Study Name	**CREDENCE Study**
Full title	**A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy**
Principal-Investigator	Adeera Levin ~ SPH / Nadia Zalunardo ~ VGH
Trial sponsor	Janssen Research and Development, LLC
Coordinator	Rachel ~ 604.682.2344, Lc. 64711; or Zainab ~ Lc. 64744
Enrollment Target	20 at each site (3700 globally)
Purpose	The purpose of this study is to determine if canagliflozin is able to protect the kidneys and heart blood vessels by reducing the progression of diabetic kidney and heart disease compared to placebo. The drug will be added to the standard of care for this study population.
Justification	Study subjects will be receiving standard of care treatment with an ACE inhibitor or ARB. The renal protective effect of canagliflozin relative to placebo is measured by the reduction in progression to end-stage kidney disease (ESKD), doubling of serum creatinine, and renal or CV death. Placebo is justified because the standard of care is not being compromised since canagliflozin and placebo is being added in addition to the medications the subject is already taking to optimize their disease.
Inclusion Criteria	1. ≥ 30 years-old with a clinical diagnosis of T2DM 2. HbA1c ≥ 6.5% to ≤10.5% 3. eGFR ≥ 30 to <90 mL/min/1.73m2 4. Urinary albumin-to-creatinine ratio (UACR) >300 mg/g to ≤5000 mg/g 5. All subjects must be on a stable maximum tolerated labeled daily dose of ACEi or ARB for at least 4 weeks prior to randomization.
Exclusion Criteria	1. History of diabetic ketoacidosis or type 1 diabetes mellitus (T1DM) 2. History of hereditary glucose-galactose malabsorption or primary renal glucosuria 3. Known medical history or clinical evidence suggesting non-diabetic renal disease 4. Renal disease that required treatment with immunosuppressive therapy or a history of chronic dialysis or renal transplant. 5. Uncontrolled hypertension (systolic BP ≥180 and/or diastolic BP ≥100 mmHg)
What do you need to do?	If you have a patient who meets this criteria please contact the coordinator, who can do further screening for eligibility. If eligible we will contact the potential subject to explain the study and determine their interest in participation. Initial contact with the subject will be made by an REB approved mail out letter.