

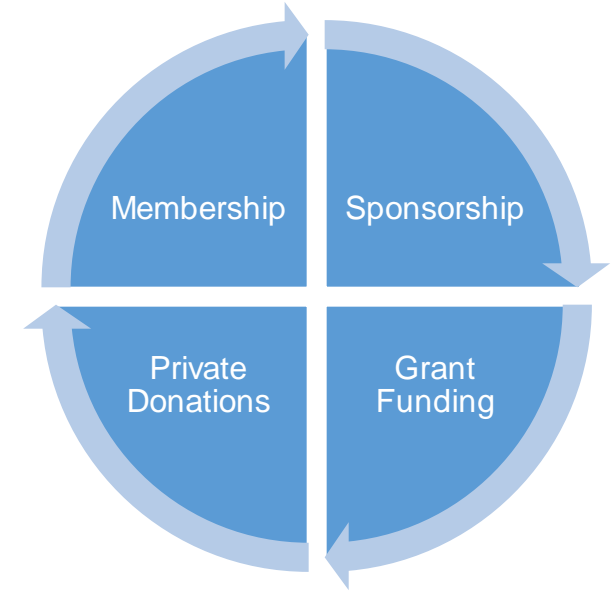
Building a Culture of Scholarly Activity in IM Programs

Riverside Medical Center
Research Day 2019



Why pursue scholarly activity?

- Expands Leadership Quality
- Recruitment of trainees
- Sources of revenue
- Advances clinical quality
- Advances Mentorship/Promotion
- Links global education to local care
- Offers expanding professional opportunity
- Is going to link to clinical revenue
- Builds reputation = recruitment



WSJ Op-Ed Piece by Eric Topol, MD

July 2017

This is an ideal and progressive article that offers technology based solutions to the current healthcare morass. However, it places the cart before the horse as the current doctor-patient culture in almost all clinical arenas is not capable of adopting the methods due to a lack of research or focus in progressive models of care.

This is mainly due to archaic financial models.

CorVita Science solves the gap in infrastructure piece by piece in order to progress local care systems already focused on patient care and outcomes while advancing new revenue models and a *Patient-Medicine solution*

THE WALL STREET JOURNAL.

ESSAY :

The Smart-Medicine Solution to the Health- Care Crisis

Our health-care system won't be fixed by insurance reform. To contain costs and improve results, we need to move aggressively to adopt the tools of information-age medicine



What constitutes scholarly work?

- Clinical Science
 - Case Reports
 - Retrospective chart review
 - Investigator initiated research
 - Large randomized clinical trials
- Basic Science
 - Bench lab results
 - Tool shops (Biomedical Engineering)
- Translational Science
 - Moving clouds of basic and clinical closer



Quality, Benchmarking and Physician Wellness

Physicians are experiencing higher burnout rates than ever before and CSF wants to help to re-establish their leadership within the US Health System by focusing **quality data collection on the physician-patient relationship**. CSF would like to reset the benchmarking data methods based on patient outcomes and setting the standards. Physicians need to manage and control their data on outcomes.



Global Research and Education

CSF will provide education, mentorship and “hands-on” research experience related to IRB preparation, submission and management of clinical trials to students, residents, fellows and cardiovascular physicians



Professional Research Group

Provide principal investigators with clinical research infrastructure and trained/locally imbedded Clinical Trial Coordinators or Research Professionals to support and enroll patients meeting inclusion/ exclusion criteria in clinical studies.

CSF will train these team members so research data collected will be **consistent** and of utmost **high quality** while able to survive audits and monitoring.



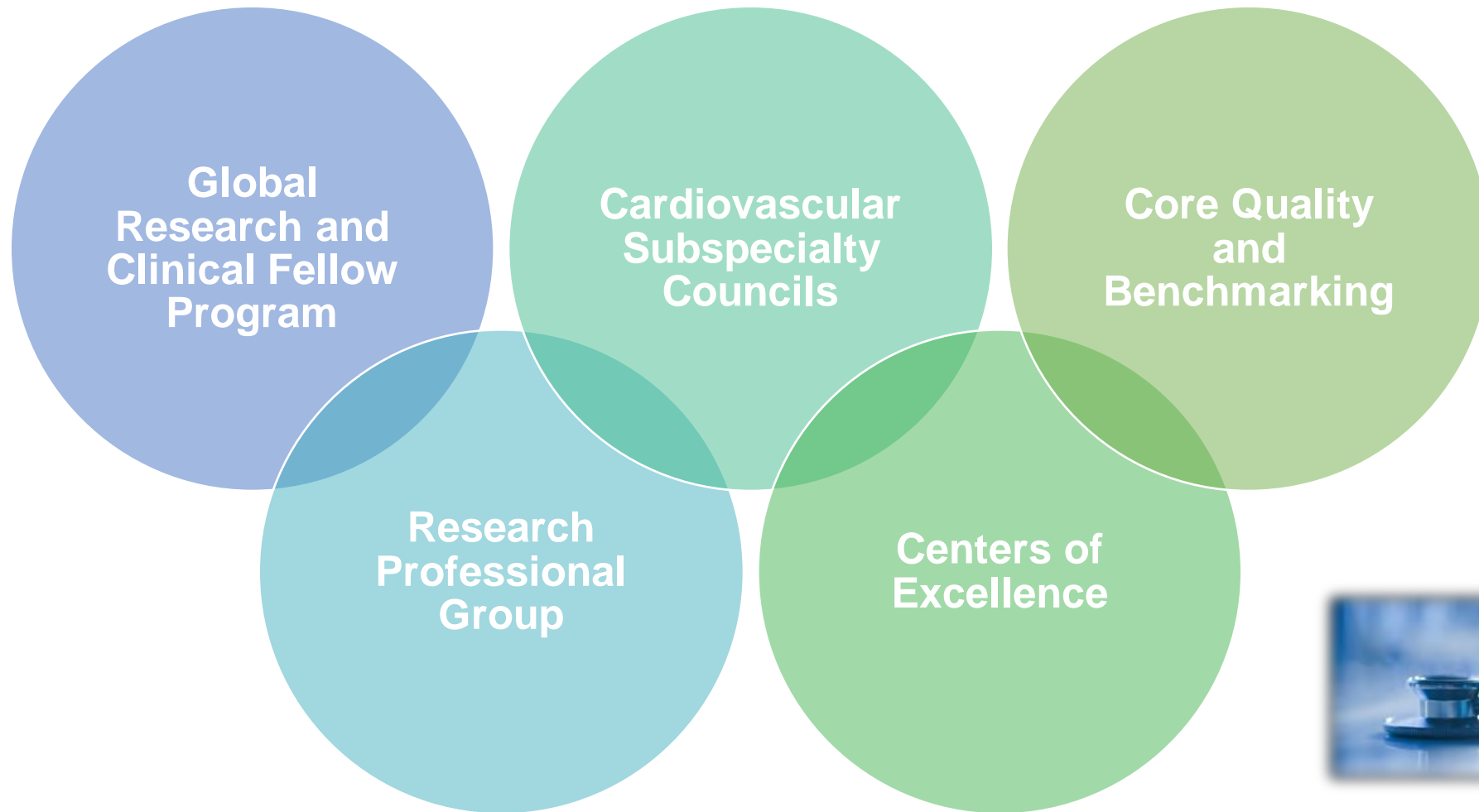
CSF research infrastructure will audit internally from time to time all clinical trials for quality source documentation.

How to develop a culture of disputation?

- Need clear leadership support
 - Cultivates Mentors (Promoters) with passion (critical thinking)
 - Guidance with minimal control or politic
- Culture starts with COMs
 - Percentage play
 - Offers clear research pathway and education
- Culture continues with clinical science degrees (PhD pathway)
- IM programs provide the clinical progressive field
- IM Fellowships drive progressive topics and produce



Organizational Strategy



How does this happen?

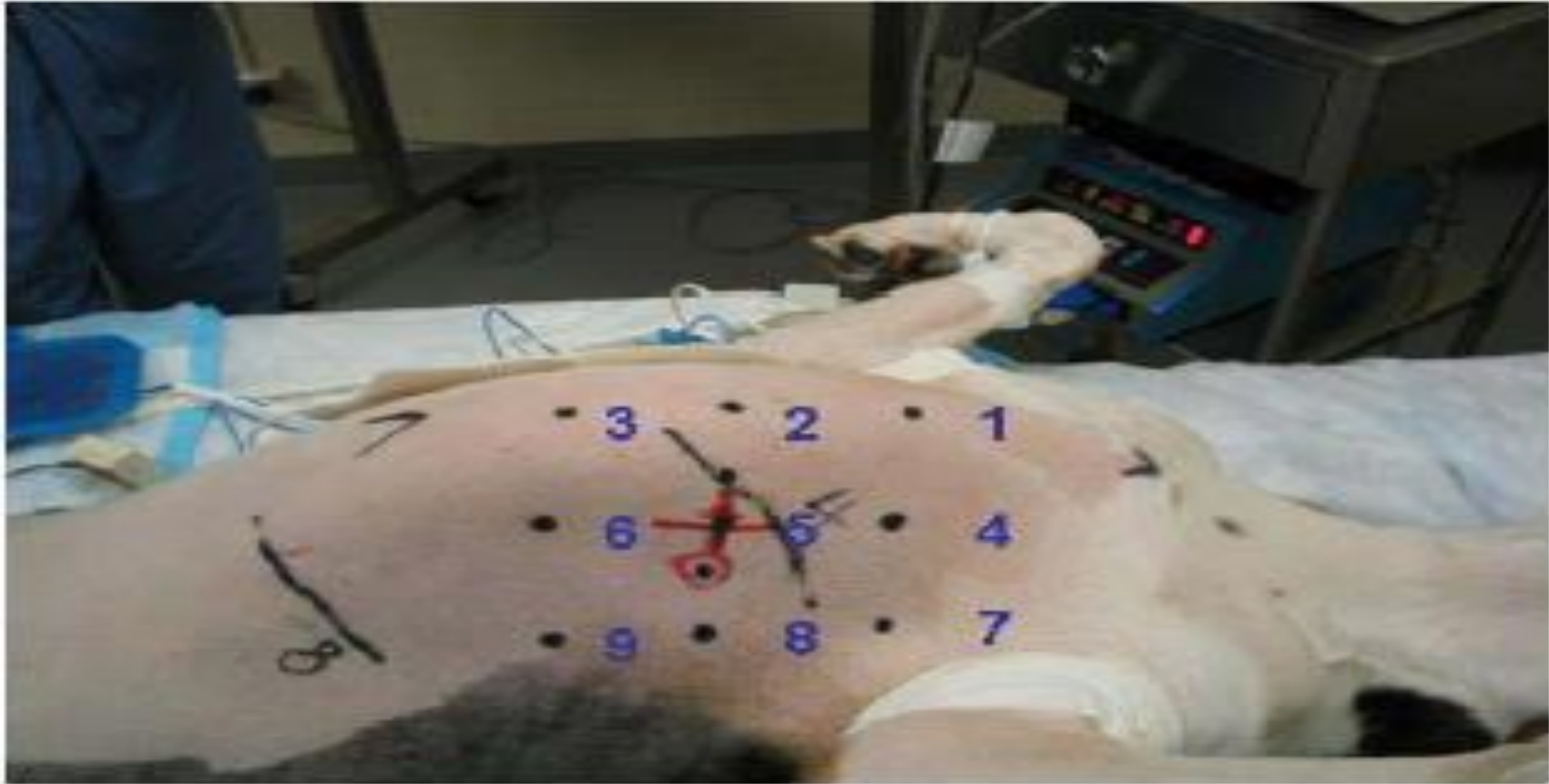
- CCOM
- Osteopathic Intern, Resident, Fellow
- Fellowship University of Chicago in EP
- Instructor to Professor (Chief) University of Chicago
- KCF for over 60 EP fellows in ACGME and non ACGME program
- Clinical research (case report-chart review-industry trial-investigator trial-partnerships with IIT-RCTs-Worldwide Principal investigator)
- Chief Medical Officer/Founder, Startups
- Chief Scientific Officer, Research and Education Foundation



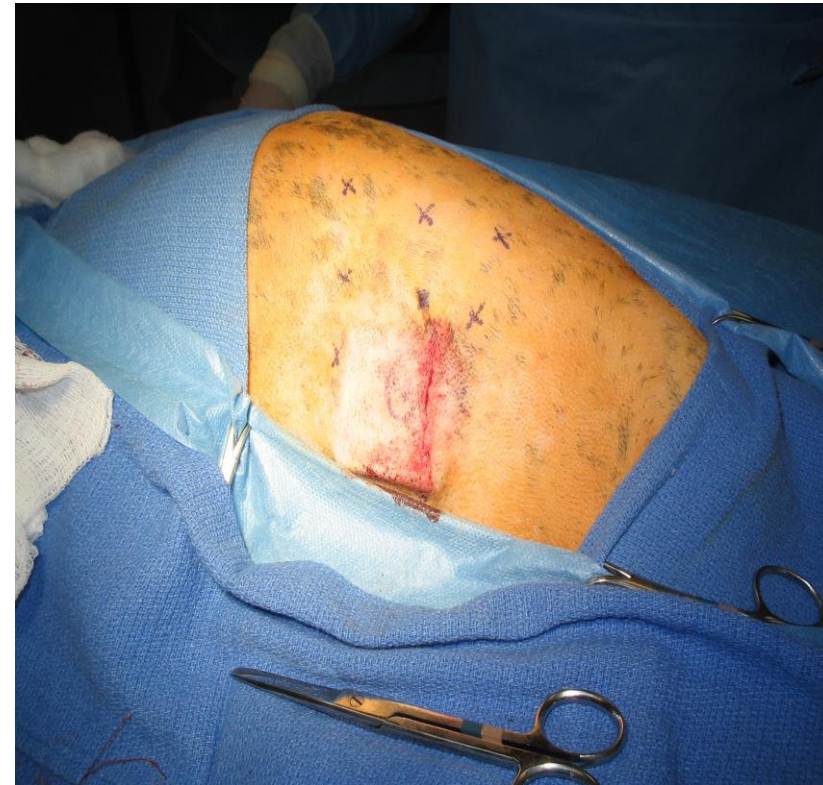
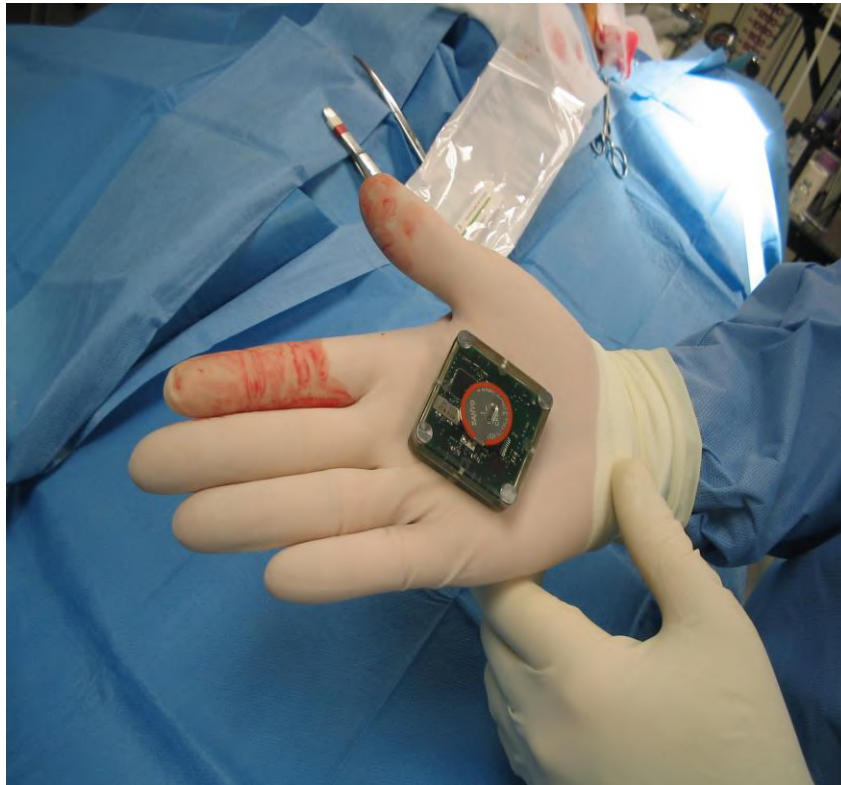
Organizational Strategy



Animal Surgical Methods



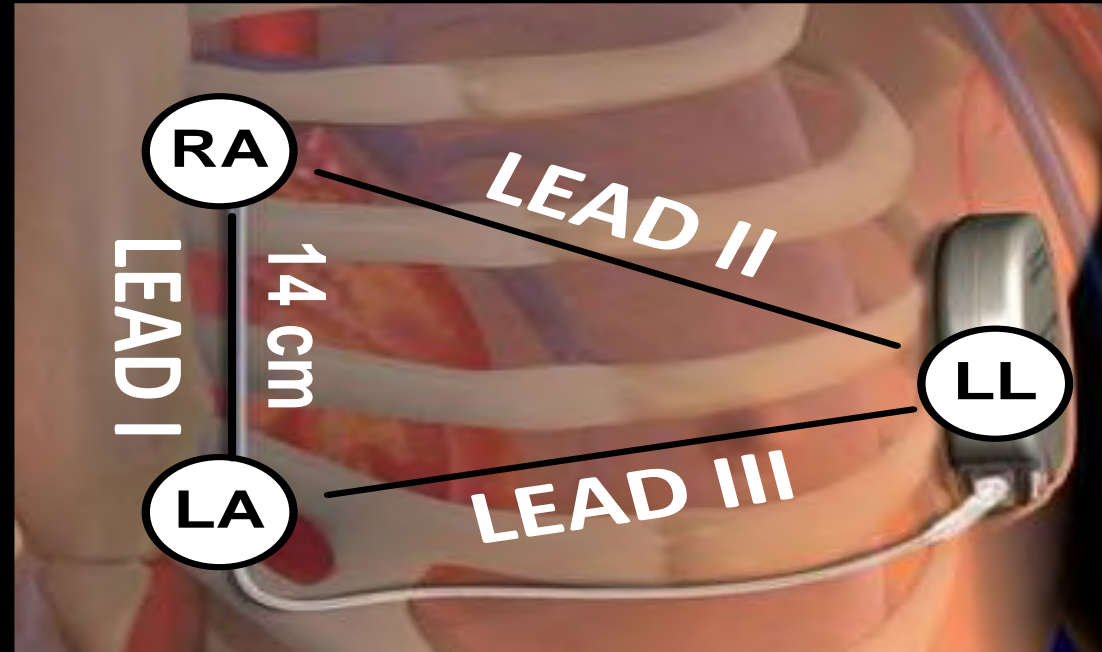
Subcutaneous cardiac arrest sensor



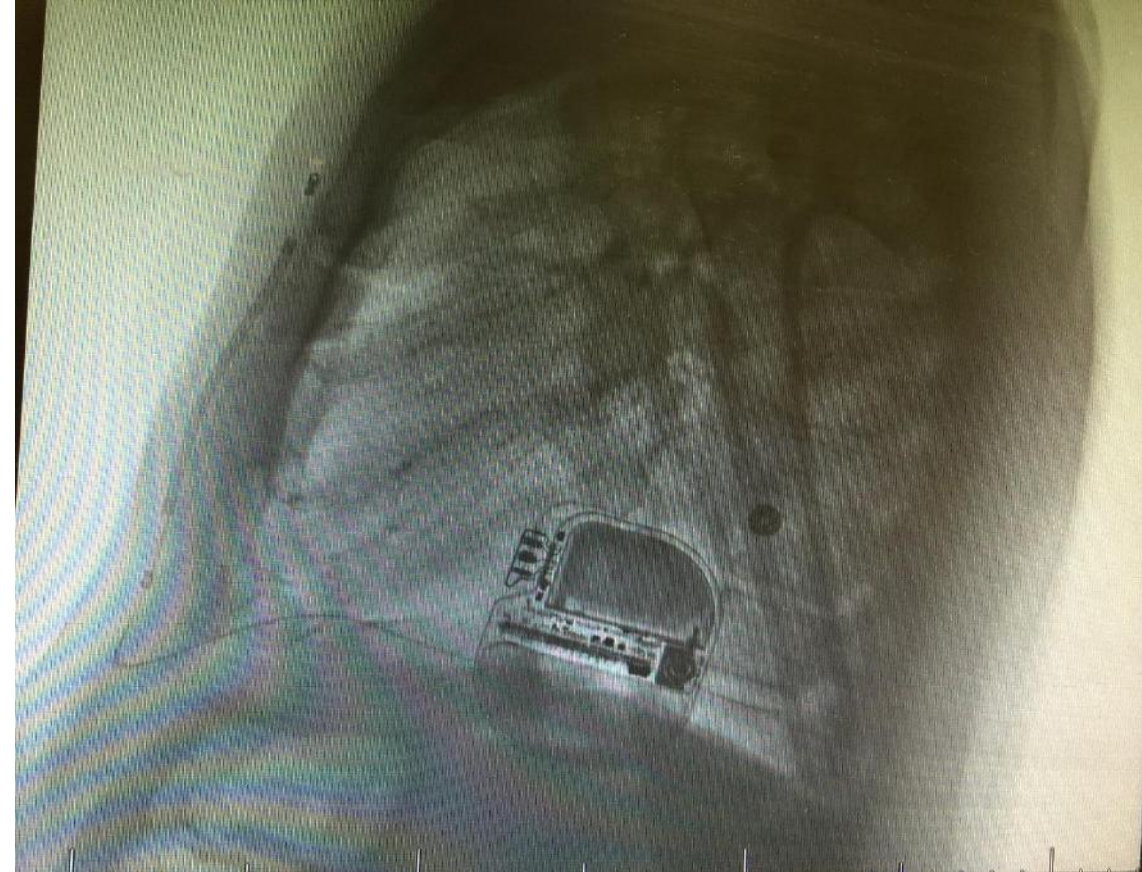
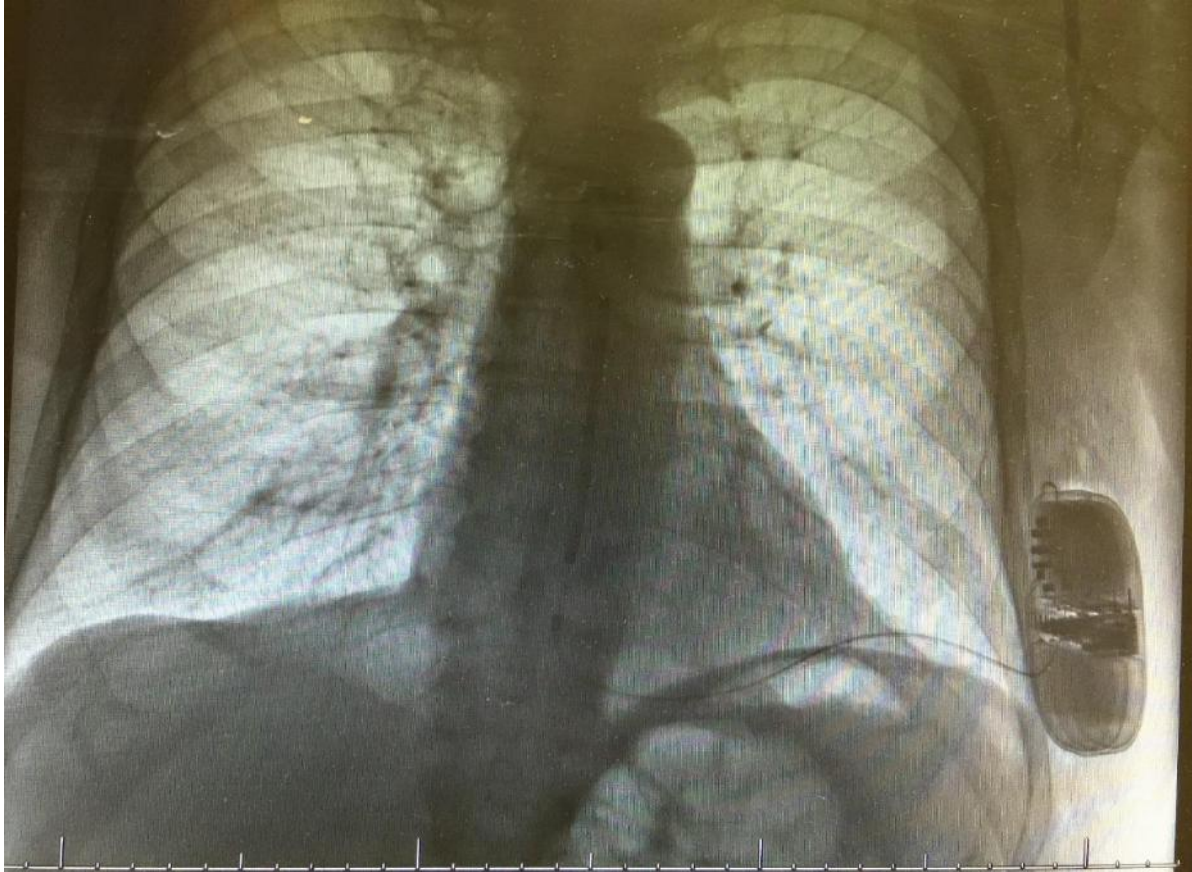
Sensor contains two ECG amplifiers, microprocessor, memory, transceiver, battery. Upon detection of VF, it transmits the event and ECG to an external receiver

An Entirely Subcutaneous ICD

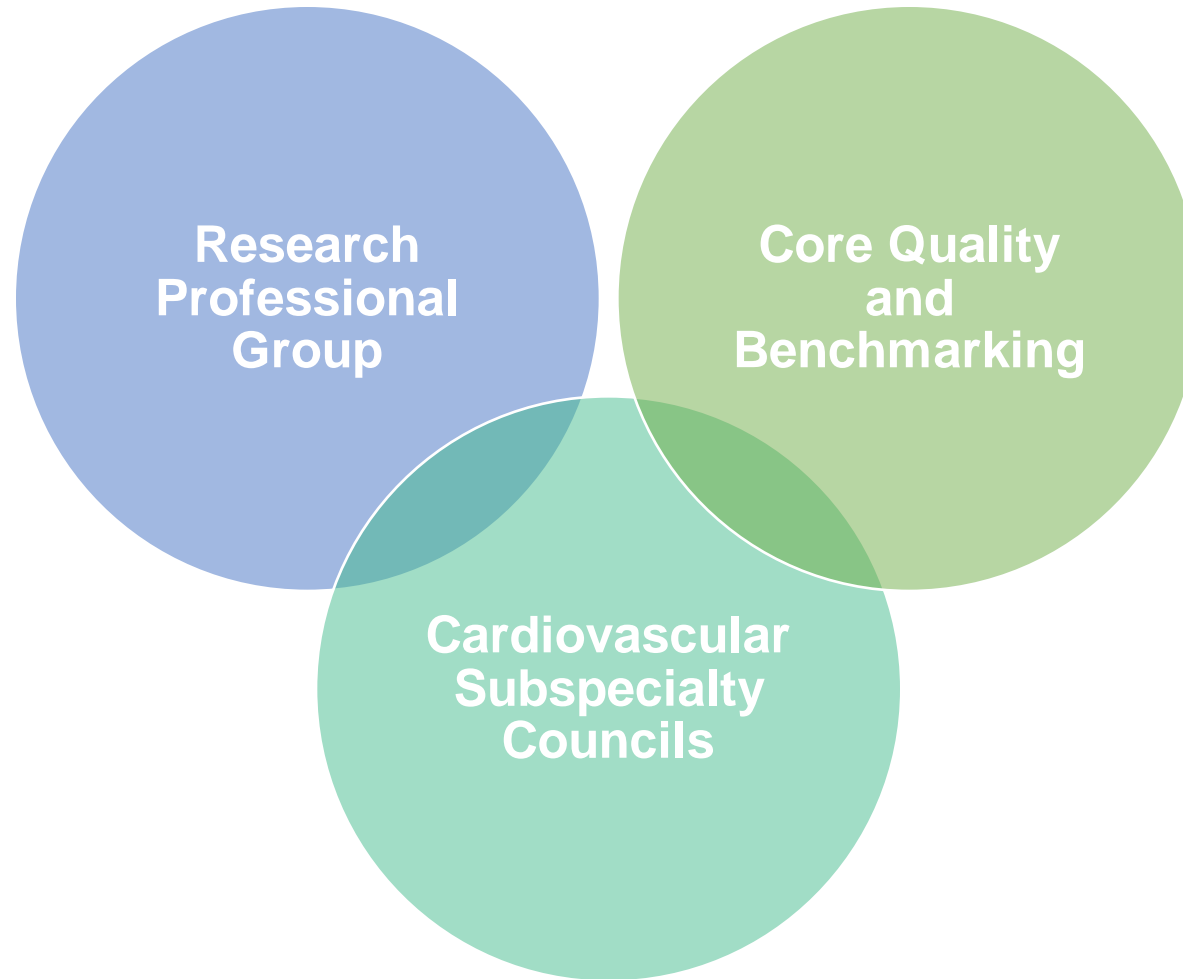
SIMULTANEOUS 3-LEAD ECG



1. **RECORD**: Supine+Standing
25 mm/s, 5-20 mm/mV



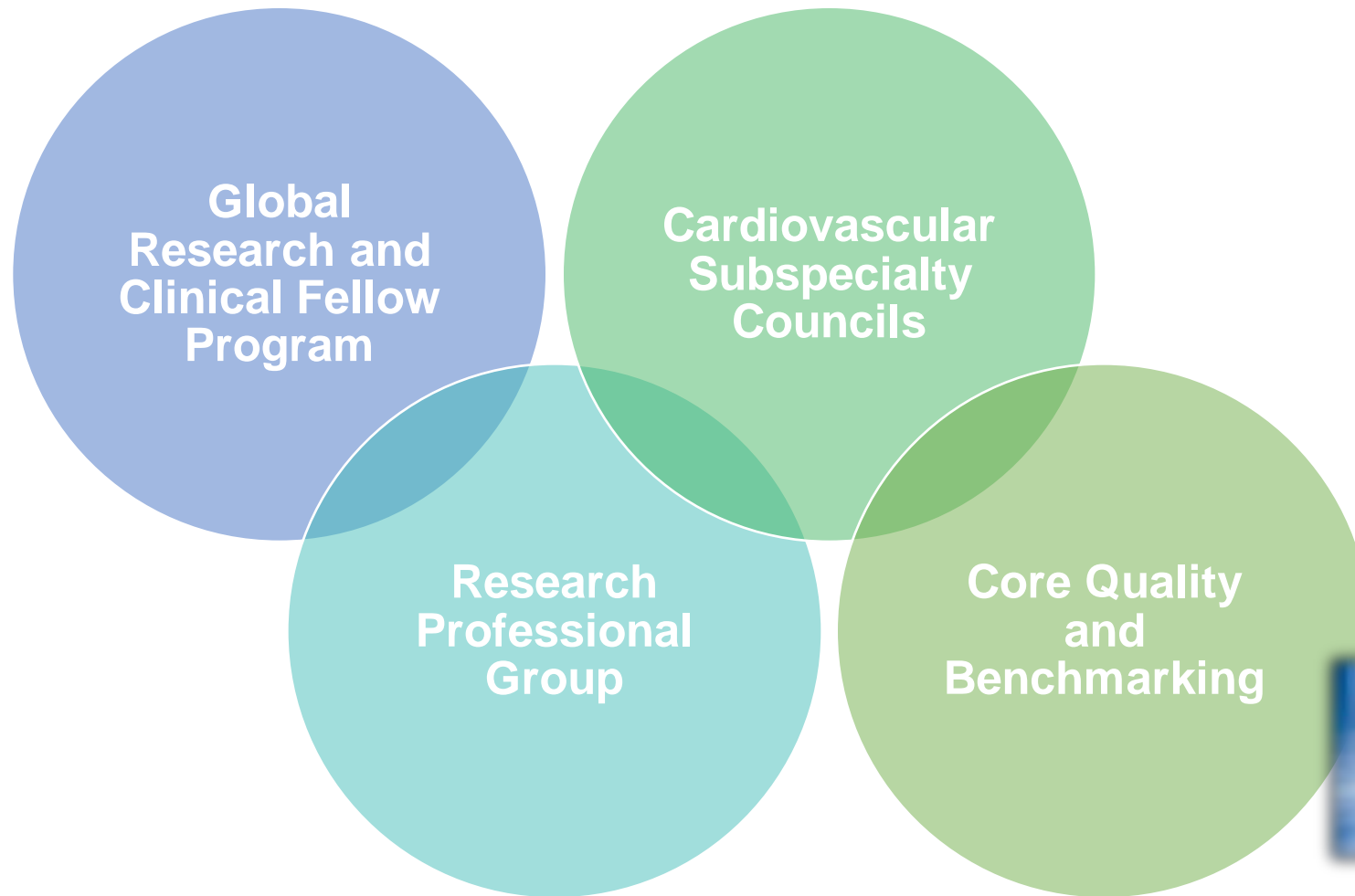
Organizational Strategy



Clinical Studies Summary

S-ICD® System STUDY	STUDY TYPE	PATIENTS	SITES	COMMENTS
Feasibility and Proof of Concept Studies	Acute	78 + 49		Study completed: 2005 Published in NEJM
Initial Human Validation Study	Chronic Safety and Performance	6	2	Study completed: 2008 Published in NEJM
CE Clinical Study	Chronic Safety and Performance	55	8	Study completed: 2009 Published in NEJM
IDE Clinical Study	Chronic IDE	330	33	Study completed: 2011 Published in Circulation
EFFORTLESS Registry	Chronic Post-Market OUS Registry	330 as of Sept 2012; Goal: 1,000	23	Study Completed; partially published in Eur Ht J
Praetorian	Prospective Randomized	300 of 900	>20	Still enrolling
S-ICD Post Approval Study	Prospective registry	1600 for 5 yrs	>30	Still enrolling

Organizational Strategy



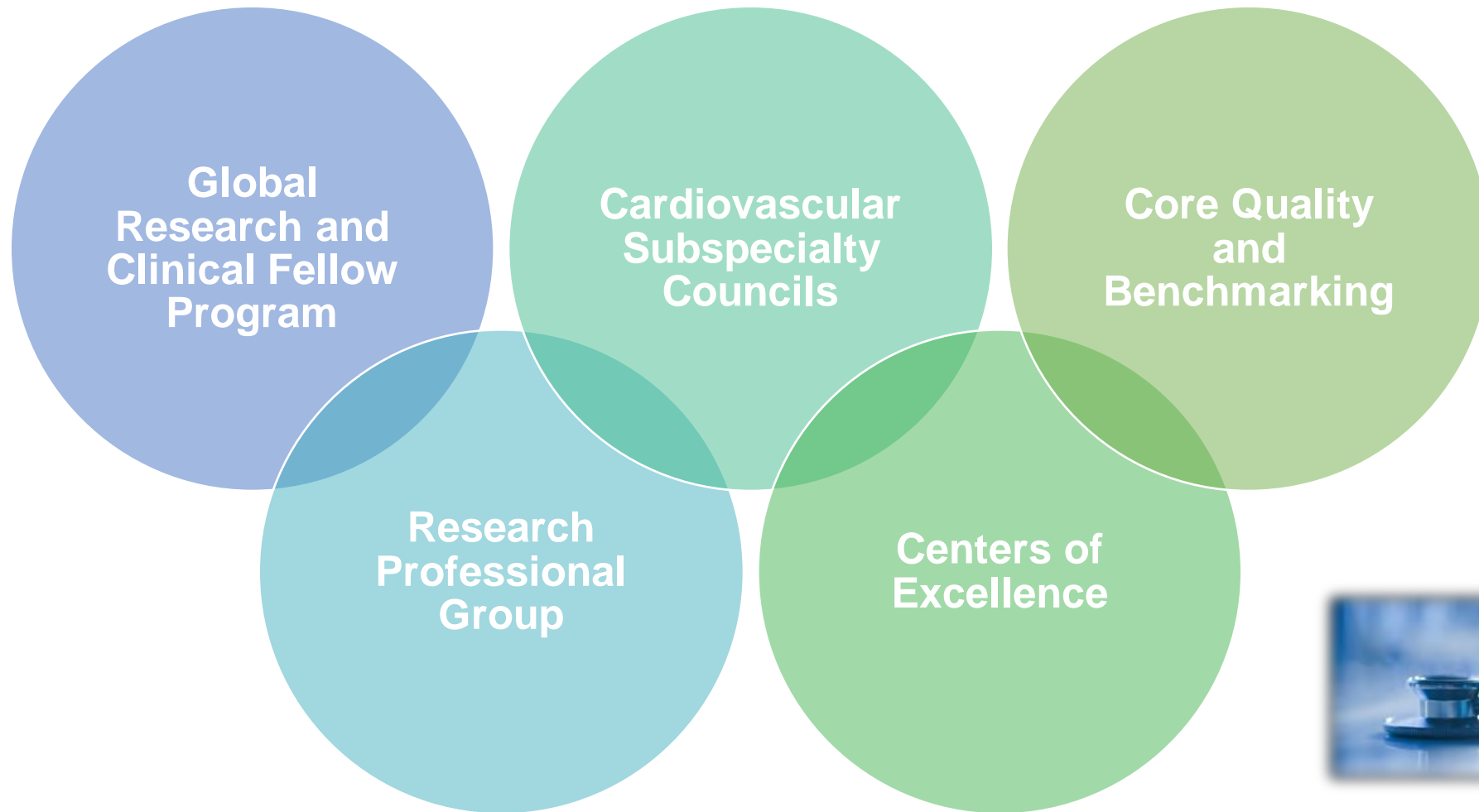
Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator:

2-year Results from a Pooled Analysis of the
IDE Study and EFFORTLESS Registry

Published online in the Journal of the American College of Cardiology April 2015

Martin C. Burke, DO, FACC; Michael R. Gold, MD, PhD, FACC, Bradley P. Knight, MD, FACC, Craig S. Barr, MD, Dominic A.M.J.Theuns, PhD, FACC, Lucas V.A. Boersma MD, PhD FESC, Reinoud E. Knops, MD, Raul Weiss, MD, FACC, Angel R. Leon, MD, FACC, John M. Herre, MD, FACC, Michael Husby, MS, MPH, Kenneth M. Stein, MD, FACC, Pier D. Lambiase, PhD FRCP FHRS

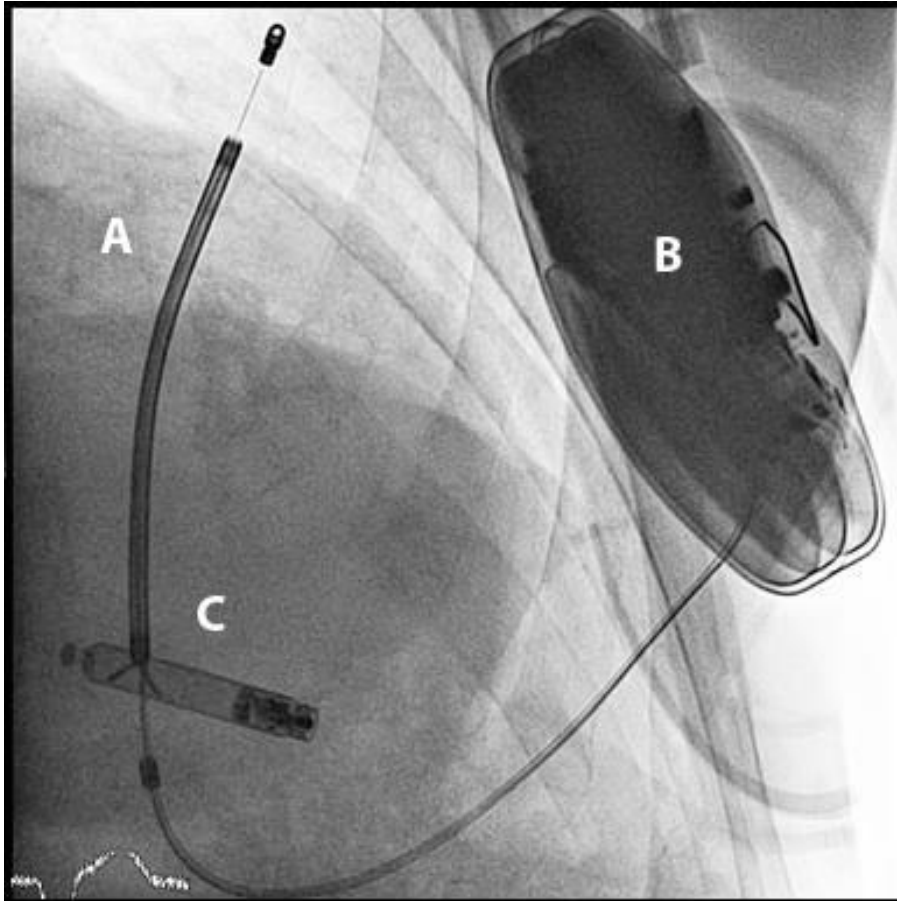
Organizational Strategy



Application of S-ICD is limited due to lack of pacing capability

Bradypacing:

Limited evidence of S-ICD with LCP & TV-Pacers



Tjong et al. Europace 2016

Anti-tachy pacing: No solution

Substantial ICD subgroup benefits from ATP therapy

Prospective registry data from single center in Germany

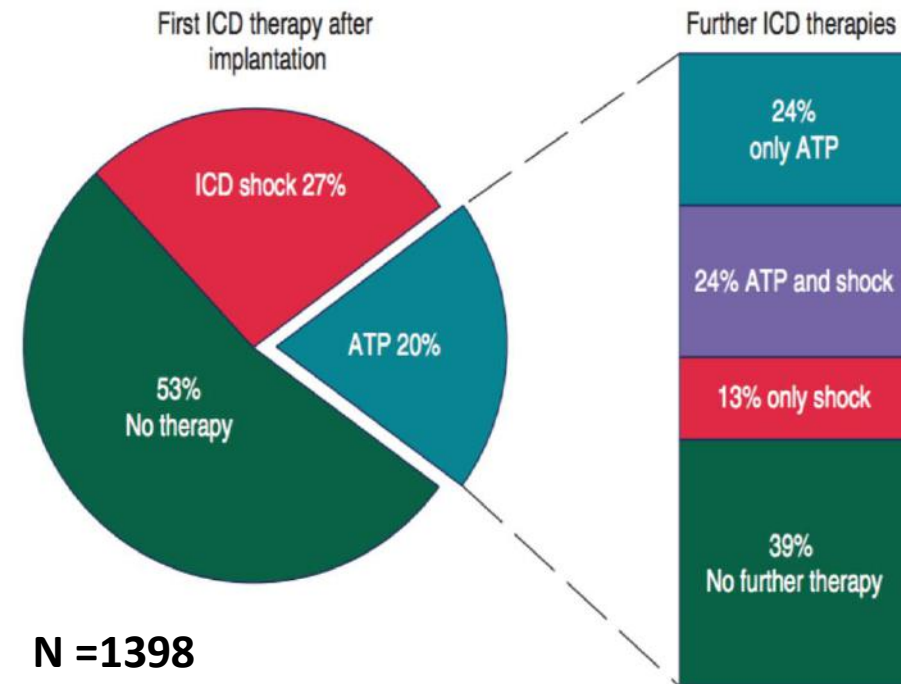
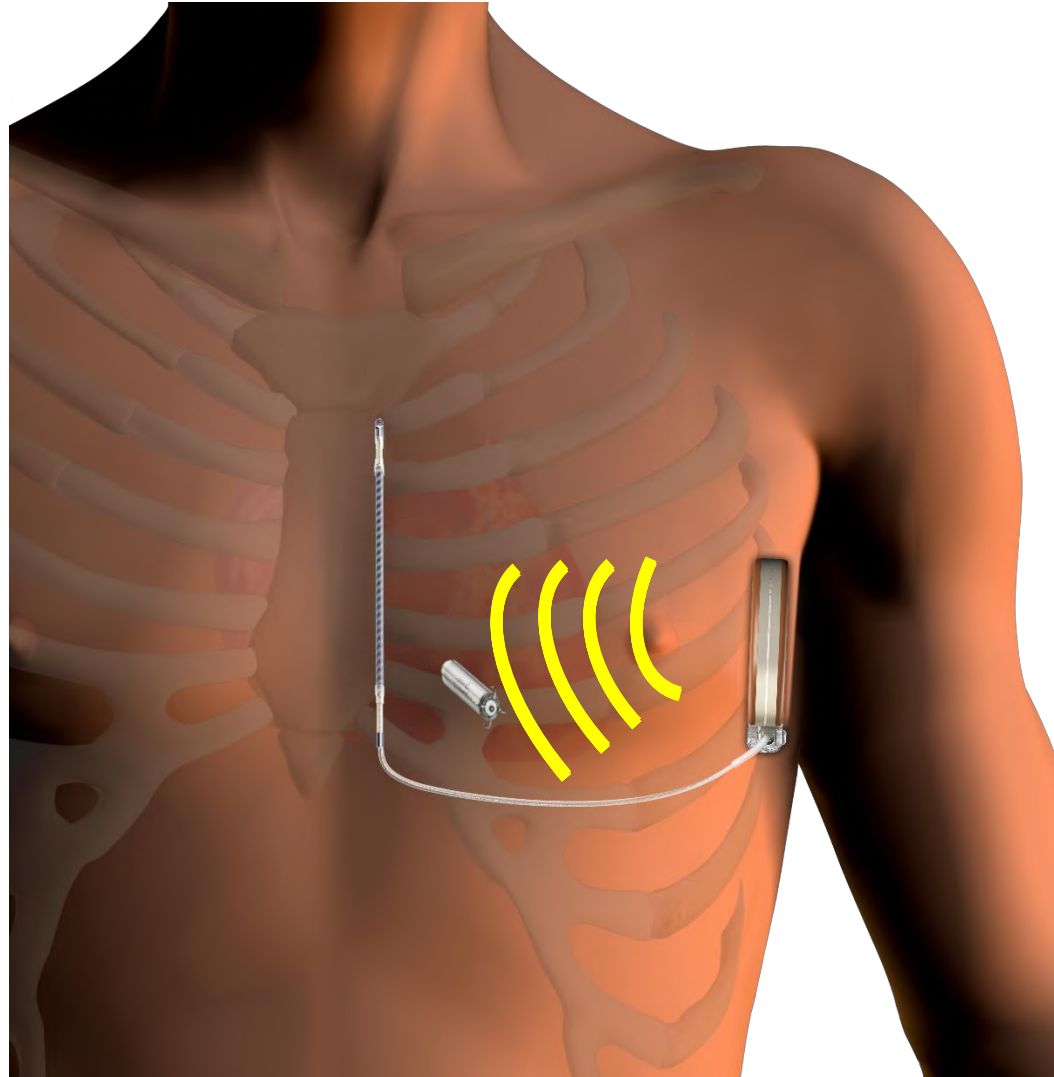


Figure I Type of ICD therapies following first ATP therapy.

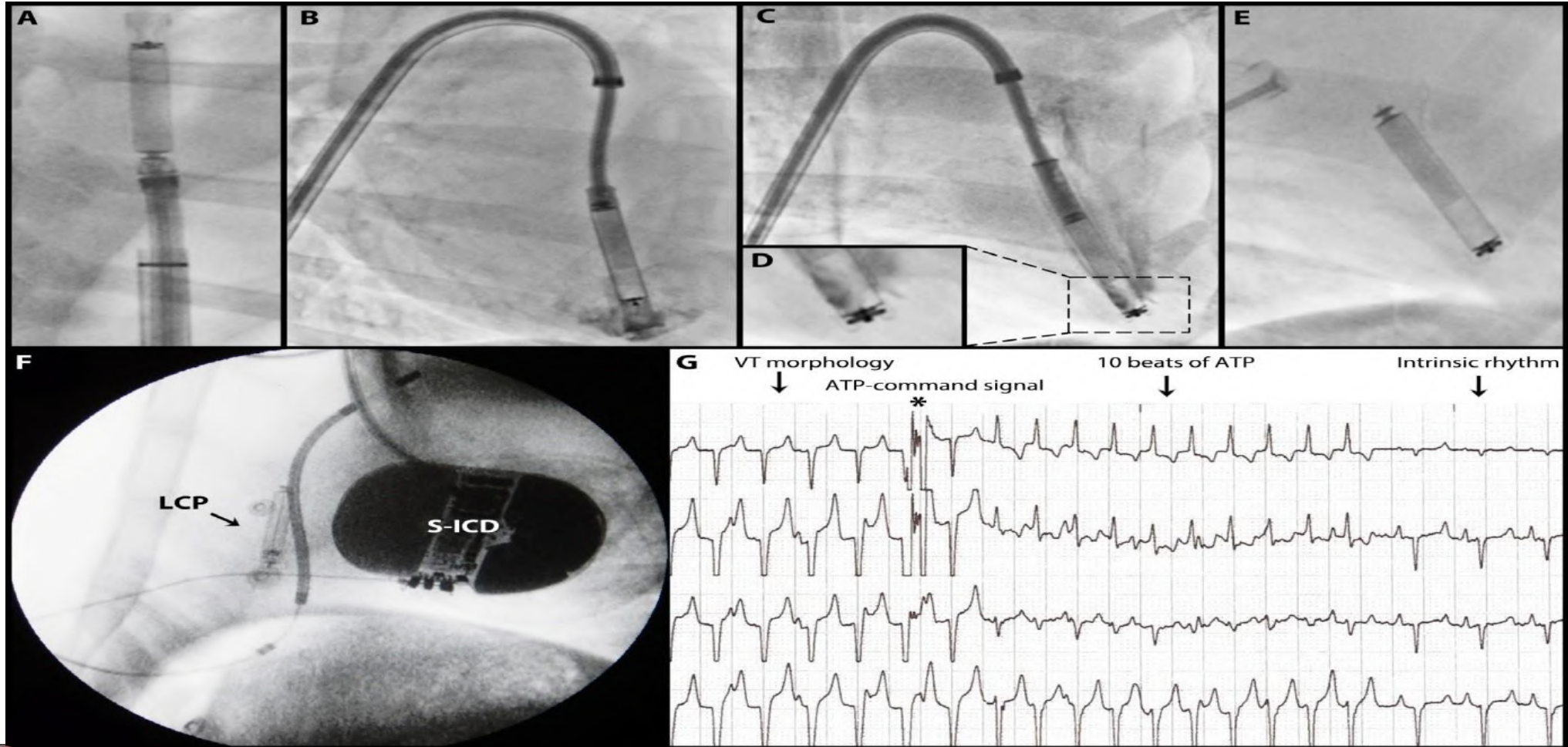
Kleemann et al. Europace 2015

Combined implant of Communicating ATP-enabled Leadless Pacemaker and S-ICD



Burke, Tjong, Knops et al.
Europace HRC 2016

Modular Devices/Medical Body Network



Clinical Science is Global?

(Trainees like it)



**A Prospective Randomised CompArative trial
of SubcutanEous ImplanTable CardiOverter-
DefibrillatoR ImplAntation with and without
DeFibrillation Testing**



PRAETORIAN DFT

Clinical study protocol

Version 0.1

20 October 2017

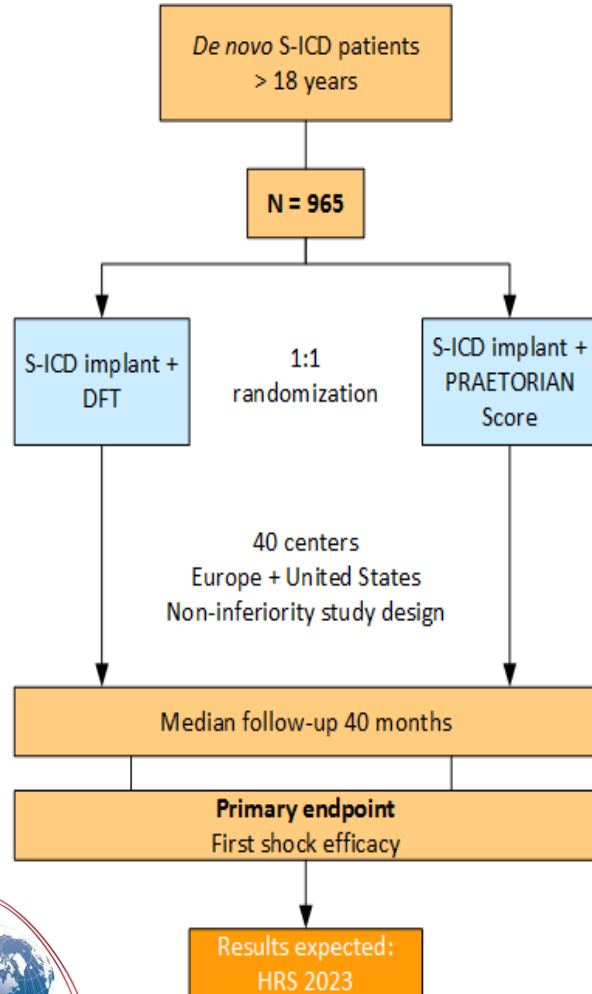
AMC Heart Center

Academic Medical Center – University of Amsterdam

The Netherlands



PRAETORIAN DFT



PRAETORIAN Score

Diagram illustrating the PRAETORIAN Score calculation steps:

Step 1) Determine the number of coil widths of fat tissue between the **nearest** half of the S-ICD coil and the sternum or ribs.

Coil-widths	Score
≤ 1	30
$> 1 \leq 2$	60
$> 2 \leq 3$	90
> 3	150

Step 2) Determine the position of the S-ICD generator in relation to the mid-line.

Generator position	Score
Generator is on or posterior of the mid-line	x 1
Entire generator is anterior of the mid-line	x 2
Entire generator is $> 1/2$ length anterior	x 4

Step 3) Determine the amount of fat tissue between the **nearest** point of the generator and the thoracic wall.

Generator-width	Score
< 1 generator-width	x 1
≥ 1 generator-width	x 1.5

Step 4)

PRAETORIAN score	Score
≥ 90	- 40
BMI $\leq 25 \text{ kg/m}^2$	= Final score
BMI $\geq 25 \text{ kg/m}^2$	

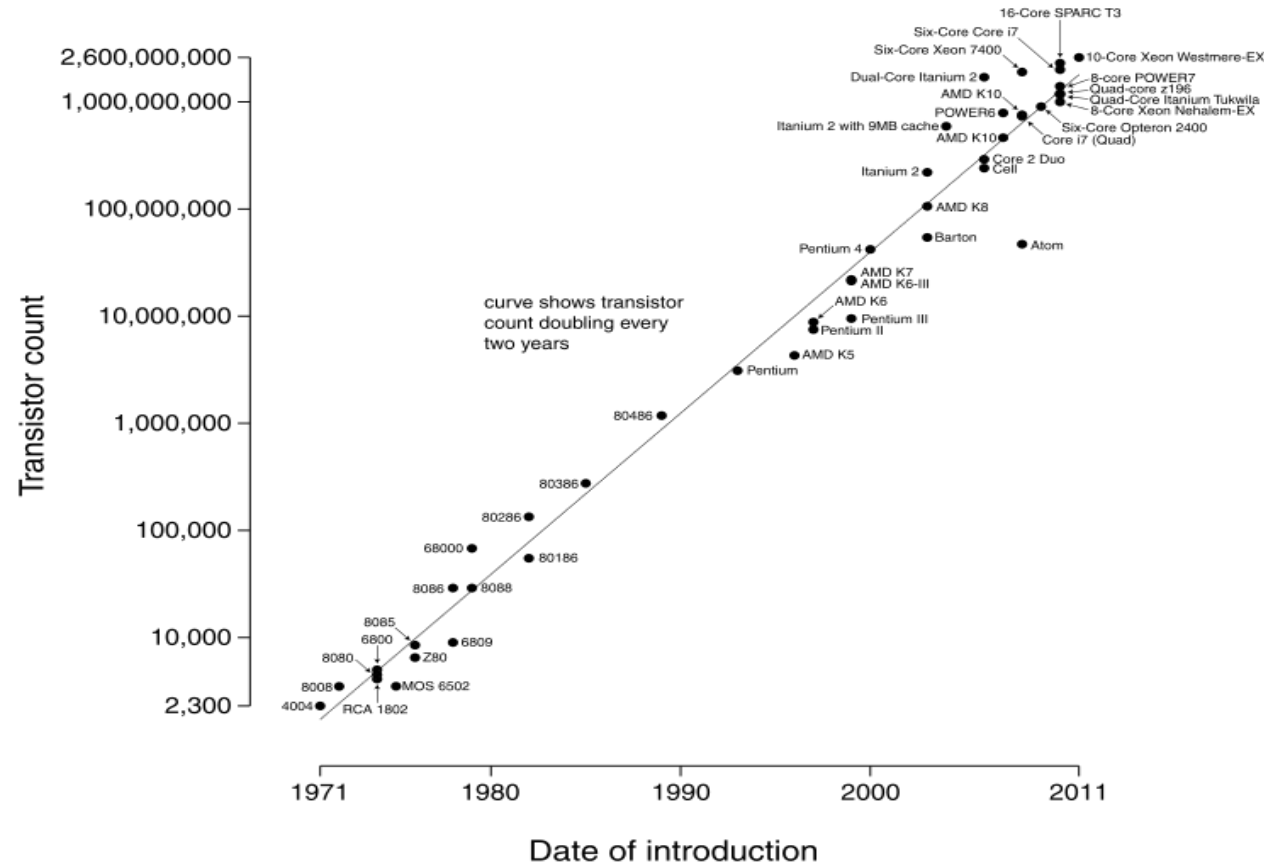
Final PRAETORIAN score

Score	Risk Level
< 90	Low risk of conversion failure
$90 < 150$	Intermediate risk of conversion failure
≥ 150	High risk of conversion failure

Enrolment started: May 2018

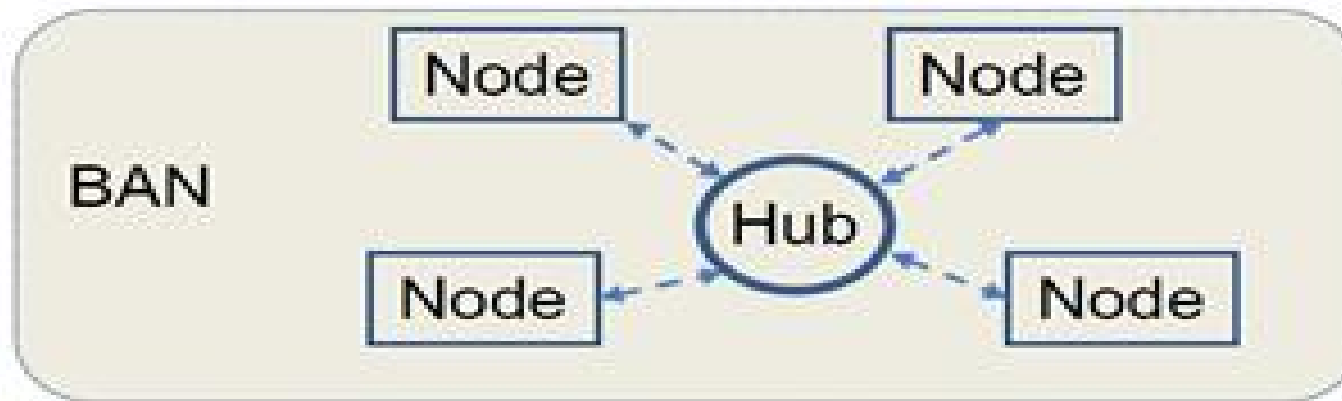
Moore's Law in healthcare

Microprocessor Transistor Counts 1971-2011 & Moore's Law

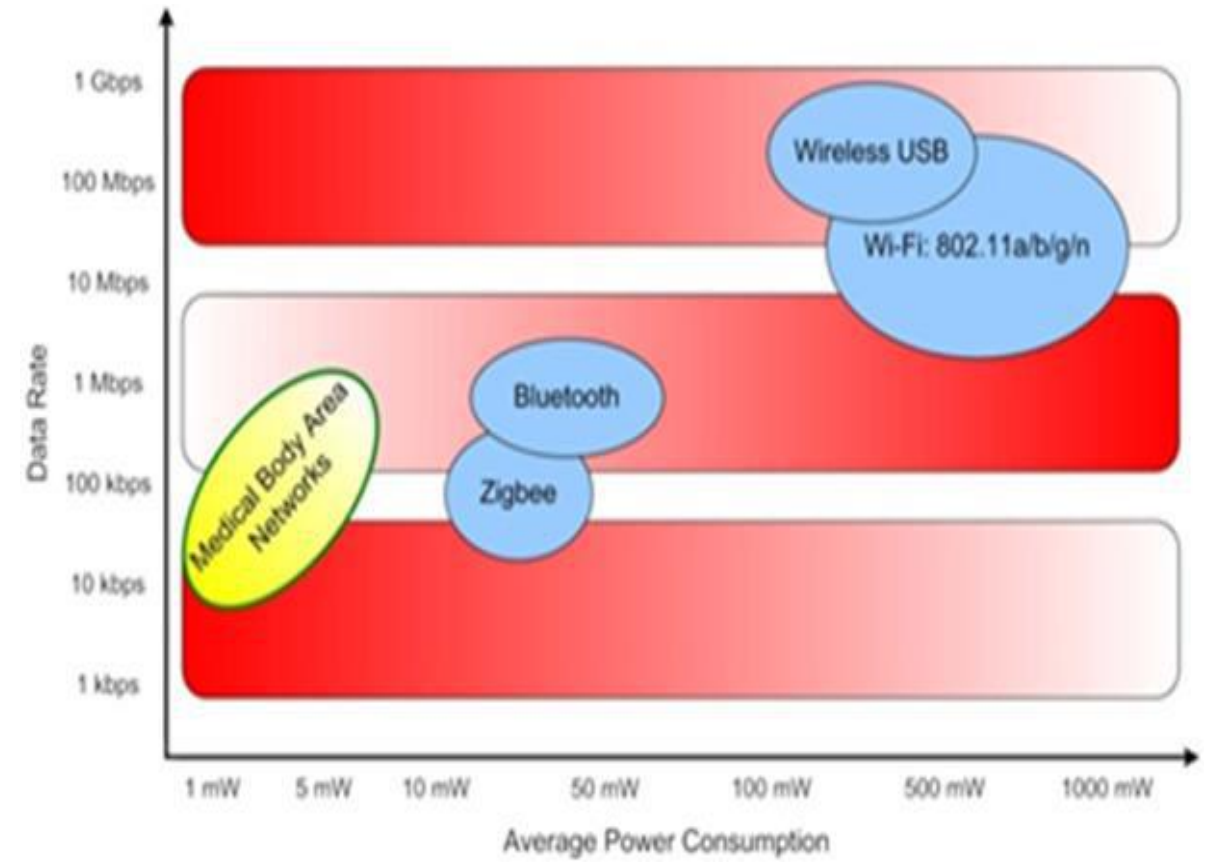


How does an MBAN system operate?

- A typical MBAN consists of:
 - a master programmer/control transmitter (“hub device”),
 - one or more client transmitters (“body sensors”), which are worn on the body and only transmit while maintaining communication with the hub that controls the transmissions.
 - The hub conveys data messages to the body-worn sensors to specify, for example, the transmit frequency that should be used. The hub and sensor devices will transmit in the 2360-2400 MHz band.



Need More Power: Battery Technology



Individual Intelligence

The CardioMEMS™ HF System



Courtesy of St Jude Medical

physIQ

Personalized Physiology Analytics

Gary Conkright, Co-founder/CEO, physIQ

October 2, 2015

Old Paradigms with New Applications: PhysIQ



ECG Classification With Deep Learning

Joris Galema, Christopher Buch Madsen, Flavio Miceli,
Abel Oakley & Florian Schroevers

2nd July 2018

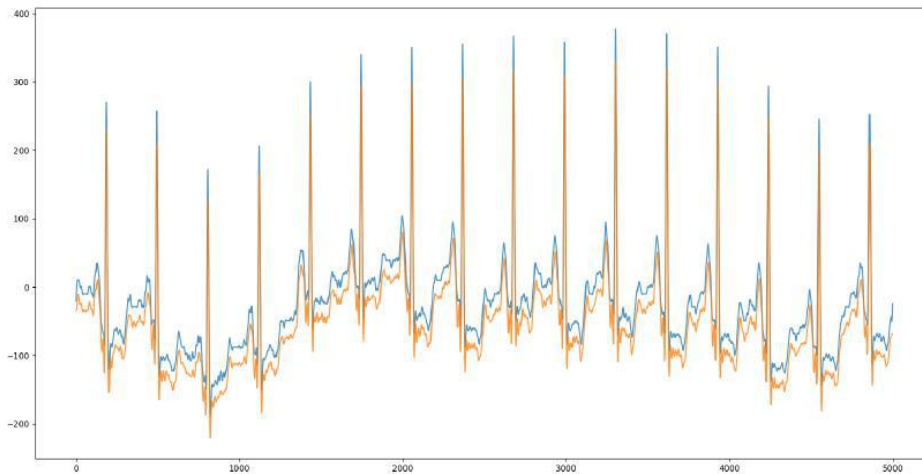


Figure 3: Fourier Approximation

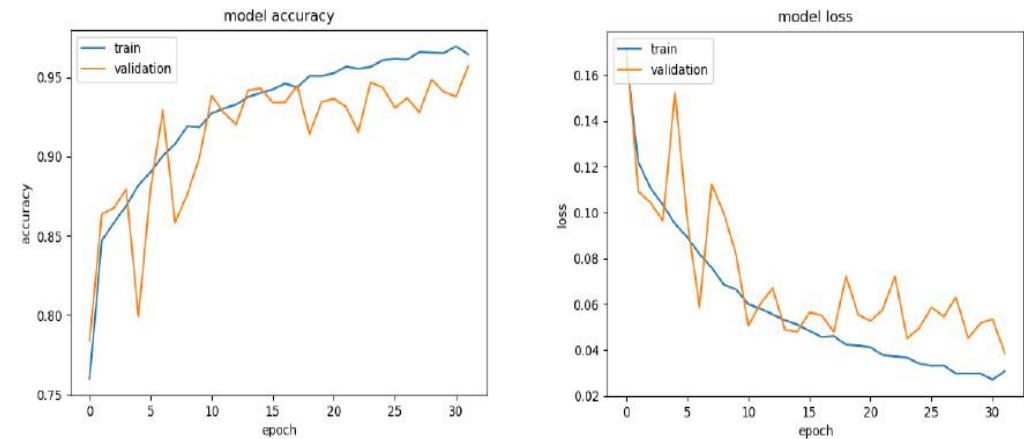
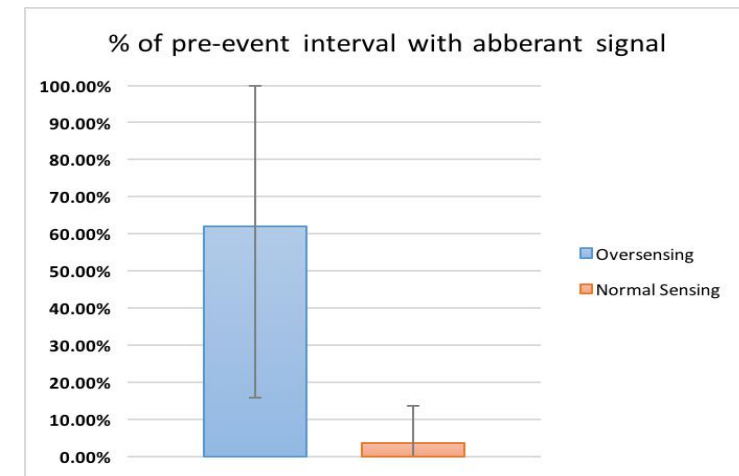
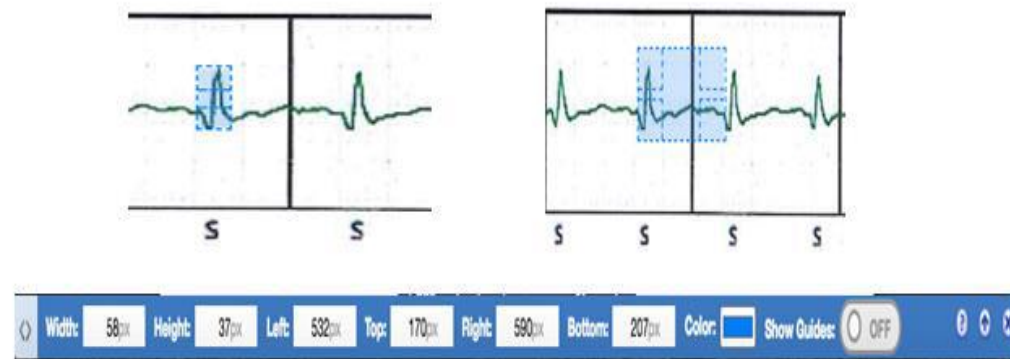
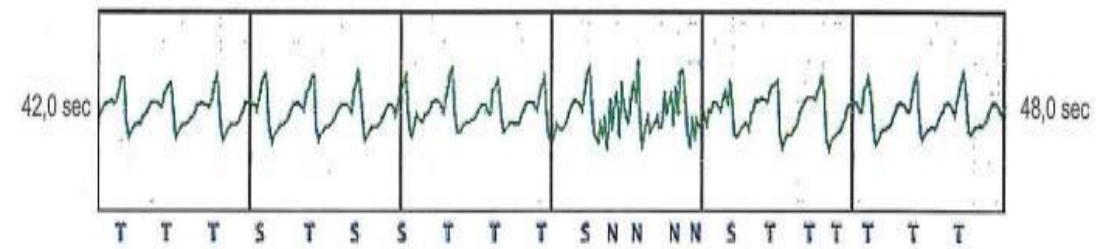
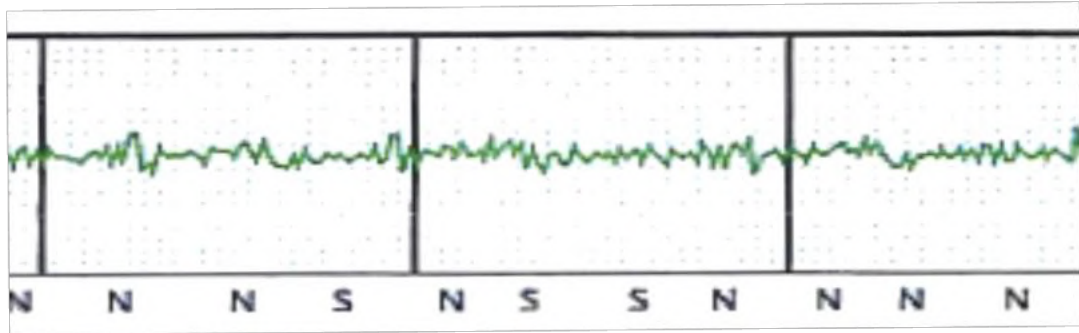


Figure 12: Accuracy and Loss per Epoch

Digitalization of SCID Charge Events Identifies Pre-Charge Electrogram Variants Leading to Oversensing

Erik Mersereau, Brett Breshears, Justin Figueroa, Martin C. Burke, DO
Midwestern University & CorVita Science Foundation, Chicago, IL
European Heart Journal 2018 abstract (ESC)



Where are Funding Sources and Infrastructure?

- Need to build an all inclusive partnership system especially with clinical research programs. (limited or no access to basic science or Biomed)
- Need access to intellectual property and expert human capital
- COMs, Hospitals, Industry Grants –Seed funding
- Non profit Foundations
- Access to clinical patients and substrates
- Government grant sources (US, worldwide)
- This builds a brand and perpetuates more funding, recruitment of human capital and patients



ACGME/IM-RRC expectations

- This is a gradual process and first and foremost access to clinical training positions that are funded.
- For ACGME,
 - Culture and reputation trumps product for a time.
 - IM KCF by percentage needs scholarly activity.
 - IM Residents have less required scholarly activity
 - IM Fellows have clear requirement and expectation
- Eventually culture of scholarly activity will matter
- Funded positions will adjust based on research



Questions/Disputes?

Thank you

