CORVITA

CREATING SOLUTIONS, ADVANCING KNOWLEDGE.

PROJECTS BRIEF Q1 FY19

1006 S. Michigan Ave, Suite 500 • Chicago, IL 60605

PRINCIPLE CENTERED MEDICINE™

CSF is happy to welcome our newest Council Chair for Clinical Electrophysiology, Dr. David Rhine. Dr. Rhine's leadership will help elevate CSF presence as he leads several new international clinical trials in the field of heart rhythm disorders including the burgeoning field of left atrial appendage occlusion. Dr. Rhine also embraces the CSF movement in Principle Centered Medicine™ to help bring the patient-doctor relationship back to the forefront of healthcare.

As Principle Centered Medicine is something CSF is very passionate about, CSF is committed to work on educating medical professionals about the importance of their relationship with their patients and how it can improve outcomes which will be collected as "official intelligence" and analyzed towards better patient care and outcomes (true quality) and presented as part of the community trust. CSF is delighted that Dr. Rhine has joined us in this quest and we have the utmost confidence in his contribution towards implementation.

RESEARCH

CSF and Midwestern University's Institute for Healthcare Innovation (IHI), are excited to announce that Midwestern students, Justin Figueroa, Brett Breshears and Erik Mersereau (who is pictured on the left), were invited to the European Society of Cardiology Annual Congress held in Munich, Germany in September as peer reviewed presenters of their research. Their poster was titled "Digitalization of SICD Charge Events Identifies Pre-Charge Electrogram Variants Leading to Oversensing." These students have been working with Dr. Martin Burke for over a year taking raw analog EKG data and reverse digitizing it, using a public domain pixel process produced by Google. Their research is part of pilot program in machine learning that is being spearheaded by CSF in collaboration with Midwestern and the University of Amsterdam's Academic Medical Center.

The collaboration between CSF and Midwestern University IHI, has taught students, like Justin, Brett and Erik, better understanding of the importance of research in medicine. The internship program is year-round with new medical student's joining the program on a quarterly basis. The program consists of weekly lectures, mentorship from physician leaders and access to data from current and past enrolled clinical trials for them to review and use in their research.

MEDICAL EDUCATION

CSF finished its first year of the research internship program with Midwestern University IHI. As mentioned above, this partnership has allowed medical students to pursue their interest in the medical science while working along physician mentors. One of our intern group presented their research, as pictured above. While we had another internship, group focused on the development of comprehensive electronic data capture system to create CSF very own registry, also known as the MANAGE-AF.

Beginning 2019, CSF will introduce several new educational opportunities for physicians, nurses, technicians and other medical professions within the Chicagoland area. These activities are meant to dive deeper into cardiovascular disease and inform medical professionals on best practices. We also plan on initiating working forums to bring physicians together to review and discuss their challenging patient cases with their colleagues to promote collaboration.

CLINICAL TRIALS (ENROLLING)

MANAGE AF– The objective of this multi-site research is to establish a contemporary and simple registry to help determine the course and progression of patients with atrial fibrillation (AF). Its main focus is the management of AF in the prevention of thrombo-embolic events using rhythm and rate control interventions.

APPRAISE ATP– The primary objective is to understand the role of anti-tachycardia pacing (ATP) in primary prevention patients indicated for ICD therapy. The incidence of all-cause shocks in subjects programmed with shocks only will be compared with subjects programmed to standard therapy (ATP and shock) to assess equivalency.

PRAETORIAN DFT– The primary objective is to determine whether the S-ICD implant without defibrillation testing using a new method of measurement (PRAETORIAN Score) is similar to the standard method of defibrillation testing with a totally subcutaneous implantable defibrillation system (S-ICD). The secondary objectives are to evaluate the PRAETORIAN score and to evaluate anesthesia protocols for implantation.

PREEMPT HF– The goal of the PREEMPT-HF study is to collect device and clinical event data to evaluate extended applications of the HeartLogic™ Heart Failure Diagnostic (HeartLogic) in a broad spectrum of heart failure (HF) patients with an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D). There are no primary safety and/or efficacy endpoints for this study.

FY19 PUBLICATIONS

CorVita continues to pride itself of its constant research and publications and will therefore share all additional publications over the course of the fiscal year. Publications are listed below:

Quast ABE, Baalman SWE, Brouwer TF, Smeding L, Wilde AAM, **Burke MC**, Knops RE. A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable defibrillator: The PRAETORIAN score. Heart Rhythm. 2018 Oct 4. doi: 10.1016/j.hrthm.2018.09.029.

Rajamannan NM. TIEG1 is upregulated in Lrp5/6-mediated valve osteogenesis. J Cell Biochem. 2018 Sep 23. doi: 10.1002/jcb.27606.

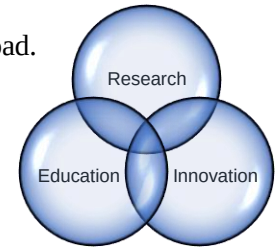
Essandoh MK, Mark GE, Aasbo JD, Joyner CA, Sharma S, Decena BF, Bolin ED, Weiss R, **Burke MC**, McClernon TR, Daoud EG, Gold MR. Anesthesia for subcutaneous implantable cardioverter defibrillator implantation: Perspectives from the clinical experience of a U.S. panel of physicians. PACE 2018; doi: 1111/pace. 13664

Theuns DAMJ, Brouwer TF, Jones PW, Allavatam V, Donnelley, S, Auricchio A, Knops RE, **Burke MC**. Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter defibrillator. Heart Rhythm 2018; 15(10): 1515-1522.

Quast ABE, Tjong FVY, Koop BE, Wilde AAM, Knops RE, **Burke MC**. Device orientation of a leadless pacemaker and subcutaneous implantable cardioverter-defibrillator in canine and human subjects and the effect on intrabody communication. Europace. 2018; 20(11): 1866-1871.

ABOUT US

The CorVita Science Foundation (CSF) is a Chicago-based nonprofit (501(c)(3)) dedicated to the accessibility and advancement of cardiovascular clinical and translational science at home and abroad.



Our partnerships and collaborations with universities around the world has allowed us to introduce new and innovative clinical data processes. CSF provides the infrastructure, educational content and direction as well as clinical data oversight and adjudication to advance the efficiency and quality of a new paradigm of clinical research amongst our partners.

Device Industry	Pharma Industry	Engineering	Biomedical Startups	Global Tech
• Successfully performed and enrolled in 50 + clinical and animal trials/studies in last 10 years mostly IDE level • Successfully navigated and passed IDE FDA audits • 25 year relationships with established industry leaders	• Successfully performed and enrolled in 10 clinical trials in last 10 years • Leaders in the Chicago area for CME events linking progressive care to colleagues, industry and partners • Known experts in clinical science worldwide with access to projects	• Link to Illinois Institute of Technology Pritzker Biomedical Engineering Center. • Access MWU BSE/DO program and curriculum • Adjunct faculty at University of Amsterdam	• Consults with new medical startups on R&D • Identifies new tech ideas at various levels of funding and development in their research plans through Venture groups • Provides access to outside US research labs to perform early stage feasibility data collection	• Centers of excellence in education and machine learning links to a global tech network using internet, telephony and social media: • IBM • Google • Apple • Amazon • Facebook • Microsoft

Doctor/Patient Relationship + **CorVita Science** + **Biomedicine Clinical Projects** = **ROI**

Our Office is Located at:

1006 S. Michigan Ave, Suite 500

Chicago, IL 60605

Office phone number: (773) 432-4888

Email us at: connect@corvitahealth.org

Or visit our website at www.corvitascience.org

PARTNERS / AFFLIATIONS

Burning Lake Productions · Illinois Institute of Technology · Carle Illinois College of Medicine · Midwest Big Data Hub · amc Academic Medical Center University of Amsterdam · AtaCor Medical · ACOI American College of Osteopathic Internists · Midwestern University Tomorrow's Healthcare Team · GMB Media