Phase 3 Efficacy Trial: Participants Are Currently Enrolled Across More than 150 Sites in 6 Countries

Primary Efficacy Objectives	Endpoints
Efficacy against confirmed COVID-19 in participants without evidence of infection before vaccination	COVID-19 incidence based on confirmed NAAT in participants with no serological or virological evidence of past SARS-CoV-2 infection
Efficacy against confirmed COVID-19 in participants with and without evidence of infection before vaccination	COVID-19 incidence based on confirmed NAAT*

Enrollment On Track

43,538 participants

enrolled and

38,955 participants

have received their second vaccination

*NAAT: Nucleic acid amplification tests

Clinical Sites Across The Globe

US | Brazil | Argentina | Germany | Turkey | South Africa

Highlights of Study Population

	%US	%Global
Black or African American	10%	10%
Hispanic	13%	26%
Native American/Alaska Native	1%	0.8%
Asian	6 %	5 %
Total Diverse Enrollment	**30%**	**~42%**
Enrollment Age 56-85	**45%**	**41%**

Data as of October 12, 2020

Breakthroughs that

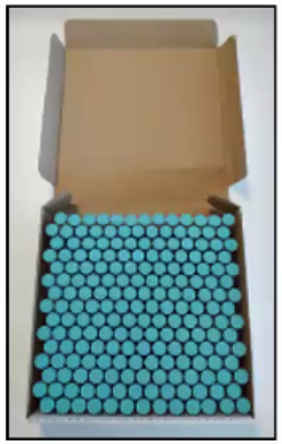
Storage, Handling and Administration

Product Packaging Overview

1 Primary Packaging

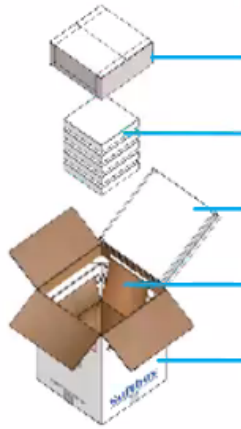
- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

2 Secondary Packaging "Single Tray"



- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

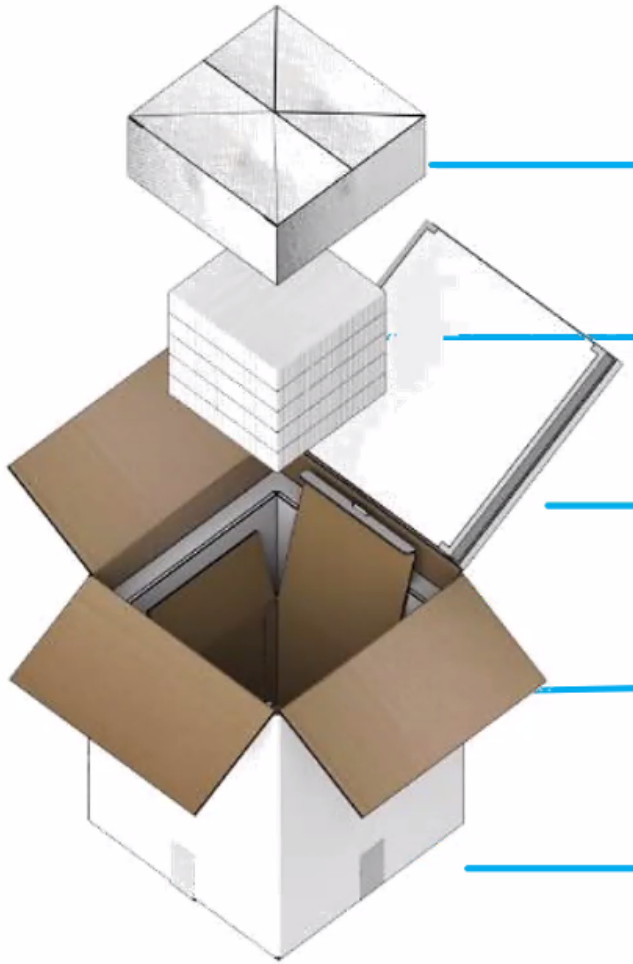
3 Tertiary Container: Thermal Shipper



Item	Description
1	Dry Ice Pod
2	Vial Trays
3	Inner Lid
4	Payload box (holds vial trays)
5	Outer Carton

- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT (-75±15°C) up to 10 days if stored at 15°C to 25°C temperatures without opening.
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice

Ultra Low Temperature Thermal Shipper – Overview of Pack Out



ITEM	DESCRIPTION
1	DRY ICE POD
2	VIAL TRAYS
3	INNER LID
4	PAYLOAD BOX (Holds vial trays)
5	OUTER CARTON

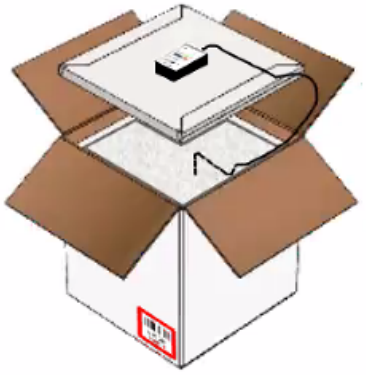
Weights and Dimensions	
Tare Weight (Inc. Dry-Ice)	8.5kg (31.5kg)
Volumetric Weight	15.0kg
Payload Space L x W x H	245x245x241mm
Shipper Dimensions L x W x H	400x400x560mm

Overview of Direct Shipments to Points of Vaccination

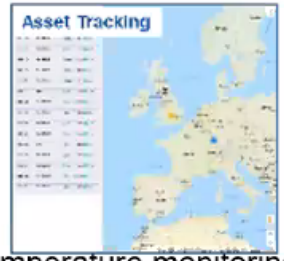
Direct Shipments* to Vaccination Center by Transport Courier

- Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

Temperature & Location Tracking During Transportation



Controlant Reusable RTM Logger



- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipment will be provided within 3 hours of pushing the STOP button of the data logger

*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the governments.
Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution

ULT Shipper – Unpacking and Re-Use General Schematics

Receipt of ULT Thermal Shipper at Point of Vaccination

- Upon receipt, GPS enabled logger should be disabled by pressing the stop button on the device.
- Upon receipt, product shipments should be visually inspected to ensure all ordered quantities were received, and in good standing (no broken vials). Inspection of product must be done in < 10 minutes to prevent premature thawing
- Issues with the shipment should be immediately communicated to Pfizer Customer Service per agreed upon terms.

If ULT Freezer Available; Transfer Trays to ULT Freezer

- Remove Dry Ice Pod from shipper.
- Take out Vial Tray(s) from Payload Box and transfer to ULT Freezer.
- Transfer of product from the thermal shipper must be done in less than 10 minutes to prevent premature product thawing.

If Thermal Shipper is Used for Temporary Storage; Replenish Dry Ice in Thermal Shipper in 24 hours of Delivery

- Dispense Dry Ice Pellets into shipper per re-icing instructions provided.
- Close the lid and ensure that the box is sealed appropriately.
- Add additional dry ice every five days accordingly.

Vaccine Storage Options* At the Point of Vaccination

1 Ultra-Low Temperature Freezer

- Emergency Use vials are labeled as -70°C±10°C,
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

2 Thermal Shipper Designed for Temporary Storage

- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Multiple dry ice replenishments possible; up to 3 re-icings.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper to be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice monitor

3 2 to 8°C Refrigerator

- Can be stored at 2 to 8°C up to 5 days
- Room temperature hold time is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

Pfizer BioNTech COVID-19 Vaccine: Dosing and Schedule General Overview - Draft- Subject to regulatory approval

- Pfizer BioNTech COVID-19 Vaccine, suspension for intramuscular injection, is provided as a preservative free Multi Dose Vial
  - The vial contains a fill volume of 0.45 mL, at a concentration of 0.5 mg/mL
- Pfizer BioNTech COVID-19 Vaccine must be diluted with 0.9% Sodium Chloride Injection (Normal Saline) before use
- After dilution with 1.8 mL of Normal Saline, the vial contains sufficient volume to deliver Five (5) 30 mcg doses in 0.3 mL injections
  - After dilution, the concentration is 0.1 mg/mL
- Schedule: Two 30 mcg doses; given 21 days apart

Vaccine Preparation and Administration

Point Of Use (POU)

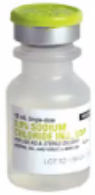
Removing the Vials to Thaw

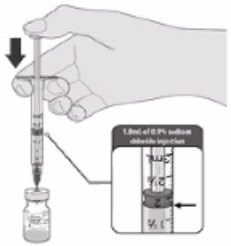
From storage, **remove 1 vial for every 5 recipients** according to planned vaccinations schedule.

Vials may be stored in the refrigerator for 5 days (120 hours).

Dilute the Vaccine

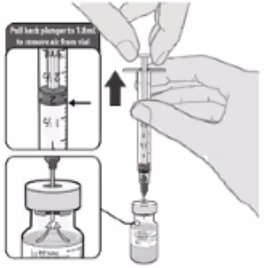
Obtain 0.9% Sodium Chloride Injection, USP for use as a diluent
Do not use any alternate diluents.



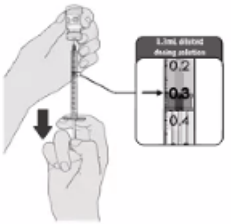


Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.

Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.



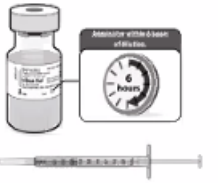
Preparing the Dose



Draw up 0.3 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection.

For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.

Vaccine Administration



Pfizer BioNTech COVID-19 Vaccine 30 mcg/0.3 mL

Diluted vials must be used within 6 hours from the time of dilution and stored between 2°C to 25°C (35°F to 77°F).

A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.

21 DAYS

Removing the Vials to Thaw

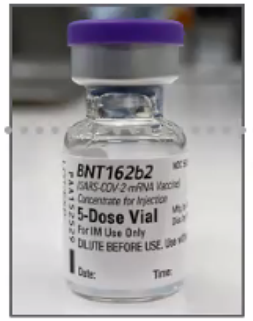
- When removing a tray from the thermal shipper, minimize the time the shipper is open (≤3 minute)
- If less than a full tray is needed, remove the number of vials needed from the tray as quickly as possible and return the tray to frozen storage. Trays should not be exposed to room temperature for more than a few minutes, as the vials can thaw very quickly
  - Vials should be transferred into a **secondary container** for safe transportation
  - Gloves allowing manual dexterity should be worn while handling frozen vials
- Transfer the frozen vials immediately to a refrigerator (2 to 8 °C)
  - An entire tray will take about 3 hours to thaw; a smaller number of vials may thaw more quickly
  - Vials needed for immediate can be thawed at room temperature (30 minutes)
  - Vials thawed at room temperature form condensation on the outside of the vial, so thawing in a **secondary container** is recommended
- Vials may be stored in the refrigerator prior to dilution for **up to 5 days** (120 hours)
- Vials may be held at room temperature for no more than 2 hours prior to dilution

Covid Vx Preparation Instructions

Point Of Use (POU)

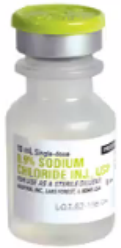
Supplies Required to Prepare:

Supplies provided by BNT/PFE



- 1 Vial Pfizer BioNTech COVID-19 Vaccine

Supplies needed by Clinic per Vial



- 1 Vial 0.9% Sodium Chloride Injection (at least 2 mL)
- 1 diluent syringe/needle (3 mL or 5mL syringe/21 G needle recommended)

- 5 dosing syringes/needles (1 mL syringe/ IM injection needle)
- Other ancillary materials such as alcohol swabs, gloves, PPE

Pfizer BioNTech COVID-19 Vaccine: Diluent Specifications

- Each thawed vial should be diluted with **1.8 mL of 0.9% Sodium Chloride Injection, USP**.
  - Bacteriostatic saline or other diluents must not be used
- Optimal diluent vial is **2 mL** (0.9% Sodium Chloride Injection, USP), however depending on the manufacturer stock availability, larger size diluent vials can be used.

- **IMPORTANT:** Regardless of the volume of the diluent vial, it must be use for ONE TIME dilution (after 1.8 mL withdrawal, the remaining diluent must be discarded)

- Diluent vial can be plastic or glass
- 2 mL saline vial is preferred to reduce diluent wastage, risk of over-dilution, and infection risk associated with excess diluent reuse.
- For US Markets – USG has purchased 2 mL vials of 0.9% Sodium Chloride, USP, which will be distributed in coordination with the US Government

Pfizer BioNTech COVID-19 Vaccine : Syringe & Needle Specifications

FOR DILUENT WITHDRAWAL & MIXING WITH PFIZER BioNTech COVID-19 VACCINE

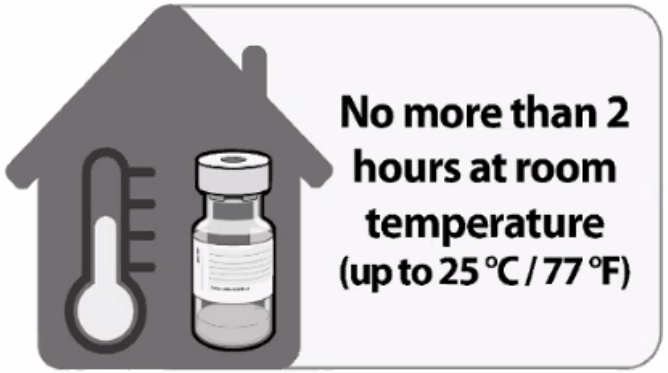
- ONE 3 ml syringe (optimal size) or 5 ml syringe to pull up 1.8 mL of 0.9% Sodium Chloride Injection, USP from each diluent vial
- ONE 21 gauge or narrower needle should be used to withdraw the diluent

FOR VACCINE ADMINISTRATION (intramuscular injection)

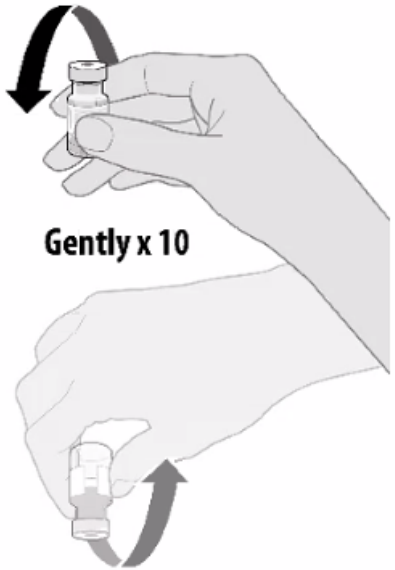
- FIVE, 1 ml syringes for each vaccine vial
  - ➢ 1 syringe for each 0.3 mL dose/patient
- FIVE 23- or 25-gauge needles for intramuscular injection for each vaccine vial
  - Needle Lengths appropriate for varied body sizes – 5/8”, 1”, 1 ½”

For US Markets – Ancillary supplies (syringes, needles, swabs) have been purchased by the US Government which will be distributed in coordination with the US Government

COVID Vx Preparation Instructions (Dilution Steps) – Draft- Subject to Regulatory Approval



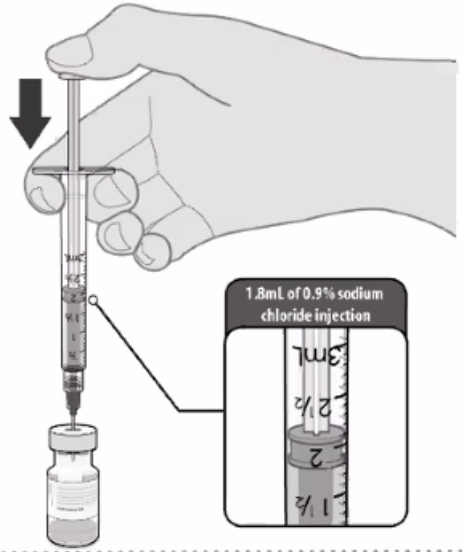
- Remove a thawed vial of Pfizer-BioNTech COVID-19 Vaccine from the refrigerator and allow it to come to room temperature.
- If using a frozen vial of Pfizer-BioNTech COVID-19 Vaccine, thaw for 30 minutes at room temperature.
- Vials at room temperature must be diluted within 2 hours.



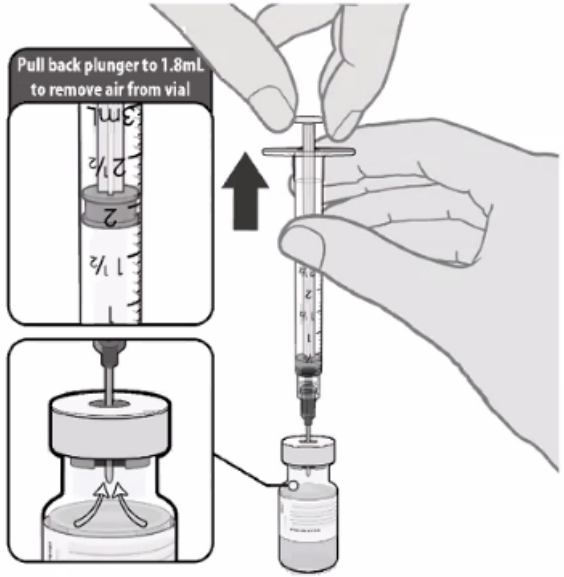
- Invert gently 10 times to mix.
- Do not shake.

Please see slide 2 for important limitations with respect to this presentation.

Covid Vx Preparation Instructions (Dilution Steps)

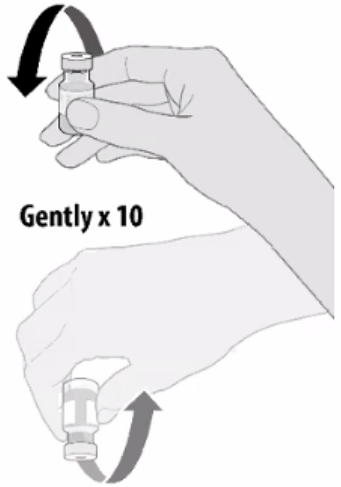


- Obtain sterile 0.9% Sodium Chloride Injection, USP
- Cleanse the vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the Pfizer-BioNTech COVID-19 Vaccine vial using a needle 21-gauge or narrower.

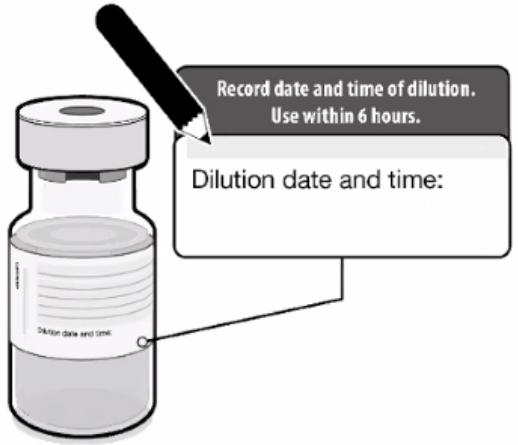


- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe

Covid Vx Preparation Instructions (Dilution Steps)

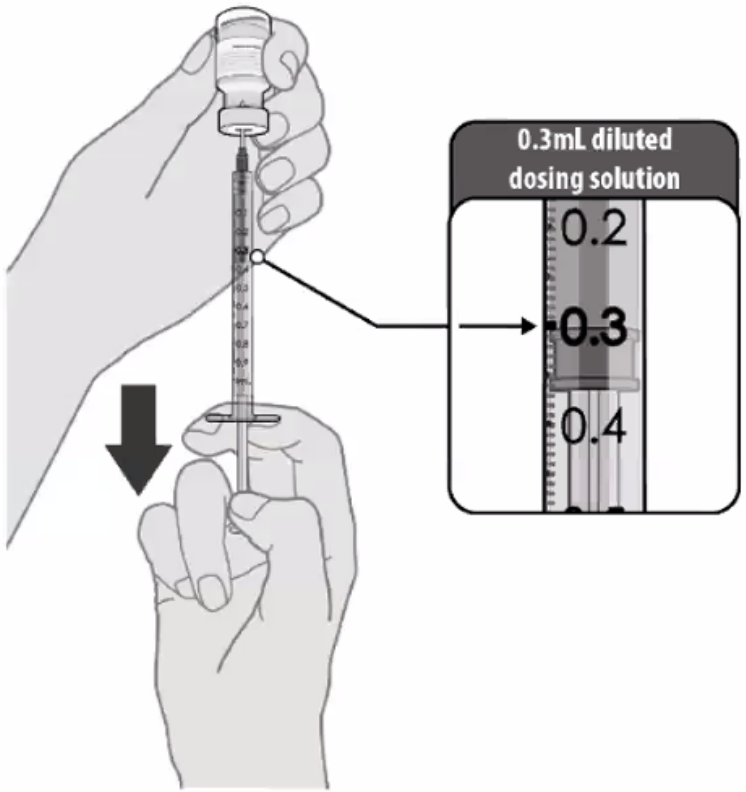


- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.



- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 6 hours after dilution.

Covid Vx Preparation Instructions (Preparing the Dose)



- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer BioNTech COVID-19 Vaccine.
- Administer immediately.

Please see slide 2 for important limitations with respect to this presentation.