

# REVEAL Long-term Study Information for Participants

### What is the purpose of the REVEAL long-term study?

Having high levels of bad cholesterol is known to increase the chances of having a heart attack or stroke. Statins are an excellent way to lower bad cholesterol and prevent these conditions. Combining statins with a different type of drug, called CETP inhibitors, could protect people even more. The REVEAL trial showed that a CETP inhibitor called anacetrapib lowered the chance of having a heart attack by 9% in around 30,000 people with heart disease who were followed up for 4 years. When the trial ended in 2017, participants stopped taking anacetrapib but were followed up for another two years off-treatment (ending in 2019). This REVEAL 'Post-Trial Follow-Up' study found the benefits of anacetrapib on heart attacks increased, but doctors cannot prescribe the drug because it takes a long time to wash out of the body. New CETP inhibitors that are stronger and don't stay in the body as long are still being developed.

The long-term study will extend the follow-up of around 8000 people who took part in REVEAL in the UK to 10 years ('UK10FU'), and 20 years ('UK20FU'). We will use NHS registries of health data to see if taking anacetrapib previously, protects against heart attacks in the long-term. We will also see if it affects other conditions that we did not see during REVEAL because they usually take longer to appear, like cancers and dementia. We think this is important because it might change how scientists do trials of new CETP inhibitor drugs in the future.

New research is also exploring the potential of repurposing CETP inhibitors to treat some forms of dementia, diabetes and obesity. Therefore, two members of the study team will explore these effects further in fulfilment of the academic requirements for Doctor of Medicine or DPhil degrees.

The REVEAL trial and its sub-studies have been reviewed and approved by the South Central – Oxford B Research Ethics Committee (Ref: 10/H0605/83).

#### Who is doing the study?

The study is being conducted by researchers at the University of Oxford, which acts as the sponsor for the research.

#### Who is being included in the study?

The study includes UK participants of the original REVEAL study who have consented to being followed up long-term.

#### What information do you hold about me?

Our data privacy notice gives details of what personal data we may hold about you, and how we will use it.

#### When will my participation finish?

Your participation by taking study treatment in REVEAL and completing the two-year post-trial followup study finished during 2019. The results of the main trial were published in 2017 and the results of the post-trial follow-up study were published in 2022. We are continuing to collect information as described about hospital admissions and other outcomes of interest from NHS datasets, which will



allow us to compare the long-term effects of the study medications. This extended follow-up is planned to continue until 2034.

#### Data Flow Diagram

## **REVEAL SIMPLE DATA FLOW DIAGRAM – Long-term Follow-up**



#### **Study results**

REVEAL results will be published in peer reviewed journals and presented at conferences. The REVEAL team will also post information about results on the study website: <u>https://www.ctsu.ox.ac.uk/research/hps3-timi55-reveal</u>.