

FIRST CARE CLINIC

MODERNA COVID-19 VACCINE CONSENT/DOCUMENTATION FORM

Patient Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Age: \_\_\_\_\_

You are being offered the MODERNA COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. The MODERNA COVID-19 Vaccine may prevent you from getting COVID-19.

The MODERNA COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle. The MODERNA COVID-19 Vaccine may not protect everyone.

The following questions will help us determine if you may receive the MODERNA COVID-19 vaccine. Please mark YES or NO for each question.

- 1) Have you ever had an allergic reaction to a vaccine? YES NO
- 2) Do you have a fever? YES NO
- 3) Do you have a bleeding disorder or are on a blood thinner? YES NO
- 4) Are you immunocompromised or are on a medicine that affects your immune system? YES NO
- 5) Are you pregnant or plan to become pregnant? YES NO
- 6) Are you breastfeeding? YES NO
- 7) Have you received another COVID-19 vaccine? YES NO

**YOU SHOULD NOT GET THE MODERNA 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

There is a remote chance that the MODERNA 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 MODERNA COVID-19 Vaccine. For this reason, **you are required to stay at the clinic for 15 minutes post vaccination for monitoring** (30 minutes if history of anaphylaxis) as per CDC vaccination guidelines.

Consent for the MODERNA COVID-19 Vaccine, depending on the response to the above questionnaire: I have been given the FDA/CDC Vaccine Information Statement. I have read this document and have no further questions at this time. I understand the risks and benefits of the vaccine. I request and voluntarily consent that the vaccine be administered to me and I acknowledge that no guarantees have been made concerning the vaccine's success. I hold harmless The First Care Clinic and individuals administering the vaccine. I understand the side effects and warnings of the vaccine.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

FOR ADMINISTRATIVE USE ONLY

Date Administered \_\_\_\_\_ Site \_\_\_\_\_ Lot \_\_\_\_\_ Expiration Date \_\_\_\_\_

Vaccine Administrator \_\_\_\_\_

12/2020

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS**  
**EMERGENCY USE AUTHORIZATION (EUA) OF**  
**THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019**  
**(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER**

You are being offered the Moderna 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 Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna 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 Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

**WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE**

**WHAT IS COVID-19?**

COVID-19 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 MODERNA COVID-19 VACCINE?**

The Moderna 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 Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 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 MODERNA COVID-19 VACCINE?**

Tell your 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 MODERNA COVID-19 VACCINE?**

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

## **WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?**

You should not get the Moderna 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 MODERNA COVID-19 VACCINE?**

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

## **HOW IS THE MODERNA COVID-19 VACCINE GIVEN?**

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

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

## **HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?**

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

## **WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?**

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

## WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

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

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna 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 Moderna 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 Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna 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 <https://vaers.hhs.gov/reportevent.html>. Please include “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

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](http://www.cdc.gov/vsafe).

**WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?**

It is your choice to receive or not receive the Moderna 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 MODERNA COVID-19 VACCINE?**

Currently, there is no FDA-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 MODERNA COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Moderna 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 MODERNA COVID-19 VACCINE GIVE ME COVID-19?**

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


**KEEP YOUR VACCINATION CARD**

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna 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.

Moderna COVID-19 Vaccine website	Telephone number
<a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a> 	1-866-MODERNA (1-866-663-3762)

**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 state or local 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/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

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

The United States FDA has made the Moderna 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.

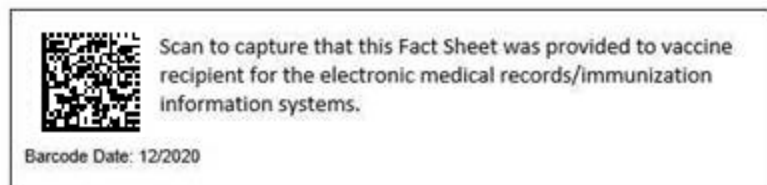
The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the 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 during the COVID-19 pandemic.

The EUA for the Moderna 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).

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Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)

Revised: 12/2020



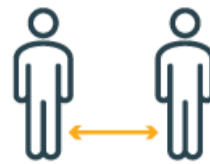
# COVID-19 (Coronavirus Disease)

MENU >

CASES ARE RISING.  
**ACT NOW!**



WEAR A MASK



STAY 6 FEET APART



AVOID CROWDS

## V-safe After Vaccination Health Checker

Updated Dec. 19, 2020



Get vaccinated.  
Get your smartphone.  
Get 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 vaccine dose.

**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 get more information. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

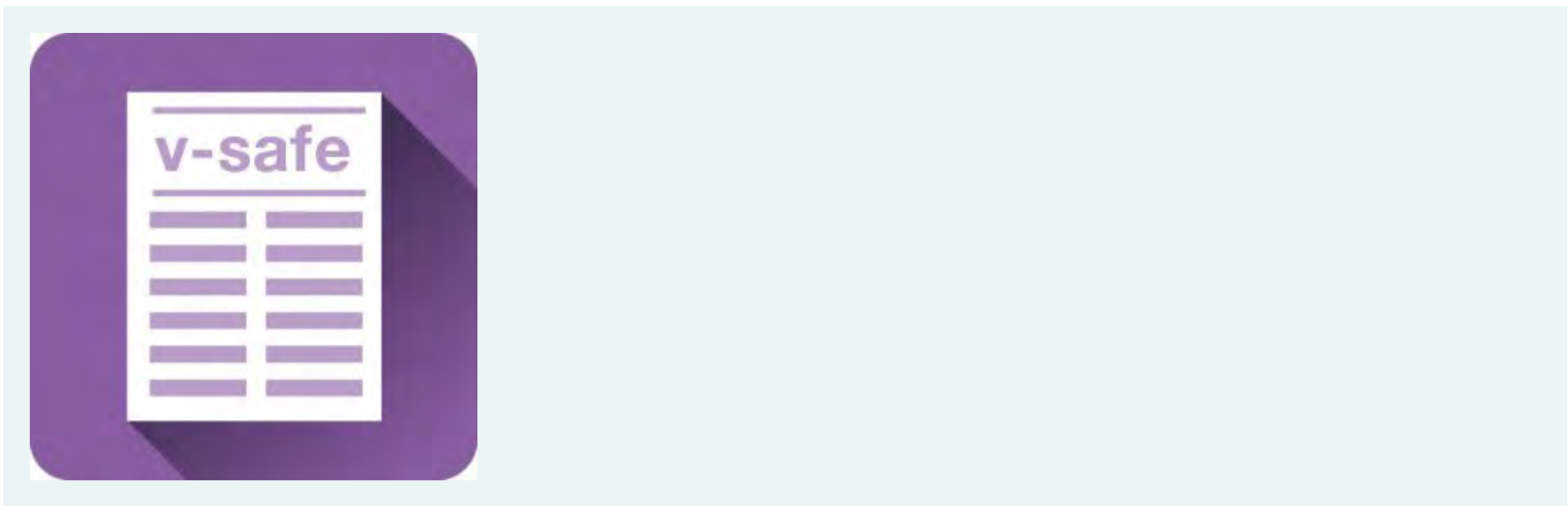
### Other v-safe Resources

[Troubleshooting](#) >

[Frequently Asked Questions about v-safe](#) >

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

When you get a COVID-19 vaccine, your healthcare provider will give you a **v-safe** information sheet. This sheet provides instructions on how to register and use **v-safe**.



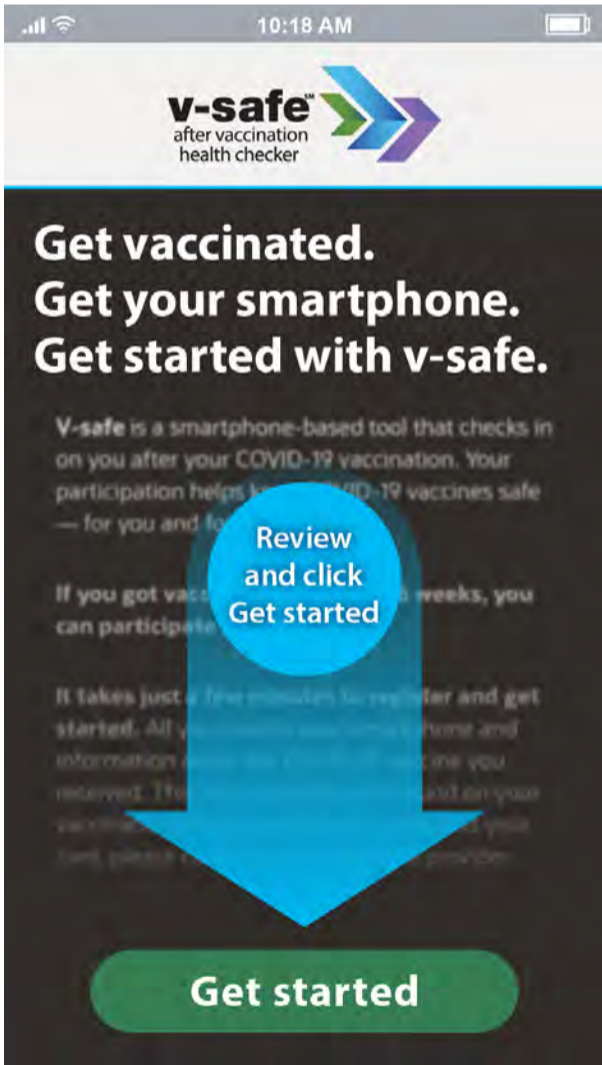
# How to register and use v-safe

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



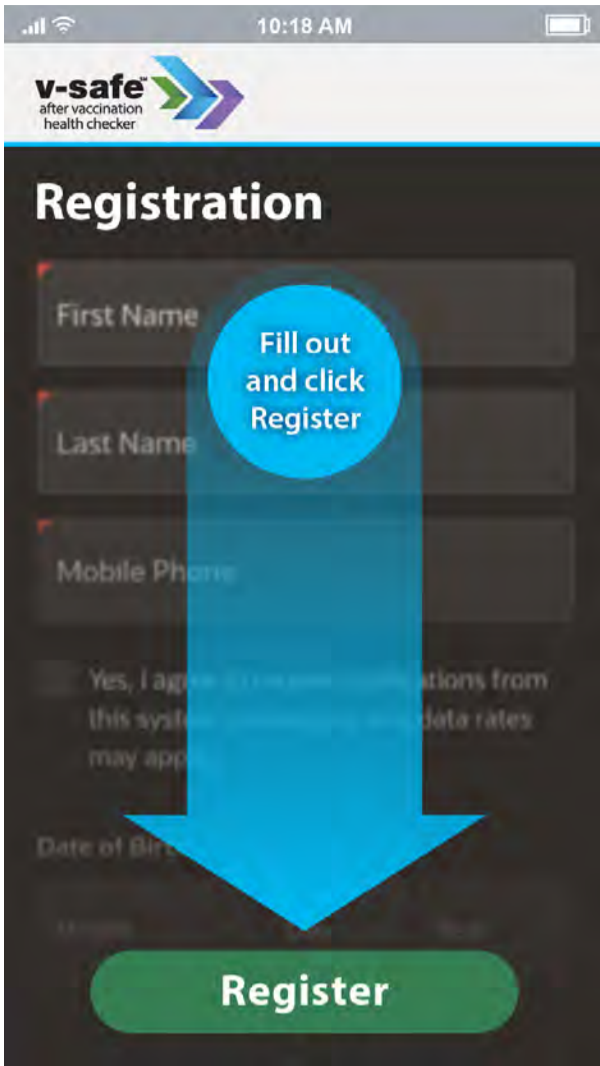
## Register

1. Go to the **v-safe** website (link provided on the **v-safe** information sheet your healthcare provider gave you during your COVID-19 vaccination). Read the onscreen instructions and click **Get Started**.

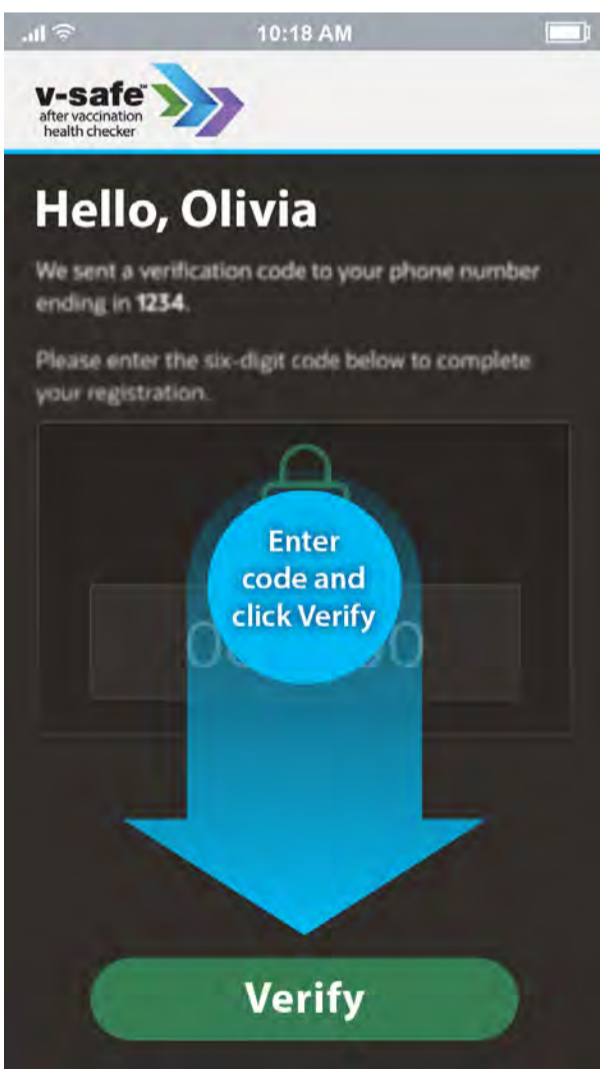




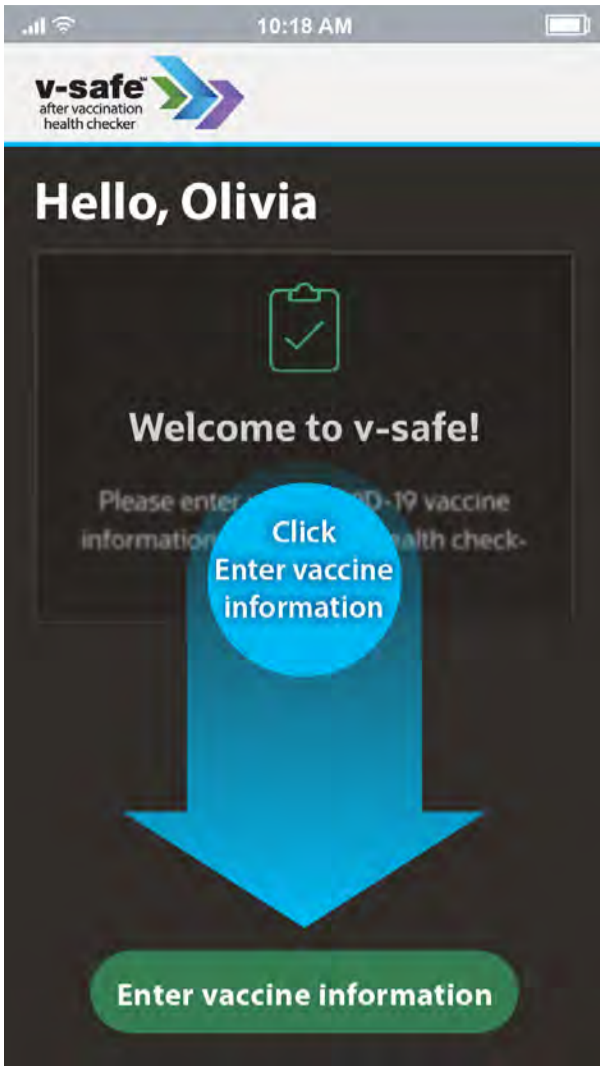
2. Enter your name, mobile number, and other requested information. Click **Register**.



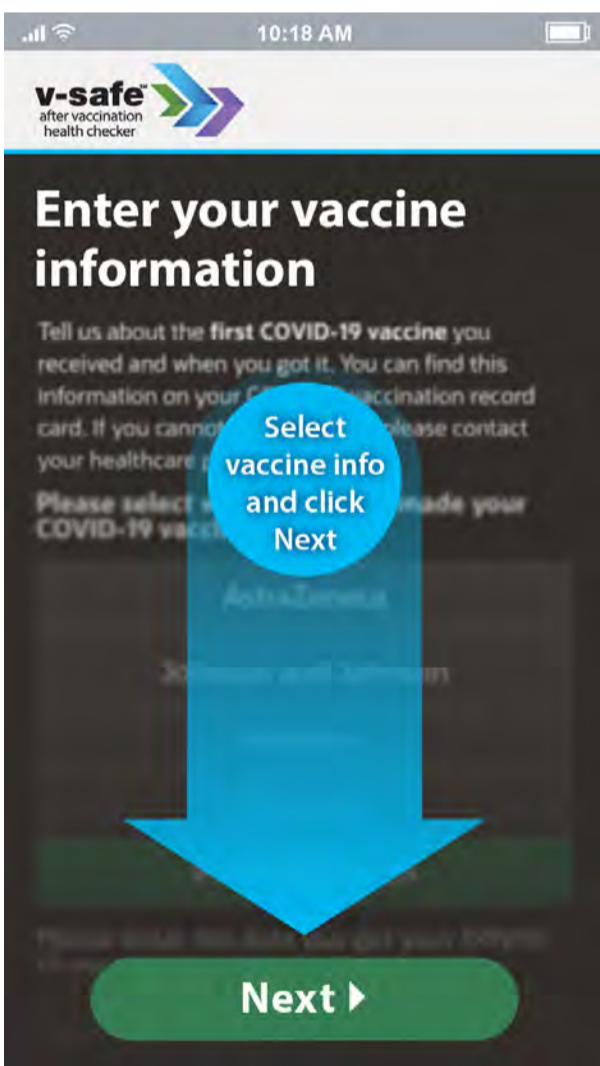
3. You will receive a text message with a verification code on your smartphone. Enter the code in v-safe and click **Verify**.



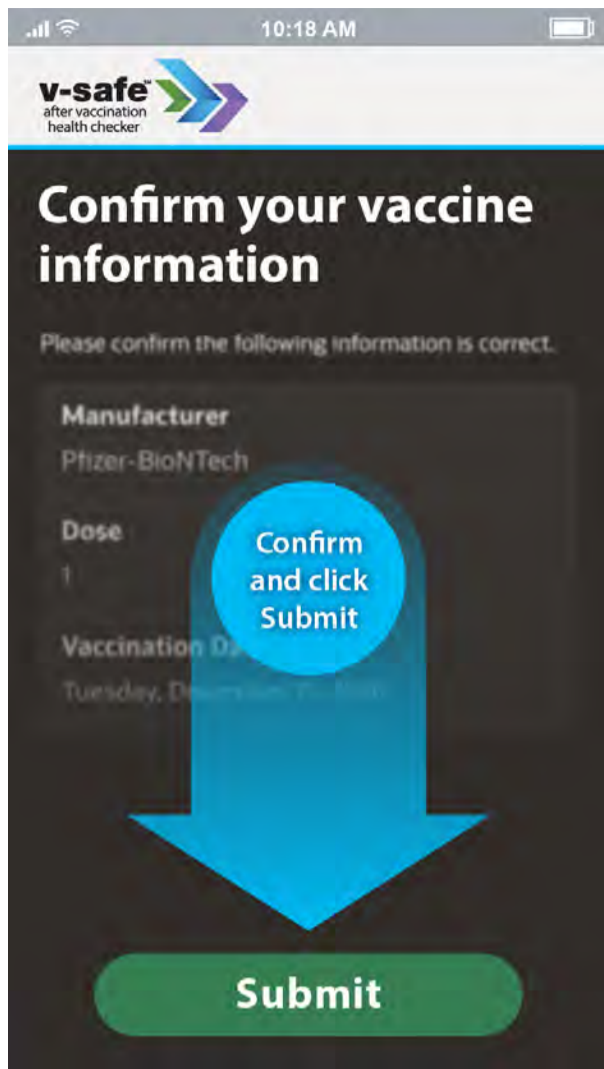
4. At the top of the screen, click **Enter vaccine information**.



5. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider) and enter the date you were vaccinated. Click **Next**.

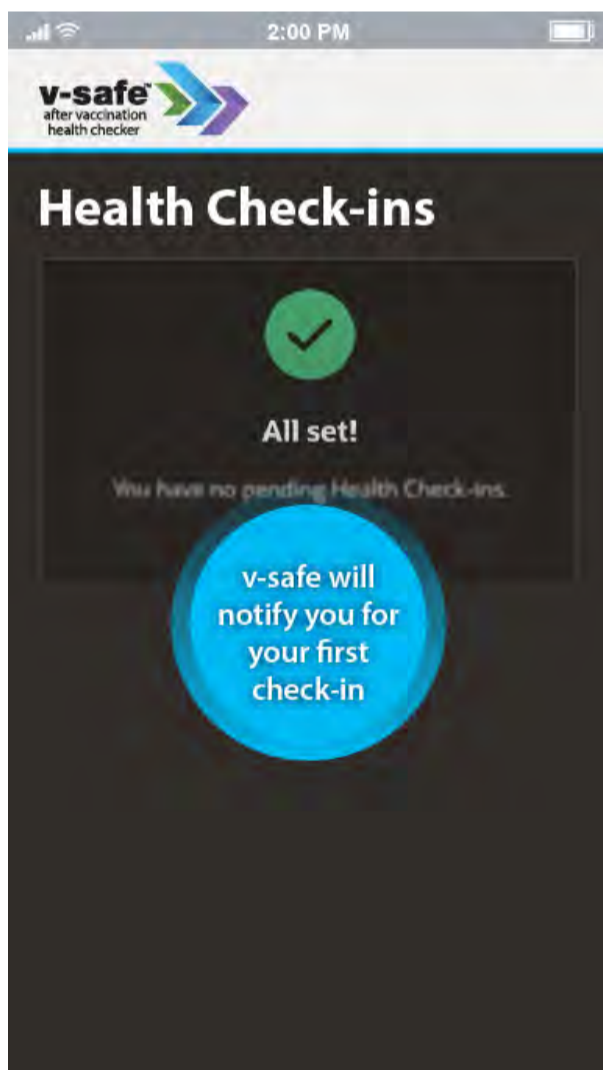


6. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.

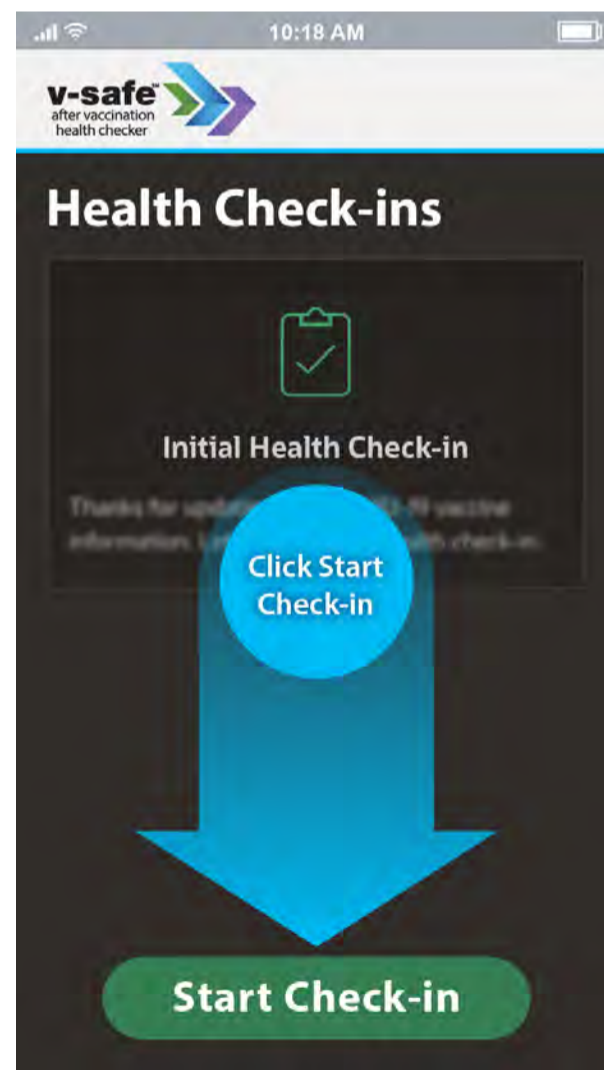


7. Congrats! You're all set! If you complete your registration before 2 p.m. local time, **v-safe** will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., **v-safe** will start your initial health check-in immediately after you register — just follow the instructions.

Registration **before** 2 p.m. local time:



Registration **after** 2 p.m. local time:



## What happens next?

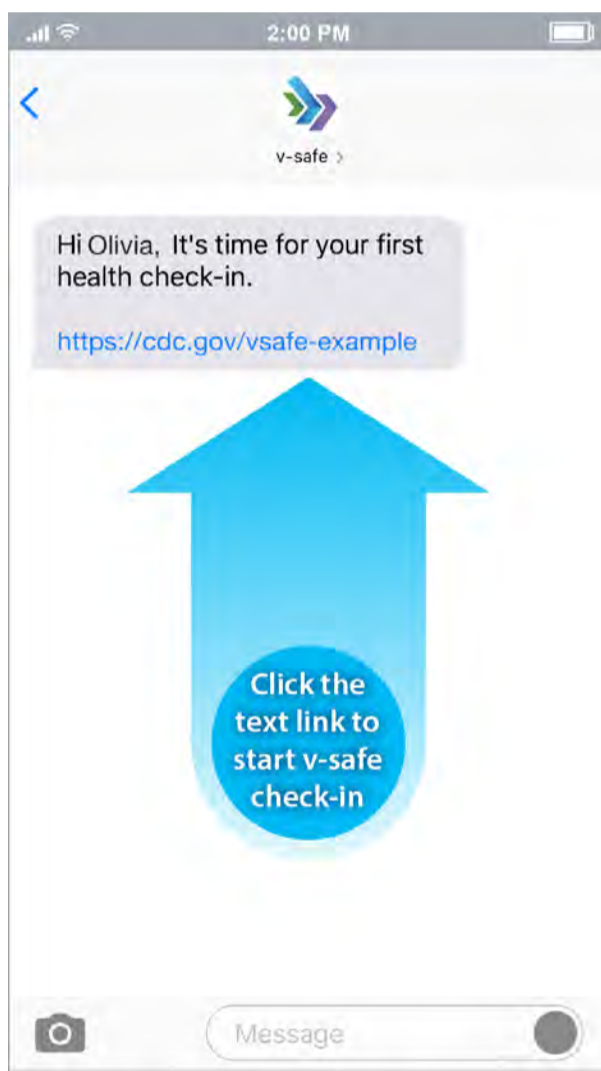
You will receive a reminder text message from **v-safe** around 2 p.m. local time for the next check-in. Just click the link in the text message to start the check-in.

the next check-in, 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.

**v-safe<sup>SM</sup>**  
after vaccination  
health checker



0%

**Hi Olivia,**

Let's start today's health check-in.

How are you feeling today? \*



Good



Poor

Follow  
instructions  
to complete  
check-in.

Next >

Your information in v-safe is protected by administrative, technical, and physical measures that safeguard the confidentiality, integrity, and privacy of personal information.



## Need help with v-safe?

Call 800-CDC-INFO (800-232-4636) TTY 888-232-6348

Open 24 hours, 7 days a week

### More Information

[Ensuring the Safety of COVID-19 Vaccines](#)

[Information about COVID-19 Vaccines](#)

[Frequently Asked Questions about COVID-19 Vaccination](#)