

## **Metropolitan Cardiovascular Consultants, LLC Clinical Research Trials 2018/19**

- **August 2018-Present Myocardial infarction**

Principal Investigator – TACT2 study- IRB # 00001790 A randomized, double blind controlled factorial clinical trial of edetate disodium-based chelation and high-dose oral vitamins and minerals to prevent recurrent cardiac events in diabetic patients with a prior Myocardial infarction.

- **2017-Present CHF with Reduced Ejection Fraction**

Principal Investigator- EMPEROR study - IRB # 1245.121-A phase III randomized double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with reduced Ejection Fraction (HFrEF).

- **2017-Present CHF with Preserved Ejection Fraction**

Principal Investigator – EMPEROR study- IRB # 1245.110 - A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with Chronic Heart Failure with preserved Ejection Fraction (HFpEF).

- **2016- Present Overweight**

Principal Investigator Weight Loss study CLIK066 IRB # LIKD66B2201 A randomized, double-blind, dose-finding study to evaluate the change in weight after 24 weeks treatment with 8 doses of LIK066 compared to placebo in obese or overweight adults, followed by 24 weeks treatment with 2 doses of LIK066 and placebo.

- **2015-Present Type 2 Diabetes**

Principal Investigator -CREDENCE study - IRB # 28431754DNE3001-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 The CREDENCE™ Trial (Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial)

- **2014-Present CAD**

Principal Investigator –THEMIS study IRB# D513BC00001 -A Multinational, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Ticagrelor twice daily on the

Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus [THEMIS - effect of Ticagrelor on Health outcomes in diabetes Mellitus patients Intervention Study]

- **2013-Present Type 2 Diabetes**

Principal Investigator- DECLARE study IRB # D1693C00001 -A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to evaluate the Effect of Dapagliflozin 10 mg Once Daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Ischemic Stroke in Patients with Type 2 Diabetes

- **2012-2017 Present Peripheral Vascular Disease**

Principal Investigator- EUCLID – A randomized, double-blind, parallel group, multicenter phase IIIb study to compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischemic stroke in patients with established peripheral artery disease.

- **2012-2018 Present Congestive Heart Failure**

Principal Investigator -GUIDING Evidence Based Therapy Using Biomarker Intensified Treatment in Heart Failure (GUIDE-IT)

- **2012-2018 Present Cardiovascular Disease**

Principal Investigator EFC11570 – ODYSSEY -Outcomes A Randomized, Double-blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of SAR236553/REGN727 on the Occurrence of Cardiovascular Events in Patients who Have Recently Experienced an Acute Coronary Syndrome

- **2011-2014 -Heart Failure**

Principal Investigator -CLCZ696B2314: A Multicenter, randomized, double-blind, and parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to Enalapril on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction.

- **2011-Present Myocardial Infarction**

Principal Investigator-CACZ885M2301: A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP

- **Jan 2012 - May 2012 Stable Cardiovascular Disease.**

Principal Investigator- DAL-OUTCOMES 2 -A Phase 3b, Multi-Center, Double-blind, Placebo-Controlled, Parallel Group Study to Evaluate the Effect of Dalcetrapib 600 mg on Cardiovascular Events in Adult Patients with Stable Coronary Heart Disease (CHD), CHD Risk Equivalents or at Elevated Risk for Cardiovascular Disease.

- **2011-2012 Hypertension**

Principal Investigator- CSPV100AUS05- A 12-week, Multi-Center, Randomized Double-Blind, Active Control Parallel Group Study to Evaluate the Efficacy and Safety of the Combination of

Valturna and Amlodipine or Valturna and Chlorthalidone Versus Valturna Alone in Patients with Stage 2 Hypertension and Diabetes

- **2010-2016 Atrial Fibrillation**

Principal Investigator - RIVAROXAFLOXAN Registry Rivaroxaban Once daily oral direct factor XA Inhibition Compared with vitamin K and antagonism of stroke and Embolism Trial in Atrial Fibrillation

- **2010-2011 Acute Coronary Syndrome**

Principal Investigator - TRILOGY ACS- a Comparison of Prasugrel and Clopidogrel in Acute Coronary Syndrome (ACS) subjects with unstable Angina/ Non-ST-Elevation Myocardial Infarction (VA/NSTEMI) who are medically managed.

- **2007-2010 Atrial Fibrillations**

Principal Investigator- ROCKET - A Fib –(Rivaroxaban Once daily oral direct factor XA inhibition compared with vitamin K and antagonism of stroke and Embolism Trial in Atrial Fibrillation.

- **2006-2008 Arrhythmia**

Principal Investigator - REDUCE Ventricular Pacing in Dual Chamber Implantable Cardioverter Defibrillators Using Autointrinsic Conduction Search Study

- **2005-2008 Arrhythmia**

Principal Investigator -ACT (Advancement in ICD Therapy) Registry