

# Run Your Research Program Like a Business

## 6 Techniques to Grow Your Site



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### Host



Tami Haas  
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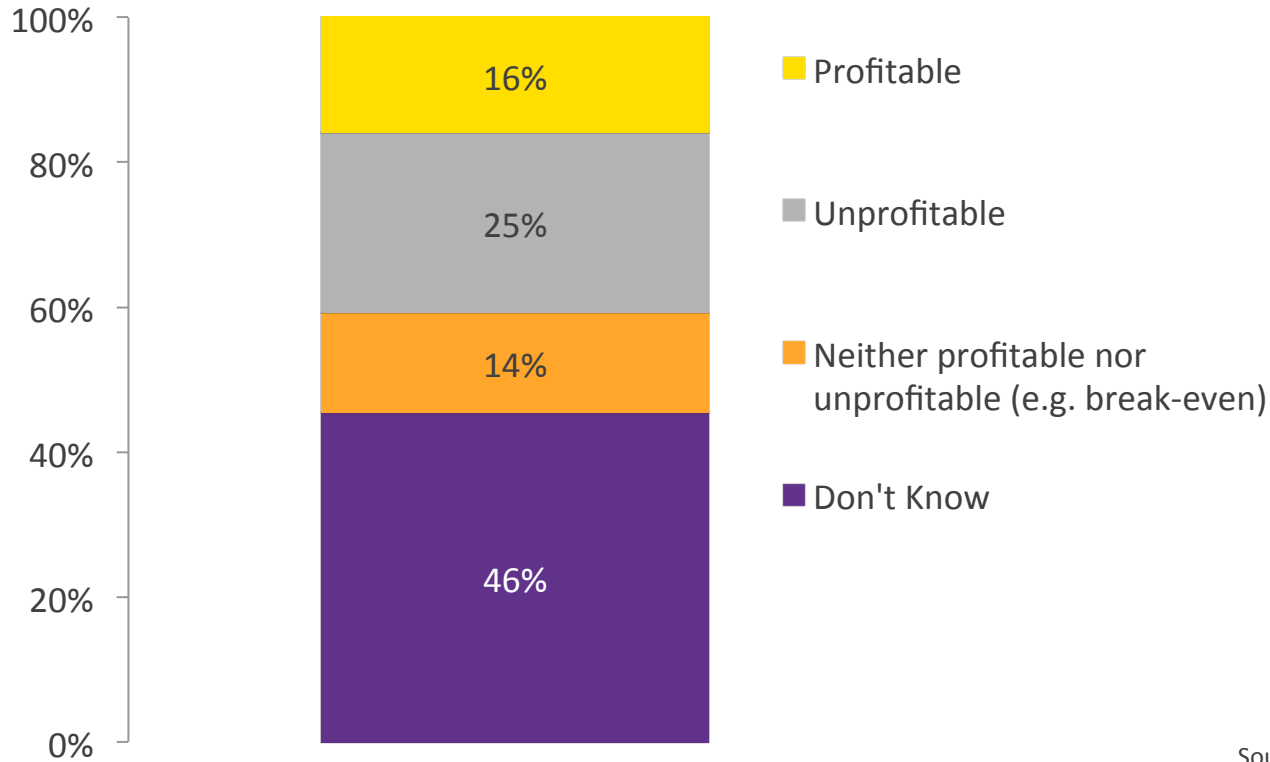
Dr. Rhonda Paz  
Chief Operating Officer  
GuideStar Clinical Trials Management

# Run Your Research Program as a Business

6 Techniques to Grow your Site

# Profitability of Research Programs

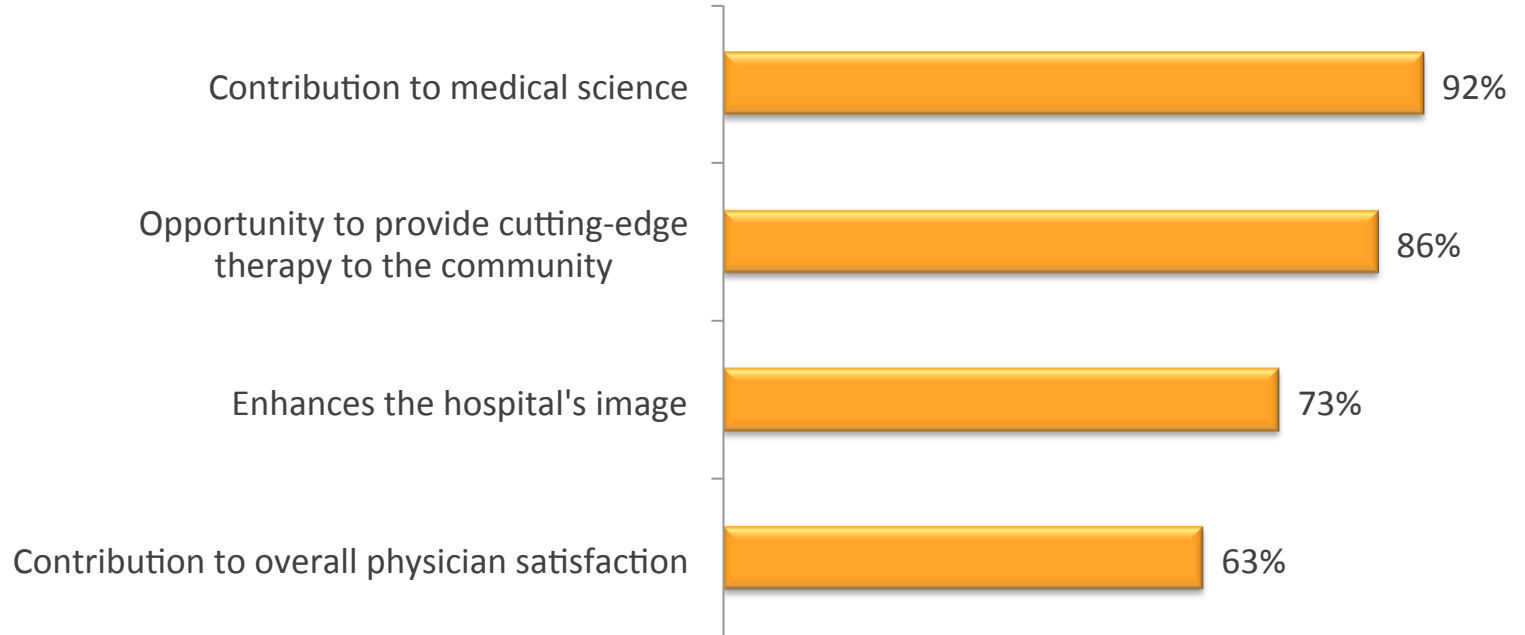
## Leadership Perception



Source: CenterWatch Survey

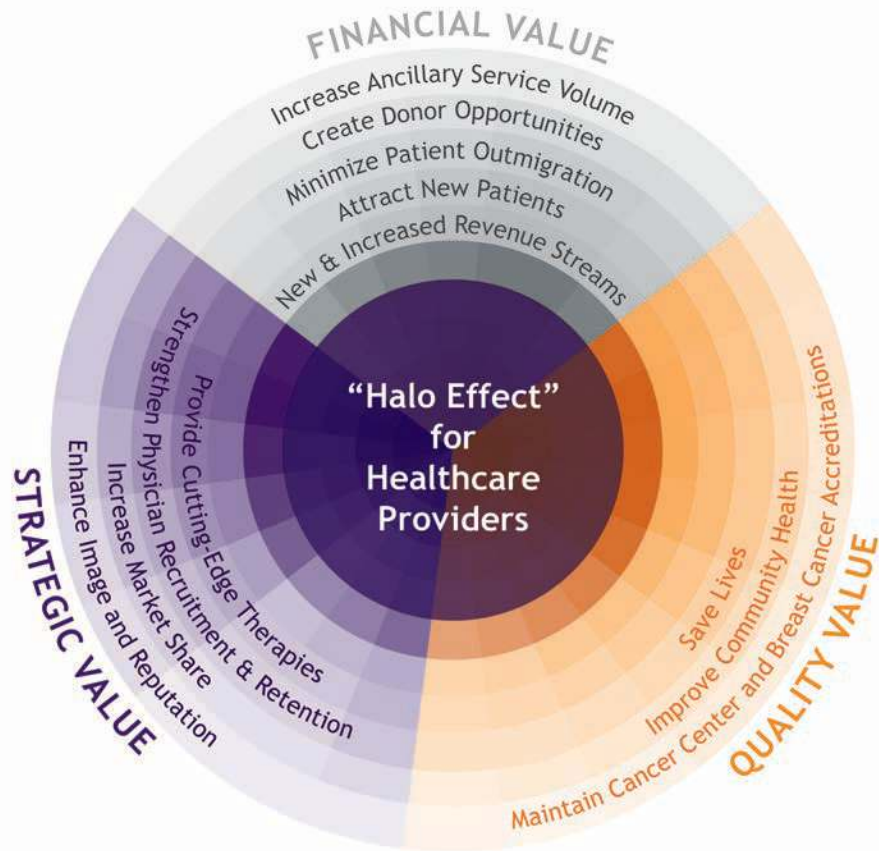
# Benefits of a Clinical Research Program

## Leadership Perception



# Why Clinical Trials

## The Halo Effect



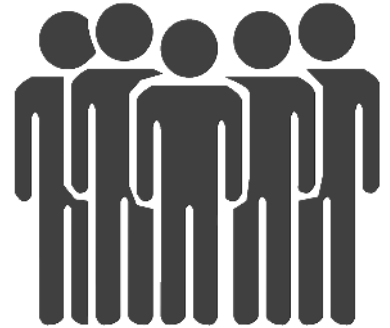
# 6 Key Business Techniques

1. Staffing and organization
2. Trial portfolio
3. Pre-award process
4. Post-award management
5. Compliance
6. Metrics for monitoring program success



# 1. Staffing and Organization

- Experienced staff
  - Employ a research finance specialist
- Specialized division of labor to ensure focus on patient recruitment to drive revenue
- Work load assessment
  - Ensure staff is operating at capacity
  - Identify staffing needs for planned growth



## 2. Trial Portfolio



Select trials that  
best fit the patient  
population to  
ensure enrollment



Focus on  
pharmaceutical and  
device industry  
sponsored trials



Close non-enrolling trials

# 3. Pre-Award Processes





# Budget Negotiations

- Negotiate every budget
- Some art some science
- Agree on term definition
- Know the intensity of the trial
- Negotiate clear payment terms
- Insist on start-up payment





# Contract Negotiation

## Nuts and Bolts

- Plan your approach
- Sell your site
- Justify your expenses
- No ultimatums

# Contract Negotiation

## Bigger Picture Negotiation Strategies

- Be strategic
  - Think bigger, longer term picture
  - Consider new sponsor vs. repeat sponsor
  - Grow your business
  - Reputation is key in securing future business
-

# Contract Language

- Ensure language that protects your hospital
- Include a financial penalty for late payment
- Incorporate an early termination clause
- Craft clear payment terms



# 4. Post-Award Management



Enforce negotiated  
terms



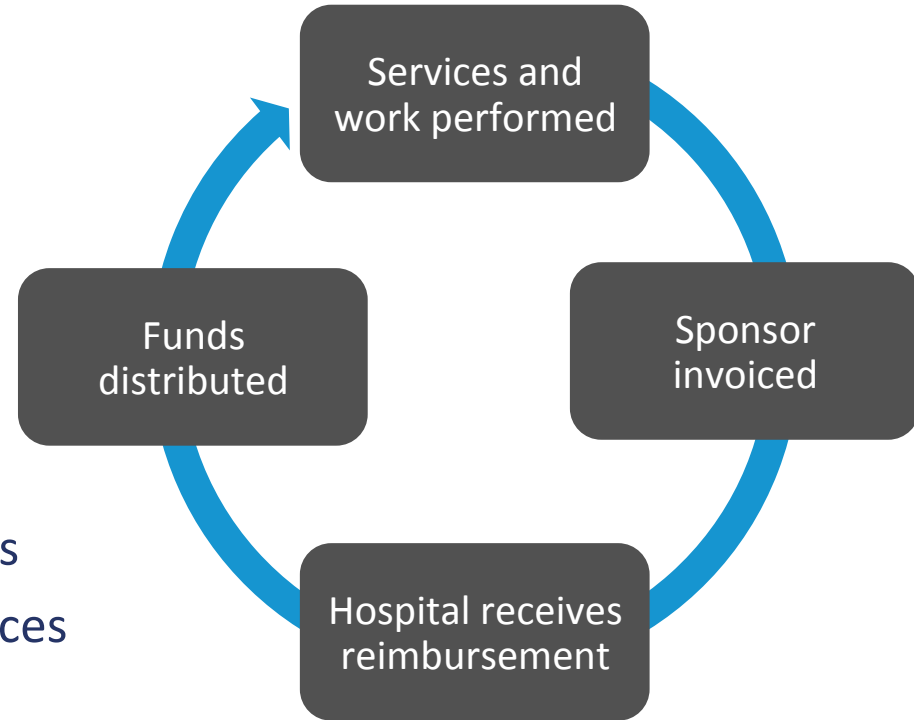
Send invoices for  
milestones



Make collections  
calls

# Allocation

- Funds follow services and work performed
- Build billing compliance steps into processes
- Typical allocation percentages
  - 60%-70% research program services
  - 18%-22% clinical and ancillary services
  - 10%-25% PI and enrolling physician



# 5. Compliance

# Billing Practices

- Determine standard of care vs. research related services
  - Perform Medicare coverage analysis
  - Establish billing practices that provide for two distinct billing pathways
  - Have study coordinators review trial patient bills before they are released
-



## Stark Law

- Prohibits physician referrals of health services for Medicare and Medicaid patients if the physician has a financial relationship with that entity

## Sunshine Act

- Requires reporting of any payments made to physicians and teaching hospitals as well as any ownership or investment interests held by physicians or the immediate family members of physicians on an annual basis
- Avoids unduly impact on healthcare decisions

# Physician Payment Model Options

- Above and beyond clinical activities
- Fair market value
- Base on time and effort
- Base on percentage of budget

# Documenting Physician Payments

## Stark Law

- How: Base all payments on time and effort documented throughout the budgeting process

## Sunshine Act

- How: Track all payments by study received from sponsors to compare to public listing prior to release

# Sunshine Law Impact

a survey by



found


**86%**

No change or more likely to  
participate as an investigator site



# 6. Metrics for Monitoring Program Success

# Metrics for Monitoring Program Success

- ✓ Overall program profit/loss
  - ✓ Individual trial profit
  - ✓ Clinical trial program cost recovery
  - ✓ Clinical trial revenue from trials
  - ✓ Patient enrollment
  - ✓ New business on the horizon
  - ✓ Staff capacity
- 

# The Bottom Line

A clinical trials program is a viable business decision and, if managed properly, results in a multitude of benefits

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Clinical trials should be run like any other business

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A trials program should generate enough revenue to cover the expense of the infrastructure to support it

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Questions?



# Thank You



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