



## Opportunity for Human Subject Research

### **Name of the Study**

Prominent- K-877-302- Pemafibrate to Reduce Cardiovascular Outcomes by Reducing Triglycerides in Patients with Diabetes

**Category: Cardiology**

**Enrollment Closing Date: 2022**

### **Description**

This research study is designed to find out if, the study drug, compared to placebo (a treatment which looks like the medicine but contains no active medication), lowers cardiovascular events, such as heart attack, stroke, and death. This study will also test whether the study drug has other possible benefits in patients with diabetes, and will test the safety of the study drug.

Users of the VA Medical Health system will be invited to participate in this study if they have been diagnosed with type-2 diabetes, have high Triglycerides (TGs), and low High Density Lipid (HDL) cholesterol, and are at risk for future cardiovascular events.

### **Requirements**

Veterans with established care at our VA site and with the following (additional requirements as well):

- Medical record documentation of diabetes longer than 12 weeks duration
- Medical record documentation of a qualifying CV event (if secondary prevention cohort)
- TG levels  $\geq 200$  mg/dL (2.26 mmol/L) and  $< 500$  mg/dL (5.65 mmol/L)
- HDL-C  $\leq 40$  mg/dL (1.03 mmol/L)
- LDL-C  $\leq 70$  mg/dL (1.81 mmol/L) if not on qualifying statin regimen or  $\leq 100$  mg/dL (2.59 mmol/L) if documented statin intolerant

### **Benefits**

Veterans may not personally benefit from taking part in the study; however, the information we get from this study may help us in the future to treat high risk patients better. The potential benefits to the participant may include improvement of their TGs and HDL levels, prevention of cardiovascular events or temporary relief of symptoms related to these conditions.

### **Contact Information**

Email: [Pratap.Arasu@va.gov](mailto:Pratap.Arasu@va.gov) (Principal Investigator)

Email: [Alisha.Hartwell@va.gov](mailto:Alisha.Hartwell@va.gov) (Study Coordinator)