#### Information about the OCEAN(a) - PreEvent clinical study

for people with raised levels of Lp(a) and at risk of developing heart disease

OCEAN(a)-PreEvent

#### With heart health, there are some risks you can't control. We want to change that.

Around 1 in 5 people inherit a raised level of a sticky particle called lipoprotein(a) [Lp(a)] in their blood, which can increase their risk of heart disease and heart damage.

There are currently no approved medications that directly target Lp(a) levels. That's why we're conducting the OCEAN(a) - PreEvent study. We want to find out if an investigational drug could help reduce the level of Lp(a) and learn about its effect on heart disease. This study could provide you with a chance to target a risk factor that is unable to be controlled with lifestyle changes and other medicines. This brochure will provide you with more information about OCEAN(a) - PreEvent and clinical research. If you have any questions or would like to learn more, please get in touch using the contact details on the last page.

We're looking for about 11,000 people to join OCEAN(a) - PreEvent, who, among other things:

- Are aged 50 and above
- Have a raised Lp(a) level
- Have a history of heart disease and/ or are considered at risk of developing heart disease\*

Hundreds of thousands of people around the world take part in clinical studies every year. In fact, every medicine available to the public will have first been investigated in clinical studies that were only possible because of their participants.

\*There are many risk factors for developing heart disease. You are considered at risk if you:

- Are aged 50 or above
- Are on medication for high blood pressure or diabetes
- Are a smoker (tobacco cigarettes)
- Have had an imaging test to see if you have plaque in the heart, brain or leg blood vessels

## What is a clinical study?

A clinical study (also known as a clinical trial) is a research experiment that helps us answer questions about an investigational drug, like:

• Is the investigational drug safe?

• Does the investigational drug work?

• Does the investigational drug work better than an existing option?

### What will this study involve?

OCEAN(a) - PreEvent will last for at least 3.5 years, but you may be in the study for longer - potentially up to 5.5 years. You will need to attend one in-person appointment every 12 weeks during the treatment period. You'll be randomly assigned to receive either the investigational drug (50%) or a placebo (50%) chance). If you decide to join OCEAN(a) -PreEvent, you'll be given a study visit guide that will explain when each of your appointments will take place and what they'll involve.

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## How will my assigned study drug be given?

Your assigned study drug (the investigational drug or placebo) will be given as a subcutaneous (under the skin) injection, once every 12 weeks.

#### What is a placebo?

A placebo looks just like the investigational drug and is given the same way but contains no medicine. Many clinical studies (like this one) use a placebo which helps researchers get a clearer picture of how the investigational drug works.







The OCEAN(a) - PreEvent study is double-blind. This means that neither you nor the study doctor will know which study drug (investigational drug or placebo) you've been given. We do this so that we can be sure that any differences we see in your health are due to the investigational drug and not some other factor, like more health monitoring than usual. However, if there is an emergency, the study doctor will be able to find out which study drug you have been given.

#### Can I take other medications?

Medications for heart disease often include lipid-lowering therapy, typically statins, in addition to other medications. So during OCEAN(a) - PreEvent, participants should continue taking their usual lipid-lowering and other medications, at the same dosage, regardless of which group they've been assigned to.

#### How is the investigational drug designed to work?

Your Lp(a) level is inherited, which means that it's determined by your genes. The gene that provides your body with instructions for producing Lp(a) is called the *LPA* gene. In people with a raised level of Lp(a), the *LPA* gene tells the body to make too much Lp(a). The investigational drug is designed to work by targeting a product of the *LPA* gene so that less Lp(a) is produced.

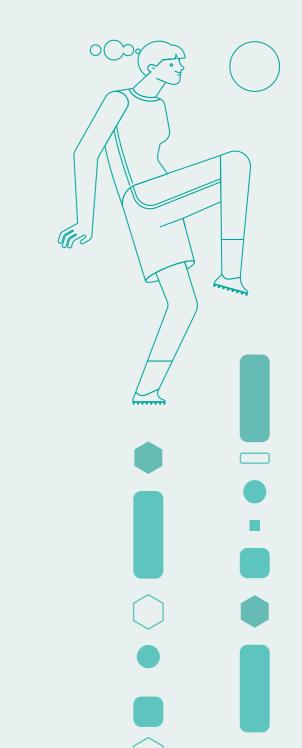


# What are the potential benefits of taking part?

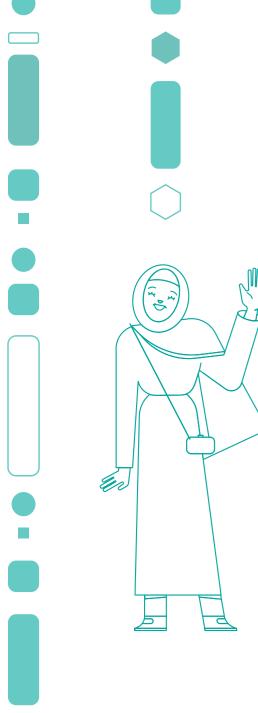
Your health may improve, but this cannot be guaranteed. If it doesn't, you'll still be contributing to our knowledge of heart disease and may even help us treat other people with the condition in the future. You may also benefit from the regular health monitoring, which, in addition to the study drug, will be provided at no cost to you.

#### What are the potential risks of taking part?

Your health may not improve during the study; it could even get worse. Some of the health assessments may be uncomfortable and your assigned study drug could cause side effects or affect your health in ways we do not yet know of. That's why it's important that you tell the study team if you notice any unusual symptoms – even if you think they're not caused by the assigned study drug.



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# Will I need to pay for anything?

No, you won't have to pay for the study drug or any of the health assessments. We may also be able to reimburse your travel costs.

#### Do I have to take part?

No, as a volunteer, you can leave OCEAN(a) -PreEvent at any time without any impact on your regular healthcare. If you change your mind and decide to stop taking the study drug and leave OCEAN(a) - PreEvent early, we'll ask you to continue to come in for study visits so we can continue to check on your health.

#### How can I learn more

If you think this study might be right for you, or if you have any further questions, please contact us. We'll be happy to help.

OCEAN(a) - PreEvent study team contact details:

Solaris Clinical Research 208-288-0123 office@solarisclinicalresearch.com





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