



TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

Vaccine Updates

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DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

December 7, 2020

Evolving Landscape for COVID-19 Vaccine

Key Assumptions for COVID-19 Vaccine



Limited doses may be available in December 2020, but **supply will increase substantially** in 2021



Initial supply will either be **approved as a licensed vaccine** or **authorized for use under an EUA** issued by the FDA







Cold chain storage and handling requirements are likely to vary from **refrigerated to ultra-cold frozen**







Two doses, separated by ≥ 21 or 28 days, will be **needed for immunity** for most COVID-19 vaccines

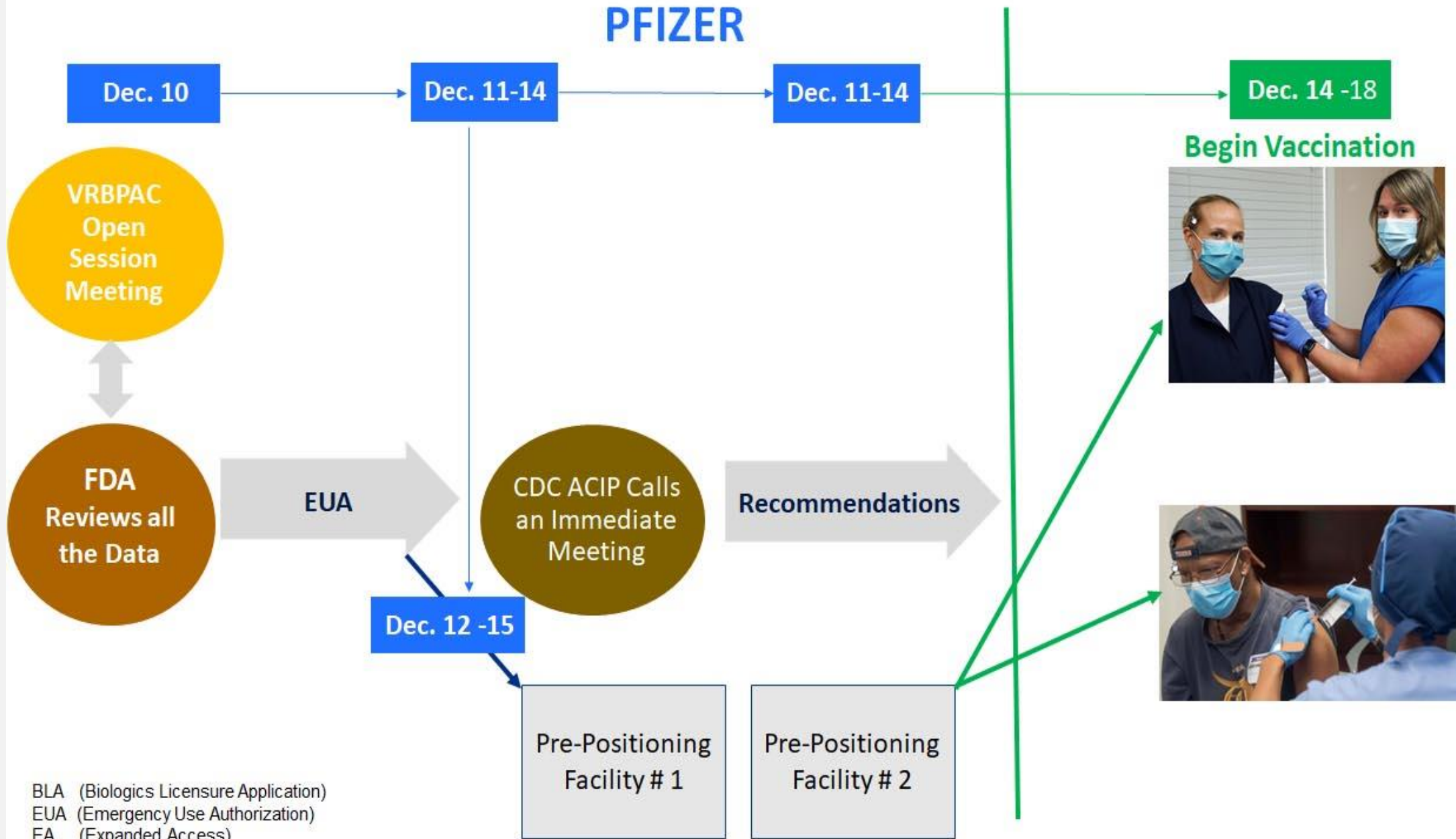


COVID-19 Vaccine Updates

Phase III Vaccine Candidates	Technology Platform	Storage & Handling	Dose (Intramuscular Injection)
	m-RNA	Ultra-low frozen: 6mos Refrigerated: 5 days	2 (0, 21 days)
	m-RNA	Frozen: 6mos Refrigerated: 30 days	2 (0, 28 days)
	Viral Vector (Non-Replicating)	Refrigerated: 6mos	2 (0, 28 days)
	Viral Vector (Non-Replicating)	Refrigerated: 6mos	1

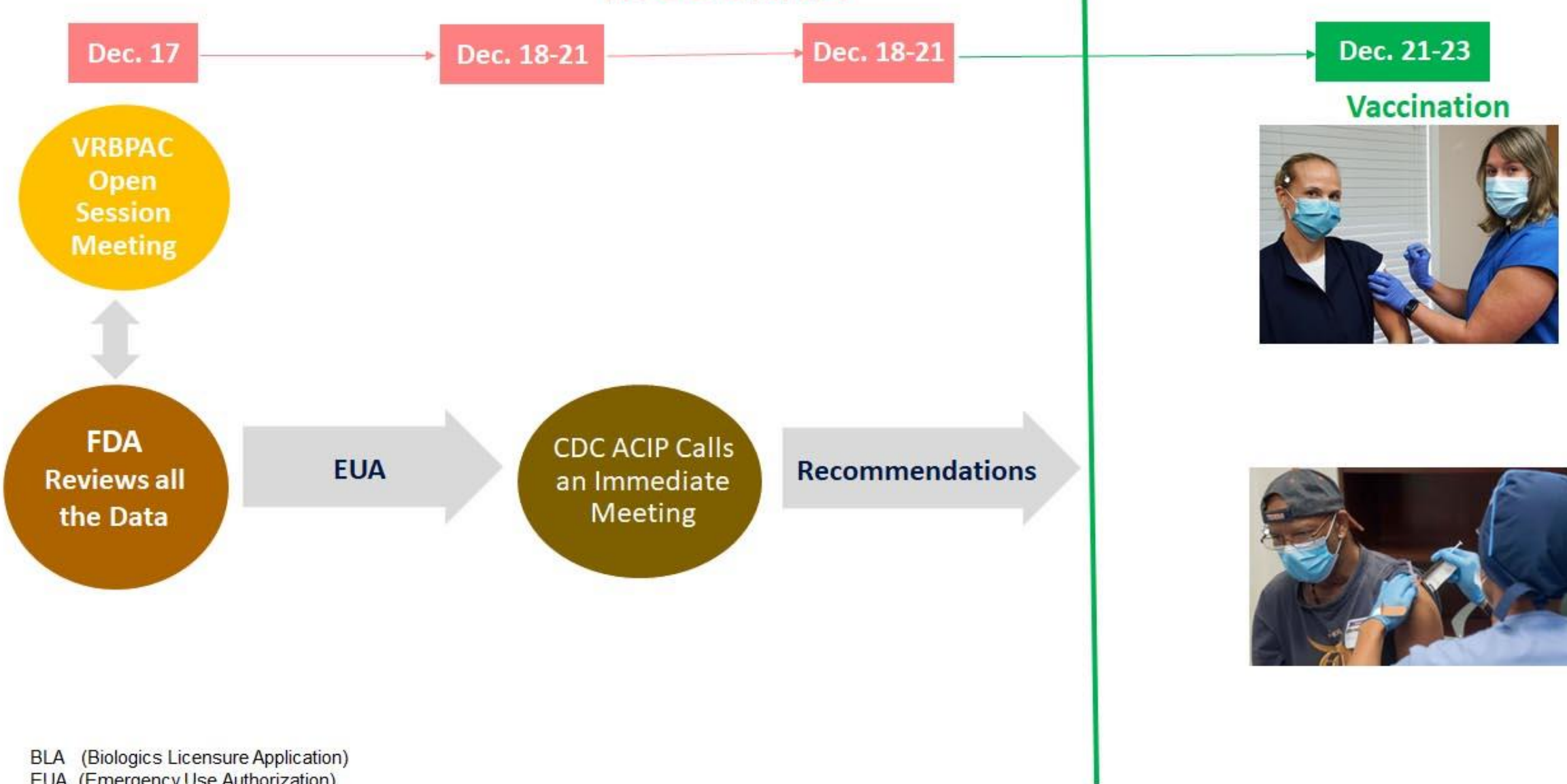
Phase III Vaccine Candidates	Technology Platform	Efficacy & Safety			Regulatory Status
		Study Design	Interim Analysis	Completion of Primary Endpoint	
	m-RNA	<ul style="list-style-type: none"> • N=44,000 • ≥ 12 yrs • Randomization (1:1) • Placebo vs. Vaccine (Saline vs. 30 μg) • 2 doses (0, 21 days) 	<ul style="list-style-type: none"> • 90% effectiveness (94 cases) 	<ul style="list-style-type: none"> • 95% vaccine efficacy (162 placebo vs. 8 vaccine) <ul style="list-style-type: none"> - 30 severe case (30 placebo vs. 0 vaccine) • Consistent efficacy across age, gender, race/ethnicity • No serious adverse reported to date 	EUA Filed
	m-RNA	<ul style="list-style-type: none"> • N=30,000 • ≥ 18 yrs • Randomization (1:1) • Placebo vs. Vaccine (Saline vs. 100 μg) • 2 doses (0, 28 days) 	<ul style="list-style-type: none"> • 94.5% vaccine efficacy (90 placebo vs. 5 vaccine) <ul style="list-style-type: none"> - 11 severe case (11 placebo vs. 0 vaccine) - 16% adults ages >65 yrs - 21% diverse population • No serious adverse reported to date Grade 3 ($>2\%$): Fatigue, myalgia, arthralgia, headache, pain, & redness at injection site 	<ul style="list-style-type: none"> • 94.1% vaccine efficacy (185 cases in placebo vs. 11 vaccine) <ul style="list-style-type: none"> - 11 severe case (11 placebo vs. 0 vaccine) - 17% adults ages >65 yrs - 21% diverse population • 1 death in the placebo group 	EUA Filed
	Viral Vector (Non-Replicating)	<p>UK Study</p> <ul style="list-style-type: none"> • N=12,390 • ≥ 18 yrs • 1 Dose vs. 2 Doses vs. MenACWY <p>Brazil Study</p> <ul style="list-style-type: none"> • N=10,300 • ≥ 18 yrs • 2 does vaccine vs. MenACWY/Saline 	<ul style="list-style-type: none"> • 90% vaccine efficacy (half dose/full dose (5×10^{10} vp) with n=2,741) • 62% vaccine efficacy (full dose/full dose (n=8,895)) • Combined efficacy of 70% (131 COVID-19 cases) • No serious adverse events have been reported thus far 		
	Viral Vector (Non-Replicating)	<ul style="list-style-type: none"> • N=60,000 • ≥ 18 yrs • Randomization (1:1) • Placebo vs. Vaccine (Saline vs. 5×10^{10} vp) • 1 doses 			

PFIZER



BLA (Biologics License Application)
EUA (Emergency Use Authorization)
EA (Expanded Access)

MODERNA



BLA (Biologics License Application)
EUA (Emergency Use Authorization)
EA (Expanded Access)

COVID-19 Vaccine Safety Monitoring

- Vaccine Adverse Event Reporting System (VAERS)
- V-safe



Texas Department of State
Health Services



VAERS

Vaccine Adverse Event Reporting System

Co-managed by
CDC and FDA

<http://vaers.hhs.gov>

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS

Report an Adverse Event

VAERS Data

Resources

Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*



What is VAERS?



REPORT AN ADVERSE EVENT

Report light care adverse events after vaccination.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find manuals, publications, training tools, and other resources.



SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

VAERS is the nation's frontline system for monitoring vaccine safety

v-safe | *after vaccination health checker*



V-safe is a smartphone-based tool that uses text messaging and web surveys to provide **personalized health check-ins** after someone receives a COVID-19 vaccination.



Vaccine recipients can quickly tell the CDC if they have any side effects. The CDC may follow up with them by phone to get more information.



V-safe will also remind them to get their second COVID-19 vaccine dose, if needed.



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 | *after vaccination health checker*

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.



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 | provider role

- Give patients a **v-safe** information sheet at the time of vaccination
- Encourage them to enroll and fill out the surveys when prompted

<https://vsafe.cdc.gov/>



**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.

When you get your COVID-19 vaccination, ask your healthcare provider about getting started with v-safe

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

12/01/20

v-safe info poster



**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.

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:

Use your smartphone's browser to go to vsafe.cdc.gov OR Aim your smartphone's camera at this code

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. **Congratulations! 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

12/01/20

v-safe info sheets

REMINDER

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December 07, 2020