

Lot Number ___

_ Brand_







Left Deltoid ☐ Right Deltoid ☐ MCIR ☐ BILLED ☐

COVID-19 VACCINE CONSENT FORM AND PREVACCINATION CHECKLIST

| _ast Name: | | | | | |
|--|--|----------------------------------|------------|---------------|------------|
| Address: | | | | - | |
| Phone: | | | _ | | |
| Physician: | Last 4 numbers of So | ocial Security numb | er | | |
| Race: WhiteAfrican AmericanAsian | Hispanic/Latino Native Hawaiian/Oth | ner Pacific Islander _ | _America | n Indian/Ala | ska Native |
| Not all individuals requesting a vaccine can safel should not get the Covid vaccine today. Answer | | | uld not b | oe vaccinat | ed: |
| 1 Are you feeling sick today? | | | Yes | No | Unsure |
| Are you feeling sick today? Have you ever received a dose of COV | /ID-19 vaccine? | | | | |
| If yes, which vaccine product did you r ☐ Pfizer ☐ Moderna ☐ Jannse | eceive? en (Johnson & Johnson) | luct | | | |
| 3. Have you ever had an allergic reaction | | | | | |
| (This would include a severe allergic reaction or EpiPen® or that caused you to go to the occurred within 4 hours that caused hives, | hospital. It would also include an allergic r | reaction that | | | |
| | e, including polyethylene glycol (PEG), which | | | | |
| Polysorbate | | | | | |
| A previous dose of COVID-19 vaccine Have you ever had an allergic reaction | to another vaccine (other than COVID-19 | vaccina) or an | | | |
| injectable medication? (This would include a severe allergic reepinephrine or EpiPen® or that caused | eaction (e.g. anaphylaxis) that required tread you to go to the hospital. It would also income caused hives, swelling, or respiratory di | atment with clude an allergic | | | |
| Have you ever had a severe allergic re component of COVID-19 vaccine, poly include food, pet, environmental, or or | | | | | |
| 6. Have you received any vaccine in the | | | | | |
| 19? | COVID-19 or has a doctor ever told you that | • | | | |
| treatment for COVID-19? | therapy (monoclonal antibodies or convale | · | | | |
| do you take immunosuppressive drugs | | ection or cancer or | | | |
| 10. Do you have a bleeding disorder or are | e you taking a blood thinner? | | | | |
| 11. Are you pregnant or breastfeeding?12. Do you have dermal fillers? | | | | | |
| Having received an explanation and informed cons and representatives harmless from further respons have received and read the EUA Patient Information and Info | sibility with regard to my receiving the injection Sheet (dated) I understand | ons. I the benefits and risks | | | _ |
| | · | | | | |
| Signature: Patient or Autho | rized Representative | | Di | ate | |
| I request that this provider be paid authorized Medany holder of medical or other information about metermine these benefits for related services. I ur coverage is not appropriate. | ne to release to the Health Care Financing Admir | nistration and its agents | any inform | nation needed | d to |
| Medicare Number(For all Private Insurance Companies pl | Medicaid Pri lease include copy of front and back of insurance | vate e card) | | | |
| Policy Number (including alpha characters) | Group Numb | per | _ | | |
| Patient or Authorized Rep Signature | Payment to Patient | √Payment to Provide | r | | |
| For Pharmacy Use: mmunizer Signature | Date | | | | |

_ IM Administration Site:



Prevaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals



For additional information on COVID-19 vaccine clinical guidance, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

For additional information on Advisory Committee on Immunization Practices *General Best Practice Guidelines for Immunization*, see https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Three COVID-19 vaccines are currently authorized for use in the United States. These vaccines are authorized for use among different age groups.

| PRODUCT | AUTHORIZED AGE GROUPS |
|--|---------------------------|
| Pfizer-BioNTech COVID-19 Vaccine | 16 years of age and older |
| Moderna COVID-19 Vaccine | 18 years of age and older |
| Janssen COVID-19 Vaccine (Johnson & Johnson) | 18 years of age and older |

Anyone outside the authorized age groups for a product should not receive the vaccine.

Postvaccination Observation Times for Persons without Contraindications to COVID-19 Vaccination

- 30 minutes: History of an immediate allergic reaction of any severity to a vaccine or injectable therapy. People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination). History of anaphylaxis due to any cause
- 15 minutes: All other persons

Are you feeling sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. **Mild illnesses are NOT contraindications to vaccination.** Do not withhold vaccination if a person is taking antibiotics.

Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.

Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccines are not interchangeable. COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose.

For two-dose products, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses. If the vaccine product used for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered. Separate doses by at least 28 days. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

| Vaccine | NUMBER OF DOSES/SERIES | INTERVAL BETWEEN DOSES |
|----------------------------------|------------------------|------------------------|
| Pfizer-BioNTech COVID-19 Vaccine | 2 | 21 days |
| Moderna COVID-19 Vaccine | 2 | 28 days |
| Janssen COVID-19 Vaccine | 1 | N/A |

^{*}The second dose should be administered as close to the recommended interval as possible. If this is not possible, the second dose of mRNA COVID-19 vaccine may be scheduled for administration up to 6 weeks (42 days) after the first dose.

03/05/2021 CS321629-E

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 www.cvdvaccine.com.

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.

1

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.

2

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)
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- severe allergic reactions

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. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. 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.

3

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 https://vaers.hhs.gov/reportevent.html. 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 |

You may also be given an option to enroll 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 on how to sign up, visit: www.cdc.gov/vsafe.

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. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

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.

4

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 https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- 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: https://www.cdc.gov/vaccines/programs/iis/about.html.

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

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

LAB-1451-2.4

Revised: 25 February 2021



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

Barcode Date: 12/2020

What to Expect after Getting a COVID-19 Vaccine

Accessible version: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

Common side effects

On the arm where you got the shot:

- Pain
- Swelling

Throughout the rest of your body:

- Fever
- Tiredness
- Chills
- Headache

Helpful tips

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot: To reduce discomfort from fever:

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

• Drink plenty of fluids.

• Dress lightly.

When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days



Ask your healthcare provider about getting started with v-safe

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 dose

Learn more about **v-safe**. www.cdc.gov/vsafe

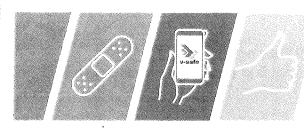
Remember

- Side effects may feel like flu and even affect your ability to do daily activities, but they should go away in a few days.
- With most COVID-19 vaccines, you will need 2 shots in order for them to work. Get the second shot even if you have side effects after the first one, unless a vaccination provider or your doctor tells you not to get a second shot.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until a week or two after your second shot.
- It's important for everyone to continue using all the tools available to help stop this pandemic as we learn more about how COVID-19 vaccines work in real-world conditions. Cover your mouth and nose with a mask when around others, stay at least 6 feet away from others, avoid crowds, and wash your hands often.

| HEALTHCARE PROVIDER, PLEASE FILL IN THE INFORMATION BELOW: |
|--|
| If your temperature is°F or°C or higher or if you have questions, call your healthcare provider. |
| Tell your healthcare provider about: |
| Healthcare provider phone number: |
| Medication (if needed): Take every hours as needed. |
| (type and dose or amount) |



cdc.gov/coronavirus



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?

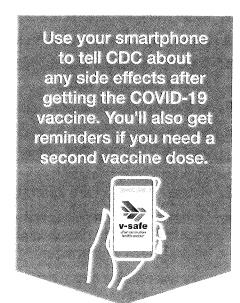
During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **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.*

*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.





Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

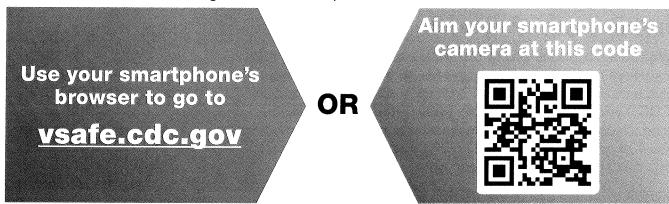


How to register and use v-safe

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.
- 4. 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.
- 6. 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

