

WELCOME TO:

# Unleashing Medtech Revenue Through Proven Value Analysis Strategies

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**Nancy Patterson**  
President and CEO  
Strategy Inc



**Lauren Rodriguez**  
Vice President  
Strategy Inc



# myCaribou is a Global Platform...

## 1. Build Partnerships

- 22,000 Manufacturers
- 22,000 Distributors/Dealers
- 150+ Countries

## 2. Manage and Collaborate with Partners

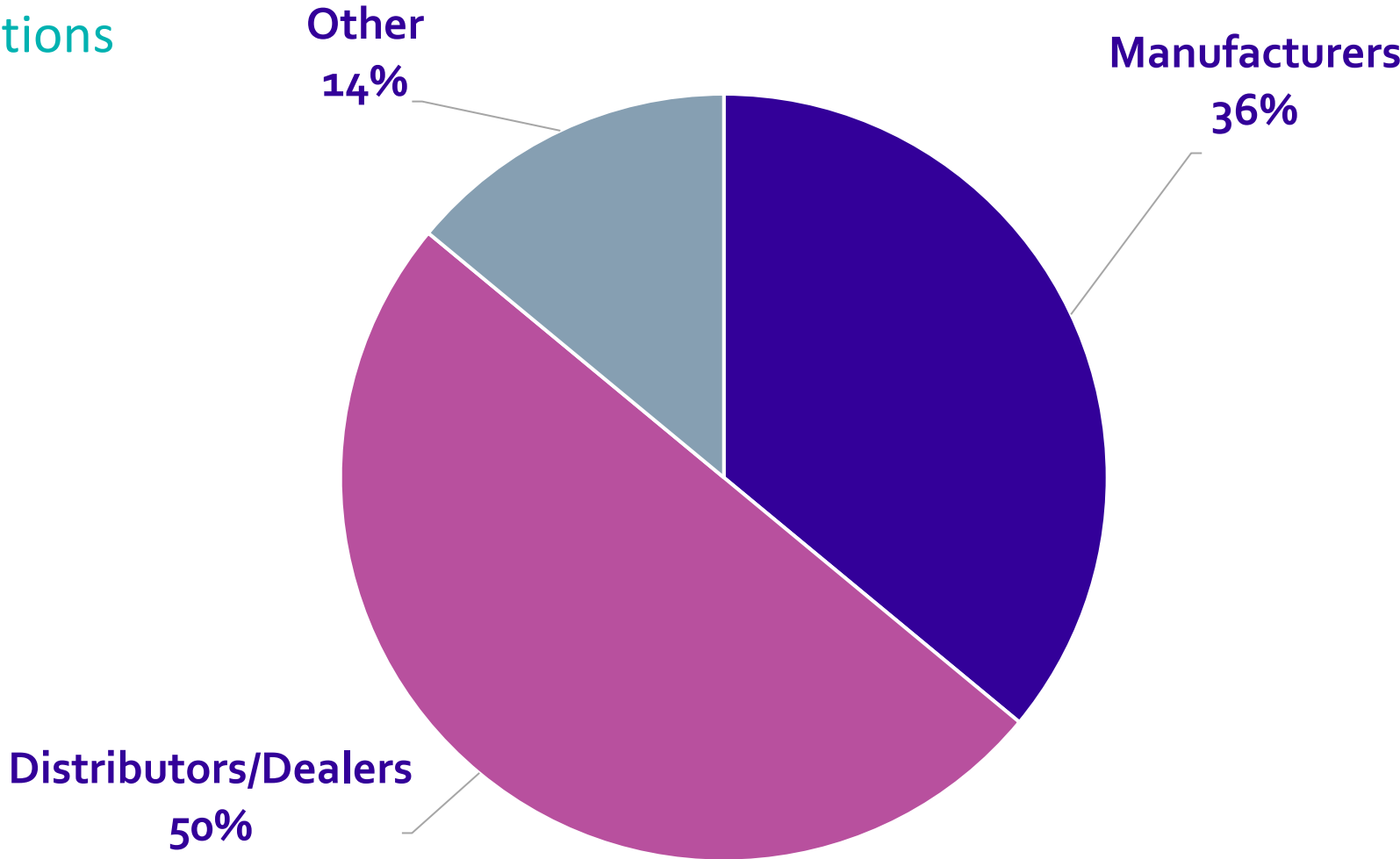
## 3. Foreign Exchange, Currency Hedging and International Payments



**Craig MacInnis**  
Co-CEO, myCaribou



# Registrations





**Nancy Patterson**  
President and CEO  
Strategy Inc



**Lauren Rodriguez**  
Vice President  
Strategy Inc



# Navigating Value Analysis Committee Acceptance to Unlock Revenue

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Nancy Patterson • Lauren Rodriguez



**STRATEGY INC.**



# Strategy Inc. Due Diligence Services

A full suite of strategic consulting services for essential market analysis and platform prioritization [Strategyinc.net](http://Strategyinc.net)



## Commercialization Strategy

Market due diligence to validate target market and adoption forecasting



## Financial Valuation

Third party valuation by experienced MedTech financial advisors



## Competitive Strategy

Scope of direct and indirect competitors both current and future



## Portfolio Analysis

Pipeline technology evaluation for market size, commercialization timeline and risk

- Strategy Inc. due diligence confirms new innovation that decision makers would purchase versus ones they are just interested in, yielding forecasting and revenue projections and informs accurate valuation and a strategy for commercialization
- Strategy Inc., founded in 2000, has performed **>3,200 primary market analyses usually** with 10 – 45 clinicians over two decades as a component of due diligence, market assessment, valuation, KOL identification and engagement, and exit strategy business
- Proven healthcare executive team have been working together for over 10 years with a track record of success and decades of combined operational experience in the medical device industry



# Agenda

- How Value Analysis Defines Revenue
- What is a Value Analysis Committee
- 4 Stages of Value Analysis Process
- Critical Diligence of a Value Analysis Strategy
- Common Pitfalls to Avoid and Strategies for Success

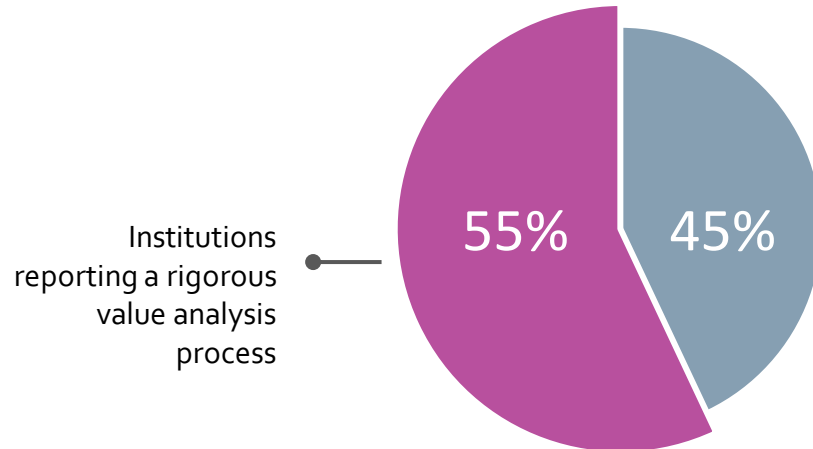




# Why Value Analysis?

- Value Analysis is the gatekeeping process for product sale at most facilities
- Trend in value-based purchasing = rise in comprehensive Value Analysis programs
- Evaluates quality of care, product use, costs, and streamlines supply chain

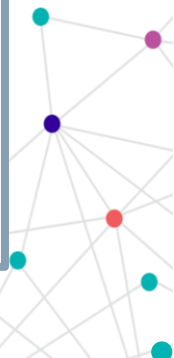
**Value = Outcomes/Cost**







# What Value Analysis Committees (VAC) Do?

- Review clinical, financial, operational **data**
  - Determine **competitive** advantages over current offerings
  - Seek documented high-quality **clinical outcomes**, efficacy markers, patient health measures
  - Evaluate **economics** – unit cost considerations, reimbursement, revenue potential
  - Determine **value-based** product offerings, control formulary, ensure clinician compliance
- 

# Who is part of a Value Analysis Committee?

## Multidisciplinary Team

Team of 6 to 7 individuals in multiple areas of proficiency



### Physicians

Physician champions, specialty department heads and key opinion leaders



### Value Analysis + Supply Chain

Value analysis professionals, supply chain managers



### Hospital Business Leadership

Financial leadership/CFO, hospital president, reimbursement specialists, revenue compliance auditors



### Other Clinical Stakeholders

Nurse managers, nurses, OR managers, etc.

# Physician Engagement in Value Analysis

57% of VACs have strong to moderate physician involvement

## Strong

Committees chaired by physicians who lead initiatives

21%

01

## Good

Physician leaders engaged, support decisions

19%

03

## Limited Involvement

Represented in some committees, participation inconsistent

43%

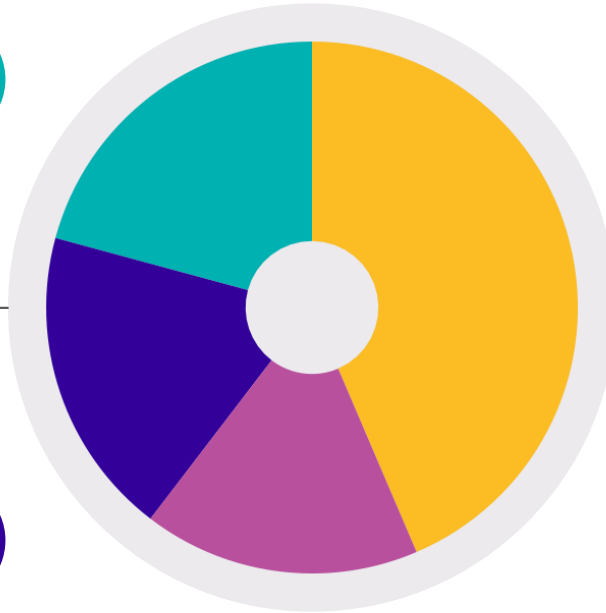
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## Moderate

Represented in all committees and actively participate

17%

04





# Value Analysis Denial Impedes Revenue

Every healthcare facility and GPO has an independent VAC –  
Securing authorization must have the full attention of development team

- Inadequate planning risks hurdles with a delay or denial from the VAC review
- Resubmission often allowed - however secondary review can be delayed
  - Delays most often between 5 and 9 months due to request for expanded data



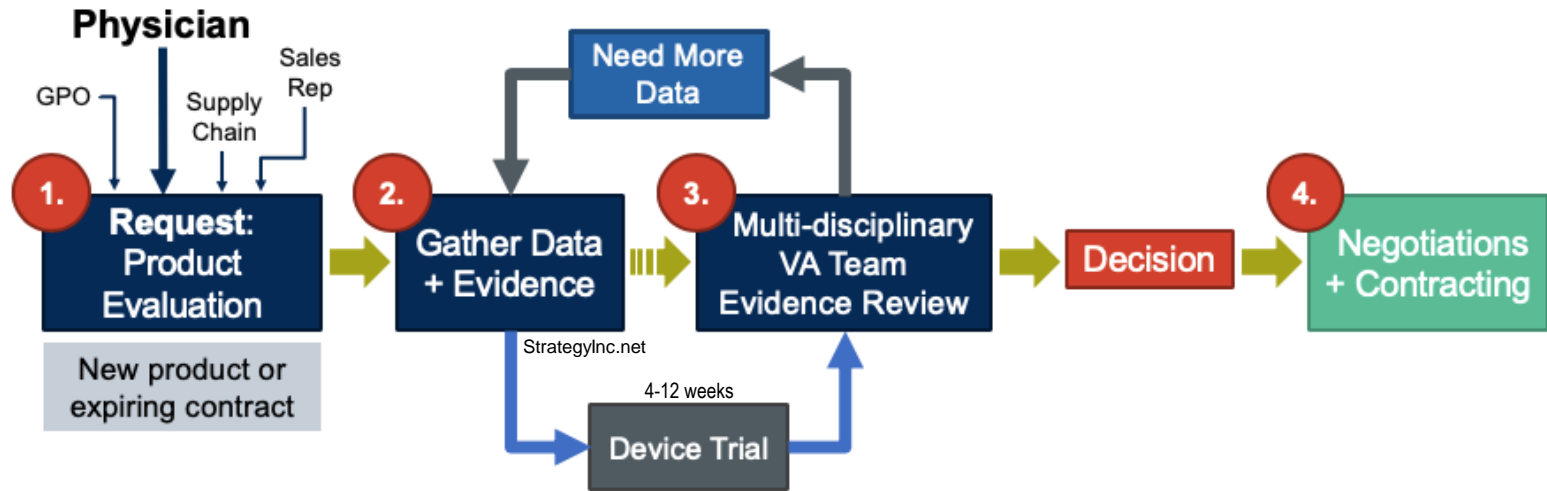
Metropolitan Medical Center

Value Analysis Committee Denial

Seek assistance from a consultant to ensure  
you are collecting the required information

The Value Analysis Committee Review has determined that the Endoscopic [REDACTED] [REDACTED] does not meet the value guidelines to existing technology in current use and cannot be included for sale. Specific areas where additional evidence is required include: comparative economic benefit, landscape review, documented physician trial and others. It is possible to resubmit to the evaluation review queue in 90 days for consideration with documentation to address the areas of concern.

# Value Analysis Process





## Step 1. How to Request a Technology Evaluation

1. Clearly **outline** the need or problem solved
2. **Partner** with a leading physician
3. **Physician champion** initiates request


- VAC review planning **prior** to initiating a request critical
- Requests are for new or existing products
- Vendor scenarios: multiple vendors, sole-source vendor, all-play situation
- Many institutions manage process with online platforms



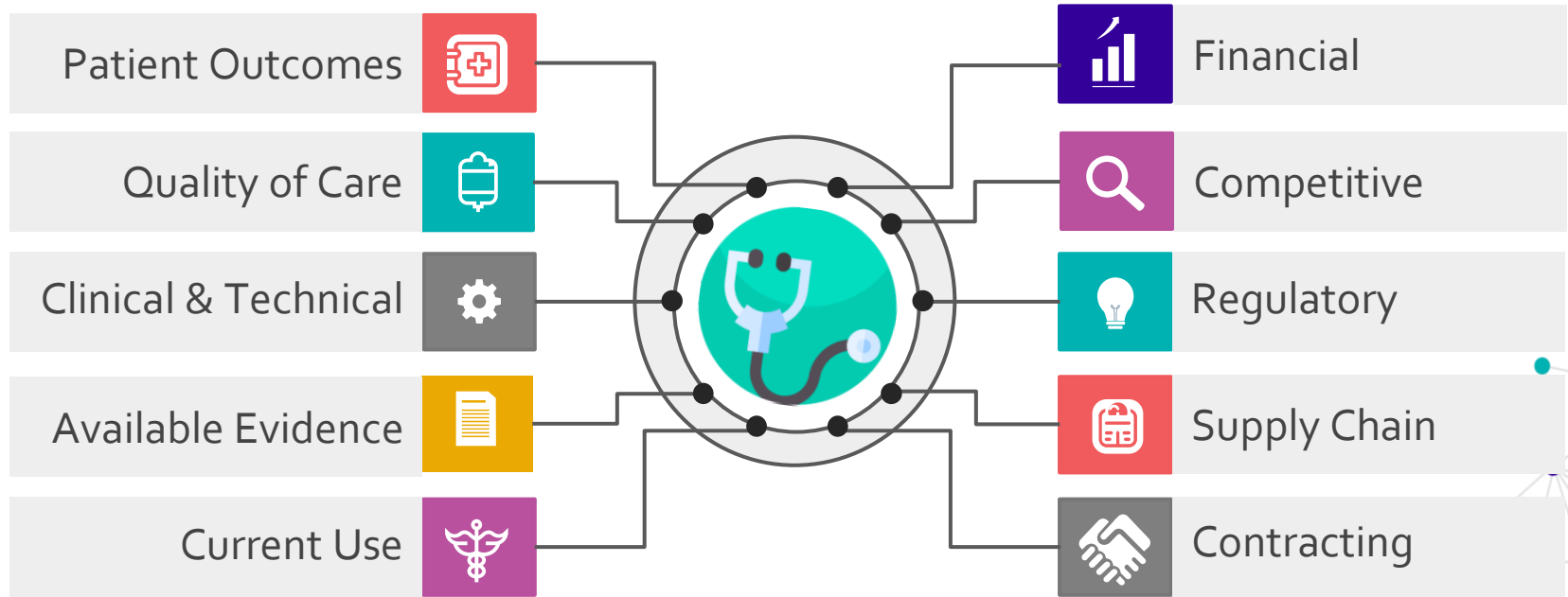
## Step 2. Gather Data and Evidence

- VACs seek evidence to answer clinical, operational and economic questions
- Vendor-driven: Present clear, organized information to expedite process

### **Required evidence:**

- Regulatory clearance/approval documentation
  - Tech Trial to confirm clinical performance / advantage claims
  - Current practice patterns and contracted products
  - Outcomes compared to alternative technologies
- 

# Gathering Evidence: Common Questions Asked







# Evidence: Common Clinical Data Sources

## CLINICAL REQUIREMENTS

Department specific clinical requirements and areas of use

## EVIDENCE-BASED LITERATURE

Evidence-based peer reviewed published literature documenting claims

## BENCHMARKING DATA

Current price, cost, quality, safety, labor and outcomes



## KEY OPINION LEADERS

Clinical and non-clinical stakeholder opinions

## CLINICAL GUIDELINES

Policy / procedure guidance from internal and regulatory bodies





# Evidence: Other Common Data Sources

## FINANCIAL/ CONTRACTING

Annual spend and supplier pricing, contracts with vendors/GPOs

## SUPPLIER CAPACITY

Historic, projected and disaster recovery plans for supply chain issues



## PRODUCT SPECIFICATIONS

Current and proposed product utilization amounts, practice and product use patterns

## REIMBURSEMENT

Applicable coding, coverage and payment, revenue potential





# Gathering Evidence: Outcomes Measures

## Clinical efficacy measures (treatment modality specific)

### Procedure Specific:

- OR time
- Reoperation rates
- Safety: complications/adverse events

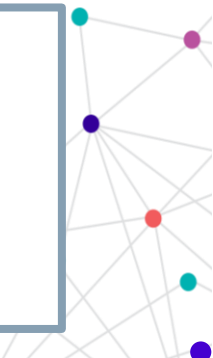
### Economic (direct and indirect costs):

- Capital equipment
- Disposables
- Personnel costs

### Burden of Disease:

- Patient survival: mortality, survival time
- Hospital admissions, length of stay, ICU days
- Readmission rates
- QALY (Quality Adjusted Life Years)

### Patient-reported:


- Health-related Quality of Life
  - Pain scores
  - Daily activity
  - Treatment tolerability
- 



## Step 3. Multidisciplinary VAC Review

- Biweekly or monthly VAC review meetings
- Products evaluated for comparative clinical and cost-effectiveness
- Some return to Gather Evidence for additional information
- Decision processes vary: vote, scoring system, leadership decision, etc.

### **Learning and Planning:**

- Determine target institution processes
  - Continue to build and expand supporting materials with each review
- 



# Example Segment of a Decision Tool

- Checklist from Premier as an example for Value Analysis Committee Review

Impact checklists can be converted into a scoring tool or a series of questions.

**OUTCOMES: Describe the product's impact on patient outcomes**

- Decreases mortality
- Decreases infections/complications
- Decreases readmissions
- Decreases length of stay
- Decreases procedural times
- No known impact on patient outcomes
- N/A
- Other \_\_\_\_\_

**Select the BEST possible option listed below that serves as a Level of Evidence (LoE) to support the product's impact on patient outcomes**

- Meta-analysis of multiple controlled trials or randomized controlled trial
- Non-randomized controlled trial
- Integrative reviews/descriptive or correlational studies
- Peer-reviewed professional organizational standards
- Vendor/Manufacturers' data
- Theory-based evidence/expert opinion/case study
- Other \_\_\_\_\_

**SAFETY and COMPLIANCE: Describe the product's impact on safety and compliance**

- Addresses Sentinel Event
- Addresses SAFE or near miss
- Addresses survey deficiency
- Insures compliance with applicable regulatory agency/body
- N/A

# Factors Influencing VAC Decision Making

## FINANCIAL IMPACT

Full margin impact

Revenue potential

New technology training costs

Total cost of care

Process improvement

Regulatory requirements

## CLINICAL IMPACT

Contribution to high quality outcomes

Strong clinical metrics

Measurable, short-term quality improvements

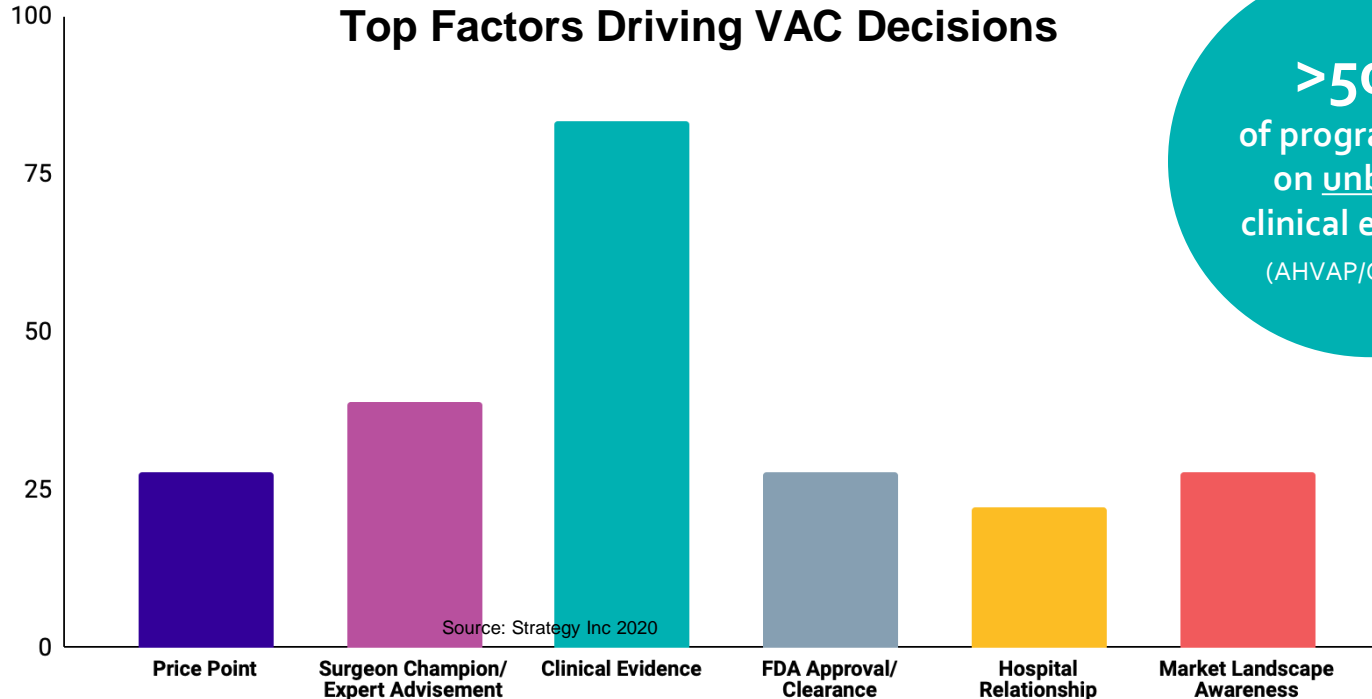
Evidence-based improved clinical efficacy and health related outcomes

Established practice patterns and product use

Patient and hospital staff safety

# Clinical Evidence the Top Decision Driver

## Top Factors Driving VAC Decisions



Source: Strategy Inc 2020

**>50%**  
of programs rely  
on unbiased  
clinical evidence  
(AHVAP/GHX 2023)

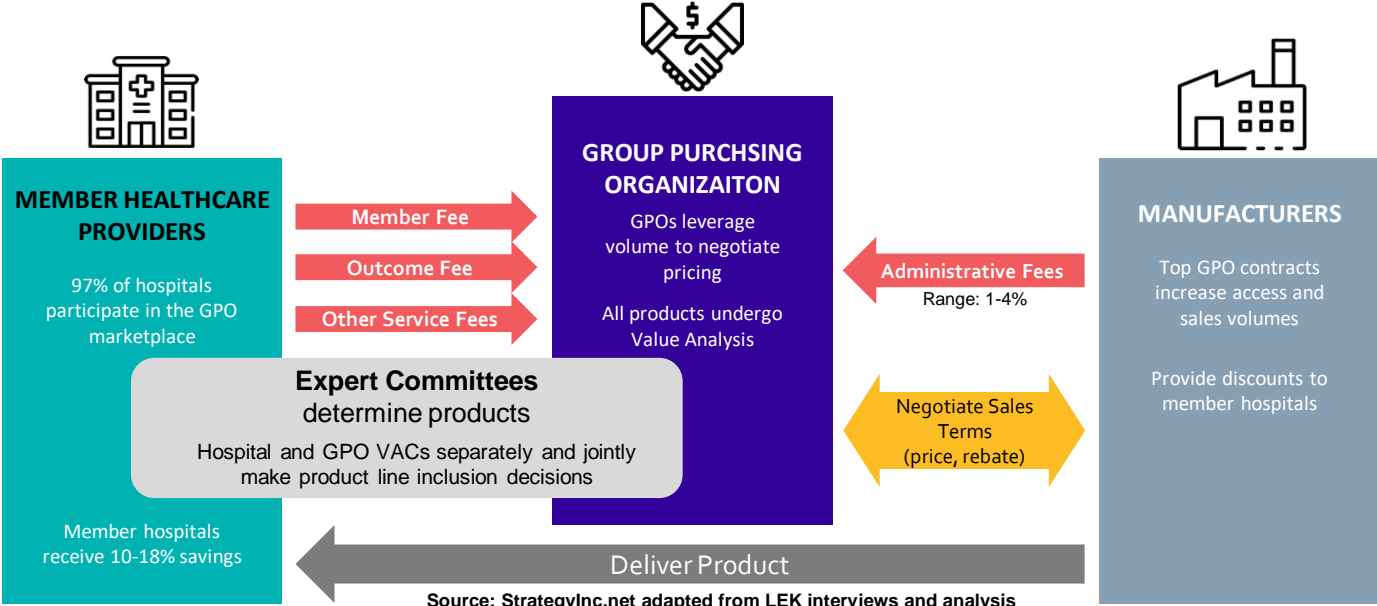


## Step 4. Negotiations and Contracting

- Negotiating and contracting occurs after VAC approves a product for sale
- Important to plan for the next steps once VAC confirms approval
- Pricing alignment is highly complex and involves product price catalogs, contract price authorization, sales tracing, price exceptions and more
- **Recent trend:** shared risk of savings programs between healthcare facilities and providers able to reduce cost of care
- May reflect a decrease in service utilization yielding decreased costs
- Healthcare providers can share in the savings per an agreed distribution method



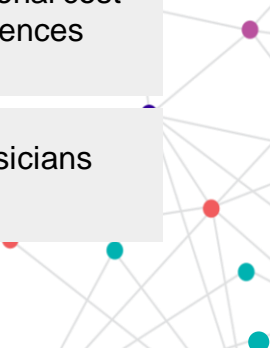
# How GPOs Engage with Value-Based Purchasing





# Value Analysis Comparisons for the Technology Developer/Manufacturer vs. the Distributor

Technology Developer/Manufacturer		Distributor
Understand current National trends for comparative data	<b>Comparative Data Requests</b>	Understand differences by country or region for data required
Ensure VAC requests for Top 5 national GPOs have been initiated	<b>GPOs</b>	Investigate top GPOs in country or region to initiate VAC process
Clarify the consistency of operational costs for prodecures being evaluated	<b>Cost Data</b>	Understand differences of operational cost data by country or region as differences can be significant
Identify Physician champions by institution or hospital systems	<b>Physician Champions</b>	Identify Key Opinion Leading Physicians by region considered influential





# Strategy Inc. Supports Value Analysis



## Economic Story

Identify and clarify cost savings opportunities with product use



## Evidence Strategy

Establish level of evidence to support clinical and health economic outcomes claims



## Adoption Projection

Confirm clinical need, market trends, and potential financial savings from product use



## Competitive Landscape

Detail competitive edge over current product offerings



## Reimbursement

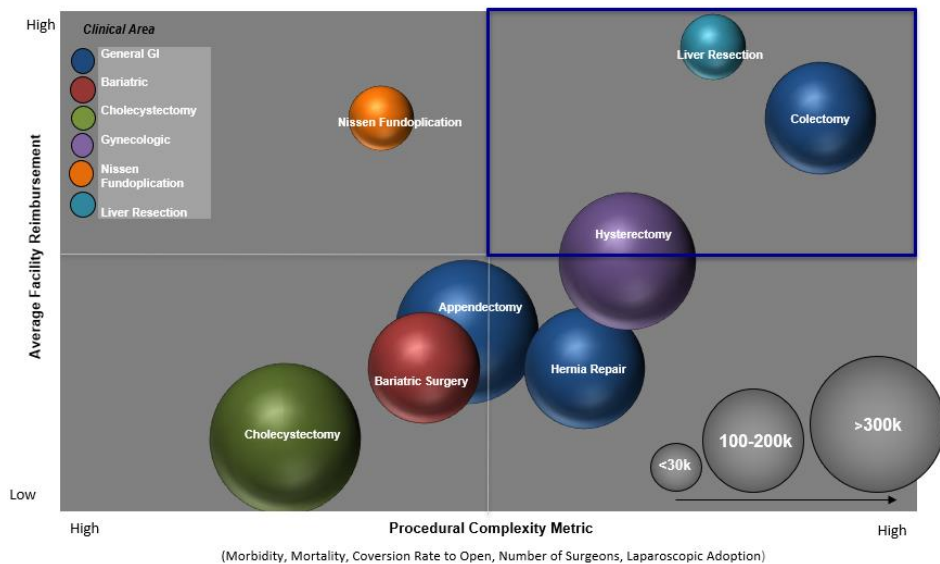
Confirm potential for payment for product use



# Economic Story of Cost Savings Opportunities

## Laparoscopic Procedure Complexity versus Average Facility Reimbursement

Circle Size Represents Annual Procedure Volume



- Build a clear economic value story critical to VAC acceptance
  - Affirm value pricing
  - Deliver reference data and visuals
  - Demonstrate long or short-term cost benefit
  - Based on competitive landscape
  - Incorporate unbiased data sources



# Evidence Strategy

- Level of evidence to support clinical and economic claims drives decision making
- Highest level of evidence = strongest support of claims



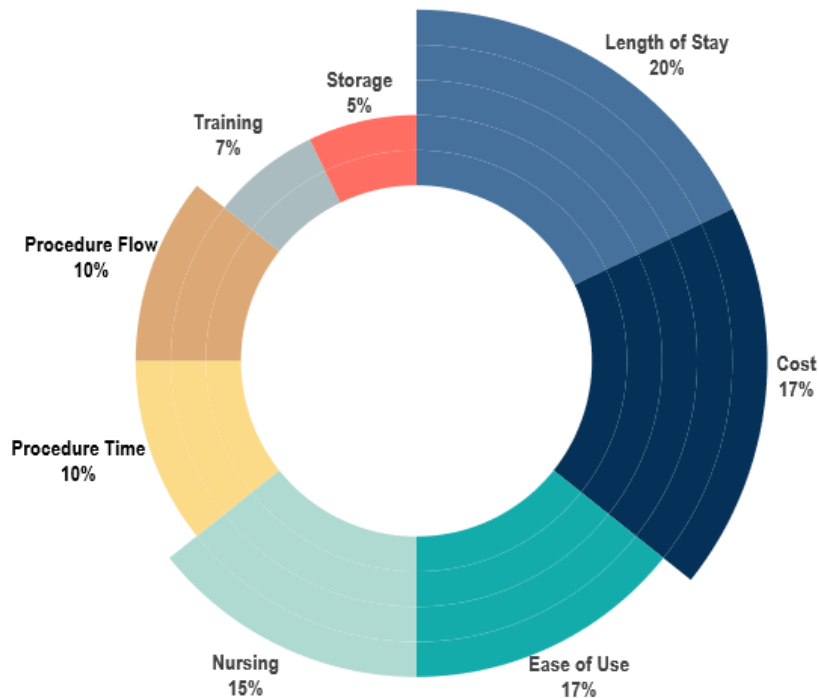
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- Non-randomized controlled trial
- Integrative reviews/descriptive or correlational studies
- Peer-reviewed professional organizational standards
- Vendor/Manufacturers' data
- Theory-based evidence/expert opinion/case study



# Adoption Projection

- **Establish** clinical need and market trends
  - **Identify** product features to drive adoption
  - **Confirm** measures influential to purchasing
  - **Validate** technology's ability to solve challenges
  - **Include** clinicians from target institutions
- **Understand** each institution's clinical focus
- **Research** the current pain points
- **Convert** interviewed KOLs into physician champions

## Perceived Product Advantages






# Landscape Analysis

**VACs consider all new technology relative to current product offerings**

- **Control** the message to guide VACs to comparative benefits
- **Establish** competitive edge over current products: outcomes, economics and user experience
- **Understand** the landscape for target indications
- **Outline** the unique value proposition
- **Expand** target users with enhanced features

	BioFire Film Array	GeneXpert	MIC qPCR	BAX Salquant	Solana	Solas8	POCKIT	Zephyr	Ramp Reader
Comparison Form Factors									
Covid19	•	•	•		•		•		•
Strep A&B	•	•			•		•	•	
RSV	•	•			•				•
Influenza A&B	•	•			•		•		•
Pneumonia	•								
Campylobac	•			•					
C. diff	•	•			•		•		
E. coli/STEC	•			•				•	
Salmonella	•			•			•	•	
Listeria	•			•				•	
Staph	•			•				•	
Dengue Virus							•		•
Zika Virus									
Norovirus		•					•		



# Reimbursement Assessment

- Critical for pricing, positioning, and messaging
- Outline current or potential coverage based on existing coverage decisions
- Confirm product eligibility within current coverage and payment
- Detail when expanded coverage is possible

2022 DRGs	Trauma Procedures	Avg Amount paid to facility per discharge	Estimated Annual Medicare claims	% per procedure classification
955	Craniotomy for multiple significant trauma	\$75,554	2,422	N.A.
956	Limb reattachment, hip + femur procedures for multiple significant trauma	\$45,336	19,392	N.A.
957	Other OR procedures for multiple significant trauma <b>with major</b> complications and comorbidities	\$79,909	22,086	60%
958	Other OR procedures for multiple significant trauma <b>with</b> complications and comorbidities	\$42,614	13,705	37%
959	Other OR procedures for multiple significant trauma <b>without major</b> complications and comorbidities	\$24,639	1,271	3%
963	Other multiple significant trauma <b>with major</b> complications and comorbidities	\$27,397	19,947	41%
964	Other multiple significant trauma <b>with</b> complications and comorbidities	\$14,141	25,339	53%
965	Other multiple significant trauma <b>without major</b> complications and comorbidities	\$9,468	2,908	6%





# 4 Potential Pitfalls to Avoid

1.

## MD Dependency

Relying too much (or too little) on the influence of a **physician champion**

2.

## Delayed Planning

Not developing a Value Analysis Strategy **early** in the development cycle

3.


## Ignore Competitors

Not fully considering the **competitive landscape**

4.

## Supply Chain

Not preparing for **scalable** supply chain





# Pitfall 1: Relying Solely on the Influence of a Physician Champion



## Advantages

### PHYSICIAN CHAMPION ADVANTAGES

- Instrumental to getting a technology in the door
- Influential in purchasing decisions
- Override the Value Analysis process at some institutions
- Physician – supplier relationships influence purchasing patterns

### PHYSICIAN CHAMPION LIMITATIONS

- Clinical and economic outcomes data drive decisions
- Trend away from physician driven purchasing
- Larger institutions less influenced by physician endorsement
- Supply chain and service line leaders most accountable for meeting savings targets



## Limits



## Pitfall 2: Not Developing a Value Analysis Strategy Early

### **A Comprehensive Value Analysis Strategy includes:**

- Clinical trial planning to capture best outcomes metrics as secondary endpoints
- Ongoing campaigns to substantiate value / build brand recognition
- Abstract, poster, and publication submissions against standard of care
- One-on-one interviews with hospital VAC members and physician champions

### **Lack of early planning leads to:**

- Delays critical insight collection until the commercialization process
- Denial decision for product sale at their facility
- Insufficient evidence = delays for additional data generation
- Failure to incorporate valuable endpoints in clinical trial design



## Pitfall 3: Ignoring the Competitive Landscape

- Decisions weigh standard of care and current product use
- Competitive comparisons include:
  - Clinical outcomes, applicable targets, safety
  - Method of use, treatment trends, training costs and requirements, pricing
  - Product features, ease of use, storage, etc.

### **Ignoring the competitive landscape risks missing market aspects:**

- Potential road blocks to adoption and approval
- Niche opportunities of competitive advantage
- Features that motivate a hospital system to change products / manufacturers



## Pitfall 4: Underpreparing for Scalable Supply Chain

- Higher hurdles for:
  - Less well-known manufacturers
  - Smaller companies
  - New market entrants
- Seek entities prepared to scale up supply with sufficient infrastructure
- History of supply challenges resulting from 'acts of God' increase concerns

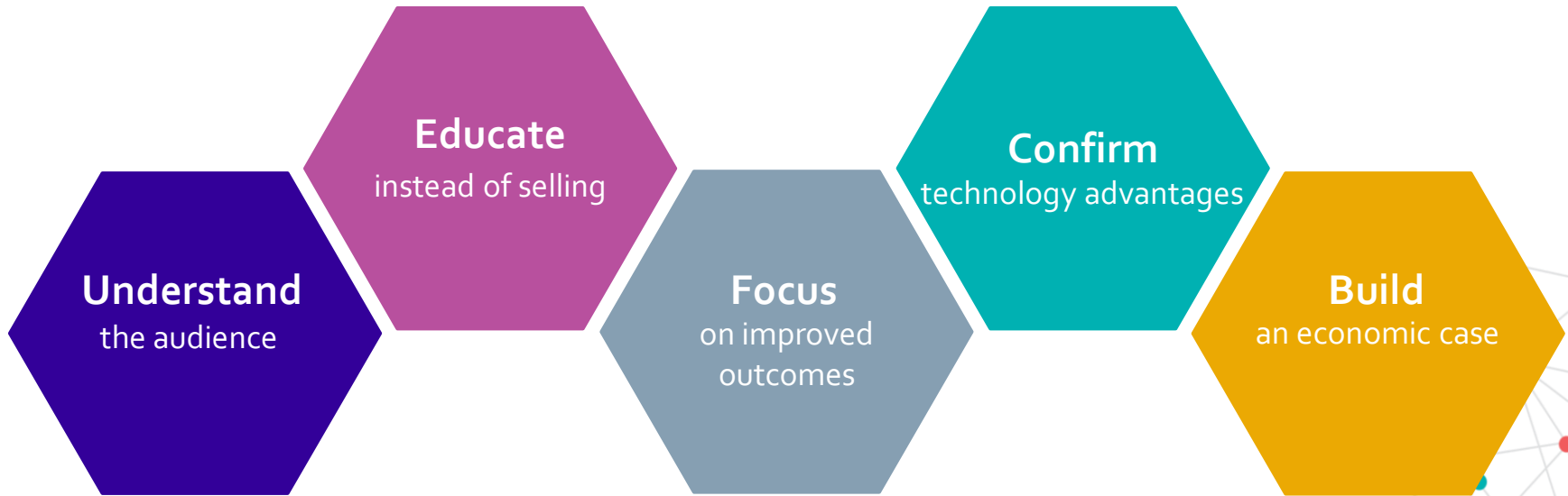
### Prepare to meeting supply concerns:

- Anticipate concerns that drive supply chain decision making
- Demonstrate a supply system is in place to meet all requirements



# 5 Summary Strategies for Success

- Designed to improve navigation of the value analysis process
- Identify a team member (internally or externally) to incorporate these strategies into your structure and materials



**Q&A**

# Thank you for attending!

## Contact Information for our Panelists

- Nancy Patterson - [nancy.patterson@strategyinc.net](mailto:nancy.patterson@strategyinc.net)
- Lauren Rodriguez - [lauren.rodriguez@strategyinc.net](mailto:lauren.rodriguez@strategyinc.net)
- Craig MacInnis - [craig.macinnis@cariboumed.com](mailto:craig.macinnis@cariboumed.com)

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