Knight Cardiovascular Institute Clinical Research

How we achieved the 60/60/60 Benchmark

DATE: March 6th  PRESENTED BY: Beth Wilson, BS  Clinical Research Manager
Who we are

• 21 Clinical Research Staff
  – 15 Coordinators, a research nurse, and a research APP
  – Operations Manager, Finance Manager, and Regulatory/Start-Up Specialist

• ~100 trials currently housed within the team
OHSU Approval Process - 2016

75 days

Enrollment
The 280 Day Study
The 280 Day Study

Risk Management

CMS

Purchasing

Hospital Feasibility

Storage Agreement

Coding and reimbursement analysis

50

130

Too Long
Lessons Learned

• Institution was not built to support device trials

• Development of new approval processes needed

• Stakeholders still needed to be verified

• OHSU needed a driver
Active Engagement

• Prospective reporting metrics
  – Internal deadlines for approvals and expectations of sponsor turnaround
  – Weekly PI meetings/Status Check-In
  – PI to sponsor relationships
Start-Up Timeline Reporting

Gowala, Harsh

Heitner, Steve

Days

Party (group)
- contracts
- IRB
- PI
- Regulatory
- Sponsor
Device Committee

- Identify institution stake holders
- Eliminate artificial bottlenecks
- Develop efficient processes for necessary internal approvals
- Allocate Master Contract Support for all device sponsors
Round 2 in 2018
New Sponsor, New Opportunity
The 280 Day vs. New Study

Regulatory Timelines

Contract Timelines

130+ Days

55 Days
Key Considerations

• Identify all stakeholders involved in approval processes for your institution AND ENGAGE THEM.

• Approach relationship with sponsor as a partnership

• Master Contracts

• Active facilitation through approval process