





### **V-INCEPTION:**

We are inviting you to be in a research study to find out if the study drug effectively lowers low-density lipoprotein cholesterol (LDL-C) (bad cholesterol) in patients with atherosclerotic heart disease and a recent acute coronary syndrome.



#### Introduction

I am conducting a research study with patients with atherosclerotic heart disease and a recent acute coronary syndrome despite being on statin medication. The study, called V-INCEPTION, is looking to evaluate if the study drug, effectively lowers LDL-C—bad cholesterol—when it is taken in addition to current therapy.



## Who can participate in V-INCEPTION?

You may be eligible to join V-INCEPTION if you:

- ♥ Are 18 years old or older
- Have high levels of cholesterol and a recent acute coronary syndrome despite being on statin medication





## Who can participate in V-INCEPTION?

The study will include 384 patients at ~65 centers across the United States

To participate in the V-INCEPTION study, you must meet certain criteria. You may be able to join if you:

- ♥ Are 18 years of age or older
- Have high levels of cholesterol and a recent acute coronary syndrome despite being on statin medication



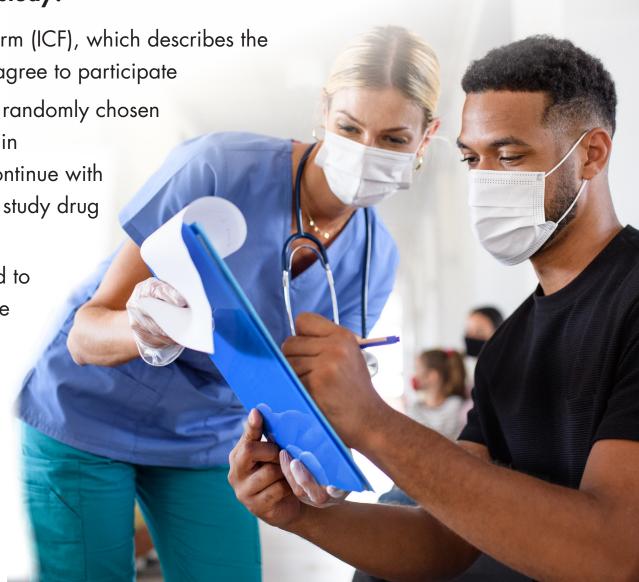
# What should I expect if I join the study?

Review the Informed Consent Form (ICF), which describes the study. By signing the form, you agree to participate

As part of the study, you will be randomly chosen to receive either the study drug, in addition to current therapy or continue with your current therapy without the study drug

✓ If you qualify and agree to join
V-INCEPTION, you will be asked to
come in for 5 study visits with the
study doctor

V-INCEPTION will last about12 months





## What should I expect if I join the study?

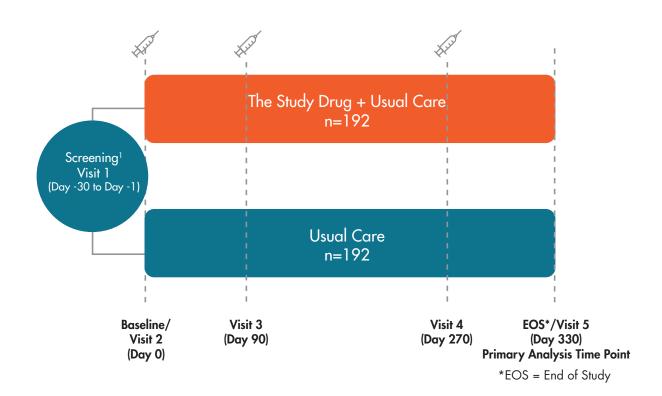
Before joining V-INCEPTION, I or one of my staff will review the Informed Consent Form (ICF) with you. This form describes the study and any potential risks or benefits of participation. By signing the form, you agree to join V-INCEPTION. As part of the study, you will be randomly chosen to receive either the study drug in addition to your current therapy or continue with your current therapy without the study drug. You will be in the study for approximately 12 months. During that time, you will need to visit the study doctor 5 times at the study site. Most study visits should take about 1 hour. However, your first visit to the study site will be longer (about 1 1/2 hours). If you are randomized to the study drug treatment you will get the study treatment (injection by study doctor) at your second, third, and fourth study visit.



## What study treatment will I get?

### You have a 1 in 2 (50%) chance of receiving:

the study drug in addition to your current therapy





## What study treatment will I get?

You have an equal chance of receiving the study drug in addition to your usual treatment or continuing with your usual treatment to manage your cholesterol without the study drug.

If you are enrolled to receive the study drug, you will receive this by injection under your skin 3 times over the course of the 12-month study.



## What happens at study visits?

At some or all of the study visits, the following will happen:

- If you are enrolled to receive the study drug, you will get the study treatment by injection at your second, third, and fourth study visits
- Review your health and ask how you are feeling
- Conduct a physical examination
- Collect blood and urine samples
- Obtain an electrocardiogram (ECG) at your first visit
- Asked to complete questionnaires about your treatments/medications





### What kind of information will be collected about me as a participant in V-INCEPTION?

At some or all of the study visits, the following will happen:

- If you are enrolled to receive the study drug, you will get the study treatment by injection at your second, third, and fourth study visits
- Review your health and ask how you are feeling
- Conduct a physical examination
- Collect blood and urine samples
- Obtain an electrical tracing of your heartbeat (ECG) at your first visit
- ♥ Asked to complete questionnaires about your treatments/medications

More information can be found in your Informed Consent Form, which we can review together.



# What are clinical research studies?

Clinical research studies help us:

Better understand the safety of an investigational procedure or medication and how it works in the body

Develop new medicines and treat conditions like heart disease





### What are clinical research studies?

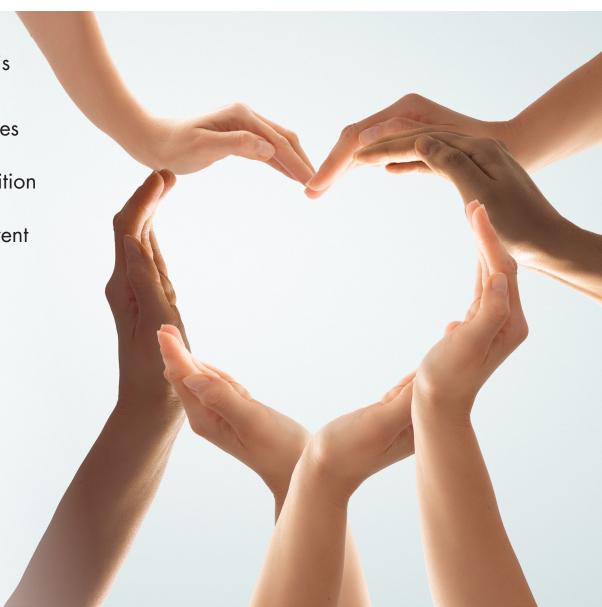
Clinical research studies are done to better understand the safety of an investigational procedure or medication and how it works in the body. Clinical trials are necessary to develop new medicines and treat conditions such as heart disease. As the study doctor for this trial, I am responsible for the study-related care of the people who join the study.



# Why should I join V-INCEPTION?

Heart disease with high cholesterol is a serious condition

V-INCEPTION will look at the changes in levels of your "bad" cholesterol when the study drug is taken in addition to current therapy. This may help doctors better understand how different medicines affect patients who have heart disease with high cholesterol





## Why should I join V-INCEPTION?

Heart disease with high cholesterol is a serious condition which affects many people throughout the United States. The information collected from this study may help doctors better understand how different medicines affect patients who have heart disease with high cholesterol.



# What if I have additional questions?

- ♥ Talk to a member of the study team
- It is your choice whether or not to join V-INCEPTION





## What if I have additional questions?

You are welcome to ask me or my staff any questions before joining V-INCEPTION and throughout your participation, should you enroll. Taking part in a research study is entirely up to you. If you sign up and later decide you do not want to continue, simply tell me, and we can review the different follow-up options available to you together.