

# STRIVE Study Information



## TRIAL: Shionogi S-217622

**STRIVE** = Strategies and Treatments for Respiratory & Viral Emergencies – the name of the study.  
**Shionogi** = the name of the company that makes the investigational drug being studied in this trial.  
**S-217622** = the investigational drug being studied in this trial.



## What should you know about STRIVE?

Strategies and Treatments for Respiratory & Viral Emergencies, or STRIVE, is a group of research studies for people in the hospital with lung infection. We are talking to you about joining the STRIVE study because you are in the hospital with COVID-19 caused by the SARS-CoV-2 virus.

Please read this information carefully or have someone you trust read and explain it to you. Take as much time as you need. You can also talk to your doctor, family, and friends about the study or ask the study team to speak with them. Ask the study team to explain any words or information that you do not understand.

Participation in STRIVE is completely voluntary. You can decide not to join, or you can leave the study at any time. The medical care you are getting will not be affected.

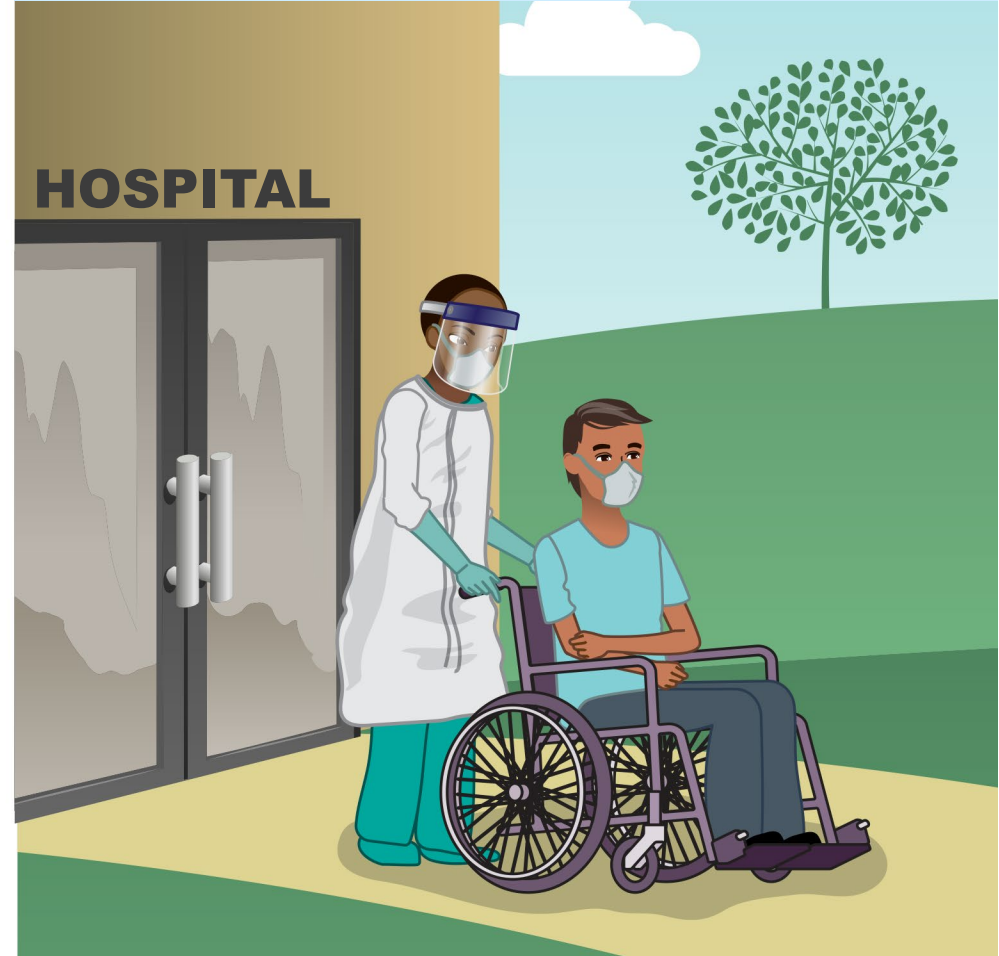


## What is a clinical research study?

A clinical research study, also known as a clinical trial, helps doctors find new ways to treat patients. We need to do clinical research studies to find out if new drugs are safe and help people get better faster. In these studies, the new drugs are “investigational,” which means they can only be used in research and have not been proven to help people with your disease.

All drugs on the market have been studied in clinical trials before being licensed or approved.

## Help patients with COVID-19 in hospital go home faster?

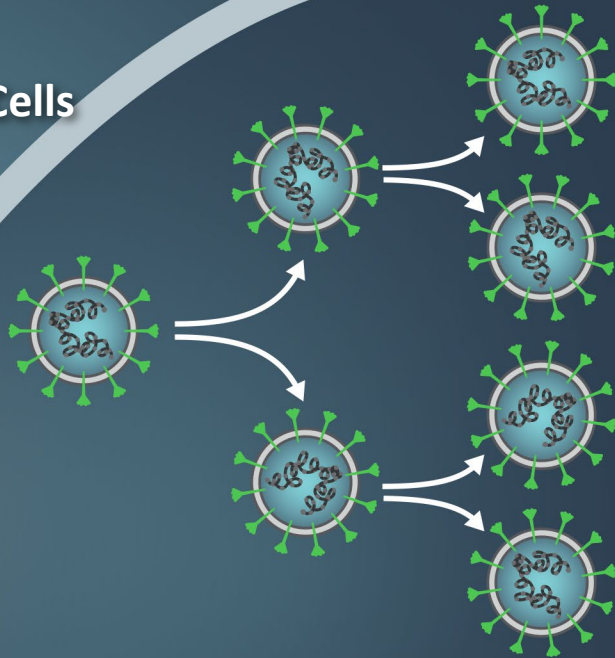


### What is this study about?

We are comparing an investigational drug called S-217622 to a placebo to see if it will help people with COVID-19 get better and go home faster. A placebo looks like the investigational drug but does not have any drug in it. It should not make you feel better or worse. Placebos are given for the same time as the investigational drug.

We expect to enroll about 1,500 people around the world for this study.

## SARS-CoV-2 Multiplies in Cells



Cell

## S-217622 Stops SARS-CoV-2 from Multiplying in Cells



S-217622

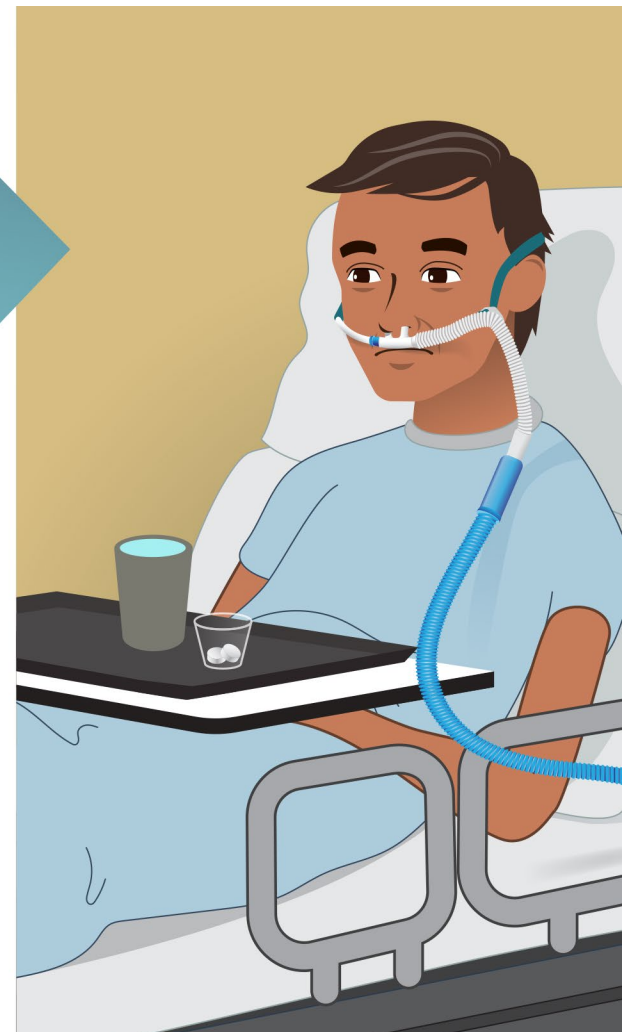
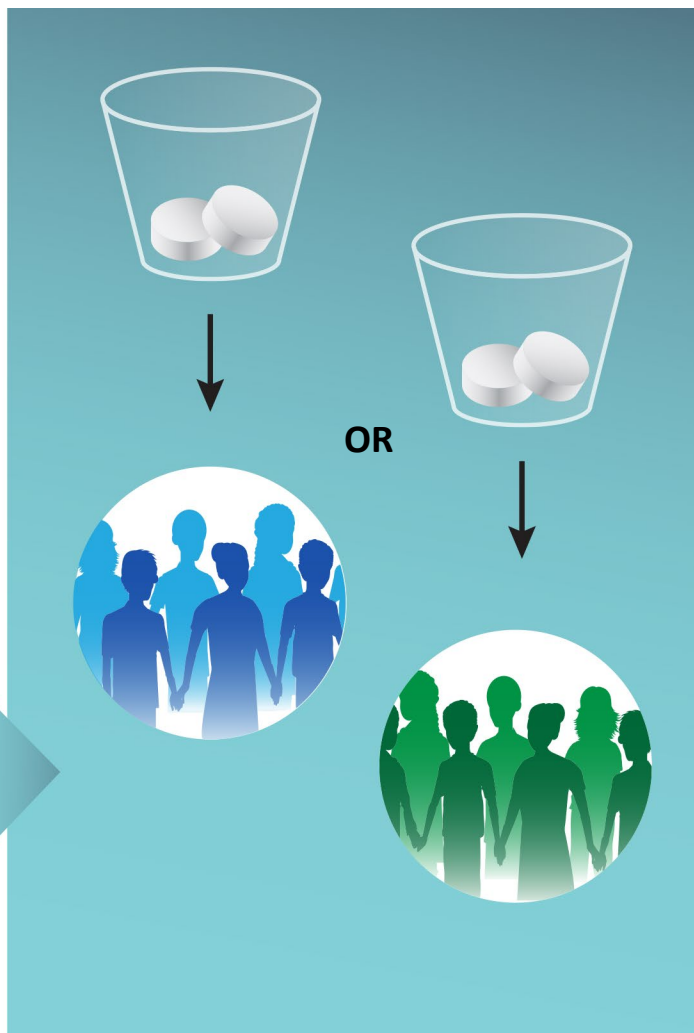
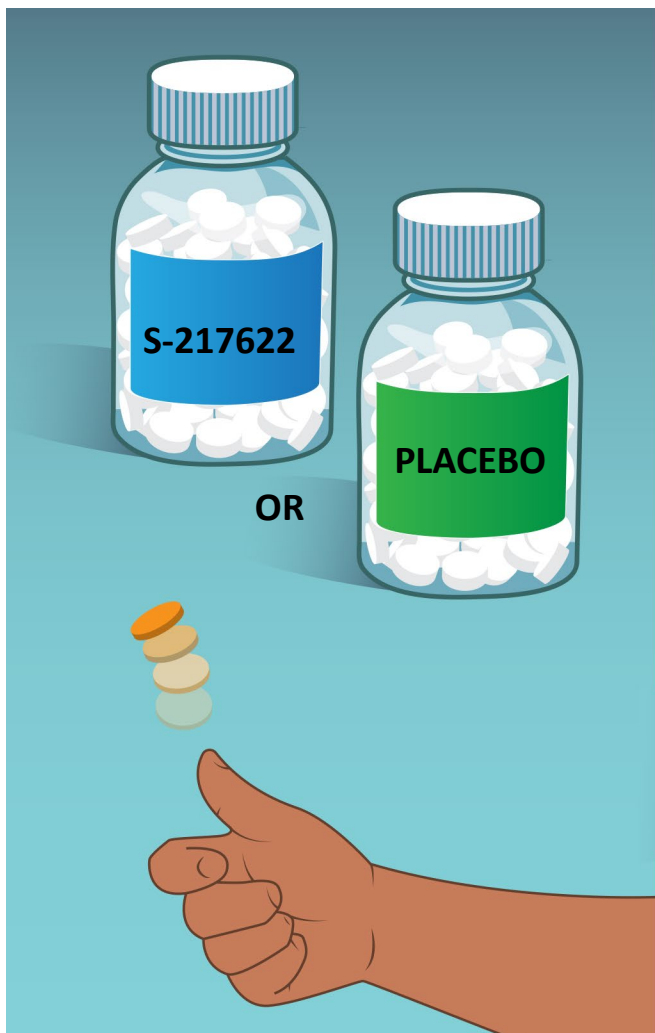
Cell

## What is S-217622?

S-217622 is the investigational drug we are studying that is made by a company called Shionogi. It is a type of antiviral drug called a protease inhibitor. It stops the virus that causes COVID-19 (SARS-CoV-2) from multiplying. This means there could be fewer viruses for your body to fight, and you may get better faster. In the lab, S-217622 works against SARS-CoV-2 variants, including omicron.

In clinical trials, hundreds of people with mild or moderate COVID-19 who were not hospitalized were selected by chance to get either placebo or the same dose of S-217622 as we are using in STRIVE. People who took S-217622 showed a faster drop in their virus levels and a faster improvement in respiratory symptoms like stuffy or runny nose, sore throat, cough, and breathing problems.





## Will you get S-217622 or placebo?

If you join the STRIVE study, you will receive either S-217622 or inactive placebo tablets. You will be given the tablets every day for five days (Days 0 to 4 of the study).

Whether you get S-217622 or placebo is decided by chance – like flipping a coin. You will have an equal chance of getting S-217622 or the inactive placebo. Your doctor and the study staff will not decide whether you get S-217622 or placebo. You, your doctor, and the study staff will not know which tablet you are getting.



## What happens if you agree to be in this study?

If you sign the consent form, it means you agree to be in the study. After you sign the consent form, we will:

- Review your past and current health as well as the medications you are taking
- Give you a brief physical exam
- Take blood for tests to check your health and to store for future tests

We may do a pregnancy test if you are able to get pregnant. We will use all this information to see if you qualify to be in this study and to monitor your health.



## Will you get other care for COVID-19?

You will be given other medications or treatments that you would usually receive in this hospital for your illness (standard care). This includes supportive care for complications of severe illness. You will receive this standard care whether or not you decide to be in the study. Your doctor and the study staff will tell you about any treatment options you may have.

S-217622 has a strong effect on blood levels of dexamethasone, a drug that is often used to treat people in the hospital with COVID-19. If dexamethasone is part of your care, you will be given a different drug which treats COVID-19 in the same way as dexamethasone.

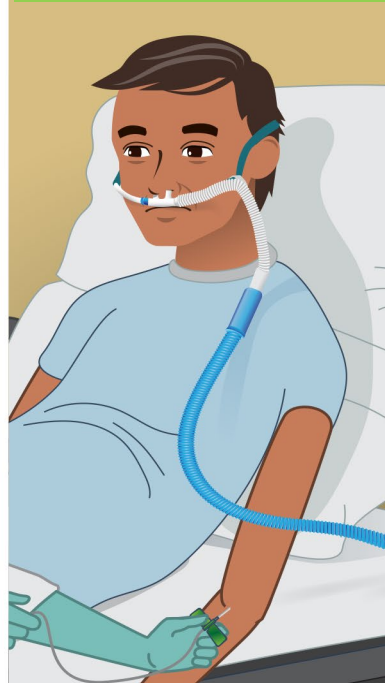


## 61 days

SUN	MON	TUE	WED	THU	FRI	SAT
	0	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31	32	33
34	35	36	37	38	39	40
41	42	43	44	45	46	47
48	49	50	51	52	53	54
55	56	57	58	59	60	

 Study Visit Days

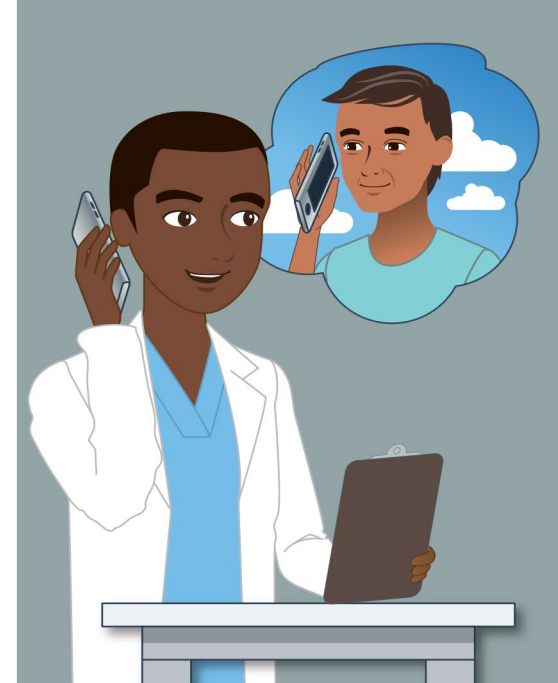
Days 0, 1, 3, 5, 14



Days 0, 5, 14



Days 6, 7, 14, 28, 42, 60



## What else will happen during this study?

You will be in the study for about 2 months. The study team will:

- Check your health every day in the first week and on Days 7, 14, 28, 42, and 60
- Check on your medications every day until Day 14 while you are in the hospital; or, if you have been discharged, on Days 5 and 14
- Take blood for lab tests to check your health on Days 0, 1, 5, and 14
- Take blood on Days 0, 3, 5, and 14 for future tests and for storage
- Do a nose swab on Days 0, 5 and 14 to test for the virus
- Ask you to complete a questionnaire about your health on Day 60

Visits on Day 6 and after may be done by phone if you are out of the hospital. We may collect information from your medical records at this hospital and any other hospital or facility you may be admitted to while you are in this study.

# Pregnancy, Breastfeeding and Contraception



What do you need to know about sex, pregnancy, and breastfeeding during this study?

If you or your partner are pregnant, please let the study team know. If you are pregnant, you cannot join this study. If you are breastfeeding, you must be able to stop while you are taking the tablets and for 30 days after you take the last tablet.

If you join the study, we strongly advise you not to have sex that could make you or a partner pregnant while you are taking the tablets and for 30 days after. You should use effective birth control (contraception) or abstain from sex while you are taking the tablets and for 30 days after you take the last tablet. The study team will discuss acceptable forms of contraception with you. If you or your partner get pregnant, please let the study team know as soon as possible.



Type of Blood Fat	Desired Level	Temporary Effects While Taking S-217622
HDL (good) Cholesterol	Higher is better	↓
Triglycerides (blood fat)	Lower is better	↑

## What are the possible risks of S-217622?

In studies of COVID-19 in hundreds of people who were not hospitalized and took the same dose of S-217622 as we are using in STRIVE, no severe side effects were seen. Some people had mild changes in blood fat and “good” cholesterol levels that did not cause symptoms and returned to normal after they finished the course of S-217622.

S-217622 may affect the blood levels of many drugs. Your study team will speak with you about medications and supplements you are taking, and whether you need to stop them or any changes that should be made if you join the study.

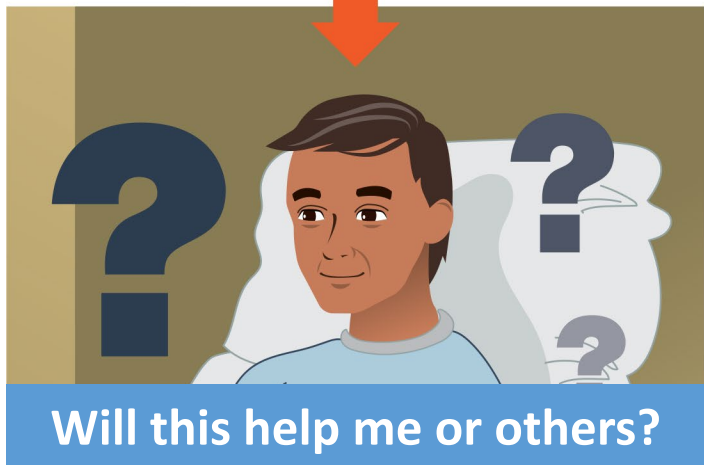
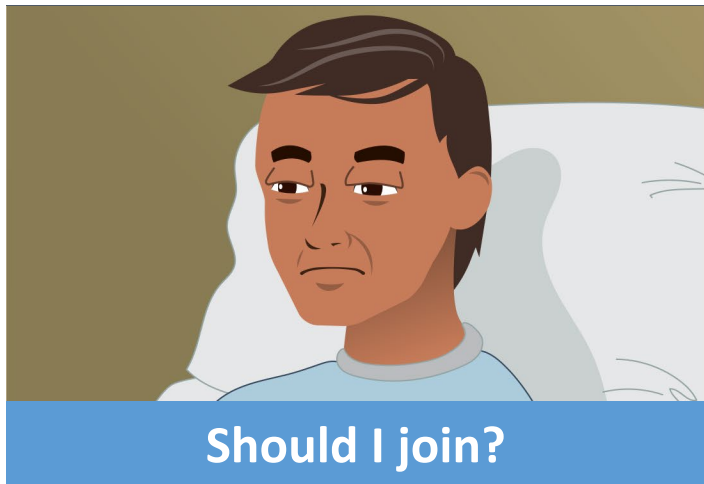
Any drug can cause an allergic reaction. Allergic reactions are not common but can be serious. They may cause skin rash, itching, hives, swelling of the face or other parts of the body, difficulty breathing, or other symptoms. We will watch over you closely and treat you right away if you have side effects that bother you.



## Are there other risks or discomforts related to this study?

Drawing blood can hurt. You may get a bruise where the needle went in. Sometimes drawing blood causes people to feel lightheaded or even to faint. There is a very small risk of getting an infection where the needle goes into the vein. This could be treated with antibiotics.

The nose swabs may cause discomfort, sneezing, bleeding, or make your eyes water.



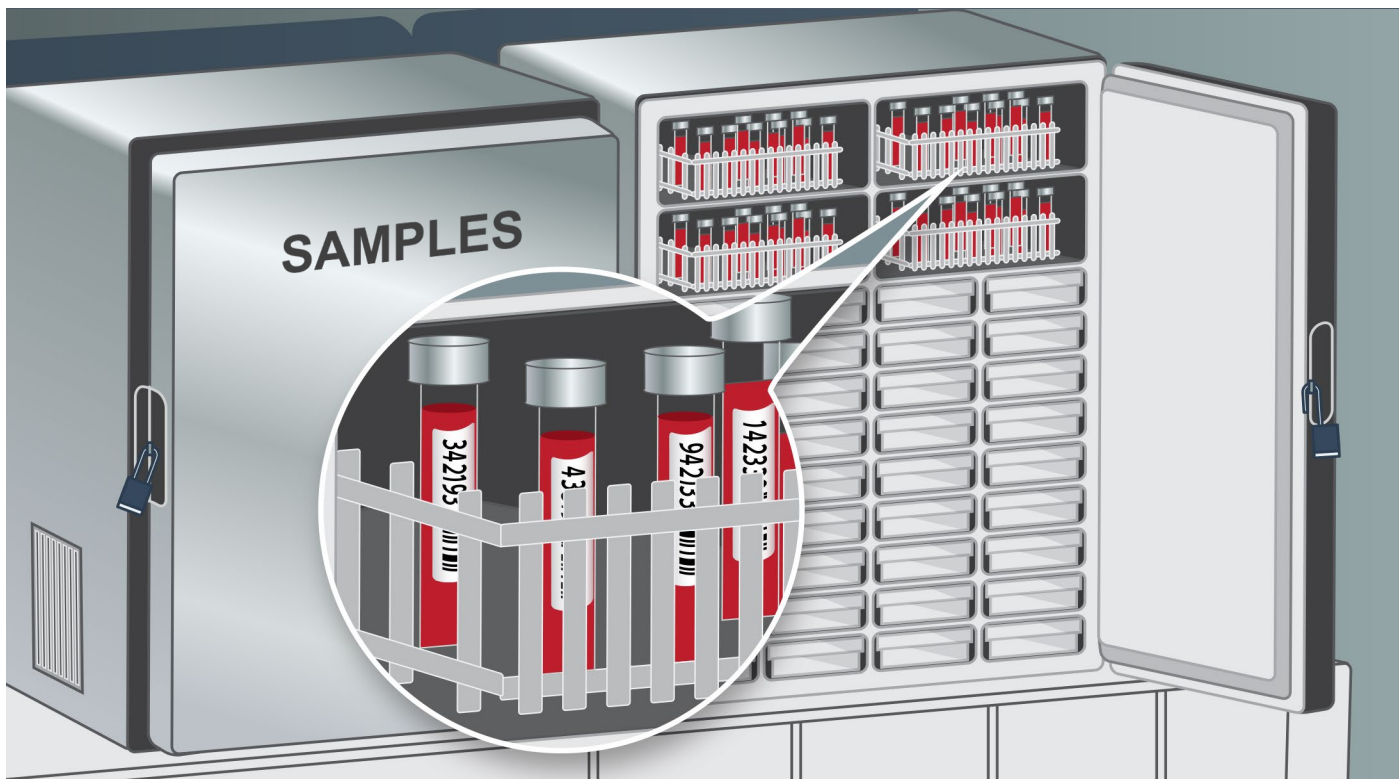
## Are there benefits of being in this study?

If you get S-217622 and it works, you may get better and go home faster. You may also have fewer and less severe symptoms. If you get placebo, it will not help your condition. We do not know if S-217622 will help people get better from their COVID-19 faster—this is what we are trying to learn.

By being in this study, you will help doctors learn more about how to treat people in the hospital with COVID-19. If S-217622 is shown to be safe and effective, there may be a large health impact with many lives saved.



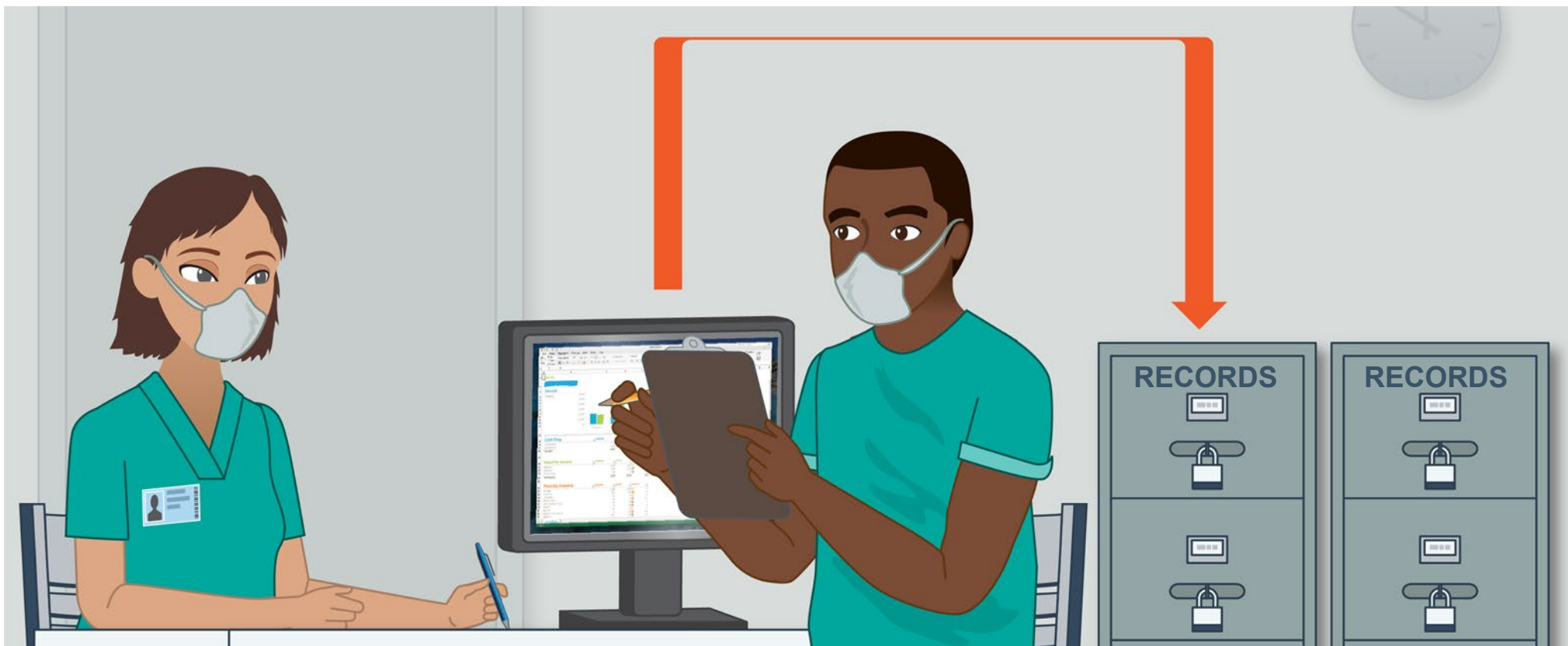
## **Other Information about the STRIVE Study**



## What will happen to your samples and personal information?

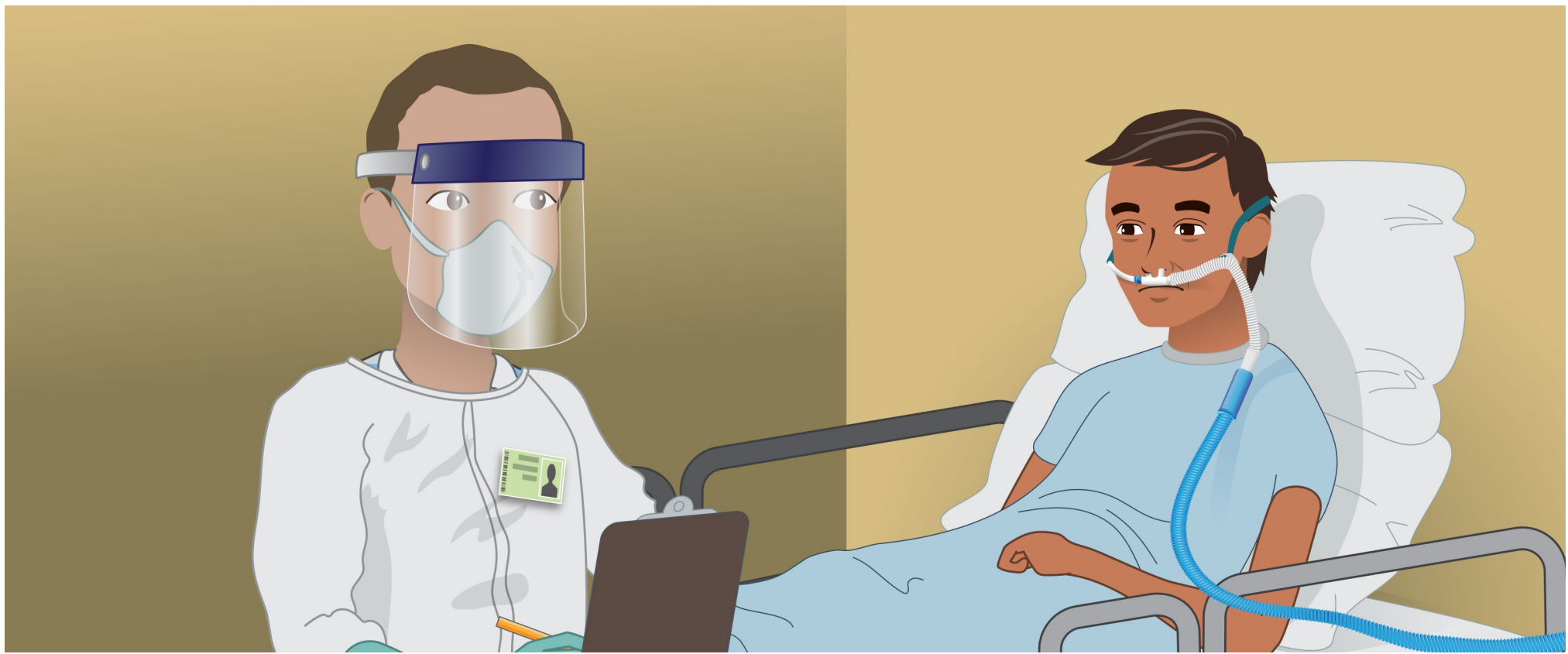
Your samples and study information will be de-identified using a code. Your name and personal details are never used. Your coded information will be sent to the University of Minnesota in the United States (US). Your coded blood and nose swab samples will be tested and stored in a US central laboratory. Any unused samples and your coded data will be stored for future COVID-19 research tests.

We will not sell your samples. To help learn more about S-217622 and COVID-19, your coded study information and samples may be shared with other researchers and the pharmaceutical company that made S-217622. You and your doctor will not get results from these research tests. If you change your mind and decide you do not want us to store your study samples or information, please let us know.



## How will your privacy be protected?

We will take every reasonable step to keep your information private and to keep anyone from misusing it. However, we cannot guarantee that no one will see it. People and staff in the following organizations may see your medical and research information: the ethics committees that are responsible for protecting the rights of participants in research studies; the sponsor, the group paying for the research (US National Institutes of Health); study research staff and study monitors; and regulatory agencies from the US (Food and Drug Administration) and other participating countries. All of these people are committed to protecting your privacy. The rights you have regarding your samples and data are described in the consent document.



## What else should you know about study participation?

- We will ask you for contact information for two people who are close to you in case we cannot reach you after you leave the hospital.
- We will give you the study drug or placebo at no cost to you. Information about hospital and other costs related to your illness is given in the consent document.
- Details about what will happen if you are hurt because of this study are given in the consent document.
- A description of this clinical trial will be available at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), and on the EU Clinical Trials Register (<http://www.clinicaltrialsregister.eu/>).

**For Sites Collecting Blood for Host Genetic Testing**





## Additional consent for blood sample for genetic testing

We would like your permission to collect a small amount of your blood and store it for researchers to analyze your genes. These genetic tests will help them understand how people's genetic makeup affects their response to COVID-19.

You and your doctor will not get any results from the genetic tests. Your sample and study information will be de-identified using codes. Your name and personal details are never used. Your sample will be stored safely in a secure sample storage facility.

We need only one sample for all the STRIVE COVID-19 studies. It will be taken with another blood draw so you will not get an extra needle stick. If you have already given blood for genetic testing as part of STRIVE, please let your study team know.

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**Thank you for considering being in this study!**  
**Together we can defeat COVID-19!**

**Any questions?**

