

# Active Research Studies at Corewell Health West

6/3/2024

## Cardiovascular Vascular

**SYMPHONY-PE**

*Evaluation of the Safety and Efficacy of the Symphony Thrombectomy System in the Treatment of Pulmonary Embolism*

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## Cardiovascular Health Cardiothoracic Surgery

**LeAPPS**

*Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction Trial  
To demonstrate the effectiveness of LAA exclusion (LAAE) for the prevention of ischemic stroke or systemic arterial embolism in subjects undergoing cardiac surgery who have risk factors for atrial fibrillation and ischemic stroke.*

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**A2CPS**

*Acute to Chronic Pain Signatures Program*

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**Terminate AF**

*To demonstrate the safety and effectiveness of the Cardioblade Surgical Ablation iRF and Cryoflex hand held devices for the treatment of non-paroxysmal atrial fibrillation in patients requiring concomitant cardiac surgery.*

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## Electrophysiology

**AVANT GUARD**

*Pulsed field ablation as first-line ablation treatment for persistent Afib versus initial treatment with anti-arrhythmic drugs*

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**REACT-AF**

*IRB submitted reliance agreement documents to JHU on 2/10*

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## Heart Failure

**Development of a computational  
model for RV dysfunction after  
LVAD implantation**

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*For information about research studies listed please use these contacts below:*

*Email: [researchassist@corewellhealth.org](mailto:researchassist@corewellhealth.org)*

*Phone: 616-391-3050*

**Electrocardiogram-based  
Artificial Intelligence-assisted  
Detection (ECG-AID) of Heart  
Disease**

*A retrospective and prospective study. Electrocardiogram-based Artificial Intelligence-assisted Detection of heart disease (ECG-AID) is an implementation study to gather real-world preliminary evidence on the utility of Tempus Air™ when integrated into a clinical system. The study will involve two phases: 1) A retrospective phase where the devices can be validated within a limited set of patients from each site and 2) a prospective phase where the diagnostic yield and clinical utility of the devices can be directly measured.*

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**Interventional**

**Dobutamine Stress Mri as a  
Predictor of Early RVF Post-  
Cardiothoracic Surgery**

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**HEAL-LAA**

*Newest generation of Watchman*

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**CERAMICS**

*Can Escalation Reduce Acute Myocardial Infarction Mortality in Cardiogenic Shock. Registry to capture MI patients in CGS.*

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**Discover HCM**

*Using Real World Evidence (FDA reporting) To estimate the incidence rate of new or worsening heart failure (HF) due to systolic dysfunction (defined as symptomatic left ventricular ejection fraction [LVEF] < 50%) among patients with symptomatic obstructive HCM during periods of exposure to mavacamten and non-mavacamten therapy*

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**SPYRAL AFFIRM**

*Renal denervation procedure to treat uncontrolled hypertension.*

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**CONFORM Trial**

*Evaluating the safety and effectiveness of the CLAAS Device by demonstrating non-inferiority to currently marketed LAAO systems in subjects with non-valvular atrial fibrillation, demonstrating the safety of a post procedure pharmacologic antiplatelet regimen that consists of DAPT alone without concomitant anticoagulation therapy (OAC or DOAC), and demonstrating the ability to safely deliver the CLAAS Device using a conscious sedation protocol without general anesthesia.*

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**Impella ECP**

*To demonstrate Impella ECP has an acceptable rate of Major Adverse Cardiovascular and Cerebrovascular Events (MACCE)*

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**Angiotensin II** *in the treatment of vasoplegia in cardiogenic shock patients supported with temporary mechanical circulatory support: A single center experience*

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**PROTECT IV (four)** *Prospective, multicenter, randomized, parallel-controlled, open-label two arm Trial with an adaptive design. Eligible subjects will be randomized in a 1:1 ratio to PCI with Impella CP® (Intervention Group) versus standard of care PCI with or without IABP (Control Group).*

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**STEMI-DTU** *To demonstrate the safety and effectiveness of primary Left Ventricular unloading and a thirty-minutes delay to reperfusion vs. current standard of care in reducing infarct size and heart failure-related clinical events in patients presenting with anterior ST-Elevation Myocardial Infarction*

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## Structural Heart

**Evolut Expand TAVR II Pivotal Trial** *Obtain safety and effectiveness data to support indication expansion for the Medtronic TAVR System to include patients with moderate, symptomatic AS*

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**Amplatzer PIVSD Study** *Amplatzer™ PIVSD Occluder Humanitarian Device Exemption Post-Approval Study. The objective of this retrospective study is to evaluate the safety and probable benefit of the PIVSD Occluder in patients undergoing implantation of the PIVSD Occluder following acute myocardial infarction.*

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**CorCinch Study** *Randomized Clinical Evaluation of the AccuCinch® Ventricular Restoration System in Patients who Present with Symptomatic Heart Failure with Reduced Ejection Fraction (HFrEF)*

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**CATALYST Trial** *Prospective, randomized, controlled, unblinded, multicenter clinical trial  
Prospective, randomized, controlled, unblinded, multicenter clinical trial of the Amplatzer™ Amulet™ device in patients with non-valvular atrial fibrillation who are at increased risk for cardioembolic events.*

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**APOLLO Trial** *Evaluate the safety and efficacy of Medtronic Intrepid™ TMVR System in patients who are candidates for conventional mitral valve surgery. One arm-TMVR with Intrepid Valve*

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## Vascular

**Correlating Neighborhood Socioeconomic Deprivation and Progression of Chronic Limb Threatening Ischemia in Michigan**

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**ROADSTER 3**

*Post-Approval Study of Transcarotid Artery Revascularization in Standard Risk Patients with Significant Carotid Artery Disease*

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**Serial AAA CT**

*The objective of this human subjects study is to perform a yearly abdominal CT examination of patients with a recently diagnosed small abdominal aortic aneurysm (AAA) and acquire basic medical history data at each yearly follow up. The scientific goal of this research is to provide a proof-of-concept strategy for implementing a nonlinear membrane based analysis for AAA rupture risk assessment.*

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