

# UNDERSTANDING THE ACTIV-2 STUDY: SNG001 (INHALED INTERFERON- $\beta$ 1A)

## PART 1

For adults  
diagnosed with  
COVID-19



TEST. JOIN. RISE ABOVE.

**RISE**  
**ABOVE**  
**COVID**

# WHAT IS THE ACTIV-2 STUDY?

The ACTIV-2 Study is testing different investigational medicines to see if they are safe and can help adults with COVID-19 who are not in the hospital.

One investigational medicine being studied is a combination of 2 drugs called **SNG001**. This type of medicine is called an **immunomodulator**. SNG001 is made in a lab, but contains a protein that is naturally found in your body to help fight diseases. It's designed to activate your immune system against the virus that causes COVID-19.

## Researchers want to see if the medicines:



Are safe for those who need them



Can help people get better faster



Can get rid of the virus



Can help keep oxygen levels up



Can keep people from getting sicker



Can prevent people from having to go to the hospital

ACTIV2-SNG-MF-En

ACTIV-2 Study - Study Welcome Guide & Schedule  
(inhaled interferon- $\beta$ 1a-Part 1) - Protocol Version 3.0 -  
11-Mar-2021 - English (Master) - V2.0

# THANK YOU FOR JOINING THE ACTIV-2 STUDY.

By being in the study, you can be a part of the solution to fight COVID-19 by helping researchers to find treatments. Finding treatments is important because the virus is spreading quickly all over the world and can cause serious sickness and even death.

Being in the study is completely voluntary and if you change your mind, you can leave the study at any time.

Contact the ACTIV-2 study team for any questions you may have.

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## The study is for adults 18 years and older who:

- Tested positive for COVID-19 (no more than 10 days ago)
- Are at home (not in the hospital)
- Have had at least 1 COVID-19 symptom within the past 8 days and still have at least 1 in the last 24 hours:

- » Body pain or muscle aches
- » Chills
- » Cough
- » Fever
- » Headache
- » Loss of taste or smell
- » Nausea or throwing up
- » Diarrhea
- » Sore throat
- » Stuffy or runny nose
- » Tiredness
- » Trouble breathing
- » Feeling “out of breath”

# WHAT HAPPENS DURING THE STUDY?

The study lasts about **24 weeks (6 months)**. You will have visits with tests to check on your health. You will also have phone calls or video chats with the researcher from your home.

There may be 2 parts to the study, Part 1 and Part 2. You are in Part 1.

Screening	Entry visit	Study visits
1 visit or phone call	1 visit	9 visits or phone calls



## Screening

If you agree to be in the study, you will give your permission by signing the **informed consent form**. You will then answer some questions to make sure the study is right for you.



## Entry visit

You will have a visit for tests and to be placed in a group to receive study medicine or placebo.

## Schedule of visits

D3

D7

D14

D - DAY | W - WEEK

# WHAT STUDY MEDICINE WILL I TAKE?

At the Entry visit, you will be placed by chance into a group to receive either the study medicine SNG001 or placebo.



A placebo looks like the real drug but doesn't have any actual medicine in it. This gives researchers something to compare the study medicine to. If a standard treatment for COVID-19 is found during the study, that treatment will be used instead of placebo.

You and the researcher will not know which group you are in until the end of the study. This helps to keep things fair.

# HOW ARE THE MEDICINES AND PLACEBO GIVEN?

SNG001 and placebo are inhaled (breathed in) through a nebulizer. The study team will show you how to take it. You will take your treatment (medicine or placebo) once a day for 14 days. Each treatment will take about 2 minutes. Try to take it about the same time every day.



A **nebulizer** changes medicine from a liquid to a mist so that you can breathe it in (inhale) more easily into your lungs.

D 28

W12

W24

W36

W48

W72

Some visits may take place at the clinic, at your home or at another location, and others may take place over the phone.

# WHAT TESTS WILL I HAVE?

Inside this brochure is a summary of tests to expect at study visits. You may not have all of these tests at each visit. Speak with the study team to learn more.

You will do your own **nose swabs** at visits and at home. The study team will teach you how and let you know when you need to do them.

# IS THERE ANYTHING ELSE I WILL HAVE TO DO?

The study team will give you a diary that you will write in at home at the same time every day for the first 28 days. Use the diary to keep track of:

- Your symptoms
- Your temperature
- Any medicines you are taking for COVID-19
- If you went to the Emergency Room
- Day and time you do each nose swab

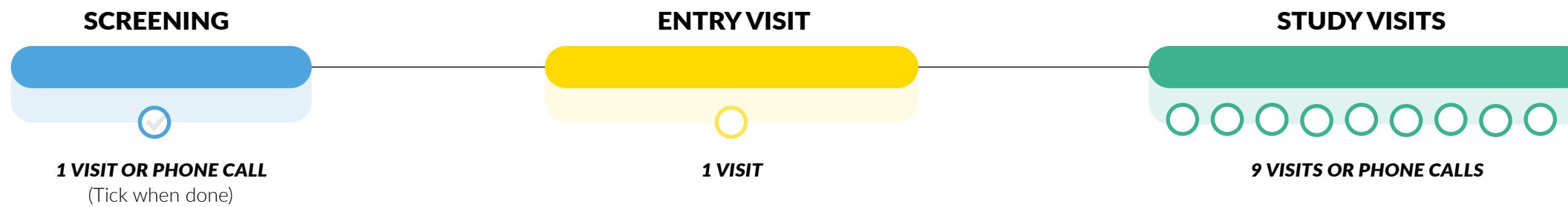
The study team will send you reminders by phone, text, or email.

You will also receive a **treatment journal** to keep track of when you take SNG001 or placebo.



## SUMMARY OF HEALTH CHECKS AND TESTS

You may not have every test at each visit.



Sign informed consent



Blood pressure (if in-person)



Checkup (if in-person)



COVID-19 symptom check



Heart rate (if in-person)



Medical history



Medicines you take



Oxygen levels (if in-person)



Pregnancy test



Temperature



Weight (if in-person)



Take study medicine or placebo



Blood pressure



Blood test



Checkup



COVID-19 symptom check



Deep nose swab



Heart rate



Medical history



Medicines you take



Nose swab



Oxygen levels



Temperature



Take study medicine or placebo (every day for 14 days)



Blood pressure



Blood test



Checkup



COVID-19 symptom check



Deep nose swab



Heart rate



Nose swab (every day for first 14 days)



Oxygen levels



Pregnancy test (if needed)



Temperature

## GLOSSARY OF TESTS:



**Blood pressure:** This measure how your heart is pumping and how blood is flowing through your blood vessels. The researcher or nurse will wrap a cuff around your arm that gently squeezes it.



**Blood test:** Small samples of blood will be taken to look at types of blood cells and how different parts of your body, like the liver and kidneys, are working. These tests can also measure the amount of study medicine in your body and how your body may be responding to it.



**Checkup:** The study team will check your overall health, including weight, temperature, heart rate (pulse), blood pressure, and oxygen levels.



**COVID-19 symptom check:** The study team will ask you about any COVID-19 symptoms you have and if they are getting better or worse. You will also keep track of your symptoms in your study diary for the first 28 days.



**Deep nose swab:** This is called a nasopharyngeal swab, or NP swab. The study team will insert a swab that goes deep through your nose toward the back of your throat. This test can detect the virus that causes COVID-19.



**Heart rate:** The study team will check the rate of your heartbeat by taking your pulse at the wrist for 1 minute.



**Informed consent:** You will be given a document that contains all the information about the study. Read through it and ask any questions you may have. If you agree to be in the study, you will give your permission by signing an informed consent form.



**Medical history:** The study team will discuss and review your current and past health, including any medical conditions, surgeries, or medical procedures you may have had. You will also be asked if you smoke or have ever smoked before.



**Nose swab:** The study team will teach you how to take your own nose swab. You will be given swabs that you will put in each nostril about 1 inch deep and rotate 5 times to collect a sample.



**Oxygen levels:** The study team will put a small device that clips onto your finger. This device can measure that amount of oxygen in your blood and how well it is being carried from the heart through the blood to the parts of your body.



**Pregnancy test:** Females who are able to become pregnant will have their blood or urine tested for pregnancy.