Efficient EFS Budget Negotiations

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Agenda

• MedStar Heart & Vascular Institute
• EFS Experience at your organization
• Example – Low Risk TAVR
• Tips and Tricks for Timely Budget Negotiation
• Summary
• General Recommendations for Ecosystem Improvement
MedStar Health: At a Glance

• MedStar Health is one of the 10 largest not-for-profit healthcare systems in the USA.
• Ten hospitals (9 acute care) from Washington to Baltimore.
• Responsible for >20% of all health care delivery in the region.
• Fiscal Year 2016 financial highlights:
  – Net operating revenues = $5.3B
  – Earnings from operations = $161M
• Provided ~$316M in indigent care & community services.

FY 2016 data (except charity care & community services, which reflect FY 2015 data)
MHVI is one of the busiest cardiovascular programs in the USA

- >2,300 OHS including ~80 VADs
- >450 TAVRs
- >13,000 cardiac catheterizations
- >4,000 PCIs
- >5,000 EP cases and implants
- >2,500 vascular surgeries
- >125 employed MD cardiovascular specialists and a number of associated independent practitioners
MHVI Spans the Following Academic Activities: Medical Education, Research and Innovation

- **Medical Education**
  - Georgetown University School of Medicine is the principal academic institution.
  - 7 of the 10 hospitals are teaching hospitals.
  - Over 1,100 residents and fellows in 90 graduate medical education programs.

- **MedStar Cardiovascular Research Network**
  - Translational nature of MCRN research – from bench to bedside to community – complements key clinical services and teaching programs.
  - Over 500 IRB approved open projects; more than 120 active principal investigators and 500+ publications & presentations/year.
  - Articulating value of health service research – research on the delivery of care using implementation science.

- **MedStar Institute for Innovation**
  - Launched in 2009 with five innovation domains: MedStar Inventor Services, National Center for Human Factors in Healthcare, Simulation Training and Education Lab (SiTEL), Center for Digital Health and Innovation, and Center for Innovation in Health/Care Delivery.
  - Founding member of 1776, a start up incubator and accelerator in Washington, D.C., and numerous partnerships.
MHVI Physician-Scientific Lead Structure

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Director, Cardiovascular Research & Advanced Education

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Director, Clinical Research Operations

Electrophysiology
- Advanced Heart Failure
- Non-Invasive Imaging
- Interventional
  - Coronary
  - Endovascular
  - Structural
  - Angio/IVUS/VH/OCT/NIRS Lab
- Invasive Imaging

Critical Care/PH
- Heart Failure

Preventive/Lipids
- Translational
- Pre-Clinical
- CardioOncology

Outcomes Research

Cardiac Surgery
Vascular Surgery
Vascular Med

MedStar Heart & Vascular Institute
Cleveland Clinic
Heart and Vascular Institute
Over ~100 dedicated staff support the physician-investigators

MHVI Research Integration Structure

- MHVI Physician Executive Director
- Director, Cardiovascular Research & Advanced Education

Scientific Areas of Research

- Electrophysiology
- Heart Failure
- Cardiac Imaging
- Clinical/Prevention/Lipids
- Intervention
- Cardiothoracic Surgery
- Translational Research
- Cardiac Oncology
- Vascular Medicine
- Cardiac Critical Care

Clinical Research Support Activities

- Clinical Research Coordination
- Clinical Trial Management
- Clinical Research Registries
- Grant Writing Support
- Research Fellowship/Internship
- Medical Writer/Publication Submission
- Core Labs
- Animal Lab
- Business Development

Core Labs

- Invasive Imaging Core Labs: Angiographic/IVUS
- Platelet Center
- Non-Invasive Core Labs Echo/CT/MRI Core Lab

Data Analysis/Statistical Support

- IST Trial Management
- Regulatory/Contracts/Finance
- Database Development

Research Fellows per discipline

- Cardiac Arrhythmia Based Research
- Advance Cardiac Support Based Research
- Cardiac Imaging Based Research
- Heart Disease Prevention Based Research
- Pulmonary Hypertension Based Research
- Women’s Heart Disease Prevention Based Research
- Cardiac Cath Lab Based Research
- Adult Congenital Heart Disease Based Research
- Aortic Disease Management Based Research
- Valvular Heart Disease Based Research
- Cardiac Surgery Based Research
Washington, DC Relationships

MedStar Heart & Vascular Institute

Knowledge and Compassion Focused on You

MedStar Heart & Vascular Institute

Cleveland Clinic
Heart and Vascular Institute
- Study budget must be detailed and represent fair market value (FMV)
  - All budget items:
    - Regulatory fees
    - Publication costs
    - Meeting attendance for presentation of results
  - Salaries of study personnel:
    - Number of hours
    - Hourly salary
    - Specific tasks to be performed
    - Benefits
  - Overhead (% of overall budget)
Lots of Activities not covered

- 8027 research subjects screened
  - 3103 unavailable during key hours
  - 4254 preliminary exclusion
  - 21 not screened for various reasons
  - 258 rejected prior to interview
  - 53 rejected after interview
  - 92 not consenting
  - 146 not medicated

100 research subjects enrolled
What goes into a budget?

- **Research Costs**
  - Protocol driven assessments (labs, EKGs, echo, cath, etc)
  - CRC time
    - Screening, enrollment, paperwork, EDC, queries, etc
  - PI time
  - Regulatory time

- **Standard of Care**
  - Clinical assessments that would be performed irrespective of trial enrollment

- **Clinic and Reimbursement**
Understand Medicare Coverage

• Medicare changes
  – what is considered standard of care
  – Do you have evidence if challenged?

• Is there an National Coverage Decision?
  – How does that fit with the proposed trial?
Example: LRT 1.0

- First IDE in the US for Low Risk TAVR, Investigator initiated IDE
- Initial CMS coverage request 2-2016
- NCD terms!
- Final approval of said request 6-2016
Budget tips

• Itemize ALL budget items – schedule of events and protocol
• Understand training needs/ costs
• Identify how to find the patients
Understand the Sponsor

- What does the protocol say!
- What really happens?
- What is your history with the sponsor?
- What are the proposed workflows for data submission
  - EDC
  - Core Lab – echos, angiograms, IVUS, etc
- Data collection work flow
- Watch out for contract language
Let's be subtle about this, we want to do business with them in the future.
Study Distribution - 2001

- Carotid
- Brachytherapy
- other
- Stent
- peripheral
- Drug
- PFO
- Carotid
Study Distribution-2011 & 2019

2011

- Valve
- Imaging
- DAPT

2019

- Aortic
- Mitral
- Other Structural
- Coronary Device
In Summary…

• Have a stable Working group/backbone
• Keep institutional support
• Negotiate well
• Diversify…Diversify..
• Keep informed
• Keep an eye on what’s coming and prepare
Recommendations

• Have investigators read protocol to start budgeting
  – For time negotiations and full understanding of standard of care activities

• Understand the training needs, screening steps, research activates

• Prior or similar studies

• Understand the study timelines and communicate throughout the system, research to hospital to industry