Need a research contact?

Looking for studies by practice area?

RESEARCH TEAM CONTACT LISTS
(click practice area to find team list):

- Valve / Structural Heart Team
- Interventional / Endovascular / Imaging / CCAD Team
- HF / Regenerative Therapies Team
- EP / Prevention Team

STUDY LISTS
(click practice area to find study list):

- Valve / Structural Heart Studies
- Interventional / Endovascular / Imaging / CCAD Studies
- HF / Regenerative Therapies Studies
- EP / Prevention Studies

Bookmark this web link to access a list of current, open featured studies: mplsheart.org/studies

MHIF Practice Areas

(click links below to access study and team contact lists)

- Valve / Structural Heart
- Interventional / Endovascular / Imaging / CCAD Science Center
- HF / Regenerative Therapies
- EP / Prevention

Bookmark this web link to access a list of current, open featured studies: mplsheart.org/studies

MHIF Featured Studies
Valve/Structural Heart

MHIF RESEARCH CONTACTS FOR: Valve / Structural Heart

- Accurate IDE for Symptomatic Severe Aortic Stenosis (AS)
- Altflo for Symptomatic clinically significant heart failure and elevated atrial pressures
- Early TAVR for asymptomatic, severe, calcific Aortic Stenosis (AS)
- Evolut Low-Risk for severe aortic valve stenosis in low surgical risk patients
- HighLife for symptomatic mitral regurgitation
- Portico NG for symptomatic severe aortic stenosis (AS)
- REPAIR MR for severe primary MR who are at moderate surgical risk
- TRILUMINATE Pivotal for severe tricuspid regurgitation

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MHIF Featured Studies:
Interventional/Endovascular/Imaging/CCAD Science Center

MHIF RESEARCH CONTACTS FOR: Interventional / Endovascular / Imaging / CCAD

- Disrupt CAD III for calcified coronary artery disease
- ECLIPSE for Coronary Artery Disease
- MINT for Myocardial Ischemia and Transfusion
- Radiance II for hypertension
- Radiance HTN for hypertension
- Spyral HTN for hypertension

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MHIF Featured Studies: HF/Regenerative Therapies

MHIF RESEARCH CONTACTS FOR: HF / Regenerative Therapies

- CORCINCH-HFrEF – ACCUCINCH 5017 ventricular repair system in patient with reduced EF
- Guide HF for heart failure
- Heart EXPAND CAP for heart failure/transplant
- Heart FID Heart failure with iron deficiency anemia
- HITSOVA for Heparin-Induced Thrombocytopenia
- Reduce LAP-HF RCT II for heart failure

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MHIF Featured Studies: EP/Prevention

MHIF RESEARCH CONTACTS FOR: EP / Prevention

- AEGIS 2 for acute coronary syndrome
- AKI for Preventing AKI post OHS
- Artesia for sub-clinical atrial fibrillation (SCAF) detected by PPM, ICD, or ICM
- Cascade FH Registry for familial hypercholesterolemia
- Prominent for high triglycerides, low HDL, T2DM, secondary cardiovascular prevention
- QDOT for paroxysmal atrial fibrillation
- Rhapsody for pericarditis
- Vesalius for high cardiovascular risk without prior myocardial infarction or stroke
- VISITAG SURPOINT for atrial fibrillation
- WARRIOR for non-obstructive CAD in Women

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VALVE AND STRUCTURAL STUDIES

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MHIF FEATURED STUDY:

ACURATE IDE

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:
Symptomatic Severe Aortic Stenosis (AS)

PI:
Santiago Garcia, MD

RESEARCH CONTACT:
Karen Meyer, RN

Karen.meyer2@allina.com | 612-863-5855

SPONSOR:
Boston Scientific

DESCRIPTION:

To evaluate safety and effectiveness of the ACURATE *neo 2*™ Transfemoral Aortic Valve System for transcatheter aortic valve replacement (TAVR) in symptomatic subjects with severe aortic stenosis who are considered at intermediate or greater risk for surgical valve replacement. Prospective , multicenter, 1:1 randomization to any commercially available TAVR device).

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

1. Severe native aortic stenosis defined as initial AVA ≤1.0 cm^2 (or AVA index ≤0.6 cm^2/m^2) AND a mean pressure gradient ≥40 mm Hg OR maximal aortic valve velocity ≥4.0 m/s OR Doppler velocity index ≤0.25 as measured by echocardiography and/or invasive hemodynamics
2. Aortic annulus size of ≥21 mm and ≤27 mm
3. Symptomatic aortic valve stenosis per IC1 definition above with NYHA Functional Class ≥ II

Exclusion

1. Unicuspid or bicuspid aortic valve.
2. Previous acute myocardial infarction within 30 days prior to the index procedure
3. Subject has severe aortic, tricuspid, or mitral regurgitation

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MHIF FEATURED STUDY:

ALTFLO

OPEN AND ENROLLING:

EPIC message to “Research MHIF Patient Referral”

CONDITION:
Symptomatic clinically significant heart failure and elevated atrial pressures

PI:
Paul Sorajja, MD

RESEARCH CONTACT:
Karen Meyer, RN

Karen.meyer2@allina.com | 612-863-5855

SPONSOR:
Edwards LifeScience

DESCRIPTION:

Multi-center, prospective, early feasibility study to evaluate initial clinical safety, device functionality and effectiveness of the Edwards Transcatheter Atrial Shunt System.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

1. Chronic symptomatic Heart Failure (HF)
2. Stable Guideline Directed Medical Therapy (GDMT) for heart failure management
3. Elevated LA (or PCWP) pressure of >15 mmHg at rest or >25 mmHg during supine ergometer exercise stress test.

Exclusion

1. Severe HF
    1. ACC/AHA/ESC Stage D, non ambulatory NYHA IV
    2. Cardiac index <2.0L/min/m2
    3. Inotropic infusion
    4. Listed for cardiac transplant
    5. LVEF <20%
2. Presence of significant valve disease (>3+MR, > 2+TR, >2+ AR or > moderate AS)

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MHIF FEATURED STUDY:

Early TAVR Trial

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:
Asymptomatic, severe, calcific Aortic Stenosis (AS)

PI:
Santiago Garcia, MD

RESEARCH CONTACT:
Aisha Ahmed
Aisha.Ahmed@allina.com | 612-863-9362

SPONSOR:
Edwards Lifesciences

DESCRIPTION:

Prospective, multicenter study, randomized 1:1 with the SAPIEN 3 valve or clinical surveillance. Patients must have suitable anatomy for transfemoral Transcatheter Aortic Valve Replacement (TAVR). **75 sites in the U.S. and 1109 patients will be enrolled.**

PARTIAL CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Aortic valve area (AVA) ≤ 1.0 $[\![cm]\!]$^2 or AVA index ≤ 0.6 $[\![cm]\!]$^2/m^2

AND

- Peak jet velocity ≥ 4.0 m/s or Mean gradient ≥ 40 mmHg
- Negative treadmill stress test
- EF ≥ 50%

Exclusion

- NYHA ≥ 2, hx of syncope, HF hospitalization within last 12 mo
- Concominent valvular or CAD requiring surgery
- Acute MI ≤ 30 days before randomization

ACTION: Do you see patients with severe aortic stenosis but remain asymptomatic?

If so, please contact Dr. Garcia or Aisha Ahmed (Study Coordinator) aisha.ahmed@allina.com

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MHIF FEATURED STUDY:

EVOLUT Low-Risk

Status:
In Follow-Up

CONDITION:
Severe aortic valve stenosis in low surgical risk patients

PI:
Paul Sorajja, MD

RESEARCH CONTACT:
Karen Meyer, RN

Karen.meyer2@allina.com | 612-863-5855

SPONSOR:
Medtronic

DESCRIPTION:

Transcatheter aortic valve replacement (TAVR) with FDA approved Medtronic Evolut TAVR system for patients at low surgical risk for surgical aortic valve replacement (SAVR). Subjects are randomized 1:1 to either TAVR or SAVR. This study is comparing SAVR to TAVR in a new patient population for this approved device.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Severe aortic stenosis, either symptomatic or asymptomatic (no bicuspid valves)
- Documented heart team agreement that the subject is considered low surgical risk (predicted risk of mortality for SAVR < 3% at 30 days)
- Follow-up is for 10 years

MHIF FEATURED STUDY:

HighLife

OPEN AND ENROLLING:

EPIC message: *Research MHIF Patient Referral*

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Symptomatic mitral regurgitation	Paul Sorajja, MD	Jane Fox Jane.fox@allina.com | 612-863-6289	HighLife Medical, Inc.

DESCRIPTION:

Purpose: to **evaluate the safety and efficacy of the HighLife trans-septal access 28mm Transcatheter Mitral valve and its delivery system (*transfemoral venous access and interatrial puncture*) in patients with moderate-severe or severe mitral regurgitation who are at a high risk for surgical treatment.**

Primary Feasibility endpoint: technical success

Safety: all cause mortality at 30 days

Performance: total MR reduction to 1+ or less as assessed by core lab

CRITERIA LIST/ QUALIFICATIONS:

Inclusion: moderate-severe or severe mitral regurgitation; NHYA class II, III; or ambulatory class IV

Exclusion: mitral stenosis; Flail Leaflet or prolapse; severe calcification; prior mitral intervention; mitral annulus <30 mm & >45 mm; Aortic prosthesis; LVEF<30%; PAS >70mmHg; TR requiring intervention

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MHIF Featured Study: **PORTICO NG**

CONDITION:
Symptomatic Severe Aortic Stenosis (AS)

PI: Paul Sorajja, MD

CONTACT: Jennifer Nguyen, CRC
Jennifer.Nguyen@allina.com; 612-863-9291

SPONSOR:
Abbott Vascular, Inc

DESCRIPTION:

Prospective, single-arm study of the Portico™ NG transcatheter aortic valve in patients with symptomatic, severe aortic stenosis at *high to extreme risk* for surgical aortic valve replacement

ACTION:

Is your patient experiencing symptomatic severe AS and at high to extreme risk for SAVR?

Contact **Dr. Sorajja** or **Jennifer Nguyen** (Study Coordinator; Jennifer.Nguyen@allina.com)

PARTIAL CRITERIA LIST / QUALIFICATIONS:

INCLUSION:

- Symptomatic, severe aortic stenosis
- High – extreme risk of mortality with surgical aortic valve replacement (STS ≥7% or heart team agreement)

EXCLUSION:

- Congenital unicuspid or congenital bicuspid aortic valve
- Severe aortic, mitral, or tricuspid regurgitation
- Pre-existing prosthetic heart valve or implant in any valve position
- Untreated, clinically significant coronary artery disease
- Severe pulmonary hypertension
- Left ventricular ejection fraction (LVEF) <25%

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MHIF FEATURED STUDY:

REPAIR-MR

Coming soon!

EPIC message: *Research MHIF Patient Referral*

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Severe primary MR who are at moderate surgical risk	Paul Sorajja, MD	Jane Fox Jane.fox@allina.com | 612-863-6289	Abbott

DESCRIPTION:

Purpose: to **compare the clinical outcome of MitraClip™ device versus open surgical repair in patients with severe primary MR who are at moderate surgical risk.**

Primary endpoint: survival, free of stroke and any cardiovascular hospitalization at 2 years; MR ≤ mild at 30 days; QOL improvement of at least 5 points at 2 years compared to baseline; hospital length of stay; rate of mitral valve replacement at index procedure

CRITERIA LIST/ QUALIFICATIONS:

Inclusion: severe primary MR (Grade III or greater mitral regurgitation mixed etiology is acceptable if principal mechanism is a degenerative mitral valve); symptomatic NHYA class II, III, or asymptomatic with EF ≤ 60%, PAS >50 mm HG, or LVESD >40 mm; 75 years or if < 75 years subject with STS predicted risk of mortality repair score >2%, or presence of comorbidities

Exclusion: ischemic or non-ischemic secondary MR; EF <30%; severe TR; severe annular calcification; valve anatomy which would preclude reducing MR to mild or less

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MHIF FEATURED STUDY:

TRILUMINATE Pivotal

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:	*NATIONAL* PI:	RESEARCH CONTACT:	SPONSOR:
Severe Tricuspid Regurgitation (TR)	Paul Sorajja, MD	Kate Jappe, RN Kate.Jappe@allina.com | 612-863-7347	Abbott Vascular Inc.

DESCRIPTION:

Prospective, randomized, multicenter trial of TriClip™ device in symptomatic patients with severe tricuspid regurgitation (TR) who have been determined to be at intermediate or greater estimated risk for mortality with tricuspid valve surgery.

PARTIAL CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Symptomatic severe TR despite optimal medical therapies (drug and/or device)
- Adequately treated per applicable standards and stable for 30 days
- Intermediate or greater surgical risk of mortality with tricuspid valve surgery

Exclusion

- Systolic pulmonary artery pressure (sPAP) >70 mmHg
- Severe uncontrolled hypertension Systolic Blood Pressure (SBP) ≥180 mmHg and/or Diastolic Blood Pressure (DBP) ≥110mmHg
- Pacemaker or ICD leads that would prevent appropriate placement of TriClip
- Left Ventricular Ejection Fraction (LVEF) ≤ 20%

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STUDIES FOR:

Interventional
Endovascular
Imaging
CCAD Science Center

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MHIF FEATURED STUDY:

DISRUPT CAD III

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:
Calcified Coronary Artery Disease

PI:
Nicholas Burke, MD

RESEARCH CONTACT:
Jo Anne Goldman, RT
JoAnne.Goldman@allina.com | 612-863-3793

SPONSOR:
Shockwave Medical

DESCRIPTION:

Phase III study to assess the safety and effectiveness of the Shockwave Coronary Intravascular Lithotripsy (IVL) System to treat de novo, calcified, stenotic, coronary lesions prior to stenting.

PARTIAL CRITERIA LIST/ QUALIFICATIONS:

Inclusion

Untreated severely calcified lesion in a coronary artery

Vessel size 2.5mm to 4.0mm

70-99% stenosis

Exclusion

STEMI

Previous stented target lesion

ACTION: Are the patients you are referring for coronary angiography appropriate for this trial?

Contact Dr. Burke or Jo Anne Goldman, RT (Study Coordinator) joanne.goldman@allina.com

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MHIF FEATURED STUDY:

ECLIPSE

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Coronary Artery Disease	Ivan Chavez, MD	Amy McMeans amy.mcmeans@allina.com | 612-863-3895	Cardiovascular Systems, Inc.

DESCRIPTION:

Prospective, randomized 1:1 (stratified by site single lesion vs multiple lesion) multicenter trial to evaluate Orbital Atherectomy compared to conventional balloon angioplasty technique for the treatment of severely calcified lesions prior to implantation of drug-eluding stents.

PARTIAL CRITERIA LIST/ QUALIFICATIONS:

Inclusion

Present with stable ischemic heart disease, NSTEMI or USA, or stabilized recent STEMI > 48hr with severe calcification

Excludes patients with previous PCI within 12 months

Excludes patients unable to take DAPT for min. of 6 months

MHIF FEATURED STUDY:

MINT

STATUS:
In Follow-Up

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Myocardial Ischemia and Transfusion	Jay Traverse, MD	Rose Peterson Rose,Peterson@@allina.com | 612-863-6051	NIH Trial

Evidence suggests it is safe to wait to give a blood transfusion; however, for those who have suffered a heart attack, there is a lack of high-quality evidence to guide transfusions. **The study's results will influence transfusion practice worldwide.**

- **DESCRIPTION:**

  MINT is a multicenter randomized clinical trial comparing red blood cell transfusion strategies for patients who have had a myocardial infarction and are anemic (positive troponins and a hemoglobin of less than10 g/dL).

  The trial will enroll 3500 hospitalized patients diagnosed with myocardial infarction who are anemic (have blood counts less than 10 g/dL) to receive either a liberal or a restrictive transfusion strategy. Patients will be followed for 6 months to assess how well they are recovering from their heart attack.

- **CRITERIA LIST/ QUALIFICATIONS:**

  Inclusion

  Positive Troponin and a hemoglobin of less than 10 g/dL

MHIF FEATURED STUDY:

RADIANCE II Study

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Hypertension	Yale Wang, MD	Rose Peterson Rose.Peterson@allina.com | 612-863-6051	ReCor

DESCRIPTION:

Designed to assess potential therapeutic benefits of catheter directed renal denervation in managing essential and resistant hypertension. The study objective is to demonstrate the effectiveness and safety of the Paradise System in subjects with Stage 2 hypertension on 0-2 medications at time of consent. Prior to randomization, subjects will be hypertensive in the absence of hypertension medication.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Age 18-75 years at time of consent (reduces potential that hypertension is due entirely to stiff arteries)
- History of being "treated" with antihypertensive medications
- Uncontrolled at screening visit (average seated office BP ≥ 140/90 mmHg and < 180/120 mmHg) on no more than 2 antihypertensive medications
- Must remain uncontrolled (daytime ABP ≥ 135/85 mmHg and < 170/105 mmHg) after a 4-week washout/run-in period
- Must have an eligible renal anatomy documented by MRA or CTA and confirmed by renal angiogram at procedure (where applicable)

Exclusion

- Lacks appropriate renal artery anatomy for treatment; known, uncorrected causes of secondary hypertension other than sleep apnea
- Type I diabetes mellitus or uncontrolled Type II diabetes; eGFR of <40; Brachial circumference ≥ 42 cm
- History of cerebrovascular event or severe cardiovascular event, or history of stable or unstable angina within 12 months; Repeat (>1) hospitalization for hypertensive crisis

RADIANCE-HTN

STATUS:
In Follow-Up

- **CONDITION:** Hypertension; Vascular Diseases
- **CONTACT INFO:** Rose Peterson, RN | Rose.Peterson@allina.com | 612-863-6051
- **DESCRIPTION: Hypertension, or high blood pressure,** affects over 1 billion people. Left untreated, high blood pressure can increase your risk of serious health problems such as heart attack, stroke, and kidney failure. Yet nearly 1 in 3 individuals with hypertension struggle to control their blood pressure despite being on medication.

  If you and your physician have been unable to control your blood pressure, or are interested in an alternative to daily medications, you may be a candidate for the **RADIANCE-HTN Clinical Study**. The study is evaluating an investigative minimally-invasive, catheter-based procedure (the Paradise® Renal Denervation System) which may lower your blood pressure and reduce your need for blood pressure medications.
- **CRITERIA LIST/ QUALIFICATIONS:** Complete this questionnaire to see if you qualify to participate in the Radiance-HTN Study.
- **INVESTIGATORS:** Yale Wang, MD
- **SPONSORS:** ReCor Medical
- **STATUS:** Open/Enrolling

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MHIF FEATURED STUDY:

SPYRAL-HTN

STATUS:
In Follow-Up

CONDITION:
Hypertension

PI:
Yale Wang, MD

RESEARCH CONTACT:
Carina Benson
Carina.Benson@allina.com | 612-863-6288

SPONSOR:
Medtronic

DESCRIPTION:

The aim of the study is to test the hypothesis that renal denervation is safe and reduces systolic blood pressure (SBP) in patients with uncontrolled hypertension compared to a sham controlled population, in the absence of antihypertensive medications (OFF MED) or uncontrolled hypertension on one, two, or three standard antihypertensive medications (ON-MED).

PARTIAL CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Office systolic blood pressure (SBP) ≥150mmHg and <180mmHg and an office diastolic blood pressure(DBP) ≥90mm Hg with or without meds

Exclusion:

- Main renal artery < 3 mm or > 8 mm ; eGFR <45 ml/min

***Screen failure if OSBP> or = 180 mm Hg**

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HEART FAILURE/REGENERATIVE STUDIES

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MHIF FEATURED STUDY:

CORCINCH-HFrEF

(aka ACCUCINCH 5017)

STATUS:
In Follow-Up

ACCUCINCH ventricular repair system in patient with reduced EF	**PI:** Peter Eckman, MD	**RESEARCH CONTACT:** Jake Jensen Jacob.jensen@allina.com | 612-863-8818	**SPONSOR:** Ancora Heart

DESCRIPTION:

The objective of this trial is to evaluate the safety and performance of the AccuCinch system in patients with HFrEF.

CRITERIA LIST / QUALIFICATIONS:

Inclusion

Dilated Ischemic Cardiomyopathy or Non Ischemic Cardiomyopathy; NYHA III-Iva; LVEF ≥ 20 and ≤ 40%

Exclusion

No mod-severe MR, AR, or AS; TAPSE >14, severe TR; no AV prosthesis; LVEDD must be ≥ 55 mm

> 3m from CRT or > 1m from ICD implant or revision (LBBB and QRS >150 required to have CRT)

~6.5 million Americans and ~25 million people worldwide have HF.

Projections show that the prevalence of HF will increase 46% from 2012 to 2030, resulting in >8 million people ≥18 years of age with heart failure.

MHIF Featured Study: **Guide HF**

EPIC message to "Research MHIF Patient Referral"

CONDITION:
Heart Failure

PI: Mosi Bennett, MD

CONTACT: Sarah Schwager 612-863-6257
Kari Thomas, 612.863.7493

SPONSOR:
Abbott Vascular

DESCRIPTION:

Study comparing CardioMEMS sensor to standard of care heart failure treatment. There are 1.2+ MILLION hospitalizations for decompensation of heart failure annually.

The CardioMEMS sensor is a wireless PA pressure monitoring system which enables providers to proactively treat heart failure and reduce the likelihood of hospitalization.

REFER PATIENTS!

PARTIAL CRITERIA LIST / QUALIFICATIONS:

Inclusion

All heart failure patients (NYHA Class II-IV)

Patients with and without a prior heart failure hospitalization

Exclusion

Received or are likely to receive an LVAD or heart transplant

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MHIF FEATURED STUDY:

Heart EXPAND CAP

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:	PI:	RESEARCH CONTACTS:	SPONSOR:
Heart Failure/Transplant	Karl Mudy, MD	Kari Thomas - Kari.M.Thomas@allina.com | 612-863-7493 Kari Williams - Kari.Williams@allina.com | 612-863-0027	TransMedics, Inc.

DESCRIPTION: a single-arm study evaluating the OCS™ Heart System and extended criteria donor hearts (those that are currently not transplanted or are seldom transplanted in the US)

CRITERIA LIST/ QUALIFICATIONS:

Donor Heart Inclusion

- Expected total cross-clamp time of ≥4 hours; **OR** expected total cross-clamp time of ≥2 hours PLUS one of the following risk factors:
  - Donor age 45-55 years, inclusive, with no coronary catheterization data
  - Donor age ≥55 years
  - Left ventricular septal or posterior wall thickness of >12 mm, but ≤16 mm
  - Reported down time of ≥20 min, with stable hemodynamics at time of final assessment
  - Left heart ejection fraction (EF) ≥40%, but ≤50% at time of acceptance of offer
  - Donor angiogram with luminal irregularities with no significant CAD (≤50%)
  - History of carbon monoxide poisoning with good cardiac function at time of donor assessment
  - Social history of alcoholism with good cardiac function at time of donor assessment
  - History of diabetes without significant CAD on angiogram (≤50%)

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Heart-FID

OPEN AND ENROLLING:
EPIC message to "Research MHIF Patient Referral"

- **CONDITION:** Heart failure with iron deficiency anemia
- **PI:** Peter Eckman, MD
- **CONTACT INFO:** Stephanie Ebnet, RN | stephanie.ebnet@allina.com | 612-863-6286
  Sarah Schwager, RN | sarah.schwager@allina.com | 612-863-6257

DESCRIPTION: This is a randomized, double blind, placebo-controlled study to investigate the efficacy and safety of Injectafer® (ferric carboxymaltose) as treatment for heart failure with iron deficiency. Study drug administration will occur as two intravenous doses every six months for duration of study.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion:

- Ejection fraction ≤35%
- Stable heart failure (NYHA II-IV) on maximally tolerated background therapy
- Hemoglobin 9.0-13.5 g/dL (females) or <15.0 g/dL (males), serum ferritin <100 ng/mL or 100-300 ng/mL with TSAT <20%

Exclusion:

- Current or planned LVAD or heart transplantation, history of recent cardiovascular events, and significant co-morbidities

SPONSOR: Luitpold Pharmaceuticals, Inc.

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MHIF FEATURED STUDY:

HITSOVA

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:
Heparin Induced Thrombocytopenia

PI:
Nedaa Skeik, MD

RESEARCH CONTACTS:
Carina Benson: carina.benson@allina.com
612-863-4393 | pgr: 612-654-5542

Jane Fox: jane.fox@allina.com | 612-863-6289

SPONSOR:
Aspen Global, Inc.

DESCRIPTION: Open-Label, Randomized, Active Controlled, Multi-Centre Phase 3 Study to Evaluate the Safety and Efficacy of Danaparoid vs Argatroban in Treatment of Subjects with Acute HIT (HITSOVA study)

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

Males or females aged ≥2 weeks

Subjects with suspected HIT by 4Ts of >3 and with reduction of platelet count of ≥ 30% at either:

a) Between Day 4 and 14 of the start of heparin exposure **OR**
b) At Day 1 of heparin exposure with pre-treatment with heparin within the last 30 days

Have adequate renal function: Glomerular filtration rate ≥ 15 mL/min/1.73 m²

Exclusion

- Life expectancy less than study duration of 44 days
- Lumbar puncture or spinal/epidural catheter placement within past 48 hrs
- Severe hepatic impairment (Child-Pugh Class C)
- Active bleeding
- Hemorrhagic cerebrovascular accident within previous 3 mos.
- Severe, uncontrolled hypertension defined as blood pressure >180/110 mmHg
- Diabetic retinopathy

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MHIF FEATURED STUDY:

REDUCE LAP-HF RCT II

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Heart Failure	Michael Samara, MD	Jane Fox jane.fox@allina.com | 612-863-6289	Corvia Medical Inc.

DESCRIPTION:

A study to evaluate the Corvia Medical, Inc. IASD® System II to **REDUC**E **E**levated **L**eft **A**trial **P**ressure **in** Patients with **H**eart **F**ailure

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Age>40 years – GDMT for 4 weeks
- HF requiring current treatment w/ diuretics for ≥ 30 days AND NYHA class II if a prior history of > NYHA class II, to ambulatory NYHA class IV
- IV diuretics or need for intensification of oral diuresis for HF 12 months prior; OR an NT-pro BNP value > 150 pg./ml in normal sinus rhythm, > 450 pg./ml in AFIB, or a BNP value > 50 in NSR or, > 150 in AFIB within past 6 months
- EF ≥ 40% within the past 6 months, without EF <30% in the past 5 years
- End-expiratory PCWP during supine ergometer exercise ≥ 25mm Hg, and > RAP by ≥ 5 mm Hg.

Exclusion

- Inability to perform 6-minute walk test (distance < 50 m), OR 6-minute walk test > 600m
- Resting RAP > 14 mmHg
- MI and/or percutaneous cardiac intervention within past 3 months; CABG in past 3 months, or current indication for coronary revascularization; AVR (surgical AVR or TAVR) within past 12 months
- Significant PH with PVR > 3.5 Woods units at rest or at peak exercise

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EP/PREVENTION STUDIES

HOPE
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MHIF FEATURED STUDY:

AEGIS 2

OPEN AND ENROLLING:

Please Refer Patients to Steph!

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Acute Coronary Syndrome	Thomas Knickelbine, MD	Stephanie Ebnet Stephanie.ebnet@@allina.com | 612-863-6286	CSL Behring

- **DESCRIPTION:**

  CSL112 is being developed for use in patients with ACS (diagnosed with either STEMI or NSTEMI and exclusive of unstable angina) to reduce the risk of CV death, MI, and stroke upon delivery of CSL112.

  Evidence from the Apo-I Event Reducing in Ischemic Syndromes-I (AEGIS-I) study has demonstrated that administration of apoA-I increases cholesterol efflux in MI patients

- **CRITERIA LIST/ QUALIFICATIONS:**

  Inclusion

  Positive Troponin with at least 50% stenosis on > 1 epicardial artery or prior cath with at least 50% stenosis on > 1 epicardial artery or prior CABG

  Additional risk factor: DM, > 65 y.o., prior hx of MI or PAD

  Exclusion

  - EF < 30%
  - ALT > 3 x ULN
  - GFR< 30
  - Body weight < 50 kg
  - Allergy to soy beans or peanuts
  - Plan for CABG

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MHIF FEATURED STUDY:

AKI

Coming soon:
Please Refer Patients!

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Preventing AKI post OHS	Dr. Shukrallah	Steph Ebnet Stephanie.ebnet@allina.com | 612-863-6286	Astellas Pharma Inc. (API)

DESCRIPTION: To evaluate the efficacy of post-surgery treatment with ASP1128 (investigational medication) in subjects at risk for acute kidney injury (AKI) following coronary artery bypass graft (CABG) and/or valve surgery. ASP1128 is a potent and highly selective PPARδ modulator, that is believed to have protective effects on kidney cells that are under cellular stress as a result of ischemia, inflammation and oxidative stress following coronary artery bypass graft and/or valve (CABG/V) surgery. In addition, ASP1128 will reduce inflammatory responses and increased oxidative stress systemically which is expected to reduce the immediate consequences of stress responses following CABG/V surgery.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Subject undergoing non-emergent open chest cardiovascular surgery with use of CPB (i.e., CABG and/or valve surgery [including aortic root and ascending aorta surgery, without circulatory arrest)
- Subject has moderate/high risk of developing AKI following surgery (must have 2 risk factors):
    - Risk factors: age > 70, eGFR < 60, CHF, DM, proteinuria/albuminuria

Exclusion

- On another investigational medication
- GFR < 30
- Prior kidney transplant
- Known or suspected glomerulopephritis
- Endocarditis or active infection
- Surgery off pump
- IV Drug abuse
- Chronic liver disorder
- LVAD

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ARTESIA

CONDITION: Sub-clinical atrial fibrillation (SCAF) detected by PPM, ICD, or ICM.

PI: JoEllyn Moore, MD

CONTACT INFO: Jacob Cohen, MS | jacob.cohen@allina.com | 612-863-4022

DESCRIPTION: Prospective, randomized, parallel group, double-blind trial to determine if the use of apixaban in patients with SCAF will reduce the incidence of stroke and systemic embolism compared to aspirin. The experimental part of being in this study is being randomized to either aspirin or apixaban.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion:

- Permanent pacemaker or defibrillator (with or without resynchronization) or insertable cardiac monitor capable of detecting SCAF
- At least one episode of device-detected SCAF ≥ 6 minutes in duration but no single episode > 24 hours in duration at any time prior to enrollment. Any atrial high rate episode with average > 175 beats/min will be considered as SCAF. No distinction will be made between atrial fibrillation and atrial flutter.
- Age ≥ 55 years
- Risk Factor(s) for Stroke:
  - Previous stroke, TIA or systemic arterial embolism **OR** Age at least 75 **OR** Age 65-74 with at least 2 other risk factors **OR** Age 55-64 with at least 3 other risk factors

Exclusion:

- Clinical atrial fibrillation documented by surface ECG (12 lead ECG, Telemetry, Holter) lasting ≥ 6 minutes, with or without clinical symptoms

SPONSOR: Hamilton Health Sciences Corporation through the Population Health Research Institute (PHRI)

Cascade FH Registry

CONDITION: Familial Hypercholesterolemia (FH), a genetic condition marked by dramatically high levels of LDL-C that are not related to diet or lifestyle.

PI: Thomas Knickelbine, MD

CONTACT INFO: Christine Majeski, RN | christine.majeski@allina.com | 612-863-3546

DESCRIPTION: A national registry tracking the longitudinal treatment, clinical outcomes and patient reported outcomes of FH with the aim of increasing awareness and family screening of FH.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion:

- Patient with existing diagnosis of FH using one of the three diagnostic tools:
  - US MedPed Program Criteria
  - Simon Broome Register Criteria with a diagnosis of “probable”
  - Dutch Lipid Clinic Network Diagnostic Criteria with a diagnosis of “probable”
- Patients with FH genetic mutation

Exclusion:

- Patients with a known medical condition other than FH thought to contribute to hyperlipidemia (i.e. untreated hyperthyroidism, nephrotic syndrome, cholestasis hypopituitarism

SPONSOR: FH Foundation

MHIF FEATURED STUDY:

PROMINENT

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:
High triglycerides, low HDL, T2DM, secondary cardiovascular prevention

PI:
Dr. Matthew Chu
SUB I'S:
Marc Newell, MD
Thomas Knickelbine, MD
Amy Cooley, CNP

RESEARCH CONTACT:
Ezi Ebere
Ezi.Ebere@allina.com | 612-863-4393

SPONSOR:
Kowa Research Institute

DESCRIPTION:

Placebo controlled trial of a potent fibrate, pemafibrate, to prevent MI, ischemic stroke, unstable angina requiring revascularization, and CV death in adults with T2DM.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion
TG > 200, HDL < 40, T2DM, LDL<70 or high dose statin or statin intolerant

Exclusion
Type 1 diabetes, HbA1c > 9.5%, NYHA Class IV HF, significant liver disease

TRIGLYCERIDES MATTER – AND THIS STUDY IS HELPING ADDRESS THEM!

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MHIF FEATURED STUDY:

QDOT

OPEN AND ENROLLING:
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CONDITION:
Proxysmal Atrial Fibrillation (PAF)

PI:
Daniel Melby, MD

RESEARCH CONTACT:
Jacob Cohen
Jacob.Cohen@allina.com | 612-863-4022

SPONSOR:
Biosense Webster

DESCRIPTION:

Prospective, non-randomized, pre-market clinical evaluation of the QDOT MICRO™ catheter for pulmonary vein isolation (PVI) in the treatment of subjects with paroxysmal atrial fibrillation.

PARTIAL CRITERIA LIST/ QUALIFICATIONS:

Inclusion

Symptomatic paroxysmal AF with one electrocardiographically documented AF episode within 6 months prior to enrollment and a physician's note indicating recurrent self-terminating AF within 7 days

Failed at least one (1) antiarrhythmic drug (AAD) (class I or III) as evidenced by recurrent symptomatic AF, contraindicated or intolerable to the AAD

Exclusion

Previous surgical or catheter ablation for atrial fibrillation

Patient on amiodarone at any time during] past 3 months prior to enrollment

Previously diagnosed with persistent or long-standing persistent AF and/or continuous AF lasting > 7 days

ACTION: Are the patients you are referring for EP consultation and ablation appropriate for this trial?

If so, please contact Dr. Melby or Jacob Cohen, MS (Study Coordinator) jacob.cohen@allina.com

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MHIF FEATURED STUDY:

Rhapsody

STATUS:
In Follow-Up

CONDITION:
Pericarditis

PI:
David Lin, MD

RESEARCH CONTACT:
Christine Majeski
Christine.Majeski@allina.com | 612-863-3546

SPONSOR:
Kiniksa Pharmaceuticals

DESCRIPTION:

First multinational, phase 3, double-blinded, placebo-controlled, randomized withdrawal, study assessing the efficacy of rilonacept, an interleukin 1 alpha and beta receptor decoy, in the treatment of recurrent pericarditis.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

Diagnosis of recurrent pericarditis

Exclusion

- Pericarditis secondary to specific prohibited etiologies, including tuberculosis (TB); neoplastic, purulent, or radiation etiologies
- Post-thoracic blunt trauma (e.g., motor vehicle accident)
- Myocarditis
- Systemic autoimmune diseases with exception of Still's disease, pregnancy, hx HIV, prednisone > 60 mg/day, positive Hep B or C, serious infection

MHIF was first in the world to enroll in this trial and has 4 subjects enrolled out of the 9 in the world.
Pericarditis patients are experiencing significant benefits and most often have no chest pain after starting this medication.

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MHIF FEATURED STUDY:

Vesalius

OPEN AND ENROLLING:
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CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
High Cardiovascular Risk Without Prior Myocardial Infarction or Stroke	Thomas Knickelbine, MD	Ezi Ebere Ezi.Ebere@allina.com | 612-863-4393	Amgen Inc.

DESCRIPTION:

The purpose of this trial is to evaluate the effect Evolocumab has in reducing the risk of coronary heart disease (CHD) death, MI, stroke, and ischemia-driven arterial revascularization in adults at high risk of cardiovascular events **without prior MI or stroke**.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- ≥ 50 years (men); or ≥ 55 years (women) to < 80 years of age (either sex)
- LDL-C ≥ 100 mg/dL (≥ 2.6 mmol/L) or HDL-C ≥ 130 mg/dL (≥ 3.4 mmol/L) on maximal tolerated therapy
- CAD w revasc
- High calcium score (≥100)
- TIA, carotid revasc, PVD
- DM with microvascular disease
- **PLUS** one high risk criteria: polyvascular disease, metabolic syndrome, Lp(a)>125, LDL ≥130, known FH, fam hx premature CAD, CRP ≥3, current tobacco, ≥ 65 yrs, eGFR < 45

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MHIF FEATURED STUDY:

VISITAG SURPOINT

OPEN AND ENROLLING:

EPIC message to "Research MHIF Patient Referral"

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Atrial Fibrillation (AF)	Daniel Melby, MD	Jacob Cohen Jacob.Cohen@allina.com | 612-863-4022	Biosense Webster

DESCRIPTION:

Primary objective of study is to **demonstrate safety and 12-month effectiveness of Tag Index-guided ablation using VISITAG SURPOINT™ Module** with External Processing Unit when used with THERMOCOOL SMARTTOUCH® SF (STSF) and THERMOCOOL SMARTTOUCH® (ST) catheters for pulmonary vein isolation (PVI) in the treatment of subjects with drug refractory symptomatic paroxysmal AF.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

1. Symptomatic paroxysmal AF; had at least 1 AF episode electrocardiographically documented within 1 year prior to enrollment Documentation may include ECG, TTM, Holter monitor or telemetry strip
2. Failed at least 1 antiarrhythmic drug (AAD Class I or III) as evidenced by recurrent symptomatic AF, or intolerable to the AAD

Exclusion

1. Previous surgical or catheter ablation for AF
2. Previous cardiac surgery (including CABG) within past 6 months (180 days)
3. Valvular cardiac surgical/percutaneous procedure (i.e., ventriculotomy, atriotomy, and valve repair or replacement and presence of a prosthetic valve)

AF is the most common sustained arrhythmia.

It affects 0.4% to 1% of the general population, and increases in prevalence with age.

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MHIF FEATURED STUDY:

WARRIOR - Women's Ischemia Trial

OPEN AND ENROLLING:

EPIC message: ***Research MHIF Patient Referral***

CONDITION:
Non-Obstructive CAD in Women

PI:
Retu Saxena, MD

RESEARCH CONTACT:
Steph Ebnet
Stephanie.ebnet@allina.com | 612-863-6286

SPONSOR:
University of FL Funded by the Department of Defense

DESCRIPTION:

The purpose of WARRIOR (Women's Ischemia Trial to Reduce Events in Non-Obstructive CAD) is to evaluate if intensive medical therapy (IMT) (**potent statin plus ACE-I or ARB**) is better than usual care in women who have s/s of suspected ischemia but no obstructive CAD (defined as <50 stenosis). The hypothesis is that IMT will reduce MACE 20% vs. usual care.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Signs and symptoms of suspected ischemia prompting referral for further evaluation by coronary angiography or coronary CT angiogram within previous 3 years
- Non-obstructive CAD defined as 0-50% diameter reduction of a major epicardial vessel

Exclusion

- Hx NIHCM
- ACS within 30 days
- LVEF< 40% NYHA HF class III-IV
- Prior intolerance to ACE/ARB
- ESRD on dialysis
- Severe valvular disease requiring TVAR within 3 years
- Stroke within 180 days

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CALLING FOR RESEARCH REFERRALS!

Talk with your patients about their options,
including clinical research.

Bookmark this link as a resource to access current, featured studies and MHIF research contact information:

mplsheart.org/studies

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