

THE LINDNER RESEARCH CENTER

20

May 2022

It's almost summertime! Here is hoping the Reds will get hot when the weather does! This month we review the extensive cardiovascular surgery portfolio. From my perspective, one of the strengths of The Christ Hospital is the wonderful collaborative relationship between Cardiology, Cardiovascular Surgery, and Vascular Surgery. We highlight Xylocor, a Gene Therapy trial encoding for multiple forms of VEGF in patients with refractory angina. We are one of the top enrolling sites and the initial reports are very encouraging! We also highlight the new LVAD trial.

We include The Christ Hospital presentations for the annual SCAI meeting next when Dr. Henry will finish his year as SCAI president and hand the gavel to Dr. Sunil Rao. It's amazing how fast the year has gone but Dr. Henry will continue to be on the executive committee for SCAI as the immediate past president.

We welcome 9 talented students who begin the summer student program on May 23, 2022. We want to thank the mentors, research coordinators, and staff that facilitate this outstanding program that continues to grow and mature each year.

Finally, we would like to highlight the GALA on May 21, 2022! If you haven't bought a table please contact Rick Kammerer at 585-3395 or by email richard.kammerer@thechristhospital.com. We are hoping to fill the 1200 seats! If you already bought a table and have spots available consider inviting key research or clinical staff from The Christ Hospital.



Final Student Summer List 2022

Mentor	Student
Dr. Eugene Chung	John Ernst
Dr. Kari Gorder/Dr. Tim Smith	Maya Sayles
Dr. Burns Blaxall	Mason Chambal
Dr. Odayme Quesada	Namrita Ashokprabhu
Dr. John Corl	Conor Bohrer
Dr. Eugene Chung	Shriya Kilarua

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Dr. Wojciech Mazur	Austin Caldwell
Dr. Odayme Quesada	Aarushi Shewale
Dr. Tim Henry	Conner Harper

CV Surgery Research Trials

Trial/ Databases	PI	Status	# Months Active	# Screened	# Enrolled	Last Patient Enrolled	Brief Description
Foldax TRIA Aortic Heart Valve Replacement Sponsor: Foldax, Inc.	Answini	Trial on hold per sponsor	27	18	9 (2 nd highest enroller)	8/13/21	The Foldax TRIA Aortic Valve offers a flexible valve alternative with the perceived advantage of both the bio prosthetics and mechanical valves without the disadvantages. Patients only require 6 months of anticoagulation. It is a prosthetic heart valve with a flexible polymer stent and annular base. Three flexible polymer leaflets are bonded to the frame using a casting process. Polymeric leaflet material surrounds the apertures, leaving a central opening in each aperture. The base of the valve is covered with ePTFE to create a sewing ring.
Foldax TRIA Mitral Heart Valve Replacement Sponsor: Foldax, Inc	Answini	Trial is on hold per sponsor	8	2	1	6/15/21	The same composition as above for patients with mitral stenosis or MR.
Apollo Sponsor: Medtronic	Answini	Enrolling	57	39	5 + 1 procedure scheduled 6/2 (TF approach) and 2 more	12/10/20	Transcatheter Mitral Valve Replacement with the Medtronic Intrepid™ TMVR System in patients with severe symptomatic mitral regurgitation via

					patients in screening.		transapical or transfemoral approach.
Xylocor Sponsor: Xylocor Therapeutics	Henry	Enrolling	29	13	4 + 1 procedure scheduled this month	12/8/21	A Phase 1/2 trial of direct administration via intracoronary infusion of AdVEGF-All6A+, a Replication-deficient adenovirus vector expressing a cDNA/Genomic hybrid of human vascular endothelial growth factor, to the ischemic myocardium of subjects with angina secondary to CAD that is refractory to drug therapy and unsuitable for revascularization.
AltaValve Sponsor: 4C Technologies	J Michael Smith/Choo	Enrolling	13	16	0	NA	4C Medical has developed a novel TMVR device for the treatment of symptomatic MR in affected patients, called AltaValve. The AltaValve is comprised of a self-expandable stent and a tissue-based valve that is deployed in the left atrium superior to the native MV, preserving the native MV. The stent has a twofold function - it anchors the implant within the LA by oversizing and performs as a scaffold for the tissue valve.
OSTENE Sponsor: Baxter	Answini	Enrolling	3	32	27	1/19/22 First in enrollment	The objective of this post-marketing study is to evaluate the effectiveness of OSTENE for the control of bleeding from bone surfaces when used during CV surgery. OSTENE is an odorless, opaque, wax-like sterile mixture of water-soluble alkylene oxide copolymers.
On-X Registry Sponsor: On-X Life Technologies	Answini	Enrolling	64	25	25	3/9/21	The purpose of the study is to assess the occurrence of bleeding, valve-related thromboembolism and valve thrombosis with the On-X Aortic Prosthetic Heart Valve when targeted at an INR level of 1.8 (1.5-

							2.0 range) during a 5-year follow-up period.
Competence Sponsor: Evaheart, Inc	Egnaczyk/ Answini	Waiting for IRB approval	1	0	0	0	Study of the EVAHEART left ventricular assist system. The system is a continuous flow centrifugal pump that employs a hydrodynamic impeller levitation system designed to preserve arterial pulsatility, minimize red cell trauma and blood stagnation and lower risk of ventricular septal suction.

Highlighted Trials

XYLOCOR

PI: Tim Henry, M.D.

Study coordinator: Denise Krabbe

A phase 1/2 trial of direct administration of AdVEGF-A116A+, a replication deficient adenovirus vector expressing a cDNA/genomic hybrid of human vascular endothelial growth factor, to the ischemic myocardium of subjects with angina pectoris secondary to coronary artery disease that is refractory to drug therapy and unsuitable for revascularization. Subjects are followed through 6 months, with a 6-month extension. Approximately 12 subjects will be enrolled into 4 ascending dose groups, followed by an expansion of the highest tolerated dose with approximately 26-32 additional subjects.

Inclusion criteria: Diagnosis of chronic angina due to obstructive CAD that is refractory to drug therapy and unsuitable for revascularization; Hx reversible left ventricular ischemia that has not resolved; Coronary angiography within 12 months; Two ECG stress tests that adhere to protocol requirements; Angina class II-IV as measured by CCS; On stable regimen of anti-anginal, anti-hypertensive, and lipid lowering medications; Formally cleared by the ERC to undergo the gene therapy procedure; Anti-adenovirus serotype 5 neutralizing antibody titer <1:321; Adequate hematologic function & renal function

Exclusion criteria: STEMI or NSTEMI within 30 days; Current hypercholesterolemia; Uncontrolled hypertension; Current electrocardiographic abnormalities that would interfere with ST-segment analysis; Untreated malignant ventricular arrhythmia; Untreated bradyarrhythmia for which an artificial pacemaker is indicated; Congestive HF; Mitral or aortic valvular disease requiring mechanical intervention; BMI that would interfere; Diabetic individuals with active proliferative diabetic retinopathy or glycosylated hemoglobin; Hx of HIV, HCV, HBV or active COVID-19 infection; Contraindication to adenosine or regadenoson; Hypersensitivity to amide-containing agents

COMPETENCE

PI(s): Gregory Egnaczyk, M.D.

Study coordinator: Ashleigh Schwartz

A prospective, multicenter, unblinded, randomized, controlled, and non-inferiority study comparing the EVA2 LVAS to the most recent magnetically levitated centrifugal LVAS (HM3) when used for the treatment of refractory NYHA Class III with dyspnea upon mild physical activity or Class IV heart failure. Subjects will be randomized at a 2:1 ratio (EVA2:HM3). Awaiting IRB approval.

Inclusion criteria: Body surface area $\geq 1.4^2$; NYHA Class III with dyspnea upon mild physical activity or Class IV; LVEF $<30\%$; Other hemodynamic parameter and mechanical circulatory assist devices: Inotrope dependent OR Cardiac Index <2.2 L/min/m 2 while not on inotropes that meet additional criteria

Exclusion criteria: HF due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amyloidosis, or restrictive cardiomyopathy; Technical difficulties that may impact increased surgical risk and clinical outcomes; Ongoing mechanical circulatory support other than IABP and Impella 5.0/5.5; Ongoing Impella (5.0 or 5.5) presenting related clinical sign and elevated LDH; Presence of mechanical aortic cardiac valve that will not be converted to a bioprosthesis; Hx of organ transplant; Platelet count $< 100,000$ /mL; Psychiatric disease/disorder, irreversible cognitive dysfunction, psychosocial issues, or hx of untreated or repeated drug abuse; Hx of confirmed, untreated abdominal aortic aneurysm > 5 cm in diameter within 6 mos; Presence of active infection; Intolerance to anticoagulant/antiplatelet therapies; Moderate to severe aortic insufficiency without plans for correction during pump implant; Planned Bi-VAD support prior to enrollment

April Publications

1. Maqsood MH, Khalil M, Maraey A, Elzanaty AM, Louka B, Elbadawi A, Ong K, Megaly M, **Garcia S**. Temporal Trends and Outcomes of Same-Day Discharge After Left Atrial Appendage Occlusion: Insight from National Readmission Database. Am J Cardiol. 2022 Apr 15:S0002-9149(22)00353-8. doi: 10.1016/j.amjcard.2022.03.049. Epub ahead of print. PMID: 35431051
2. Sedhom R, Megaly M, Saad M, Elbadawi A, Witzke CF, **Garcia S**, Latib A, Gafoor SA. Transcatheter edge-to-edge repair of the tricuspid valve: The US experience. Catheter Cardiovasc Interv. 2022 Apr 1. doi: 10.1002/ccd.30141. Epub ahead of print. PMID: 35362665.
3. Blankstein R, Shaw LJ, Gulati M, Atalay MK, Bax J, Calnon DA, Dyke CK, Ferencik M, Heitner JF, **Henry TD**, Hung J, Knuuti J, Lindner JR, Phillips LM, Raman SV, Rao SV, Rybicki FJ, Saraste A, Stainback RF, Thompson RC, Williamson E, Nieman K, Tremmel JA, Woodard PK, Di Carli MF, Chandrashekhar YS. Implications of the 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Chest Pain Guideline for Cardiovascular Imaging: A Multisociety Viewpoint. JACC Cardiovasc Imaging. 2022 May;15(5):912-926. doi: 10.1016/j.jcmg.2022.02.021. PMID: 35512960.
4. Sharma J, McAlister J, Aggarwal NR, Wei J, Mehta PK, **Quesada O**, Mattina D, Scott NS, Michos ED, Mahmoud Z, Kurrelmeyer K, Moraes De Oliveira GM, Lindley KJ. Evaluation and management of blood lipids

through a woman's life cycle. *Am J Prev Cardiol.* 2022 Mar 13;10:100333. doi: 10.1016/j.ajpc.2022.100333. PMID: 35345879; PMCID: PMC8956895.

5. Megaly M, Sedhom R, Hakam L, **Garcia S**. The MANTA vascular closure device: Requiring attention from beginning to end, reply. *Cardiovasc Revasc Med.* 2022 Apr 20:S1553-8389(22)00177-4. doi: 10.1016/j.carrev.2022.04.004. Epub ahead of print. PMID: 35469758.
6. Fukui M, Cavalcante JL, Ahmed A, Bae R, Bapat VN, Gössl M, **Garcia S**, Enriquez-Sarano M, Sorajja P. Clinical Outcomes of Mitral Valve Disease With Mitral Annular Calcification. *Am J Cardiol.* 2022 Apr 18:S0002-9149(22)00337-X. doi: 10.1016/j.amjcard.2022.03.041. Epub ahead of print. PMID: 35450733.
7. Kern MJ, Applegate B, Bittl J, Block P, Butman S, Dehmer G, Garratt KN, **Henry TD**, Hirshfeld J, Holmes DR Jr, Kaplan A, King S, Klein LW, Krucoff MW, Kutcher MA, Naidu SS, Pichard A, Ruiz CE, Skelding KA, Tobis JM, Tommaso C, Weiner BH, White C. Conversations in cardiology: Late career transitions-Retool, retire, refocus. *Catheter Cardiovasc Interv.* 2022 Apr 21. doi: 10.1002/ccd.30210. Epub ahead of print. PMID: 35446473.
8. Singh J, Durr MR, Deptuch E, Sultana S, Mehta N, **Garcia S**, **Henry TD**, Dehghani P. Cardiac Registries During the COVID-19 Pandemic: Lessons Learned. *Curr Cardiol Rep.* 2022 Apr 5:1–7. doi: 10.1007/s11886-022-01686-5. Epub ahead of print. PMID: 35380385; PMCID: PMC8981885.
9. **Kereiakes DJ**. Invited Editorial. Differential Clinical Benefit With Contemporary Drug-Eluting Stents: Fact or Fancy? *JACC Asia.* 2022 April;2(2):194-196.
10. Thomas AW, **Kereiakes DJ**, Baumbauch A, Windecker S, Pietras C, Dressler O, Issever MO, Curtis M, Bertolet B, Zidar JP, Smits PC, Jimenez Diaz VA, McLaurin B, Cequier A, Takahashi A, Cannon LA, Amoroso G, Kakuta T, Saito S, Leon MB, Lansky A. Safety and Efficacy of the Supreme Biodegradable Polymer Sirolimus-Eluting Stent in Patients With Diabetes Mellitus. *JSCAI.* 2022 March;1(2).

Research and Lindner Highlights

SCAI Scientific Sessions

May 18-21, 2022 (In-Person)

Wednesday, May 18th, 2022

Time: 7:15 pm – 8:00 pm (Eastern)	Session: SCAI Global Case-Based Leadership Summit: Complex Interventions Without Borders Complex Coronary Live Case Location: Centennial I Dr. Timothy Henry - Panelist
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Thursday, May 19th, 2022

Time: 8:15 am – 9:30 am (Eastern)	Session: Controversies of Chronic CAD Management Location: Hyatt Regency Atlanta, Regency VII Dr. Timothy Henry - Moderator, Dr. Santiago Garcia - Panelist
Time: 9:00 am – 9:10 am (Eastern)	Session: Featured Clinical Research: Part 1 Location: Hyatt Regency Atlanta, Centennial I Title: Sex Differences in Clinical Characteristics, Management Strategies, and Outcomes of STEMI Patients With COVID-19 Authors: Odayme Quesada, Logan Van Hon, Mina Madan, Mehmet Yildiz, Cristina Sanina, Laura Davidson, Wah Wah Htun, Jacqueline Saw, Santiago Garcia , Payam Dehghani, Larissa Stanberry, Timothy D. Henry , Cindy L. Grines, Catherine Benziger
Time: 12:30 pm – 1:00 pm (Eastern)	Session: President's and Program Chair's Welcome and Award Presentations Location: Hyatt Regency Atlanta, Centennial I Dr. Timothy Henry - Presenter
Time: 4:45 pm – 6:15 pm (Eastern)	Session: Case Exchange: Optimal Revascularization Strategy in STEMI Patients with Multivessel Disease Location: Hyatt Regency Atlanta, The Learning Center Dr. Timothy Henry - Moderator

Friday, May 20th, 2022

Time: 8:30 am – 8:50 am (Eastern)	Session: SCAI Town Hall Location: Hyatt Regency Atlanta, Centennial I Dr. Timothy Henry - Presenter/Moderator
Time: 9:00 am – 10:30 am (Eastern)	Session: Case Exchange: Optimal Revascularization Strategy in STEMI Patients with Multivessel Disease. Featured Clinical Research Part 2 Location: Hyatt Regency Atlanta, Centennial I Dr. Timothy Henry - Moderator
Time: 2:40 pm – 2:49 pm (Eastern)	Session: Dealing with Complications: When an Ounce of Prevention Fails Location: Title: Protecting the Kidneys: Tools for Minimizing AKI Dr. Santiago Garcia - Presenter

Saturday, May 21st, 2022

Time: 6:30 am – 7:00 am (Eastern)	Session: Breakfast Program: An Emerging Interventional Therapy for Refractory Angina – The Next Frontier Location: Hyatt Regency Atlanta, Regency VII Dr. Timothy Henry - Moderator/Presenter
Time: 8:00 am – 8:50 am (Eastern)	Session: Women in Innovation (WIN) Challenging Case Sessions: Coronary Location: Hyatt Regency Atlanta, Grand Hall CD Dr. Timothy Henry - Panelist
Time: 9:00 am – 10:30 am (Eastern)	Session: Case Exchange: Challenging High-Risk Intervention Location: Hyatt Regency Atlanta, The Learning Center Dr. Timothy Henry - Panelist

The Christ Hospital Gala

Imagine Bold Foundation. Boundless Future.

Benefitting The Christ Hospital Heart & Vascular Institute

www.thechristhospital.com/about-the-network/foundation/gala

The Christ Hospital Gala will be a celebration of all that Greater Cincinnati's Heart Hospital has accomplished over the past four decades and will set the stage for the future of heart care in our great city.

SATURDAY, MAY 21, 2022

IMAGINE
BOLD FOUNDATION BOUNDLESS FUTURE

BENEFITING
**The Christ Hospital
Heart & Vascular Institute**

**DUKE ENERGY
CONVENTION CENTER
GRAND
BALLROOM
6:30 P.M.
COCKTAIL ATTIRE
ALL ATTENDEES VACCINE VERIFIED**

**The
Christ Hospital
Health Network**

Event Details

May 21, 2022

6:30 p.m.

Duke Energy Convention Center, Grand Ballroom

For more information, contact Dianne Fisk at: Dianne.Fisk@TheChristHospital.com or [513-585-0881](tel:513-585-0881).

Staff Spotlights



Mark Hoyle RN, BSN, MBA

Interventional Nurse Coordinator

I achieved a BSN eighteen years ago. Since that time, I have worked in Colorado, California, Washington, Oregon, Germany, and now Ohio. When I crossed the stage to receive my degree, I would have never imagined my nursing degree would give me the opportunity to work in so many different places. In addition, I've been fortunate to meet and provide care to patients in Med/Surg units, ICU, Preop/Postop, PACU, Cardiac Rehab, Schools, and now Research. This year, my husband and I moved to Ohio due to an incredible job opportunity with the Army Corp of Engineers. Ohio was never on our radar, and we didn't have any family or friends in Ohio, but when the opportunity came up, we agreed we were up for another adventure. I say adventure because I feel like our life has been one incredible adventure after another, from adopting two wonderful sons, working in many states and Germany, and many travel opportunities. Now that we've found a house, beginning to feel settled, and establishing friendships, we are looking forward to exploring the tri-state area.

Reminders

Research Group Meeting
June 08, 2022, 6:30-7:30am
Microsoft Teams