizer-BioNTech COVID-19 pediatric vaccines require diluent. The diluent is provided with ancillary supplies which are configured specifically for use in children. **Reconstitution of the product for use in 6 months through 11-year-olds uses a different volume of diluent than the adult formulation.**[3,4] Please note that once a vial is reconstituted, all 10 doses must be used within 12 hours. The vial must be discarded after 10 doses have been drawn and partial doses from different vials cannot be combined to make a full dose.

Moderna:

The Moderna COVID-19 pediatric vaccine **does not** require dilution. The vial must be discarded once a full dose can no longer be drawn from the vial and **partial doses from different vials cannot be combined to make a full dose**.

Storage Requirements

Pfizer-BioNTech:

Delivery: The packaging configuration for the Pfizer-BioNTech pediatric COVID-19 vaccines (for ages 5-11 years old and 6 months-4 years old) is 10-dose vials in cartons of 10 vials each (100 doses total). The product is delivered in a new product shipper at -80°C (-112F) on dry ice. The shipper contains a temperature monitoring device and instructions for using and returning the device[5]. The product can be stored before puncture and until expiration at -90 to -60°C (-130F to -76F).

On-Site Storage: Once the product arrives at the provider site, it can be stored for up to 10 weeks at refrigerated temperatures of 2 to 8°C (36F to 46F) before puncture. No standard freezer storage is approved for the new pediatric formulation. After puncture the vaccine can be stored 8 to 25°C (46F to 77F) for up to twelve hours. Vaccine not used after twelve hours must be discarded.

Moderna:

Delivery: The packaging configuration for the Moderna pediatric COVID-19 vaccines for ages 6-11 years old is 5-dose vials in cartons of 20 vials each (100 doses total). The 6 months-5 years old vaccine comes in 10-dose vials in cartons of 10 vials each (100 doses total). The product cannot be stored at ultra-low temperatures (ULT). The shipper contains a temperature monitoring device and instructions for using and returning the device[5]. The product can be stored before puncture and until expiration at -50 to -15°C (-58F to 5F).

On-Site Storage: Once the product arrives at the provider site, it can be stored for up to 30 days at refrigerated temperatures of 2 to 8°C (36F to 46F) before puncture or 8 to 25°C (46F to 77F) for a total of 24 hours. After puncture the vaccine can be stored 2 to 25°C (36F to 77F) for up to twelve hours. Vaccine not used after twelve hours must be discarded.

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[3] Instructions for dilution, preparation, and handling of the Pfizer 5-11y vaccine are available in the *Fact Sheet for Healthcare Providers Administering Vaccine* document in **Appendix B**.

[4] Instructions for dilution, preparation, and handling of the Pfizer 6m-4y vaccine are available in the *Fact Sheet for Healthcare Providers Administering Vaccine* document in **Appendix C**.

[5] Examples of a temperature monitoring device and its packaging are available for viewing **here**.

Vaccine Expiration

All vaccines have expiration dates, and some routinely recommended vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first punctured and the storage information in the package insert. Whenever a vial of COVID-19 vaccine is moved to storage conditions that affect BUD or a multidose vial is punctured, label the vial(s) with the beyond use date/time. The BUD must never exceed the labeled expiration date.

Pfizer-BioNTech

Pediatric vaccine vials do not have expiration dates printed on the label. Instead, the date of manufacture is printed on the label, along with the lot number. The expiration date is currently driven by the beyond use date, which is either twelve months after manufacture date if stored in ULT or 10 weeks if stored in the refrigerator.

Pfizer Pediatric (Maroon Cap 6m-4y): **Beyond-Use Date (BUD) Tracking Labels for Vaccine During Refrigerator Storage**

Pfizer Pediatric Tris (Orange Cap 5y-11y): **Beyond-Use Date (BUD) Tracking Labels for Vaccine During Refrigerator Storage**

Moderna

To obtain the expiration date of the lot number received, providers can scan the QR code located on the vial or carton or access the manufacturer's website directly, enter the lot number and the expiration date will be displayed. Moderna vaccines may be stored in standard freezer at temperatures between -50°C and -15°C (-58°F and 5°F) until expiration date. If vaccine is stored in a refrigerator, beyond use dates must be tracked.

Moderna Pediatric COVID-19 Vaccine (6m-5y): **Beyond-Use Date (BUD) Tracking Label for Vaccine During Refrigerator Storage o Refrigerator**

Providers should plan to minimize waste to the best of their ability but should not miss the opportunity to vaccinate a willing individual, even if it results in other wasted doses. See **Documenting Vaccine Wastage** for more information.

Vaccinator Training

The CDC requires specific COVID-19 vaccine administration training based on professional qualifications.

(Required) General Vaccine Safety: *General Overview of Immunization Best Practices for Healthcare Providers* **https://www2.cdc.gov/vaccines/ed/covid19/SHVA/index.asp**

(Required) Pfizer-BioNTech Specific Training: *Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know*. **https://www2.cdc.gov/vaccines/ed/covid19/pfizer/index.asp**

(Required) Moderna Specific Training: *Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know*. **https://www2.cdc.gov/vaccines/ed/covid19/moderna/index.asp**

Additional trainings are available to assist pediatric providers with their COVID-19 vaccine administration:
Web-Based Education Opportunities through CDC: **https://www.cdc.gov/vaccines/covid-19/training-education/index.html**
New COVID-19 Vaccination Provider Trainings: **https://ahpnetwork.com/cdc-covid-19-provider-trainings/**

Ordering COVID-19 Vaccine

To start an order

Open NYSIIS from the HCS homepage. On the left side, under "Inventory" click "Manage Orders." A "Create Order" button will appear. Record the quantity of vaccine you would like to order at the bottom of the screen. Use the "Order Notes" section to provide details about the order such as a specific need for increased doses than previously ordered. Orders can be modified if they are in Saved or Pending status by clicking on the status hyperlink of the order you would like to edit on the "Manage Order" screen.

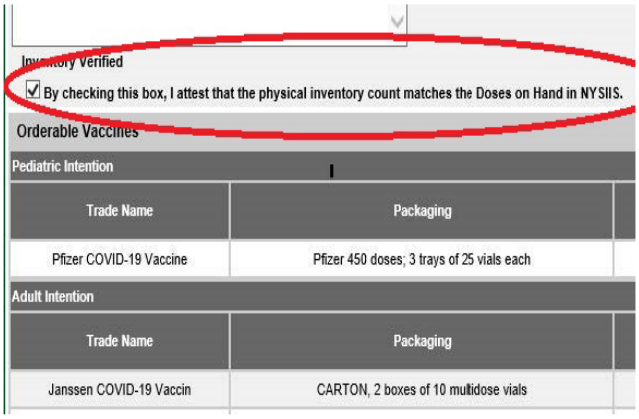
The Orderable Vaccines[6] section displays what is available to order based on the campaign(s) the Vaccine Program has you enrolled in. If you are enrolled in Vaccines for Children or Vaccine for Adults, additional vaccines will appear in addition to COVID-19 vaccine.

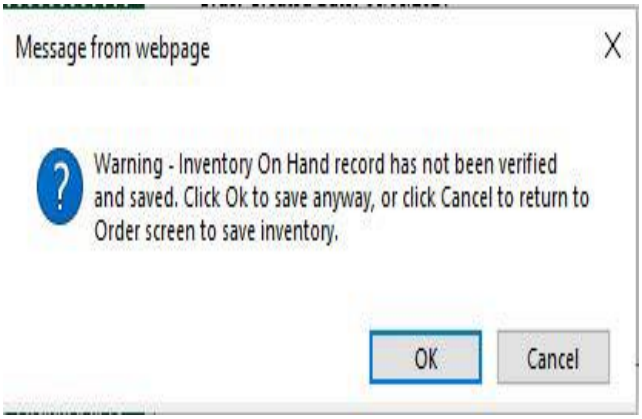
Although COVID-19 vaccine is ordered through NYSIIS like routine vaccine, **COVID-19 vaccines must be ordered separately from all other vaccines**. If you submit an order containing COVID-19 and another type of vaccine, your order will be denied.

Vaccine orders should be placed to support approximately three weeks of inventory or the minimum order quantity[7]. This will ensure doses are used in a timely manner, to avoid wastage of vaccine not used before expiration or beyond use date.

You must enter the request in DOSES, not packages. Orders must be in multiples of the doses per package. NYSIIS will round up to the nearest order (i.e. if you enter 10 for the Moderna vaccine, your order quantity will change to 100 upon saving).

Before saving or submitting your order, review your inventory on hand and ensure it is accurate. You must check the inventory verification box prior to saving or submitting. If modifications are needed, please access your NYSIIS Inventory module to correct inventory. If you do not check the inventory verification, a warning will appear.





[6] Orderable vaccines are separated by Intention (Pediatric vs Adult). Intention may relate to the age indication or the ancillary kit supplied with the vaccine. It is important to pay attention to the NYSIIS package description for age indication of different products.

[7] Orders of COVID-19 vaccine, automatically include a shipment of ancillary supplies, including record cards for each vaccinated patient. No additional order is needed to receive ancillary supplies. Ancillary kits arrive either with vaccine or one to two days before vaccine arrives. Ancillary supplies are disbursed based on the intention (Adult or Pediatric) selected when ordering vaccine. An example of the ancillary kits that are shipped with the vaccine are included as **Appendix D**.

Shipping and Inventory

Orders placed in NYSIIS are typically delivered within three to five business days. Orders are not delivered on Saturdays, Sundays, or holidays. Pfizer-BioNTech has provided a checklist to help prepare your office for receipt, storing, & handling the vaccine that is available **here**.

Accepting Vaccine into Inventory

When your shipment is received, check it over. Make sure you received what was ordered and approved and no vaccine has been damaged in transit. If there are any issues with the shipment, including temperature monitoring alarms, you must notify the Vaccine Program **the day the order is received** by emailing **COVID19Vaccine@health.ny.gov**. After placing the vaccine into your storage unit, log into NYSIIS and accept these vaccine lots into your NYSIIS inventory. It is important to do this **before** using any vaccine from the delivery so that doses administered properly deduct from inventory.

Click on "Manage Transfers" on the left menu panel.

If there are transfers(orders) that need to be accepted, they will display as hyperlinks under the "Transfer ID" column. A Transfer ID may have a single or multiple vaccine products ready to be accepted.

Click on one of the Transfer IDs that needs to be accepted. Navigate to the "Receive Transfer" screen. Here detailed information about the order is displayed including: quantity shipped, trade name, lot number, expiration date, and NDC description. Inspect the physical inventory received and make sure it matches all of the information in NYSIIS. Next, click the "Accept Transfer" button in the upper right-hand corner.

Once the item or items are accepted, NYSIIS will populate your inventory with the lot information automatically. Note: only orders placed in NYSIIS and received via a shipment from the manufacturer or distributor will appear in the "Manage Transfers" screen.

Vaccine Preparation and Handling

Pfizer-BioNTech:

The Pfizer-BioNTech pediatric COVID-19 vaccine requires dilution to be administered. The additional steps and supplies needed to prepare the vaccine require more space. Please view the special handling needs for the Pfizer-BioNTech 5-11y pediatric COVID-19 vaccine beginning on page six of **Appendix B** and the Pfizer-BioNTech 6m-4y pediatric COVID-19 vaccine beginning on page six of **Appendix C**. Ideally, the space should be well lit, stocked with all needed supplies to draw the vaccine (alcohol wipes, needles, sharp containers, recording cards, etc.), and be located in close proximity to where the vaccine is stored.

Moderna:

Although the Moderna vaccine does not require dilution, the space where vaccines are drawn should still be well lit, stocked with all needed supplies to draw the vaccine (alcohol wipes, needles, sharp containers, recording cards, etc.), and be located in close proximity to where the vaccine is stored.

Preparing for Adverse Reactions

While rare, vaccinating providers must be prepared to manage adverse reactions, such as anaphylaxis, following vaccination with the COVID-19 vaccine.

Emergency kits must be located near the area of vaccine administration. Kits should include age appropriate doses of epinephrine (at least 3 doses), H1 antihistamine (e.g. cetirizine, diphenhydramine), blood pressure monitoring (equipped with size appropriate cuffs), and a timing device to assess pulse.

Emergency kits may also include, if feasible: pulse oximeter, oxygen, bronchodilator (e.g. albuterol), H2 antihistamine (e.g. famotidine, cimetidine), intravenous fluids, intubation kit, pocket mask with one-way valve (adult and pediatric sizes).

If there is a suspicion of anaphylaxis, an algorithm for management is available at the CDC website **here.**

Vaccinating in Your Office

Screening Checklists and Consent Forms

Screening checklists and consent forms are provided by the New York State Department of Health, Bureau of Immunization. The checklist and consent form for children and adolescents ages 6 months-11 years is available for download **here**. The consent form includes information about the vaccine's availability under emergency use authorization (EUA).

Use of the screening checklist and consent form provided by the New York State Department of Health is optional; however, appropriate screening, disclosure of the EUA, and consent to receive a pediatric COVID-19 vaccine must be documented for each patient. Patients under 18 years of age must have consent by a parent or guardian to receive the COVID-19 vaccine.

Common Workflows

There are several ways to integrate COVID-19 vaccination into your practice:

- **Incorporate vaccination into other office visits:**
  Include COVID-19 vaccination into existing appointments (well visits, chronic condition management visits, medication management visits, etc.).
- **Standalone appointments for vaccination**:
  Patients are scheduled for appointments where vaccination against COVID-19 is the only service performed.
- **Combination of standalone and incorporated vaccination**:
  Patients are vaccinated against COVID-19 during regularly scheduled appointments ***or*** during vaccine only appointments.
- **Vaccinating siblings and caregivers:**
  If the provider has the opportunity and appropriate vaccine supply to vaccinate siblings and adults, they may choose to do so.

Emergency Use Authorization (EUA) Fact Sheet

The pediatric Pfizer-BioNTech COVID-19 and Moderna vaccines are currently available to the public under FDA emergency use authorization. As such, the EUA disclosure must be made available to each patient receiving the vaccine or their caregiver.

- Moderna 6 months through 5 years: Download the disclosure **here**.
- Moderna 6 years through 11 years: Download the disclosure **here**.
- Pfizer-BioNTech 6 months through 4 years: Download the disclosure **here**.
- Pfizer-BioNTech 5 years through 11 years: Download the disclosure **here**.

Monitoring Space

After administering a pediatric COVID-19 vaccine, providers should have recipients wait under supervision for 30 or 15 minutes based on CDC recommendation. Individuals with a history of non-severe, immediate (onset less than 4 hours) allergic reaction after previous COVID-19 vaccine; a history of an immediate allergic reaction after any vaccine or injectable therapy; or individuals with a history of anaphylaxis due to any cause should wait 30 minutes. All others can wait for 15 minutes. Ultimately, a longer period of observation based on clinical concerns is up to the discernment of the vaccinating provider.

If the vaccine is administered as part of an incorporated workflow, the examination room used for the visit can be used for the supervision period.

If the vaccine is administered as part of a standalone workflow, a dedicated supervision space is needed. In accordance to additional COVID-19 prevention efforts, the space should be one that appropriately considers social distancing.

Best Practices

Vaccine Program Coordinator

A vaccine program ambassador/coordinator should be identified. The program ambassador will serve as the main point of contact for ordering vaccine, accepting shipments, scheduling, and reporting.

Vaccine Co-Administration

Providers should try to eliminate wastage, but no opportunity to vaccinate should be missed. Whenever possible, vaccination against COVID-19 should be administered along with other childhood vaccines during the course of a provider visit for eligible patients, even if it means wasting additional vaccine doses from a vial.

Using Standing Orders

Standing orders are an easy and effective way to improve vaccination in your office.

- Moderna: **Standing Order Template 6 months-5 years**
- Moderna: **Standing Order Template 6 years-11 years**
- Pfizer-BioNTech: **Standing Order Template 6 months-4 years**
- Pfizer-BioNTech: **Standing Order Template 5 years-11 years**

Pre-Appointment Consents and Forms

If your office uses patient portals, deliver a **consent form** and the appropriate emergency use authorization form before the visit. The NYS Consent and Information Form is no longer required as of May 1, 2022.

Scheduling Second Dose Appointment at First Dose Appointment

Not only is it best practice, but **New York State requires providers** to schedule the second dose at the time the first dose is administered.

	Pfizer 6m-4yr	Moderna 6m-5yr	Pfizer 5yr-11yr	Moderna 6y-11
Second Dose	3 weeks after 1st dose	1 month (4 weeks after dose 1)	3 weeks after 1st dose	1 month (4 weeks after 1st dose)
Third Dose	At least 8 weeks after 2nd dose	Immunocompromised: Minimum 1 month between 2nd and 3rd dose		Immunocompromised: Minimum 1 month between 2nd and 3rd dose

Leverage Your Electronic Medical Record (EMR)

- Auto-scheduling in the electronic medical record can help facilitate the process for subsequent doses. Auto-scheduling can be used for patients needing the two-dose primary series, or the needing the three-dose primary series due to a weakened immune system.
- Add the Pfizer-BioNTech and Moderna pediatric vaccine CPT codes, applicable administration CPT codes, and the EUA to your EMR in the same way you would add other pediatric vaccines[8].
- Create a unique appointment code for COVID-19 vaccination. Use the code to run nightly reminders for upcoming visits.
- If vaccinating parents or caregivers, add them to your EMR, but remember to keep them "inactive."

[8] The American Medical Association's COVID-19 Vaccine CPT Code Resource: **https://www.ama-assn.org/find-covid-19-vaccine-codes**

COVID-19 Vaccine Coding and Reimbursement

Providers who administer COVID-19 vaccines in the office can receive reimbursement for their efforts. The American Academy of Pediatrics has developed a coding resource based on CMS guidance for the special considerations regarding COVID-19 vaccination.

The AAP resource provides information about instances of vaccine counseling with no administration and specific payers (Medicare, Medicaid, Private Insurance, Uninsured). View the quick guide **here** or the website **here**.

New York State Department of Health released Medicaid guidance for **COVID-19 vaccine administration** and **counseling**.

New York State Reporting Requirements - Vaccine Administration, Adverse Reactions, and Wastage

Vaccine Administration

New York State requires providers to report the administration of a COVID-19 vaccination within 24 hours of the vaccine being given. This reporting is done through NYSIIS and satisfies additional federal reporting requirements as well. See the full reporting requirements **here**.

Reporting Adverse Reactions

As a provider administering a vaccine that is for use under emergency use authorization (EUA), you are required to report vaccine administration errors, serious adverse events, cases of Multisystem Inflammatory Syndrome, and cases of COVID-19 that result in hospitalization or death. Adverse reactions must be reported to the Vaccine Adverse Event Reporting System (VAERS). More information regarding reporting is available on the VAERS website (**https://vaers.hhs.gov/**). Reporting of any other clinically significant adverse reactions is recommended.

Anyone can report adverse reactions and the CDC has developed a new, voluntary, phone-based tool called v-safe that uses text messages and web surveys to provide patients with health check-ins after receiving COVID-19 vaccination. Patient takeaways and other printable resources are available **here**.

Documenting Vaccine Wastage

To report wastage, you must be an Administrative User in NYSIIS. Vaccine wastage needs to be tracked for each clinic day and reported into NYSIIS by the NYSIIS Administrative User for your practice. [9] Wastage is reported using the NYSIIS "Manage Returns and Wastage" module.

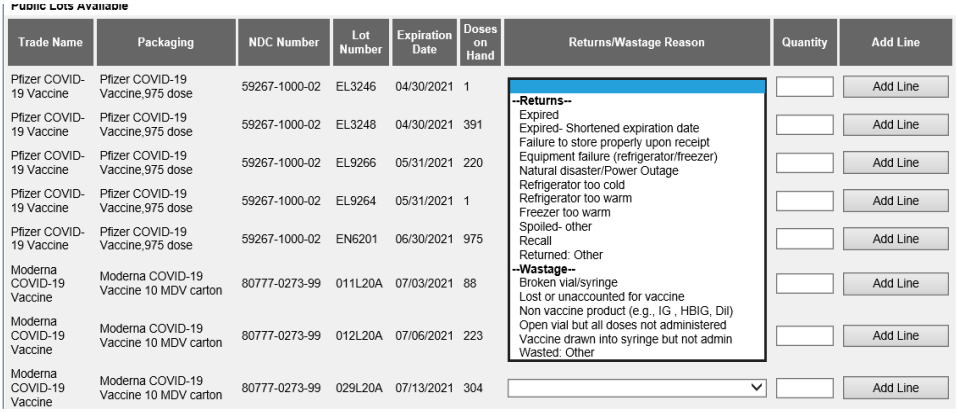
Create a Wastage Request in NYSIIS

From the homepage, select "Manage Returns and Wastage" on the left, and click "create a request."

The bottom portion of the Create Returns/Wastage screen, the Public Lots Available section (Figure 3), displays a table to record the quantity of each lot of COVID-19 vaccine that will be reported as wastage, and the reason.

1. Identify the lot that has wasted doses.
2. Select a wastage reason.
    a. Do not choose any reason listed under 'Returns', only use 'Wastage' reasons.[10]
3. If you have more than one reason for a given lot, click "Add Line" which will add the same vaccine information below so you can select the additional reason.
4. Enter the number of wasted doses in the "Quantity" box.[11]

[9] Do not return expired or spoiled COVID-19 vaccine to the manufacturer or the distribution center. All vaccine that is expired or spoiled must be reported as wastage because it cannot be returned. Dispose of vaccine as medical waste.
[10] See **Appendix E** for the full guidance on vaccine wastage reporting.
[11] You cannot enter a quantity that exceeds the number of Doses on Hand.


Public Lots Available

Trade Name	Packaging	NDC Number	Lot Number	Expiration Date	Doses on Hand	Returns/Wastage Reason	Quantity	Add Line
Pfizer COVID-19 Vaccine	Pfizer COVID-19 Vaccine,975 dose	59267-1000-02	EL3246	04/30/2021	1			Add Line
Pfizer COVID-19 Vaccine	Pfizer COVID-19 Vaccine,975 dose	59267-1000-02	EL3248	04/30/2021	391			Add Line
Pfizer COVID-19 Vaccine	Pfizer COVID-19 Vaccine,975 dose	59267-1000-02	EL9266	05/31/2021	220			Add Line
Pfizer COVID-19 Vaccine	Pfizer COVID-19 Vaccine,975 dose	59267-1000-02	EL9264	05/31/2021	1			Add Line
Pfizer COVID-19 Vaccine	Pfizer COVID-19 Vaccine,975 dose	59267-1000-02	EN6201	06/30/2021	975			Add Line
Moderna COVID-19 Vaccine	Moderna COVID-19 Vaccine 10 MDV carton	80777-0273-99	011L20A	07/03/2021	88			Add Line
Moderna COVID-19 Vaccine	Moderna COVID-19 Vaccine 10 MDV carton	80777-0273-99	012L20A	07/06/2021	223			Add Line
Moderna COVID-19 Vaccine	Moderna COVID-19 Vaccine 10 MDV carton	80777-0273-99	029L20A	07/13/2021	304			Add Line

5. Click on **Save and Submit**.
    a. A dialog box will appear which asks "Are you sure you want to submit list?"
    b. IMPORTANT: DO NOT ATTEMPT TO GO INTO YOUR PUBLIC INVENTORY AND MAKE MODIFICATIONS TO LOT QUANTITIES THAT WERE IMPACTED BY RETURNS/WASTAGE REQUESTS. When your request reaches a "Final-Approved" status, your inventory will decrement automatically.

Your request will display in the "Current Returns/Wastage" section with a *Pending* status. Once the Vaccine Program opens your request, the status will change to "Under View by VFC" *(*Vaccine Program). When the request is approved you will see a status of "Final-Approved".[12]

If you have questions about wastage reporting, please email **COVID19Vaccine@health.ny.gov**.

[12] If the Vaccine Program needs the provider to modify the request (such as incorrect reason selected, or insufficient information provided), the status will change to "Denied". If this happens, the Vaccine Program will contact you with instructions.

Vaccine Hesitancy, Misinformation, and Supporting Resources

Widespread vaccination against COVID-19 is needed to end the COVID-19 pandemic. Several resources are available to help providers combat misinformation and disinformation in the community and improve vaccination rates.

Ana Chat Bot

As a collaborative effort, the Association of University Centers on Disabilities developed a series of posters to promote confidence in the pediatric COVID-19 vaccine. The posters feature a QR code linking the user to 'Ana,' the COVID-19 Vaccine Information Bot. Ana allows users to select common concerns and questions about the COVID-19 vaccine and access resources using the chat feature. Ana is available in English and Spanish and posters are available on our resource page **here**.

American Academy of Pediatrics (AAP)

The American Academy of Pediatrics' COVID-19 Vaccine Campaign Toolkit features printable posters, videos, and graphics designed for various social media platforms. View the social media toolkit **here**.

Elmo gets the COVID-19 vaccine with his dad, Louie. Watch the video **here**.

Community Toolkit for Addressing Health Misinformation

The Office of the U.S. Surgeon General released a toolkit designed to help community members, including healthcare professionals, combat misinformation in their community. The toolkit offers definitions, examples, and possible reasons why misinformation exists and spreads. View the toolkit **here**.

Customizable Vaccine Letter to Send to Parents/Caregivers

The CDC has a letter template that providers can send to the parents or caregivers of children eligible for COVID-19 vaccination. Outlined in the letter is the importance of vaccination, explanation of the EUA, and typical COVID-19 vaccination side effects. The template is available to download **here**.

Finger Lakes COVID-19 Vaccine Hub

The Finger Lakes COVID-19 Vaccine Hub has a list of frequently asked questions and answers. Providers may utilize the vaccine hub FAQ during vaccine counseling with families. The FAQs can be found **here**.

Golisano Children's Hospital

Golisano Children's Hospital's webpage features up-to-date resources surrounding COVID-19 vaccination in pediatric populations, tools for addressing common questions and concerns, information about testing, and additional vaccine resources. Visit the site here.

U.S. Department of Health and Human Services (DHHS)

The U.S. DHHS has a toolkit developed in partnership with the AAP with new, culturally tailored materials. The video includes posters, videos, and social media sample posts. View it **here**.

V-Safe

After COVID-19 vaccination, patients are eligible to sign up for v-safe, a personalized and confidential health check-in via text and web survey. V-safe allows patients and their parents/caregivers to share how they are feeling after vaccination. This information helps the CDC monitor the safety of COVID-19 vaccine in near real time. Information sheets and printable flyers are available for download **here**.

Appendix A- Health Commerce System Help Sheet

Health Commerce System

If your practice is enrolling in the NYSDOH COVID-19 Vaccination Program, all prescribers at your facility that may write orders for COVID-19 vaccine need to be enrolled in the NYSDOH COVID-19 Vaccination Program. Therefore, each individual must have a New York State Health Commerce System (HCS) account. These accounts **cannot** be shared. Access to HCS is required to access the New York State Immunization Information System (NYSIIS)

Use an Existing HCS Account

To login to your HCS account go to the **Health Commerce System login page** and enter your user ID and password.

If you believe you have worked with the HCS system before but are unable to login, contact your organization's HCS Coordinator. If you do not know who your HCS Coordinator is, contact the Commerce Management Unit (CAMU) at 1-866-529-1890 or **hinhpn@health.state.ny.us**.

Create New HCS Account

To create a new account, go to the **Health Commerce System login page** and click "Sign Up Here." A pop-up will appear asking whether you are a medical or non-medical professional. This will determine the type of account you can register for. Select the appropriate answer. On the next page, follow instructions to register for an account.

If you need help creating an HCS account, contact your organization's HCS Coordinator. If you do not know who your HCS Coordinator is, contact the Commerce Management Unit (CAMU) at 1-866-529-1890 or **hinhpn@health.state.ny.us**.

Medical Professionals

Medical professionals must have a NYS Driver License or Non-driver Photo ID and their NYS Education Department registered medical professional license to create an HCS account. A step-by-step guide to registering for an HCS account as a medical professional can be found **here**. Medical professionals are automatically considered "HCS Coordinators."

Non-Medical Professionals

Staff involved in COVID-19 efforts who will be utilizing NYSIIS also need to have an HCS account. User setup for staff is a two-part process. First, staff register for an HCS account **here**. Second, the HCS Coordinator for the medical practice logs into their HCS account and adds the user to the medical practice following the steps outlined in part B. of the help document attached **here**.

Appendix B- Fact Sheet for Healthcare Providers Administering Pfizer-BioNTech 5y-11y Vaccine (Vaccination Providers)

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

FOR 5 THROUGH 11 YEARS OF AGE
DILUTE BEFORE USE

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, for active immunization to prevent COVID-19 in individuals 5 years of age and older.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with an orange cap and a label with an orange border which is authorized for use to provide a 2-dose primary series to individuals 5 through 11 years of age. The vaccine is also authorized to provide a third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise. The vial labels state: Age 5y to <12y. The carton labels state: For age 5 years to <12 years.

Pfizer-BioNTech COVID-19 Vaccine which is supplied in a multiple dose vial with an orange cap and a label with an orange border, should not be used in individuals 12 years of age and older.[1]

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 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. See “MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

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

[1] Notwithstanding the age limitations for use of the different formulations and presentations described above, individuals who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA) (supplied in multidose vials with orange caps); or (2) COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 mcg modRNA) (supplied in multidose vials with gray caps and multidose vials with purple caps).

The Pfizer-BioNTech COVID-19 Vaccine, which is supplied in a multiple dose vial with an orange cap and a label with an orange border, is administered, after dilution, as a primary series of 2 doses (0.2 mL each) 3 weeks apart in individuals 5 through 11 years of age.

A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders (0.2 mL) at least 28 days following the second dose is authorized for administration to individuals 5 through 11 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

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 for active immunization against 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 which is supplied in a multiple dose vial with an orange cap and a label with an orange border and **MUST BE DILUTED** before use.

Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial with Orange Cap and a Label with an Orange Border

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
5 through 11 years (Vial labels state: Age 5y to <12y)	Dilute with 1.3 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

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 multiple dose vials with orange caps and labels with orange borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice.

Once received, frozen vials may be immediately transferred to the refrigerator [2ºC to 8ºC (35ºF to 46ºF)], 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 vials may take up to 4 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed they should not be refrozen.

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may also arrive at 2°C to 8°C. If received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons. Expiry dates based on 9 months from the date of the manufacture are shown below.

Printed Manufacturing Date	9-Month Expiry Date
06/2021	28-Feb-2022
07/2021	31-Mar-2022
08/2021	30-Apr-2022
09/2021	31-May-2022
10/2021	30-Jun-2022
11/2021	31-Jul-2022
12/2021	31-Aug-2022
01/2022	30-Sep-2022
02/2022	31-Oct-2022

Vial Storage During Use

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

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to dilution.

After dilution, the vial should be held between 2ºC to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution.

Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this Fact Sheet supersedes the number of hours printed on vial labels and cartons.

Transportation of Vials

If local redistribution is needed, undiluted 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

The Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders is administered intramuscularly as a primary series of 2 doses (0.2 mL each) 3 weeks apart to individuals 5 through 11 years of age.

A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders (0.2 mL) at least 28 days following the second dose is authorized for administration to individuals 5 through 11 years of age who have undergone solid organ

transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Pfizer-BioNTech COVID-19 Vaccine that is supplied in vials with purple or gray caps should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

Dose Preparation

Each vial **MUST BE DILUTED** before administering the vaccine.

Prior to Dilution

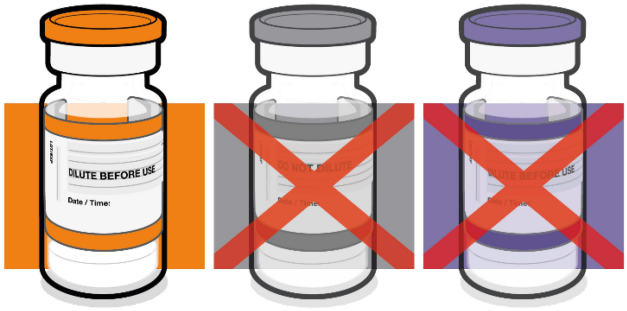
- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with an orange cap and a label with an orange border contains a volume of 1.3 mL, and is supplied as a frozen suspension that does not contain preservative.
- Each vial must be thawed before dilution.
  - Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)].
  - Refer to thawing instructions in the panels below.

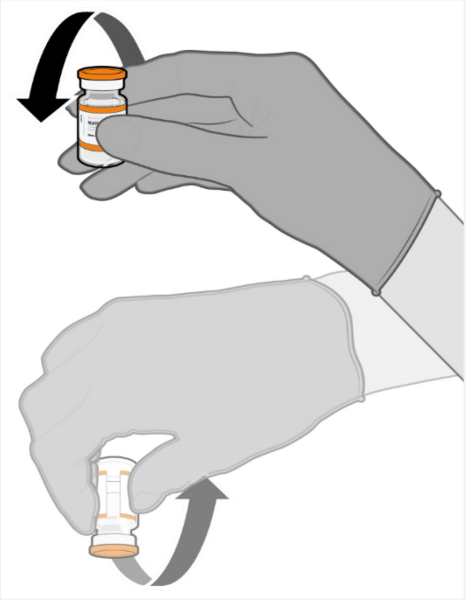
Dilution

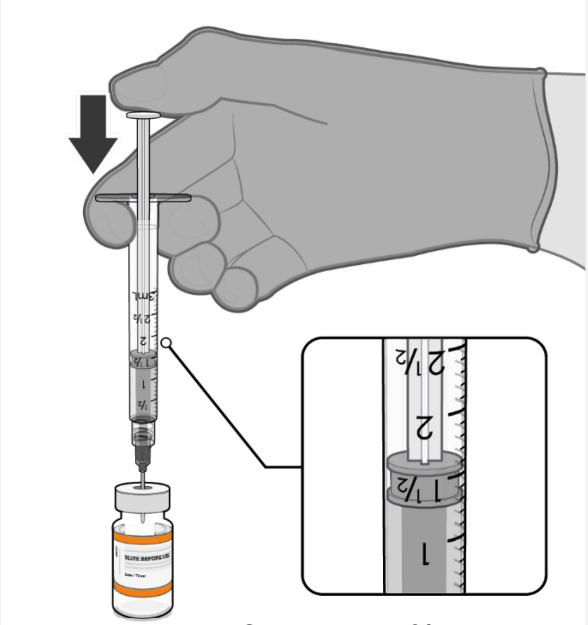
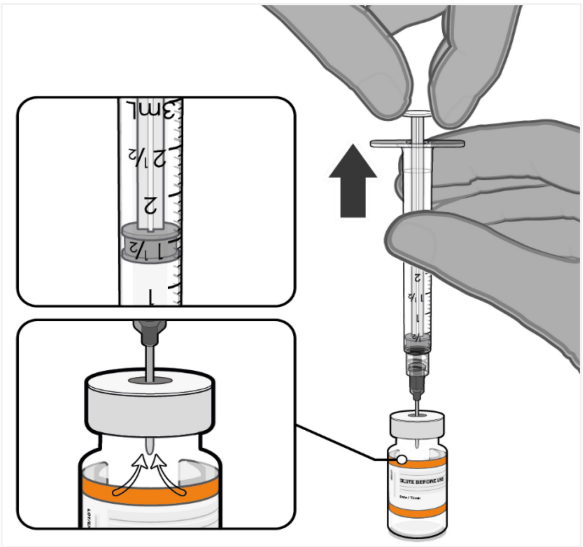
Dilute the vial contents using 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.

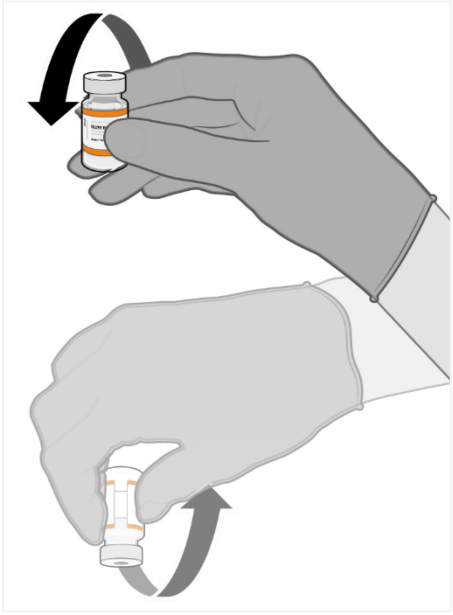
ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.3 mL of diluent.

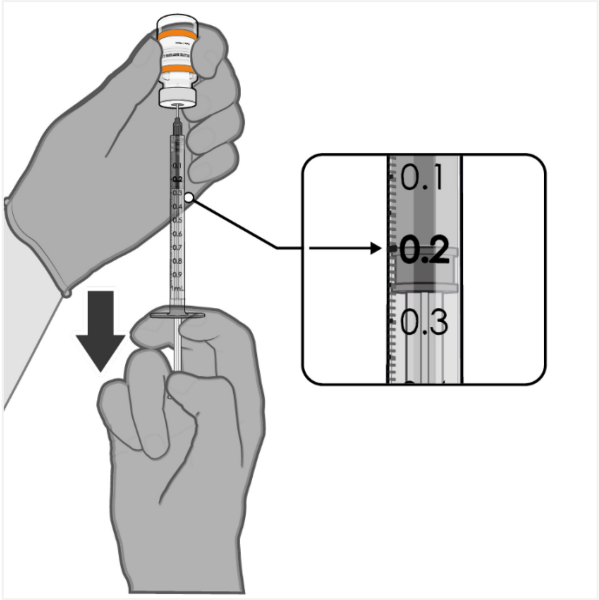
After dilution, 1 vial contains 10 doses of 0.2 mL.

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – VIAL VERIFICATION	
 ✓ **Orange plastic cap and label with orange border.**	• Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states "Age 5y to < 12y."
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – THAWING PRIOR TO DILUTION	
 **Store in the refrigerator for up to 10 weeks prior to use.**	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: ○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks. ○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. ○ Vials may be stored at room temperature [up to 25ºC (77ºF)] for up to 12 hours prior to use.

Dilution and Preparation Instructions	
 **Gently × 10**	• Before dilution, mix by inverting vaccine vial gently 10 times. • <u>Do not shake</u>. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – DILUTION	
 **Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.**	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.
 **Pull back plunger to 1.3 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.

<table>
<tr><th colspan="2">Dilution and Preparation Instructions</th></tr>
<tr><td> 
Gently × 10</td><td>• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
• <u>Do not shake</u>.
• Inspect the vaccine in the vial.
• The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.</td></tr>
<tr><td> 
Use within 12 hours after dilution.</td><td>• Record the date and time of first vial puncture on the vial label.
• Store between 2°C to 25°C (35°F to 77°F).
• Discard any unused vaccine 12 hours after dilution.</td></tr>
</table>

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border - WITHRAWAL OF INDIVIDUAL 0.2 mL DOSES	
 **Withdraw 0.2 mL dose of vaccine.**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.2 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine with orange caps and labels with orange borders contain 10 doses of 0.2 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

Contraindications

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

Monitor Pfizer-BioNTech COVID-19 Vaccine 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 data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. 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.

Limitation of Effectiveness

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

Adverse Reactions

Adverse Reactions in Clinical Trials
Adverse reactions in children 5 through 11 years following administration of the primary series included pain at the injection site, fatigue, headache, injection site redness, injection site swelling, muscle pain, chills, fever, joint pain, lymphadenopathy, nausea, malaise, decreased appetite, and rash *(see Full EUA Prescribing Information)*.

Adverse Reactions in Individuals 12 years of Age and Older 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), and syncope have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

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

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

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine 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) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, 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 to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

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 second-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 ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION[2]

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, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine 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 is authorized for use in individuals 5 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine 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.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

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),

[2] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

- 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 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 MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine 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 Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

There may be clinical trials or availability under EUA of other COVID-19 vaccines.

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 for active immunization against COVID-19. Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with an orange cap and a label with an orange border is authorized for use to provide a 2-dose primary series in individuals 5 through 11 years of age.

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 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 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.

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
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LAB-1502-3.0

Revised: 03 January 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

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

* 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 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 5 years of age and older.

This EUA Prescribing Information pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with an orange cap and a label with an orange border, which is authorized for use in individuals 5 through 11 years of age. The vial labels state: Age 5y to <12y. The carton labels state: For age 5 years to <12 years.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

The storage, preparation, and administration information in this Prescribing Information apply to the Pfizer-BioNTech COVID-19 Vaccine, which is supplied in a multiple dose vial with an orange cap and a label with an orange border.

Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial with Orange Cap and a Label with an Orange Border

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
5 through 11 years (Vial labels state: Age 5y to <12y)	Dilute with 1.3 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

2.1 Preparation for Administration

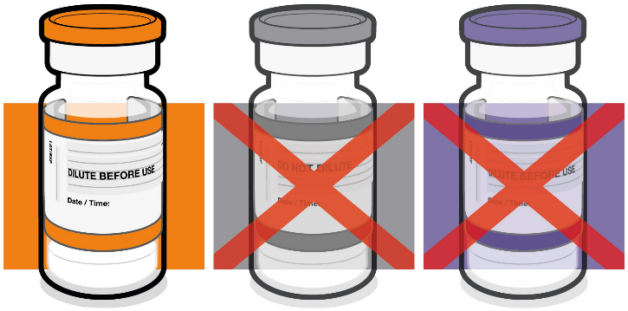
Each vial **MUST BE DILUTED** before administering the vaccine.

Prior to Dilution

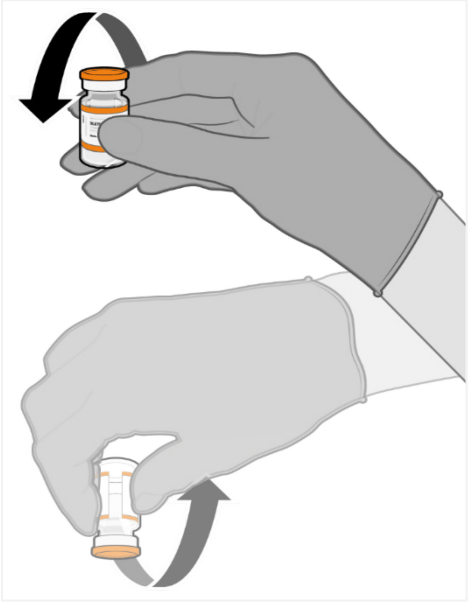
- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with an orange cap and a label with an orange border contains a volume of 1.3 mL, and is supplied as a frozen suspension that does not contain preservative.
- Each vial must be thawed before dilution.
  - Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)].
  - Refer to thawing instructions in the panels below.

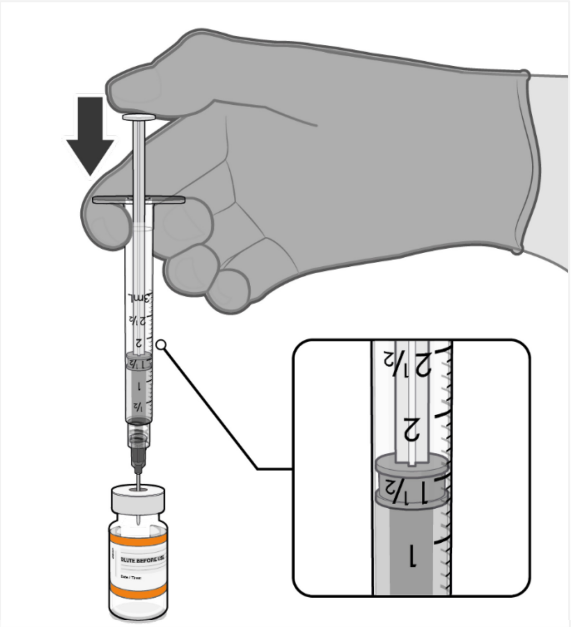
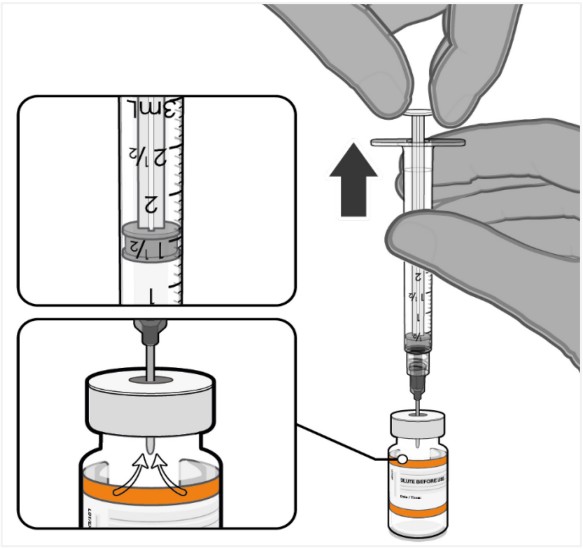
Dilution

- Dilute the vial contents using 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.
- ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.3 mL of diluent.
- After dilution, 1 vial contains 10 doses of 0.2 mL.

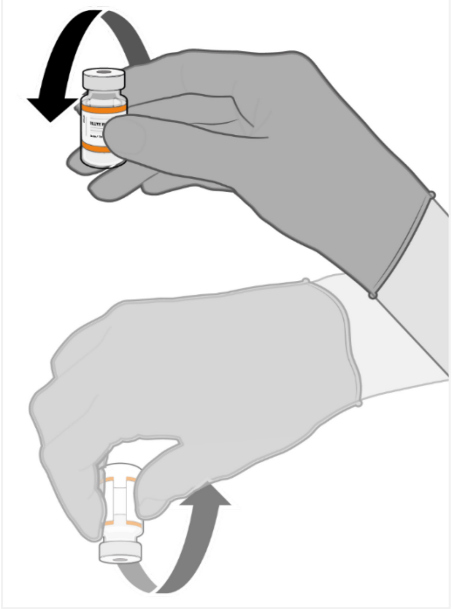
<table>
<tr><th colspan="2">Dilution and Preparation Instructions</th></tr>
<tr><td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – VIAL VERIFICATION</td></tr>
<tr><td> 

✓ Orange plastic cap and label with orange border.</td><td>• Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states “Age 5y to < 12y.”.</td></tr>
<tr><td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – THAWING PRIOR TO DILUTION</td></tr>
<tr><td> 
</td><td>• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
o Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
o Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
o Vials may be stored at room temperature [up to 25ºC (77ºF)] for 12 hours prior to use.</td></tr>
</table>

Dilution and Preparation Instructions	
 **Gently × 10**	• Before dilution, mix by inverting vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – DILUTION	
 **Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.**	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.
 **Pull back plunger to 1.3 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.

Dilution and Preparation Instructions

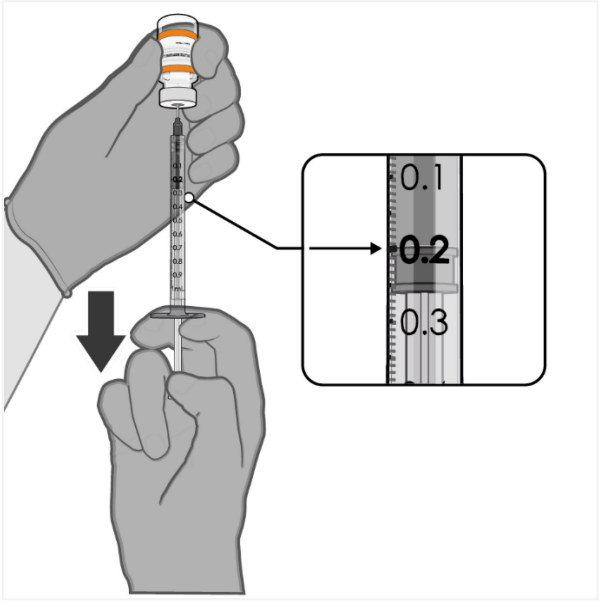


Gently × 10

- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

Use within 12 hours after dilution.

- Record the date and time of first vial puncture on the vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after dilution.

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – WITHDRAWAL OF INDIVIDUAL 0.2 mL DOSES	
 **Withdraw 0.2 mL dose of vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.2 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine with orange caps and labels with orange borders contain 10 doses of 0.2 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

2.3 Vaccination Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 2 doses (0.2 mL each) 3 weeks apart in individuals 5 through 11 years of age.

A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders (0.2 mL) at least 28 days following the second dose is authorized for

administration to individuals 5 through 11 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

3 DOSAGE FORMS AND STRENGTHS

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

After preparation, each dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders is 0.2 mL for individuals 5 through 11 years of age *[see Dosage and Administration (2.1)]*.

4 CONTRAINDICATIONS

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

Monitor Pfizer-BioNTech COVID-19 Vaccine 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 data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. 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.

5.5 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine 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 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.[3] 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.

In a clinical study in children 5 through 11 years of age who received Pfizer-BioNTech COVID-19 Vaccine containing 10 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 (10 mcg modRNA), adverse reactions following administration of any primary series dose included pain at the injection site (84.3%), fatigue (51.7%), headache (38.2%), injection site redness (26.4%), injection site swelling (20.4%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%).

Post Authorization Experience in Individuals 12 Years of Age and Older

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

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

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.

The safety of the primary series Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 5 years of age and older in 3 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 (30 mcg modRNA); 21,728 placebo] in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively) and 2,260 adolescents are 12 through 15 years of age (1,131 and 1,129 in the vaccine and placebo groups, respectively). Study C4591007 (Study 3) is a Phase 1/2/3 multicenter, randomized, dose-finding, open-label (Phase 1) and multinational, saline placebo-controlled,

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

observer-blind, immunogenicity and efficacy (Phase 2/3) study that has enrolled 4,695 participants 5 through 11 years of age, of whom 3109 participants received Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA) and 1538 participants received placebo in Phase 2/3.

In Study 2 and Study 3, all participants 5 through 11 years of age, 12 through 15 years of age, and 16 years of age and older in the reactogenicity subset, 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, 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]. Tables 1 and 2 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID 19 Vaccine (10 mcg modRNA) and placebo in children 5 through 11 years of age.

Children 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 (10 mcg modRNA) 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 (10 mcg modRNA) 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 (10 mcg modRNA) 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 (10 mcg modRNA), 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.

Solicited Local and Systemic Adverse Reactions

The mean duration of pain at the injection site after Dose 2 was 2.3 days (range 1 to 11 days), for redness 2.2 days (range 1 to 10 days), and for swelling 2.2 days (range 1 to 10 days) for children in the Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA) group up to the cutoff date of September 06, 2021.

Table 1: Study 3 – Frequency and Percentages of Participants With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Children 5 Through 11 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1511 n[c] (%)	**Placebo Dose 1 N[a,b]=748 n[c] (%)**	**Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1501 n[c] (%)**	**Placebo Dose 2 N[a,b]=740 n[c] (%)**
Redness[d]				
Any (≥0.5 cm)	222 (14.7)	43 (5.7)	278 (18.5)	40 (5.4)
Mild	143 (9.5)	37 (4.9)	143 (9.5)	31 (4.2)
Moderate	79 (5.2)	6 (0.8)	132 (8.8)	9 (1.2)
Severe	0	0	3 (0.2)	0

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1511 n[c] (%)	Placebo Dose 1 N[a,b]=748 n[c] (%)	Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1501 n[c] (%)	Placebo Dose 2 N[a,b]=740 n[c] (%)
Swelling[d]				
Any (≥0.5 cm)	158 (10.5)	20 (2.7)	229 (15.3)	20 (2.7)
Mild	85 (5.6)	13 (1.7)	117 (7.8)	15 (2.0)
Moderate	72 (4.8)	7 (0.9)	112 (7.5)	5 (0.7)
Severe	1 (0.1)	0	0	0
Pain at the injection site[e]				
Any	1119 (74.1)	234 (31.3)	1065 (71.0)	218 (29.5)
Mild	890 (58.9)	204 (27.3)	793 (52.8)	192 (25.9)
Moderate	225 (14.9)	30 (4.0)	267 (17.8)	26 (3.5)
Severe	4 (0.3)	0	5 (0.3)	0

Note: Reactions were collected in an electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

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

b. The denominators (N) used in the percentage calculations for redness and swelling were 749 after Dose 1 and 741 after Dose 2 in the placebo group, due to an e-diary error.

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

d. Mild: ≥0.5 to ≤2.0 cm; Moderate: >2.0 to ≤7.0 cm; Severe: >7.0 cm.

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

* Randomized participants who received at least 1 dose of the study intervention.

± Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA).

Table 2: Study 3 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Children 5 Through 11 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1511 n[c] (%)	Placebo Dose 1 N[a,b]=748 n[c] (%)	Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1501 n[c] (%)	Placebo Dose 2 N[a,b]=740 n[c] (%)
Fever				
≥38.0°C	38 (2.5)	10 (1.3)	98 (6.5)	9 (1.2)
≥38.0°C to 38.4°C	23 (1.5)	4 (0.5)	51 (3.4)	5 (0.7)
>38.4°C to 38.9°C	12 (0.8)	5 (0.7)	38 (2.5)	3 (0.4)
>38.9°C to 40.0°C	3 (0.2)	1 (0.1)	8 (0.5)	1 (0.1)
>40.0°C	0	0	1 (0.1)	0
Fatigue[d]				
Any	508 (33.6)	234 (31.3)	592 (39.4)	180 (24.3)
Mild	333 (22.0)	150 (20.1)	321 (21.4)	96 (13.0)
Moderate	171 (11.3)	83 (11.1)	260 (17.3)	83 (11.2)
Severe	4 (0.3)	1 (0.1)	11 (0.7)	1 (0.1)
Headache[d]				
Any	339 (22.4)	180 (24.1)	420 (28.0)	138 (18.6)
Mild	249 (16.5)	131 (17.5)	281 (18.7)	93 (12.6)
Moderate	88 (5.8)	45 (6.0)	136 (9.1)	45 (6.1)
Severe	2 (0.1)	4 (0.5)	3 (0.2)	0

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1511 n[c] (%)	Placebo Dose 1 N[a,b]=748 n[c] (%)	Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1501 n[c] (%)	Placebo Dose 2 N[a,b]=740 n[c] (%)
Chills[d]				
Any	70 (4.6)	35 (4.7)	147 (9.8)	32 (4.3)
Mild	54 (3.6)	30 (4.0)	105 (7.0)	24 (3.2)
Moderate	16 (1.1)	5 (0.7)	40 (2.7)	7 (0.9)
Severe	0	0	2 (0.1)	1 (0.1)
Vomiting[e]				
Any	33 (2.2)	11 (1.5)	28 (1.9)	6 (0.8)
Mild	26 (1.7)	11 (1.5)	27 (1.8)	6 (0.8)
Moderate	7 (0.5)	0	1 (0.1)	0
Severe	0	0	0	0
Diarrhea[f]				
Any	89 (5.9)	31 (4.1)	79 (5.3)	35 (4.7)
Mild	79 (5.2)	31 (4.1)	72 (4.8)	32 (4.3)
Moderate	10 (0.7)	0	7 (0.5)	3 (0.4)
Severe	0	0	0	0
New or worsened muscle pain[d]				
Any	137 (9.1)	51 (6.8)	175 (11.7)	55 (7.4)
Mild	96 (6.4)	35 (4.7)	116 (7.7)	38 (5.1)
Moderate	40 (2.6)	16 (2.1)	58 (3.9)	17 (2.3)
Severe	1 (0.1)	0	1 (0.1)	0
New or worsened joint pain[d]				
Any	50 (3.3)	41 (5.5)	78 (5.2)	27 (3.6)
Mild	34 (2.3)	31 (4.1)	57 (3.8)	20 (2.7)
Moderate	16 (1.1)	10 (1.3)	21 (1.4)	7 (0.9)
Severe	0	0	0	0
Use of antipyretic or pain medication[g]	217 (14.4)	62 (8.3)	296 (19.7)	60 (8.1)

Note: Events and use of antipyretic or pain medication were collected in an electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. The denominators (N) used in the percentage calculations for fever and use of antipyretic or pain medication were 749 after Dose 1 and 741 after Dose 2 in the placebo group, due to an e-diary error.
c. n = Number of participants with the specified reaction.
d. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
e. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
f. 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.
g. Severity was not collected for use of antipyretic or pain medication.
* Randomized participants who received at least 1 dose of the study intervention.
± Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA).

Unsolicited Adverse Events

In the following analyses of Study 3 in children 5 through 11 years of age (1,518 of whom received Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA) 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 (10 mcg modRNA) 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 – 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 (10 mcg modRNA) 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 (10 mcg modRNA) group vs. 1 (0.1%) in the placebo group. In the expansion cohort from Dose 1 through the cut-off date, lymphadenopathy was reported in 6 (0.4%) participants in the Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA) 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.

Adolescents 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 adolescents [1,131 Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA); 1,129 placebo] were 12 through 15 years of age. Of these, 1,308 (660 Pfizer-BioNTech COVID-19 Vaccine and 648 placebo) adolescents 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 adolescents who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the adolescents 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 adolescents 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 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 (30 mcg modRNA) 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 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 7,960 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.

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

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS[4]

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 Pfizer-BioNTech COVID-19 Vaccine 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 Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

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

*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
- 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 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 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 with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

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 (mRNA) (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 on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders for use in individuals 5 through 11 years of age is based on safety and effectiveness data in this age group and in adolescents and adults.

For adolescents 12 through 17 years of age, a different formulation and a different presentation of this formulation of the Pfizer-BioNTech COVID-19 Vaccine are authorized.

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 5 years of age.

11.4 Use in Immunocompromised

Safety and effectiveness of the Pfizer-BioNTech COVID-19 Vaccine in children with immunocompromise has been extrapolated from adult data. An independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)* described the safety and effectiveness of a third dose of the Pfizer-BioNTech COVID-19 vaccine in adult persons that received solid organ transplants. In this report describing 99 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported in recipients who were followed for 1 month following post Dose 3. The administration of a third dose of vaccine appears to be only moderately effective in increasing potentially protective antibody titers. Patients should still be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine in multiple dose vials with orange caps and labels with orange borders is supplied as a frozen suspension; each vial must be diluted with 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each 0.2 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders contains 10 mcg of modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.2 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders also includes the following ingredients: lipids (0.14 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 10.3 mg sucrose, 0.02 mg tromethamine, and 0.13 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 0.9 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine 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 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

18.1 Efficacy of Primary Series 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 3 presents the specific demographic characteristics in the studied population.

Table 3: 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)

	Pfizer-BioNTech COVID-19 Vaccine* (N=18,242) n (%)	Placebo (N=18,379) n (%)
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)
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/m^2)
   - 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 4.

Table 4: 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± Na=18,198 Cases n1b Surveillance Timec (n2d)**	**Placebo Na=18,325 Cases n1b Surveillance Timec (n2d)**	**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± Na=19,965 Cases n1b Surveillance Timec (n2d)**	**Placebo Na=20,172 Cases n1b Surveillance Timec (n2d)**	**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 adolescents 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 in Children 5 Through 11 Years of Age

A descriptive efficacy analysis of Study 3 has been performed in 1,968 children 5 through 11 years of age without evidence of infection prior to 7 days after Dose 2. This analysis evaluated confirmed symptomatic COVID-19 cases accrued up to a data cutoff date of October 8, 2021.

Table 5 presents the specific demographic characteristics in participants who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose.

Table 5: Demographics Characteristics – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Phase 2/3 – 5 Through 11 Years of Age – Evaluable Efficacy Population

	Pfizer-BioNTech COVID-19 Vaccine* 10 mcg/Dose (N[a]=1305) n[b] (%)	**Placebo (N[a]=663) n[b] (%)**
Sex		
Male	679 (52.0)	343 (51.7)
Female	626 (48.0)	320 (48.3)
Age at Vaccination		
Mean (SD)	8.2 (1.93)	8.1 (1.98)
Median	8.0	8.0
Min, max	(5, 11)	(5, 11)
Race		
White	1018 (78.0)	514 (77.5)
Black or African American	76 (5.8)	48 (7.2)
American Indian or Alaska Native	<1.0%	<1.0%
Asian	86 (6.6)	46 (6.9)
Native Hawaiian or other Pacific Islander	<1.0%	<1.0%
Other[c]	110 (8.4)	52 (7.8)
Ethnicity		
Hispanic or Latino	243 (18.6)	130 (19.6)
Not Hispanic or Latino	1059 (81.1)	533 (80.4)
Not reported	<1.0%	<1.0%
Comorbidities[d]		
Yes	262 (20.1)	133 (20.1)
No	1043 (79.9)	530 (79.9)

* Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA).

a. N = number of participants in the specified group from the evaluable efficacy population with no evidence of SARS CoV-2 infection prior to 7 days after Dose 2. This value is the denominator for the percentage calculations. Evaluable efficacy population included all eligible randomized participants who received all vaccination(s) as randomized within the predefined window, had no other important protocol deviations as determined by the clinician.

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

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: defined as participants who had at least 1 of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile).

The descriptive vaccine efficacy results in children 5 through 11 years of age without evidence of prior SARS-CoV-2 infection are presented in Table 6. None of the cases accrued met criteria for severe COVID-19

or multisystem inflammatory syndrome in children (MIS-C). No cases of COVID-19 were observed in either the vaccine group or the placebo group in participants with evidence of prior SARS-CoV-2 infection.

Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection Prior to 7 Days After Dose 2 – Phase 2/3 –Children 5 Through 11 Years of Age Evaluable Efficacy Population

First COVID-19 occurrence from 7 days after Dose 2 in children 5 through 11 years of age without evidence of prior SARS-CoV-2 infection*			
	Pfizer-BioNTech COVID-19 Vaccine± 10 mcg/dose N[a]=1305 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=663 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
Children 5 through 11 years of age	3 0.322 (1273)	16 0.159 (637)	90.7 (67.7, 98.3)

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 (10 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.

18.3 Immunogenicity of Primary Series in Children 5 Through 11 Years of Age

SARS-CoV-2 50% neutralizing antibody titers (NT50) 1 month after the primary series were compared between randomly selected subsets of Phase 2/3 participants 5 through 11 years of age from study C4591007 and the efficacy study C4591001 Phase 2/3 participants 16 through 25 years of age, using a microneutralization assay against the reference strain (USA_WA1/2020). The primary immunobridging analyses compared the geometric mean titers (using a geometric mean ratio [GMR]) and the seroresponse (defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from before Dose 1) rates in the evaluable immunogenicity population of participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 2 in each group. The prespecified immunobridging criteria were met for both the GMR and the seroresponse difference (Table 7 and Table 8).

Table 7: SARS-CoV-2 GMTs (NT50) at 1 Month After Primary Series – Immunobridging Subset - Participants 5 Through 11 Years of Age (Study 3) and Participants 16 Through 25 Years of Age (Study 2) – Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2 – Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine		GMT Ratio (95%CI) (5 Through 11 Years of Age/ 16 Through 25 Years of Age)[d,e]
		10 mcg/Dose* 5 Through 11 Years of Age n[a]=264	30 mcg/Dose± 16 Through 25 Years of Age n[a]=253	
Assay	Time Point[b]	GMT[c] (95% CI[c])	GMT[c] (95% CI[c])	
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1 month after Dose 2	1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)

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 post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at pre-Dose 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at pre-Dose 1 and pre-Dose 2, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

* Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA).

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

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.

b. Protocol-specified timing for blood sample collection.

c. 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 × LLOQ.

d. GMT ratio and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [5 through 11 years of age] - Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).

e. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the GMT ratio is greater than 0.67 and the point estimate of the GMR is ≥0.8.

f. 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 8: Percentages of Participants with Seroresponse at 1 Month After Primary Series – Immunobridging Subset –Participants 5 Through 11 Years of Age (Study 3) and Participants 16 Through 25 Years of Age (Study 2) Without Evidence of Infection up to 1 Month After Dose 2 – Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine		Difference in Seroresponse Rates %[e] (95% CI[f]) (5 Through 11 Years of Age minus 16 Through 25 Years of Age)[g]
		10 mcg/Dose* 5 Through 11 Years of Age N[a]=264	30 mcg/Dose± 16 Through 25 Years of Age N[a]=253	
Assay	Time Point[b]	n[c] (%) (95% CI[d])	n[c] (%) (95% CI[d])	
SARS-CoV-2 neutralization assay - NT50 (titer)[h]	1 month after Dose 2	262 (99.2) (97.3, 99.9)	251 (99.2) (97.2, 99.9)	0.0 (-2.0, 2.2)

Abbreviations: LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer 50; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Seroresponse 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 ≥4 × LLOQ is considered a seroresponse
Note: Participants who had no serological or virological evidence (up to 1 month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

* Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA).
± Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).
a. N = number of participants with valid and determinate assay results both before vaccination and at 1 month after Dose 2. These values are the denominators for the percentage calculations.
b. Protocol-specified timing for blood sample collection.
c. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
e. Difference in proportions, expressed as a percentage (Group 1 [5 through 11 years of age] – Group 2 [16 through 25 years of age]).
f. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
g. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the difference in proportions is greater than -10.0%.
h. 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 in Solid Organ Transplant Recipients

Immunogenicity of the Pfizer-BioNTech COVID-19 Vaccine in children with immunocompromise has been extrapolated from adult data. From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, a single arm study has been conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously. A third dose of the Pfizer-BioNTech COVID-19 vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Among the 59 patients who had been seronegative before the third dose, 26 (44%) were seropositive at 4 weeks after the third dose. All 40 patients who had been seropositive before the third dose were still seropositive 4 weeks later. The prevalence of anti-SARS-CoV-2 antibodies was 68% (67 of 99 patients) 4 weeks after the third dose.

19 HOW SUPPLIED/STORAGE AND HANDLING

The information in this section applies to the Pfizer-BioNTech COVID-19 Vaccine that is supplied in multiple dose vials with orange caps and labels with orange borders. These multiple dose vials are supplied in a carton containing 10 multiple dose vials (NDC 59267-1055-4). After dilution, 1 vial contains 10 doses of 0.2 mL.

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 multiple dose vials with orange caps and labels with orange borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice.

Once received, frozen vials may be immediately transferred to the refrigerator [2ºC to 8ºC (35ºF to 46ºF)], 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 vials may take up to 4 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed they should not be refrozen.

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may also arrive at 2°C to 8°C. If received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons. Expiry dates based on 9 months from the date of the manufacture are shown below.

Printed Manufacturing Date	**9-Month Expiry Date**
06/2021	28-Feb-2022
07/2021	31-Mar-2022
08/2021	30-Apr-2022
09/2021	31-May-2022
10/2021	30-Jun-2022
11/2021	31-Jul-2022
12/2021	31-Aug-2022
01/2022	30-Sep-2022
02/2022	31-Oct-2022

Vial Storage During Use

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

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to dilution. After dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution.

Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this Full EUA Prescribing Information supersedes the number of hours printed on vial labels and cartons.

Transportation of Vials

If local redistribution is needed, undiluted 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).

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
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

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

Manufactured by
Pfizer Inc., New York, NY 10017

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

LAB-1503-3.0

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Appendix C- Fact Sheet for Healthcare Providers Administering Pfizer-BioNTech 6m-4y Vaccine (Vaccination Providers)

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

FOR 6 MONTHS THROUGH 4 YEARS OF AGE
DILUTE BEFORE USE

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, for active immunization to prevent COVID-19 in individuals 6 months of age and older.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a maroon cap and a label with a maroon border, which MUST BE DILUTED PRIOR TO USE.

The vial labels may state "Age 2y to < 5y" or "Age 6m to < 5y" and carton labels may state "For age 2 years to < 5 years" or "For age 6 months to < 5 years". Vials with either printed age range can be used for individuals 6 months through 4 years of age.

Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a maroon cap and a label with a maroon border is authorized for use to provide a 3-dose primary series to individuals 6 months through 4 years of age.

Pfizer-BioNTech COVID-19 Vaccine, which is supplied in a multiple dose vial with a maroon cap and a label with a maroon border, should not be used in individuals 5 years of age and older because of the potential for vaccine administration errors, including dosing errors.[1]

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 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. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

[1] For vaccination of individuals 5 through 11 years of age and 12 years of age and older, refer to the respective Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine.

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

The Pfizer-BioNTech COVID-19 Vaccine for individuals 6 months through 4 years of age is supplied in a multiple dose vial with a maroon cap and a label with a maroon border. The Pfizer-BioNTech COVID-19 Vaccine is administered, after dilution, as a primary series of 3 doses (0.2 mL each). The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose in individuals 6 months through 4 years of age.

Individuals who will turn from 4 years to 5 years of age between any doses in the primary series may receive:

- a 2-dose primary series with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA, supplied in multiple dose vials with orange caps and labels with orange borders)

  OR

- a 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (each 0.2 mL dose containing 3 mcg modRNA, supplied in multiple dose vials with maroon caps). Each of Doses 2 and 3 may be with:
  - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (supplied in multiple dose vials with maroon caps), or
  - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 years through 11 years of age (supplied in multiple dose vials with orange caps and labels with orange borders).

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 for active immunization against 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 which is supplied in a multiple dose vial with a maroon cap and a label with a maroon border and **MUST BE DILUTED** before use.

Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial with Maroon Cap and a Label with a Maroon Border

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
6 months through 4 years*	Dilute with 2.2 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

* The vial labels may state “Age 2y to < 5y” or “Age 6m to < 5y” and carton labels may state “For age 2 years to < 5 years” or “For age 6 months to < 5 years”. Vials with either printed age range can be used for individuals 6 months through 4 years of age.

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 multiple dose vials with maroon caps and labels with maroon borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice.

Once received, frozen vials may be immediately transferred to the refrigerator [2ºC to 8ºC (35ºF to 46ºF)], 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 vials may take up to 2 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) for up to 12 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 multiple dose vials with maroon caps and labels with maroon borders are received at 2°C to 8°C (35ºF to 46ºF), they should be stored at 2°C to 8°C (35ºF to 46ºF). 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 12 months from the date of manufacture printed on the vial and cartons. Expiry dates based on 12 months from the date of the manufacture are shown below.

Printed Manufacturing Date	12-Month Expiry Date
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023
04/2022	31-Mar-2023
05/2022	30-Apr-2023
06/2022	31-May-2023

Vial Storage During Use

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

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with maroon caps and labels with maroon borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to dilution.

After dilution, the vial should be held between 2ºC to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution, even though some vial and carton labels may state that a vial should be discarded 6 hours after dilution. The information in this Fact Sheet supersedes the information printed on vial labels and cartons.

Transportation of Vials

If local redistribution is needed, undiluted 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

The Pfizer-BioNTech COVID-19 Vaccine for individuals 6 months through 4 years of age is supplied in multiple dose vials with maroon caps and labels with maroon borders. The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 3 doses (0.2 mL each) The initial 2 doses are administered

3 weeks apart followed by a third dose administered at least 8 weeks after the second dose in individuals 6 months through 4 years of age.

Individuals who will turn from 4 years to 5 years of age between any doses in the primary series may receive:

- a 2-dose primary series with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA, supplied in multiple dose vials with orange caps and labels with orange borders)

  OR

- a 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (each 0.2 mL dose containing 3 mcg modRNA, supplied in multiple dose vials with maroon caps). Each of Doses 2 and 3 may be with:
  - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (supplied in multiple dose vials with maroon caps), or
  - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 years through 11 years of age (supplied in multiple dose vials with orange caps and labels with orange borders).

<u>Dose Preparation</u>

Each vial **MUST BE DILUTED** before administering the vaccine.

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with a maroon cap and a label with a maroon border contains a volume of 0.4 mL, and is supplied as a frozen suspension that does not contain preservative.
- Each vial must be thawed before dilution.
  - Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)].
  - Refer to thawing instructions in the panels below.

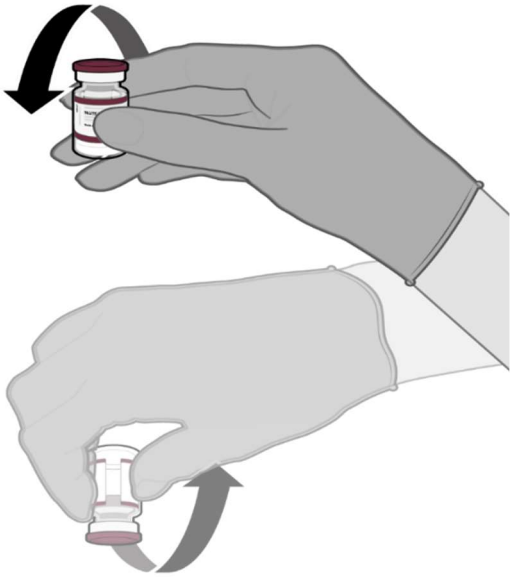
Dilution

Dilute the vial contents using 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.

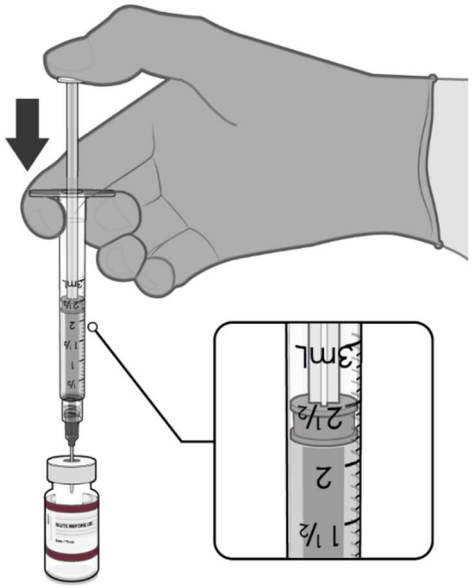
ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. <u>Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent</u>. Do not add more than 2.2 mL of diluent.

After dilution, 1 vial contains 10 doses of 0.2 mL.

<table>
<tr><th colspan="2">Dilution and Preparation Instructions</th></tr>
<tr><td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border –
VIAL VERIFICATION</td></tr>
<tr><td> 
✓ Maroon plastic cap and label with maroon border.</td><td>• Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a maroon plastic cap and a label with a maroon border.</td></tr>
<tr><td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border –
THAWING PRIOR TO DILUTION</td></tr>
<tr><td> 
Store in the refrigerator for up to 10 weeks prior to use.</td><td>• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of 10 vials may take up to 2 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
• Vials may be stored at room temperature [up to 25ºC (77ºF)] for up to 12 hours prior to use.</td></tr>
</table>

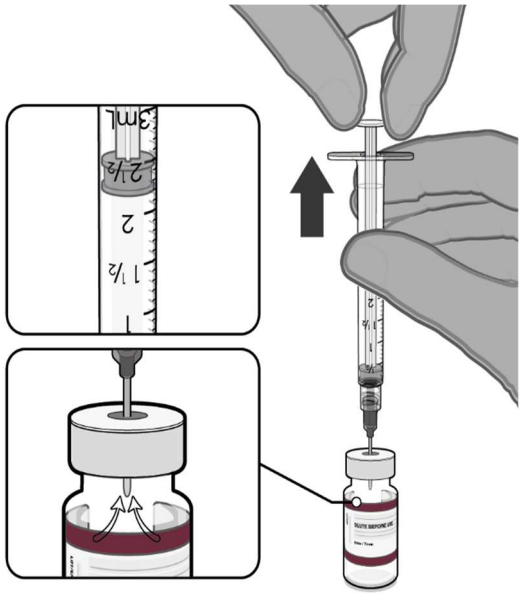
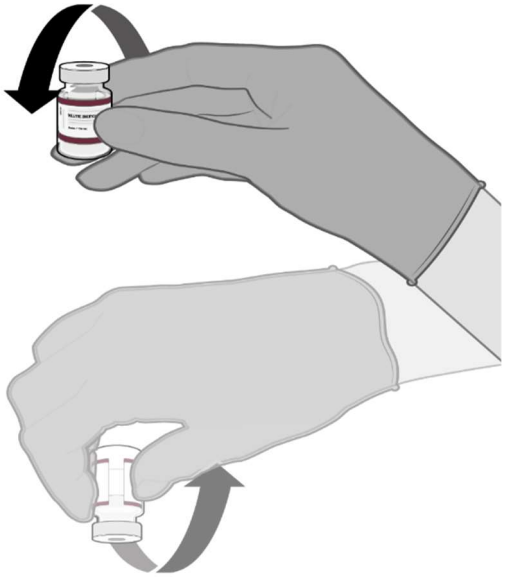
<table>
<tr>
<td> 
Gently × 10</td>
<td>

Before dilution, mix by inverting vaccine vial gently 10 times.
<u>Do not shake</u>.
Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.
Do not use if liquid is discolored or if other particles are observed.

</td>
</tr>
<tr>
<td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border – DILUTION</td>
</tr>
<tr>
<td> 
Add 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP.</td>
<td>

Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
Using aseptic technique, withdraw 2.2 mL of diluent into a transfer syringe (21-gauge or narrower needle).
Cleanse the vaccine vial stopper with a single-use antiseptic swab.
Add 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.

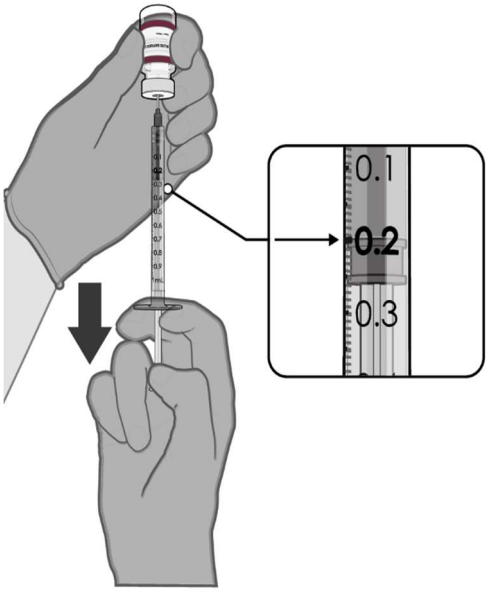
</td>
</tr>
</table>

 **Pull back plunger to 2.2 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial by withdrawing 2.2 mL air into the empty diluent syringe.
 **Gently × 10**	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • <u>Do not shake</u>. • Inspect the vaccine in the vial. • The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

Record the date and time of dilution.
Use within 12 hours after dilution.

- Record the date and time of dilution on the vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after dilution.

Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border -
WITHRAWAL OF INDIVIDUAL 0.2 mL DOSES



Withdraw 0.2 mL dose of vaccine.

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.2 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine with maroon caps and labels with maroon borders contain 10 doses of 0.2 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

Contraindications

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

Monitor Pfizer-BioNTech COVID-19 Vaccine 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 data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. 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.

Limitation of Effectiveness

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

Adverse Reactions

Adverse Reactions in Clinical Trials

Adverse reactions in participants 6 through 23 months of age following administration of the Pfizer-BioNTech COVID-19 Vaccine included irritability, decreased appetite, tenderness at the injection site, injection site redness, fever, injection site swelling, and lymphadenopathy *(see Full EUA Prescribing Information)*.

Adverse reactions in participants 2 through 4 years of age following administration of the Pfizer-BioNTech COVID-19 Vaccine included pain at the injection site, fatigue, injection site redness, fever, headache, injection site swelling, chills, muscle pain, joint pain, and lymphadenopathy *(see Full EUA Prescribing Information)*.

Adverse Reactions 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), and syncope 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 more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine 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 "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet for Recipients and Caregivers) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, 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 to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

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 second-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 ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

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, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine 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 is authorized for use in individuals 6 months of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

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 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 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 MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine 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 Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

There may be clinical trials or availability under EUA of other COVID-19 vaccines.

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 for active immunization against 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 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 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

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1516-0.7

Revised: 17 June 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

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

* 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 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 6 months of age and older.

This EUA Prescribing Information pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a maroon cap and a label with a maroon border, which is authorized for use in individuals 6 months through 4 years of age.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

The storage, preparation, and administration information in this Prescribing Information apply to the Pfizer-BioNTech COVID-19 Vaccine, which is supplied in a multiple dose vial with a maroon cap and a label with a maroon border.

Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial with Maroon Cap and a Label with a Maroon Border

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
6 months through 4 years*	Dilute with 2.2 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

* The vial labels may state "Age 2y to < 5y" or "Age 6m to < 5y" and carton labels may state "For age 2 years to < 5 years" or "For age 6 months to < 5 years". Vials with either printed age range can be used for individuals 6 months through 4 years of age.

2.1 Preparation for Administration

Each vial **MUST BE DILUTED** before administering the vaccine.

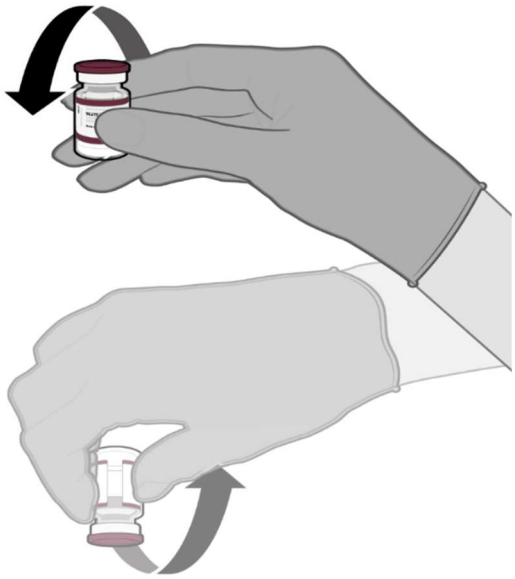
Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with a maroon cap and a label with a maroon border contains a volume of 0.4 mL, and is supplied as a frozen suspension that does not contain preservative.
- Each vial must be thawed before dilution.
  - Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)].
  - Refer to thawing instructions in the panels below.

Dilution

- Dilute the vial contents using 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.
- ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 2.2 mL of diluent.
- After dilution, 1 vial contains 10 doses of 0.2 mL.

<table>
<tr><th colspan="2">Dilution and Preparation Instructions</th></tr>
<tr><td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border – VIAL VERIFICATION</td></tr>
<tr><td> 
✓ Maroon plastic cap and label with maroon border.</td><td>• Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a maroon plastic cap and a label with a maroon border.</td></tr>
<tr><td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border – THAWING PRIOR TO DILUTION</td></tr>
<tr><td> 
Store in the refrigerator for up to 10 weeks prior to use.</td><td>• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
o Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of 10 vials may take up to 2 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
o Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
• Vials may be stored at room temperature [up to 25ºC (77ºF)] for up to 12 hours prior to use.</td></tr>
</table>

<table>
<tr>
<td> 
Gently × 10</td>
<td>

Before dilution, mix by inverting vaccine vial gently 10 times.
Do not shake.
Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.
Do not use if liquid is discolored or if other particles are observed.

</td>
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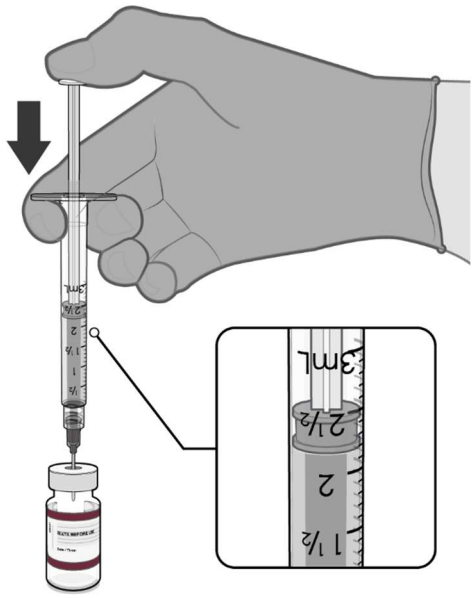
<tr>
<td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border – DILUTION</td>
</tr>
<tr>
<td> 
Add 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP.</td>
<td>

Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
Using aseptic technique, withdraw 2.2 mL of diluent into a transfer syringe (21-gauge or narrower needle).
Cleanse the vaccine vial stopper with a single-use antiseptic swab.
Add 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.

</td>
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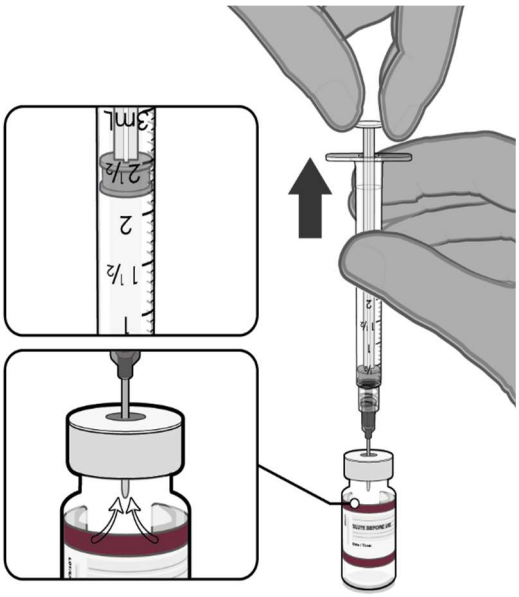
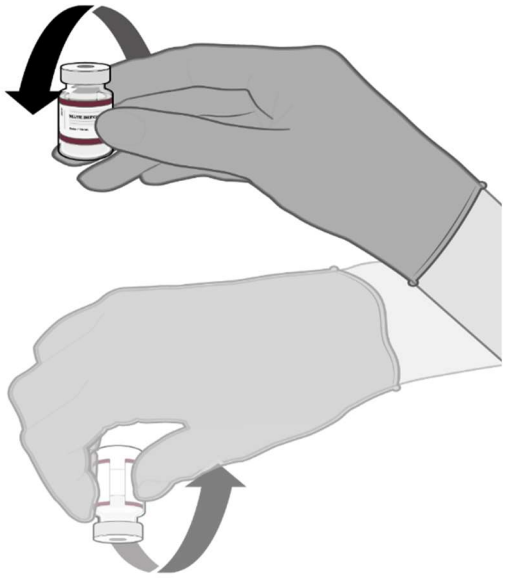
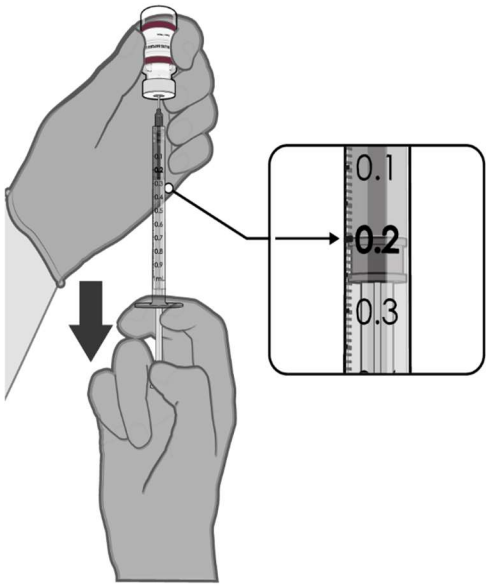
</table>

 **Pull back plunger to 2.2 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial by withdrawing 2.2 mL air into the empty diluent syringe.
 **Gently × 10**	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • <u>Do not shake</u>. • Inspect the vaccine in the vial. • The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

<table>
<tr>
<td> 

Record the date and time of dilution.
Use within 12 hours after dilution.</td>
<td>• Record the date and time of dilution on the vial label.
• Store between 2°C to 25°C (35°F to 77°F).
• Discard any unused vaccine 12 hours after dilution.</td>
</tr>
<tr>
<td colspan="2">Pfizer-BioNTech COVID-19 Vaccine Vial with Maroon Cap and Label with Maroon Border - WITHRAWAL OF INDIVIDUAL 0.2 mL DOSES</td>
</tr>
<tr>
<td> 

Withdraw 0.2 mL dose of vaccine.</td>
<td>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
• Each dose must contain 0.2 mL of vaccine.
• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
• Administer immediately.</td>
</tr>
</table>

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.2 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine with maroon caps and labels with maroon borders contain 10 doses of 0.2 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

2.3 Vaccination Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 3 doses (0.2 mL each) in individuals 6 months through 4 years of age. The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose.

Individuals who will turn from 4 years to 5 years of age between any doses in the primary series may receive:

- a 2-dose primary series with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA, supplied in multiple dose vials with orange caps and labels with orange borders).

  OR

- a 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (each 0.2 mL dose containing 3 mcg modRNA, supplied in multiple dose vials with maroon caps). Each of Doses 2 and 3 may be with:
  - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (supplied in multiple dose vials with maroon caps), or
  - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 years through 11 years of age (supplied in multiple dose vials with orange caps and labels with orange borders).

3 DOSAGE FORMS AND STRENGTHS

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

After preparation, each dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with maroon caps and labels with maroon borders is 0.2 mL for individuals 6 months through 4 years of age *[see Dosage and Administration (2.1)]*.

4 CONTRAINDICATIONS

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

Monitor Pfizer-BioNTech COVID-19 Vaccine 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 data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. 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.

5.5 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine 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 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. 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.

In a clinical study (Study 3) in participants 6 through 23 months of age who received Pfizer-BioNTech COVID-19 Vaccine containing 3 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 (3 mcg modRNA), adverse reactions following administration of any dose

included irritability (68.4%), decreased appetite (38.6%), tenderness at the injection site (26.4%), injection site redness (17.8%), fever (14.4%), injection site swelling (7.3%), and lymphadenopathy (0.2%).

In a clinical study (Study 3) in participants 2 through 4 years of age who received Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA), adverse reactions following administration of any dose included pain at the injection site (47.0%), fatigue (44.8%), injection site redness (18.9%), fever (10.5%), headache (8.7%), injection site swelling (8.4%), chills (5.7%), muscle pain (5.0%), joint pain (2.4%), and lymphadenopathy (0.1%).

Post Authorization Experience

Severe allergic reactions, including anaphylaxis, 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.

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.

The safety of the primary series Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 6 months of age and older in 3 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 (30 mcg modRNA); 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). Study C4591007 (Study 3) is a Phase 1/2/3 multicenter, randomized, dose-finding, open-label (Phase 1) and multinational, saline placebo-controlled, observer-blind, immunogenicity and efficacy (Phase 2/3) study that has enrolled 4,695 participants 5 through 11 years of age, of whom 3,109 participants received Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA) and 1,538 participants received placebo in Phase 2/3. Study 3 also enrolled 1,776 participants 6 through 23 months of age, of whom 1,178 participants were in the Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA) group and 598 participants in the placebo group; and also enrolled 2,750 participants 2 through 4 years of age, of whom 1,835 participants were in the Pfizer-BioNTech COVID-19 Vaccine group and 915 participants in the placebo group in Phase 2/3.

In Study 2 and Study 3, all participants 6 months through 4 years of age, 5 through 11 years of age, 12 through 15 years of age, and a subset of participants 16 years of age and older, 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, including serious adverse events, throughout the study [from Dose 1 through 1 month after the last vaccination (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination]. Tables 1 through 4 present the frequency and severity of solicited local and

systemic reactions, within 7 days following each dose of Pfizer-BioNTech COVID 19 Vaccine and placebo in participants 6 months through 4 years of age.

Participants 6 Through 23 Months of Age (3-Dose Primary Series)

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.

Solicited Local and Systemic Adverse Reactions

The mean duration of tenderness at the injection site after Dose 3 was 1.5 days (range 1 to 9 days), for redness 1.5 days (range 1 to 5 days), and for swelling 1.8 days (range 1 to 3 days) for participants 6 through 23 months of age in the Pfizer-BioNTech COVID-19 Vaccine group in the blinded placebo-controlled follow-up period (cutoff date of April 29, 2022).

Table 1: Study 3 – Frequency and Percentages of Participants With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 6 Through 23 Months of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1159 to 1173 n[b] (%)	**Placebo Dose 1 N[a]=591 to 595 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1137 to 1147 n[b] (%)**	**Placebo Dose 2 N[a]=590 to 591 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine± Dose 3 N[a]=362 to 365 n[b] (%)**	**Placebo Dose 3 N[a]=170 n[b] (%)**
Redness[c]						
Any (≥0.5 cm)	124 (10.6)	44 (7.4)	107 (9.3)	39 (6.6)	26 (7.1)	9 (5.3)
Mild	114 (9.7)	41 (6.9)	97 (8.5)	36 (6.1)	17 (4.7)	8 (4.7)
Moderate	10 (0.9)	3 (0.5)	10 (0.9)	3 (0.5)	8 (2.2)	1 (0.6)
Severe	0	0	0	0	1 (0.3)	0
Swelling[c]						
Any (≥0.5 cm)	46 (3.9)	15 (2.5)	45 (3.9)	9 (1.5)	10 (2.7)	3 (1.8)
Mild	40 (3.4)	13 (2.2)	39 (3.4)	8 (1.4)	7 (1.9)	3 (1.8)
Moderate	6 (0.5)	2 (0.3)	6 (0.5)	1 (0.2)	3 (0.8)	0
Severe	0	0	0	0	0	0
Tenderness at the injection site[d]						
Any	192 (16.6)	66 (11.2)	171 (15.0)	50 (8.5)	58 (16.0)	20 (11.8)
Mild	181 (15.6)	61 (10.3)	154 (13.5)	42 (7.1)	51 (14.1)	17 (10.0)
Moderate	11 (0.9)	5 (0.8)	16 (1.4)	8 (1.4)	7 (1.9)	3 (1.8)
Severe	0	0	1 (0.1)	0	0	0

* Randomized participants who received at least 1 dose of the study intervention.
± Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA).

Note: Reactions were collected in an electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
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: ≥0.5 to ≤2.0 cm; Moderate: >2.0 to ≤7.0 cm; Severe: >7.0 cm.
d. Mild: hurts if gently touched; Moderate: hurts if gently touched with crying; Severe: causes limitation of limb movement.

Table 2: Study 3 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 6 Through 23 Months of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1159 to 1173 n[b] (%)	**Placebo Dose 1 N[a]=591 to 595 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1137 to 1147 n[b] (%)**	**Placebo Dose 2 N[a]=590 to 591 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine± Dose 3 N[a]=362 to 365 n[b] (%)**	**Placebo Dose 3 N[a]=170 n[b] (%)**
Fever						
≥38.0°C	85 (7.2)	43 (7.2)	85 (7.4)	36 (6.1)	25 (6.8)	10 (5.9)
≥38.0°C to 38.4°C	42 (3.6)	22 (3.7)	41 (3.6)	18 (3.0)	14 (3.8)	7 (4.1)
>38.4°C to 38.9°C	23 (2.0)	14 (2.4)	20 (1.7)	11 (1.9)	5 (1.4)	2 (1.2)
>38.9°C to 40.0°C	19 (1.6)	6 (1.0)	23 (2.0)	7 (1.2)	5 (1.4)	1 (0.6)
>40.0°C	1 (0.1)	1 (0.2)	1 (0.1)	0	1 (0.3)	0
Decreased appetite[c]						
Any	257 (22.2)	125 (21.2)	252 (22.2)	106 (18.0)	73 (20.2)	23 (13.5)
Mild	138 (11.9)	73 (12.4)	157 (13.8)	63 (10.7)	42 (11.6)	13 (7.6)
Moderate	116 (10.0)	51 (8.6)	91 (8.0)	42 (7.1)	27 (7.5)	10 (5.9)
Severe	3 (0.3)	1 (0.2)	4 (0.4)	1 (0.2)	4 (1.1)	0
Drowsiness[d]						
Any	313 (27.0)	173 (29.3)	271 (23.8)	125 (21.2)	72 (19.9)	22 (12.9)
Mild	251 (21.7)	130 (22.0)	201 (17.7)	98 (16.6)	50 (13.8)	15 (8.8)
Moderate	60 (5.2)	41 (6.9)	66 (5.8)	26 (4.4)	21 (5.8)	6 (3.5)
Severe	2 (0.2)	2 (0.3)	4 (0.4)	1 (0.2)	1 (0.3)	1 (0.6)
Irritability[e]						
Any	593 (51.2)	279 (47.2)	539 (47.4)	240 (40.7)	158 (43.6)	64 (37.6)
Mild	245 (21.1)	106 (17.9)	213 (18.7)	89 (15.1)	56 (15.5)	27 (15.9)
Moderate	341 (29.4)	173 (29.3)	319 (28.1)	146 (24.7)	101 (27.9)	37 (21.8)
Severe	7 (0.6)	0	7 (0.6)	5 (0.8)	1 (0.3)	0
Use of antipyretic or pain medication[f]	281 (24.0)	117 (19.7)	243 (21.2)	111 (18.8)	70 (19.2)	28 (16.5)

* Randomized participants who received at least 1 dose of the study intervention.
± Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA).
Note: Events and use of antipyretic or pain medication were collected in an electronic diary (e-diary) from Day 1 to Day 7 after each dose.
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: decreased interest in eating; Moderate: decreased oral intake; Severe: refusal to feed.
d. Mild: increased or prolonged sleeping bouts; Moderate: slightly subdued interfering with daily activity; Severe: disabling; not interested in usual daily activity.
e. Mild: easily consolable; Moderate: requiring increased attention; Severe: inconsolable; crying cannot be comforted.
f. Severity was not collected for use of antipyretic or pain medication.

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.

Participants 2 Through 4 Years of Age (3-Dose Primary Series)

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.

Solicited Local and Systemic Adverse Reactions

The mean duration of pain at the injection site after Dose 3 was 1.7 days (range 1 to 14 days), for redness 1.5 days (range 1 to 3 days), and for swelling 1.8 days (range 1 to 4 days) for participants 2 through 4 years of

age in the Pfizer-BioNTech COVID-19 Vaccine group in the blinded placebo-controlled follow-up period (cutoff date of April 29, 2022).

Table 3: Study 3 – Frequency and Percentages of Participants With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 2 Through 4 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1814 to 1825 n[b] (%)	**Placebo Dose 1 N[a]=905 to 909 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1772 to 1779 n[b] (%)**	**Placebo Dose 2 N[a]=877 to 878 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine± Dose 3 N[a]=547 to 552 n[b] (%)**	**Placebo Dose 3 N[a]=262 n[b] (%)**
Redness[c]						
Any (≥0.5 cm)	160 (8.8)	77 (8.5)	202 (11.4)	50 (5.7)	60 (10.9)	9 (3.4)
Mild	137 (7.5)	67 (7.4)	170 (9.6)	43 (4.9)	53 (9.6)	7 (2.7)
Moderate	22 (1.2)	9 (1.0)	31 (1.7)	7 (0.8)	7 (1.3)	2 (0.8)
Severe	1 (0.1)	1 (0.1)	1 (0.1)	0	0	0
Swelling[c]						
Any (≥0.5 cm)	67 (3.7)	26 (2.9)	102 (5.7)	18 (2.1)	17 (3.1)	3 (1.1)
Mild	59 (3.2)	21 (2.3)	81 (4.6)	16 (1.8)	16 (2.9)	3 (1.1)
Moderate	8 (0.4)	5 (0.6)	21 (1.2)	2 (0.2)	1 (0.2)	0
Severe	0	0	0	0	0	0
Pain at the injection site[d]						
Any	559 (30.8)	186 (20.6)	550 (31.0)	178 (20.3)	146 (26.7)	35 (13.4)
Mild	522 (28.8)	178 (19.7)	514 (29.0)	169 (19.3)	130 (23.8)	33 (12.6)
Moderate	37 (2.0)	7 (0.8)	36 (2.0)	8 (0.9)	16 (2.9)	2 (0.8)
Severe	0	1 (0.1)	0	1 (0.1)	0	0

* Randomized participants who received at least 1 dose of the study intervention.

± Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA).

Note: Reactions were collected in an electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

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: ≥0.5 to ≤2.0 cm; Moderate: >2.0 to ≤7.0 cm; Severe: >7.0 cm.

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

Table 4: Study 3 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 2 Through 4 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1813 to 1824 n[b] (%)	Placebo Dose 1 N[a]=905 to 909 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1772 to 1779 n[b] (%)	Placebo Dose 2 N[a]=877 to 878 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine± Dose 3 N[a]=547 to 552 n[b] (%)	Placebo Dose 3 N[a]=262 n[b] (%)
Fever						
≥38.0°C	95 (5.2)	48 (5.3)	88 (4.9)	46 (5.2)	28 (5.1)	11 (4.2)
≥38.0°C to 38.4°C	57 (3.1)	24 (2.6)	41 (2.3)	17 (1.9)	16 (2.9)	4 (1.5)
>38.4°C to 38.9°C	24 (1.3)	16 (1.8)	26 (1.5)	21 (2.4)	8 (1.4)	4 (1.5)
>38.9°C to 40.0°C	13 (0.7)	8 (0.9)	19 (1.1)	8 (0.9)	4 (0.7)	3 (1.1)
>40.0°C	1 (0.1)	0	2 (0.1)	0	0	0
Fatigue[c]						
Any	539 (29.7)	277 (30.6)	456 (25.7)	201 (22.9)	134 (24.5)	57 (21.8)
Mild	335 (18.5)	176 (19.4)	267 (15.1)	120 (13.7)	87 (15.9)	35 (13.4)
Moderate	198 (10.9)	96 (10.6)	181 (10.2)	78 (8.9)	45 (8.2)	22 (8.4)
Severe	6 (0.3)	5 (0.6)	8 (0.5)	3 (0.3)	2 (0.4)	0
Headache[c]						
Any	81 (4.5)	44 (4.9)	81 (4.6)	36 (4.1)	27 (4.9)	11 (4.2)
Mild	63 (3.5)	35 (3.9)	63 (3.6)	23 (2.6)	19 (3.5)	10 (3.8)
Moderate	18 (1.0)	8 (0.9)	18 (1.0)	12 (1.4)	8 (1.5)	1 (0.4)
Severe	0	1 (0.1)	0	1 (0.1)	0	0
Chills[c]						
Any	41 (2.3)	22 (2.4)	53 (3.0)	23 (2.6)	18 (3.3)	7 (2.7)
Mild	28 (1.5)	16 (1.8)	35 (2.0)	17 (1.9)	14 (2.6)	7 (2.7)
Moderate	10 (0.6)	6 (0.7)	18 (1.0)	6 (0.7)	3 (0.5)	0
Severe	3 (0.2)	0	0	0	1 (0.2)	0
Vomiting[d]						
Any	54 (3.0)	24 (2.7)	61 (3.4)	29 (3.3)	9 (1.6)	10 (3.8)
Mild	44 (2.4)	14 (1.5)	55 (3.1)	26 (3.0)	7 (1.3)	9 (3.4)
Moderate	10 (0.6)	10 (1.1)	6 (0.3)	3 (0.3)	2 (0.4)	1 (0.4)
Severe	0	0	0	0	0	0
Diarrhea[e]						
Any	139 (7.7)	72 (8.0)	118 (6.7)	64 (7.3)	28 (5.1)	13 (5.0)
Mild	130 (7.2)	64 (7.1)	105 (5.9)	57 (6.5)	21 (3.8)	10 (3.8)
Moderate	9 (0.5)	8 (0.9)	12 (0.7)	7 (0.8)	7 (1.3)	3 (1.1)
Severe	0	0	1 (0.1)	0	0	0
New or worsened muscle pain[c]						
Any	43 (2.4)	15 (1.7)	46 (2.6)	21 (2.4)	11 (2.0)	4 (1.5)
Mild	33 (1.8)	13 (1.4)	33 (1.9)	17 (1.9)	8 (1.5)	4 (1.5)
Moderate	9 (0.5)	2 (0.2)	13 (0.7)	4 (0.5)	3 (0.5)	0
Severe	1 (0.1)	0	0	0	0	0
New or worsened joint pain[c]						
Any	14 (0.8)	18 (2.0)	24 (1.4)	9 (1.0)	7 (1.3)	2 (0.8)
Mild	12 (0.7)	13 (1.4)	18 (1.0)	6 (0.7)	5 (0.9)	2 (0.8)
Moderate	2 (0.1)	5 (0.6)	6 (0.3)	3 (0.3)	1 (0.2)	0
Severe	0	0	0	0	1 (0.2)	0

	Pfizer-BioNTech COVID-19 Vaccine± Dose 1 N[a]=1813 to 1824 n[b] (%)	Placebo Dose 1 N[a]=905 to 909 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine± Dose 2 N[a]=1772 to 1779 n[b] (%)	Placebo Dose 2 N[a]=877 to 878 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine± Dose 3 N[a]=547 to 552 n[b] (%)	Placebo Dose 3 N[a]=262 n[b] (%)
Use of antipyretic or pain medication[f]	197 (10.8)	83 (9.1)	177 (9.9)	74 (8.4)	47 (8.5)	18 (6.9)

* Randomized participants who received at least 1 dose of the study intervention.
± Pfizer-BioNTech COVID-19 Vaccine (3 mcg modRNA).
Note: Events and use of antipyretic or pain medication were collected in an electronic diary (e-diary) from Day 1 to Day 7 after each dose.
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.

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 (3 mcg modRNA) 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 5 Through 11 Years of Age (2-Dose Primary Series)

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 (10 mcg modRNA) 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 (10 mcg modRNA) 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 (10 mcg modRNA) 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 (10 mcg modRNA), 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 [10 mcg modRNA] 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 (10 mcg modRNA) 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 – 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 (10 mcg modRNA) 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 (10 mcg modRNA) group vs. 1 (0.1%) in the placebo group. In the expansion cohort from Dose 1 through the cut-off date, lymphadenopathy was reported in 6 (0.4%) participants in the Pfizer-BioNTech COVID-19 Vaccine (10 mcg modRNA) 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 12 Through 15 Years of Age (2-Dose Primary Series)

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 (30 mcg modRNA); 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 16 Years of Age and Older (2-Dose Primary Series)

At the time of the analysis of Study 2 for the EUA, 37,586 [18,801 Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) 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 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 7,960 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.

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

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 Pfizer-BioNTech COVID-19 Vaccine 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 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
- 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 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 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 with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.3 Pediatric Use

Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 6 months through 17 years of age. This authorization is based on safety and effectiveness data in this age group and adults.

Pfizer-BioNTech COVID-19 Vaccine is not authorized for use in individuals younger than 6 months of age.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine in multiple dose vials with maroon caps and labels with maroon borders is supplied as a frozen suspension; each vial must be diluted with 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each 0.2 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with maroon caps and labels with maroon borders contains 3 mcg of modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.2 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with maroon caps and labels with maroon borders also includes the following ingredients: lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.01 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.02 mg cholesterol),

3.2 mg sucrose, 0.006 mg tromethamine, and 0.04 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.52 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine 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 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

18.1 Efficacy of a 2-Dose Primary Series 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)

	Pfizer-BioNTech COVID-19 Vaccine* (N=18,242) n (%)	Placebo (N=18,379) n (%)
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)
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/m^2)
   - 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± Na=18,198 Cases n1b Surveillance Timec (n2d)**	**Placebo Na=18,325 Cases n1b Surveillance Timec (n2d)**	**Vaccine Efficacy % (95% CI)**
All participants[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± Na=19,965 Cases n1b Surveillance Timec (n2d)**	**Placebo Na=20,172 Cases n1b Surveillance Timec (n2d)**	**Vaccine Efficacy % (95% CI)**
All participants[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 Effectiveness of a 3-Dose Primary Series in Participants 6 Months Through 4 Years of Age

Effectiveness in individuals 6 months through 4 years of age is based on a comparison of immune responses in this age group to individuals 16 through 25 years of age.

Immunogenicity in Participants 2 Through 4 Years of Age

Immunogenicity analyses have been performed in the immunobridging subset of 143 Study 3 participants 2 through 4 years of age without evidence of infection up to 1 month after Dose 3 based on a data cutoff date of April 29, 2022.

The evaluable immunogenicity population without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 3 of Pfizer-BioNTech COVID-19 Vaccine was comprised of 143 participants 2 through 4 years of age. Most participants in this analysis population were White (69.2%), with 5.6% Black or African American participants, 11.2% Asian participants, and 11.9% multiracial participants. There were 11.2% Hispanic/Latino participants. The median age was 3.0 years and 44.1% of participants were male. There were 6.3% of participants reported as obese. In the evaluable immunogenicity population (regardless of evidence of prior infection), 11/204 participants (5.4%) were baseline positive for prior SARS-CoV-2 infection.

SARS-CoV-2 50% neutralizing antibody titers (NT50) were compared between an immunogenicity subset of Phase 2/3 participants 2 through 4 years of age from Study 3 at 1 month after the 3-dose primary series and a randomly selected subset from Study 2 Phase 2/3 participants 16 through 25 years of age at 1 month after the 2-dose primary series, using a microneutralization assay against the reference strain (USA_WA1/2020). The primary immunobridging analyses compared the geometric mean titers (using a geometric mean ratio [GMR]) and the seroresponse (defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from before Dose 1) rates in the evaluable immunogenicity population of participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 3 in participants 2 through 4 years of age and up to 1 month after Dose 2 in participants 16 through 25 years of age. The prespecified immunobridging criteria were met for both the GMR and the seroresponse difference (Table 7 and Table 8, respectively).

Table 7: SARS-CoV-2 GMTs (NT50) at 1 Month After Vaccination Series – Immunobridging Subset - Participants 2 Through 4 Years of Age (Study 3) 1 Month After Dose 3 and Participants 16 Through 25 Years of Age (Study 2) 1 Month After Dose 2 – Without Evidence of SARS-CoV-2 Infection – Evaluable Immunogenicity Population

	Pfizer-BioNTech COVID-19 Vaccine		
	3 mcg/Dose 2 Through 4 Years of Age (1 Month After Dose 3) n[a]=143	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) n[a]=170	GMR (95%CI) (2 Through 4 Years of Age/16 Through 25 Years of Age)[d,e]
Assay	**GMT[c] (95% CI[c])**	**GMT[c] (95% CI[c])**	
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1535.2 (1388.2, 1697.8)	1180.0 (1066.6, 1305.4)	1.30 (1.13, 1.50)

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 Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood sample collection)] of past SARS-CoV-2 infection [(i.e., N-binding antibody [serum] negative at Dose 1, Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab]

at Dose 1, Dose 2, and Dose 3 (Study 3) study visits, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection)] and had no medical history of COVID-19 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. Protocol-specified timing for blood sample collection.
c. 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 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers ([2 through 4 years of age] - [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).
e. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the GMR ratio is greater than 0.67 and the point estimate of the GMR is ≥0.8.
f. 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 8: Difference in Percentages of Participants with Seroresponse at 1 Month After Vaccination Series – Immunobridging Subset –Participants 2 Through 4 Years of Age (Study 3) 1 Month after Dose 3 and Participants 16 Through 25 Years of Age (Study 2) 1 Month after Dose 2 Without Evidence of Infection – Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine		
		3 mcg/Dose 2 Through 4 Years of Age (1 Month After Dose 3) N[a]=141	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) N[a]=170	Difference in Seroresponse Rates %[e] (95% CI[f]) (2 Through 4 Years of Age minus 16 Through 25 Years of Age)[g]
Assay		n[c] (%) (95% CI[d])	n[c] (%) (95% CI[d])	
SARS-CoV-2 neutralization assay - NT50 (titer)[h]		141 (100.0) (97.4, 100.0)	168 (98.8) (95.8, 99.9)	1.2(-1.5, 4.2)

Abbreviations: LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer 50; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Seroresponse 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 ≥4 × LLOQ is considered a seroresponse.
Note: Participants who had no serological or virological evidence (up to 1 month after Dose 2 [(Study 2) or 1 month after Dose 3 (Study 3) blood sample collection)[of past SARS-CoV-2 infection [(i.e., N-binding antibody [serum] negative at pre-Dose 1, pre-Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab] at pre-Dose 1, pre-Dose 2, and pre-Dose 3 (Study 3) study visits, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection)] and had no medical history of COVID-19 were included in the analysis.

a. N = number of participants with valid and determinate assay results both before vaccination and at 1 month after Dose 2. These values are the denominators for the percentage calculations.
b. Protocol-specified timing for blood sample collection.
c. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
e. Difference in proportions, expressed as a percentage ([2 through 4 years of age] – [16 through 25 years of age]).
f. 2-sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
g. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the difference in proportions is greater than -10.0% provided that the immunobridging criteria based on GMR were met.
h. 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.

Using a non-validated fluorescence focus reduction neutralization test assay against the Omicron variant of SARS-CoV-2 (BA.1), the NT50 GMT at 1 month after Dose 3 among a subset of 34 study participants without evidence of prior SARS-CoV-2 infection (82.5 [95% CI: 55.4, 122.9]) was increased compared to the NT50 GMT before Dose 3 (14.0 [95% CI: 10.6, 18.5]).

Immunogenicity in Participants 6 Through 23 Months of Age

Immunogenicity analyses have been performed in the immunobridging subset of 82 Study 3 participants 6 through 23 months of age without evidence of infection up to 1 month after Dose 3 based on a data cutoff date of April 29, 2022.

The evaluable immunogenicity population without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 3 of Pfizer-BioNTech COVID-19 Vaccine was comprised of 82 participants 6 through 23 months of age. Most participants in this analysis population were White (72.0%), with 1.2% Black or African American participants, 13.4% Asian participants, and 12.2% multiracial participants. There were 15.9% Hispanic/Latino participants. The median age was 16.0 months and 62.2% of participants were male. In the evaluable immunogenicity population (regardless of evidence of prior infection), 6/132 participants (4.5%) were baseline positive for prior SARS-CoV-2 infection.

SARS-CoV-2 50% neutralizing antibody titers (NT50) 1 month after the vaccination series were compared between an immunogenicity subset of Phase 2/3 participants 6 through 23 months of age from Study 3 and a randomly selected subset from Study 2 Phase 2/3 participants 16 through 25 years of age, using a microneutralization assay against the reference strain (USA_WA1/2020). The primary immunobridging analyses compared the geometric mean titers (using a GMR) and the seroresponse (defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from before Dose 1) rates in the evaluable immunogenicity population of participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 3 in participants 6 through 23 months of age and up to 1 month after Dose 2 in participants 16 through 25 years of age. The prespecified immunobridging criteria were met for both the GMR and the seroresponse difference (Table 9 and Table 10, respectively).

Table 9: SARS-CoV-2 GMTs (NT50) at 1 Month After Vaccination Series – Immunobridging Subset - Participants 6 Through 23 Months of Age (Study 3) 1 Month After Dose 3 and Participants 16 Through 25 Years of Age (Study 2) 1 Month After Dose 2 – Without Evidence of SARS-CoV-2– Evaluable Immunogenicity Population

	Pfizer-BioNTech COVID-19 Vaccine		
	3 mcg/Dose 6 Through 23 months of Age (1 Month After Dose 3) n[a]=82	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) n[a]=170	GMR (95%CI) (6 Through 23 months of Age/16 Through 25 Years of Age)[d,e]
Assay	**GMT[c] (95% CI[c])**	**GMT[c] (95% CI[c])**	
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1406.5 (1211.3, 1633.1)	1180.0 (1066.6, 1305.4)	1.19 (1.00, 1.42)

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 Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood sample collection)] of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Dose 1, Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab]

at Dose 1, Dose 2, and Dose 3 (Study 3) study visits, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection)] and had no medical history of COVID-19 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. Protocol-specified timing for blood sample collection.
c. 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 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers ([6 through 23 months of age] - [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).
e. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the GMR ratio is greater than 0.67 and the point estimate of the GMR is ≥0.8.
f. 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 10: Difference in Percentages of Participants with Seroresponse at 1 Month After Vaccination Series – Immunobridging Subset – Participants 6 Through 23 months of Age (Study 3) 1 Month After Dose 3 and Participants 16 Through 25 Years of Age (Study 2) to 1 Month After Dose 2 Without Evidence of Infection – Evaluable Immunogenicity Population

	Pfizer-BioNTech COVID-19 Vaccine		
	3 mcg/Dose 6 Through 23 months of Age (1 Month After Dose 3) N[a]=80	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) N[a]=170	Difference in Seroresponse Rates %[e] (95% CI[f]) (6 Through 23 months of Age minus 16 Through 25 Years of Age)[g]
Assay	**n[c] (%) (95% CI[d])**	**n[c] (%) (95% CI[d])**	
SARS-CoV-2 neutralization assay - NT50 (titer)[h]	80 (100.0) (95.5, 100.0)	168 (98.8) (95.8, 99.9)	1.2 (-3.4, 4.2,)

Abbreviations: LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer 50; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Seroresponse 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 ≥4 × LLOQ is considered a seroresponse.
Note: Participants who had no serological or virological evidence [(up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at pre-Dose 1, Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab] at pre-Dose 1, pre-Dose 2, and pre-Dose 3 (Study 3) study visits, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection)] and had no medical history of COVID-19 were included in the analysis.

a. N = number of participants with valid and determinate assay results both before vaccination and at 1 month after Dose 2. These values are the denominators for the percentage calculations.
b. Protocol-specified timing for blood sample collection.
c. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
e. Difference in proportions, expressed as a percentage ([6 through 23 months of age] – [16 through 25 years of age]).
f. 2-sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
g. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the difference in proportions is greater than -10.0% provided that the immunobridging criteria based on GMR were met.
h. 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.

Using a non-validated fluorescence focus reduction neutralization test assay against the Omicron variant of SARS-CoV-2 (BA.1), the NT50 GMT at 1 month after Dose 3 among a subset of 32 study participants without

evidence of prior SARS-CoV-2 infection (127.5 [95% CI: 90.2, 180.1]) was increased compared to the NT50 GMT before Dose 3 (16.3 [95% CI: 12.8, 20.8]).

19 HOW SUPPLIED/STORAGE AND HANDLING

The information in this section applies to the Pfizer-BioNTech COVID-19 Vaccine that is supplied in multiple dose vials with maroon caps and labels with maroon borders. These multiple dose vials are supplied in a carton containing 10 multiple dose vials (NDC 59267-0078-4). After dilution, 1 vial contains 10 doses of 0.2 mL.

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 multiple dose vials with maroon caps and labels with maroon borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice.

Once received, frozen vials may be immediately transferred to the refrigerator [2ºC to 8ºC (35ºF to 46ºF)], 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 vials may take up to 2 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) for up to 12 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 multiple dose vials with maroon caps and labels with maroon borders are received at 2°C to 8°C (35ºF to 46ºF), they should be stored at 2°C to 8°C (35ºF to 46ºF). 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 12 months from the date of manufacture printed on the vial and cartons. Expiry dates based on 12 months from the date of the manufacture are shown below.

Printed Manufacturing Date	**12-Month Expiry Date**
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023
04/2022	31-Mar-2023
05/2022	30-Apr-2023
06/2022	31-May-2023

Vial Storage During Use

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

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with maroon caps and labels with maroon borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to dilution.

After dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution, even though some vial and carton labels may state that a vial should be discarded 6 hours after dilution. The information in this Full EUA Prescribing Information supersedes the information printed on vial labels and cartons.

Transportation of Vials

If local redistribution is needed, undiluted 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).

20 PATIENT COUNSELING INFORMATION

Advise the caregiver to read the 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
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

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

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1515-0.9

Revised: 17 June 2022

Appendix D- CDC Ancillary Kit Guide

COVID-19 Vaccine Ancillary Supply Kit Guidance

Purpose:

This guidance provides an overview of the COVID-19 vaccine ancillary supply kits the U.S. Department of Health and Human Services (HHS) is providing to enrolled COVID-19 vaccination providers as part of the federal COVID-19 Vaccination Program. It includes a general description of different COVID-19 vaccine ancillary kit configurations for administration, as well as a list of select corresponding products, product descriptions, and product quantities. For reference and to access additional product-specific information and training resources, this document also includes website hyperlinks and contact information for select product manufacturers.

Background:

HHS is providing ancillary supply kits for the administration of COVID-19 vaccine. The Strategic National Stockpile (SNS), managed by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), is partnering with McKesson Corporation to produce, store, and distribute these vaccine ancillary supply kits on behalf of the SNS.

How to use this guide:

Jurisdictional immunization program staff–use this guide to help you:

- Learn about products that will arrive in ancillary kit(s).

COVID-19 vaccination providers–use this guide to help you:

- Learn about products that will arrive in ancillary kit(s).
- Prepare storage space for the ancillary kit products you will receive.

Ancillary kit basics:

How does a provider order ancillary kits?

You do not need to order ancillary kits. When you order COVID-19 vaccine in VTrckS, ancillary supplies will automatically be ordered in amounts to match the vaccine orders.

Note: To receive COVID-19 vaccine, vaccination provider facilities and organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program.

How much do ancillary kits cost?

Ancillary kits will be provided at no cost to enrolled COVID-19 vaccination providers.

How will needles and syringes be packaged?

Needles and syringes for vaccine administration may be packaged as integrated units (i.e., combo needles and syringes for which NO assembly required) or as separate items in a kit (i.e., assembly required).

Can I order specific brand(s) of needles and/or syringes?

Due to a limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. Products included in the kits may vary over time. In order to meet the demand for supplies, the federal government has purchased single-use, sterile needles and syringes from multiple manufacturers (to include foreign sources) to ensure adequate supplies. These products are approved by the U.S. Food and Drug Administration, safety-engineered and compliant with standards established by the Occupational Safety and Health Administration.

What is considered "pediatric" and "adult"?

For the purpose of immunizations pediatric is birth through 18 years and adult is 19 years and older. Refer to each product's EUA for age indications.

*The number of doses is limited by the dose volume extracted (i.e., 0.5 mL or 0.25 mL) and the number of times the vial stopper is punctured. Do not puncture the vial more than 20 times. Discard the vial after 20 punctures, including any remaining vaccine.
†Currently unavailable for order (8/20/2021)

COVID-19 Vaccine Ancillary Supply Kit Guidance *(continued)*

Related guidance and resources:

- COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations - PDF

Contact for questions:

Vaccination providers should contact the manufacturer with questions related to proper product use.

Becton Dickinson (BD) Worldwide	https://www.bd.com/en-us/	844-823-5433
Cardinal Health	https://www.cardinalhealth.com/en.html	1-800-964-5227
HTL Strefa	https://htl-strefa.com/home-page/	877-660-1900
Duopross Meditech Corp	https://www.duopross.com/	1-800-844-1350
Retractable Technologies Inc. (RTI)	https://retractable.com/	888-703-1010
Marathon/Smiths Medical	N/A	941-704-7864

For any issues with equipment (e.g., faulty equipment), contact McKesson Customer Service Team at 833-272-6634 or SNSSupport@McKesson.com.

Possible Ancillary Kits—COVID-19 Vaccines Supporting 100 Doses (Janssen)

The following tables list the contents of each possible ancillary kit by product and quantity. All kits are configured for 100 doses with 5% surplus.

*Needle and Syringe Sizes for **Adult** Ancillary Kits*

PRODUCT	QUANTITY
Needle (22–25G x 1")	85
Needle (22–25G x 1.5")	20
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

*Needle and Syringe Sizes for **Pediatric** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	105
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

*Needle and Syringe Sizes for **Mixed (Pediatric/Adult)** Ancillary Kits*

PRODUCT	QUANTITY
Adult/Pediatric Needle (22–25G x 1")	95
Adult Needle (22–25G x 1.5")	10
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Needle Gauge and Length Chart: www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

Possible Ancillary Kits:
COVID-19 Vaccine Supporting 100 primary series doses or 200 booster doses (Moderna)

The following tables list the contents of each possible ancillary kit by product and quantity. Two supply kits will be provided with each minimum order size of Moderna. All kits are configured for 100 primary series doses or 200 booster doses with 5% surplus (i.e., two supply kits will support a maximum of 200 booster doses).

*Needle and Syringe Sizes for **Adult** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	85
Needle (25G x 1.5")	20
Syringe (1 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

*Needle and Syringe Sizes for **Pediatric** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	105
Syringe (1 mL)	105
Alcohol pads (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Possible Ancillary Kits—COVID-19 Vaccine Supporting 140 Doses (Moderna)

Ancillary kits included with Moderna 14 vaccine orders will include*:

- One 140-dose ancillary kit, with standard syringes (3 mL and/or 1 mL)
- One 100-dose ancillary kit, with only small syringes (1mL)

This approach will support administration of booster doses and primary series doses using the Moderna 14 carton. There will continue to be surplus ancillary supplies because each vial can only be safely punctured 20 times.

*Needle and Syringe Sizes for **Adult** Ancillary Kits*

PRODUCT	QUANTITY
Needle (22–25G x 1")	75
Syringe (1 mL or 3mL, LDV)	75
Needle (22–25G x 1")	50
Syringe (1 mL or 3mL)	50
Needle (22–25G x 1.5")	25
Syringe (1 mL or 3 mL)	25
Alcohol Pad (sterile, individually sealed)	300
Vaccination Record Card	150
Needle Gauge and Length Chart	1
Face Shield	3
Surgical Mask	6

*Needle and Syringe Sizes for **Pediatric** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	75
Syringe (1 mL or 3 mL, LDV)	75
Needle (25G x 1")	75
Syringe (1 mL or 3 mL)	75
Alcohol pads (sterile, individually sealed)	300
Vaccination Record Card	150
Needle Gauge and Length Chart	1
Face Shield	3
Surgical Masks	6
Face Shield	3
Surgical Mask	6

*Needle and Syringe Sizes for **Mixed (Pediatric/Adult)** Ancillary Kits*

Kit contents not yet available

Note: Kit contents for mixed (pediatric/adult) kits currently unavailable.

*Beginning for orders approved Saturday, October 30, 2021

Possible Ancillary Kits—COVID-19 Vaccine Supporting 100 Pediatric Doses (Pfizer)

*Needle and Syringe Sizes for **Pediatric** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	70
Syringe (1 mL, LDV)	70
Needle (25G x 1")	35
Syringe (1 mL)	35
Needles, Mixing (21–25G x 1.5")	20
Syringe, Mixing (3 mL or 5 mL)	20
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	3
Surgical Mask	6
Diluent, 10 mL	10

Possible Ancillary Kits—COVID-19 Vaccine Supporting 300 Pediatric Doses (Pfizer)

*Needle and Syringe Sizes for **Pediatric** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	210
Syringe (1 mL, LDV)	210
Needle (25G x 1")	105
Syringe (1 mL)	105
Needles, Mixing (21–25G x 1.5")	60
Syringe, Mixing (3 mL or 5 mL)	60
Alcohol Pad (sterile, individually sealed)	630
Vaccination Record Card	300
Needle Gauge and Length Chart	3
Face Shield	9
Surgical Mask	18
Diluent, 10 mL	30

Possible Ancillary Kits—COVID-19 Vaccine Supporting 450 Doses (Pfizer-BioNTech)

Needle and Syringe Sizes for Large Combined ***Adult*** *Ancillary Kits (currently unavailable)**

PRODUCT	QUANTITY
Needle (22–25G x 1")	315
Syringe (1 mL, LDV)	315
Needle (22-25G x 1")	75
Syringe (1 mL)	75
Needle (22–25G x 1.5")	85
Syringe (1 mL)	85
Needle, Mixing (21-25G x 1.5")	80
Syringe, Mixing (3 mL or 5 mL)	80
Alcohol Pad (sterile, individually sealed)	1,200
Vaccination Record Card	450
Needle Gauge and Length Chart	4
Face Shield	10
Surgical Mask	20
Diluent	75

Needle and Syringe Sizes for Large Combined ***Pediatric*** *Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	315
Syringe (1 mL, LDV)	315
Needle (25G x 1")	160
Syringe (1 mL)	160
Needle, Mixing (21–25G x 1.5")	80
Syringe, Mixing (3 mL or 5 mL)	80
Alcohol Pad (sterile, individually sealed)	1,200
Vaccination Record Card	450
Needle Gauge and Length Chart	4
Face Shield	10
Surgical Mask	20
Diluent	75

* Over the course of the program, requests for adult ancillary kits have exceeded anticipated demand while requests for pediatric ancillary kits have been lower than anticipated. As a result, we have exhausted the adult kits and we will ship the pediatric ancillary kit for all Pfizer 450 vaccine orders until the inventory is depleted.

As a reminder, the difference between the Pfizer 450 adult and pediatric ancillary kits is the adult kits include ~20% 1.5" needles used to vaccinate certain adults, based on weight. Pediatric kits include 100% 1" needles. With substitution of a pediatric ancillary kit for an adult ancillary kit, sites should proactively acquire a stock of the 1.5" needles to vaccinate residents/patients/staff who require the longer needle length, as needed. Refer to the Vaccine Administration: Needle Gauge and Length chart included with ancillary kits for information about when the 1.5" needle length should be used.

Possible Ancillary Kits—COVID-19 Vaccine Supporting 1,170 Doses (Pfizer-BioNTech)

*Needle and Syringe Sizes for Large Combined **Adult** Ancillary Kits**

PRODUCT	QUANTITY
Needle (22–25G x 1")	830
Syringe (1 mL, LDV)	830
Needle (22-25G x 1")	185
Syringe (1 mL)	185
Needle (22–25G x 1.5")	225
Syringe (1 mL)	225
Needle, Mixing (21-25G x 1.5")	205
Syringe, Mixing (3 mL or 5 mL)	205
Alcohol Pad (sterile, individually sealed)	2,900
Vaccination Record Card	1,200
Needle Gauge and Length Chart	10
Face Shield	25
Surgical Mask	50
Diluent	200

Needle Gauge and Length Chart: www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

* Some needles from the adult kit may be used for adolescents age 12 through 18 years. Choose the correct needle gauge and needle length using CDC's Vaccine Administration: Needle Gauge and Length job aid (https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf). For adolescents age 12–18 years, use the 22-25 gauge, 1-inch needles from the ancillary kit. For adults age 19 years and older, see the chart referenced previously to determine the correct size based on sex and weight.

General Needle and Syringe Resources

Web Resources:

- Vaccine Administration Resource Library: Includes resources for preparing, administering, and documenting vaccines

PDF Resources:

- Vaccine Administration: Needle Gauge and Length–PDF
- Vaccine Administration: Intramuscular (IM) Injection Children 7 through 18 years of age–PDF
- Vaccine Administration: Intramuscular (IM) Injection Adults 19 years of age and older–PDF

Video Resources:

- Intramuscular (IM) Injection: Supplies (Children Birth through 18 Years of Age): This training addresses how to select the equipment needed to prepare an intramuscular (IM) injection for children from birth through 18 years of age.
- Intramuscular (IM) Injection: Supplies (Adults 19 Years of Age and Older): This training addresses how to select the equipment needed to prepare an intramuscular (IM) injection for adults 19 years of age and older.
- Intramuscular (IM) Injection Sites: This training helps providers identify intramuscular (IM) injection sites. A needle is used to inject the vaccine into the muscle.

Training Resources:

- Vaccine Administration e-Learn: A self-paced vaccine administration course that provides comprehensive training using videos, job aids, and other resources

Specific Ancillary Kit Products and Product Information

The following tables, organized by manufacturer or broker, list possible ancillary kit products with an example image (colors may vary) and links to more information. Resources for additional information include:

- **Web** resources
- **PDF** resources
- **Video** resources

Becton Dickinson Products (Phone: 844-823-5433)

ITEM	WHERE TO FIND MORE INFORMATION
Hypodermic Needle PrecisionGlide™ Conventional* ■ Gauge: 22-25/Length: 1.5″ 	PrecisionGlide™ Conventional Needle overview Visit Becton Dickinson catalog and search product numbers: 305127, 305156, 305194
Safety Hypodermic Needle BD Eclipse™ ■ Gauge: 22-25/Length: 1-1.5″ ■ Gauge: 23/25/Length: 1-1.25″ 	BD Eclipse™ Needle overview Visit Becton Dickinson catalog and search product numbers: 22-25G, 1-1.5″: 305762, 305761, 305763, 305767 23/25, 1-1.25″: 305866, 305891, 305892 BD Eclipse™ directions for use BD Eclipse™ Needle instruction video
Safety Combo, Syringe with BD Eclipse™ Needle 3mL BD Luer-Lok™ Syringe ■ Gauge: 22-25/ Length: 1-1.5″ 	BD Eclipse™ Needle overview Visit Becton Dickinson catalog and search product numbers: 305782, 305783, 305787 BD Eclipse™ directions for use BD Eclipse™ Needle Instruction video
1mL/3mL BD Luer-Lok™ Syringe 	Conventional syringe overview Visit Becton Dickinson catalog and search product numbers: 309628, 309657
Conventional Combo*  ■ Syringe (3mL/5mL) with attached needle Gauge: 22-25/Length: 1-1.5″	Conventional syringe overview Visit Becton Dickinson catalog and search product numbers: 309361, 309571, 309572, 309574, 309581, 309582, 309589

*For mixing ONLY and NOT for vaccine administration

Becton Dickinson Product catalog: http://catalog.bd.com/

PrecisionGlide™ Conventional Needle overview: https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/conventional-syringes-and-needles/conventional-needles

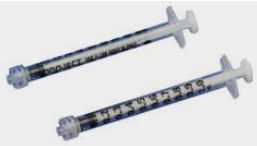
BD Eclipse™ Needle overview: https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/safety-syringes-and-needles/safety-needles/bd-eclipse-needle

BD Eclipse™ directions for use: https://www.bd.com/documents/guides/directions-for-use/MPS_HY_Eclipse-needle-usage-guidelines_DF_EN.pdf

BD Eclipse™ Needle instruction video: https://www.bd.com/en-us/company/video-gallery?video=6186777712001

Conventional Syringe overview: https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/conventional-syringes-and-needles/conventional-syringes

Cardinal Health (Phone: 1-800-964-5227)

ITEM	WHERE TO FIND MORE INFORMATION
Tuberculin Syringe Monoject™ ■ 1mL Luer Lock Tip Conventional Syringe 	1 mL Luer Lock Syringes product page Visit Cardinal Health webpage and search product numbers: 1180100777, 1180300777
Magellan™ 3mL Syringe with Hypodermic Safety Needle ■ Gauge: 23/25/Length: 1″ 	Magellan™ Safety Needle and Syringe Combination product page Visit Cardinal Health webpage and search product numbers: 8881833310, 8881833510
Magellan™ Hypodermic Safety Needle ■ Gauge: 23/25 Length: 1″ 	Magellan™ Hypodermic Safety Needle Product page Visit Cardinal Health webpage and search product numbers: 8881850310, 8881850510

Cardinal Health webpage: https://www.cardinalhealth.com/en.html

1 mL luer Lock Syringes product page: https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/1-ml-luer-lock-syringes.html

Magellan™ Safety Needle and Syringe Combination product page: https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safety-needles-and-syringes/magellan-safety-needle-and-syringe-combination.html

Magellan™ Hypodermic Safety Needle product page: https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safety-needles-and-syringes/magellan-safety-needles.html

Duopross Meditech Corp (Phone: 1-800-844-1350)

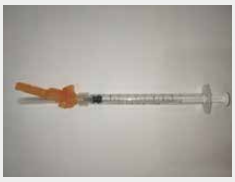
ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle* ■ Gauge: 23- 25/Length: 1-1.5″ 	Website and product information currently unavailable.
Safety Combo, 3mL Syringe with Safety Needle* ■ Gauge: 23-25/Length: 1-1.5″ 	Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not currently available.

Goldbelt (Contact information currently unavailable)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Needle* ■ Gauge: 23-25/Length: 1-1.5″ 	Website and product information currently unavailable.
Conventional Syringe 1mL* 	Website and product information currently unavailable.
Conventional Syringe 3mL* 	Website and product information currently unavailable.
Conventional Syringe 5mL* 	Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not available currently.

Gold Coast (contact information not currently available)*

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle ■ Gauge: 23/Length: 1″ 	Product Number: Carepoint 35-8204 See page 31 of this guide for additional information.
Safety Combo, 1mL Syringe with Safety Needle ■ Gauge: 25/ Length: 1″ 	Product Number: Carepoint 35-8203 See page 31 of this guide for additional information.
Safety Combo, FlipLock 3mL Syringe with Safety Needle ■ Gauge: 23/Length: 1″ 	Product Number: 822331 See page 32–34 of this guide for additional information.
Safety Combo, FlipLock 3mL Syringe with Safety Needle ■ Gauge: 25/ Length: 1″ 	Product Number: 825231 See page 32–34 of this guide for additional information.
Safety Needle ■ Gauge: 25/ Length: 1″ ■ Gauge: 23/ Length: 1″ 	Product Numbers: 25G x 1″: EasyTouch 802501 23G x 1″: EasyTouch 812301 See page 32–34 of this guide for additional information.

HTL Strefa (Phone: 877-660-1900)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle ■ Gauge: 25/Length: 1″ 	HTL Strefa home page (product 6054 currently unlisted) See page 35 of this guide for instructions for use.
Safety Combo, 3mL Syringe with Safety Needle ■ Gauge: 23/Length: 1″ 	HTL Strefa home page (product 6053 currently unlisted) See page 35 of this guide for instructions for use.
Safety Combo, 3mL Syringe with Safety Needle ■ Gauge: 25/Length: 1″ 	HTL Strefa home page (product 6055 currently unlisted) See page 35 of this guide for instructions for use.

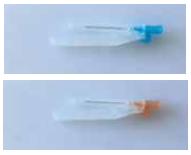
HTL Strefa home page: https://htl-strefa.com/home-page/

Marathon/Smiths Medical (Phone: 941-704-7864)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 3mL Syringe with Safety Needle* ■ Gauge: 22-25/Length: 1-1.5″ 	Website and product information currently unavailable. See page 33 for Identification and Connection Guide and QR code for a short video describing the connections. Product numbers: 4234, 4236, 423510

*Image for product is a placeholder stock image only. Product image is not available currently.

Medline (Contact information currently unavailable)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle ■ Gauge: 23/Length: 1″ ■ Gauge: 25/Length: 1″ 	Website and product information currently unavailable.
Safety Needle ■ Gauge: 23/Length: 1-1.5″ ■ Gauge: 25/Length: 1″ 	Website and product information currently unavailable.
Conventional Syringe ■ 1mL ■ 3mL 	Luer Lock Syringe product page Visit Medline webpage and search product numbers: SYR101010, SYR103010

Luer Lock Syringe product page: https://www.medline.com/product/Luer-Lock-Syringes/Syringes-without-Needle/Z05-PF11377?question=SYR103010&index=P1&indexCount=1#mrkOrderingInfoTable

Medline webpage: https://www.medline.com

Quality Impact (Contact information currently unavailable)*

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle† ■ Gauge: 23-25/Size: 1″ 	Website and product information currently unavailable.
Safety Combo, 3mL Syringe with Safety Needle† ■ Gauge: 23-25/Size: 1″ 	Website and product information currently unavailable.

* HHS discontinued use of HAIOU syringes, distributed by Quality Impact, in March 2021 due to feedback received from providers about the poor quality. HHS replaced all of the HAIOU needles/syringes that were reported to HHS and/or McKesson Customer Service.

†Image for product is a placeholder stock image only. Product image is not available currently.

Retractable Technologies Inc. (Phone: 888-703-1010)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo Unit, 1mL/3ml, with attached needle  ■ Gauge: 23/25/Length: 1″	Visit Retractable Technologies Inc. webpage and search product numbers: 10161, 10311, 10391 VanishPoint® Syringes brochure VanishPoint® Syringes product usage information VanishPoint® Syringes video

Retractable Technologies Inc. webpage: https://retractable.com/Products

VanishPoint® Syringes brochure: https://d2ghdaxqb194v2.cloudfront.net/577/166728.pdf

VanishPoint® Syringes product usage information: https://d2ghdaxqb194v2.cloudfront.net/577/166715.pdf

VanishPoint® Syringes video: https://youtu.be/wC-uXq3uUdQ

Gold Coast CarePoint Safety Needles and Syringes

Available at: http://www.allisonmedical.com/?product=safety-needle **and** http://www.allisonmedical.com/?product=safety-needle-combinations

CAREPOINT™ SAFETY 1st™

SAFETY NEEDLES

25/23 Gauges (Variety of Lengths)

- Boxes of 50, sterile needles are sealed in individual packages for assurance and convenience
- Compatible with all major brands of luer lock syringes
- Lubricated needle provides smooth injection
- Easy, three-way safety wing activation: forefinger, thumb or hard surface
- Needles are UV bonded to ensure stability
- Easy to read tri-lingual packaging

Item Number	Product Description	UPC	Box Quantity	Case Quantity
32-8700	25G x 5/8" (.625)	786227081005	50 ct.	16/bxs
32-8701	25G x 1"	786227081015	50 ct.	16/bxs
32-8702	25G x 1 1/2" (1.5)	786227081025	50 ct.	16/bxs
32-8703	23G x 1"	786227081035	50 ct.	16/bxs
32-8704	23G x 1 1/2" (1.5)	786227081045	50 ct.	16/bxs

LUER LOCK SYRINGES WITH SAFETY NEEDLES

3cc Syringes

- Boxes of 50, sterile needles are sealed in individual packages for assurance and convenience
- Compatible with all major brands of luer lock syringes
- Lubricated needle provides smooth injection
- Easy, three-way safety wing activation: forefinger, thumb or hard surface
- Needles are UV bonded to ensure stability
- Easy to read tri-lingual packaging

Item Number	Product Description	UPC	Box Quantity	Case Quantity
35-8200	25G x 5/8" 3cc	786227082005	50 ct.	8/bxs
35-8201	25G x 1" 3cc	786227082015	50 ct.	8/bxs
35-8202	23G x 1" 3cc	786227082025	50 ct.	8/bxs

info@allisonmedical.com • allison medical • www.allisonmedical.com
inspired innovation

For questions regarding the CarePoint Safety Line, contact Allison Medical Customer Service at: 1-800-886-1618

Gold Coast Easy Touch FlipLock Safety Syringes Brochure

Easy•Touch®
FlipLock™ Safety Syringes

SIMPLE & SMART

EasyTouch FlipLock Safety Syringes offer an easy and simple solution in caregiver protection. After injection, just flip the protective shield over the needle until it clicks and locks in place. Hands and fingers stay away from the exposed needle. Simple, smart and cost-effective.

- ✓ Easy to Use
- ✓ Protective Cover Shields Needle After Use
- ✓ Familiar Technology Requires Limited Training
- ✓ Multi-lock Safety System
- ✓ Contains No Natural Rubber Latex
- ✓ Heavy-Duty Barrel
- ✓ Disposable
- ✓ Sterile, Individually wrapped
- ✓ Needle Attaches to Any Luer Lock Barrel
- ✓ Safety Engineered

Gold Coast Easy Touch FlipLock Safety Syringes Brochure

Easy•Touch®
FlipLock™ Safety Syringes

FlipLock™ Safety Syringe w/ Exchangeable Needle

	ITEM#	ML/CC	GAUGE	LENGTH	BOX QTY	CASE QTY	NDC# 08496-
	822331	3mL	23G	25mm, 1"	100/box	6/case	0263-01
	822337	3mL	23G	40mm, 1.5"	100/box	6/case	0293-01
	825231	3mL	25G	25mm, 1"	100/box	6/case	7012-01
	825211	1mL	25G	25mm, 1"	100/box	6/case	0248-01

FlipLock™ Needles

	ITEM#	GAUGE	LENGTH	BOX QTY	CASE QTY	NDC# 08496-
	812301	23G	25mm, 1"	50/box	5/case	0201-01
	812307	23G	40mm, 1.5"	50/box	5/case	0202-01
	812501	25G	25mm, 1"	50/box	5/case	0204-01

Luer Lock Barrels

	ITEM#	ML/CC	DESCRIPTION	BOX QTY	CASE QTY	NDC# 08496-
	802015	1mL	Luer Lock Barrel (INS)	100/box	6/case	0164-01
	802030	3mL	Luer Lock Barrel (TB)	100/box	6/case	0159-01

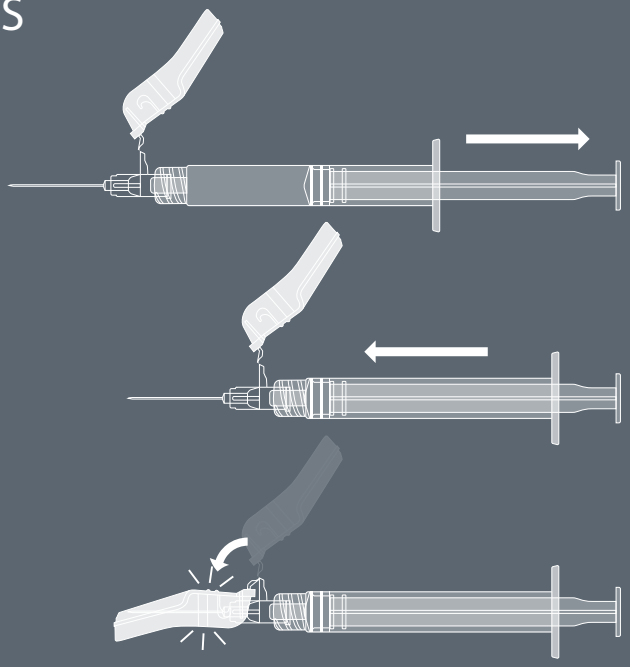
Gold Coast Easy Touch Fluringe Fliplock Safety Syringes

Easy•Touch®
FLURINGE®
FLIPLOCK™ SAFETY SYRINGES

1 **LOAD SYRINGE**
Pull the plunger back to load the syringe

2 **INJECT**
Push the plunger in one smooth motion to administer medication

3 **FLIP**
Flip the protective shield over the used needle until it clicks into place. Discard according to local regulations



HTL Strefa DropSafe Syringe with Safety Needle Instructions for Use

DropSafe
Syringe with Safety Needle

Manufactured for:
HTL-STREFA S.A.
ul. Adamówek 7, 95-035 Ozorków, Poland
T: +48 42 270 00 10; F: +48 42 270 00 20
www.htl-strefa.com, E: info@htl-strefa.pl

Distributed by:
HTL-STREFA, Inc.
3005 Chastain Meadows Pkwy, Suite 300
Marietta, GA 30066, USA
T: +1 770 528 0410; F: +1 770 528 0411
www.htl-strefa.com; E: info@htl-strefa.com

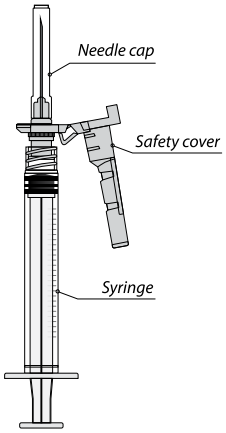
The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose.

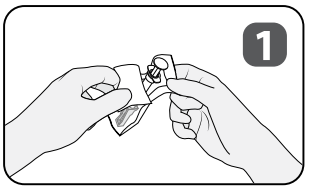
Ask your healthcare professional for assistance in choosing the needle length, injection site and technique appropriate for you.

The needle fits any standard luer lock or luer slip syringe and it is equipped with a safety cover, that prevents needle stick self-injury after use.

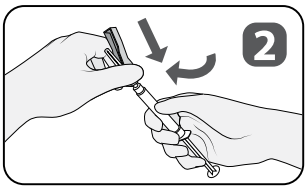
INSTRUCTIONS FOR USE

Follow your recommended clinical procedures for drug injections. See the patient information leaflet of the drug.

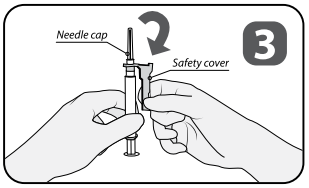




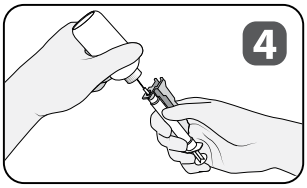
Peel blister pack of the DropSafe Syringe with Safety Needle. Use aseptic technique.



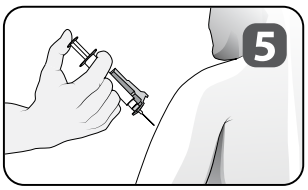
Ensure needle is firmly attached to the luer lock or luer slip syringe.



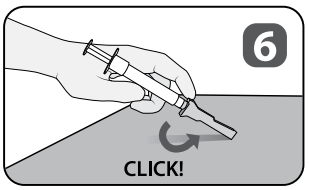
Pull back the safety cover to enable a clear view of the injection site then remove the needle cap.



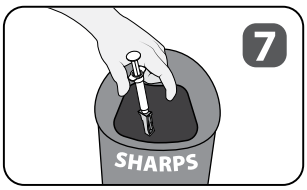
Draw up the medication according to its reference information. Prime the needle, if required.



Administer injection according to established protocol.



Do not recap needle with needle cap. Immediately after injection, activate the safety cover by pressing down on a flat surface until you feel or hear an audible click, indicating the cover is securely locked over the needle.



Once the cover is securely locked over the needle, dispose of syringe and needle in an approved sharps container.

Retractable Technologies Inc VanishPoint® Syringe Flyer

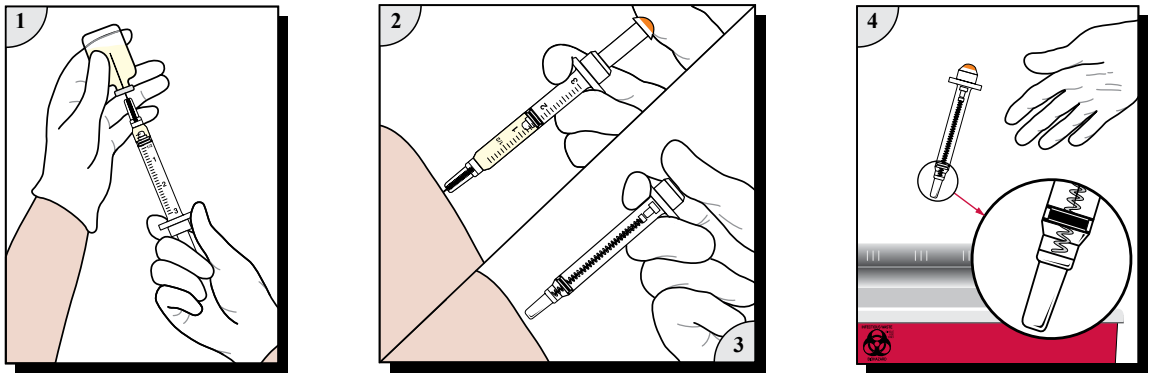
Available at: https://d2ghdaxqb194v2.cloudfront.net/577/166715.pdf

CE 2797

VANISHpoint®

Syringe

Standard Draw Procedure | In-Patient, Automated Retraction | Non-Reusable



Product Usage Information:

1. Prepare and give injection using aseptic technique according to institutional policy.
2. For injection into patients, continue depressing plunger to activate automatic needle retraction ***while needle is still in patient.*** For injection into IV ports, continue depressing plunger to activate automatic needle retraction and ***immediately remove needle from port. Full dose is administered only when needle retraction is activated.***
3. Needle will automatically retract into syringe, preventing exposure to contaminated needle and rendering syringe non-reusable. In the event that needle retraction mechanism does not activate, discard syringe in an appropriate sharps container per protocol of institution. Do not recap contaminated needles.
4. Dispose of VanishPoint® syringe in an appropriate sharps container per protocol of institution.

Precautions:

- Single use only. Reuse of this device may result in exposure to bloodborne pathogens, including Hepatitis B virus (HBV), Hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
- Contents are sterile, non-toxic, and non-pyrogenic. Do not use if product or package is damaged.
- Not made with natural rubber latex.
- Use only with attached needle. Needle cannot be changed.
- Automated needle retraction occurs only when barrel is emptied and plunger is fully depressed.
- For applications where full dose is not administered, expel remaining contents according to institutional policy and activate needle retraction.
- U.S. Federal Law restricts this device to sale by or on the order of a physician.

RETRACTABLE TECHNOLOGIES, INC.
www.retractable.com

511 Lobo Lane
Little Elm, Texas 75068-5295
Tel: (972) 294-1770 Fax: (972) 294-4400
Toll Free 1-888-703-1010

M001 REV. 11 EN, JUL 2019
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Smiths Medical Needle-Pro® and Needle-Pro® Edge™ Safety Devices

Needle-Pro® and Needle-Pro® Edge™ Safety Devices

Identification and Connection Guide

Smiths Medical offers the Needle-Pro® and Needle-Pro® Edge™ hypodermic safety devices. It is important to identify which device you are using and review the Instructions for Use prior to using. The information below is to assist you in identifying which device you are using and to help ensure the connections are tightened and secure prior to use.

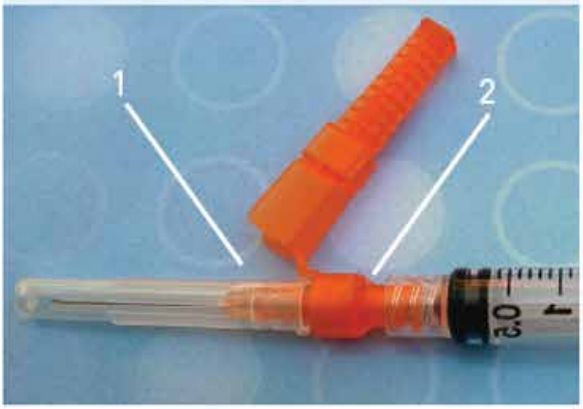
Needle-Pro® Hypodermic Safety Device

Two points of connection

- Needle to Needle-Pro® orange safety device (1)
- Needle-Pro® orange safety device to syringe (2)

Ensure the 2 connections are secure by:

1. Twisting to tighten the needle into the Needle-Pro® orange safety device AND
2. Twisting to tighten the Needle-Pro® orange safety device into the syringe



Needle-Pro® EDGE™ Hypodermic Safety Device

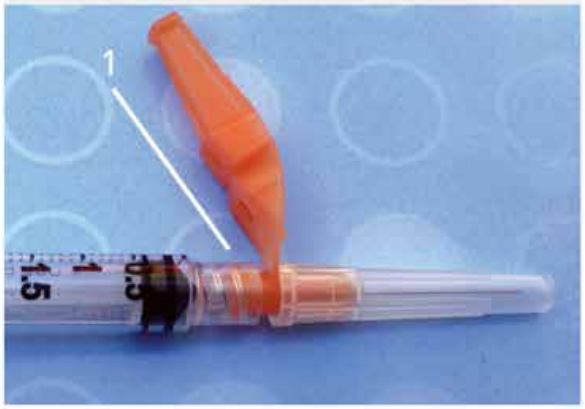
One connection

- Needle-Pro® Edge™ safety device to syringe (1)

Ensure the connection is secure by:

1. Twisting to tighten the connection between the Needle-Pro® Edge™ and syringe prior to use

Scan the QR Code for a short video describing the connections.



Contact customer services at 1-800-258-5361 or at www.smiths-medical.custhelp.com

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA
Phone: 1-214-618-0218
Toll-Free USA 1-800-258-5361

Rx ONLY

smiths medical

Find your local contact information at: www.smiths-medical.com/customer-support

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Pfizer-BioNTech COVID-19 Vaccine and Low Dead-Volume (LDV) Syringes and/or Needles

Available at: https://www.cvdvaccine-us.com/images/pdf/Low-Dead-Volume-Syringe-Brochure.pdf

Pfizer-BioNTech COVID-19 Vaccine and
LOW DEAD-VOLUME (LDV) SYRINGES AND/OR NEEDLES

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

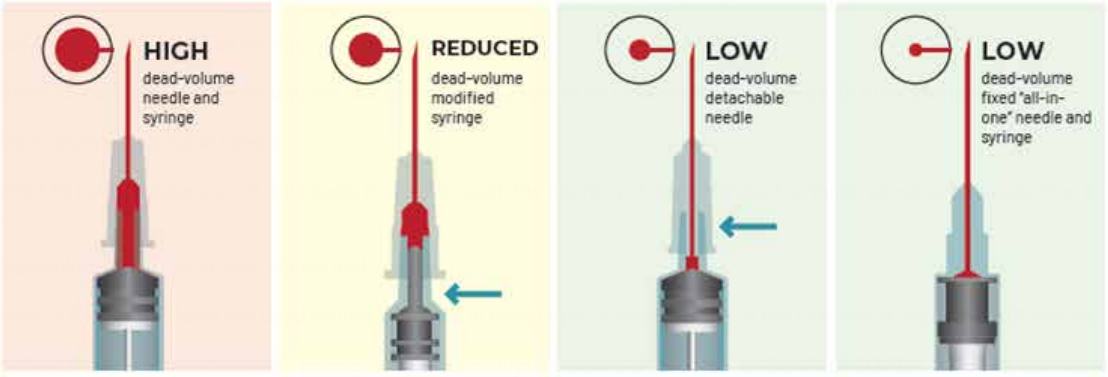
Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial.

Use of low dead-volume (LDV) syringes and/or needles may maximize the potential number of vaccine doses and minimize vaccine wastage[1]

Low dead-volume (also called low dead-space) is the amount of fluid remaining within the syringe and needle after an injection is completed[2]

Characteristics of LDV syringes and needles



Withdrawal of 6 doses is unlikely with standard detachable needles with standard syringe

LDV SYRINGES have **plungers molded to the luer cone**, allowing fluid to be cleared from the syringe tip during injection

LDV NEEDLES have an **extension of the needle** that fits through the opening of some standard syringes, allowing for a reduction in dead space

FIXED-NEEDLE SYRINGES have low dead volumes and will, in most cases, achieve 6 doses of the Pfizer-BioNTech COVID-19 Vaccine

Compatible LDV syringe and/or needle pairings may successfully withdraw 6 doses of Pfizer-BioNTech COVID-19 Vaccine, but not all combinations have been assessed or have a low dead volume that is small enough to allow extraction of a sixth dose.

The Centers for Disease Control and Prevention (CDC) is partnering with McKesson to provide ancillary kits containing needles and syringes for use with all COVID-19 vaccines. Please reach out to your state, local, or tribal health department and/or the CDC for more information. Pfizer makes no guarantee of the type or quality of the needles and syringes within the ancillary kits or the capability to withdraw 6 doses. For further information, please contact the manufacturer directly.

Find out more about the Pfizer-BioNTech COVID-19 Vaccine at
www.cvdvaccine-us.com

References: 1. Jarrahian C, Rein-Weston A, Saxon G, et al. Vial usage, device dead space, vaccine wastage, and dose accuracy of intradermal delivery devices for inactivated poliovirus vaccine (IPV). *Vaccine*. 2017;35:1789-1796. 2. Kesten JM, Ayres R, Neale J, et al. Acceptability of low dead space syringes and implications for their introduction: a qualitative study in the West of England. *Int J Drug Policy*. 2017;39:99-108.

Pfizer
Manufactured by
Pfizer Inc.
New York, NY 10017

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

PP-CVV-USA-0180
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Appendix E- Wastage Reporting Guidance

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

New York State COVID-19 Vaccination Program
Reporting Vaccine Wastage

When COVID-19 vaccine doses are unused, spoiled, damaged, or expired they are considered vaccine wastage. The COVID-19 Vaccination Program requires providers to report wastage daily in NYSIIS. This is necessary to accurately maintain and report vaccine inventory.

Responsible Wastage

The CDC released guidance on May 11, 2021, regarding wastage with the critical message to "take every opportunity to vaccinate every eligible person." As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated. Once punctured, multidose vials must be used within:

- 12 hours [Moderna, Pfizer Pediatric (Orange Cap, age 5-11), Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent)]
- 6 hours (Pfizer-BioNTech 12+ purple cap vials)
- 6 hours (refrigerated) or up to 2 hours at room temperature (J&J/Janssen). These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

Wastage when administering Moderna booster doses

Despite the volume of the booster dose being 0.25 mL, providers should still report a full dose as administered in NYSIIS. NYSIIS inventory must only be reported in whole doses and providers should continue to maintain reporting of wastage in whole doses. Wastage should only be reported if the total doses administered from a vial, regardless of volume or series, is less than the vial dose count. For example, if one primary and five booster doses were administered from a 10-dose vial, 6 doses would be reported as administered and 4 doses wasted. If at least 10 doses (booster or primary) were administered from a 10-dose vial, no wastage would be reported even if there is vaccine remaining in the vial.

Reporting Wastage in NYSIIS

Accurate reporting of wasted doses must be tracked to include information such as manufacturer, lot number, and wastage reason. **See Appendix A for a list of NYSIS COVID-19 vaccine wastage reasons and definitions.** Before getting started, please note:

a. Tracking wastage each clinic day is necessary to be able to report in NYSIIS. The COVID-19 Vaccine Wastage Tracking Sheet in Appendix C may be used to document any vaccine waste throughout the day (this tracking sheet MUST be used daily for state run vaccination sites). At the end of each day, documentation of any wasted doses should be provided to the designated NYSIIS Administrative User who will enter the information in NYSIIS. Any questions regarding wastage reporting should be sent to the designated NYSIIS Administrative User who will contact COVID19Vaccine@health.ny.gov, if necessary.

b. COVID-19 vaccine wastage is reported in NYSIIS under the module called "Manage Returns and Wastage". This module is also used for the Vaccines for Children (VFC) program. Under the VFC program, certain wasted vaccine is returned. This is NOT the case for COVID-19 vaccine. Expired or spoiled COVID-19 vaccine vials are **not** being returned to the manufacturer or the McKesson distribution center. For this reason, you must report any expired or spoiled COVID-19 vaccine doses as wastage, even if the reason fits a "return" category in NYSIIS. All COVID-19 vaccine wastage should be disposed as medical waste, such as by placing in a sharps container.

c. In NYSIIS, the terminology for reporting wastage is called creating a "wastage request". The word "request" here refers to requesting the Vaccine Program to review and approve the wastage report for proper reconciliation of inventory.

d. Use the following instructions to report wastage. To begin, log in to NYSIIS from the Health Commerce System and navigate to NYSIIS Production. Note: You must be an Administrative user in NYSIIS to access the Inventory section to report wastage.

Creating a Wastage Request in NYSIIS

Step 1: From the NYSIIS Home Page, click on **Manage Returns and Wastage** under the **Inventory** section on the side menu panel (Figure 1).

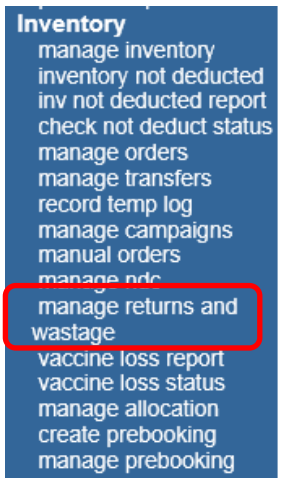

Figure 1

Step 2: On the **Manage Returns and Wastage Requests** screen (Figure 2), click on **Create Request** to create a new Wastage Request.

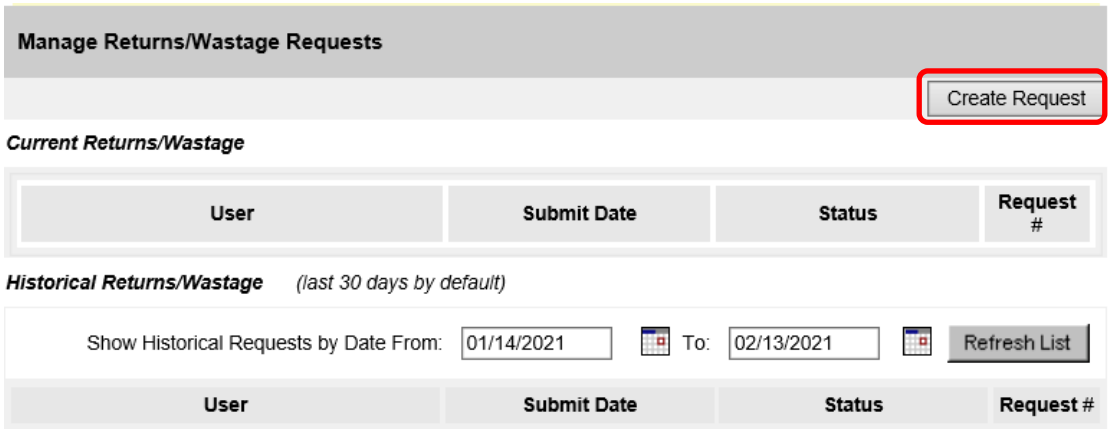

Figure 2

Step 3: The bottom portion of the **Create Returns/Wastage** screen, or the *Public Lots Available* section (Figure 3), displays a table to record the quantity of each lot of COVID-19 vaccine that is to be reported as wastage, along with the reason.

a. Identify the Lot that had wasted doses

b. Select a Wastage Reason. **Do not choose any reason listed under 'Returns', only use 'Wastage' reasons. See Appendix A for a list of NYSIS COVID-19 vaccine wastage reasons and definitions.**

- If you have more than one reason for a given lot, click Add Line (will add same vaccine information below). Two duplicate lots cannot be listed with the same Returns/Wastage Reasons for both.

c. Enter the number of wasted doses in the "Quantity" box. You cannot enter a quantity that exceeds the number of Doses on Hand.

Note: This area displays all of your public lots with a quantity > zero in order of expiration date. This includes expired, not expired, active and inactive public lots. Lots that are listed in red have been expired >6 months.

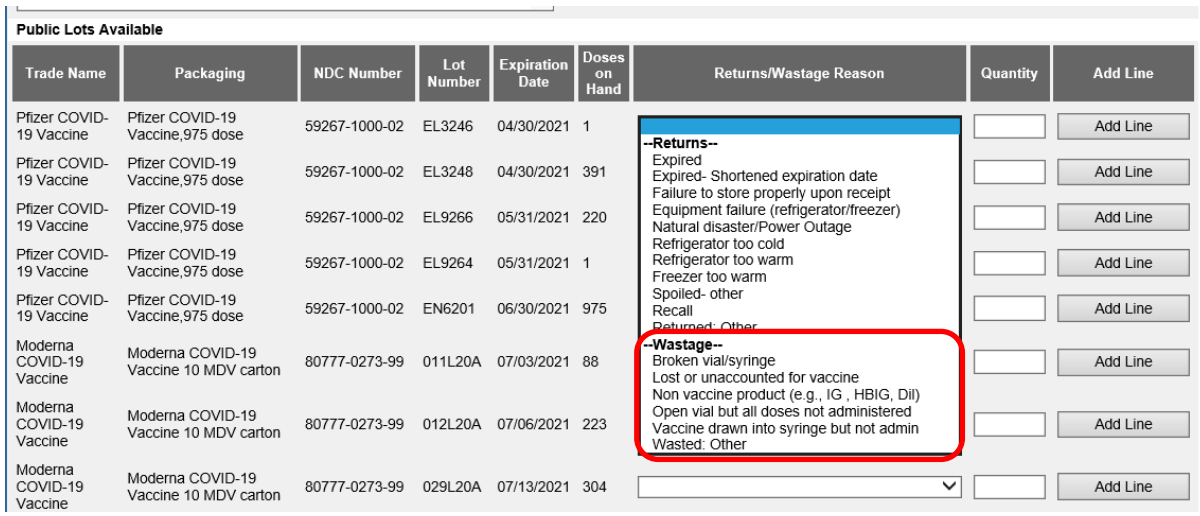

Figure 3

d. Enter a Request Note to describe the waste being reported. This is **required** if you have selected "Wasted: Other." (Figure 4)

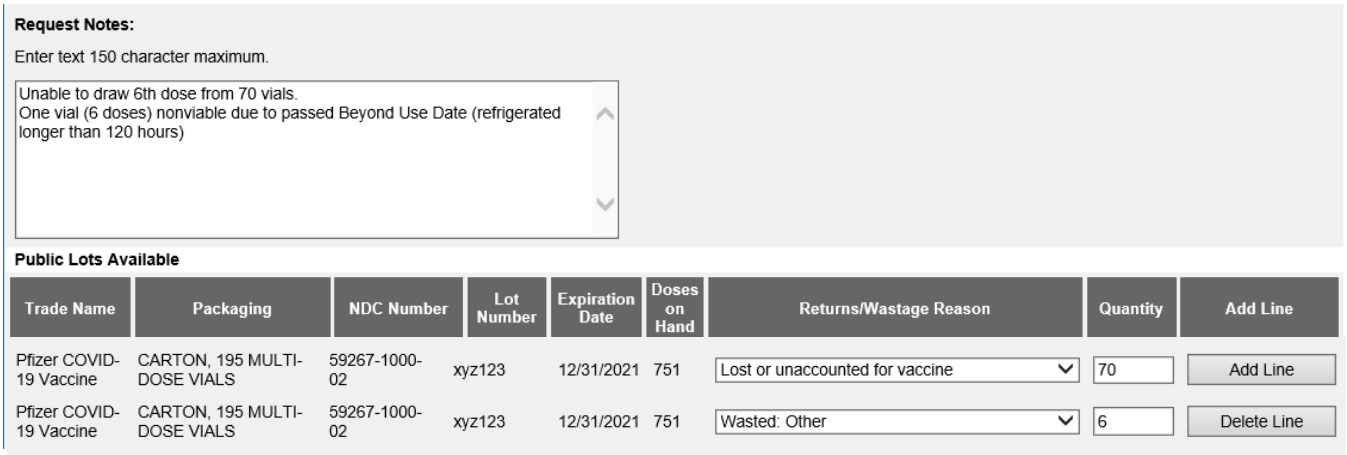

Figure 4

Step 4: Once all daily waste has been entered through selecting *Reason*, entering *Quantity,* and adding a *Request Note,* click on **Save and Submit**. Note: if you click Save, the request is not yet submitted. You must submit for the request to be processed to update your inventory.

a. A dialog box will appear which asks "Are you sure you want to submit list?"

Step 5: Confirm the information then click on ***OK*** to proceed (Figure 5).

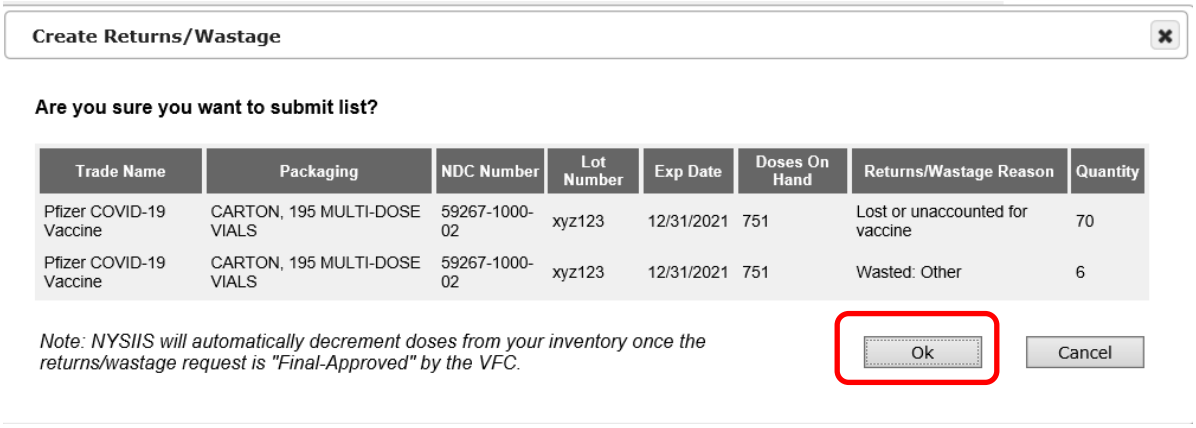

Figure 5

IMPORTANT: DO NOT ATTEMPT TO GO INTO YOUR PUBLIC INVENTORY AND MAKE MODIFICATIONS TO LOT QUANTITIES THAT WERE IMPACTED BY RETURNS/WASTAGE REQUESTS. **When your request reaches a "Final-Approved" status, your inventory will decrement automatically**.

Step 6: After the request has been submitted, you will be automatically redirected back to the *Manage Returns/Wastage Requests* screen (Figure 6).

a. Your request will display in the *Current Returns/Wastage* section with a *Pending* status*. The request has been submitted to the NYS Vaccine Program.

b. Once the Vaccine Program opens your request, the status will change to *Under View by VFC.* Vaccine Program reviews requests each morning Monday-Friday.

c. When the request is approved you will see a status of *Final-Approved*. **This is when the quantity deducts from your inventory.**

d. If the Vaccine Program need the provider to modify the request (such as incorrect reason selected, or insufficient information provided) the status will change to *Denied*. Vaccine Program will contact you with instructions.

*** See Appendix B for a description of all request Statuses**

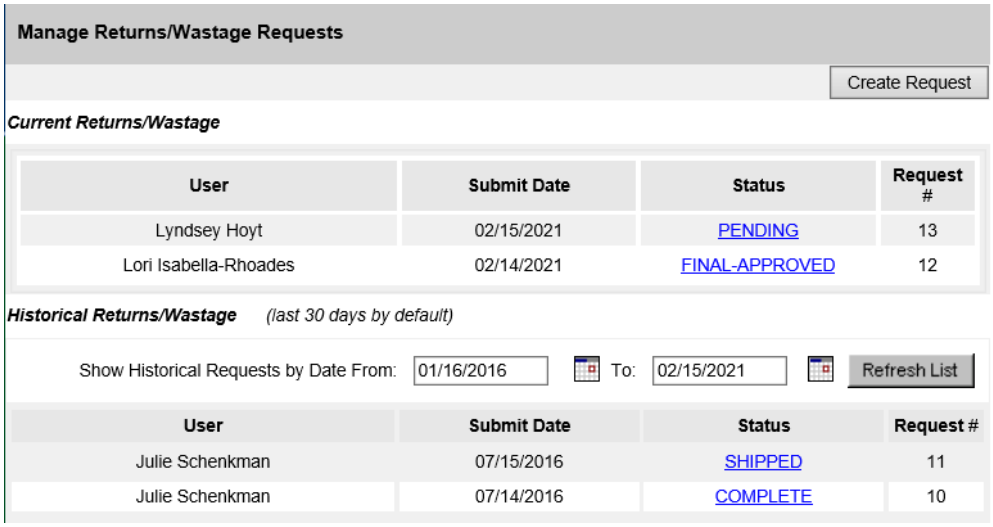

Figure 6

Appendix A

NYSIIS Wastage Reasons and Definitions

Reason	Definition/Example
Broken vial/syringe	**Vaccine vial or syringe that was damaged. Example: If an entire Pfizer 12+ vial is broken, report 6 doses wasted.** **Syringe dropped on floor.**
Lost or unaccounted for vaccine	**Unable to draw standard dose count from a vial. *Examples: If staff are only able to draw 5 doses from a 6-dose vial (not enough vaccine remaining for a full 6th dose), report 1 dose wasted. If staff are only able to draw 9 doses from a 10-dose vial, report 1 dose wasted.*** **Vaccine that was lost or unaccounted for (such as a shipping shortage).**
Open vial but all doses not administered	**An open multi-dose vial of vaccine, with doses remaining that passed the beyond use time (time limit after mixing or puncturing vial).**
Vaccine drawn into syringe but not administered	**Vaccine that was drawn into a syringe but was not administered.**
Wasted: Other	**Vaccine that became non-viable due to a temperature excursion (too cold or too warm).** **Vaccine that has passed the expiration date or the refrigerated beyond-use date (BUD).** **Vaccine that is contaminated (discolored, contains particulates, etc.)** **NOTE: If there is no example listed that covers the wastage reason, categorize as "Wasted - Other" and enter a Request Note with explanation for all wastage categorized as "Other".**

Appendix B
Returns/Wastage Requests: Statuses and Descriptions

Status	Description
Saved	**The request has been created by the provider and has been saved but not yet submitted. The request can still be modified or cancelled by the requesting provider organization. If not submitted, saved requests will automatically be cancelled 30 days after the create date and will display with a *Cancelled* status.**
Pending	**The request has been submitted by the provider organization and it will now appear in the Pending list for the NYS Vaccine Program. The request has not yet been viewed by the NYS Vaccine Program and can still be modified or cancelled by the requesting provider organization.**
Cancelled	**The request was cancelled by the requesting organization or was not opened and modified within 30 days of the save or deny date. Requests can be cancelled by the provider organization only during the *Saved* or *Pending* status. Once a request is cancelled, it can no longer be submitted, and is considered a historical request.**
Under review by VFC	**The request has been received and opened/viewed by the NYS Vaccine Program. This request can no longer be edited or cancelled by the provider organization. The NYS Vaccine Program can approve or deny the request in this status. ("VFC" in the status name refers broadly to the Vaccine Program, not just the Vaccines for Children Program.)**
Final-Approved	**The request has been reviewed and finalized by the NYS Vaccine Program and is ready to be included on an export file. This type of request can no longer be modified but is considered a non-historical or current request. Decrements from the provider's public inventory lots occur at this point.**
Denied	**The NYS Vaccine Program staff sent the request back for Provider to modify. The provider must then modify and save and submit the request to send it back to NYS Vaccine Program again and restart the approval cycle. If the provider does not re-open and make modifications to this request within 30 days of the date it was denied, the status will automatically change to *Cancelled.***
Completed	**This status will show when the request has been uploaded to CDC. Completed requests show in the historical Returns/Wastage area.**

Appendix C

COVID-19 Vaccine Wastage Tracking Sheet

Use this sheet to record wastage as it occurs. Provide completed sheets to designated individual to data enter into NYSIIS at the end of each day.

Vaccine Administration Site Name: _____ **PIN #:**_____

Name of Individual Reporting Wastage: _____ **Date:** _____

Wastage Reason	Definition/Example(s)
1 = Broken vial/syringe	Vaccine vial or syringe that was damaged. *Example: If an entire Pfizer 12+ vial is broken, report 6 doses wasted.* Syringe dropped on floor.
2 = Lost or unaccounted for vaccine	Unable to draw all doses that need to be accounted for from a vial. *Examples: If staff are only able to draw 5 doses from a 6-dose vial (not enough vaccine remaining for a full 6th dose), report 1 dose wasted. If staff are only able to draw 9 doses from a 10-dose vial, report 1 dose wasted.* Vaccine that was lost or unaccounted for (such as a shipping shortage).
3 = Open vial but not all doses administered	An open multi-dose vial of vaccine, with doses remaining that passed the beyond use time (time limit after mixing or puncturing vial).
4 = Vaccine drawn into syringe but not administered	Vaccine that was drawn into a syringe but was not administered.
5 = Wasted: Other	Vaccine that became non-viable due to a temperature excursion (too cold or too warm). Vaccine that has passed the refrigerated beyond use date or expiration date. Vaccine that is contaminated (discolored, contains particulates, etc.) NOTE: If there is no example listed that covers the wastage reason, categorize as "Wasted: Other" Enter a note of explanation for all wastage categorized as “Other”.

Manufacturer	Lot Number	Wastage Reason #	Quantity (Doses)	If wastage reason is #5 “Other” briefly explain: