

## **What is the clinical need and scientific rationale for the REDUCE-IT study (Updated March 19, 2019)?**

### Clinical Need Response

Cardiovascular (CV) disease is an enormous and worsening public health burden. There is a significant unmet need to help more patients reduce the risk of CV disease; lowering cholesterol alone is not enough. CV disease is the leading cause of death in the U.S. More deaths are attributable to heart disease than to all cancers combined. Annual treatment costs for CV disease exceed half a trillion dollars per year as cost related to the diagnosis of and treatment for strokes, heart attacks and other adverse cardiovascular events are expensive in direct financial terms as well as in terms of pain, suffering and loss of productivity.

### Scientific Rationale Response

Amarin published the paper “Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl – Intervention Trial” in the March, 2017 issue of Clinical Cardiology.

The article can be accessed [here](#). Also, an Amarin [press release](#) has been issued related to this publication.

The following are key points regarding the study design for REDUCE-IT:

#### REDUCE-IT: Study Design

REDUCE-IT was a landmark global study involving approximately 8,000 patients

It was a randomized, multicenter, double-blind, placebo-controlled study designed to determine if treatment with VASCEPA® 4 g/day versus placebo reduces major adverse cardiovascular events (MACE) in statin-treated patients with persistent hypertriglyceridemia and high cardiovascular risk

The primary endpoint of the study was the time to the first occurrence of the composite endpoint of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina

Secondary endpoints included time to event analyses of components of the primary endpoint

The study was conducted under a special protocol assessment agreement with the FDA

For more information, please [click here](#)