

**Why has an outcomes study not been conducted with VASCEPA of patients with TG levels  $\geq$ 500 mg/dL to demonstrate that lowering TG levels in this population lowers the risk of pancreatitis?**

TG levels  $\geq$  500 mg/dL are associated with increased risk of acute pancreatitis, an inflammatory condition of the pancreas that is painful and at times deadly<sup>1</sup>. Acute pancreatitis can lead to extreme levels of pain requiring emergency medical care and other medical complications, including death. It is considered impractical and unethical to conduct a clinical trial as part of which a group of patients (the placebo-group of the trial) is exposed to a risk when that risk has a generally accepted standard of care treatment that could potentially prevent it. Accordingly, no outcomes study has been conducted for any drug specific to the study of pancreatitis in patients with TG levels  $\geq$  500 mg/dL nor has such a trial been required by regulatory authorities for approval of drugs for treatment of such patient population. Medical guidelines recognize that such patients should be treated despite the absence of outcomes study results.

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<sup>1</sup> <https://pancreasfoundation.org/patient-information/acute-pancreatitis/>