

2024 New Study

If your Doctor say that you have RSV you may qualify

# Shine a light on potential new treatments for RSV

# The SHINE-HR clinical trial

For people with RSV infection

www.chearcenter.com

Please take one to learn more.

# If you qualify you will receive:

+ Free Transportation
+ Free Care
+ Free Study medication
+ up to \$109.00 per visit
+ up to 8 visits in 5 weeks

# Interested Call / Text: 718 600 1679 CHEAR Center Clinic

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384 East 149th Street, Suite 205, Bronx NY 10455

# Tomorrow's breakthroughs start today with you

Participants in this clinical trial will receive care from a team of specialists and contribute to research on RSV infection that may help protect more people from severe illness caused by this virus.

Your participation in a clinical trial can help advance a potential medicine for people with RSV infection across the globe. So, thank you for taking the time to learn more.



# Your safety and rights as a participant

Your safety is the top priority of this clinical trial.



Regulatory agencies and institutional review boards (also known as independent ethics committees) ensure that participants' rights, safety, and well-being are protected.

Your health may get better, get worse, or stay the same. If your health gets worse, your trial team and your trial doctor will help you decide what to do, which may mean stopping your participation in the trial.

Potential benefits from taking part in the trial may include:

- The study medicine might reduce your chances of getting very ill from an RSV infection
- Your health will be closely monitored during the trial
- Participation may help people in the future by increasing our understanding of the study medicine and RSV infection

Potential risks from taking part in the trial may include:

- Feeling sick and/or vomiting
- Diarrhea
- Stomach pain

### **Clinical trials are voluntary**

Taking part in a trial is your choice. You are free to stop being in this trial at any time and for any reason.

If you decide to stop being in the trial, which you can do at any time, please tell the trial team and your doctor so that you can end participation in the safest way. Your decision will not affect your regular medical care or any benefits to which you are entitled.

# The basics of clinical trials

Clinical trials are a type of medical research in which people volunteer to take part.

All medicines that become available today for use in people are first tested in trials involving hundreds to thousands of volunteers. Clinical trials gather knowledge about medical conditions and the *investigational* or study medicine that is being researched, such as:



Is the potential medicine safe?



Is the potential

medicine

effective?

#### Help advance research

By choosing to take part in the SHINE-HR clinical trial, you can help make a difference for people with RSV infection.

# *Investigational* means that the study medicine has not yet been approved for use in patients with RSV infection.

This means it is not available to patients with this condition except to those who are participating in a clinical trial.

## About the RSV clinical trial

This RSV trial will help us learn if a study medicine is safe to use in people with RSV infection who have other health risks, and if it can prevent them from getting seriously ill because of RSV.

The study medicine is thought to work by specifically blocking a protein that the virus uses to enter cells, thereby preventing it from causing harm.

# Who can take part in this RSV clinical trial

#### This trial is enrolling about 2,700 people.

The SHINE-HR clinical trial may be right for you if you are an adult with confirmed RSV infection.

If your age is between 18 and 64, you can participate if you have one or more of the following which increase the risk of RSV severity:

- a long-term lung disease
- heart failure
- a condition that weakens the immune system

If you are 65 (+), you can participate even if you do not have any of these conditions listed above.

You will need to meet a few other criteria to take part in this clinical trial. The trial team will talk you through these criteria in person.

#### You could make a difference

Many factors, including genetics, race, ethnicity, and sex, can impact how people respond to a medicine. That is why it is so important that clinical trials include people of all backgrounds. The greater the diversity among clinical trial participants, the more we can learn about potential medicines, including how they work for different people.

When you participate in a trial, you're helping to represent both your community and all people who are affected by RSV infection. Your participation could make a difference.

#### Informed consent is required

Informed consent is one of the most important tools to help you understand how your rights, safety, and well-being will be addressed throughout the trial.

During informed consent, you will be given all details about the trial, including potential benefits and risks of taking part.

# **RSV trial overview**

### How long will participants be in this trial?

About 5 weeks.

### How many visits are required?



About 7-8 visits.

#### How long do visits last?

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Most visits last for about 1-3 hours. Some visits may take place over the phone.



## What to expect

#### Screening visit

• The trial team will see if this trial could be a good fit for participants.

### **Treatment period**

• Participants will receive the study medicine or a placebo. A placebo does not have any medicine in it but looks just like the medicine being studied.

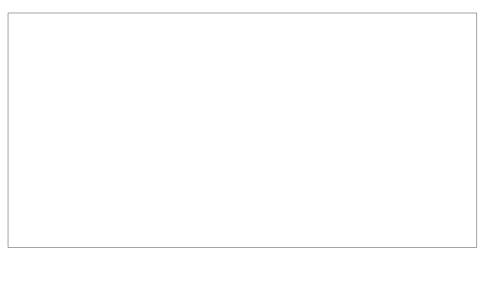
### **Monitoring period**

• The trial team will perform some tests and monitor participants' health over time.

Through a process called **randomization**, participants will be assigned to a treatment group by chance (like flipping a coin) rather than by choice.

This trial is **double-blind**, which means that neither participants nor the trial team will know whether the participants are receiving the study medicine or the placebo.

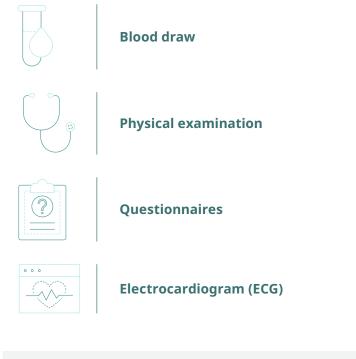
Notes



## **Visits and activities**

In this trial, you will have certain tests, procedures, and activities. What happens at each visit will vary and some visits may take longer than others.

Activities may include:



#### What is an ECG?

An ECG is a common test that checks on your heart. A member of the trial team will put some patches on your chest, wrists and ankles and ask you to lay down still for few minutes while running the test.

## We are here to support you

You don't have to make this decision alone. Feel free to discuss this trial and your participation with your loved ones and your doctor. With their help, you can decide what's best for you.



You will be reimbursed for any reasonable expenses that you may have as a result of taking part in this trial. This may include parking, meals, or other travel-related expenses.



[US ONLY: Participants do not need health insurance to take part.]



The study medicine and any trial-related procedures are generally covered at no cost.

#### Remember to reach out to your trial team

If you have any questions, the trial team will be more than happy to answer them. Contact details are on the back cover.

### Notes

# How clinical trials come to life



Participant safety is the top priority of any clinical trial. Before anyone receives a study medicine in a trial, it first has to be researched in a lab.



Regulatory agencies and institutional review boards (also known as independent ethics committees) then ensure that participants' rights, safety, and well-being are protected.



One way they do this is by reviewing the *protocol* before allowing people to take part.



Without these trials and the volunteers who take part in them, modern medicine would not exist.



Your participation could help us understand how the study medicine potentially works in people with RSV infection around the world.

### What is a protocol?

A *protocol* is a detailed plan that explains the purpose of the trial and how it will be run. It also includes the length of the trial, information about who can participate, trial activities, and more.

# Remember, your safety is the most important part of this clinical trial.

#### Your safety matters to us!

Your health will be carefully monitored and protected throughout the clinical trial.



# Thank you for taking the time to learn more about the **SHINE-HR** clinical trial.

# Ready to learn more? Call or visit us: 718 600 1679

Please reach out to the trial team for more information. We look forward to hearing from you!

# CHEAR Center LLC 384 East 149th street Suite 205 Bronx NY 10455

[US/COUNTRIES WITH WEBSITE ONLY: Or visit www.pfizerRSVtrial.com for more information.]

# www.chearcenter.com



