

OTAC Study Information



OTAC = Outpatient Treatment with Anti-Coronavirus Immunoglobulin – the name of the study.

INSIGHT = International Network for Strategic Initiatives in Global HIV Trials – the clinical trial network conducting the OTAC study.

INSIGHT012 – the number INSIGHT uses to identify the OTAC study.



What you should know about this study

We are talking to you about joining this clinical research study because you have COVID-19 and may be at a higher risk of getting very sick from it.

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 family and friends about the study. Ask the study team to explain any words or information that you do not understand.

You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part, or you can leave the study at any time.

There will be no loss of benefits if you decide not to join or later decide to leave the study. The medical care you are getting will not be affected.



What is a clinical research study?

A clinical research study helps researchers test new ways to treat a particular disease. One way to do this is by studying new drugs to see if they work and are safe. In a study, the new drugs are “investigational,” or study drugs, which means they have not been proven to work. That is why studies are needed in people with the disease to find out if new drugs are safe and help people get better faster.



**Help patients with
COVID-19 get better
faster?**

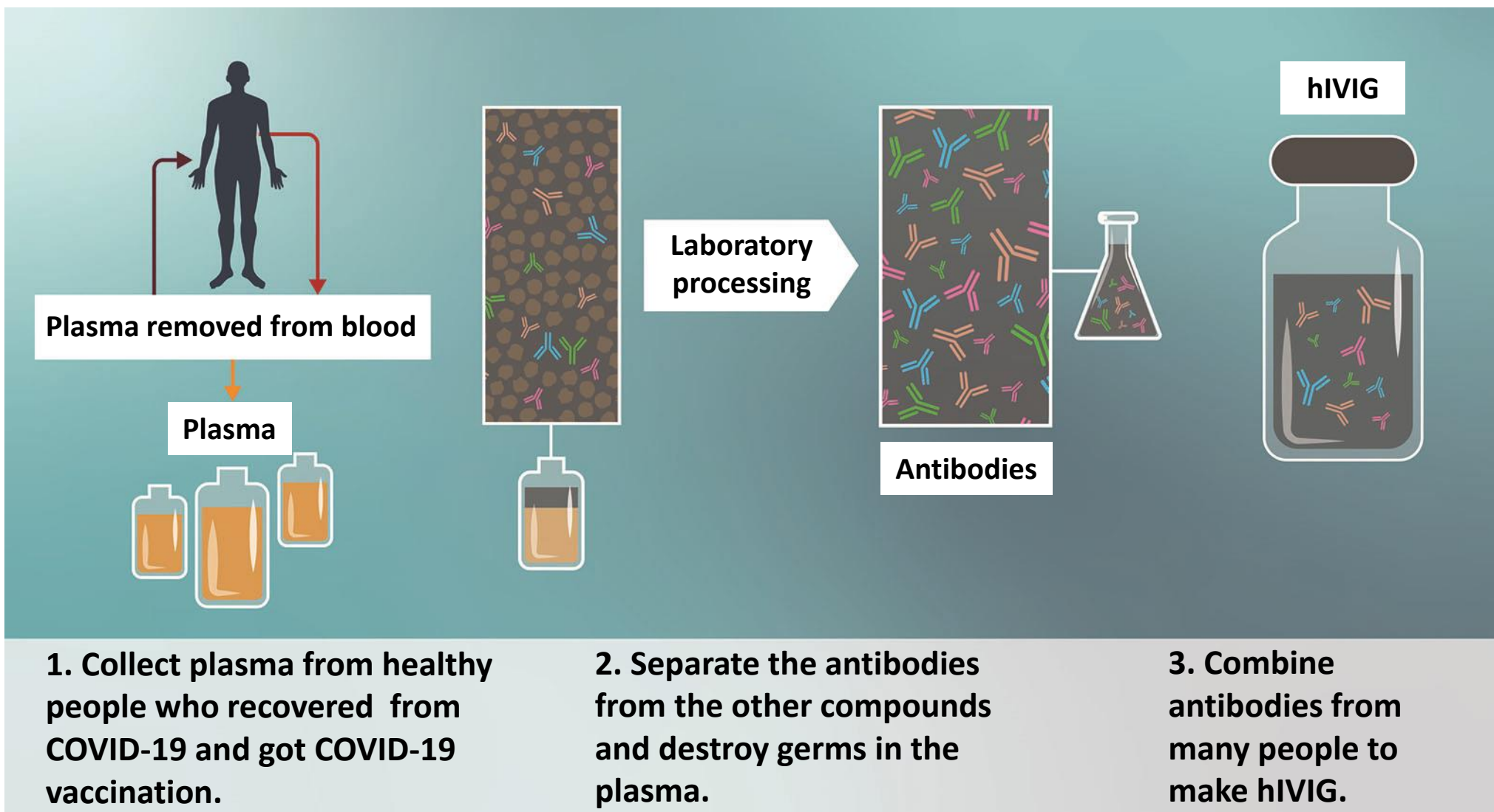
What is this study about?

We are looking for new treatments for patients with COVID-19. We want to find out if the investigational study drug (hIVIG) is safe and will help people stay out of the hospital and have fewer problems with COVID-19.

We expect to enroll at least 820 people around the world.

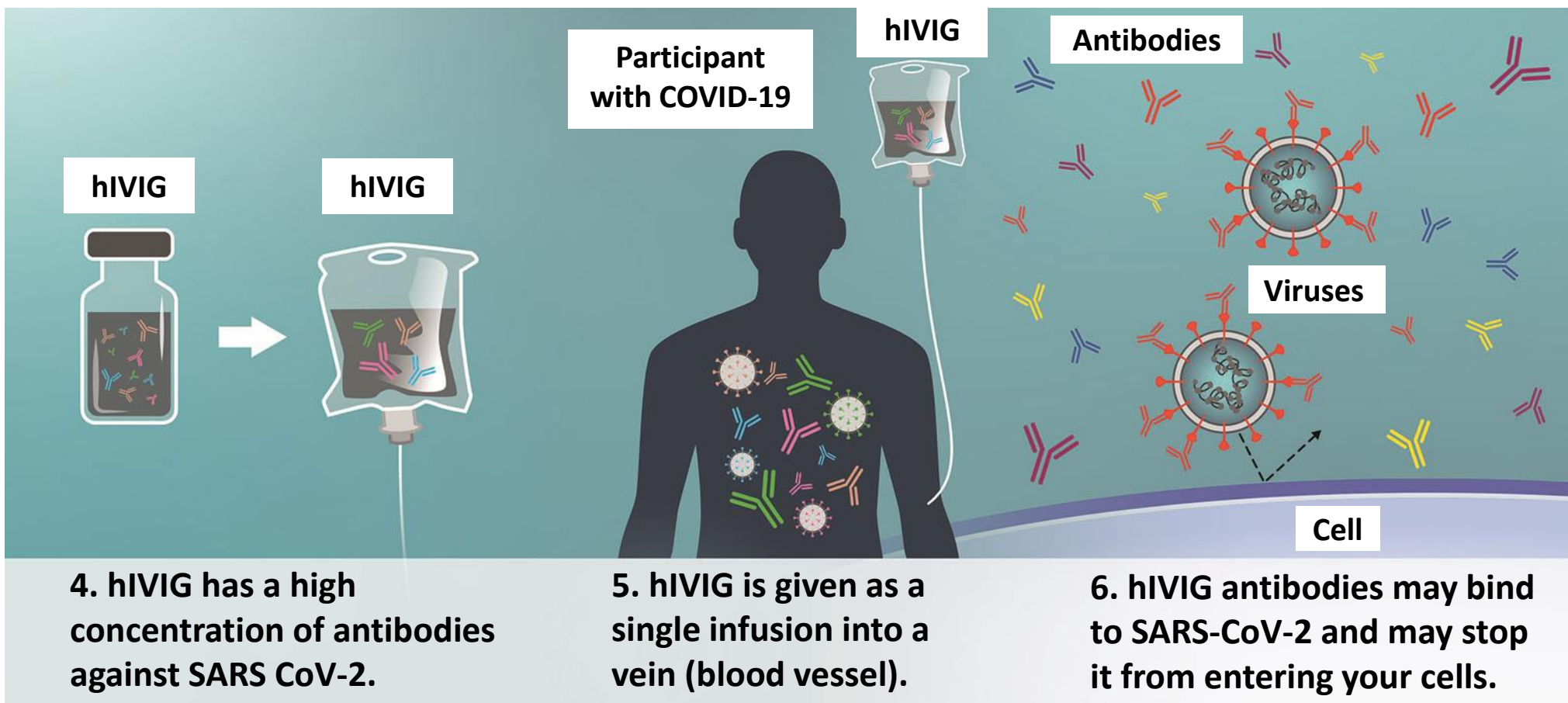
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What drug is being studied?

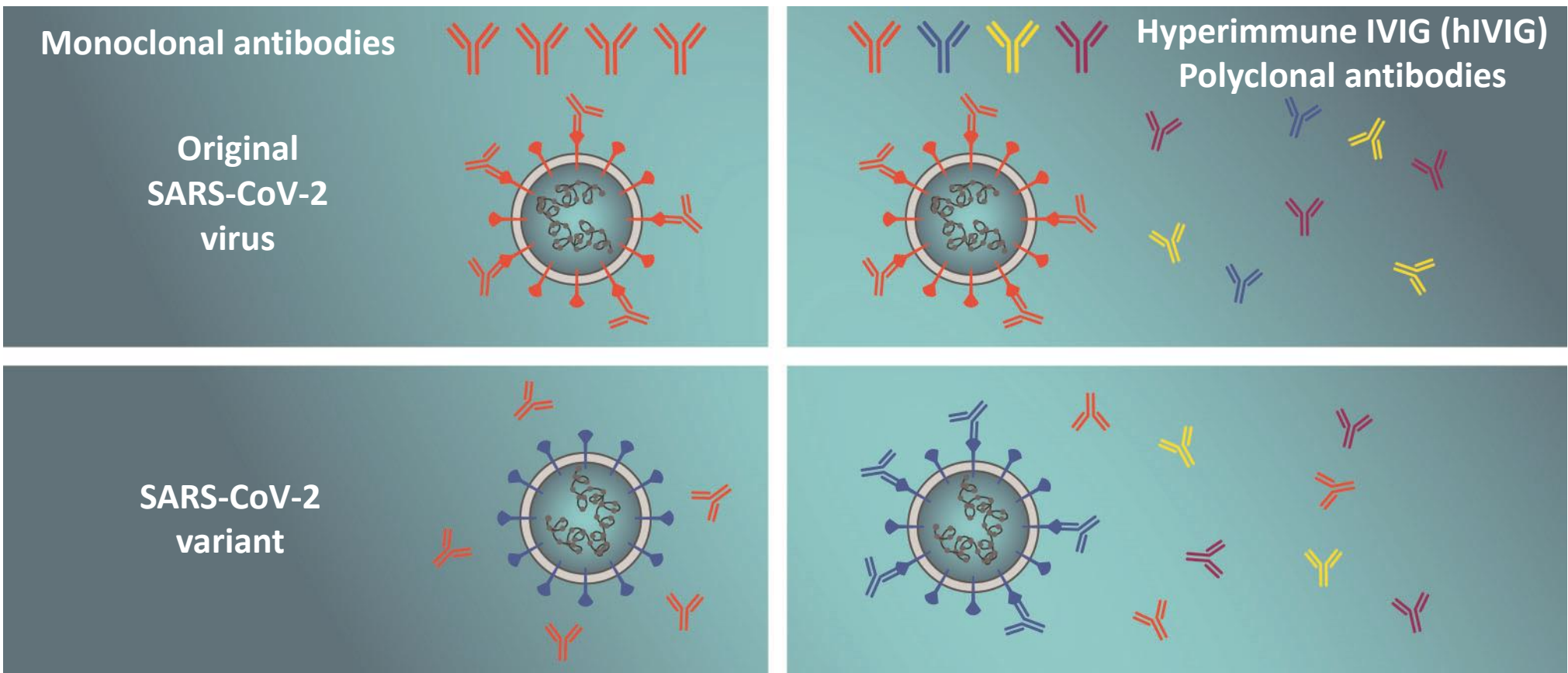
We are studying an investigational drug called hyperimmune IVIG, or hIVIG. It is made up of antibodies against SARS-CoV-2, the virus that causes COVID-19. hIVIG is made by combining and concentrating antibodies from many healthy people who have recovered from COVID-19 and received the COVID-19 vaccination. This means that hIVIG contains a mixture of different antibodies against SARS-CoV-2.



How do antibodies work against COVID-19?

Antibodies are made by your body to help fight disease. When SARS-CoV-2 enters your body, your immune system makes antibodies to fight it. The investigational drug, hIVIG, has high levels of many different antibodies against SARS-CoV-2. We hope hIVIG can help stop the virus from getting into your cells and keep you from getting very ill.

Treatments with “monoclonal” antibodies contain only one or two types of antibody. hIVIG contains many different types of antibodies (called “polyclonal” antibodies) against SARS-CoV-2.

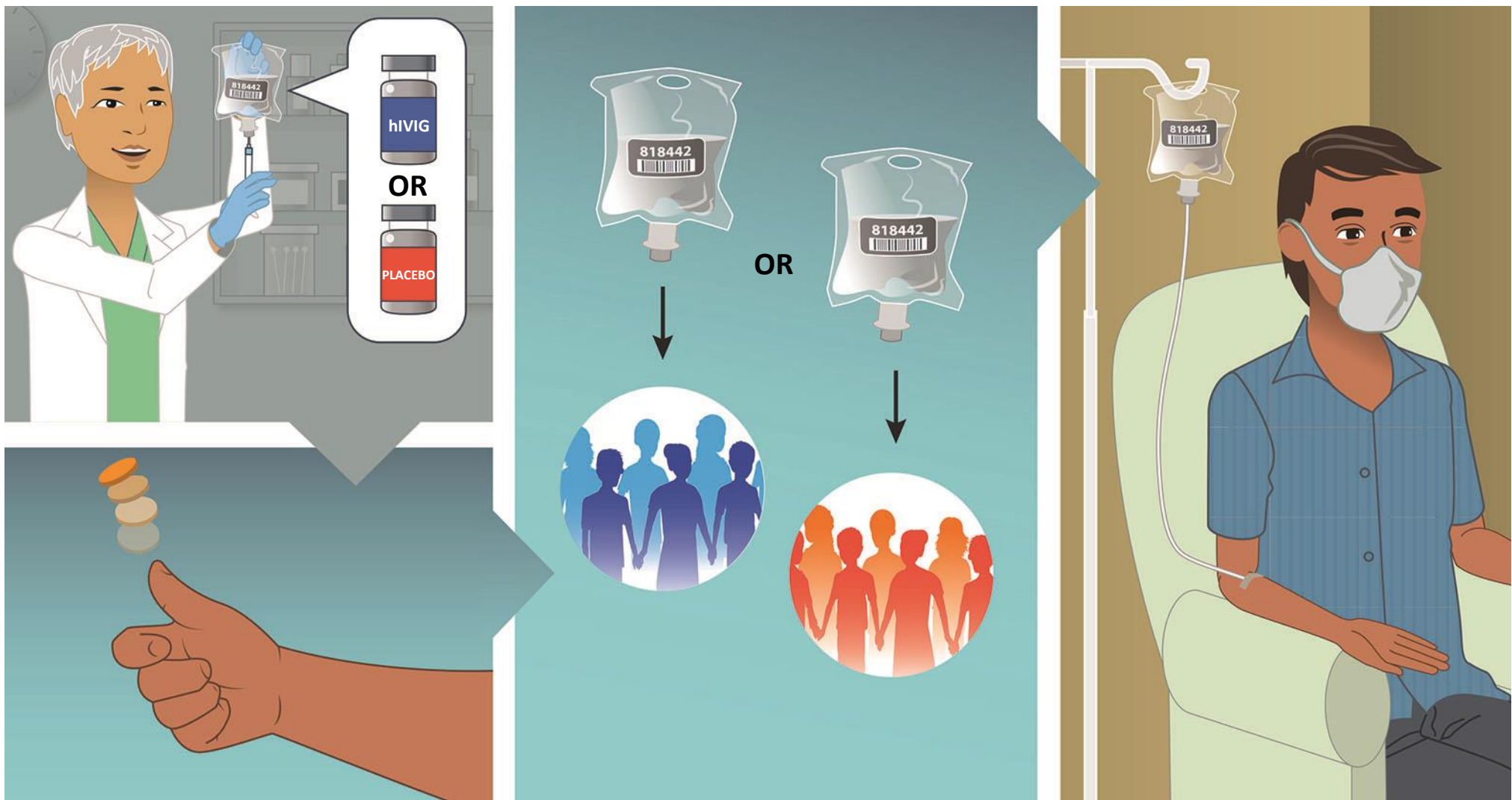


Will hIVIG work against the new viral variants?

New variants of SARS-CoV-2 have developed, and more are expected. Several monoclonal antibody treatments have stopped working against some variants.

hIVIG has antibodies from donors who recovered from COVID-19 and were vaccinated. New hIVIG will be made during the study. This will help the product better match the virus going around at the time each person enters the study. We will use the available hIVIG product that has the most antibodies against the virus that is most common in your area.

We do not know if hIVIG will work against the variants that are now most common. The OTAC study will help us find out if hIVIG works against new variants of the virus.



Does everybody in the study receive hIVIG?

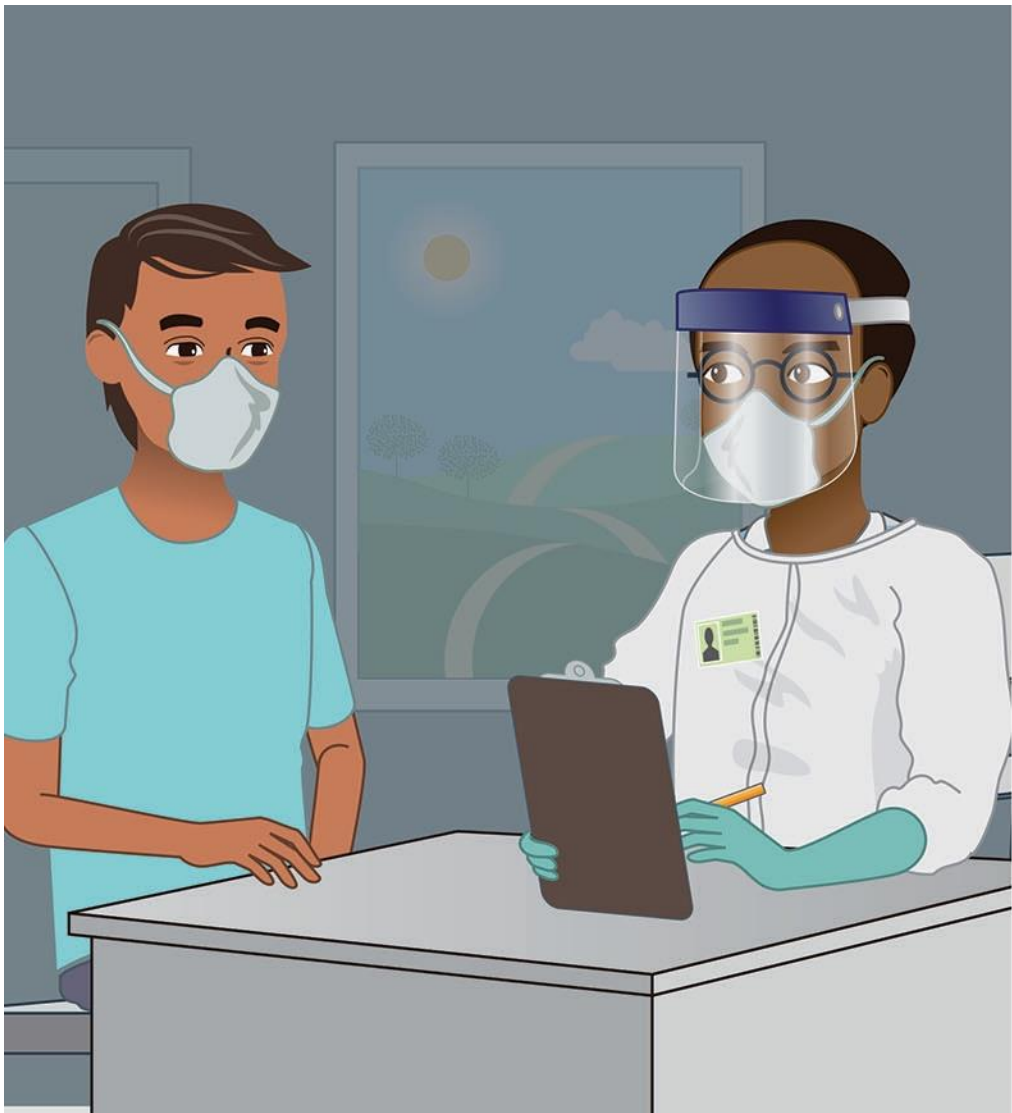
If you join the OTAC study, you will receive either the investigational drug, hIVIG, or inactive placebo. The placebo is salt water that does not have any drug in it.

Whether you get hIVIG or placebo is decided by chance – like flipping a coin. You will have an equal chance (50:50) of getting hIVIG or placebo. Your doctor and the study staff will not decide whether you get hIVIG or placebo. You, your doctor, and the study clinic staff will not know which infusion you are getting.



Will you get standard treatments?

You will be given standard treatment(s) that you would usually receive for COVID-19 as recommended and available in your country. You will receive standard medical care whether or not you decide to be in the study.



What happens if you agree to be in OTAC?

If you sign the consent form, it means you agree to be in the study.

After you sign the consent, we will make sure you qualify, and it is safe for you to be in the study. We will review your past and current health, COVID-19 symptoms, and test results. We will take blood for tests and, if you are able to get pregnant, collect urine to do a pregnancy test.



What does the study involve?

If you join the study, you will get one infusion of either the investigational hVIG or the placebo. The infusion will be intravenous (IV) through a vein in your arm.

The infusion amount will depend on the COVID-19 variants being seen in your area. You will be given the amount that we expect will be needed to fight those variants. The infusion will take between 30 minutes and 3 hours but may take longer depending on the amount and how your body reacts.

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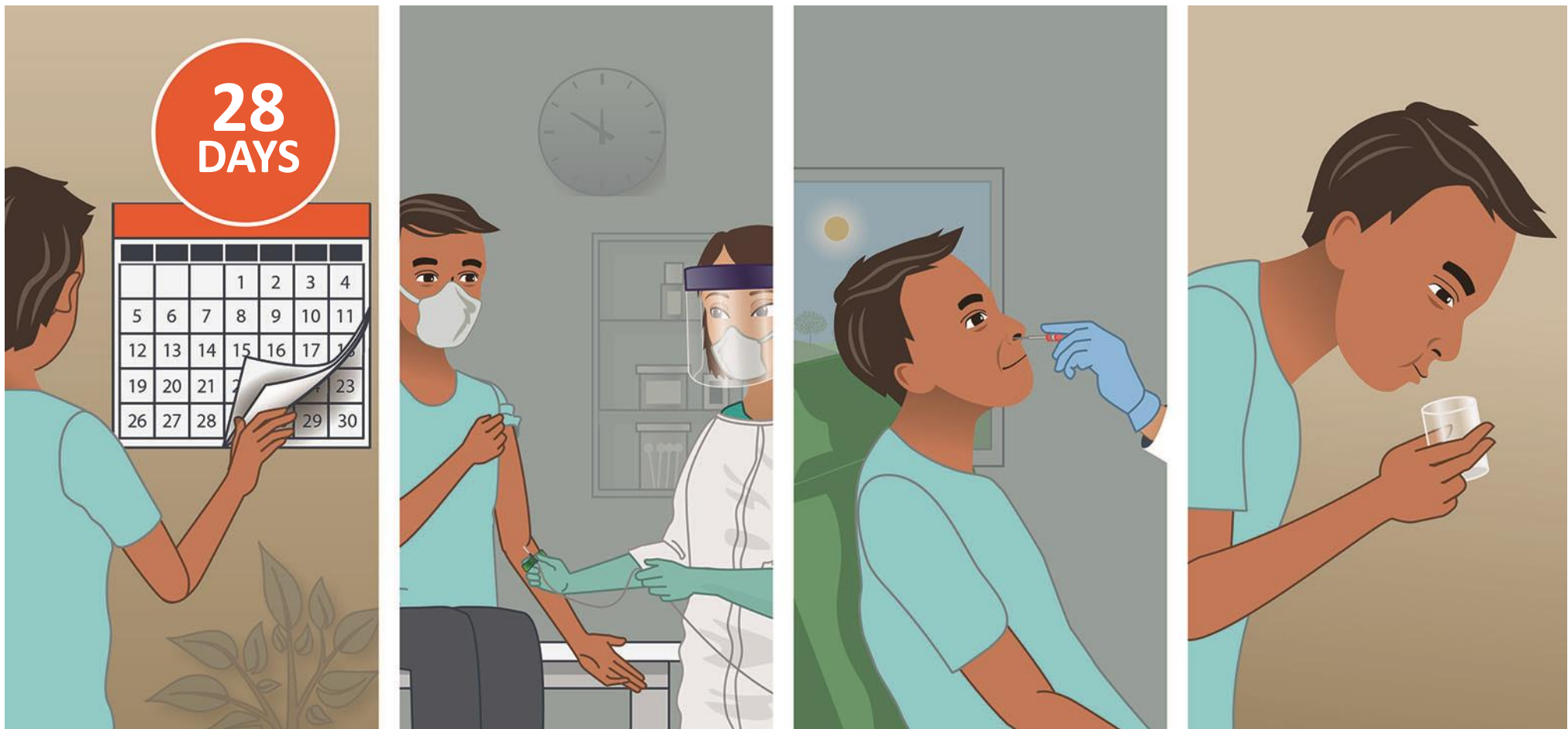
What could be the side effects from the infusion?

IVIg products, like hIVIg, are safe and have been used to treat other diseases over many years. Most people have no side effects. The most common side effects are headache, fever, chills, nausea, vomiting, dizziness, shortness of breath, and a rash. They are usually not serious and go away on their own or with short-term treatment.

Other rare but more serious side effects of IVIg products include blood clots, kidney problems, and fluid overload, especially in patients who have a history of heart failure or kidney disease. A very small number of people getting other types of IVIg for other illnesses had a serious reaction to it, which caused lung injury.

Any drug, including hIVIg, may cause an allergic reaction. Allergic reactions are rare 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 during and after the infusion and treat you right away if you have side effects that bother you.



What else will happen during this study?

You will be in the study for 28 days and have up to 7 study visits. The study visits may take place in the study clinic, at your home, or over the phone.

At each study visit, we will ask how you are feeling and if you have been in the hospital. We will collect blood and saliva samples and do a nose swab 2 times. We will ask you to check and record your temperature and oxygen levels at home. If you have to be hospitalized, we may need to collect information from your medical record.



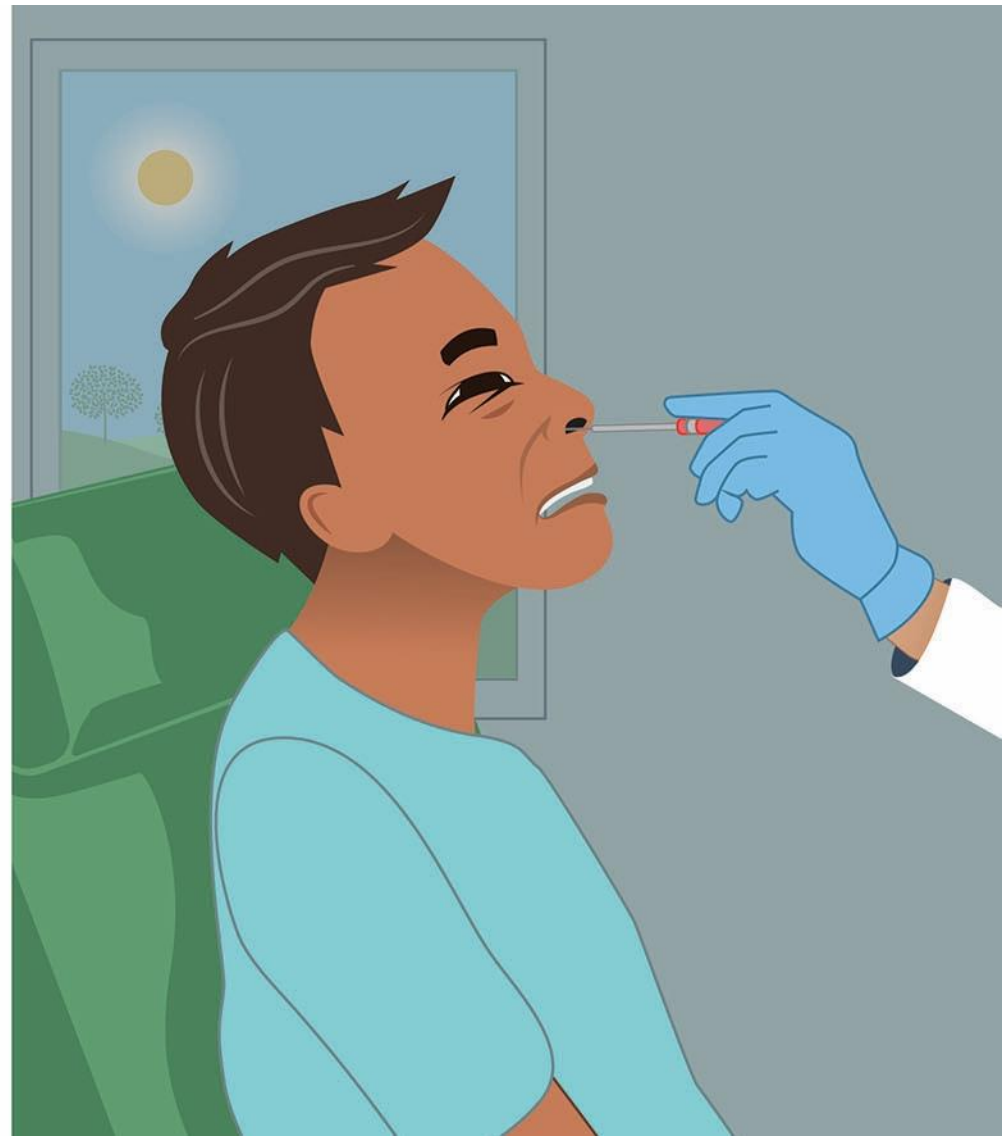
DAILY RECORDINGS		
Date and Time	Temperature	Oxygen Level
AM PM	°C/F	SpO2%
AM PM	°C/F	SpO2%
AM PM	°C/F	SpO2%
AM PM	°C/F	SpO2%
AM PM	°C/F	SpO2%
AM PM	°C/F	SpO2%
AM PM	°C/F	SpO2%



How do you check your temperature and oxygen levels?

We will ask you to check and record your temperature and oxygen levels at home. These are simple procedures. We will provide you with a thermometer and oxygen monitor and teach you how to use them.

We will arrange phone calls with you while you are at home during the first week after your infusion to get the measurements you recorded and check on your health.



Are there any other risks related to this study?

Drawing blood or placing an IV line 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 went into the vein. This could be treated with antibiotics.

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



If it works and is safe, hIVIG may reduce hospitalizations for COVID-19



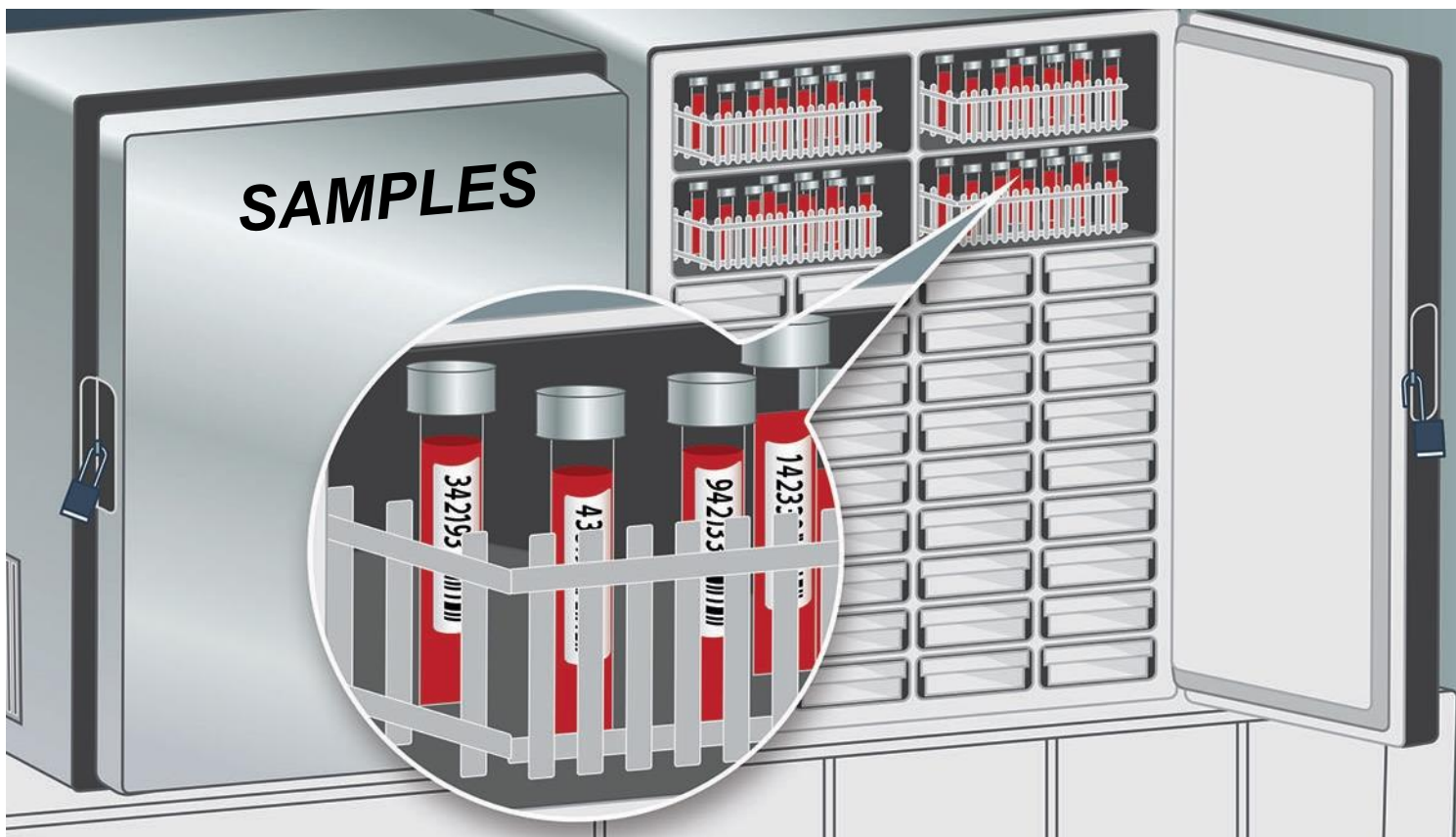
Are there benefits of being in this study?

If you get the investigational drug, hIVIG, it may help you stay out of the hospital and have fewer problems from COVID-19, but we do not know that. It is important to remember that half of the people in this study will get placebo and not get hIVIG. If you get placebo, it will not help you.

By being in this study, you will help doctors learn more about how to treat COVID-19 in people who are at risk for getting severe illness. If hIVIG is shown to be safe and effective, there may be a large health impact.

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Other Information about the OTAC Study

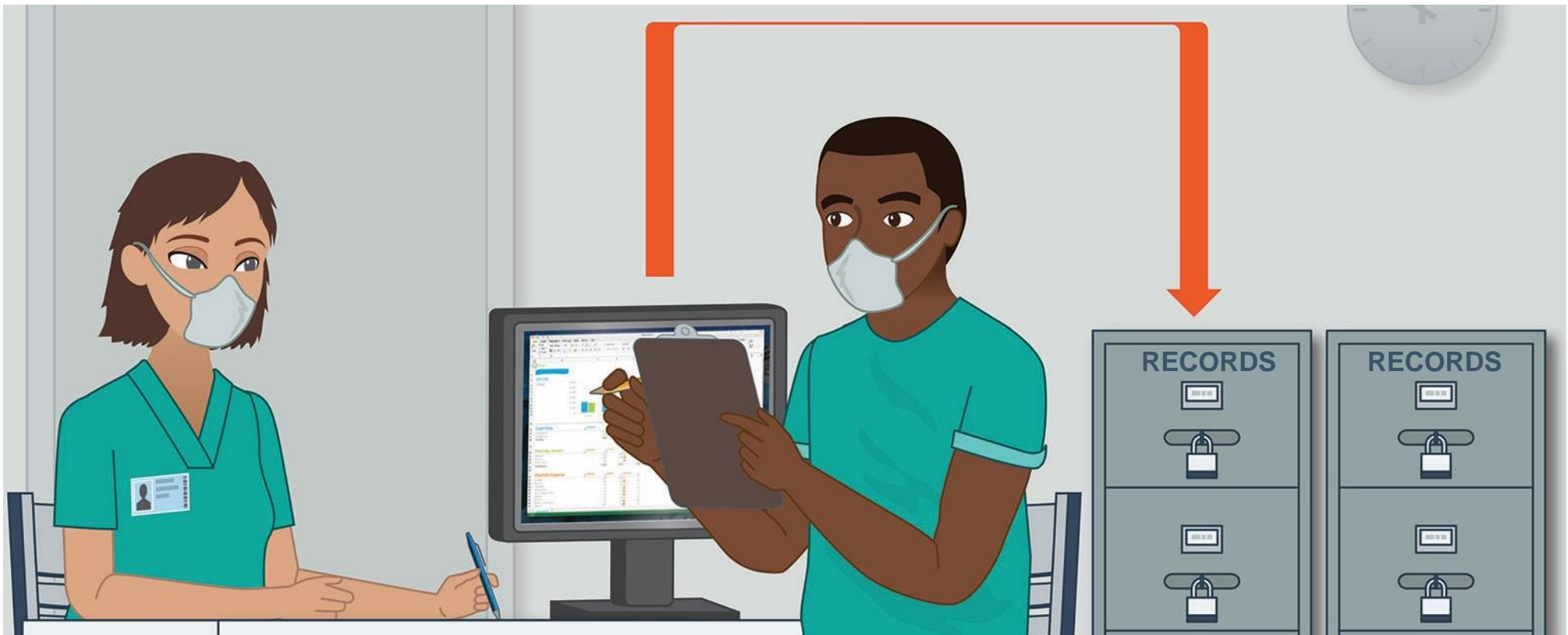


What will happen to your samples and personal information?

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) and your coded blood, nose swab, and saliva samples will be tested and stored in a laboratory in the US. Any unused samples and your coded data will be stored for future COVID-19 research tests.

We will not sell your samples. Your coded study information and samples may be shared with other researchers and the pharmaceutical company that made HIVIG to learn more about HIVIG and COVID-19. 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 samples or study information, please let us know.

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How will your privacy be protected?

Your personal information will be treated with great care. It will only be seen by people who are linked to the study and are required to protect your privacy, such as:

- The ethics committee that protects your rights as a participant in the study
- The US National Institutes of Health, the sponsor paying for the study
- Research staff and staff who monitor the study
- Health agencies in countries where the study is being done, such as the US FDA (Food and Drug Administration).

Your health information and samples will be coded to remove your name and personal details before they leave this study site. Your rights over your samples and data are described in the consent document.

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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.

We will give you the study treatment at no cost. Information about 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.

If you join this study, you will need to agree not to participate in any other COVID-19 study for the first 7 days you are in this study, unless you become sicker with COVID-19 and are hospitalized.

A description of this clinical trial will be available at www.ClinicalTrials.gov and on the European Union Clinical Trials Register (<http://www.clinicaltrialsregister.eu/>).

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**Thank you for considering being in this study!
Together, we can learn how to treat COVID-19!**

Any questions?

