

#### PERSONAL AND CONTACT INFORMATION

Please fill out ALL the information below

First Name: Last Name:

#### **RISK LEVEL INFORMATION**

Are you responsible for caring/cleaning in areas with COVID Patients?

- □ Yes
- □ No

Are you responsible for performing tasks with high risk of aerosolization (intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR)?

- □ Yes
- 🗆 No

#### Are you responsible for handling decedents with COVID?

- □ Yes
- □ No

#### Are you planning to be responsible for administration of the Vaccine?

- □ Yes
- □ No

For Provider: If Recipient answers Yes to any of these questions, please enter Risk = High. If No to all question, please enter Risk = Low

#### What is the name of the organization you work/reside in?

#### What is the type of organization listed above? (Please Select One):

- Public Health Department
- □ Family or Internal Medicine
- Geriatric Medicine
- □ Hospital
- Pediatrician
- □ STD/HIV Services
- Urgent Care
- □ Long-Term Care Facility
- □ Family Planning
- □ Pediatrician
- □ Pharmacy
- □ Other Health Care Facility

- □ Home / Personal / Community
  - Aid
- Dentist
- □ Homeless or Crisis Care
- $\Box$  CHC / FQHC / RHC
- Group or Congregate Living
- □ Migrant or Refugee Services
- □ Mortician / Funeral Home
- □ Childcare / School / College
- □ Prison
- Emergency Services
- □ Government Agency

- □ Religious Organizations
- □ Tribal or Indian Health Services
- □ Retail / Grocery
- □ Food Processing,
  - Preparation, or Serving
- □ Transportation
- □ Manufacturing /
- Farming □ Construction
- □ Other



Do you work or reside in the organization listed above?

Work
Reside

□ Both

For Provider: If Work or Both chosen, please select Type = Employee. If Reside Chosen = Individual

Date of Birth:		
Email:		
I do not have an email/ I do not wish to	disclose this information	
Street:		
City:	County:	
State:	Zip Code:	
Home Phone:	Mobile Phone:	
Communication Preference:		
<ul><li>Email</li><li>SMS</li></ul>	<ul><li>Both</li><li>None</li></ul>	
Race:	Ethnicity:	Gender:
<ul> <li>American Indian or Alaska Native</li> <li>Asian</li> <li>Black or African American</li> <li>White</li> <li>Other</li> </ul>	<ul><li>Hispanic or Latino</li><li>Not Hispanic or Latino</li></ul>	<ul><li>Male</li><li>Female</li><li>Unknown</li></ul>
Are you an Essential Frontline Worker (Police, I	Food Processing, Teachers, etc.)?	
If yes, what is the name of your employer?		
Do you reside or work in a long-term care/assis	sted living facility?	
□ Yes		
🗆 No		

If yes, what is the name of the facility?\_\_\_\_\_



#### Are you a member of a state or federal recognized tribal nation?

□ Yes

🗆 No

If yes, what is the name of the community?\_\_

#### MEDICAL INFORMATION

Review the below list of conditions known to increase risk of severe illness to COVID-19:

- Asthma
- Cancer
- Cerebrovascular Disease
- Chronic Obstructive Pulmonary
   Disease
- Chronic Kidney Disease
- Cystic Fibrosis
- Hypertension or High Blood
   Pressure
- Type 1 Diabetes Mellitus
- Type 2 Diabetes

- Immunocompromised from solid organ transplant
- Immunocompromised state (weakened immune system)
- Liver Disease
- Neurologic conditions, such as Dementia
- Obesity

- Overweight (BMI > 25 kg/m2, but < 30 kg/m2)</li>
- Pregnancy
- Pulmonary Fibrosis (having damaged or scarred lung tissues)
- Sickle Cell Disease
- Smoker
- Thalassemia (a type of blood disorder)

#### How many conditions known to increase risk of severe illness from COVID-19 do you have?

- □ None
- □ 1
- □ 2 or more

#### CONSENT

□ I certify that I am: (a) at least 18 years of age (b) the parent or legal guardian of the minor patient; or (c) the legal guardian of the patient. Further, I hereby give my consent to the licensed healthcare provider administering the vaccine, as applicable (each an "applicable Provider"), to share my personal, demographic and health condition information in order to provide me with vaccination services for the COVID-19 vaccine. I understand that the health data shared within this questionnaire will be used to determine my eligibility for receiving the COVID-19 vaccination and further determine timing of when the vaccine will be made available to me.

#### **INFORMED CONSENT FOR COVID -19 VACCINATION**

#### 1. Consent

I agree to voluntarily receive the **PFIZER-BIONTECH COVID-19 VACCINE**.

I acknowledge that I have received and read the fact sheet regarding the vaccine, and that the risks and benefits of this treatment have been explained to me. I have been given the opportunity to ask questions regarding possible side effects and adverse outcomes.

I acknowledge that I have read this form in its entirety or it has been read to me, and I understand potential side effects and the risks and benefits of the vaccine. I accept the risks, rules, and regulations set forth. Knowing these and having had an opportunity to ask questions which have been answered to my satisfaction, I consent to being vaccinated.

#### 2. Inquiries

Any questions about the use of, potential side effects and the risks and benefits of **PFIZER-BIONTECH COVID-19 VACCINE** are welcome. If you have any doubts or questions, please ask us for further explanation.

#### **3.** Use of Medical Records

The information that is obtained while you are receiving the vaccine will be treated as privileged and confidential. It is not to be released or revealed to any person except your physician without your written consent unless authorized in accordance with state and/or federal law. The information obtained, however, may be used for statistical analysis or scientific purposes with your right to privacy retained.

Signature of Patient or Legal Representative

Print Name

Relationship to Patient

Signature of Witness

Date and Time

Date and Time

Print Name

Signature of Translator/Interpreter (if applicable)

Date and Time

Print Name

Authorization not valid beyond one year from date of signature.

Please provide a copy of the FAQ and/or fact sheet to the patient for the medication at issue.

## FACT SHEET FOR RECIPIENTS AND CAREGIVERS

#### EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see <u>www.cvdvaccine.com</u>.

## WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE?

#### WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, 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.

#### WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

## WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

## WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

## WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

## WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

## HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

## HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

## WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

## WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

#### WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <u>https://vaers.hhs.gov/reportevent.html</u>. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

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

#### WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

# ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

# CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

## WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

## WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?

No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

#### **KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

## ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

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

#### HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <a href="https://www.cdc.gov/coronavirus/2019-ncov/index.html">https://www.cdc.gov/coronavirus/2019-ncov/index.html</a>.
- Visit FDA at <u>https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization</u>.
- Contact your local or state public health department.

## WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: <u>https://www.cdc.gov/vaccines/programs/iis/about.html.</u>

## WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

## WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



Manufactured by Pfizer Inc., New York, NY 10017

# BIONTECH

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

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

# Get vaccinated. Get your smartphone. Get started with v-safe.

# What is v-safe?

*V-safe* is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through *v-safe*, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And *v-safe* will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's *v-safe* makes a difference – it helps keep COVID-19 vaccines safe.

# How can I participate?

Once you get a COVID-19 vaccine, you can enroll in *v-safe* using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from *v-safe* around 2pm local time. To opt out, simply text "STOP" when *v-safe* sends you a text message. You can also start *v-safe* again by texting "START."

# How long do v-safe check-ins last?

During the first week after you get your vaccine, *v-safe* will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions *v-safe* asks should take less than 5 minutes to answer. If you need a second dose of vaccine, *v-safe* will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

# Is my health information safe?

Yes. Your personal information in *v-safe* is protected so that it stays confidential and private.\*



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at

vsafe.cdc.gov

OR

Aim your smartphone's camera at this code



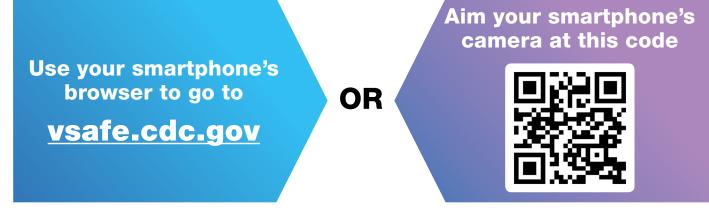
<sup>\*</sup>To the extent *v-safe* uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

# How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

# Register

1. Go to the *v-safe* website using one of the two options below:



- 2. Read the instructions. Click Get Started.
- 3. Enter your name, mobile number, and other requested information. Click Register.
- You will receive a text message with a verification code on your smartphone. Enter the code in *v-safe* and click Verify.
- 5. At the top of the screen, click Enter your COVID-19 vaccine information.
- Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click Next.
- 7. Review your vaccine information. If correct, click Submit. If not, click Go Back.
- 8. Congrats! You're all set! If you complete your registration before 2pm local time, v-safe will start your initial health check-in around 2pm that day. If you register after 2pm, v-safe will start your initial health check-in immediately after you register just follow the instructions.

You will receive a reminder text message from *v-safe* when it's time for the next check-in – around 2pm local time. Just click the link in the text message to start the check-in.

# Complete a v-safe health check-in

- 1. When you receive a *v-safe* check-in text message on your smartphone, click the link when ready.
- 2. Follow the instructions to complete the check-in.

# Troubleshooting

# How can I come back and finish a check-in later if I'm interrupted?

 Click the link in the text message reminder to restart and complete your check-in.

# How do I update my vaccine information after my second COVID-19 vaccine dose?

 V-safe will automatically ask you to update your second dose information. Just follow the instructions.

#### Need help with v-safe?

Call 800-CDC-INFO (800-232-4636) TTY 888-232-6348 Open 24 hours, 7 days a week Visit www.cdc.gov/vsafe

