revascularization in a statin-treated subject, wherein: (a) the statin-treated subject has been identified as having a fasting baseline triglyceride level of at least 150 mg/dL, and (b) the composition is to be administered to the statin-treated subject per day for a period sufficient to reduce the need for peripheral arterial revascularization.

**[0004b]** In one example, the present disclosure refers to a method of determining whether a subject is in need of peripheral arterial revascularization, the method comprising: (a) identifying the subject as being on a statin therapy; (b) measuring a fasting baseline triglyceride level of the subject; and (c) determining the need for peripheral arterial revascularization if the subject has a fasting baseline triglyceride level of at least about 150 mg/dL.

**[0004c]** In one example, there is described use of a pharmaceutical composition in the manufacture of a medicament for treating a subject at risk for peripheral arterial revascularization, wherein the pharmaceutical composition is to be administered to the subject, wherein the subject has been determined to be at risk for peripheral arterial revascularization by measuring a fasting baseline triglyceride level of the subject, and wherein the subject has a fasting baseline triglyceride level of at least about 150 mg/dL.

**[0005]** In some examples, the present disclosure provides methods of reducing a need for peripheral arterial revascularization in a statin-treated subject, the method comprising: (a) identifying a statin-treated subject as having a fasting baseline

# CLAIMS

What is claimed is:

1. Use of a pharmaceutical composition comprising 1 g to 4 g of eicosapentaenoic acid ethyl ester in the manufacture of a medicament for reducing a need for peripheral arterial revascularization in a statin-treated subject, wherein:

(a) the statin-treated subject has been identified as having a fasting baseline triglyceride level of at least 150 mg/dL, and

(b) the composition is to be administered to the statin-treated subject per day for a period sufficient to reduce the need for peripheral arterial revascularization.

2. The use of claim 1, wherein the composition is to be administered to the statin-treated subject in 1 to 4 dosage units per day.

3. The use of claim 1 or claim 2, wherein the eicosapentaenoic acid ethyl ester comprises at least 96 wt.% of all omega-3 fatty acids in the pharmaceutical composition.

4. The use as in any one of the preceding claims, wherein the statin-treated subject has one or more of: a baseline non-HDL-C value of 200 mg/dL to 300 mg/dL; a baseline total cholesterol value of 250 mg/dL to 300 mg/dL; a baseline VLDL-C value of 140 mg/dL to 200 mg/dL; a baseline HDL-C value of 10 to 30 mg/dL; and/or a baseline LDL-C value of 40 to 100 mg/dL.

5. The use as in any one of the preceding claims, wherein the statin-treated subject is on a stable statin therapy.

6. The use of claim 5, wherein the statin therapy comprises a statin and optionally, ezetimibe, to be administered to the statin-treated subject.

7. The use as in any one of the preceding claims, further comprising identifying the statin-treated subject as having no clinical adverse changes in LDL levels during therapy.

8. The use as in any one of the preceding claims, wherein the statin-treated subject has a fasting baseline triglyceride level of 200 mg/dL to 499 mg/dL.

9. The use as in any one of claims 1 to 7, wherein the statin-treated subject has a fasting baseline triglyceride level of 500 mg/dL to 1500 mg/dL.

10. The use as in any one of claims 1 to 7, wherein the subject exhibits a reduction in a risk for cardiovascular death, coronary revascularization, unstable angina, stroke, and/or myocardial infarction.