**DESIGN OF FUTURE REVASCULARIZATION EVALUATION IN PATIENTS WITH DIABETES MELLITUS: OPTIMAL MANAGEMENT OF MULTIVESSEL DISEASE (FREEDOM TRIAL)**

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Indication: Treatment of multivessel coronary artery disease (CAD) in patients with diabetes.

Objective: To evaluate whether percutaneous coronary intervention (PCI) with drug-eluting stenting (PCI/DES) is more or less effective than the existing standard of care, coronary artery bypass surgery (CABG)

Subject Population: 1,900 adults with diabetes mellitus (Type 1 or Type 2) with angiographically confirmed multivessel CAD and morphology amenable to either PCI or CABG, with indication for revascularization based upon symptoms or angina and/or objective evidence of myocardial ischemia.

Study Design: Multicenter, two-arm, open label prospective randomized superiority trial with equal allocation, of 6.75 years duration with a minimum of 2.0 years of follow-up. Patients who consent will be randomized on a 1:1 basis either to CABG or multivessel stenting using drug-eluting stents, and followed at 30 days, 1 year and then annually for at least 2.0 years but up to 6.75 years.

Primary Endpoint: The composite of all-cause mortality, nonfatal myocardial infarction and stroke at the end of the 6.75-year patient accrual and follow-up period

(minimum follow-up 2.0 years).