ROBERT S. ROSENSON:

So we consider PCSK9 inhibitor therapy for individuals who have an LDL cholesterol greater than or equal to 70 milligrams per deciliter on a maximally tolerated statin and/or ezetimibe. Most often due to insurance requirements, patients need to fail a statin and ezetimibe before they can be considered for a PCSK9 inhibitor.

Who are those patients? These are individuals who have cardiovascular disease, particularly those who had a recent myocardial infarction, multivessel coronary disease, and multivessel disease, disease affecting the lower extremities, or a prior stroke. These subgroups have been identified in the Fourier Trial as individuals who have particularly high risk for cardiovascular events and individuals who have the largest absolute reduction for PCSK9 inhibitors.

The Odyssey Outcome Study showed, the higher the entry LDL cholesterol, the greater the benefit from the therapy. And this supports our well known paradigm-- the lower the LDL cholesterol, the lower the cardiovascular risk, data that's been established from many meta-analyses and supported with the PCSK9 inhibitors that are so effective for lowering LDL cholesterol.