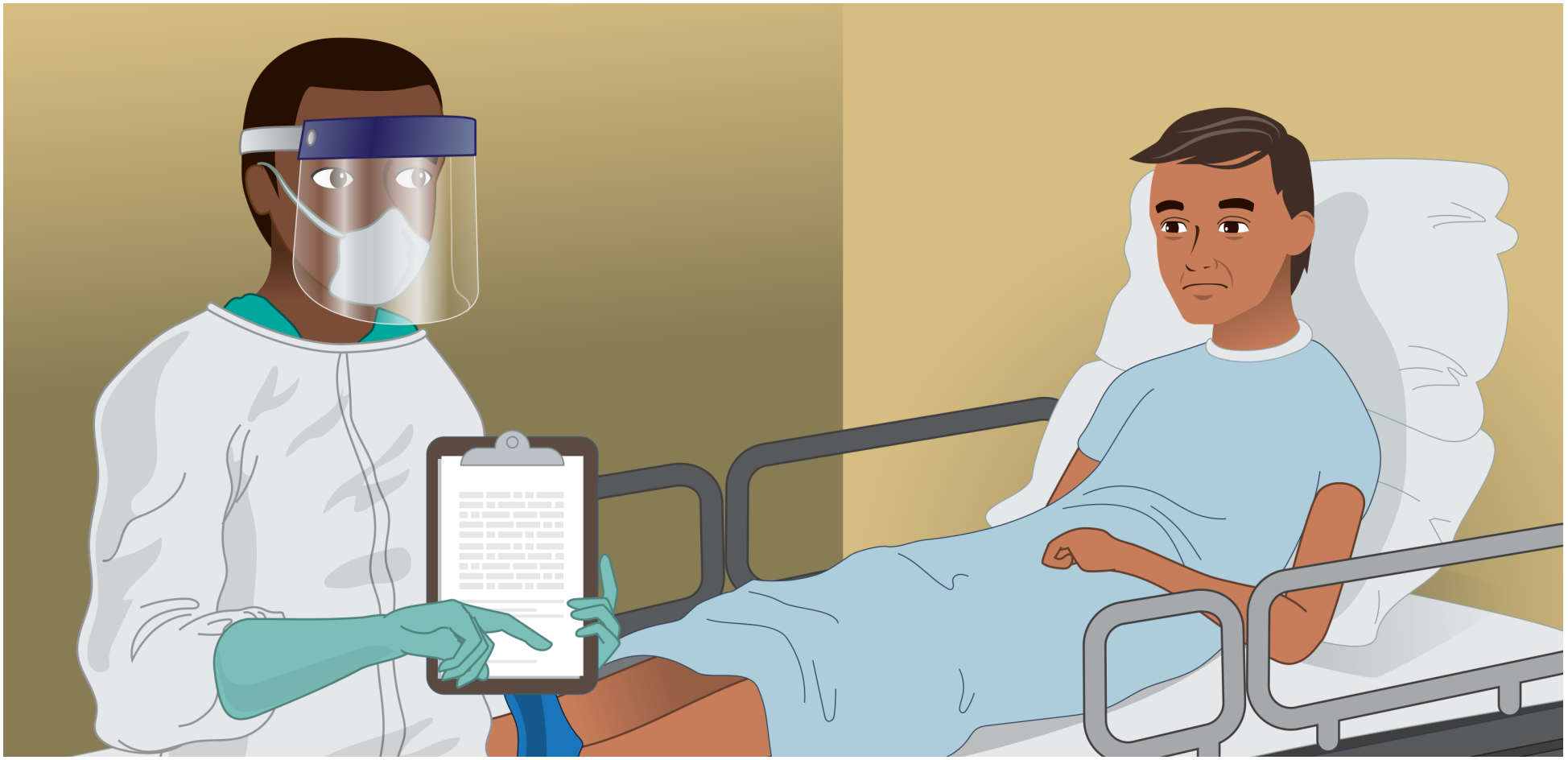
ACTIV 3 Study Information

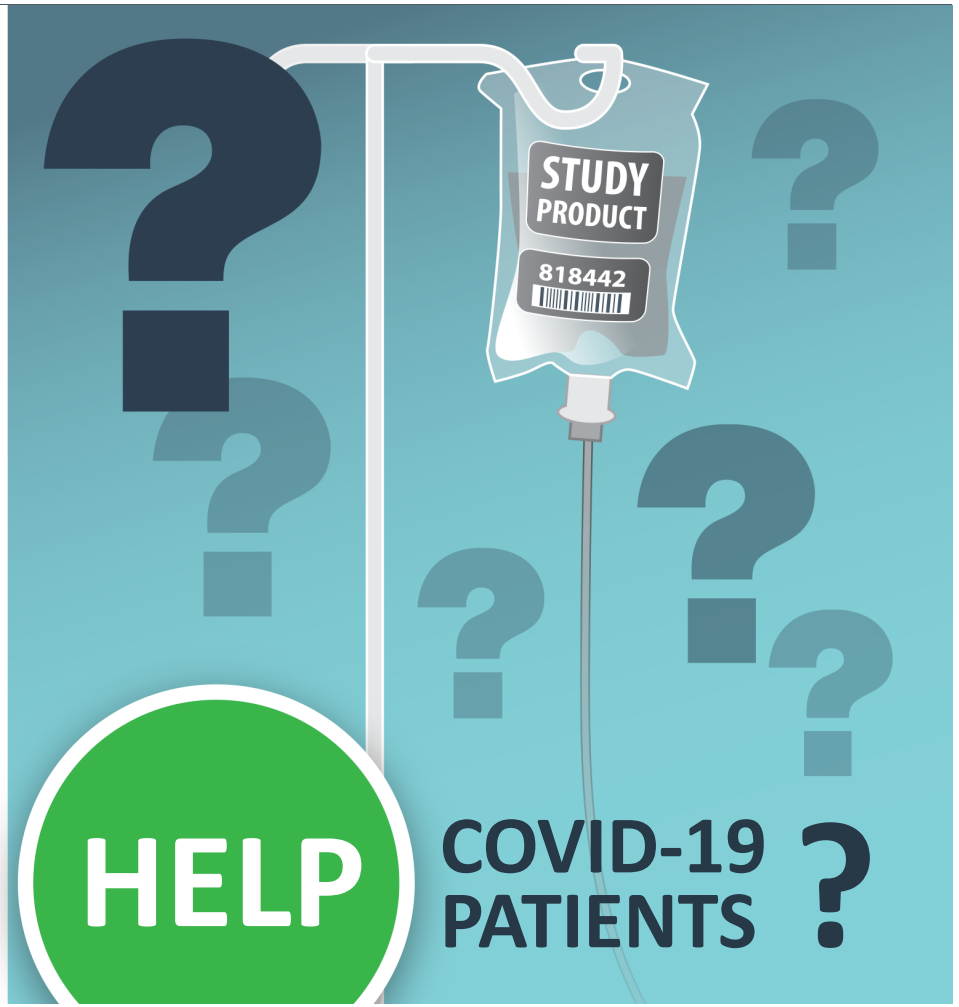


What should you know about this ACTIV 3 study?

- We are talking to you about this clinical research study because you are in the hospital with COVID-19 and you may wish to join.
- 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.

What is a clinical research study?

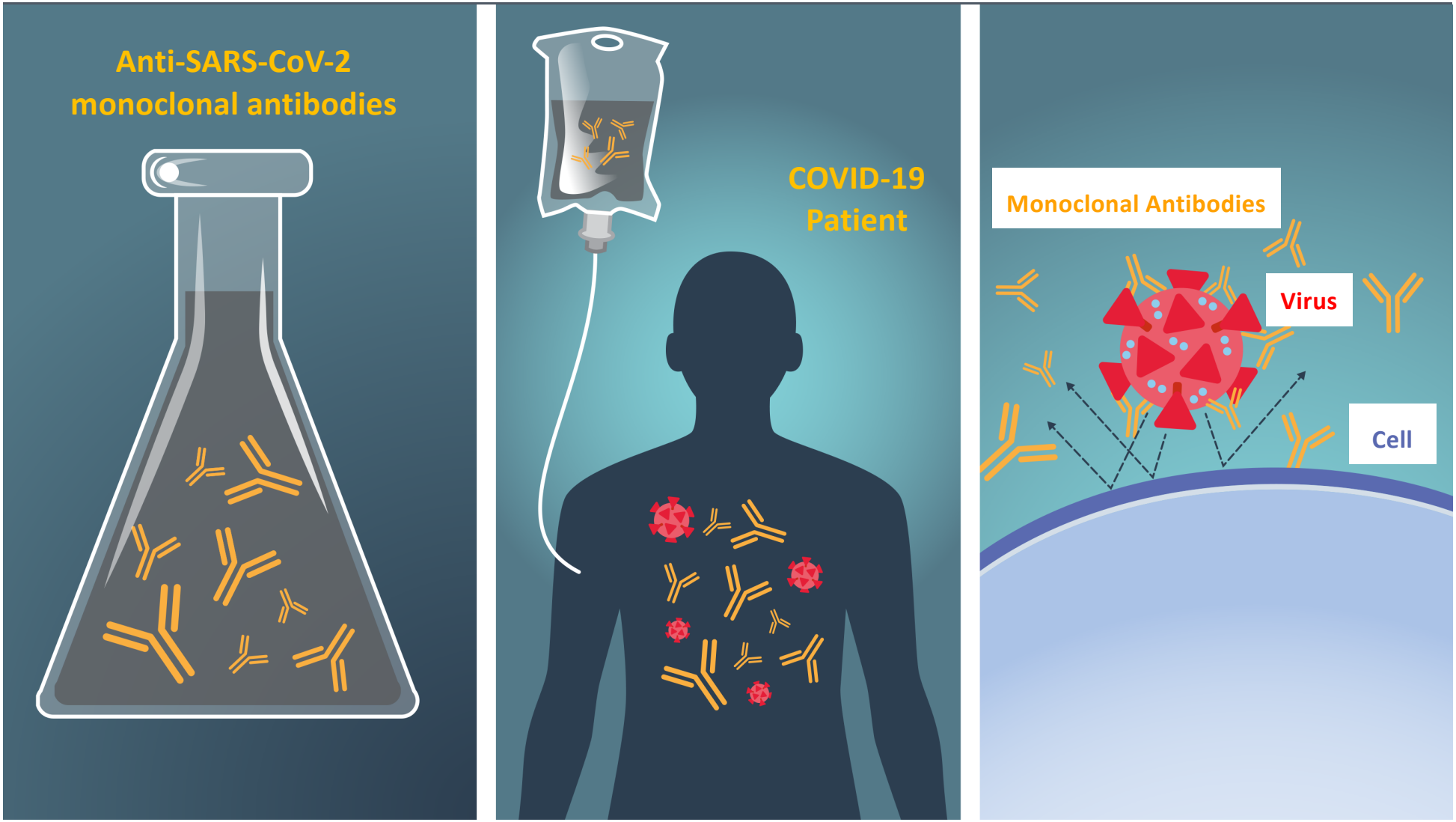
A clinical research study helps doctors find new ways to treat patients with a particular disease. One way to do this is by studying new drugs, to see if they work to treat the disease. In a study, the drugs are "experimental," which means they have not been proven to work. That is why studies are needed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



What is this study about?

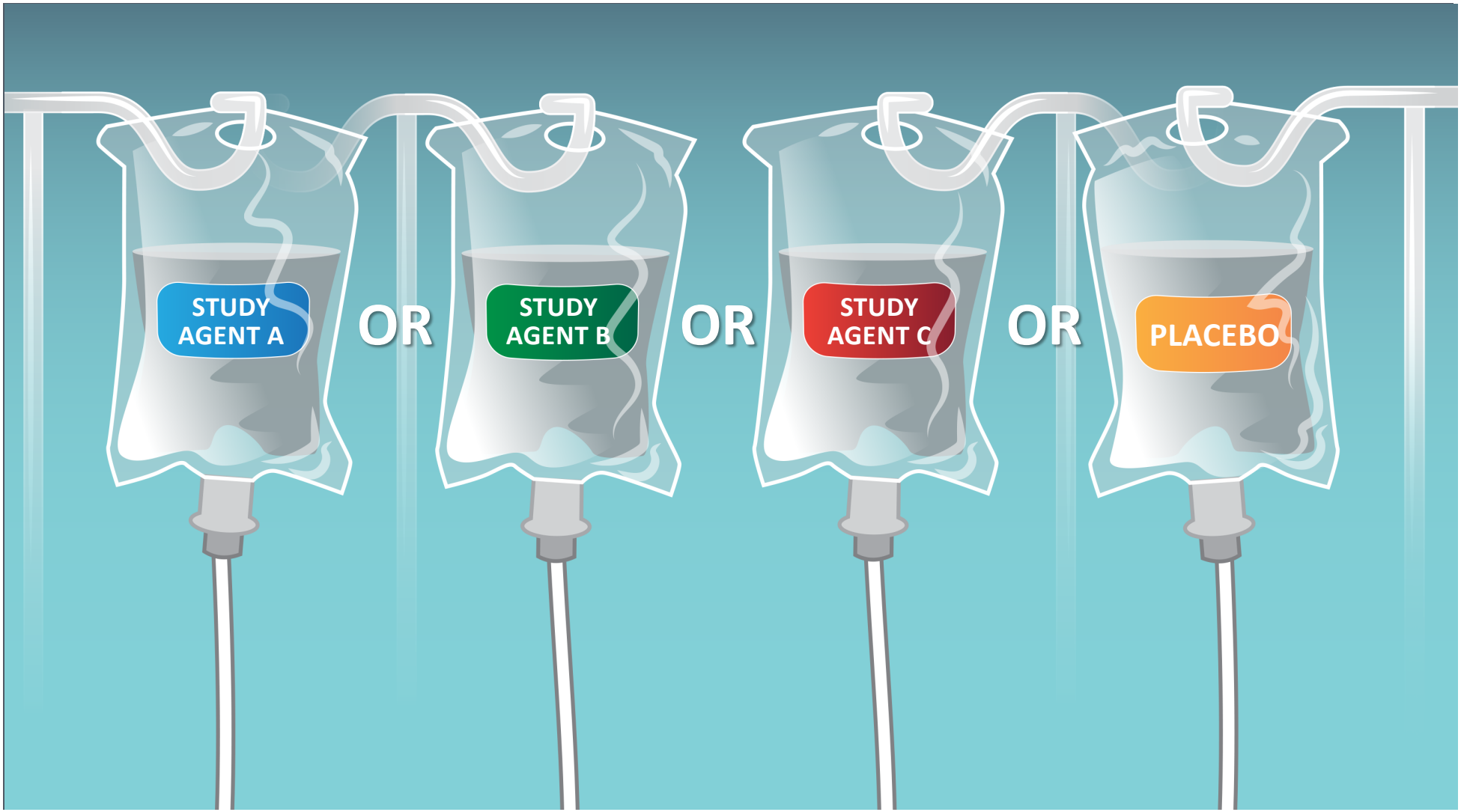
We are looking for new treatments for COVID-19. We are studying experimental drugs to find out if they can help people in the hospital with COVID-19 have fewer bad effects from the disease and go home faster. We also want to find out if they are safe.

This study is taking place in several countries. We expect to enroll about 1000 people around the world.



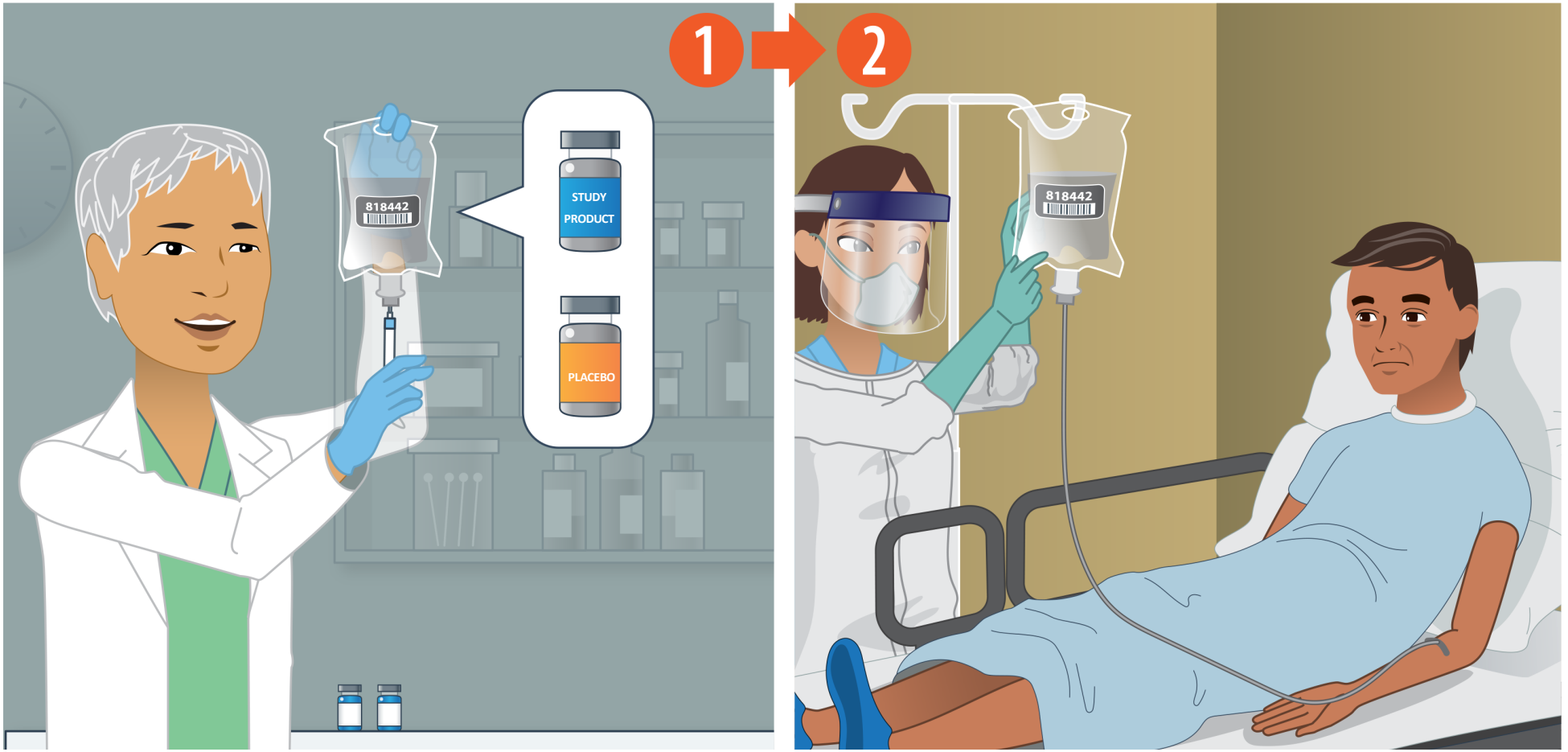
What drugs are being studied?

We are studying three drugs that are monoclonal antibodies. When germs, like the SARS-CoV-2 virus that causes COVID-19, enter your body, your immune system makes antibodies to fight that germ. Monoclonal antibodies can be made in a lab to act like natural antibodies. We hope these monoclonal antibodies can help stop SARS-CoV-2 from entering your cells and help you get better faster from COVID-19.



Does everyone in the study receive one of the study drugs?

Not everyone in the study will receive one of the study drugs. One out of every 4 people in the study will receive a placebo. The placebo is a liquid that looks like the study drug but does not have the drug in it. To find out if the study drugs helps people get better sooner and is safe, we compare them to placebo. Both the placebo and the study drugs are given as an infusion through a plastic tube in your arm.



Will you get the study drug or placebo?

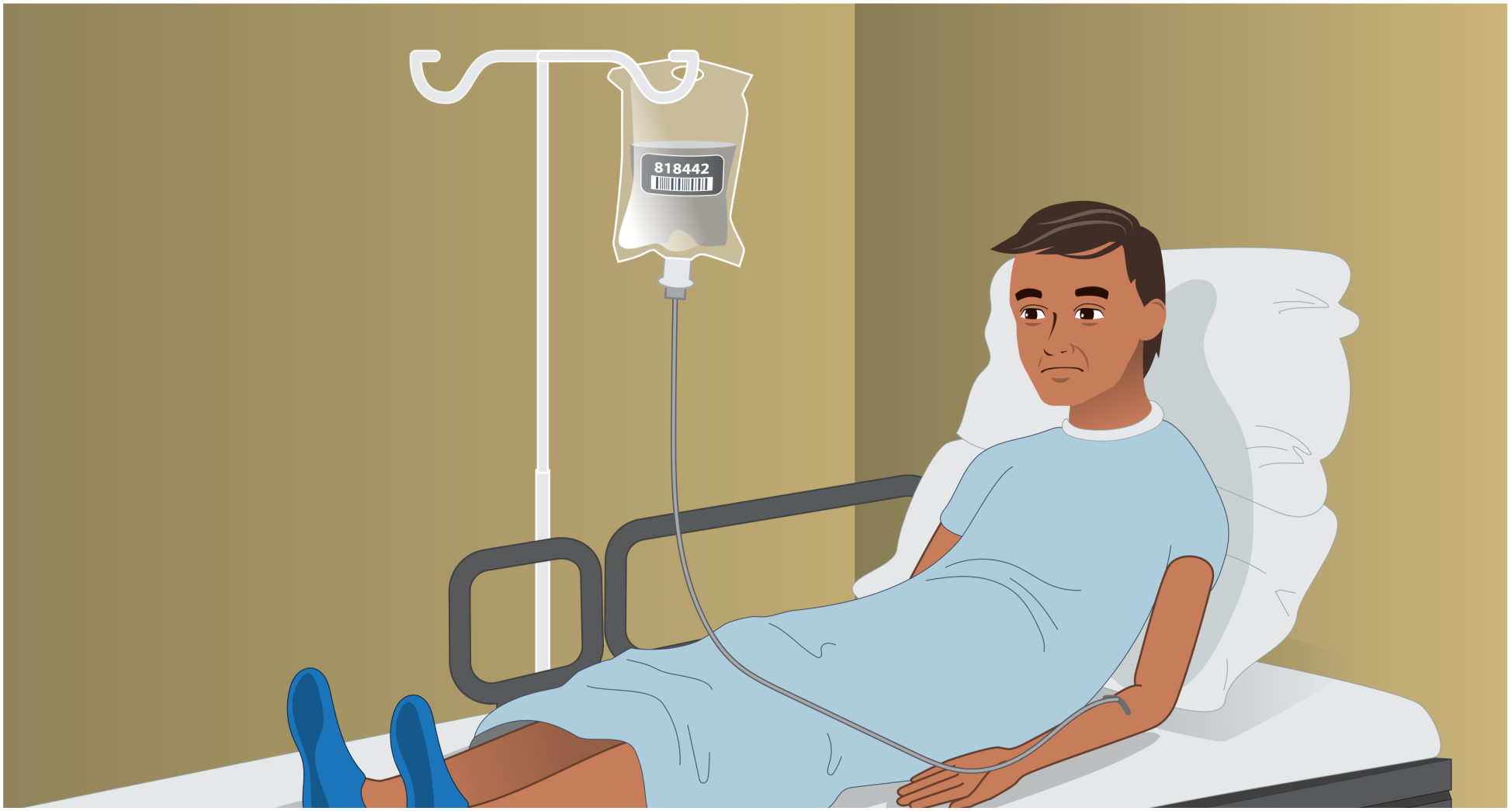
If you join the study, you will be randomly put into either the placebo group or one of the three study drug groups. This is decided by chance. Out of every 4 people on this study, 3 will get a study drug and 1 will get placebo. You and the study staff will not know if you are getting a study drug or the placebo.

All people in the study will also receive a new COVID-19 medicine called remdesivir. Remdesivir has been shown in studies to shorten the length of time people with COVID-19 have to stay in the hospital.

What happens if you agree to be in this study?

If you sign the consent form, it means that you agree to be in the study. If you do choose to join the study, you can change your mind at any time and leave the study. You do not have to be in the study.

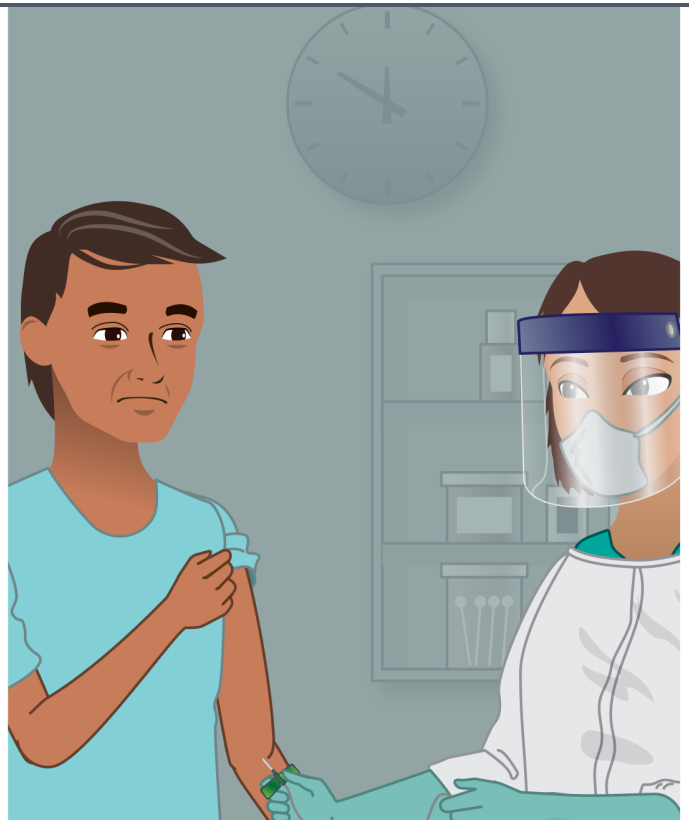
After you sign the consent, we will ask you questions about how you are feeling and look at tests commonly done for COVID-19 to see if you qualify to be in this study.



What does the study involve?

If you join the study, you will get one infusion of either one of the experimental study drugs or the placebo at the beginning of the study. The infusion will take about an hour, but may take longer depending on how your body reacts to the infusion. We will watch you closely for side effects during and for about 2 hours after the infusion.

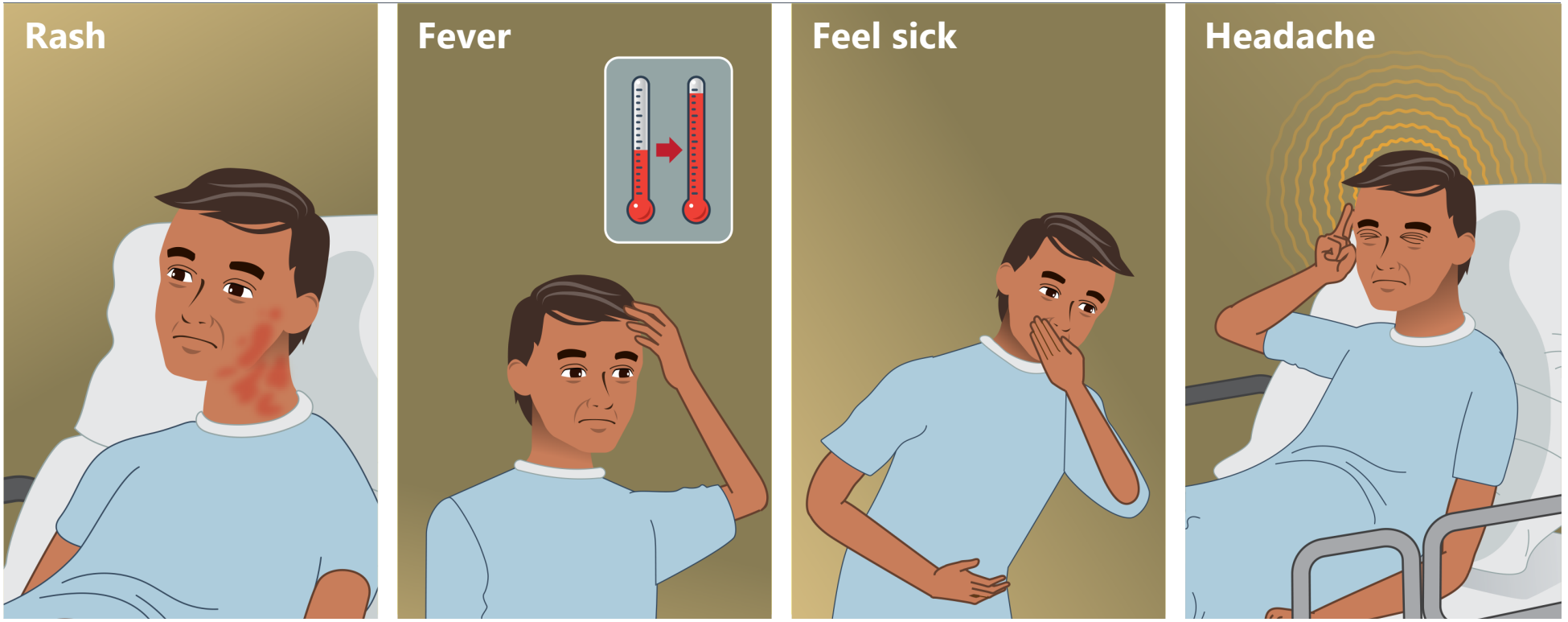
Any other medications or treatments you receive will be medicines you would usually receive in this hospital for your condition, including remdesivir.



What else will happen on this study?

You will be in the study for a total of 18 months. Most of your study visits are in the first 90 days. While you are in the hospital, your study visits will take place in the hospital. After you leave the hospital, the visits may take place in the study clinic, over the phone, or at your home. After 90 days, the study team will call you at 6, 12, and 18 months to see how you are and ask if you have been in the hospital.

During this study, we will collect information from your medical records at the hospital, as well as any other hospital or facility you may be admitted to while you are in this study. We will check your health every day that you are in the hospital. We will ask how you are feeling at each study visit and will ask about medicines you have taken at some study visits. We will collect a blood sample at 6 visits and a nose swab at 1 visit.



What could be the side effects from the infusions?

There may be side effects from either of the three study drugs or the remdesivir. Side effects of these drugs have occurred in other studies and can be severe and/or life threatening, but they are uncommon. The study team will monitor you and provide treatment for side effects.

Side effects seen in people receiving monoclonal antibodies include: chills, itching, rash, headache, fever, feeling dizzy, a fast heart rate, difficulty breathing, and changes in some laboratory tests that measure blood cell counts.

The most common side effects of remdesivir are: abnormal liver function test results, abnormal blood clotting test results, constipation, nausea, vomiting, decreased appetite, and headache.

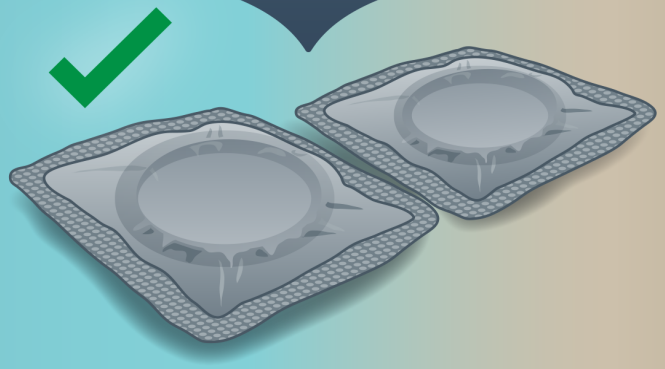
The study drugs and the remdesivir may also cause an allergic reaction. Allergic reactions are rare but can be serious. Allergic reactions can be treated by slowing or stopping the infusion and giving medicine like Benadryl.

Are there other risks or discomforts related to this study?

The needle used to draw blood or place 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 swab can cause pressure and discomfort. It can also cause a nosebleed.

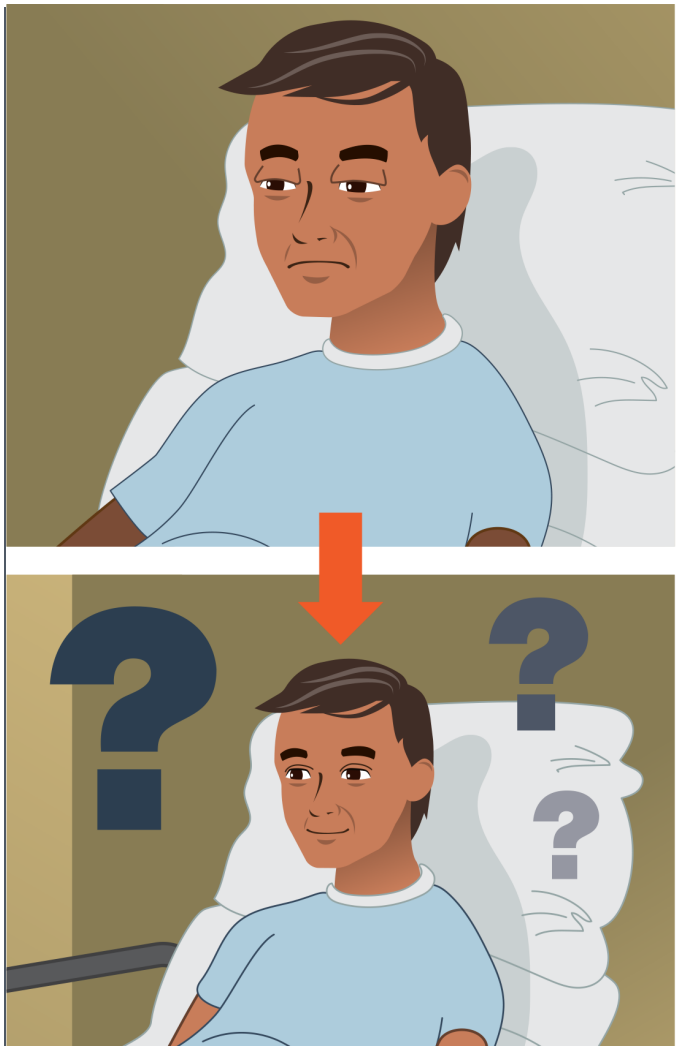
18 MONTHS



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

Women, if you are pregnant or breastfeeding, you cannot join this study. If you are of the age where you can get pregnant and you join the study, you should use contraception while you are in the study.

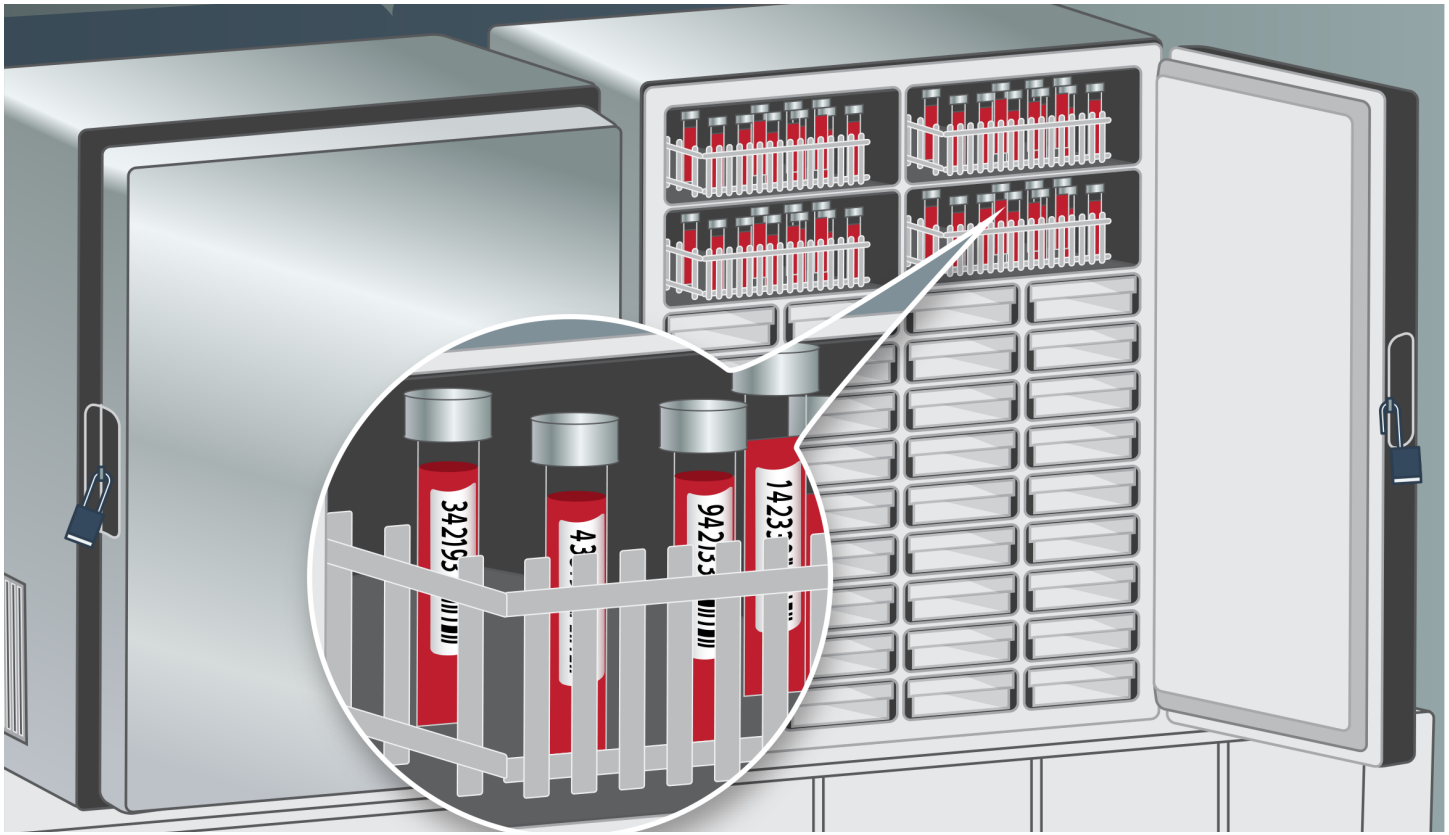
Men, you should use contraception if having sex with a woman who can get pregnant while you are in the study. If your partner is pregnant, you should abstain from sex or use a condom.



Are there benefits of being in this study?

If you get one of the study drugs, it may help you get better and go home faster, but we do not know that. The study drug may not be helpful, or it may have harmful side effects. It is important to remember that 1 of every 4 people in this study will get placebo and will not get one of the study drugs. If you get placebo, it will not help you.

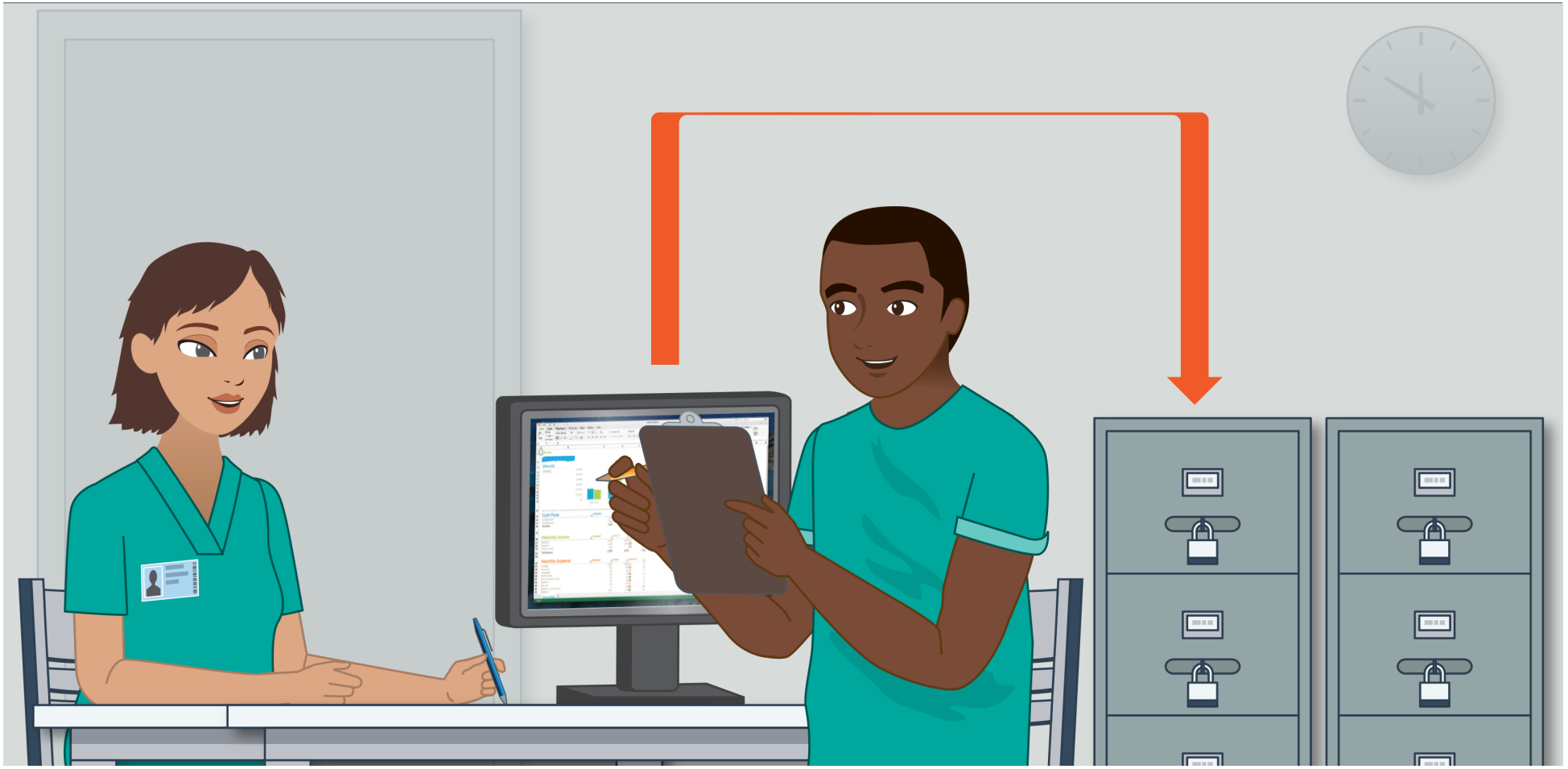
By being in this study, you will help doctors learn more about how to treat COVID-19 in people in the hospital. If the study drug is shown to be safe and effective there may be a large health impact with many lives saved.



What will happen to your samples and personal information?

Your samples and study information will be marked with a code. Your name and personal details are never used. Your coded information is sent to the University of Minnesota in the US. Your coded blood and swab samples will be sent to the ACTIV-3 laboratory in the US for testing and storage. The samples will be stored for many years and used for future COVID-19 research.

You and your doctor will not get results from these research tests. We will not sell your samples. Some of your coded study information and samples may be shared with other researchers and the pharmaceutical company that made the study drug, to help learn more about its effects. If you change your mind and decide you do not want us to store your samples or study 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 get it. The following people 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); other study research staff and study monitors; the regulatory agencies from the US (Food and Drug Association) 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?

- If you join this study, you should wait to get a vaccine against the virus that causes COVID-19 for at least 90 days after you receive the study drug. This is because the study drugs may change the way your body responds to the vaccine. It is also possible that any effects could last longer than 90 days, but we do not know if they will.
- We will ask you for an additional contact in case we cannot reach you after you leave the hospital.
- We will give you the study treatment at no cost. Information about hospital and other costs related to your illness is given in the informed consent document.
- Details about what will happen if you are hurt because of this study are given in the informed consent.
- A description of this clinical trial will be available at www.ClinicalTrials.gov, and on the EudraCT website (eudract.ema.europa.eu).