



**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT
CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS
5 THROUGH 11 YEARS OF AGE**

FOR 5 THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 through 11 years of age.¹

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 5 through 11 years of age.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

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

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. 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 leading to death. 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.

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

¹ You may receive this Vaccine Information Fact Sheet even if your child is 12 years old. Children 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 formulation authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

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

The vaccine is administered as a 2-dose series, 3 weeks apart.

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?

Your child should not get the vaccine if your child:

- 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 VACCINE?

The 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), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAS THE VACCINE BEEN USED BEFORE?

Millions of individuals 12 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In other clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. The vaccine that is authorized for use in children 5 through 11 years of age includes the same mRNA and lipids but different inactive ingredients compared to the vaccine that has been used under EUA in individuals 12 years of age and older and that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be readily prepared to deliver appropriate doses to the 5 through 11 year-old population.

WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?

There is a remote chance that the 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 vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child’s healthcare provider if your child has any side effects that bother your child 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 HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child’s standard medical care.

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

For children 5 through 11 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child’s healthcare provider.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?

If your child is pregnant or breastfeeding, discuss the options with your healthcare provider.

WILL THE VACCINE GIVE MY CHILD COVID-19?

No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.


KEEP YOUR CHILD’S VACCINATION CARD

When your child gets the first dose, you will get a vaccination card to show when to return for your child’s next dose(s) of the vaccine. Remember to bring the card when your child returns.

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
<p data-bbox="315 1509 620 1539">www.cvdvaccine.com</p> 	<p data-bbox="950 1583 1219 1654">1-877-829-2619 (1-877-VAX-CO19)</p>

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 CHILD'S VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns for the second dose. For more information about IISs visit:

<https://www.cdc.gov/vaccines/programs/iis/about.html>.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. 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).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

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>.

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)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An 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 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.

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.



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1486-0.3

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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: 09/30/2021



Notice of Privacy Practices

Original notice effective April 14, 2003

Revised notice effective September 23, 2013

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.

PLEASE READ CAREFULLY.

WE ARE REQUIRED BY LAW TO PROTECT MEDICAL INFORMATION ABOUT YOU.

We are required by law to protect the privacy of medical information about you and that identifies you. We are also required to give you this Notice about our Privacy Practices, explaining our legal duties and your rights concerning your health information. We must follow the privacy practices described in this Notice while it is in effect. We reserve the right to make changes to our privacy practices and the terms of this Notice at any time, provided such changes are permitted by applicable law. We reserve the right to make changes in our privacy practices and the terms of our Notice effective for all health information that we maintain, including health information we created or received before we made the changes. Before we make a significant change in our privacy practices, we will change this Notice and make the new Notice available upon request. You may request a copy of our Notice at any time. If you have questions about information in this Notice or about our privacy policies, procedures or practices, you can contact us using the contact information at the end of this notice.

HOW WE MAY USE AND DISCLOSE MEDICAL INFORMATION ABOUT YOU IN CERTAIN CIRCUMSTANCES

We use and disclose health information about you for treatment, payment, and healthcare operations. The examples given are for illustrative purposes and are not exhaustive.

- **Treatment:** We may use or disclose your health information to a physician or other healthcare provider providing treatment to you. For example, your health information may be provided to another health care practitioner to whom you have been referred to ensure that the party has the necessary information to diagnose or treat you.
- **Payment:** We may use and disclose your health information to obtain payment for services we provide to you. For example, we may disclose your health information to your health plan in order to obtain approval for a procedure.
- **Healthcare Operations:** We may use and disclose your health information in connection with our healthcare operations. For example, we may disclose your health information for case management purposes. Healthcare operations may include quality assessment and improvement activities, reviewing the competence or qualifications of healthcare professionals, evaluating practitioner and provider performance, conducting training programs, accreditation, certification, licensing or credentialing activities.
- **Your Authorization:** Unless you give us a written authorization, we cannot use or disclose your health information for any reason except those described in this Notice. In addition to our use of your health information for treatment, payment or healthcare operations, you may give us written authorization to use your health information or to disclose it to anyone for any purpose. If you give us an authorization, you may revoke it in writing at any time. Your revocation will not affect any use or disclosures permitted by your authorization while it was in effect.
- **Psychotherapy Notes:** Most uses and disclosures of psychotherapy notes will require your written authorization. You may inquire about specific uses and disclosures of psychotherapy notes permitted without your authorization.
- **Fundraising:** You have the right to opt out of receiving fundraising communications.
- **Genetic Information:** Your genetic information will not be used or disclosed for underwriting purposes.
- **Sale of Health Information:** Any use or disclosure that constitutes the sale of health information is not permitted without your authorization.
- **Disclosures to You, To Your Family, or to Your Friends:** We must disclose your health information to you in accordance with the Patient Rights section of this Notice. We may disclose your health information to a family member, friend or other person to the extent necessary to help with your healthcare or payment for your healthcare, but only if you authorize us to do so.
- **Persons Involved In Your Care:** We may use or disclose health information to notify, or assist others in notifying a family member, your personal representative or other person responsible for your care of your location, your general condition, or death. If you are present, we will provide you with an opportunity to object to such disclosures of your health information prior to use or disclosure of that information. In the event you become incapacitated or have a medical emergency, we will disclose your health information based on our professional judgment that such disclosure is directly relevant to that person's involvement in your healthcare. We will also use our professional judgment and experience to make decisions about your best interest in allowing a person to pick up filled prescriptions, medical supplies, x-rays, or other similar forms of health information.

- **Marketing Health-Related Services:** Use or disclosure of health information for marketing purposes will require your written authorization.
- **Required by Law:** We may use or disclose your health information when we are required to do so by law.
- **Abuse or Neglect:** We may disclose your health information to appropriate authorities if we reasonably believe that you may be the victim of abuse, neglect, domestic violence or other crimes. We may disclose your health information to the extent necessary to avert a serious threat to your health or safety or the health or safety of others.
- **National Security:** We may disclose to military authorities the health information of Armed Forces personnel under certain circumstances. We may disclose to authorized federal officials health information required for lawful intelligence, counterintelligence, and other national security activities. We may disclose to correctional institutions or law enforcement officials having lawful custody of protected health information of inmate or patient under certain circumstances.
- **Appointment Reminders:** We may use or disclose your health information to provide you with appointment reminders (such as voicemail messages, postcards, or letters).

PATIENT RIGHTS

- **Access:** You have the right to look at or get copies of your health information, with limited exceptions. You may request that we provide copies in a format other than photocopies. We will use the format you request unless we cannot practicably do so. You must make this request in writing to obtain access to your health information. You may obtain a form to request access from your care provider. We may charge you a reasonable cost-based fee for expenses such as copies and staff time. For details about when this request may be denied, please speak with your care provider.
- **Disclosure Accounting:** You have the right to receive a list of instances in which we or our business associates disclosed your health information for purposes other than treatment, payment, healthcare operations and certain other activities for the last 6 years, but not before April 14, 2003. If you request this accounting more than once in a 12-month period, we may charge you a reasonable, cost-based fee for responding to the additional requests.
- **Restriction:** You have the right to request that we place additional restrictions on our use or disclosure of your health information. Except in the case of paying out of pocket as described below, we are not required to agree to these additional restrictions, but if we do, we will abide by our agreement (except in an emergency).
- **Paying Out of Pocket:** If you are paying out of pocket **in full** for a service or item in question, then you have the right to request that we restrict disclosure of your health information related to that service or item for purposes of payment or health care operations. Paying only the insurance deductibles or copayments does not exercise this right. We must abide by this request unless disclosure is otherwise required by law. You must request additional restrictions and pay out of pocket in full to restrict to restrict disclosure of follow up care.
- **Alternative Communication:** You have the right to request that we communicate with you about your health information by alternative means or to alternative locations. **{You must make your request in writing.}** Your request must specify the alternative means or location, and provide satisfactory explanation how payments will be handled under the alternative means or location you request.
- **Amendment:** You have the right to request that we amend your health information. (Your request must be in writing, and it must explain why the information should be amended.) We may deny your request under certain circumstances.
- **Electronic Notice:** If you receive this Notice on our website or by electronic mail (e- mail), you are entitled to receive this Notice in written form upon request.
- **Breach Notification:** You have the right to be notified if we determine that a breach of your health information has occurred.

QUESTIONS AND COMPLAINTS

If you want more information about our privacy practices or have questions or concerns, you may contact us using the information at the end of this notice. If you are concerned that we may have violated your privacy rights, or if you disagree with a decision we made about access to your health information or in response to a request you made to amend or restrict the use or disclosure of your health information or to have us communicate with you by alternative means or at alternative locations, you may complain to us using the contact information listed at the end of this Notice. You also may submit a written complaint to the U.S. Department of Health and Human Services. We will provide you with the address to file your complaint with the U.S. Department of Health and Human Services upon request.

We support your right to the privacy of your health information. We will not retaliate in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.

Transylvania County Government
101 South Broad Street, Brevard, NC 28712
www.transylvaniacounty.org

Transylvania Public Health
106 East Morgan Street, Suite 105, Brevard, NC 28712
828.884.3135 | www.transylvaniahealth.org



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 2 p.m. 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



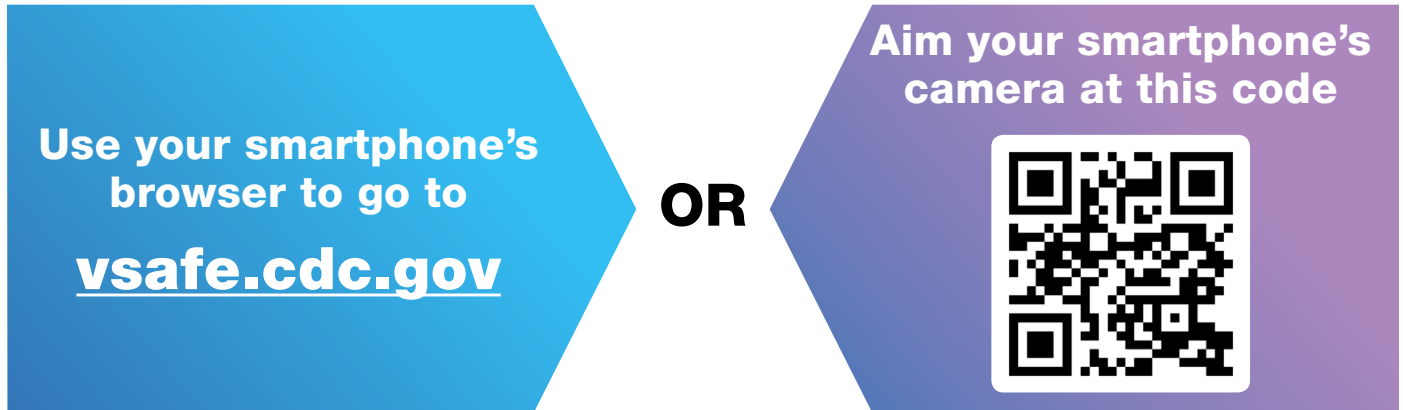
*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

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 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 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. You will receive a reminder text message from v-safe when it's time for the next check-in — around 2 p.m. 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





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EVERYDAY. EVERYWHERE. EVERYONE.