CV Outcomes Study of Alogliptin in Subjects with Type 2 Diabetes and Acute Coronary Syndrome (EXAMINE)

**History:** Identifying safe and efficacious glucose-lowering therapies to reduce CV events in high-risk patients with diabetes has been a challenge. Clinical trial data demonstrate that improved glycemic control slows microvascular deterioration, however, long-term CV safety or efficacy data on recently approved antidiabetic therapies are lacking.

**Questions to answer:** In patients with type 2 DM and acute coronary syndrome, what are the CV outcomes of an orally administered antidiabetic drug, alogliptin, once per day, versus patients with placebo?

**Trial Design**
Patients with T2DM and well-defined ACS events were randomized in a double-blind trial to standard of care and either a new dipeptidyl peptidase 4 (DPP-4) drug, alogliptin, or placebo, comparing CV outcomes in a multicenter prospective design. Median follow up was 18 months. N = 5380.

**Primary Endpoint**
Composite of CV death, nonfatal MI and nonfatal stroke

**Trial Results**
No increase in cardiovascular morbidity or mortality: alogliptin 11.3%; placebo 11.8% (p<0.001)
Rates of CV events were not increased in high-risk CV patients and ACS with type 2 diabetes when alogliptin is given in addition to drug therapy. Other disease incidences were alike with both placebo and alogliptin groups, including cancer, hypoglycemia and time to dialysis.

**Take Away:** Results showed that using alogliptin in high-risk CV patients with type 2 diabetes resulted in no increase in cardiovascular events.