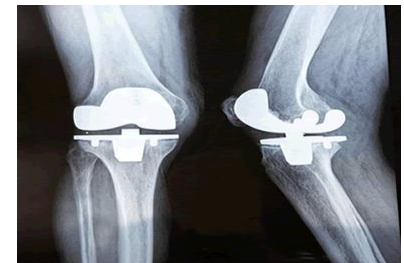


Financial Management of the Clinical Research Enterprise

November 13th, 2013



About the Speakers



Rob Smith, Manager

Rob has 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, and financial enhancements to new and existing CTMS technologies.



Patrick Bassett, Manager

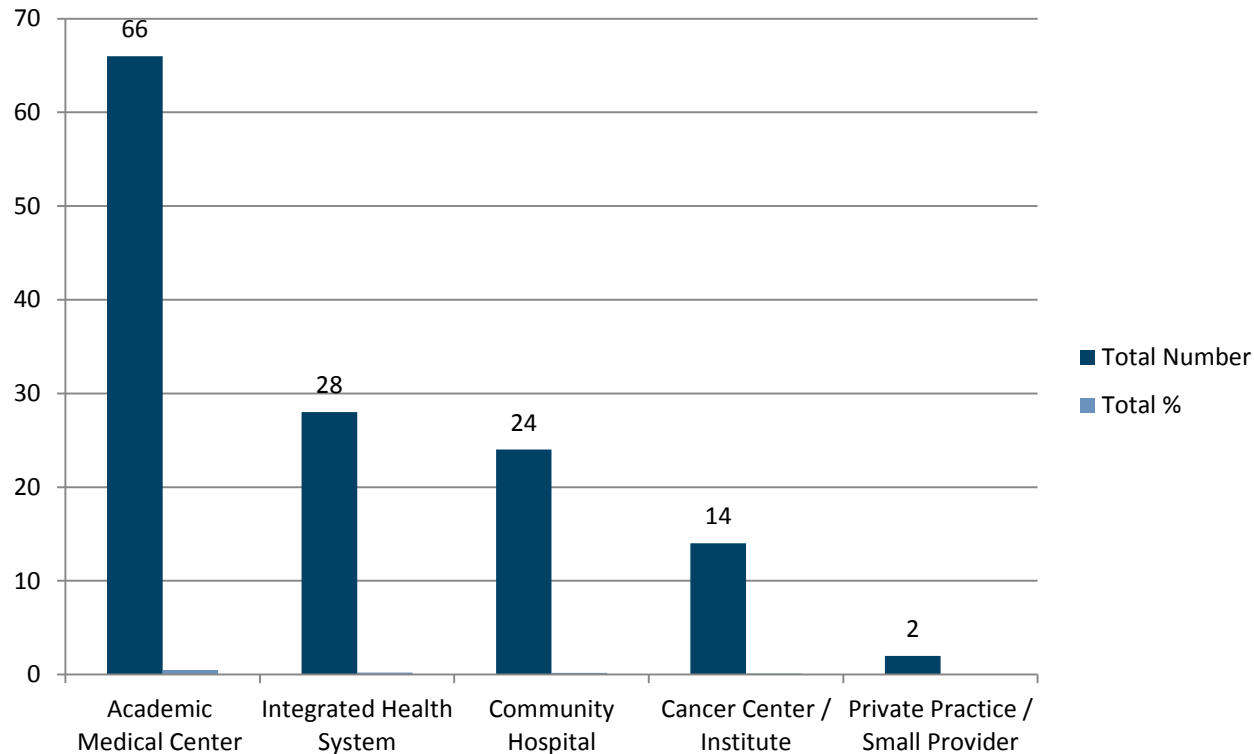
Patrick has over 10 years of experience in basic and clinical research operations and financial management within independent research institutes and academic medical centers, including: institutional budgeting and strategic planning, federal indirect rate preparation, clinical trial contract budgeting and negotiation, clinical trial billing, and policy and procedure development.

Session Agenda

- Introduction
- Economic & Operational Challenges Impacting Research Finance
 - External Environmental & Economic Pressures
 - Internal Pressures
- Key Elements to Organizational Success
- Case Study: Research Portfolio Management
- Strategies for Improved Financial Management & Performance
 - Organizational Structures & Services
 - Cost Reductions / Cost Containment
 - Revenue Enhancements
 - Implementing Performance Metrics
- Closing Remarks

Poll Question #1 Results

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

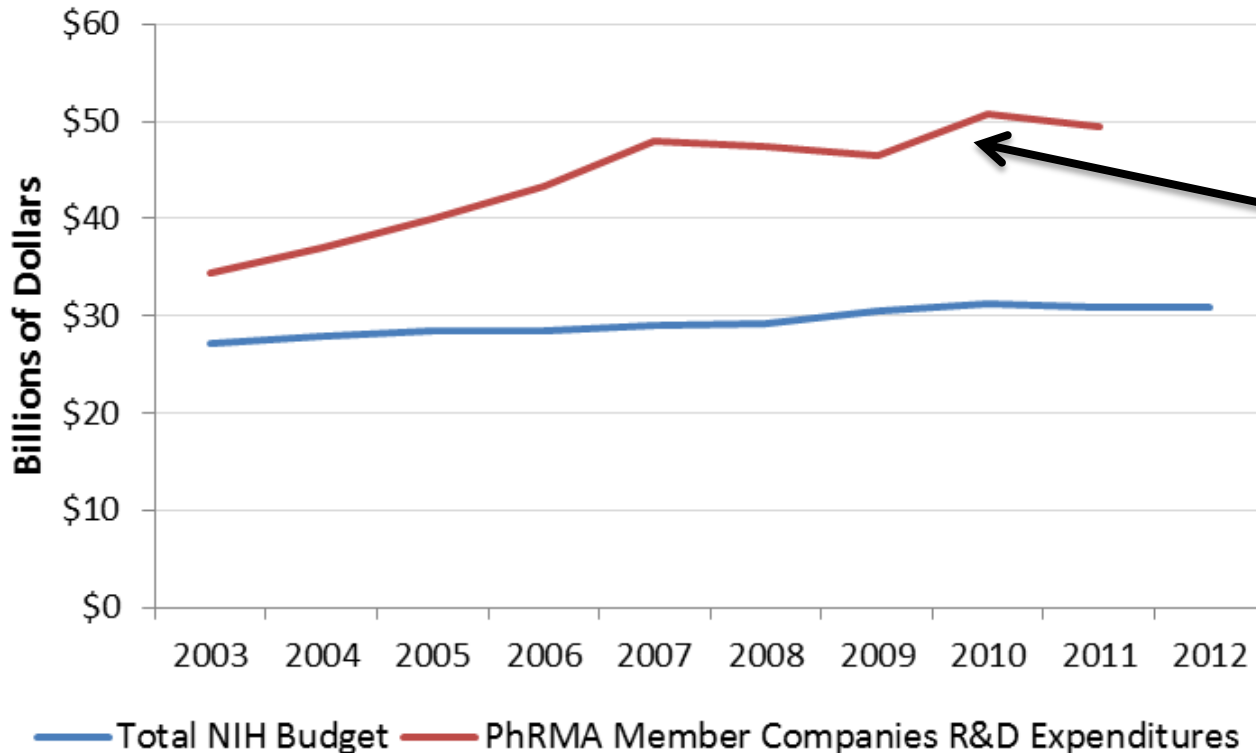


Economic & Operational Challenges Driving Change

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 traditional sources of research funding;
 - Tighter clinical margins
 - Globalization of clinical trials
- Evolution of Technology;
 - CTMS
 - Financial systems (PeopleSoft, Lawson, SAP)
 - Social media
- Increased complexity of research design;
- Regulatory complexity and reporting requirements;
- Regionalization in the form of larger, complex research networks

Economic & Operational Challenges Impacting Sites

CURRENT TRENDS IMPACTING THE CLINICAL PORTFOLIO

Some of the current economic and operations trends impacting how a clinical research portfolio is managed include:

- External economic and regulatory pressures;
- Internal pressures, including:
 - Unclear strategic plan or vision for research;
 - Unclear leadership or research governance structure;
 - Disparate technology systems / tools;
 - Insufficient education/training/resources;
 - Insufficient adoption of policies and procedures

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

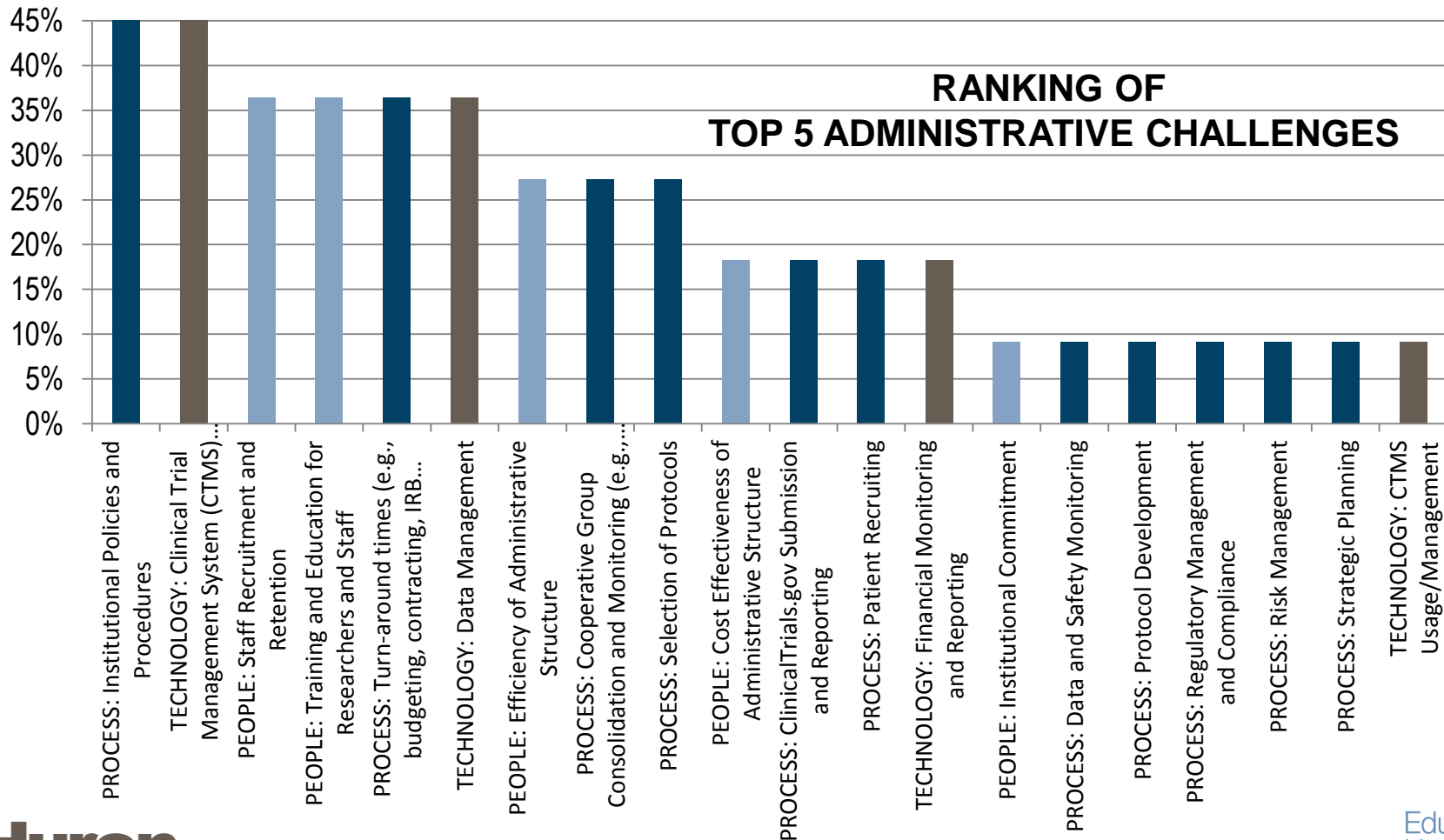
Internal dynamics are also causing challenges to the conduct and financial management of clinical research studies. Some of these include:

- 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

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

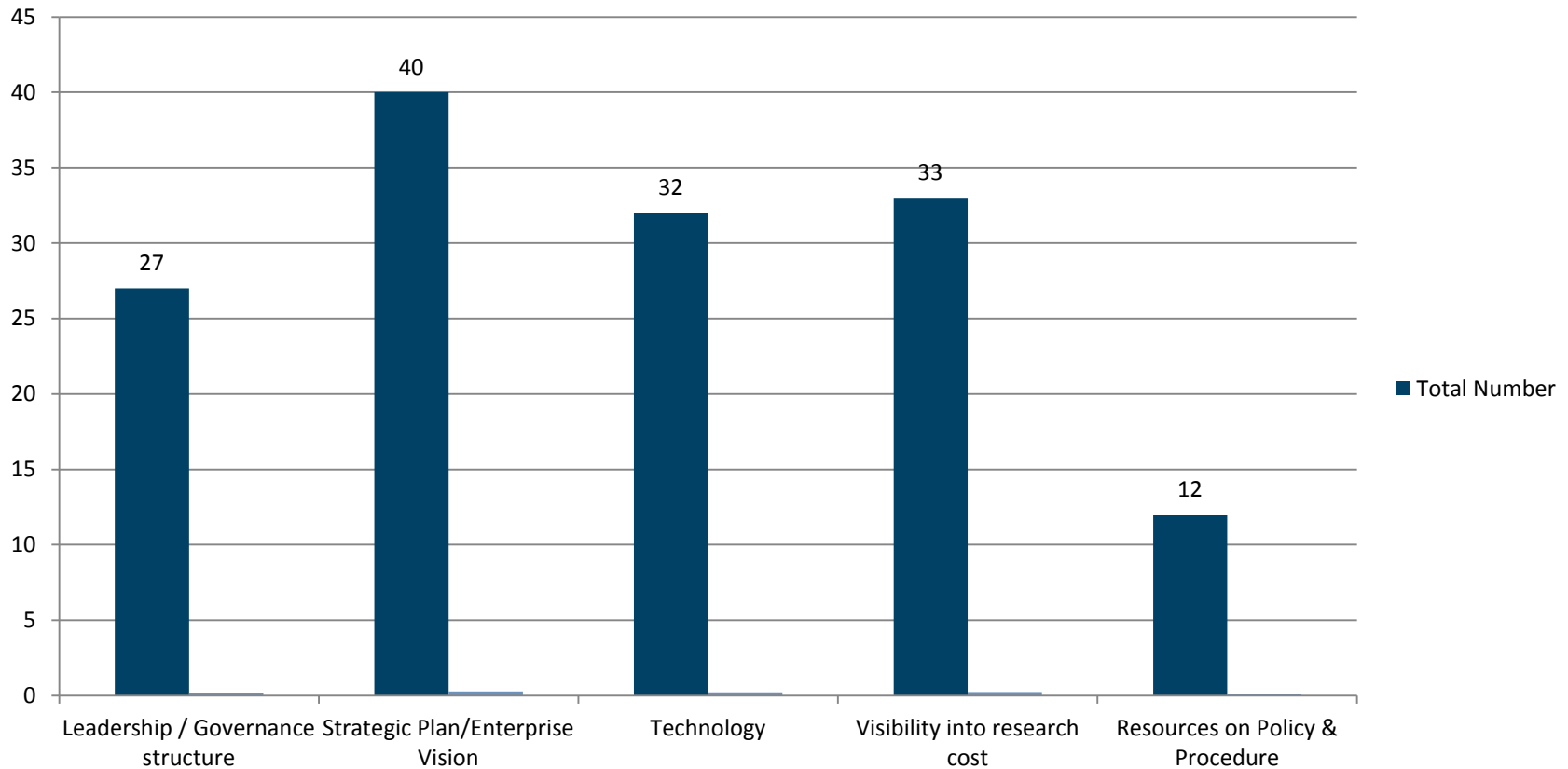


Key Considerations For Change

- Research is a significant and important source of revenue and expense for many institutions.
- Research revenues rarely cover the expenses incurred, often falling short by 10% - 20% or more.
 - This revenue shortage represents an institutional subsidy for research.
- Accordingly, it is important to understand and actively manage the research enterprise by:
 - Evaluating and quantifying baseline metrics to measure progress;
 - Monitoring ongoing financial performance against baseline;
 - Employing key performance indicators
- Lastly, the financial impact of future investments in research should be determined prior to committing institutional resources.

Poll Question #2 Results

Which of the following represent the biggest financial management challenge at your organization?



Key Elements to 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:

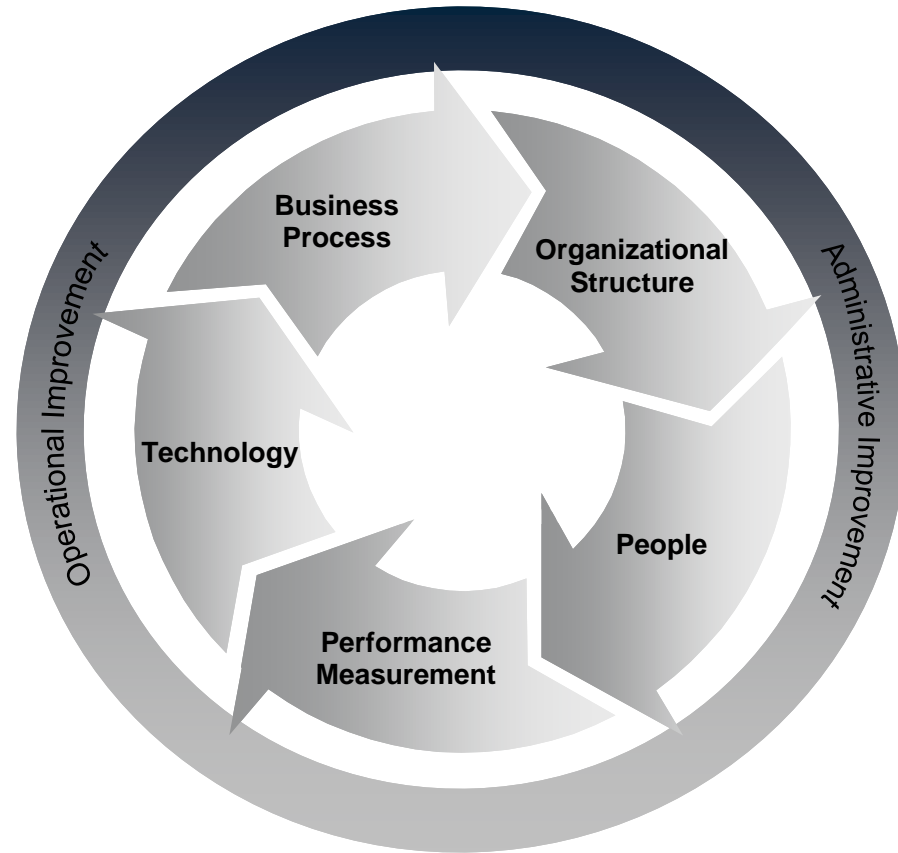
- Do we have the appropriate people to enable business processes?

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, effectiveness managers rely on more fundamental concepts, including:

- Authority to initiate change;
- Culture that embraces change;
- Balancing a research vision with an understanding of what is realistic to achieve

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

– Charles Darwin

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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.

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CHALLENGES - PEOPLE

People:

- **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.

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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.

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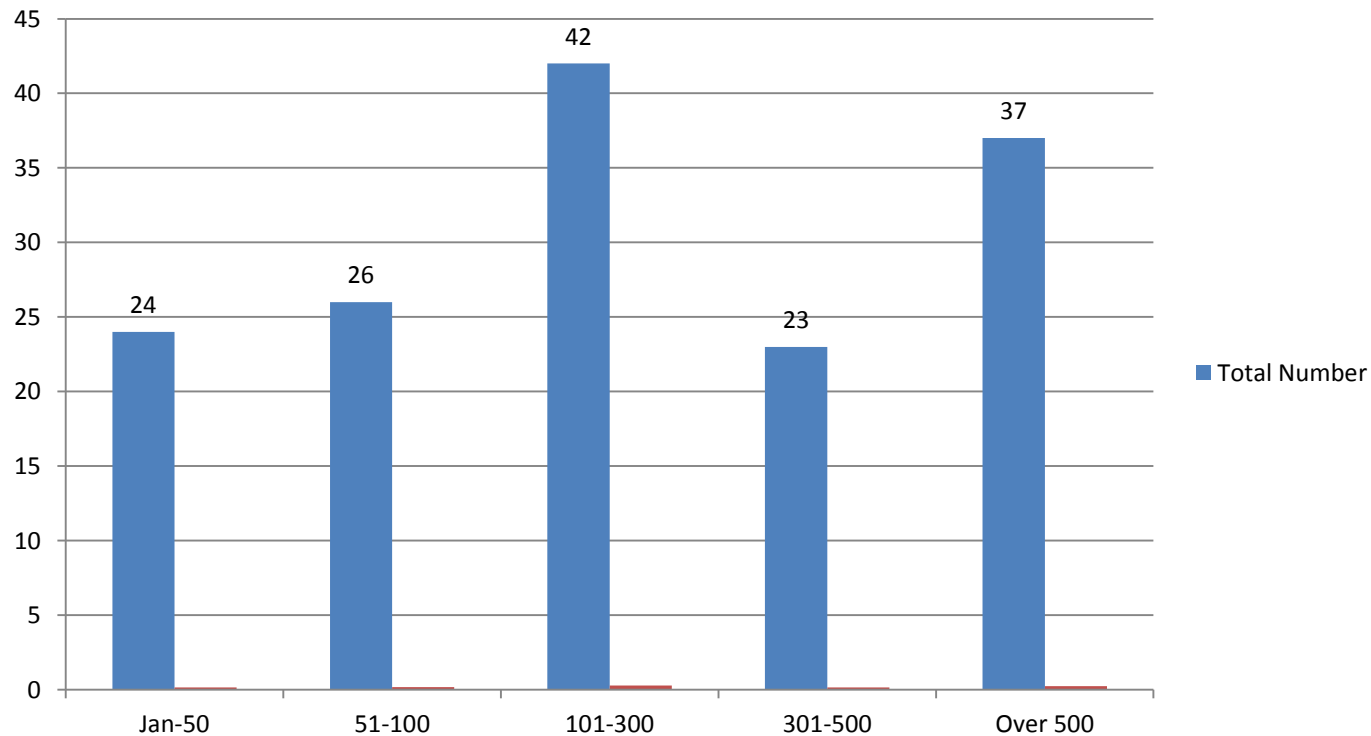
CHALLENGES – PERFORMANCE MEASUREMENT

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 definitions 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 the variable work load requirements between a complex clinical trial versus a retrospective chart review

Polling Question #3

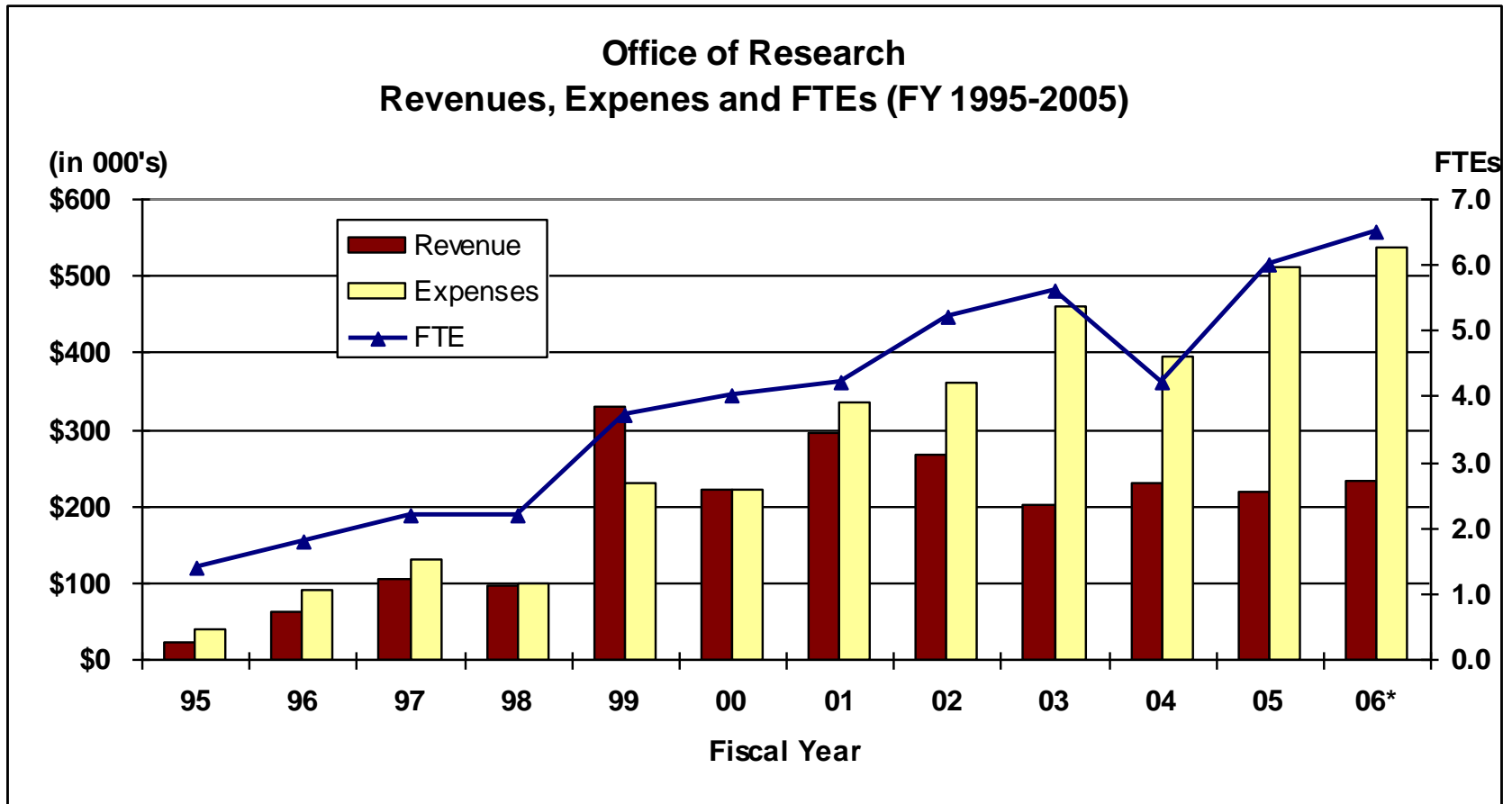
What is the number of active clinical research studies under management at your Institution? (*defined as studies enrolling subjects or those where financial activity continues*)



Case Study

PORTFOLIO MANAGEMENT

- Example research portfolio revenue & expense over 12 year period.
- The institution was subsidizing **\$1.29** for every dollar of research revenue.

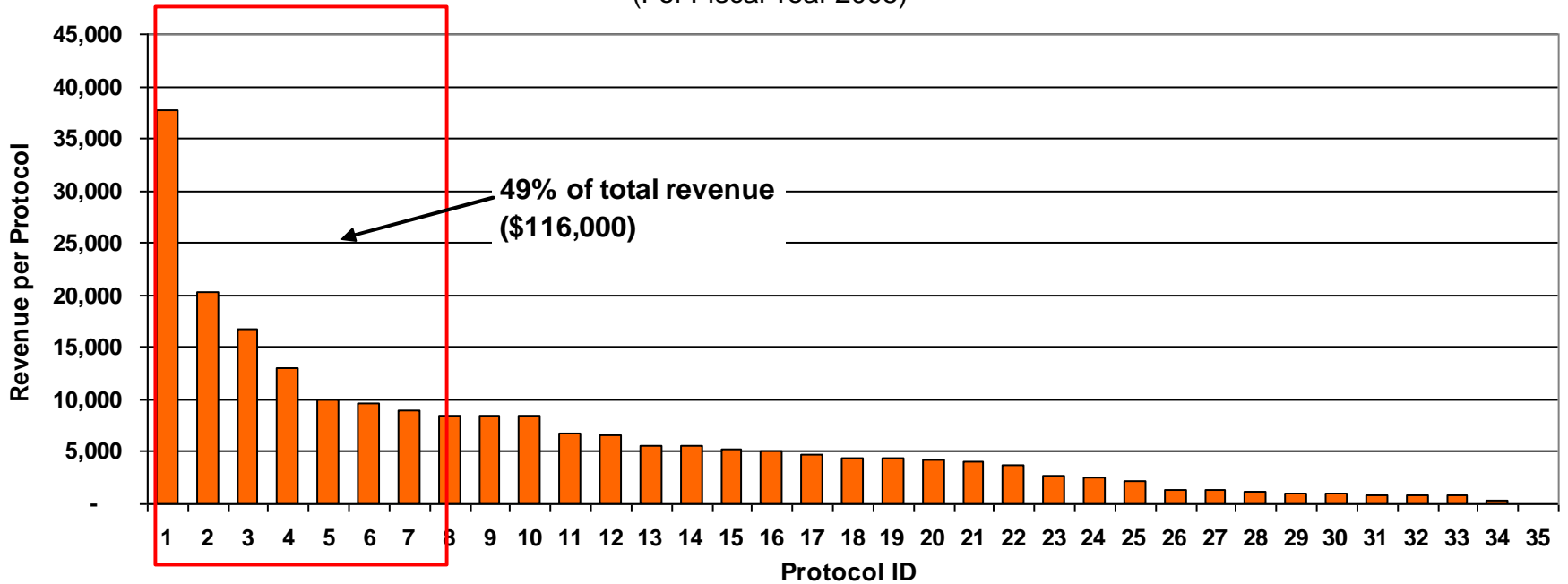


Case Study

PORTFOLIO MANAGEMENT

- Of the approximately 75 active protocols, 35 had revenues in 2004.
- Of the 35 protocols with revenue, 7 protocols accounted for 50% of the total revenue.

Percentage of Total Revenue by Protocol
(For Fiscal Year 2005)



Strategies for Improved Financial Management & Performance

Strategies for Financial Management & Performance

ORGANIZATIONAL STRUCTURES & SERVICES

Organizational Structure

- Create targeted committees and empower them to address institutional issues.
 - Clinical Research Advisory Committee
 - Clinical Research Feasibility Committee
 - Clinical Research Information Systems Committee
- Develop a set of guiding principles and a strategic plan to guide strategic initiatives.

Benefits:

- Clear institutional leadership
- Improved accountability
- Facilitate communication between researchers and IT/IS offices

Strategies for Financial Management & Performance

COST REDUCTION / COST CONTAINMENT

To have a sustained positive impact on the programs bottom line an organization needs to control the growth in expenses as well as identify targeted opportunities for cost reduction. To accomplish this an organization needs to address operational inefficiencies/constraints. Examples include:

- **Establish a Feasibility Committee** – which would likely be structured around departments or divisions and include components such as:
 1. Scientific review to ensure the study has scientific merit.
 2. Patient population assessment to determine ability to reach target enrollment
 3. Review competing protocols to reduce/eliminate competition for the same patient population
 4. Staff Effort / Resource Assessment

Strategies for Financial Management & Performance

COST REDUCTION / COST CONTAINMENT

- **Close underperforming studies:** Improve the performance of the research portfolio by eliminating underperforming studies when feasible to do so.
- **Centralize resources to maximize utilization:**
 - **Quality:** Often organizations that operate more decentralized have people that are “Jack-of-all-Trades” and master on none.
 - **Cost:** Centralized services can be more efficient as a result of having more experienced individuals performing tasks but you often then lose the more personal support often desired by PI’s.

Strategies for Financial Management & Performance

COST REDUCTION / CONTAINMENT

Standardize and streamline processes to improve financial management and compliance.

- Centralize regulatory and administrative services to :
 - Budgeting
 - Contracting
 - Coordinator pools or “research portfolios”
 - Biostatistics and Bioinformatics
 - Data management
 - Regulatory review and submissions
- Utilize systems to monitor enrollment
- Consider staffing an Enrollment Coordinator

Don't Duplicate Services!

Strategies for Financial Management & Performance

COST REDUCTION SERVICE MODEL EXAMPLE

Many research institutions opt for centralization in the management of clinical trials. A recent Huron survey posed the following questions:

1. Did the organization have a central clinical trial office? (79 out of 112 indicated yes)
2. What services were provided by the central office? The chart below summarizes which services were provided and whether they were optional or mandatory.



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

REVENUE ENHANCEMENTS

Standardize and streamline study initiation

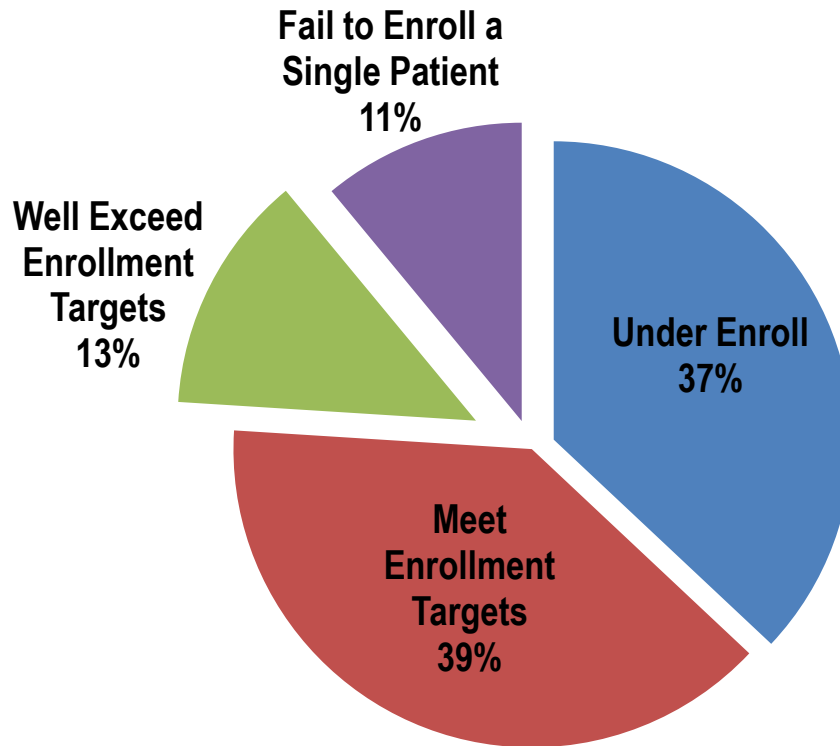
- Ensure startup fees are sufficient and invoiced
- Budget development
 - Standard fee schedules
 - Standard budget elements (i.e. ancillary services and invoiceable items)
- Focus on viable studies - Understand the impact of low enrolling studies and get rid of under-performing studies
 - Maximize coordinator utilization
 - Eliminate low enrolling studies

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REVENUE ENHANCEMENTS

Typical Enrollment Performance

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



46% of all studies meet their enrollment timelines

Only 21% of all studies meet their 'original' timelines

Source: Tufts CSDD, 2011.

Strategies for Financial Management & Performance

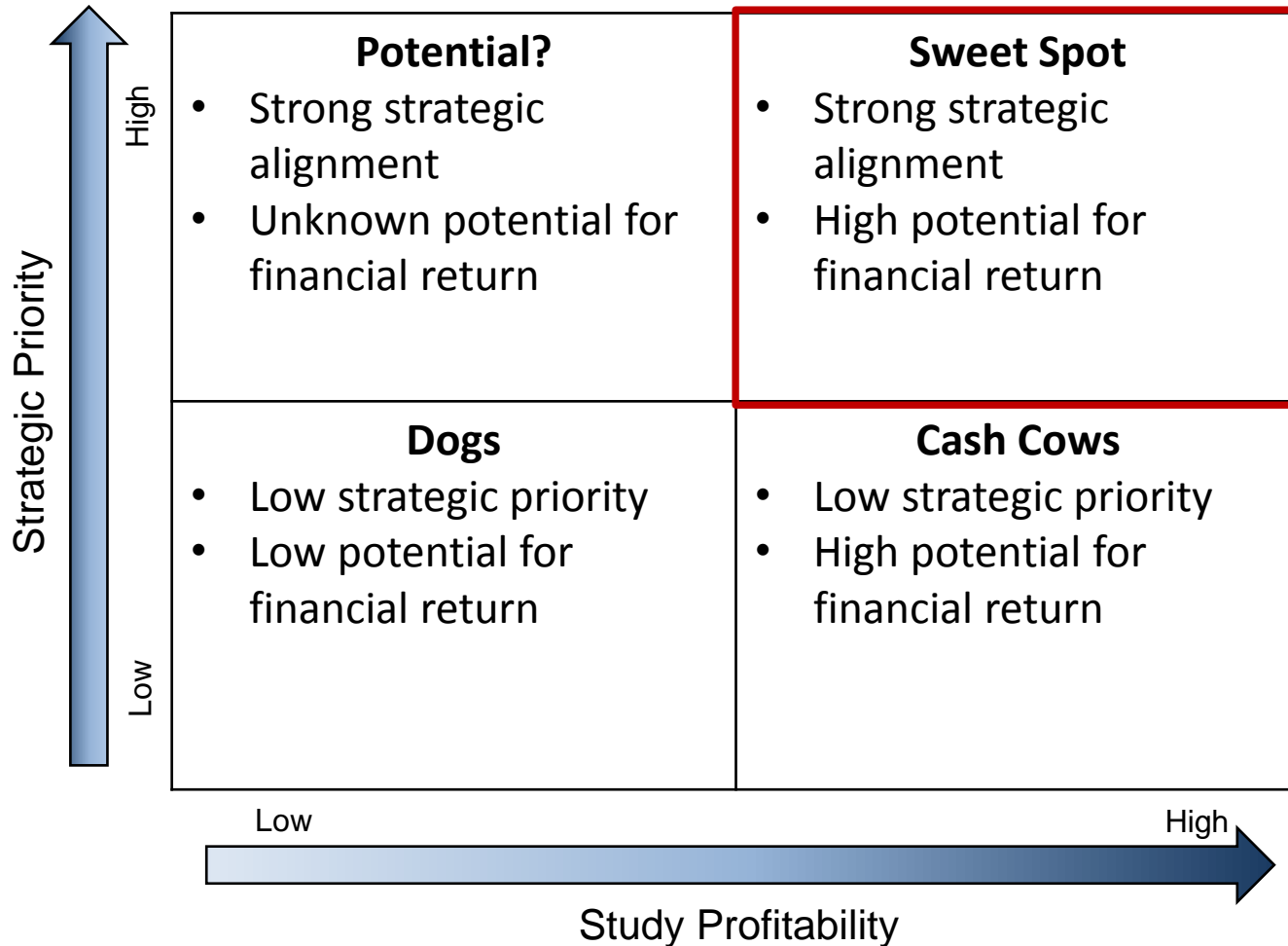
REVENUE ENHANCEMENT

Standardize Budgeting

- Develop policies & procedures to guide the budget development process
- Standardized administrative fee schedules:
 - Start-Up fees
 - Invoiceable Items
 - Screen fails
 - Monitoring visits
 - Closeout costs
 - 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

RESEARCH FEASIBILITY MATRIX



Strategies for Financial Management & Performance

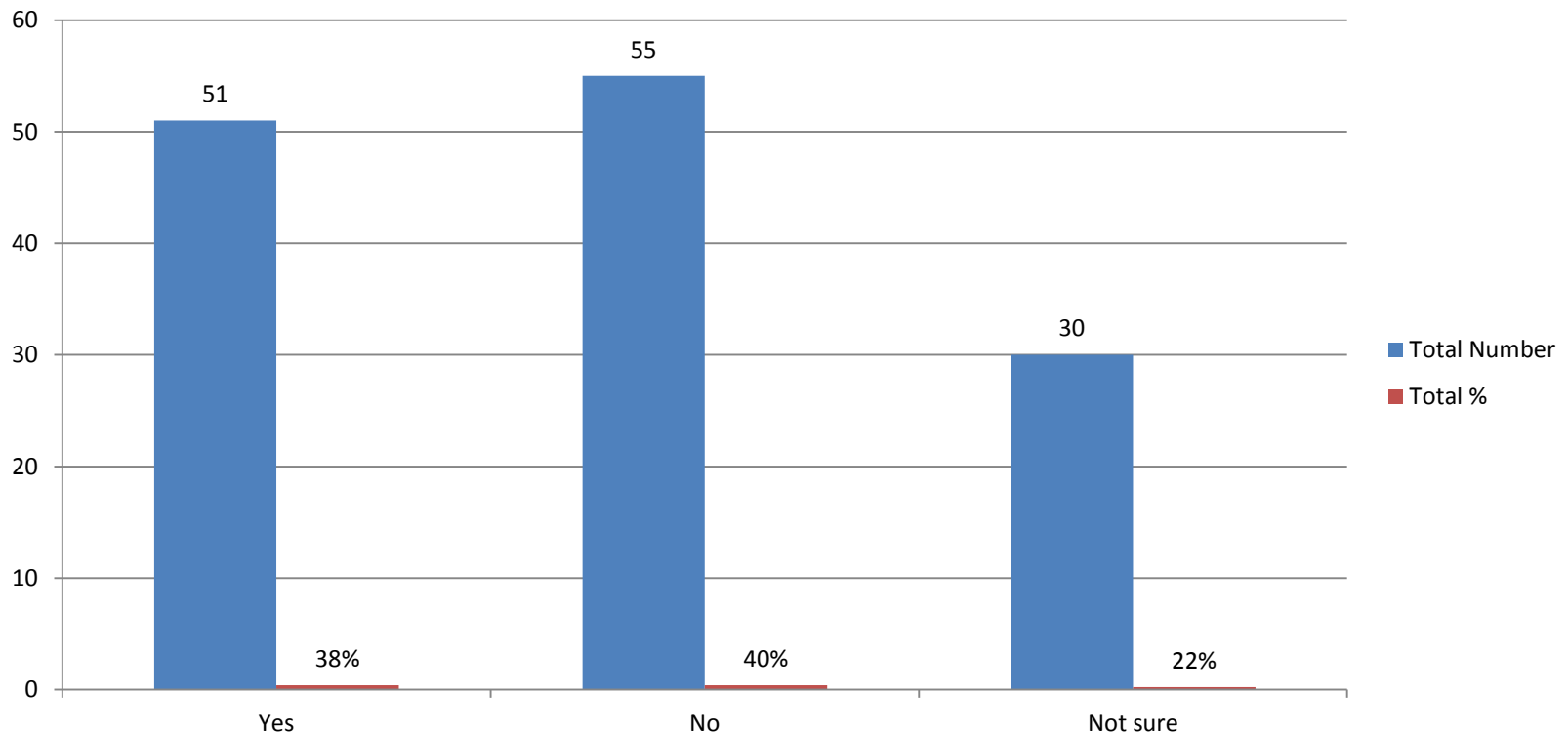
ESTABLISH & IMPLEMENT FINANCIAL METRICS

Implement financial metrics and a reporting framework to support the improved monitoring of financial performance.

- Establish performance metrics and publishing periodically, to:
 - Help establish customer service expectations
 - Facilitate identifying potential compliance risk
 - Reveal potential staffing and training weaknesses
 - Align allocation of resources based on measurable and demonstrated need

Polling Question #4

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



Example Financial Performance Metrics

Strategies for Financial Management & Performance

METRICS

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

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.

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

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

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).

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

Strategies for Financial Management & 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. In a March 2010 Report of the Operational Efficiency Working Group (OEWG) of the Clinical Trials and Translational Research Advisory Committee specified that investigator-initiated trials should be approved within 90 days of submission for scientific review.

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.

Strategies for Financial Management & Performance

METRICS

Additional example financial performance metrics include:

CTO	
<ul style="list-style-type: none">◆ Average number of days to review and approve a proposal◆ Average number of days to set-up contracts	<ul style="list-style-type: none">◆ Studies per coordinator◆ Subjects per coordinator◆ Total enrolled subjects per coordinator
Clinical Trial Financial Management	
<ul style="list-style-type: none">◆ Average number of days to set-up awards◆ Monthly unbilled balance (\$)◆ Number of active contracts past end date (+90 days)	<ul style="list-style-type: none">◆ Average accounts receivable balance (\$)◆ Amount of accounts receivable over (+90 days)◆ Accounts receivable aging (30/60/90 days)
Departments or Centers	
<ul style="list-style-type: none">◆ Number of accounts in overdraft◆ Number of active contracts past end-date (+90 days)	<ul style="list-style-type: none">◆ Number of departmental cost transfers

“You cannot change what you cannot measure.”
- W. Edwards Deming

Questions?

Contact Information

QUESTIONS?

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- More than 95 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