

# A Guide to Successfully Navigating Hospitals' New Product Evaluation Process

Alan Davis, M.D.  
Orthopedic Surgeon, Cleveland Clinic  
Managing Director, BioStar Capital

Sponsored by  
 **Paragon  
Medical**





## Hospital System Evaluation of New Technology

Alan Davis, MD  
Orthopaedic Surgeon & Venture Capitalist

# About me:



## Orthopaedic Surgeon Cleveland Clinic:

- **Michigan State University**
- Boonshoft School of Medicine (WSU)
- CCF Orthopaedic Residency
- CCF Foot And Ankle Fellowship
- Private Practice Managing Partner 1990-1999
- CCF Innovations And Supply Chain (Excelerate-GPO)
- Former Chairman Orthopaedic Department  
FGH, and SJWSH



## BioStar Capital, Managing Director:

- BioStar V: \$>100M
- BioStar IV, MOIC 6x, Net IRR 72%
- Venture Capital Investments In CardioVasc,  
Ortho and Robotics
- 100+ Physician Investors, MVP Model,  
Strong Business Advisors
- Team: Previous CEO Boston Scientific,  
CEO CVRS, KOL Physicians
- Examples: OrthoSpace. Ellipse, CD Diagnostics
- Transformational technologies

# How hospitals and surgeons evaluate new technologies & ideas:

- Patient care is the #1 priority
- Unmet clinical need
- Novel vs. iteration (unique product)
- Adoption potential
- Clinical validation/outcomes
- FDA approval and indications
- Cost effective
- Additional resources necessary
- Insurance approval (codes available)
- Marketing potential/market dynamics



# Contract management: New products

## Physician KOL Champion: Internal Introduction

- New products request form (online/7 pages)
- Department Chair approval
- Clinical justification letter
- Patient benefits and limitations
- All product information
- Additional resources to utilize product (capital/disposable)
- Replacement of currently used product
- Written quote from vendor on their letterhead
- Reimbursement and market comparisons
- Types of procedures (CPT codes)
- Adoption/# physician utilization/uses per year
- Names of who will use, different specialties
- Previously trialed/trial discount/free trial
- FDA classification (approved/IDE/Humanitarian)
- Clinical data, safety, efficacy, outcomes
- Conflict of interest (financial disclosure)
- In-person presentation



# Contract management: Sourcing process

## Request for proposal: RFP process

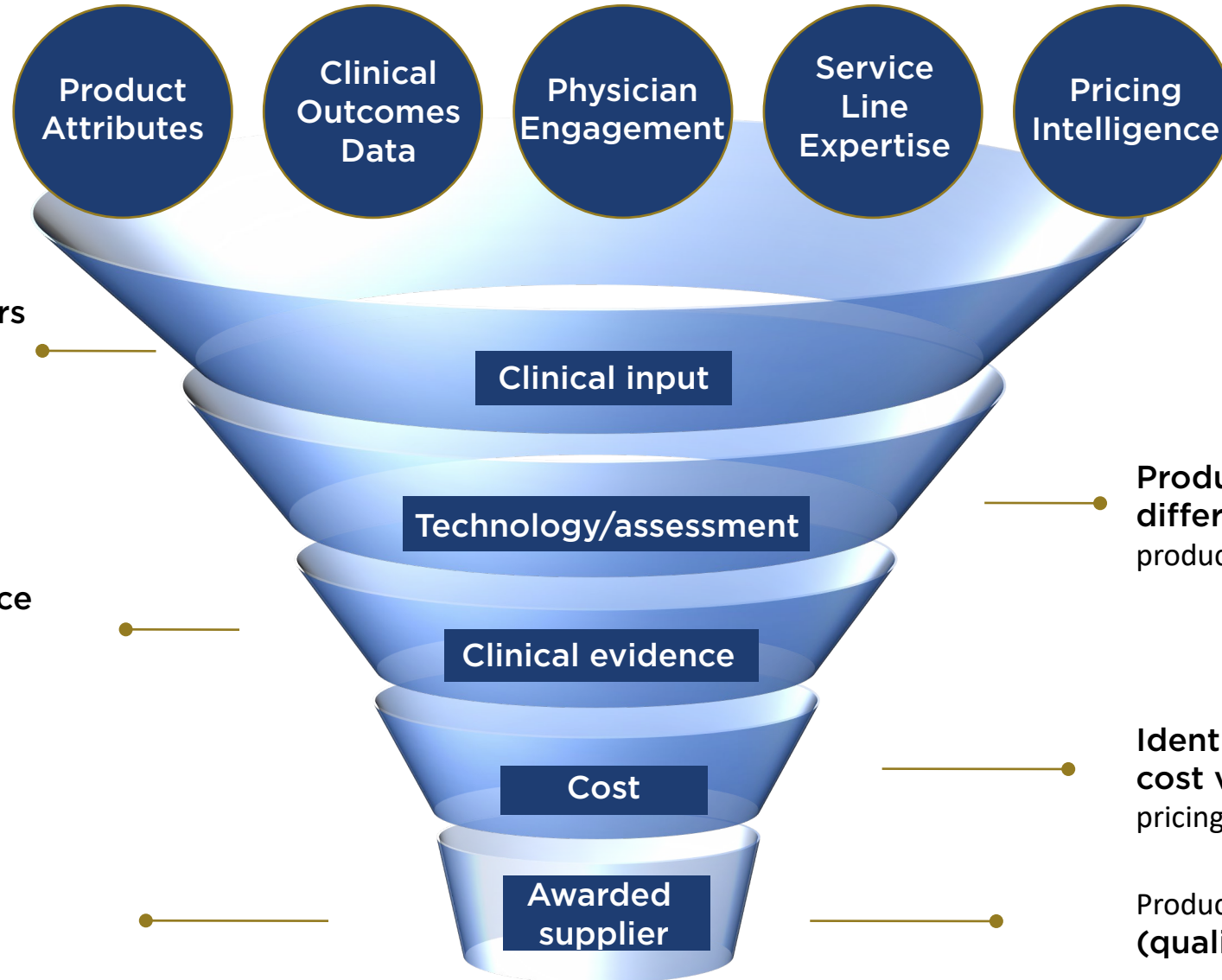
- High impact categories
- Key clinical areas
- Expiring contracts
- Scope of contract
- Crossover utilization (Orthopaedic subspecialties/other)
- Service reps track records, commitment, product knowledge
- Loaner fees
- Current inventory (cost of transition, logistic/education)
- Member feedback (physician engagement)
  - Physician coordinator works with supply chain personnel
  - Member input survey (end users)
  - Product differentiation, attributes, clinical outcomes
  - Member input conference call
  - Avoid conflict of interest



# QUALITY

# VALUE

# \$COST\$



Product Attributes

Clinical Outcomes Data

Physician Engagement

Service Line Expertise

Pricing Intelligence

Champion service line leaders provide practice area subject matter expertise

Clinical input

Product attribute differentiation informs product acceptance

Technology/assessment

Level 1 and 2 clinical evidence is assessed to distinguish product superiority or equality

Clinical evidence

Identify products with cost variability utilizing pricing intelligence

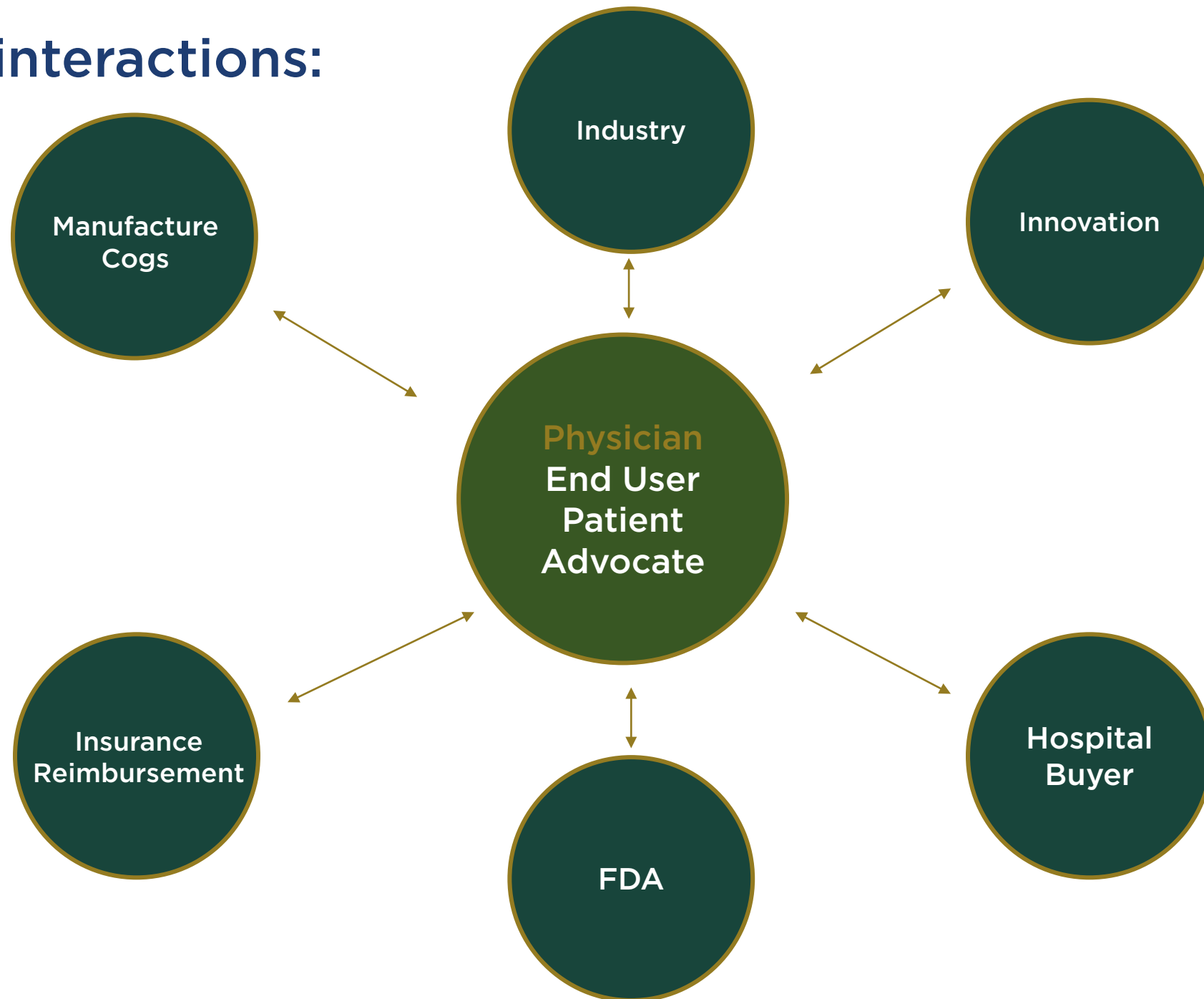
Cost

Quality with cost strategies are combined

Awarded supplier

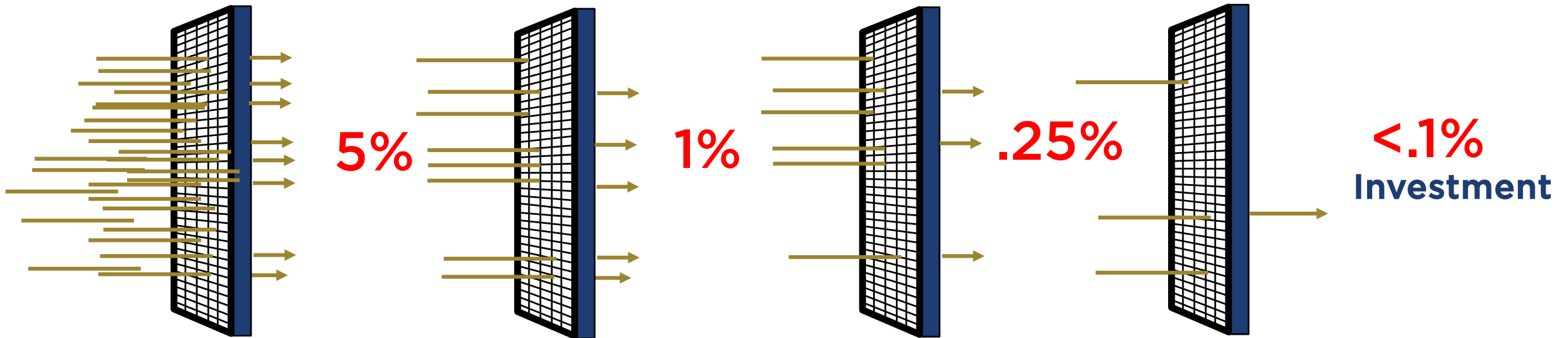
Product that has best value (quality and cost) is selected

# Complex interactions:





# Investment process: Assesses value/cost vs. clinical impact



## Initial Review by Diligence Team:

- BioStar compatibility
- Transformational innovation
- Leverage MVP experience
- Strong intellectual property
- Successful leadership team

## Leadership Team Review:

- Management assessment
- Market opportunity
- Fit with portfolio
- BioStar value-add
- Transformation vs. iteration

## Deep Clinical Diligence by MVP/Physician LPs:

- Clinical need and benefit
- Device design
- Data and research
- Commercial relevance
- Strategic market

## Investment Committee Extensive Negotiation:

- BioStar clinical impact
- Company capital needs valuation
- Board positions
- BioStar's influence for exits
- Carve-out for BioStar

# Closing remarks:

## #1: Screen for unmet opportunities:

- Enhance global access to quality care
- Create health provider delivery efficiencies via digital health, AI, simplify procedures
- Can leverage and/or benefit from BioStar's expertise, brand reputation, relationships
- Potential to lower costs for health delivery systems, and/or payers

## #2: If a potential opportunity checks the boxes, evaluate:

- Higher than market growth profile (e.g., digital, DM, Women's)
- Performed in alternate sites of care or remotely and traditionally
- Platform opportunities for potential acquiring companies
- Improves patient's outcomes and/or procedural effectiveness
- Has a CEO with proven experience that is aligned with the company's phase of development



# Within CV and Orthopaedics:

## For discussion

- Transformational devices in areas of high unmet need? (*e.g., TMDX*)
- Valve repair & replacement? (*e.g., Versa Medical*)
- Robotic navigation and tissue repair? (*e.g., MMI*)
- Regenerative bioprinted bone and cartilage tissue? (*e.g., EpiBone*)
- Solutions for peripheral vascular disease? (*i.e., AVS, REVA*)
- Smart sensor surgical and post-operative monitoring technology?
- AI/ML assisted tech, monitoring and wearables
  - Improve provider care, decisions, outcomes and/or efficiencies
  - Enabling technologies





THANK  
YOU

GO  
GREEN!