

# **Building A Clinical Research Unit: What Does It Take?**

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# Disclosure Slide

- **Dr Puskas is a consultant to Medtronic and Maquet.**
- **Medtronic and Maquet sponsor research within the Emory Division of Cardiothoracic Surgery.**
- **Dr Puskas served as International PI of the Cardica PAS-Port FDA trial, but has no financial relationship with Cardica whatsoever.**
- **Dr Puskas serves as International PI of the ON-X valve PROACT FDA trial, but has no financial relationship with MCRI whatsoever.**

# What It Takes:

- 1) Commitment of attending surgeon leaders and Director:**
  - **Active personal involvement; available**
- 2) \$\$\$ from multiple sources**
- 3) Dedicated staff, FTEs not shared/part time**
- 4) Perseverance/sense of humor/joy in work**
- 5) Share success/credit (co-authorship)/CRU serves our entire Division of CT Surgery**

# **Sources of \$\$\$**

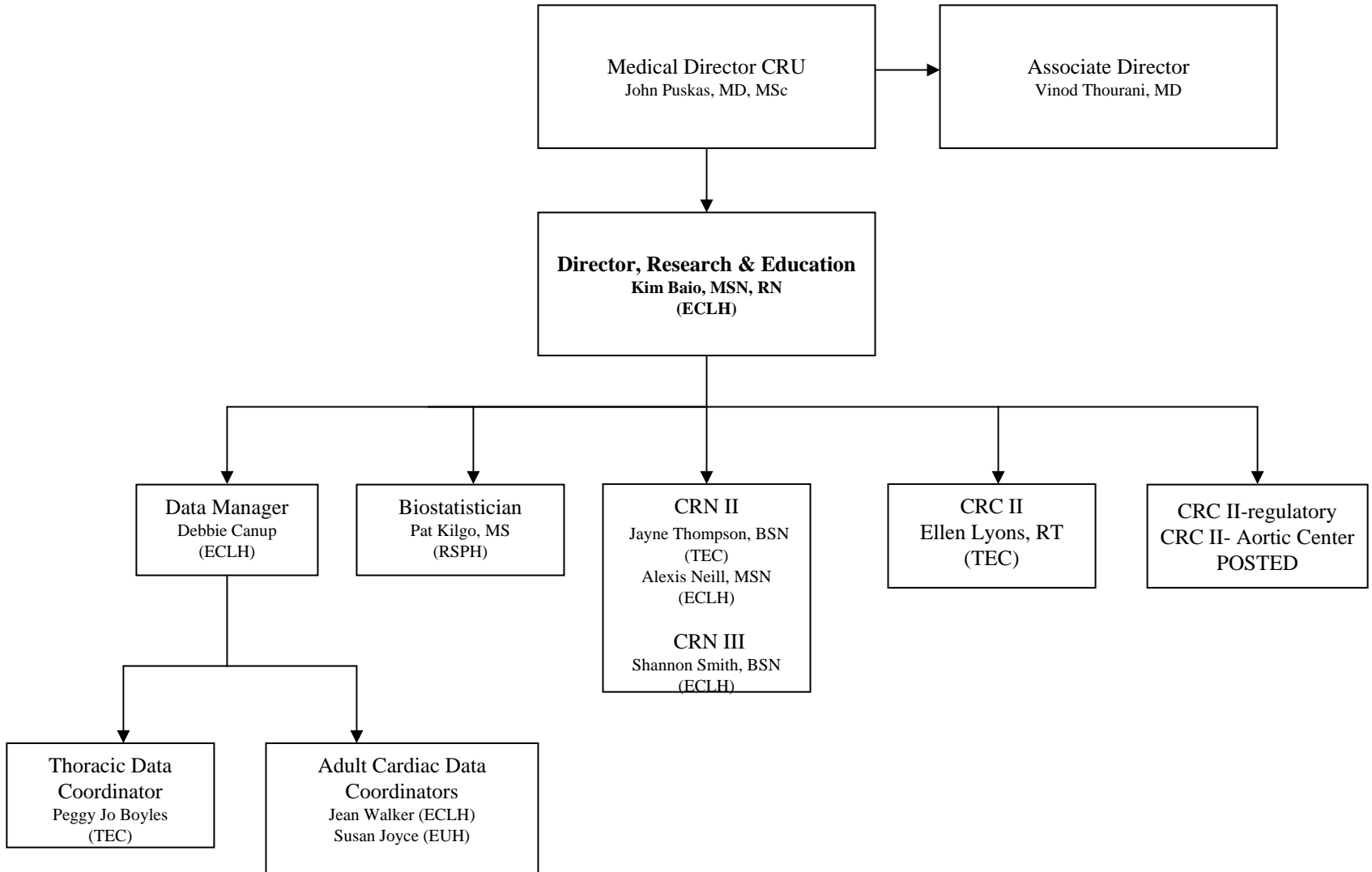
## **(Temporal Order)**

- 1) Clinical revenues of our CT Division**
- 2) Industry**
- 3) Institutional/hospital funding**
- 4) Intramural grants: Coulter, EHC**
- 5) Extramural grants: AHA, NIH**

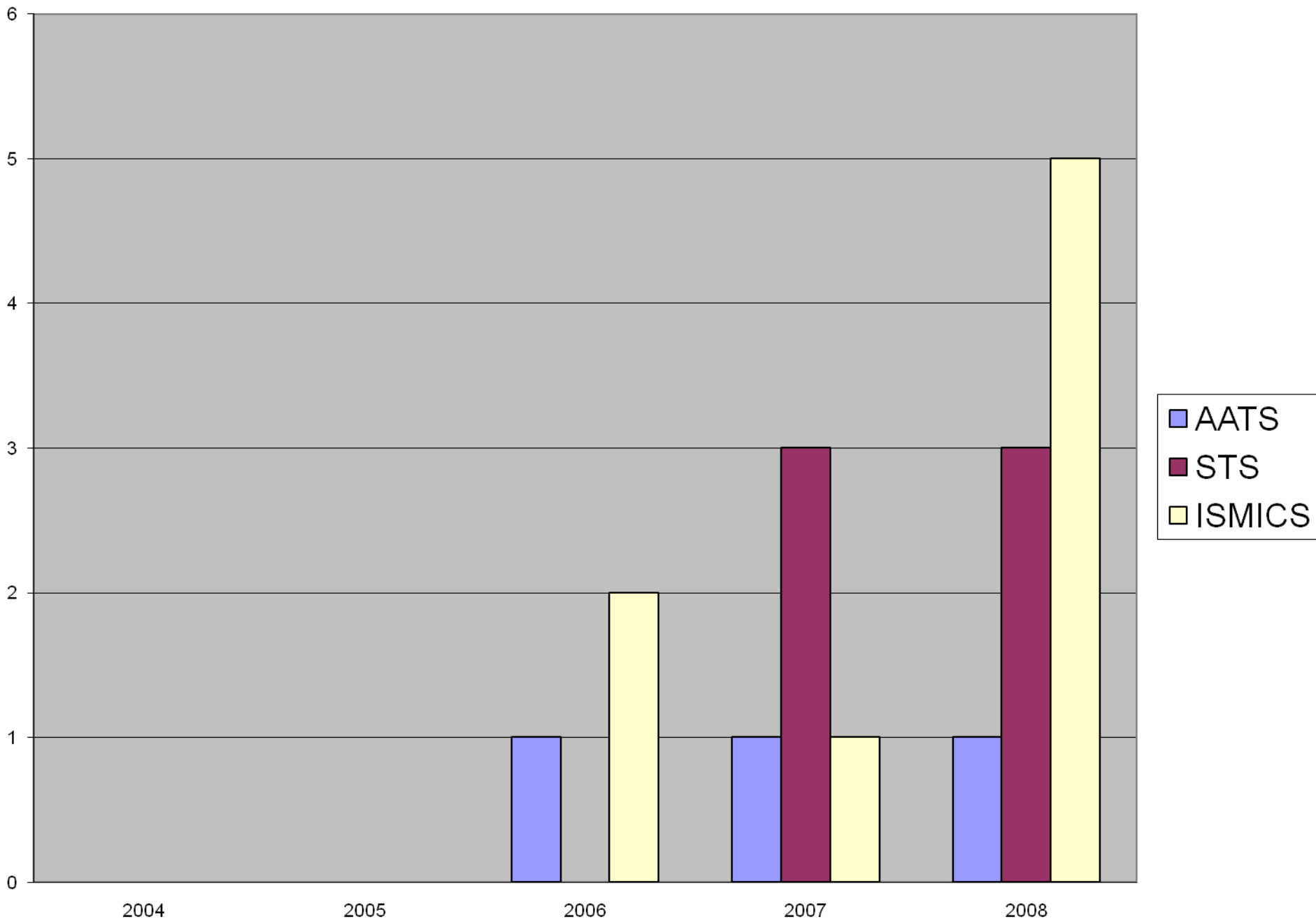
Date	Staff	FTEs	\$\$\$	Source of \$\$\$
1996	1 CRC/database 1 surgeon (part time)	1	\$70k	clinical
2003	1 CRC 1 surgeon 1 database	2	\$140k	clinical admin industry
2004	1 CRC 1 surgeon 1 database 1 biostatistician (20%)	2.2	\$155k	clinical admin industry
2005	1 CRU Director 2 CRCs 1 surgeon 2 database 1 biostatistician (40%)	5.4	\$350k	clinical admin/ <b>hosp</b> industry grants
2008	1 CRU Director 4 CRCs 2 surgeons; 5 PIs 4 database 1 biostatistician (80%) 1 research fellow	10.8	\$750k	Clinical Admin/hosp Industry Grants (UO1)

# Clinical Research Unit – Cardiothoracic Surgery

February 2009



# Peer-Reviewed Presentations



# 2011

- **Director**
- **8 CRCs**
- **2 surgeons; 8 PIs**
- **4 database**
- **1 biostatistician (1.0)**
- **2 research fellows (MDs)**

# Stumbling Blocks:

- 1) **Regulatory/Institutional processes and requirements. OSP/IRB/CTO are dysfunctional silos that do not communicate well with us or with each other**
- 2) **Clinical demands on PIs limit their time and focus for research**
- 3) **Geographical separation of sites/hospitals**
- 4) **Recruitment of best talent**
- 5) **Uncertainty of longitudinal support**
  - **“sell” value to the institution**
  - **Renew grants!**

# How We Could Fail

- **Regulatory Infractions**
- **COI**
- **Lose Institutional support (politics; value)**
- **Fail to renew grants**

# 2012 And Beyond

- ? Add Cardiology and provide CRU services to the entire Emory Heart and Vascular Center
- ? Increased role in QI/patient safety
- ? Increase role in marketing
- ? Expand biostatistical capability
- ? Expand to become a CRO for hire (InChoir; NERI; DCRI)