INTERNATIONAL Medicine Center
Experts in Tropical + Travel Medicine

RENSIMER & ASSOCIATES
INTERNAL MEDICINE / INFECTIOUS DISEASES

Thank you for choosing us for your healthcare needs.

It is our goal to simplify your vaccine experience, while ensuring that you have the medical understanding and have been given the opportunity to read and understand the significance of taking the Moderna Vaccine.

The process has 3 parts:

1. Complete the attached form and submit
    a. You can save and send via email to imc@traveldoc.com
    b. You can send via fax at 713.973.0805
2. A member of our staff will verify insurance
    - You must have submitted forms prior to coming for appointment to ensure proper coverage
3. Our Walk- In Vaccine hours are:
    a. Tuesday 9 am – 3 pm
    b. Friday 9 am – 1 pm

This packet has been broken into 3 portions:

1. Demographics and Medical History
2. Vaccine Checklist and Consents
3. Vaccine Information

Spring Valley Medical Plaza

9230 Katy Freeway - Suite 400, 4th Floor

Houston, Texas 77055

INTERNATIONAL Medicine Center
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COVID-19 VACCINE PROCEDURE

RENSIMER & ASSOCIATES
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Rensimer & Associates is providing this vaccine, but demand is high and supply varies. The process of getting the vaccine to the most people as fast and as safely as possible must be controlled and efficient. So, these are the main principles of our procedure.

1. As an approved site for providing the vaccine, we are expected to follow Centers for Disease Control (CDC) Guidelines. You must fit U.S. Centers for Disease Control Guidelines for vaccine medical necessity- i.e. who should get it first. You will not be given the vaccine in violation of the guidelines, unless there are extenuating circumstances permitted by the physician.

2. All paperwork must be completed before an appointment will be made (no "walk-ins" to do paperwork in our facility).

3. PAYMENT: Any insurance information provided or payment **must be made PRIOR TO the actual appointed visit**.
   The cost of the vaccination itself has been supplemented by your insurance payor and/ or monies set aside by your tax dollars.

   In this way the vaccine is being provided nationwide via the EMERGENCY USE ADMINISTRATION (EUA) approval of the U.S. Food and Drug Administration (FDA).

   Rensimer and Associates **WILL BILL YOU** or your insurance **FOR THE ADMINISTRATION of this service**. Please note that we are **NOT IN-NETWORK** with ALL payorsand it is **your responsibility to verify your coverage prior to being given an appointment**. Because not all providers have been approved or set up to provide the vaccine, most payors have chosen to allow patients to receive the vaccine regardless of network participation. If you have questions about coverage of any costs, please contact your payor.

   Rensimer and Associates office visit charge for this service is $40.00 per vaccine dose. ($80.00 total for 2-dose vaccine)

   NOTE: If we cannot be sure that your insurance will cover the service, you will need to self-pay prior to being given an appointment, then deal with your insurer on reimbursement.

4. Our operational goal is,
   a. To have least exposure of you and others to each other.
   b. To administer the vaccine within several minutes of your arrival in our facility, but for operational efficiency we will try to "group shots".
   c. To observe you for 15 minutes post vaccination, with your exit immediately after.
   d. Optimally, your time here should not exceed 30 minutes.
   e. Your second dose appointment will be about 28 days (Moderna Vaccine) after the first, optimally, but can be up to 42 days (6 weeks) after the first dose.

5. If you have questions about the vaccine, you can schedule an appointment (request a telemedicine appointment).

6. **A "NO-SHOW"** for your appointment may result in **your vaccine being given to someone else**.

7. **ATTENTION**: You **MUST notify our staff of any positive answers** on any of the CDC documents and our COVID-19 Screening Questionnaire (below).

To proceed, please read and complete the following forms and submit. We will call or provide directions to schedule you.
If you have questions, call 713-973-6078.

Edward R. Rensimer, MD
Director

COVID-19 Screening Questionnaire

1. In the past 3 weeks, have you had __ fever, __ cough, __ sore throat, __ shortness of breath, __ diarrhea, or change in sense of __ taste or __smell? **(mark all that apply)** ○ NO ○ YES
2. Have you had known exposure to someone with known or suspected COVID-19? ○ NO ○ YES
3. Have you been tested for COVID-19 in the past 3 weeks? ○ NO ○ YES
   If "YES", □ Nasal Swab PCR □ Antibody (blood) Results: ○ NEG ○ POS

ATTENTION: If ANY answers are "**YES**" or "POS", **DO NOT enter our office**; Call us for instructions: 713-973-0341

STAFF: If any answers are "YES" or "POS", immediately present this form to the physician with the patient's chart.

Pre-Vaccination Checklist for COVID-19 Vaccines

First Name: _____ Last Name: _____

Date of Birth: _____ Age: _____ Gender: ☐ Female ☐ Male

Address: _____ City, State, Zip: _____

Phone Number: _____ Email: _____

PATIENT INSURANCE

Insurance Name: _____ **Provider/ Customer Phone Number:** _____

I.D. Number: _____ **Group No.:** _____

Insured Cardholder: _____ **Relationship to Patient:** _____

Insured Date of Birth: _____ **Employer:** _____

APPOINTMENT DATE

DOSE 1: _____ TIME: _____ *** OFFICE USE ONLY ***

DOSE 2: _____ TIME: _____

HEALTHCARE PROVIDER

*** OFFICE USE ONLY ***

Complete BEFORE vaccine administration

1. I have reviewed the **Patient Information** and **Screening Questions.** **Initial Here:** _____
2. I have verified that this is the **vaccine requested** by the patient. **Initial Here:** _____
3. This vaccine is appropriate for this patient based on the **Age Guidelines and Other Guidelines** provided by federal and/or state regulations and company policies. **Initial Here:** _____

   3a. Does this patient have a high-risk medical condition? ☐ YES ☐ NO
   - If yes, please list medical condition(s): _____
4. I have verified the **Expiration Date** is greater than today's date and have entered the **Lot # and Expiration Date** in the field below. **Initial Here:** _____
5. I have been informed whether the patient **HAS A PROBLEM WITH NEEDLES** or injections **(LAY DOWN FOR SHOTS)**. **Initial Here:** _____

Complete DURING the patient interaction

6. I have reviewed the **Screening Questions** and answers. **Initial Here:** _____
7. I provided a CDC Pre-Vaccination Checklist for COVID -19 Vaccines document to the patient or their agent. **Initial Here:** _____

Complete AFTER vaccine administration

Vaccine Name	Manufacturer	Dosage	Vaccine Dose	Site of Administration	Lot #	Exp. Date	Administration Date
	Moderna		Dose 1				
	Moderna		Dose 2				

DOSE 1:
Clinician's Printed Name: _____ **Clinician's Signature:** _____

DOSE 2:
Clinician's Printed Name: _____ **Clinician's Signature:** _____

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INTERNAL MEDICINE / INFECTIOUS DISEASES

Vaccine Checklist and Consents

INTERNATIONAL Medicine Center
Experts in Tropical + Travel Medicine

Pre-Vaccination Checklist for COVID-19 Vaccines

For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. **If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name: _____

Date of Birth: _____

Age: _____

	Yes	No	Don't know
1. Are you feeling sick today?	☐	☐	☐
2. Have you ever received a dose of COVID-19 vaccine?	☐	☐	☐
• If yes, which vaccine product? ○ Pfizer Date: _____ ○ Moderna Date: _____ ○ Another product _____ Date: _____			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?	☐	☐	☐
• Was the severe allergic reaction after receiving a COVID-19 vaccine?	☐	☐	☐
• Was the severe allergic reaction after receiving another vaccine or another injectable medication?	☐	☐	☐
4. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?	☐	☐	☐
5. Have you received another vaccine in the last 14 days?	☐	☐	☐
6. Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?	☐	☐	☐
7. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?	☐	☐	☐
8. Do you have a bleeding disorder or are you taking a blood thinner?	☐	☐	☐
9. Are you pregnant or breastfeeding?	☐	☐	☐
10. Do you have a **FEAR OF NEEDLES/ INJECTIONS** or a hinting of dizziness, near-fainting, etc. with injections? If you marked yes, **YOU SHOULD REQUEST TO LIE DOWN DURING SHOT.**	☐	☐	☐

Form reviewed by Office Staff _____ **Date** _____

Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists

COVID -19 VACCINE INFORMED CONSENT

I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient; or (c) a person authorized to consent on behalf of the patient where the patient is not otherwise competent or is unable to consent for themselves. Further, I hereby give my consent to these licensed healthcare professionals to administer the vaccine I have requested, shown above. I understand that it is not possible to predict all possible side-effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) are not completely known and have received, read, and/or had explained to me the CDC Checklist document on the vaccine I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised that the patient should remain near the vaccination location for observation for approximately 15 minutes after administration.

On my behalf or on behalf of the patient, the patient's heirs and personal representatives, I hereby release and hold harmless each applicable medical professional and the staff, agents, successors, affiliates, officers, directors, contractors, employees and owners of Rensimer & Associates and International Medicine Center, as well as those business entities, from any and all liabilities, losses, direct or indirect, or claims of damages or injury, whether known or unknown, arising out of, in connection with, or in any way related to the administration of the vaccine or the vaccine itself, listed above.

I acknowledge that I have read the U.S. Center for Disease Controls (CDC) "Pre-Vaccination Checklist for COVID -19 Vaccines" document and have reviewed the vaccine ingredients listed.

I have brought to the attention of the medical professionals providing the vaccine any issues of concern or any of my answers to the questions on these COVID-19 Vaccine informational documents that should be further discussed prior to receiving the vaccine.

I agree to receive the second dose of COVID- 19 about 28 days from the first dose.

I agree to immediately report any significant adverse reaction to staff providing the vaccine.

I agree to continue COVID-19 safety practices such as wearing a face mask, social distancing, and frequent hand-washing, where appropriate per CDC guidelines and as required by the medical professionals staffing the facility where I am receiving the vaccine.

I understand that potential protection from the vaccine against COVID-19 may not be effective until at least 7 days after the second dose.

I understand that receiving this vaccine does not guarantee that I will not contract COVID-19; that I will not suffer serious COVID-19 illness and complications, even death; and that I will not infect others with SARs-COV-2 virus (COVID-19) to others if I contract it.

I acknowledge that though this website and communications through it are considered "secure" by usual industry standards, any information displayed or communicated electronically is always at risk for security breaches and hacking, and so at risk for falling into the hands of third parties. Such communications can never be guaranteed as secure.

I have notified the medical staff if I have a problem with injections/ needles and am a risk for near-fainting or other reactions; and so, have requested to lie down during and for a few minutes after the injection, as needed.

By submitting this acknowledgement, I *am requesting to receive* the COVID-19 vaccine.

_____	_____	_____
Staff Printed Name	Patient/ Patient's Agent Printed Name	Date
_____	_____	
Staff Signature	Patient / Patient's Agent Signature	

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Vaccine Information And FAQ

INTERNATIONAL Medicine Center
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Pre-Vaccination 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 ACIP general recommendations, see: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

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

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

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

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 (e.g., upper respiratory infections, diarrhea) 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. Currently authorized COVID-19 vaccines require two doses. Both doses of the series should be completed with the same product. Product dosing schedules vary.

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.

PRODUCT	**DOSING SCHEDULE** Between doses 1 and 2
Pfizer-BioNTech COVID-19 Vaccine	21 days
Moderna COVID-19 Vaccine	28 days

The second dose should be administered as close to the recommended interval as possible. The vaccine can be given up to four days in advance of the recommended interval if a patient presents early and you are concerned they will not return at the appropriate interval for vaccination. However, there is no maximum interval between the first and second dose for either vaccine. The series does not need to be restarted.

Pre-Vaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

COVID-19 Vaccine Components

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102 (Proprietary to Moderna)
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?

Allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications) are NOT a contraindication or precaution to vaccination with currently authorized COVID-19 vaccine. HOWEVER, individuals who have had severe allergic reactions to something, regardless of cause, **should be observed for 30 minutes after vaccination.** All other persons should be observed for 15 minutes.

Was the severe allergic reaction after receiving a COVID-19 vaccine?

History of severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of the COVID-19 vaccine product being offered is a contraindication to any current COVID-19 vaccine. Ask questions about previous severe reactions that might indicate an allergy to a vaccine component. For example, PEG may have been a component of medication for a colonoscopy.

Was the severe allergic reaction after receiving another vaccine or another injectable medication?

History of severe allergic reaction (e.g., anaphylaxis) to another vaccine or a component of another vaccine OR anaphylactic reaction to any other injectable medication is a **precaution to currently authorized COVID-19 vaccine.** Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. These individuals should be observed for 30 minutes after vaccination. A history of mild allergic reaction to a vaccine or injectable therapy is not a precaution to vaccination.

Healthcare professionals should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.
See Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC for additional guidance.

Have you received passive antibody therapy as treatment for COVID-19?

Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, **vaccination should be deferred for at least 90 days,** as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

Have you received another vaccine in the last 14 days?

COVID-19 vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with other vaccines. This recommendation is based on the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines.

Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?

Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation.

Persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired, because current evidence suggests reinfection is uncommon during this time.

Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?

Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19, including wearing a mask, social distancing, and washing hands frequently.

Do you have a bleeding disorder or are you taking a blood thinner?

COVID-19 vaccine may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Are you pregnant or breastfeeding?

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. For pregnant people seeking guidance in making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated. There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.

ATTENTION: For additional, detailed information on the Moderna COVID-19 Vaccine, see pages 9 -13

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.

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 trihydrate, 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?
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

Side effects that have been reported in a clinical trial 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

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions

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.

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
www.modernatx.com/covid19vaccine-eua	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.

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, 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 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)?

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

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