

## Diabetes & Heart Disease

Don't let diabetes lead to heart problems

### **What is the PROMINENT Study?**

The PROMINENT Study will include approximately 10,000 adults worldwide who have type 2 diabetes and elevated triglycerides. The main goal of the PROMINENT Study is to learn if a potential new medication (study medication) called pemafibrate can help prevent heart attacks and other heart-related conditions. It will also look at how safe the study medication is, and whether it can help reduce the level of triglycerides in blood.

If you join the study, you will continue taking your current statin medications (medications to lower “bad” cholesterol, also called LDL or low-density lipoprotein cholesterol).

### **What will taking part in the PROMINENT Study involve?**

The PROMINENT Study will last for about 5 years and has three main periods. We know this will be a long-term commitment for you. During the study, you will have in-person study center visits and visits by phone. You will need to let the study team know of any changes in your phone number, email, or address. The diagram shows what will happen during each of the study periods.

### **What is a randomized clinical research study?**

The PROMINENT Study is a randomized clinical research study. That means, by chance, half of all participants will receive the active study medication and half will receive placebo (which looks just like the study medication, but contains no actual medication).

When completed, the PROMINENT Study will tell us whether or not those who received the active study medication had fewer heart attacks and strokes compared with those who received placebo, among adults with type 2 diabetes and elevated triglycerides.

If successful, your participation in the PROMINENT Study will thus be important for future patients with type 2 diabetes and elevated triglycerides.

### **What is a Triglycerides?**

Triglycerides are a type of fat in your blood. If you take in more calories from food than your body needs, the body converts those calories into triglycerides.

Triglycerides are stored in fat cells. High levels of triglycerides can increase your chances of having heart disease, especially in women.

### **What can I expect if I participate?**

If you choose to participate in the PROMINENT Study, you will be followed for about 5 years. Study visits should take 30 minutes to 1 hour. Some visits will take place at the study center and others will be by phone. During the study, visits may include:

Physical examination  
Vital signs (including blood pressure and heart rate)  
Contact information gathering  
Questions about your medical history  
Checking that you receive and return the study medication  
Fasting (not eating or drinking anything except water before your visit)  
Height and weight measurements  
Blood and urine tests  
Pregnancy tests (only for women who are able to have children)

### **Am I eligible to participate in the PROMINENT Study?**

You may be able to take part in the PROMINENT Study if you:  
have a diagnosis of type 2 diabetes for 12 weeks or longer  
are 18 years of age or more with systemic atherosclerosis (also called artery disease, which is a hardening or narrowing of the arteries)  
have been told you have moderately high triglyceride levels. Please ask your doctor if you are not sure.

At the first study center visit, the study team will check whether you are eligible for the study.

### **What should I do next?**

If you are interested in finding out more about the PROMINENT Study, the study team will be happy to answer any questions you may have. They can explain the potential risks and benefits of taking part. Please contact them by either go the HOME page and complete the survey / email us at [admin@johese.co.za](mailto:admin@johese.co.za)  
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