CORVITA

CREATING SOLUTIONS, ADVANCING KNOWLEDGE.

PROJECTS BRIEF Q4 FY18

www.corvitascience.org

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PRINCIPLE CENTERED MEDICINE™

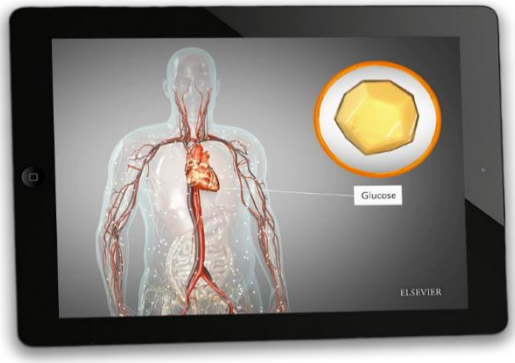
What is it? Principle Centered Medicine is practiced around the world every day but remains undervalued. Principle Centered Medicine is a movement dedicated to re-building and placing the majority capital and support towards the doctor-patient relationship/interaction and CorVita is all in. A principled physician is only motivated by data and care that generates a benefit to patients rather than that which checks a box on a computer impersonally. Patients deserve a culture of Principle Centered Medicine that values prevention, individual patient focused treatments and perspectives gained by listening rather than being assigned as a number on an insurer's or clinic's list. In collaboration with the American College of Osteopathic Internists, CSF will drive an evidence - based collection of principle centered data (described below in RESEARCH) and use these points of care to drive better patient outcomes, better insurance reimbursement for principled clinics and for advancement of a culture of safe care. Ultimately this will make not only patients but as important their physicians, who are burning out at alarming rates, more well.

MEDICAL EDUCATION

CSF in partnership with Midwestern University's Institute for Healthcare Innovation (IHI), has established a cutting-edge training program for medical students seeking further education in clinical research. These students have access to data from current and past enrolled clinical trials providing a real-life apprenticeship in clinical scholarly activity. The education curriculum for the students include: Fundamentals of Clinical Trials in Cardiovascular Medicine; Review of Federal and Regulatory Guidelines; Standard IRB Process; Evaluation of Contract Agreements; CV specific project mentoring linked to clinical questions and care; Instruction in developing evidence-based data for clinical medicine. CSF has also help guide the students to ensure that they are asking the right questions and creating their own methodologies for improving patient care.

VIDEO EDUCATION LAB

CSF is in the early works of a video education program. The Education Laboratory will focus on bringing science, research and medical information globally to students, residents, fellows and physician. The **v**ideo series will include advance cardiovascular disease education modules which will be followed-up with corresponding questions after each section to test the viewers comprehension. Initially, a video series will include highlighting recently published journal articles and reviewing the results of recent clinical research studies along with introducing an expert viewpoint of the new clinical information.



RESEARCH

CSF has collaborations with colleagues around the world. These collaborations have increased CSF global scale allowing the physicians to collaborate on ideas and patient information.

Clean well-adjudicated data is king. CSF experts in the field of cardiovascular medicine are trained and experienced physicians and researchers using computing technology to create smarter machines and algorithms by adjudicating and validating large training sets centered on patient outcomes and individual responses. The computing speed has a great deal of bandwidth and not enough data. The algorithms only become intelligent with well officiated and expert classification of the data. Choosing the data that is important to patient care and outcomes becomes extremely important. CSF has invested great capital and effort into setting the stage to solve the lack of data with programs such as ADHERE AF and MANAGE AF. These two studies are designed for extended understanding of outcomes with specific points of data collection to drive better patient care algorithms.

CLINICAL TRIALS (ENROLLING)

ADHERE AF– The aim of this study is to assess how many atrial fibrillation (AF) patients in general AF population there are with predicted low adherence using the Medication Adherence Score (MAS).

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.

PREEMT HF– The goal of the PREEMPT-HF study is to collect device and clinical event data to evaluate extended applications of the HeartLogicTM 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.

FY18 PUBLICATIONS

CorVita had several publications over the last fiscal year. Publications are listed below:

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. Pacing Clin Electrophysiol. 2018 May 13. doi: 10.1111/pace.13364.

Frankel D, **Burke MC**, Callans D, Stivland T, Duffy E, Epstein A. (2018). Impact of Body Mass Index on Safety and Efficacy of the Subcutaneous Implantable Cardioverter-Defibrillator. JACC: Clinical Electrophysiology. 10.1016/j.jacep.2017.11.019.

Quast AF, Tjong F, Koop B, Wilde AAM, Knops RE, **Burke MC**. (2018). Device orientation of a leadless pacemaker and subcutaneous implantable cardioverter-defibrillator in canine and human subjects and the effect on intrabody communication. EP Europace. 10.1093/europace/euy019.

Theuns DAMJ, Brouwer TF, Jones P, Allavatam V, Donnelley S, Auricchio A, Knops RE, **Burke MC**, A Prospective, Blinded Evaluation Of A Novel Sensing Methodology Designed To Reduce Inappropriate Shocks By The Subcutaneous Implantable Defibrillator, Heart Rhythm (2018), doi: 10.1016/j.hrthm.2018.05.011

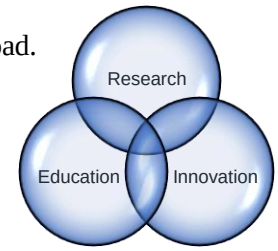
Tjong FVY, Brouwer TF, Koop B, Soltis B, Shuros A, Schmidt B, Swackhamer B, Quast AEB, Wilde AAM, **Burke MC**, Knops RE. Acute and 3-Month Performance of a Communicating Leadless Anti-tachycardia Pacemaker and Subcutaneous Implantable Defibrillator. JACC Clin Electrophysiol. 2017 Dec 26;3(13):1487-1498. doi: 10.1016/j.jacep.2017.04.002. Epub 2017 May 31.

Waxman AB, McElderry HT, Gomberg-Maitland M, **Burke MC**, Ross EL, Bersohn MM, Pangarkar SS, Tarver JH, Zwicke DL, Feldman JP, Chakinala MM, Frantz RP, Thompson GB, Torres F, Rauck RL, Clagg K, Durst L, Li P, Morris M, Southall KL, Peterson L, Bourge RC. Totally Implantable IV Treprostinil Therapy in Pulmonary Hypertension Assessment of the Implantation Procedure. Chest. 2017 Dec;152(6):1128-1134. doi: 10.1016/j.chest.2017.04.188. Epub 2017 Jun 3.

Gold MR, Aasbo JD, El-Chami MF, Niebauer M, Herre J, Prutkin JM, Knight BP, Kutalek S, Hsu K, Weiss R, Bass E, Husby M, Stivland TM, **Burke MC**. Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. Heart Rhythm. 2017 Oct;14(10):1456-1463. doi: 10.1016/j.hrthm.2017.05.016. Epub 2017 May 11.

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**

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