

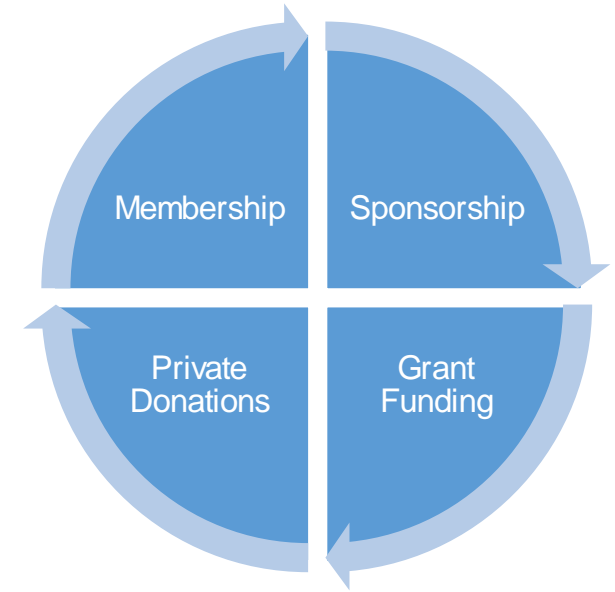
# Building a Culture of Scholarly Activity in IM Programs

Trainer's Congress 2017



# 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



# 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

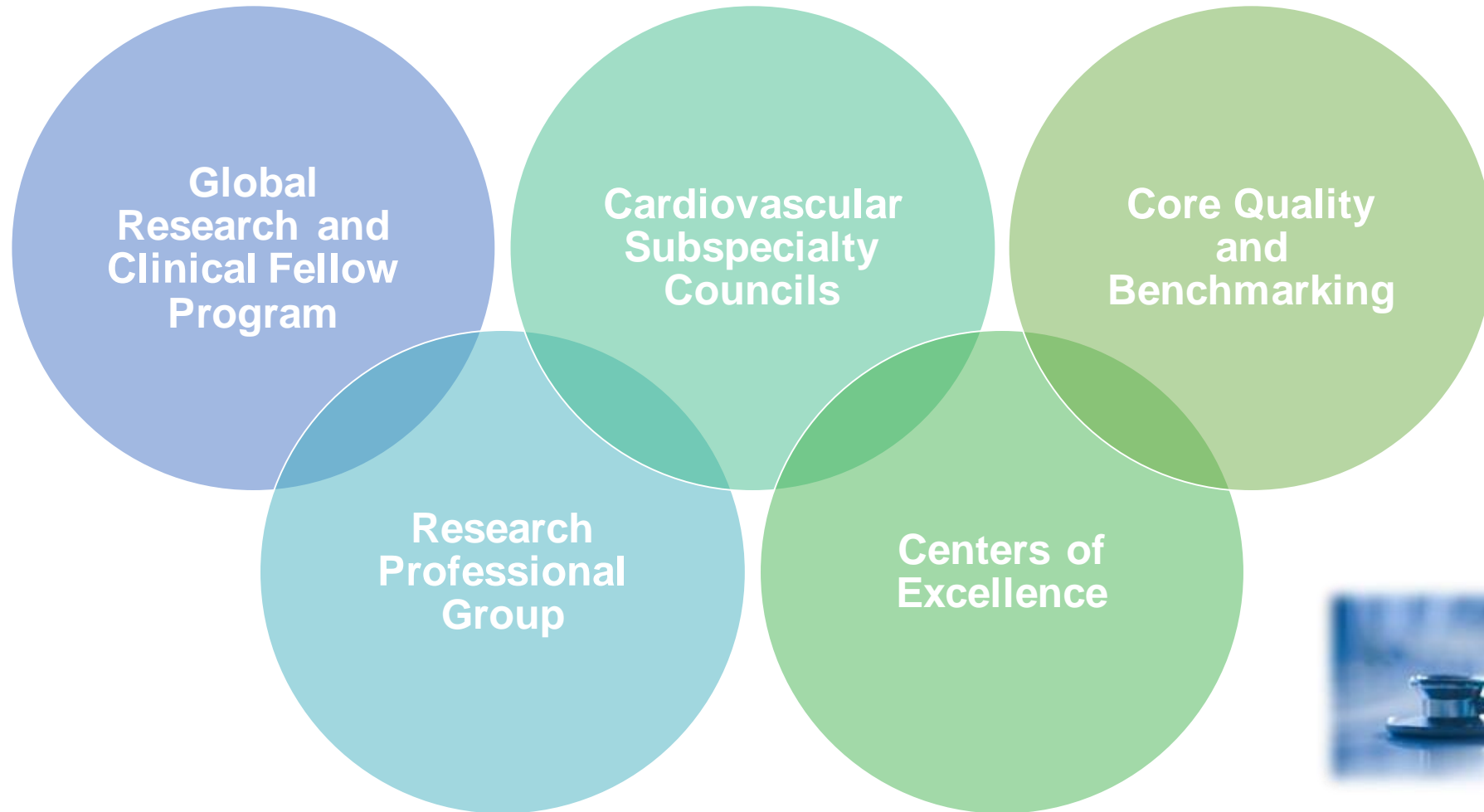


# How to develop a culture of disputation?

- 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?

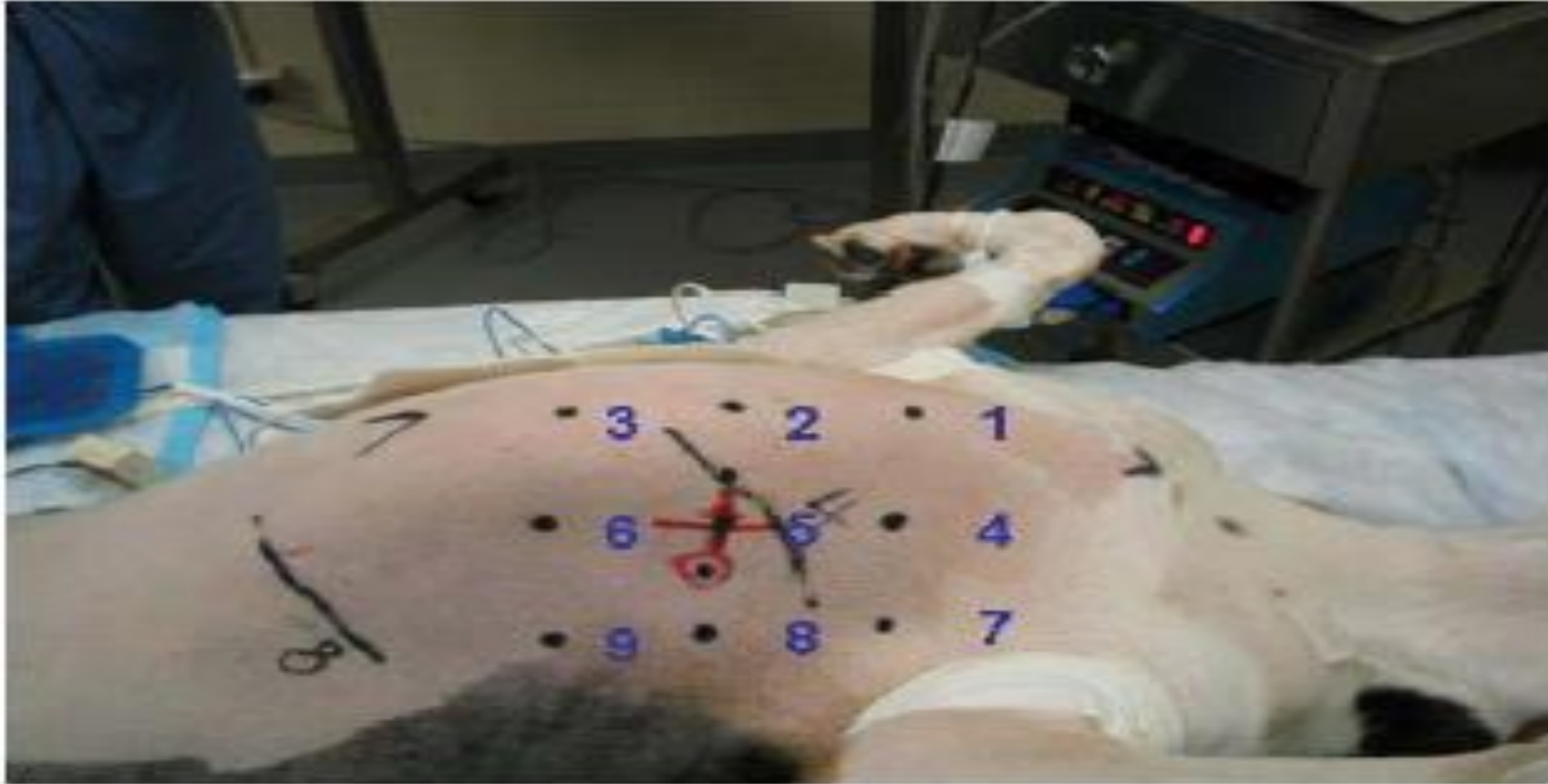
- CCOM
- Osteopathic Intern, Resident, Fellow
- Fellowship University of Chicago in EP
- Instructor to Professor (Chief) University of Chicago
- KCF for over 60 EP fellows in ACGME and non ACGME program
- Clinical research (case report-chart review-industry trial-investigator trial-partnerships with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



# Organizational Strategy

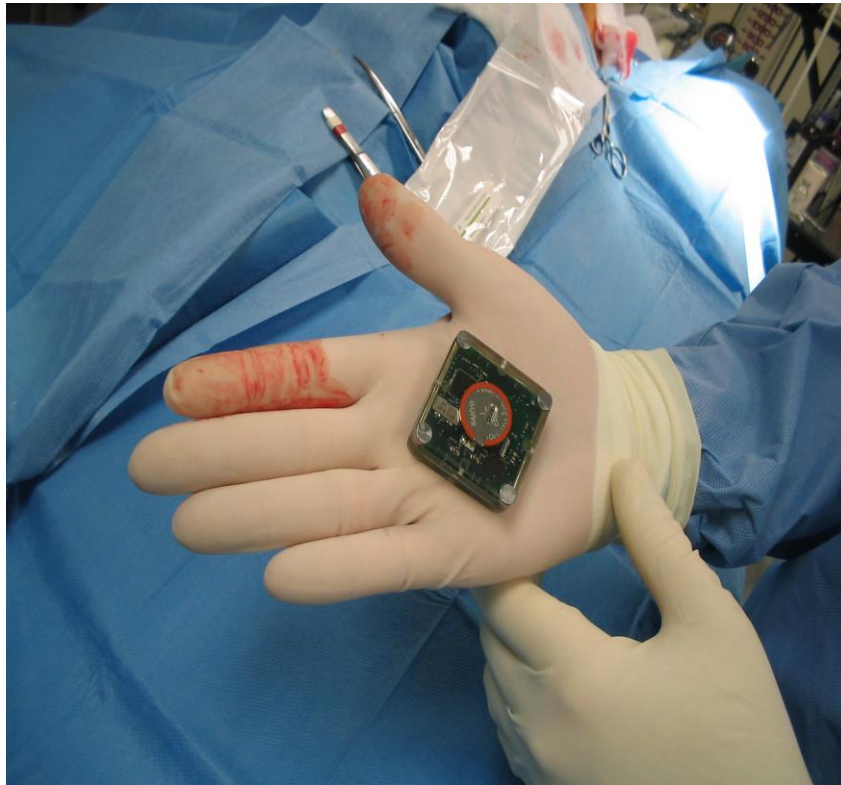


# Animal Surgical Methods





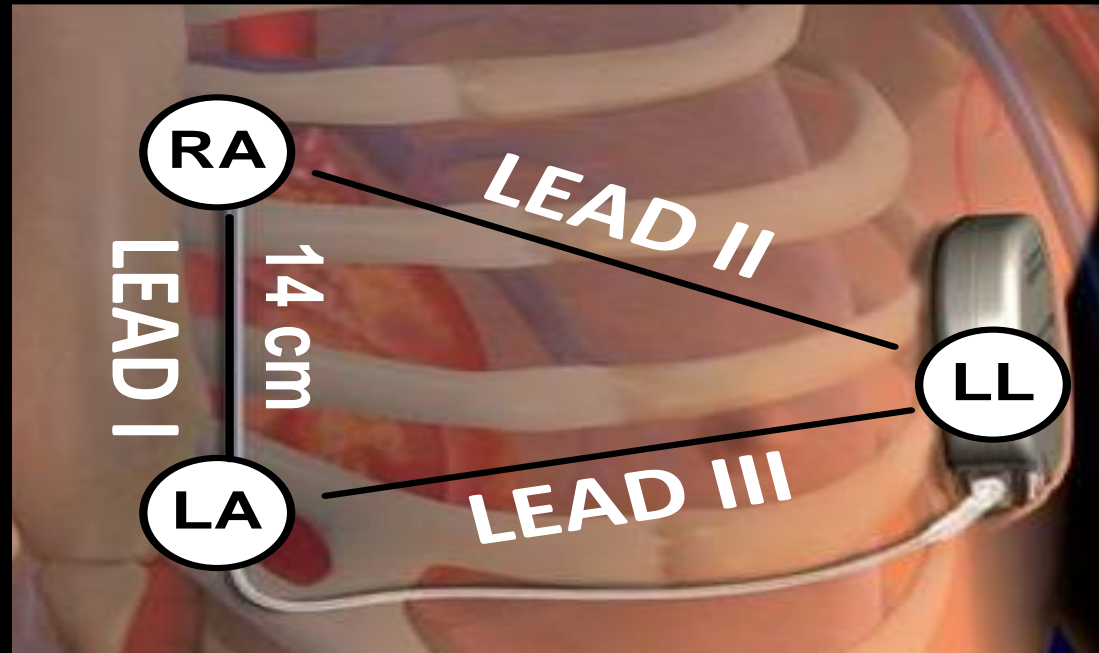
# Subcutaneous cardiac arrest sensor



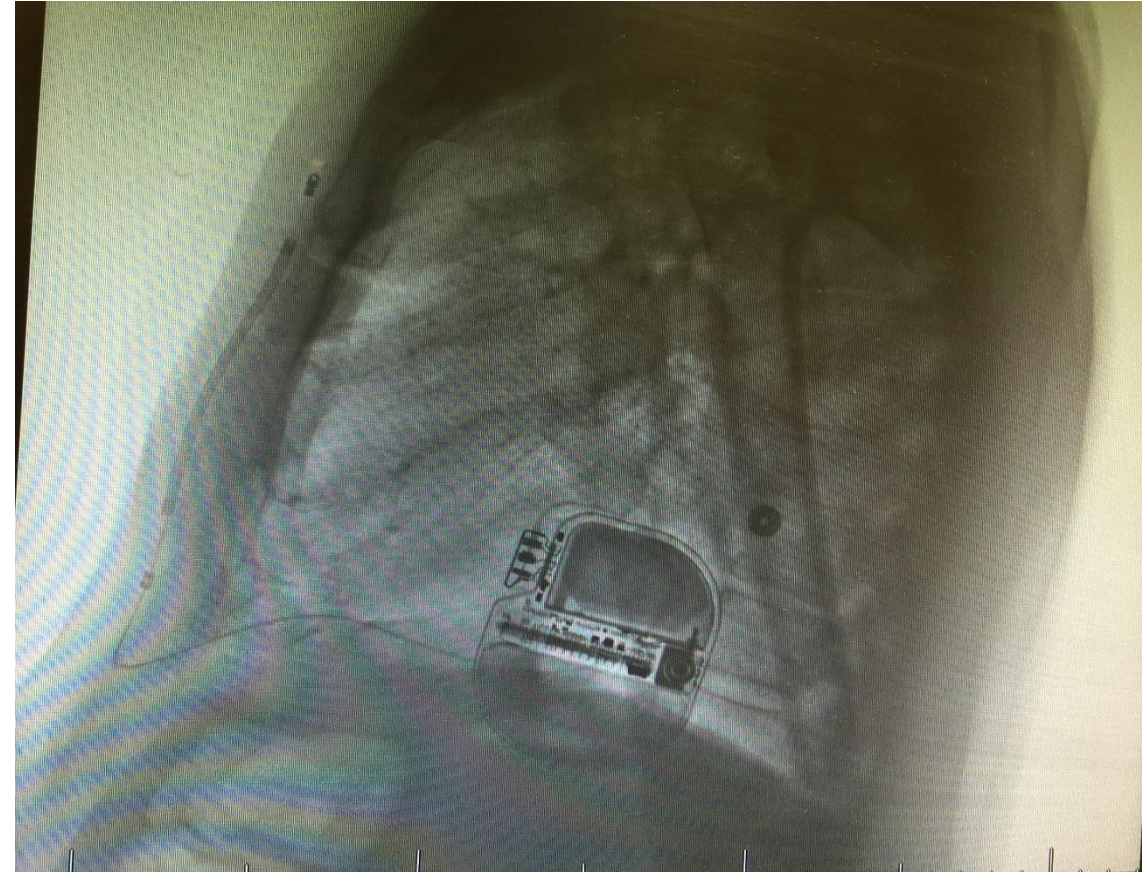
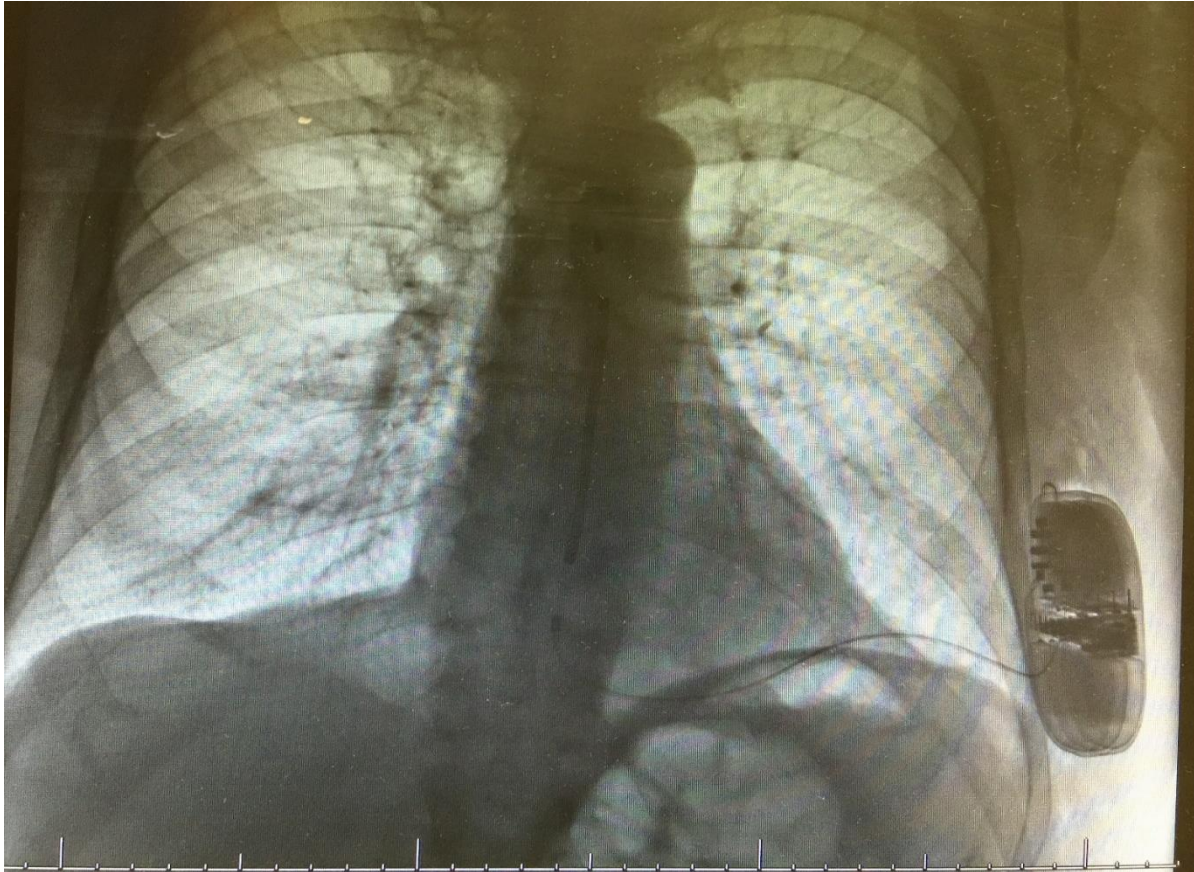
**Sensor contains two ECG amplifiers, microprocessor, memory, transceiver, battery. Upon detection of VF, it transmits the event and ECG to an external receiver**

# An Entirely Subcutaneous ICD

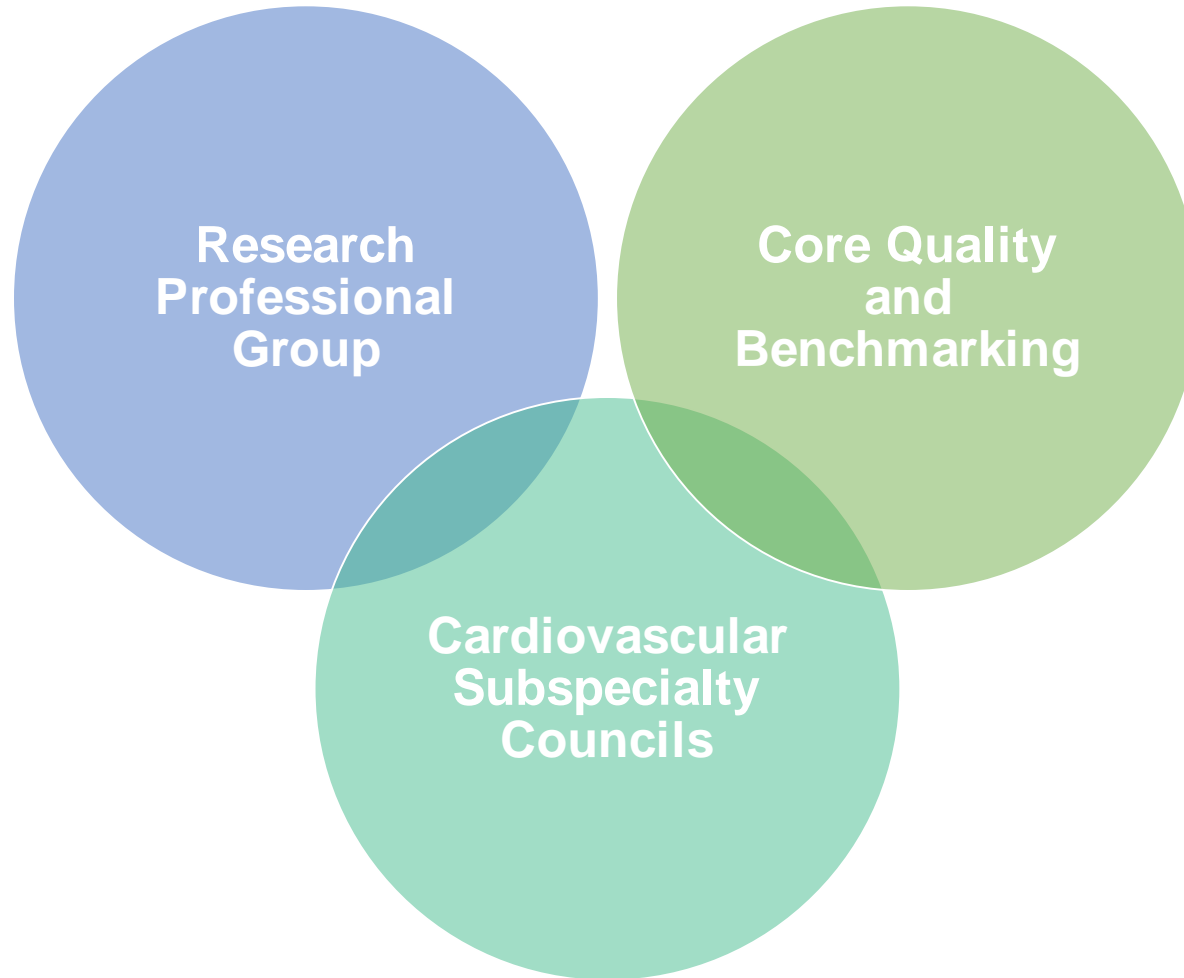
## SIMULTANEOUS 3-LEAD ECG



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



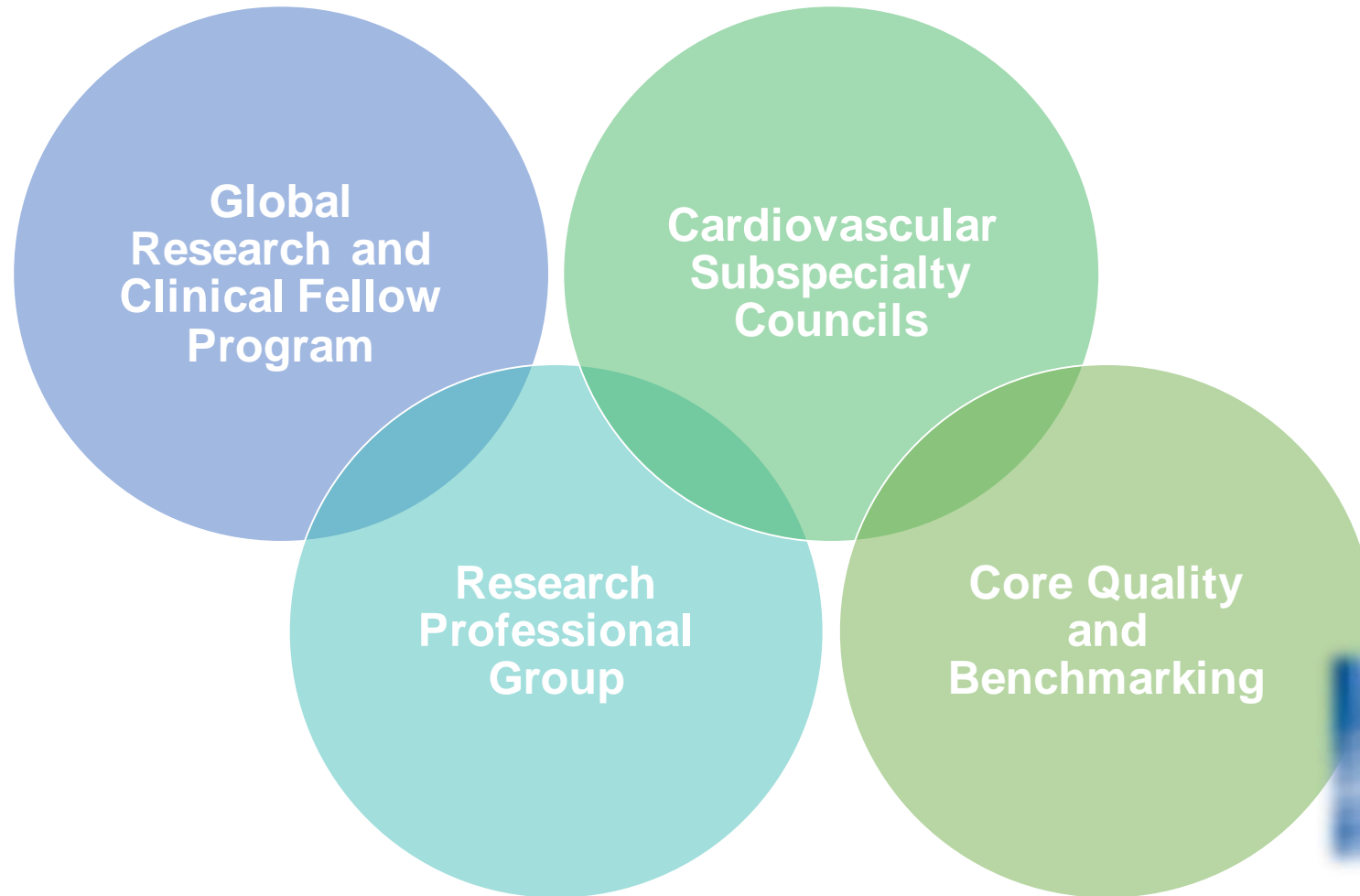
# Organizational Strategy



# Clinical Studies Summary

S-ICD <sup>®</sup> 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:

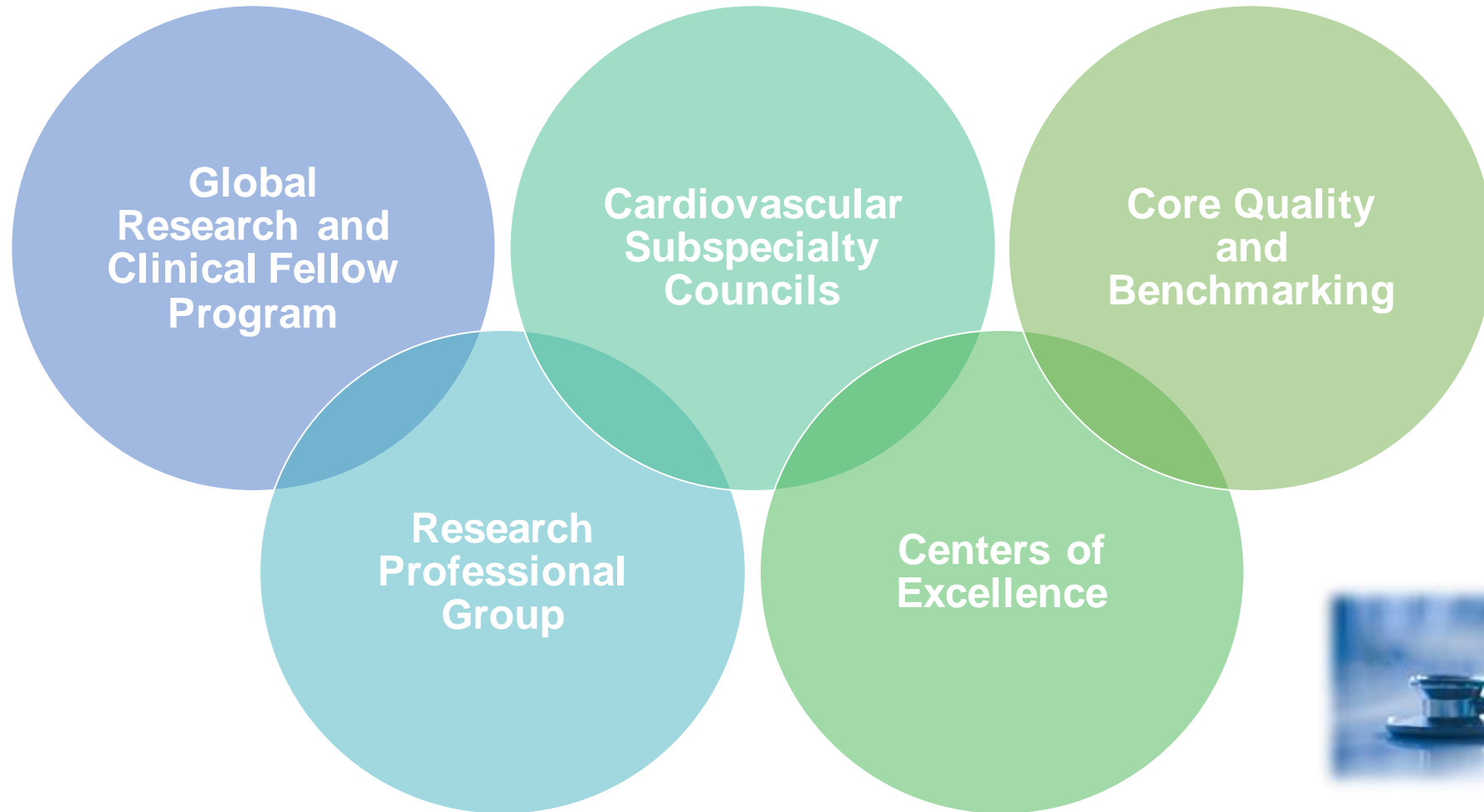
2-year Results from a Pooled Analysis of the  
IDE Study and EFFORTLESS Registry

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

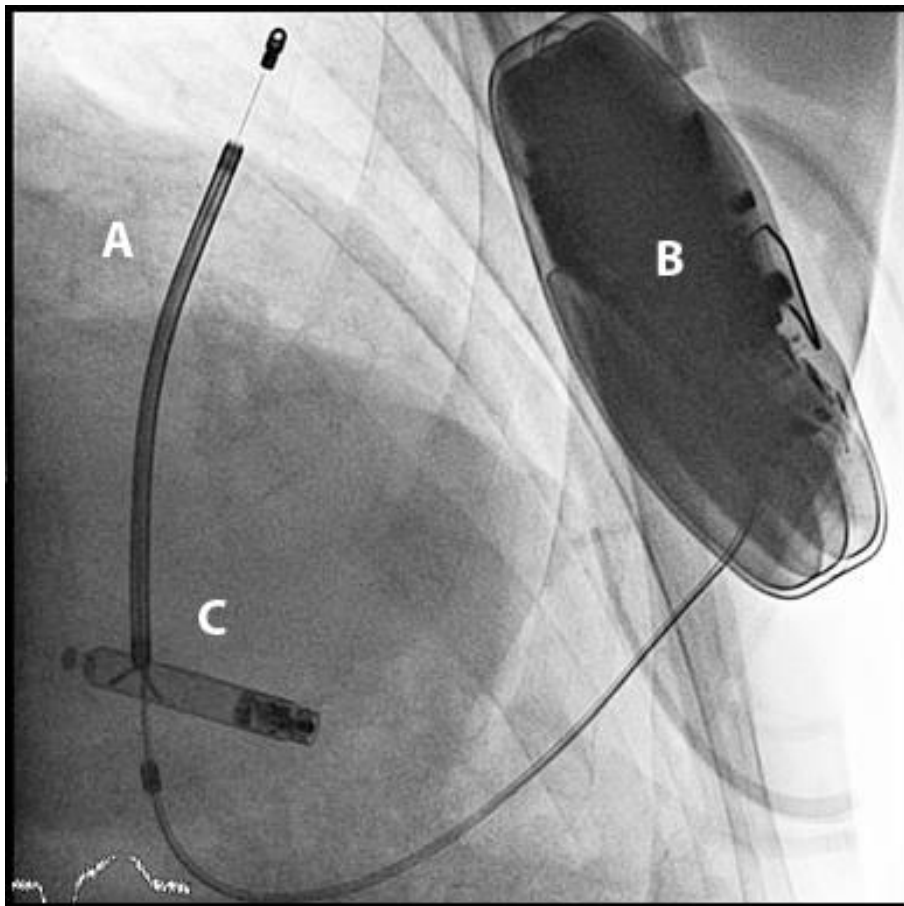




# Application of S-ICD is limited due to lack of pacing capability

## Bradypacing:

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

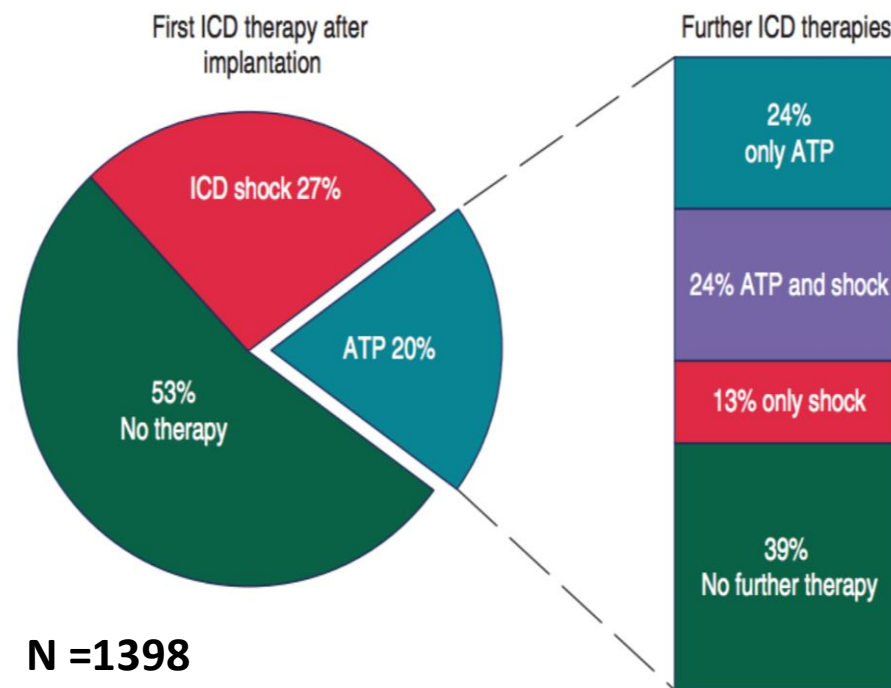


Tjong et al. Europace 2016

## Anti-tachy pacing: No solution

Substantial ICD subgroup benefits from ATP therapy

Prospective registry data from single center in Germany

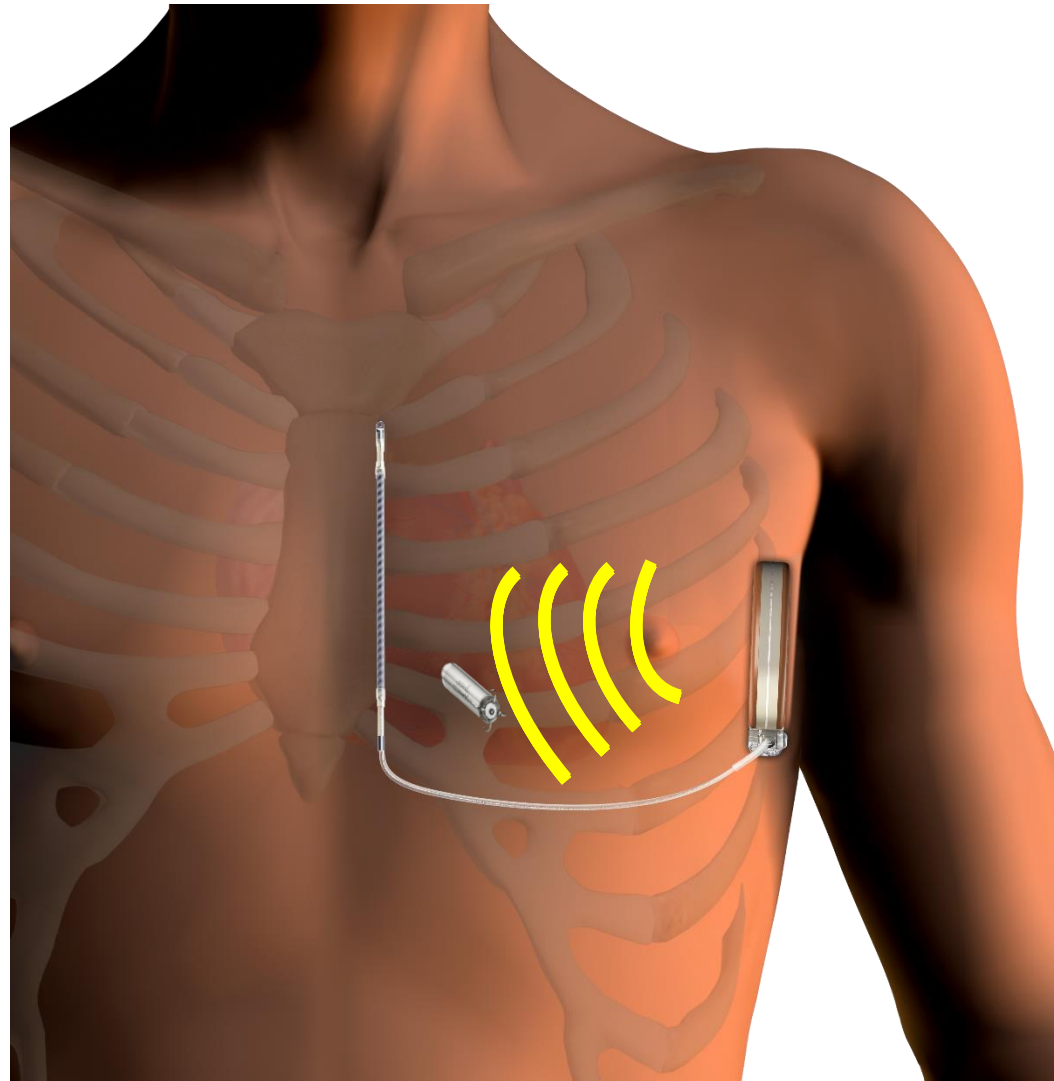


N = 1398

Figure 1 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

# Clinical Science is Global?

(Trainees like it)



# 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

