Referring your patient

The UPMC Heart and Vascular Institute is a leader in conducting research studies and clinical trials to better understand and treat heart failure and pulmonary hypertension.

To refer a patient, please call 1-84-HVI-TRIAL (844-848-7245) or email 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.

Heart Failure

**COAPT**: Prospective, randomized, parallel-controlled clinical evaluation of the safety and effectiveness of the MitraClip® System for the treatment of functional mitral regurgitation in symptomatic heart failure subjects who are treated per standard of care and who have been determined by the site’s local heart team as not appropriate for mitral valve surgery. Eligible subjects will be randomized in a 1:1 ratio to the MitraClip® device (device group) or to no MitraClip® device (control group).

- **Inclusion Criteria**: Symptomatic functional MR (> 3+) of either ischemic or non-ischemic origin, not a surgical candidate, NYHA Class II, III, or ambulatory IV, (LVEF) is ≥ 20% and ≤ 50%, heart failure hospitalization in past 12 months and/or corrected BNP ≥ 300 pg/ml within 90 days of enrollment.
- **Principal Investigator**: Conrad Smith, MD

**DREAM-HF**: Double-blind, randomized, sham-procedure-controlled study to determine whether transcendocardial delivery of 150 million (M) allogeneic human bone marrow derived MPCs (CEP-41750) administered during a single cardiac catheterization with intracardiac mapping is more effective than a scripted sham procedure in patients with chronic heart failure due to LV systolic dysfunction of either ischemic or non-ischemic etiology.

-Inclusion criteria: Age 18-80 with diagnosis of chronic HF of ischemic or non-ischemic etiology for at least six months before the initiation of screening procedures, NYHA Class II-III symptoms, on stable and optimally tolerated dosages of heart failure therapies without change in dose for at least one month before study intervention; LVEF ≤ 40% by 2-D echo. Not on anticoagulation.
- **Principal Investigator**: Marc Simon, MD
- **Primary Interventional Cardiologist**: Catalin Toma, MD

**MedaMACS Study**: Registry.

-Inclusion criteria: Age 18-80, NYHA class III-IV heart failure for 45 of last 65 days, LVEF < 35%, heart failure diagnosis or typical symptoms for 12 months, use of oral medications (beta-blockers, ACE-inhibitors/ARBs, aldosterone antagonist) for at least three months prior to enrollment; hospitalization for heart failure within previous 12 months.
- **Principal Investigator**: Jeffrey Teuteberg, MD
**CardioMEMS Study**: Registry – Study to evaluate the use of the CardioMEMSTM Heart Failure system in a commercial setting.

- **Inclusion Criteria**: Age 18 or older, NYHA Class III, at least one HF admission within the last 12 months, reduced LVEF, HF receiving beta blockers for three months, and an ACE-I or ARB for one month. The study involves recording information from the CardioMEMSTM device implant as part of their standard of care.

- **Principal Investigator**: Michael Mathier, MD

**GRAHF-2**: Multicenter National Institutes of Health-sponsored study looking at the use of a fixed dose combination of nitrates and hydralazine (trade name BIDIL) in African Americans. There is no placebo group. Subjects get FDA-approved BIDIL free for two years. Hypothesis to be tested is that roughly half the cohort (those with a certain genotype, GNB3 TT) will get much greater benefit based on their AHEFT composite scores which combines survival, hospitalization for CHF, and change in quality of life.

- **Inclusion Criteria**: CHF w/LVEF < 35% by echo for at least six months, NYHA Class II-IV, self-designated African American or black, on standard HF background therapy.

- **Principal Investigator**: Dennis McNamara, MD

**Pulmonary Hypertension**

**BEAT Trial**: Multicenter, double-blind, randomized, placebo-controlled, Phase III study to assess the efficacy and safety of oral BPS-314d-MR added-on to treprostinil, inhaled (Tyvaso®) in subjects with pulmonary arterial hypertension.

- **Inclusion Criteria**: Ages 18-80, WHO Group 1, Functional Class III-IV, are on or going to be started on Tyvaso®.

- **Principal Investigator**: Marc Simon, MD

**TDE 310/311**: Phase III, international, multicenter, randomized, double-blind, placebo-controlled, event-driven study to compare the time to first clinical worsening in subjects with pulmonary arterial hypertension receiving UT-15C in combination with a PDE5-I or ERA compared with a PDE5-I or ERA alone.

- **Inclusion Criteria**: Single background PAH-specific oral therapy for greater than 30 days, age 18-75, males and females of childbearing age agree to use medically acceptable method of contraception.

- **Exclusion Criteria**: Pregnant or breastfeeding females, uncontrolled sleep apnea, uncontrolled high blood pressure, unstable psychiatric condition, severe renal disease, current alcohol or drug abuse.

- **Principal Investigator**: Michael Mathier, MD

**REPAIR Trial**: Prospective, multicenter, single-arm, open-label, Phase IV study of the effects of macitentan on right ventricular remodeling in pulmonary arterial hypertension assessed by cardiac magnetic resonance imaging.

- **Inclusion criteria**: Males or females age 18-75, diagnosis of WHO Group 1 pulmonary arterial hypertension, on a stable dose of PAH-specific therapy for a least three months, males and females of childbearing age agree to use medically acceptable method of contraception.

- **Exclusion criteria**: Pregnant or breastfeeding females, weigh less than 88 lbs., BMI greater than 35, recently started or planning to start cardiopulmonary rehab, history of pulmonary embolism or deep vein thrombosis, uncontrolled diabetes, cancer, need dialysis, moderate to severe lung disease, claustrophobia.

- **Principal Investigator**: Marc Simon, MD

**PH Biobank**: Registry.

- **Inclusion Criteria**: WHO Group 1, mean PAP > 25 mmHg, PCWP < 18 mmHg, patients can be both incident (newly diagnosed) and prevalent (actively on PH therapy). Also patients that have been previously enrolled in the REVEAL registry.

- **Principal Investigator**: Marc Simon, MD

**LIBERTY**: Phase 2, randomized, double-blind, placebo-controlled study of ubenimex in patients with pulmonary arterial hypertension (WHO Group 1).

- **Inclusion criteria**: Males or females age 18-75, body weight of at least 88 lbs., diagnosis of WHO Group 1 pulmonary arterial hypertension, on a stable dose of PAH-specific therapy for a least two months, males and females of child bearing age agree to use medically acceptable method of contraception.

- **Exclusion criteria**: Pregnant or breastfeeding females, uncontrolled high blood pressure, persistent low blood pressure, recently starting cardiac or pulmonary rehab, newly diagnosed pulmonary arterial hypertension, severe lung disease, diagnosis of hepatitis B or hepatitis C, BMI greater than 40, history of cancer within the last five years, substance abuse within the last six months.

- **Principal Investigator**: Marc Simon, MD

**TRITON**: Multicenter, double-blind, placebo-controlled, Phase IIIb study to determine the efficacy and safety of initial triple versus initial dual oral combination therapy in patients with newly diagnosed pulmonary arterial hypertension.

- **Inclusion criteria**: Newly diagnosed (within six months) WHO Group 1 pulmonary arterial hypertension, males or females age 18-75, males and females of childbearing age agree to use medically acceptable method of contraception.

- **Exclusion criteria**: Taking any PAH specific drug therapy, BMI greater than 40, participating in cardiac or pulmonary rehab, stroke with 12 weeks of starting the study, history of permanent atrial fibrillation, severe liver disease, ongoing or planned dialysis, females that are pregnant or breastfeeding, current alcohol or drug abuse.

- **Principal Investigator**: Michael Mathier, MD

**RAPAMYCIN**: Phase 1 clinical trial of ABI-009, an mTOR inhibitor, for patients with severe pulmonary hypertension. Subjects will receive IV infusion weekly for 16 weeks to evaluate maximum tolerated dose and safety.

- **Inclusion criteria**: WHO Group 1 PAH, functional class III or IV, on two or more standard PAH therapies.

- **Principal Investigator**: Marc Simon, MD

**Oral Nitrite for Fatigability in HfPEF**: Double-blind, randomized controlled trial of 20-40 mg oral sodium nitrite (capsules) for ~ 4 weeks duration. Pre- and post-drug testing includes functional evaluation, MRI spectroscopy, muscle biopsy, optional right heart cath for central cardiac performance measures.

- **Inclusion Criteria**: Age ≥ 70 years, EF > 40%, diagnosis of HfPEF by prior diagnosis of HF via one of these: medical record diagnosis by attending cardiologist, verbal confirmation of HfPEF with attending cardiologist or PI review of medical record to confirm HfPEF.

- **Principal Investigator**: Daniel E. Forman, MD