

# 2019 Cardiac Surgery Clinical Trials

Is your patient a candidate for a clinical trial?

## Referring your patient

The UPMC Heart and Vascular Institute is a leader in conducting research studies and clinical trials to better understand and treat cardiovascular disease.

To refer a patient, please call **1-84-HVI-TRIAL (844-848-7425)** or email [HVIresearch@upmc.edu](mailto:HVIresearch@upmc.edu).

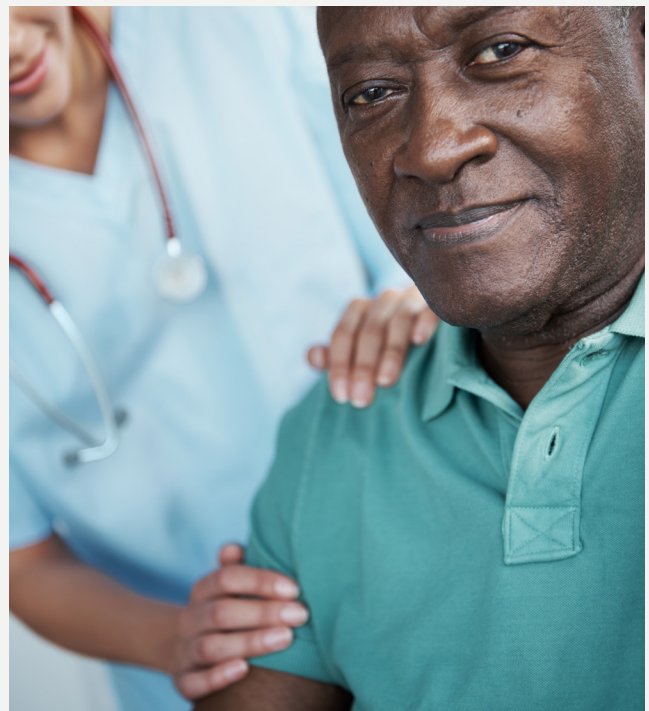
For more information about the UPMC Heart and Vascular Institute, please call **1-855-UPMC-HVI (876-2484)** or visit [UPMC.com/HVI](http://UPMC.com/HVI).

### **REPRISE IV: REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus™ Valve System – Continued Access**

Prospective, multicenter single-arm study designed to evaluate the safety and effectiveness of the LOTUS Edge Valve System for TAVR in symptomatic subjects who have severe native aortic stenosis and are considered at intermediate risk for surgical valve replacement.

**Inclusion criteria:** Subject has documented severe aortic stenosis defined as initial AVA  $\leq 1.0$  cm<sup>2</sup> (or AVA index  $\leq 0.6$  cm<sup>2</sup>/m<sup>2</sup>) and a mean pressure gradient  $\geq 40$  mm Hg OR maximal aortic valve velocity  $\geq 4.0$  m/s OR Doppler velocity index  $\leq 0.25$  as measured by echocardiography and/or invasive hemodynamics

**Principal Investigator:** Thomas Gleason, MD



### **MOMENTUM 3 Multi-Center Study of MagLev Technology in Patients Undergoing MCS Therapy with HeartMate 3™**

Single arm, prospective, multicenter study for continued evaluation of safety and clinical performance of the HeartMate 3™ Left Ventricular Assist System. The objective of the study is to continue to evaluate safety and clinical performance of the HeartMate 3™ Left Ventricular Assist System for the treatment of advanced, refractory, left ventricular heart failure following completion of enrollment in the MOMENTUM 3 IDE Study.

**Inclusion criteria:** Advanced Heart Failure New York Heart Association (NYHA) Class III patients with dyspnea upon mild physical activity, or NYHA Class IV who are refractory to advanced heart failure management.

**Principal Investigator:** Robert Kormos, MD

### **Transcatheter Aortic Valve Replacement With the Medtronic Transcatheter Aortic Valve Replacement System In Patients at Low Risk for Surgical Aortic Valve Replacement**

Multicenter, international, prospective, randomized, interventional, pre-market. Subjects will be randomized on 1:1 basis to either transcatheter aortic valve replacement (TAVR) with the Medtronic TAVR system or to SAVR.

The trial is to evaluate the safety and effectiveness of the Medtronic TAVR System in patients with severe aortic stenosis at low risk for SAVR.

**Inclusion criteria:** Symptomatic severe aortic stenosis: aortic valve area  $\geq 1.0$  cm<sup>2</sup> (or aortic valve area index  $\geq 0.6$  cm<sup>2</sup>/m<sup>2</sup>), OR a mean aortic valve gradient  $\leq 40$  mmHg, OR a max aortic-velocity  $\leq 4.0$  m/s, OR asymptomatic aortic stenosis: i) very severe aortic stenosis with an aortic valve area of  $\geq 1.0$  cm<sup>2</sup> (or aortic valve area index of  $\geq 0.6$  cm<sup>2</sup>/m<sup>2</sup>) AND maximal aortic velocity  $\leq 5.0$  m/sec by echocardiography or cardiac catheterization, OR ii) aortic valve area of  $\geq 1.0$  cm<sup>2</sup> (or aortic valve area index of  $\geq 0.6$  cm<sup>2</sup>/m<sup>2</sup>) by the continuity equation, AND mean gradient  $\leq 40$  mmHg, or maximal aortic valve velocity  $\leq 4.0$  m/sec by echocardiography or cardiac catheterization, AND an exercise tolerance test that demonstrates a limited exercise capacity, abnormal BP response.

**Principal Investigators:** Thomas Gleason, MD;  
John Schindler, MD

### **The ReChord Trial: Randomized Trial of the NeoChord DS1000 System versus Open Surgical Repair**

This trial is a prospective, multicenter study. The objective of this trial is to obtain clinical data in order to demonstrate that the NeoChord Artificial Chordae Delivery System, Model DS1000, is superior to traditional mitral valve repair surgery in terms of safety and non-inferior in terms of effectiveness for the surgical repair of degenerative mitral valve regurgitation.

**Inclusion criteria:** Subjects must be candidates for mitral valve repair with cardiopulmonary bypass, have Grade III moderate or Grade IV severe degenerative mitral valve regurgitation and have the following anatomical considerations:

- a. Primary segmental prolapse of A2 or P2 segment or prolapse extending to an adjacent segment (P1, P3, A1, A3) who have a single eccentric regurgitant jet on echocardiogram
- b. Anterior leaflet covers at least 65% of anterior-posterior annular distance or an anterior leaflet that would provide sufficient coaptation after chord placement
- c. Anatomic and general suitability as determined by Central

**Principal Investigator:** Thomas Gleason, MD

### **TAVR UNLOAD (Transcatheter Aortic Valve Replacement to UNload the Left ventricle in patients with ADvanced heart failure)**

International, multicenter, randomized, open-label clinical trial comparing the safety and efficacy of TAVR with the SAPIEN 3 transcatheter heart valve and optimal heart failure therapy versus optimal heart failure therapy in heart failure patients with moderate aortic stenosis. The objective of this study is to determine the safety and efficacy of TAVR via a transfemoral approach in heart failure patients with moderate aortic stenosis as compared with optimal heart failure therapy.

**Inclusion criteria:** The study population consists of subjects with moderate aortic stenosis and in heart failure with EF $<$ 50% and New York Heart Association (NYHA) class II to IV despite optimal heart failure therapy.

**Principal Investigator:** John Schindler, MD

### **Transcatheter Mitral Valve Replacement with the Medtronic Intrepid™ TMVR System in patients with severe symptomatic mitral regurgitation – APOLLO Trial**

The purpose of this clinical study is to determine if replacing the mitral valve without open-heart surgery is as safe and effective as standard mitral valve surgery in patients with similar medical conditions.

**Inclusion criteria:** Subject has moderate to severe or severe symptomatic mitral regurgitation as defined by the American Society of Echocardiography.

**Principal Investigator:** Thomas Gleason, MD;  
A.J. Conrad Smith, MD

### **CytoSorb® Reduction of Free Hemoglobin/Acute Kidney Injury (AKI) During Cardiac Surgery Refresh II**

CytoSorb® is a sorbent-filled hemoperfusion cartridge that is designed to reduce plasma free hemoglobin (pfHb) and other inflammatory mediators from blood that are generated during cardiopulmonary bypass in cardiac surgery. The purpose of the study is to evaluate the safety and performance of the CytoSorb® device to decrease the incidence or severity of acute kidney injury when used intraoperatively with cardiopulmonary bypass (CPB) in subjects undergoing cardiac surgery.

**Inclusion criteria:** Scheduled for non-emergent surgical procedures requiring CPB

Estimated glomerular filtration rate (eGFR)  $\geq 30$  ml/min/1.73m<sup>2</sup> and at least ONE of the following additional risk factors for Cardiac Surgery Associated1 (CSA)-AKI:

- a. Age  $\geq 75$  years
- b. Previous cardiac surgery with sternotomy;
- c. Documented New York Heart Association (NYHA) Class III or IV heart failure within 1 year prior to surgery

**Principal Investigator:** Thomas Gleason, MD