

Clearing the path to lower cholesterol

For people with, or at high risk for, cardiovascular disease (heart disease) who are unable to tolerate statin medications

What will happen at the study visits?

There will be a number of health checks and tests. They may include:

- questions about your health and medical history
- physical examination (a check of your overall health, including your height and weight)
- a check of your vital signs (blood pressure and pulse)
- blood and urine tests
- pregnancy tests (if you are a woman able to have children)
- electrocardiogram (ECG; to check your heart rhythm).

Not all of these tests will be done at every visit.

What else do I need to consider?

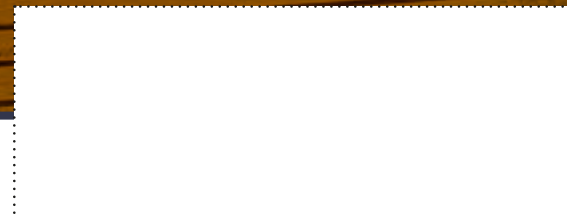
Taking part in the CLEAR Outcomes Study is your choice.

The study team will explain the risks and benefits of taking part in the study.

Study medication and tests will be provided at no cost.

Who should I contact for more information?

If you are interested in learning more about the CLEAR Outcomes Study, please contact the study team using the details provided.



CLEAROutcomes

a CLEARProgram study

Patient Brochure [VoI USA]

CLEAROutcomes

a CLEARProgram study



What is a clinical research study?

- Clinical research studies help to determine whether potential new medications (known as “investigational medications”) are safe and how well they work.
- In a clinical research study, a group of people agree to take the investigational medication while being looked after by study doctors, nurses and other staff.
- Clinical research studies provide the best information for health-related decision-making, new medications and new treatments.

What is the CLEAR Outcomes Study?

The CLEAR Outcomes Study will include more than 12,000 people worldwide who have cardiovascular disease (also known as heart disease), or who are at high risk for cardiovascular disease, and who cannot tolerate taking cholesterol-lowering medications called statin medications. The main purpose of the

CLEAR Outcomes Study is to see if an investigational medication reduces the risk of major cardiovascular (heart and blood vessel-related) events in patients with, or at high risk for, cardiovascular disease. The study will also look at how the investigational medication may affect the level of cholesterol and how safe it is.

Can I take part in the study?

You may be able to take part in the CLEAR Outcomes Study if you:

- are 18 years of age or older, or the age considered an adult in your country, whichever is older
- have, or are at high risk for, cardiovascular disease
- cannot tolerate taking statin medications (have tried two or more statin medications, but you had problems taking them because of side effects).

At the first study visit, the study team will check whether the study is right for you.

What will the CLEAR Outcomes Study involve?

The CLEAR Outcomes Study will last for 2–5 years (with an average length of 3.5 years). It will involve three main periods. The diagram shows what will happen during each of the study periods.

Screening period

(Up to 5 weeks)

1 or 2 visits



Run-in period

(4 weeks)

**Take study medication daily
1 visit**



Treatment period

(2–5 years)

**Take study medication daily
Four study center visits during the first 6 months
Alternating telephone calls and study center visits every 3 months thereafter**



End of study

End of study (EOS) visit and follow-up telephone call (30 days later)