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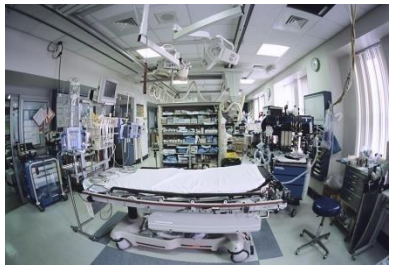
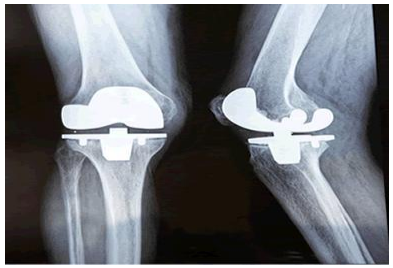
Strategies for Managing and Measuring Clinical Trial Financial Performance

September 17th, 2014



About the Speakers

Rob Smith, Manager
Rob has over 14 years of experience serving academic and community healthcare organizations with the administrative management and financial oversight of the clinical research enterprise. He has experience providing clients with strategic planning support, process improvement recommendations. Prior to Huron, Rob was a Research Manager at the NYU School of Medicine.

Patrick Bassett, Manager
Patrick has over 11 years of experience in basic and clinical research operations and financial management within independent research institutes and academic medical centers, including: institutional budgeting, strategic planning, federal indirect rate preparation, clinical trial contract budgeting and negotiation. Prior to Huron, Patrick was a Financial Manager at Seattle Children's.

Mindy Muenich, Manager
Mindy has a diverse background in the health care and research industry including 25 years of clinical and research operations management, business development, physician services, and quality process improvement/design. Recent client services include clinical research billing process redesign, research operations optimization and CRMS implementation. Prior to Huron, Mindy was the Director of Clinical and Translational Research at Cincinnati Children's Hospital Medical Center and UC Health.

Session Agenda

- Introduction
- Challenges to Clinical Trial Financial Management
- Elements of Organizational Success
- Financial Management Strategies
  - Clinical Research Vision & Goals
  - Cost Reduction and Revenue Enhancement
- Measuring Financial Performance
  - Choosing Performance Metrics
  - Implementing Performance Metrics
- Example Metrics / Calculations
- Closing Remarks & Questions

"If you can't measure it, you can't manage it."

Attributed to Peter Drucker

"You cannot change what you cannot measure."

- W. Edwards Deming

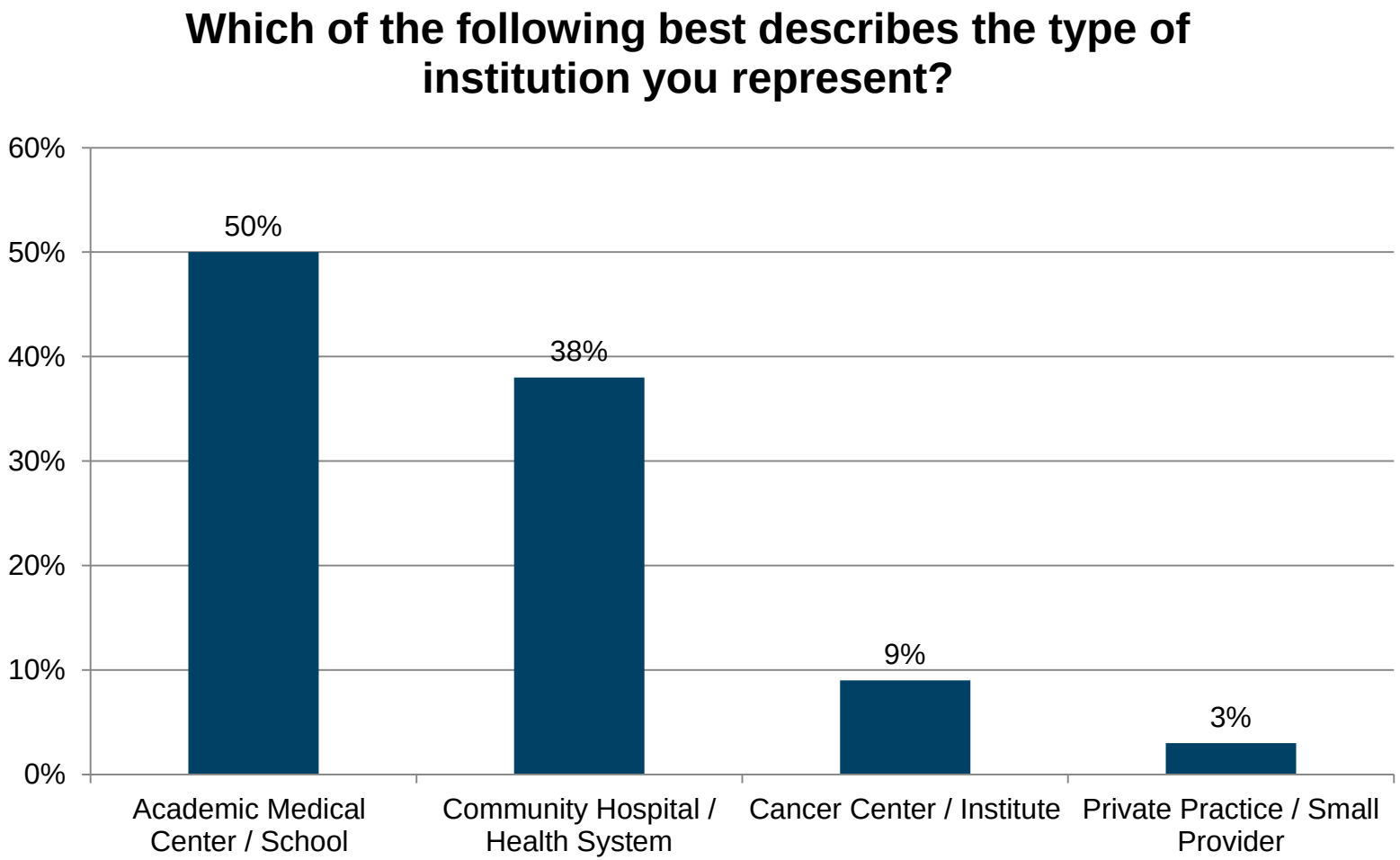
Polling Question 1

Polling Question #1

Which of the following best describes the type of institution you represent?

A. Academic Medical Center / School
B. Community Hospital / Health System
C. Cancer Center / Institute
D. Private Practice / Small Provider

Polling Question #1: Responses

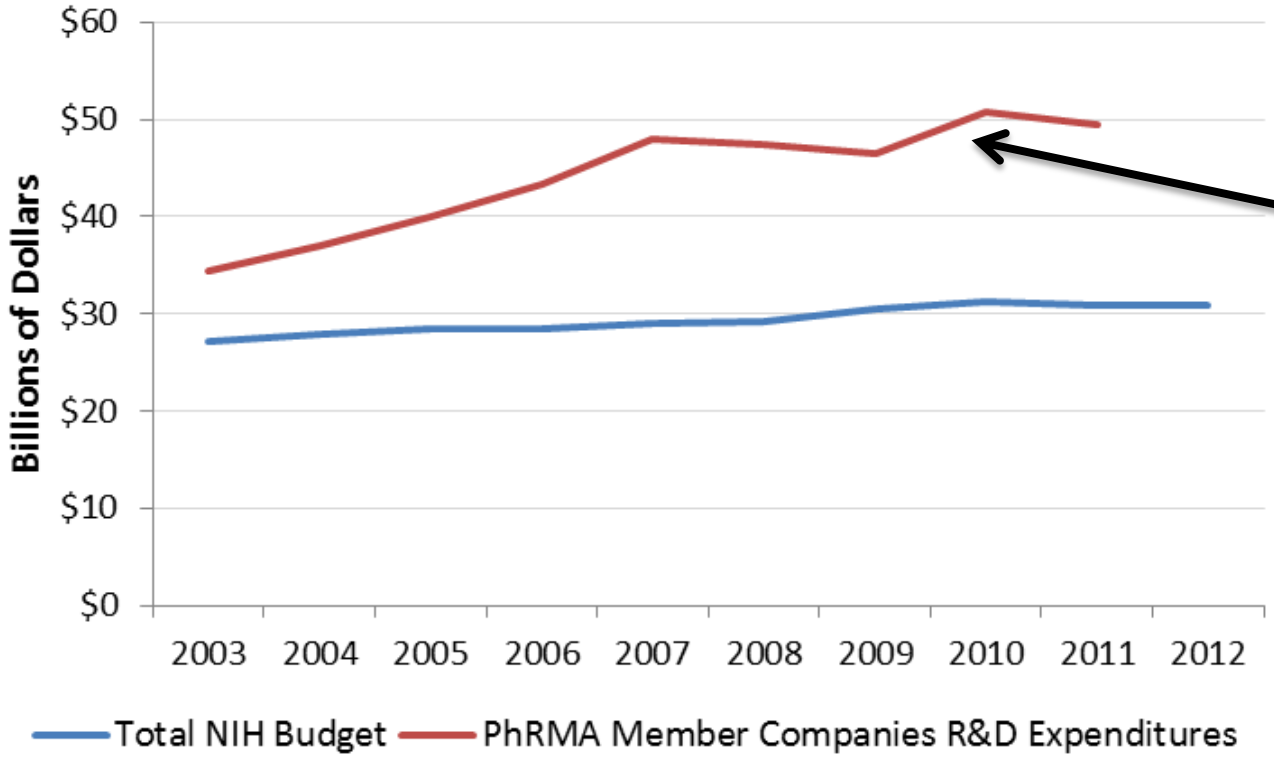


Challenges to Clinical Trial Financial Management

What is Driving Change?

EXTERNAL FUNDING

Funding from NIH and Pharma / Med Device companies has been relatively flat for the past decade.



- Industry sponsors have cut back on the number of studies and R&D spending due to the economy and patent cliff
- More clinical trials are moving outside of the US

Source: NIH Reporter; *PhRMA Biopharmaceuticals in Perspective, 2012; PAREXEL Biopharmaceutical RD Statistical Sourcebook 2012_2013 Section 3*

Site Challenges Impacting Research Finance

WHAT IS DRIVING CHANGE?

Some of the operational challenges driving the need for change at research sites include:

- Changes to research funding landscape due to:
  - Decreasing NIH dollars, federal budget deficits
  - Tighter pharma requirements, globalization of clinical trials
  - Increase in formative of co-operative groups, sub-award funding
- Evolution of technology, which is not always centralized;
  - CTMS
  - Financial systems (PeopleSoft, Lawson, SAP)
  - Time/effort tracking systems
- Increased complexity of research design, individualized bio-medicines
- Focus on regulatory enforcement, reporting requirements, and importance of research compliance programs

External Economic & Regulatory Pressures

CHALLENGES – EXTERNAL ENVIRONMENT

External forces in the economy and the clinical research industry are introducing challenges to sites. Some of these external factors include:

- Healthcare reform (PPACA) – uncertain research coverage;
- Research billing compliance;
- Updates to research conflict of interest regulations;
- Sequestration - NSF & NIH cuts up to 5%;
- Changing regulations and increased reporting requirements (CMS, NIH);
- Research market globalization and pharmaceutical outsourcing;
- Local and national competition

Internal Challenges in the Research Enterprise

CHALLENGES – INTERNAL DYNAMICS

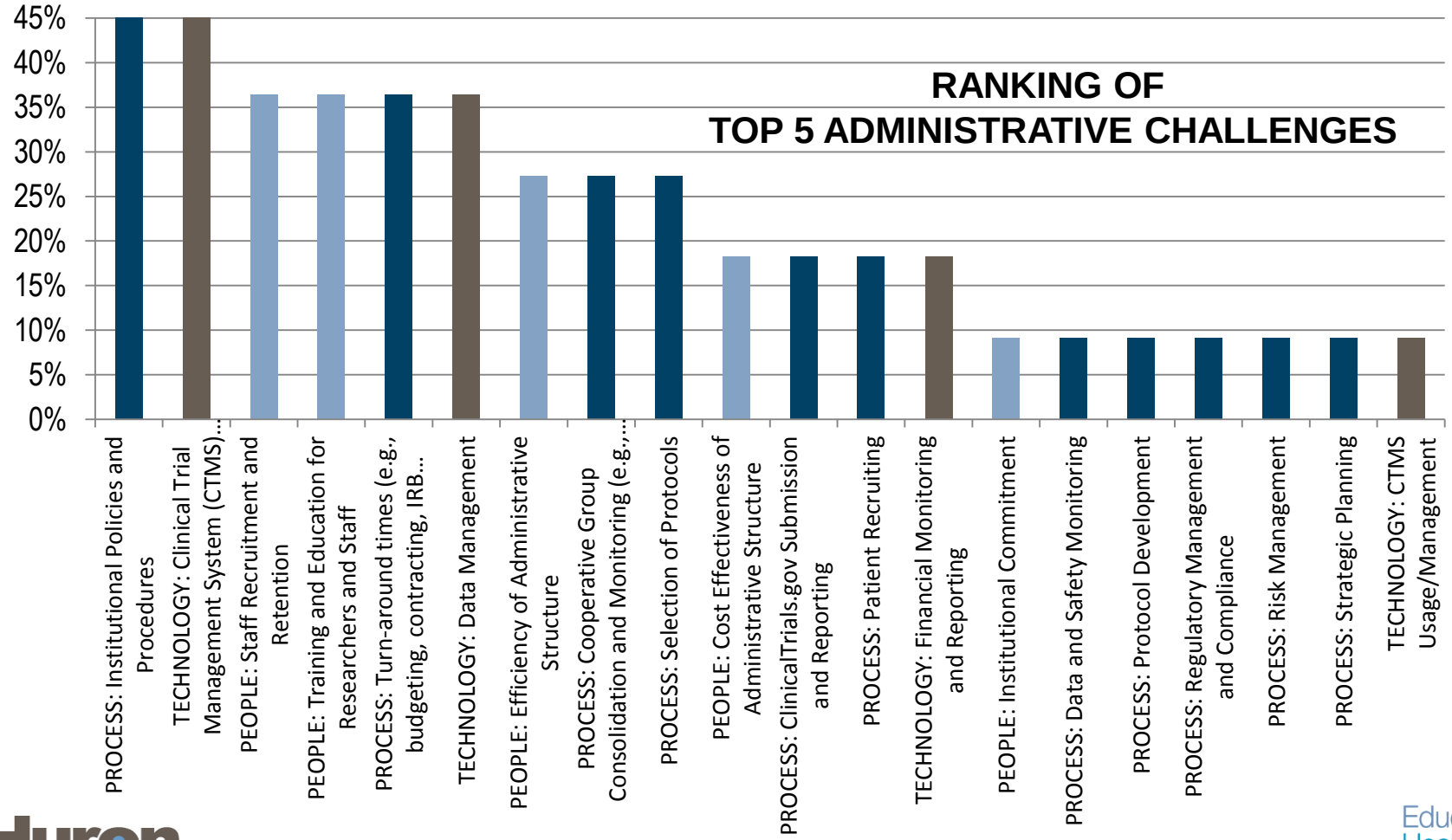
Internal dynamics are also causing challenges to the conduct and financial management of clinical research studies. Some of these include:

- Moving towards shared service models;
- Centralizing administrative service operations for research;
- Managing and recovering the fixed costs of centralized study coordinators or other clinical staff made available to Investigators;
- Desire to improve workflow, time to enrollment, and cost recovery
- Implementing policies and procedures in response to external challenges but implemented with limited communication and training resources;
- Technology systems chosen and implemented require a level of integration with other systems to deliver desired solutions

Huron Survey Results: Top Administrative Challenges

PEOPLE, PROCESS, TECHNOLOGY – SURVEY RESULTS

What are the top five administrative challenges or concerns about organizational capabilities at your institution? *(Huron's Site survey 2013)*



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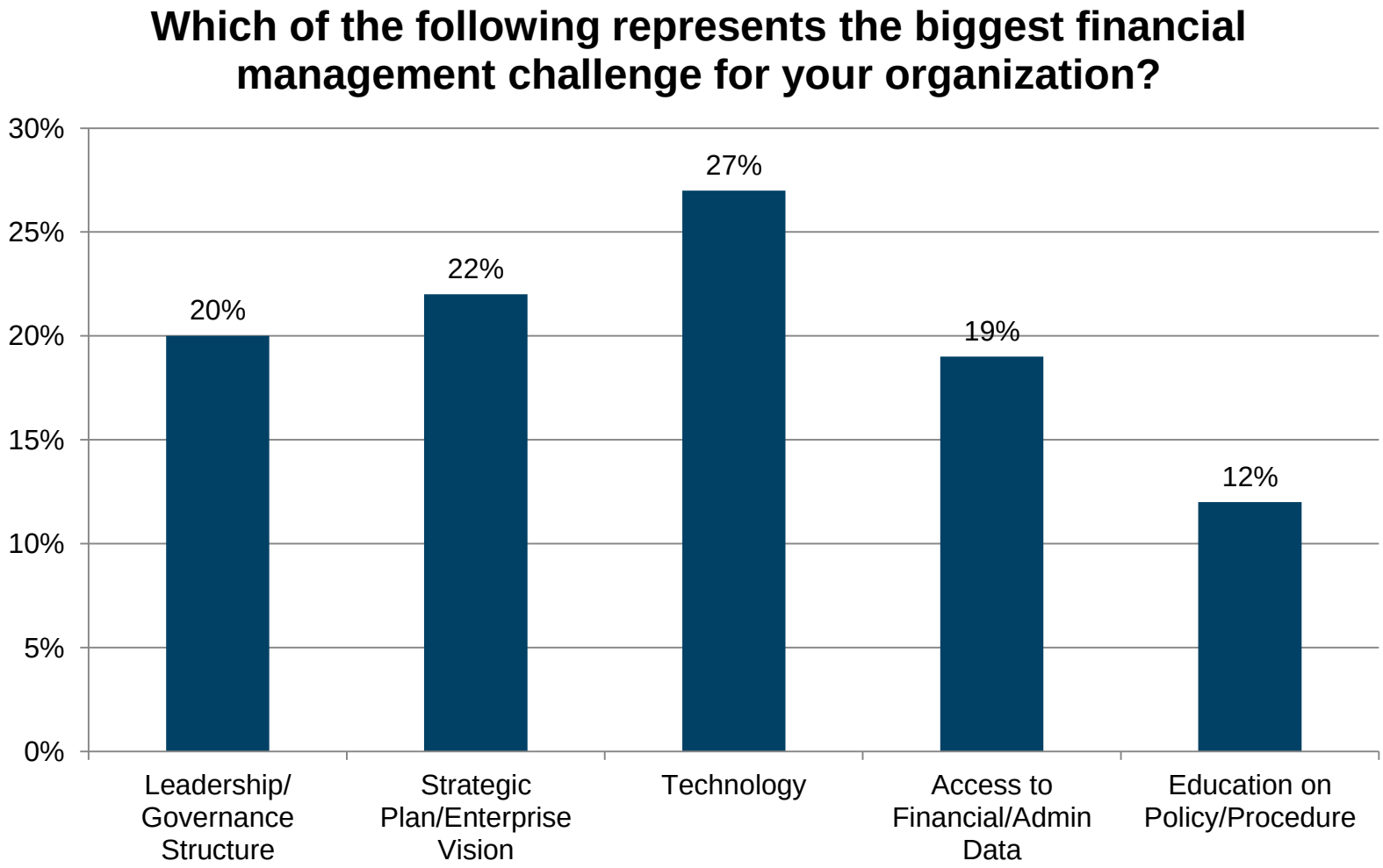
Polling Question 2

Polling Question #2

Which of the following represents the biggest financial management challenge for your organization?

A. Leadership/Governance Structure
B. Strategic Plan/Enterprise Vision
C. Technology
D. Access to Financial/Admin Data
E. Education on Policy/Procedure

Polling Question #2: Responses



Elements of Organizational Success

Research Financial Management Success

FIVE KEY ELEMENTS OF AN EFFECTIVE ORGANIZATION

The following five key elements of a successful clinical research operation also represent significant challenges to the financial health of a portfolio. The key elements include:

Governance & Organizational Structure:

- How can organizational structure and leadership positions most optimally support and manage the organization?

Business Process:

- What is the most efficient and effective way to serve process customers or users?

People:

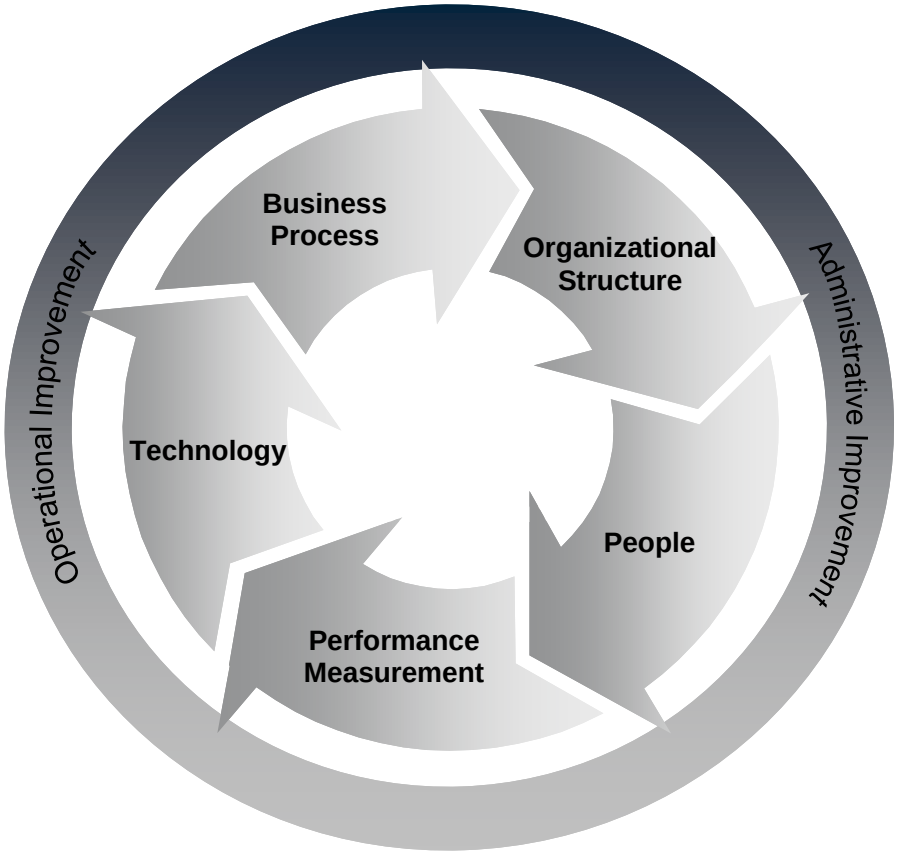
- Do we have the appropriate people to enable business processes?

Technology:

- Is technology appropriately enabling business processes?

Performance Measurement:

- Are we constantly evaluating and improving our performance?



Financial Management of Clinical Research

CHALLENGES – GOVERNANCE & ORGANIZATIONAL STRUCTURE

Governance & Organizational Structure: How an institution is governed and structured as an organization has a direct and significant impact on an organizations ability to achieve strategic initiatives.

While these larger governance qualifications are important, effective managers rely on more fundamental concepts, such as:

- Establishing authority to initiate change;
- Building a research culture that can facilitate change;
- Balancing a research vision with an understanding of what is financially required to achieve that vision across the portfolio

"It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change."

– Charles Darwin

Financial Management of Clinical Research

CHALLENGES – BUSINESS PROCESS

Business Process: When implementing a change to an existing business process, some of the challenges include:

- New or updated processes are not formalized, and communication and messaging across the institution is often lacking.
- Complex sub-processes can be adopted by decentralized teams without training or awareness of downstream consequences
- Departments and research teams develop their own processes, often with extra layers of oversight and complexity.

Financial Management of Clinical Research

CHALLENGES - PEOPLE

People: As organizations expand/contract, a significant challenge can be having the right people in the right positions, and providing the appropriate resources to successfully execute their role.

- Clear roles and responsibilities to guide daily operations and emphasize customer service.
- Sufficient resources to implement initiatives, as well as sufficient timelines to manage with limited resources.
- Educated & experienced personnel executing their responsibilities and with sufficient training to perform their role.

Financial Management of Clinical Research

CHALLENGES - TECHNOLOGY

Technology:

- Use of shadow systems: Financial systems at many organizations do not provide for project or fund accounting, which require the use of separate manual-systems and/or spreadsheets to monitor and report on the portfolio.
- Lack of system integration: More robust systems are utilized but often lack integration with other systems.
- Manual financial reporting: Without integrated information systems, financial reporting often requires a manual approach to summarize the state of the portfolio.

Financial Management of Clinical Research

CHALLENGES – PERFORMANCE MEASUREMENT

Performance Measurement:

- Lack of system integration that results in manual reporting processes;
- Data extraction and consolidation is frequently managed by multiple roles in the organization;
- Variable business processes or differing data sources often lead to challenges identifying an “apples to apples” comparison for management decision making. Example include:
  - Identifying the scope of the portfolio being measured (number and types of studies)
  - Outlining and controlling for variable work load requirements between a complex clinical trial versus a retrospective chart review
  - Collecting time/effort on a study-by-study basis
  - Ensuring performance metrics are reliable and valid

Polling Question 3

Polling Question #3

What is the number of active clinical research studies under management at your Institution?

A. 1-50

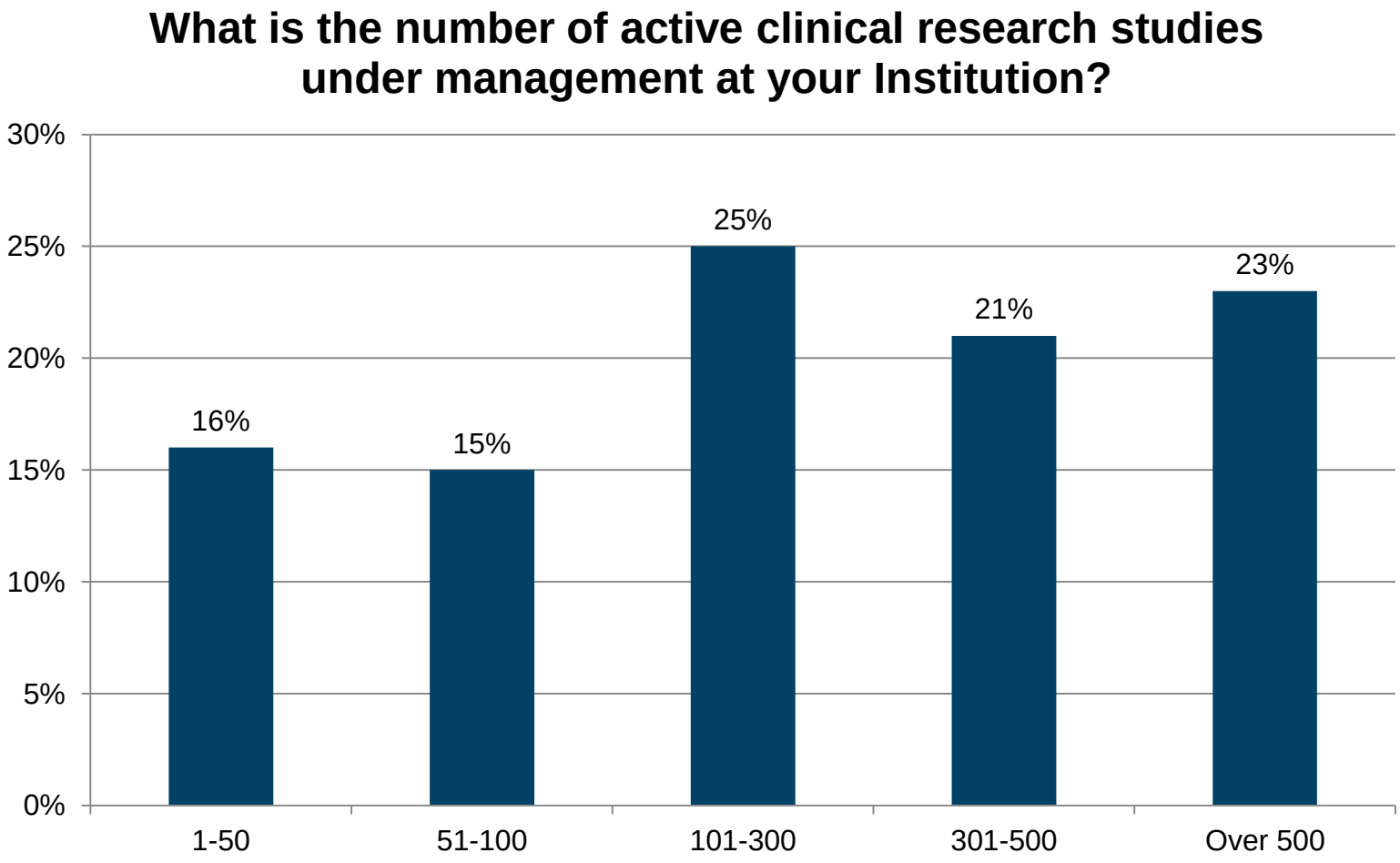
B. 51-100

C. 101-300

D. 301-500

E. Over 500

Polling Question #3: Responses

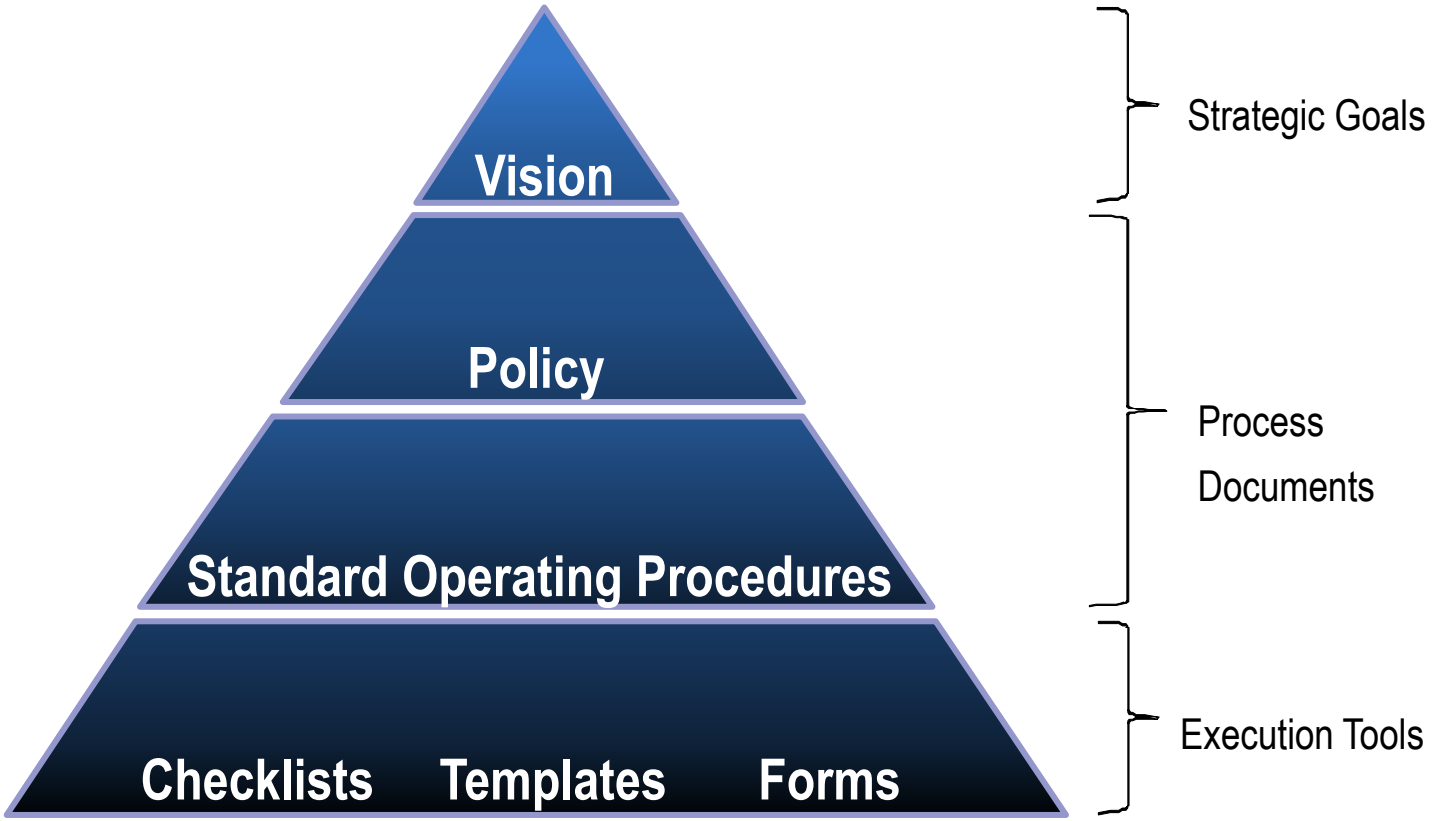


Financial Management Strategies

Strategies for Financial Management & Performance

CLINICAL RESEARCH VISION & GOALS

Before choosing and implementing performance measurements, the institution should first consider its strategic and financial goals for engaging in research.



Strategies for Financial Management & Performance

ORGANIZATIONAL STRUCTURES & GOVERNANCE

Governance Strategies

- Create targeted committees and empower them to address institutional issues. Examples of these committees include:
  - Clinical Research Advisory Committee
  - Clinical Research Feasibility Committee
  - Clinical Research Information Systems Committee
- Empower the committees to develop guiding principles and a strategic plan, including a definition of financial "success" in clinical trial performance.

Benefits

- Clearer institutional leadership and oversight
- Established body able to review results, suggest corrections, and guide decisions
- Improved accountability that engages more than just the Investigator
- Facilitated communication between researchers and information sources

Strategies for Financial Management & Performance

COST REDUCTION & REVENUE ENHANCEMENT

Cost Reduction and Revenue Enhancement

To have a sustained positive impact on the financial bottom line an organization needs to (1) control the growth in expenses and (2) identify targeted opportunities for cost reduction.

To accomplish this an organization needs to address inefficiencies/constraints across all clinical research business processes while also balancing the regulatory requirements. Some strategies include:

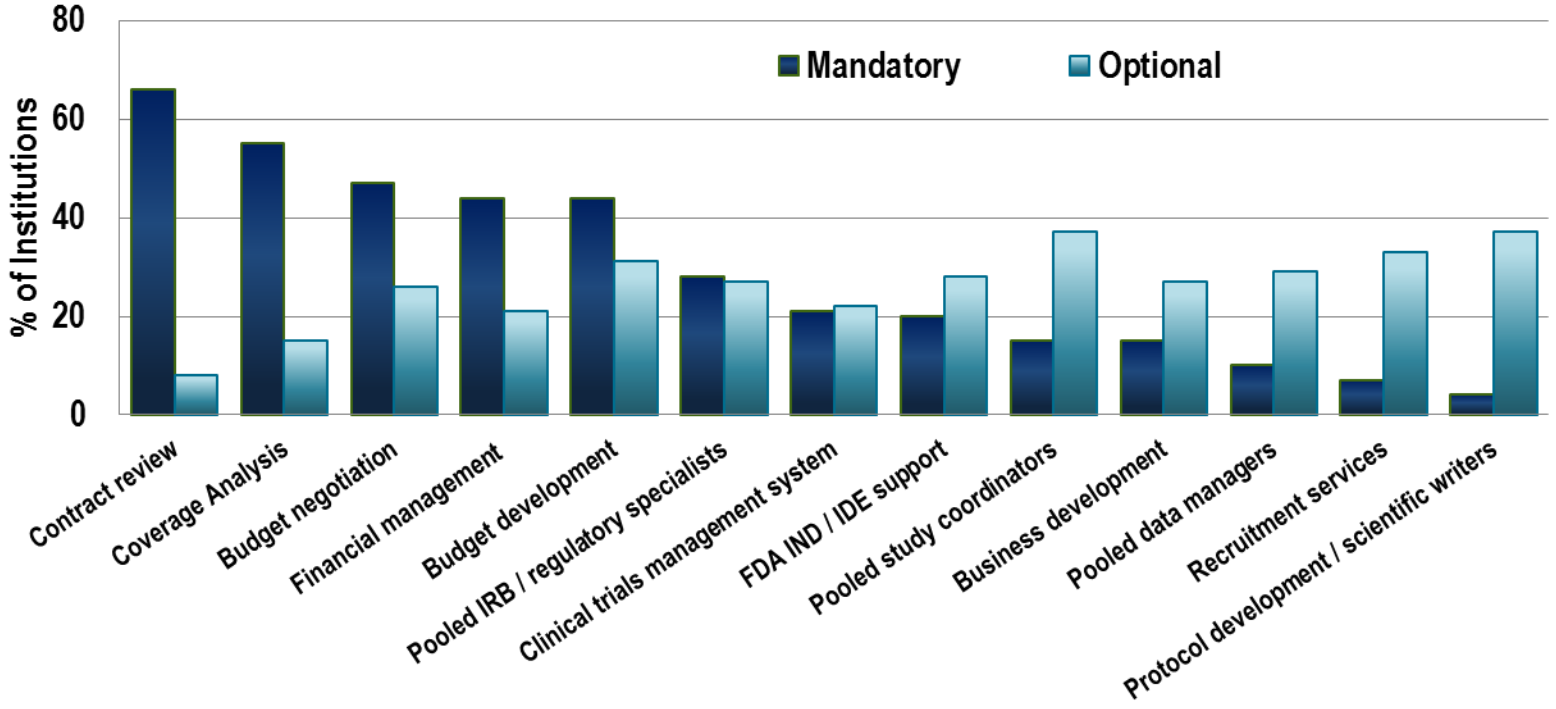
- Monitoring and managing under-performing research studies
- Evaluating staffing resources to maximize value and return on research dollars
- Assessing pre and post-award administrative processes to ensure:
  - Timely initiation of high revenue generating trials
  - Reduction in time/effort associated with non-enrollment activities
  - Increased institutional awareness of financial viability to support the continuity of research activity

Strategies for Financial Management & Performance

COST REDUCTION & REVENUE ENHANCEMENT BUSINESS INTEL MODEL

Institutions that recognize the mandatory and optional business processes that contribute to their current costs are better positioned to make informed decisions.

Data collection by a Huron survey demonstrates some of these common processes :



Source: Huron Life Sciences Clinical Research Management Webinar Series: Results of Huron's Clinical Research Operations Benchmarking Survey, April 20, 2011.

Strategies for Financial Management & Performance

COST REDUCTION & REVENUE ENHANCEMENTS: PRE-AWARD

Pre-Award Considerations

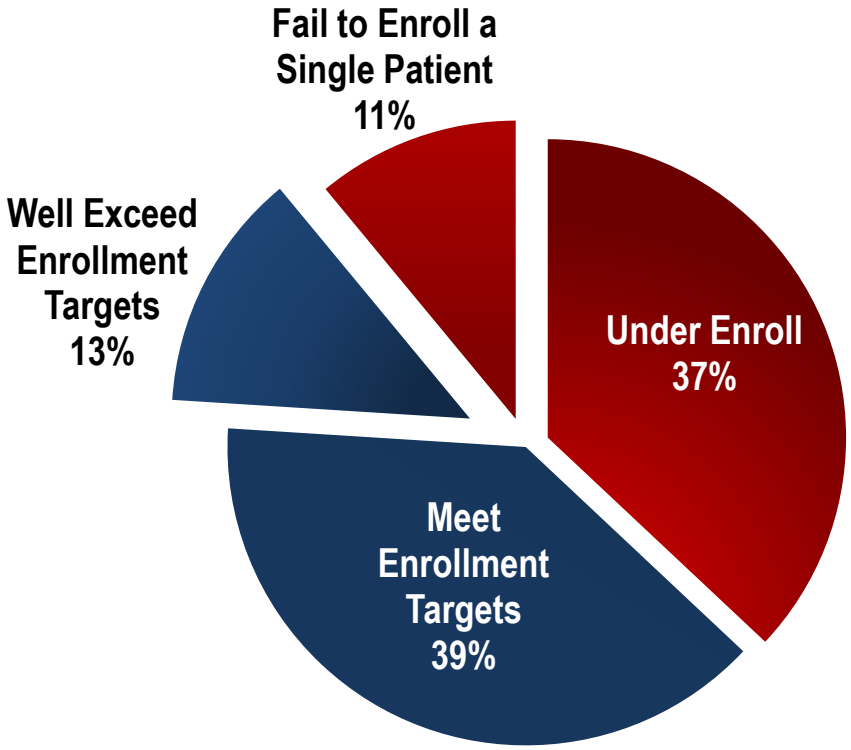
- Ensure startup fees are sufficient and invoiced
- Budget development and negotiation
  - Consistent approach
  - Standard fee schedules
  - Standard budget elements (i.e. ancillary services and invoiceable items)
- Focus on viable studies
  - Study selection process (feasibility)
  - Maximize coordinator utilization
  - Eliminate low enrolling studies

Strategies for Financial Management & Performance

COST REDUCTION & REVENUE ENHANCEMENTS: PRE-AWARD

Typical Enrollment Performance

(N = 15,965 sites participating in 153 global, Phase II and III clinical trials)



Source: *Tufts CSDD*, 2011.

Strategies for Financial Management & Performance

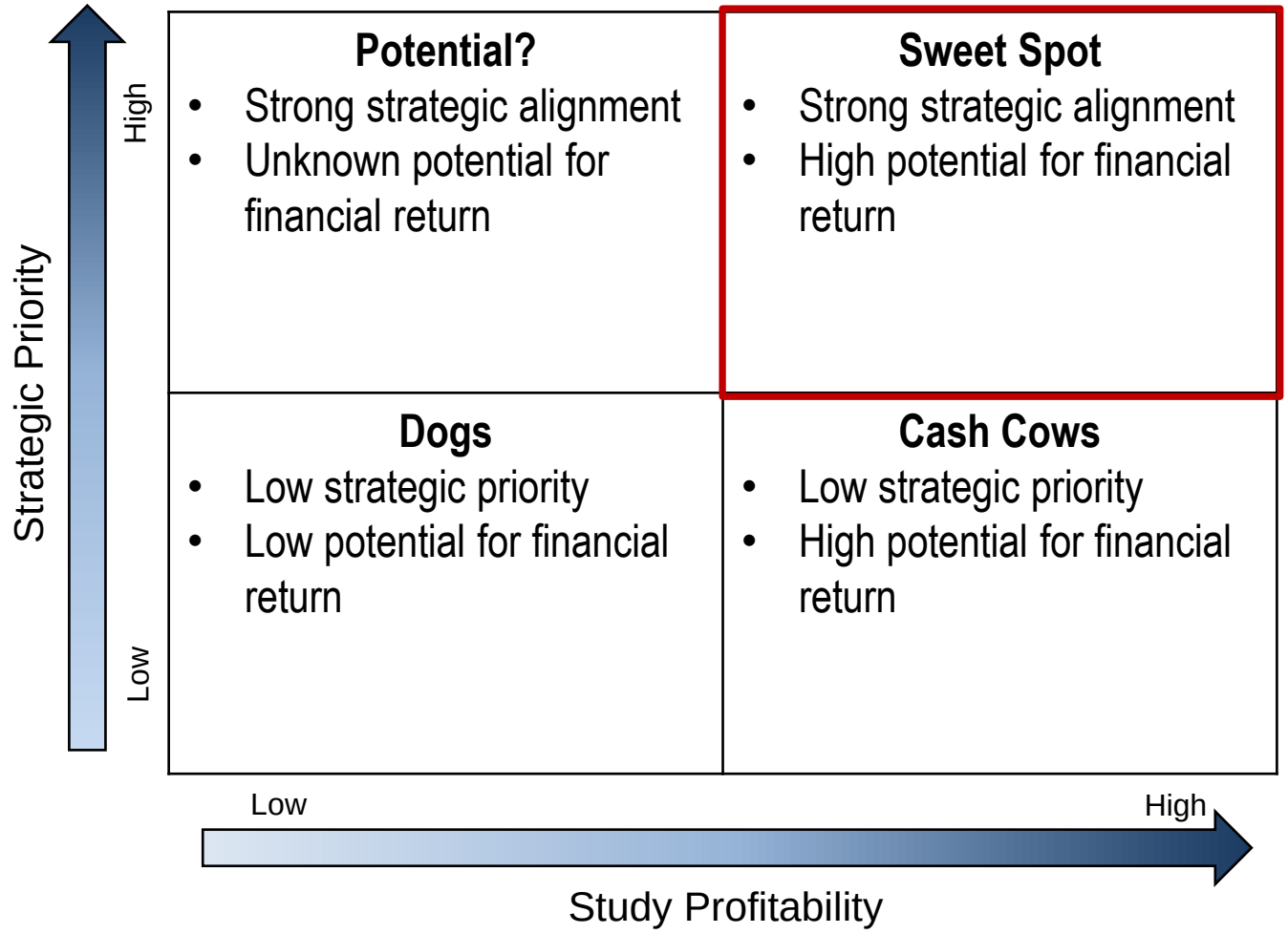
COST REDUCTION & REVENUE ENHANCEMENTS: PRE-AWARD

Standardize Budgeting and Contracting

- Develop policies and procedures to guide the budget development process
- Ensure the right person is negotiating the budget
- Standardized administrative fee schedules
  - Start-up and closeout costs
  - Invoiceable items
  - Screen fails
  - Monitoring visits
  - PI and coordinator time
- Contracting
  - Advance payments
  - Monthly invoicing
  - Standard terms and conditions (Master Agreements)
- Renegotiate unprofitable trials (be willing to walk away!)

Strategies for Financial Management & Performance

COST REDUCTION & REVENUE ENHANCEMENTS: PRE-AWARD



Strategies for Financial Management & Performance

COST REDUCTION & REVENUE ENHANCEMENTS: POST-AWARD

Post-Award Considerations

- Develop policies and procedures to guide the post-award financial management processes, including:
  - Timely and accurate study-start-up invoicing
  - Regularly scheduled trial invoicing and booking of A/R
  - Time/effort tracking on a study-by-study basis
  - Cash application and transfer procedures to ensure clinical departments see earned revenue based on internal budget agreements
  - Administrative oversight and actions for underperforming clinical trials
  - Study closeout procedures, including financial reconciliation of all revenues and expenses
- Renegotiate unprofitable/problematic trials when warranted
- Develop an evaluation process at closeout (report card / outcomes report)

Polling Question 4

Polling Question #4

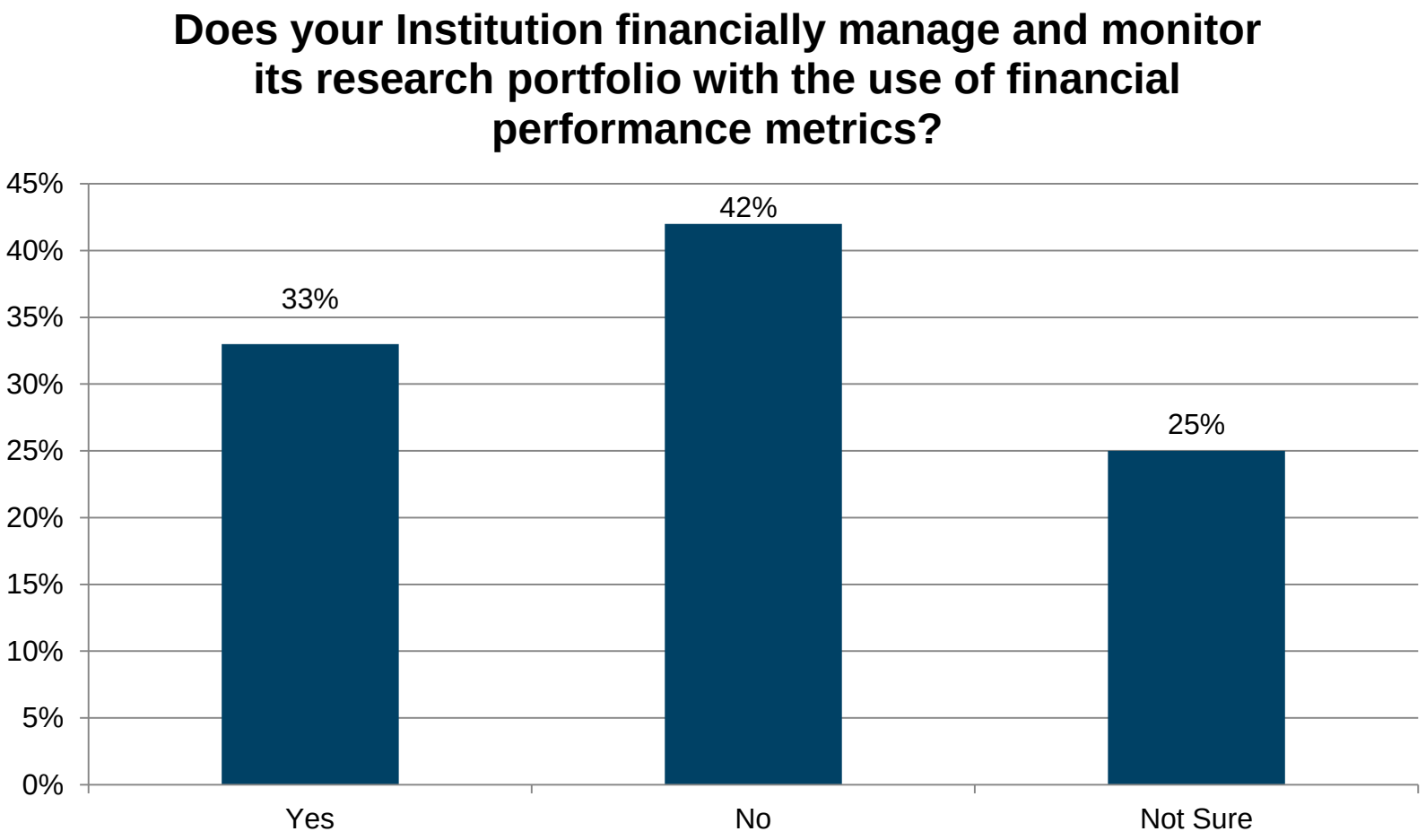
Does your Institution financially manage and monitor its research portfolio with the use of financial performance metrics?

A. Yes

B. No

C. Not Sure

Polling Question #4: Responses



Measuring Financial Performance

Measuring Financial Performance

CLINICAL TRIAL METRICS: CHOOSING WHAT TO MEASURE

What should we measure?

- Financial data that can provide insight into operations and present that information in a way that informs business decisions
- Information that represents the current-state of performance and serves as a mode of monitoring financial and other trends visually / numerically
- Collection of data that can be used to benchmark the institution against itself

How do we know what is meaningful?

- Know the difference between reliable data and the relevance / validity of data when reviewing financial metrics.
  - Reliable - data that is consistently collected by the same source using the same inputs and outputs, usually easy to collect operational data
  - Relevant / Valid – data that is proven to be meaningful and is able to be reliably collected

Measuring Financial Performance

CLINICAL TRIAL METRICS: CHOOSING WHEN TO MEASURE

When do we collect and review clinical trial metrics?

- Metrics are most useful when they can be reliably collected in a timely manner and shared with the audiences on whom the metric reflects. This may include:
  - *weekly, monthly, quarterly, and annual data collections*
- More importantly, metrics that are easily retrievable by those impacted increases the likelihood of the usefulness of the metric being implemented. This increases the availability of information that can be distributed.
- For example:
  - Study teams able to respond to sponsor feasibility requests with timely and accurate reports on past performance.
  - Management teams able to illustrate revenue trends to support resource requests.
  - Faster access to historical enrollment performance in therapeutic areas to evaluate the feasibility of meeting enrollment targets.

Measuring Financial Performance

CLINICAL TRIAL METRICS: IMPLEMENTATION METHODOLOGY

Considerations for performance metric selection & implementation include:

- Who is the intended audience to review the data?
- Does the metric represent an actionable piece of information for that audience?
- How will the resources reliably collect the data being measured?
- What access to information would that resource require that he/she may not have?
- What tool(s) will be required to collect, report, and archive results?

Example Performance Metrics

Strategies for Financial Management & Performance

METRICS BY ADMINISTRATIVE AREA

CTO	
◆ Average number of days to review and approve a proposal ◆ Average number of days to set-up contracts	◆ Studies per coordinator ◆ Subjects per coordinator ◆ Total enrolled subjects per coordinator
Clinical Trial Financial Management	
◆ Average number of days to set-up awards ◆ Monthly unbilled balance ($) ◆ Number of active contracts past end date (+90 days)	◆ Average accounts receivable balance ($) ◆ Amount of accounts receivable over (+90 days) ◆ Accounts receivable aging (30/60/90 days)
Departments or Centers	
◆ Number of accounts in overdraft ◆ Number of active contracts past end-date (+90 days)	◆ Number of departmental cost transfers

Strategies for Financial Management & Performance

METRICS BY ADMINISTRATIVE AREA

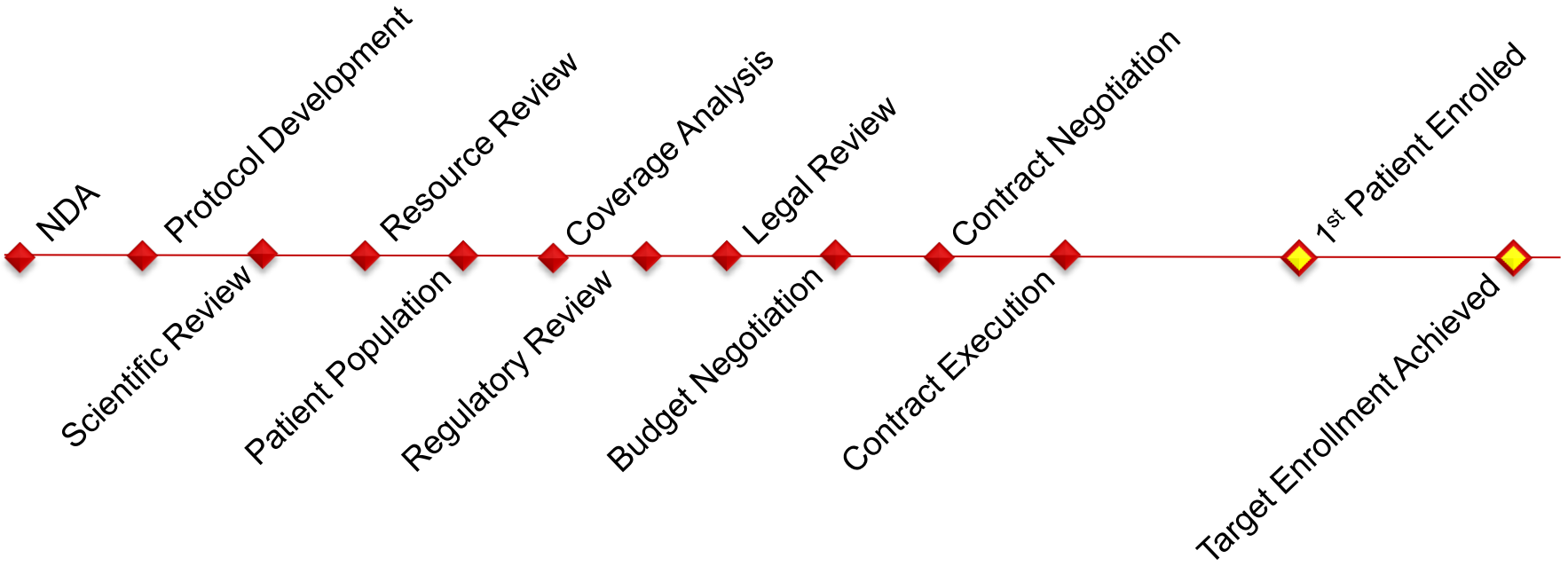
Study feasibility	
◆ Duration of Scientific Review ◆ Duration of Coverage Analysis ◆ Duration of Budget Review ◆ Duration of COI Review	◆ Duration of Patient Population Initial Review ◆ Duration of Contract / Legal Review ◆ Duration of IRB Initial Review ◆ Duration of IRB Annual Review

Department	
◆ Number of protocols with participant accruals ◆ Number of protocols with no participant accruals ◆ Number of PIs with active protocols	◆ Participants on active protocols ◆ Total participants in FY

Strategies for Operational Management

STUDY INITIATION TIMELINE

Where do the delays occur in your Study Initiation Timeline? Below is an illustration of common hand-offs in the study initiation timeline. Measuring the duration for each will enable you to identify the areas contributing to your overall study initiation timeline.



Example Performance Metrics

STUDY INITIATION PERFORMANCE METRICS

Study Initiation Timeline

Many organizations can take up to 12 months to complete study initiation, including: budgeting, contracting, IRB, and conflict of interest.

Time to First Enrollment

Time to first enrollment measures from the time of contract execution to the first participant enrolled on the study. The longer it takes to enroll the first patient, the shorter the enrollment window will be, leading to less efficient/successful studies.

Time to Last Enrollment

Time to last enrollment measures from the time of contract execution to the last participant enrolled on the study (Target Enrollment). Studies may quickly enroll their first participant but if they never reach target enrollment, or enroll a second participant, financial performance will suffer.

Example Performance Metrics

CLINICAL TRIAL ACCRUAL METRICS

Accrual Efficiency Ratio (AER) = $\frac{\text{Actual Study Accrual}}{\text{Target Study Accrual}}$

Accrual Efficiency Ratio is a measure of a studies actual accrual compared to target accrual. The higher the ratio, the better the study is performing. Studies with an AER less than .3 should be evaluated to determine if the study has appropriate resources or a viable patient population.

$$\frac{\text{5 Subjects Accrued}}{\text{10 Subjects Target}} = .50 \text{ AER}$$

Program Efficiency Ratio (PER) = $\frac{\text{Total Portfolio Accrual}}{\text{Target Portfolio Accrual}}$

Program Efficiency Ratio is a performance measure of an institution's total clinical trial portfolio. The higher the ratio, the better the overall portfolio of studies is performing. This ratio can be further refined to measure the performance of a single department, PI or even phase of a study (I, II, III, IV).

$$\frac{\text{500 Subjects Accrued}}{\text{1000 Subjects Target}} = .50 \text{ PER}$$

Polling Question 5

Polling Question #5

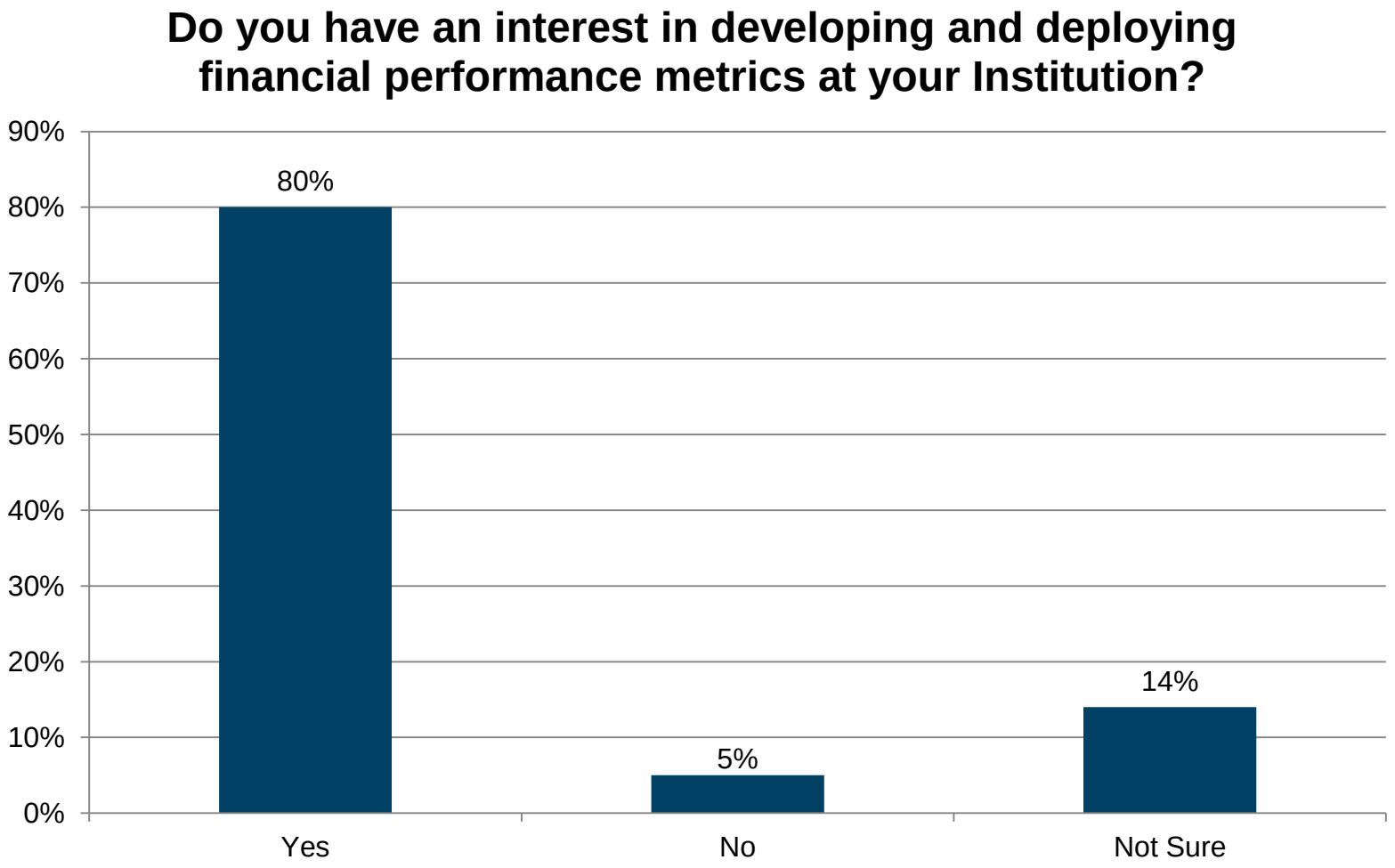
Do you have an interest in developing and deploying financial performance metrics at your Institution?

A. Yes

B. No

C. Not Sure

Polling Question #5: Responses



Questions?

Contact Information

QUESTIONS?

Rob Smith:
rsmith@huronconsultinggroup.com
Phone: (312) 771-1192

Patrick Bassett:
pbassett@huronconsultinggroup.com
Phone: (206) 484-3527

Mindy Muenich
mmuenich@huronconsultinggroup.com
Phone: (513) 207-0626

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Clients include:

- More than 90 of the top 100 research universities
- Nine of the top ten largest healthcare systems

  - ranked by Modern Healthcare
- Eight of the top ten largest Children's hospitals
- Many of the premier academic medical centers