

WNICER CLINICAL TRIALS

(not an exhaustive list)

INVESTED Trial: Influenza Vaccine to Effectively Stop Cardio Thoracic Events and Decompensated Heart Failure. 5388 participants enrolled in 190 locations across three countries. **WNICER PIs: Drs. Jay Udell, Michael Farkouh and Shaun Goodman**

EMPACT-MI Trial: A Study to Test Whether Empagliflozin Can Lower the Risk of Heart Failure and Death in People Who Had a Heart Attack (Myocardial Infarction). Study enrollment target to start in Q4 of 2020; expected enrollment is 4,000 patients. **WNICER PI: Dr. Jay Udell**

ACAC-CHD: To evaluate the effect of an antibiotic combination therapy on fractional flow reserve (FFR) (coronary arterial flow) in participants with Coronary Heart Disease. 60 participants enrolled in Australia. **WNICER PI: Dr. John French**

ACT-2: The Appropriateness of Coronary investigation in myocardial injury and Type 2 myocardial infarction. Multi-centre open-label randomised clinical trial with blinded endpoint adjudication. **WNICER PIs: Drs. John French, Michael Farkouh and Derek Chew**

dal-GenE: The primary objective of this trial is to evaluate the potential of dalcetrapib to reduce cardiovascular morbidity and mortality (cardiovascular death, resuscitated cardiac arrest, nonfatal myocardial infarction (MI) and non-fatal stroke) in subjects with a documented recent ACS and the AA genotype at variant rs1967309 in the ADCY9 gene. 6,000 participants in 563 locations across 33 countries. **WNICER PIs: Drs. Wolfgang Koenig, John French and Jose Nicolau**

GALACTIC-HF: To evaluate the effect of treatment with omecamtiv mecarbil (OM) compared with placebo on the time to cardiovascular (CV) death or first HF event, whichever occurs first, in subjects with chronic HF with reduced ejection fraction (HFrEF) receiving standard of care (SoC) therapy. 8256 participants in 1,034 locations across 36 countries. **WNICER PI: Dr. John French**

STREAM-2: STRategic Reperfusion in elderly patients Early After Myocardial Infarction. Open-label, prospective, randomised, parallel, comparative international multi-centre trial. 600 participants in 48 locations across 9 countries. **WNICER PI: Dr. John French**

SODIUM-HF: A multicenter clinical trial in ambulatory patients with chronic HF to evaluate the efficacy of a low sodium containing diet on a composite clinical outcome composed of all-cause mortality, cardiovascular hospitalizations and cardiovascular emergency department visits. The hypothesis of this study is that patients following a low-sodium containing diet will have fewer clinical events (fewer hospital readmissions or emergency department visits, longer survival) than those randomized to Usual Care. 1,000 participants in 26 locations across 5 countries. **WNICER PI: Dr. Jorge Escobedo**

ATTACC: Antithrombotic Therapy to Ameliorate Complications of COVID-19. This is a prospective, open-label, multicentre, Bayesian adaptive randomized clinical trial to establish whether therapeutic-dose parenteral anticoagulation improves outcomes for patients hospitalized with COVID-19 (e.g., reduces intubation or mortality). 3,000 estimated participants in 26 locations across 4 countries. **WNICER PIs: Drs. Patrick Lawler, Mandeep Sidhu, Robert Rosenson, Jose Nicolau, and Jorge Escobedo**

PARADISE-MI: Prospective ARNI vs ACE Inhibitor Trial to Determine Superiority in Reducing Heart Failure Events After MI. A multi-center, randomized, double-blind, active-controlled, parallel group Phase 3 study to evaluate the efficacy and safety of LCZ696 compared to ramipril on morbidity and mortality in

high risk patients following an acute myocardial infarction. Estimated 5,650 participants in 573 locations across 41 countries. **WNICER PI: Dr. Jorge Escobedo**

AFFIRM-AHF: A Randomised, Double-blind Placebo Controlled Trial Comparing the Effect of Intravenous Ferric Carboxymaltose on Hospitalisations and Mortality in Iron Deficient Patients Admitted for Acute Heart Failure. 1,100 participants in 15 countries. **WNICER PI: Dr. Jose Nicolau**

AEGIS-II: Phase 3, multicenter, double-blind, randomized, placebo-controlled, parallel-group study designed to investigate the efficacy and safety of CSL112 (intravenous ApoA1) on the occurrence of major adverse cardiovascular events (MACE) in subjects with ACS who are receiving standard of care (SOC) therapy. Estimated 17,400 participants in 961 locations across 49 countries. **WNICER PI: Dr. Jose Nicolau**

SOLOIST-WHF: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effects of SOTagLiflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes POST Worsening Heart Failure. 4,000 participants in 466 locations across 32 countries. **WNICER PI: Dr. Jose Nicolau**

PRIORITIZE HF: This is an international, multicentre, parallel-group, randomised, double-blind, placebo controlled, phase II study to evaluate the benefits and risks of using sodium zirconium cyclosilicate (ZS) to initiate and intensify renin angiotensin aldosterone system inhibitor (RAASi) therapy in heart failure patients. 182 participants in 74 locations across 9 countries. **WNICER PI: Dr. Jose Nicolau**

CLEAR Outcomes: The purpose of this randomized, double-blind, placebo-controlled study is to determine if treatment with bempedoic acid (ETC-1002) versus placebo decreases the risk of cardiovascular events in patients who are statin intolerant. 14,014 participants in 1,360 locations worldwide. **WNICER PI: Dr. Jose Nicolau**

REAL-TIMI 63B: This is a Phase 2b randomized, blinded, placebo controlled study to evaluate the efficacy, safety, PK/pharmacodynamic, and immunogenicity of repeat doses of MEDI6012 in adult subjects presenting with acute STEMI (ST segment elevation myocardial infarction). 594 participants across 10 countries. **WNICER PI: Dr. Jose Nicolau**

VIP-ACS: Phase III, randomized, controlled, multicenter, open label, superiority, 1:1 allocation, blind assessment of clinical outcomes and intention-to-treat analysis clinical trial to determine whether increased doses of influenza vaccine in the hospital phase, when compared to usual dose vaccination (30 days hospital discharge), reduce the risk of major cardiovascular events (cardiovascular mortality, acute myocardial infarction and stroke) in patients with acute coronary syndrome. 9,200 participants in 9 locations in Brazil. **WNICER PI: Dr. Jose Nicolau**

DETERMINE: International, Multicentre, Parallel-group, Randomised, Double-blind, Placebo-controlled, Phase III Study Evaluating the effect of Dapagliflozin on Exercise Capacity in Heart Failure Patients with Reduced Ejection Fraction (HFrEF). 313 participants in 76 locations across 9 countries. **WNICER PI: Dr. Jose Nicolau**

VESALIUS-CV: This study will assess the effect of lowering low-density lipoprotein cholesterol (LDL-C) with evolocumab on major cardiovascular events in adults without a prior myocardial infarction (MI) or stroke who are at high risk of a cardiovascular event. 12,000 participants in 471 locations worldwide. **WNICER PI: Dr. Jose Nicolau**