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Commercial Viability:

Understanding its components and where the USA fits

James Sargent & Kevin Sweeney

November 19, 2024

Rules

+ Interactive
+ Safe environment
+ Respectful of confidentiality

Introduction

James Sargent

Managing Partner, RQR Advisors

Commercial and General Management, Boston Scientific

Experience:

- 30+ years in healthcare with a focus on medical device commercialization
- General Manager & commercial leadership with Boston Scientific in USA, Europe, and Asia Pacific
- Marketing representative on 9 integrated product development teams at Boston Scientific
- Team member and commercial integration lead for Watchman and Rhythmia at Boston Scientific

Introduction

Kevin Sweeney

Commercial Viability Council, RQR Advisors

Product Development, Manufacturing, Supply Chain, Boston Scientific

Experience:

- 40+ years in healthcare with a focus on medical device product development
- Manufacturing leadership with Boston Scientific in USA and Europe
- Product design and manufacturing lead on 7 product development teams at contract design and manufacturing organization (Resolution Medical)
- Experience in product design from initial prototype development to full scale manufacturing

RQR Commercial Viability Council: Cross-Functional Team

Council Bios in Appendix

Cross-functional expertise across all domains

50+ FDA Approvals

$5B New Product Revenue

75+ Design verification tests

150+ Years experience

25+ Manufacturing Transfers

15+ reimbursement codes

50+ product launches

20+ preclinical trials

USA market: A necessary market to create value

+ USA is **large and necessary** to maximize commercial viability
+ The USA is a highly **complex** market, however it is **manageable**
+ Have a **better understanding** of USA strategies
+ Healthcare in the USA is a **business**

United States Healthcare

Netherlands Healthcare

WHAT'S THE DIFFERENCE?

United States Healthcare

$3.65 Trillion Annually

329M people (2019)

$19.39 Trillion GDP (2017)

Healthcare ~19% GDP or 3,650B

Netherlands 10.13% GDP

Highest healthcare spend per person

$9,500 per capita

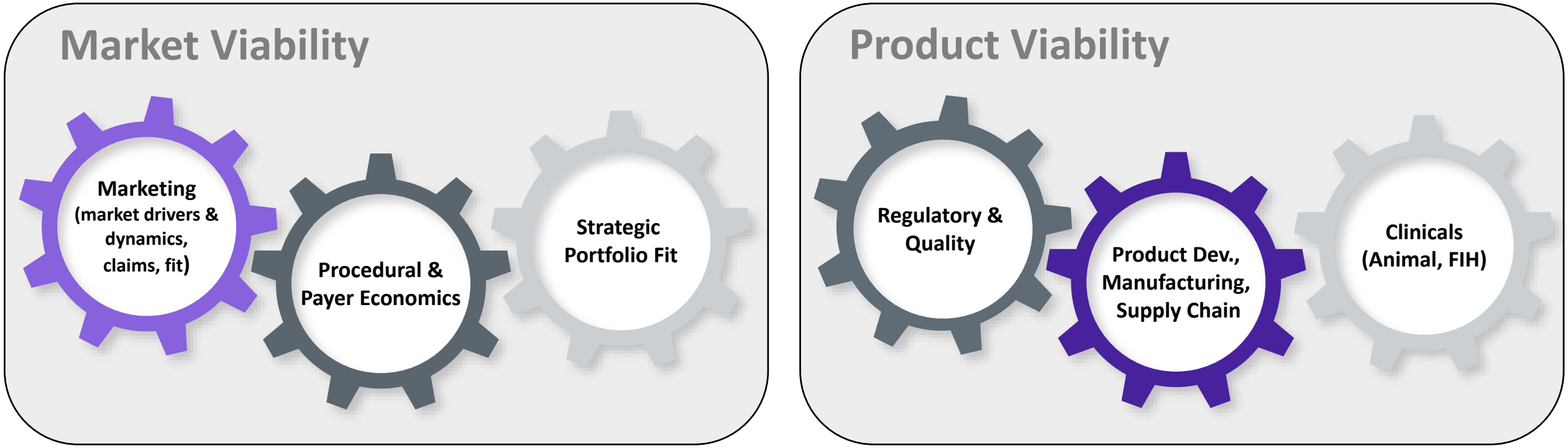
Netherlands $5,335

Commercial Viability *noun [U]* the ability of a business, product, or service to compete effectively and to make a profit.

Commercial Viability: Two Core Components

Commercial viability requires an interrelated understanding and application of all aspects of **market viability** and **product viability** at the earliest stages.

Most founders focus too heavily on product viability while deferring market considerations.



Market Viability is a multiplier in the commercial viability equation

Product Viability = Turning technology into a product

"As engineers, we can design and build a product using your technology, but private investment will be more attainable and sustainable with a business model based on commercial viability."

- Kevin Sweeney, RQR Advisors

Product viability without market viability

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Market Viability: Key Questions to Answer

- What is the level of clinical relevance for the technology?
- What price is the market willing to pay for the technology?
- What are the market dynamics and drivers for the technology?
- What are the procedural economics for the technology?
- What is the defined exit for shareholder and investor returns?

Commercial Viability: Commercial Quotient® Equation

$$\frac{\text{Product Viability} \times \text{Market Viability}}{\text{Commercial Viability}}$$

Market Viability: A Beyond the Spreadsheet® Value Multiplier

The United States medical device market, which comprises approximately 50% of the global market, is a ***highly contractually driven market*** at the national, regional and local levels. Many of the categories within medical devices are contracted in dual vendor agreements for 80% of the device expenditures, creating a ***premium on portfolio breadth and depth*** when these contracts are negotiated and awarded.

Market Share Optimization

With attractive technologies, the Strategics would ***leverage*** the price elasticity and high gross margins of the technology to gain market share across the portfolio. By offering concessions in pricing, they could ***pull through incremental revenue*** across their entire portfolio in the categories where product differentiation is harder to achieve and price sensitivity is common.

Strategic Market Access

Companies desire to control market access. Value beyond revenue is where significant leverage is realized by a company seeking more access in the space. Such leverage could provide the basis for ***maintaining or increasing their current position*** or for ***reopening negotiations*** for those contracts where they are not actively participating, or as a defensive position for a market leader in another related segment.

Executing a ***portfolio leverage strategy*** is well understood and widely accepted in the USA by hospitals, physicians, and administrators alike. The strategic value to an individual company goes beyond just top-line revenue as it can be used offensively to ***gain market share across the entire portfolio in contracting.***

Commercial Viability

Product Viability

Market Viability

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Perspectives From The C-Suite…

Why and How Will A Strategic Acquire Me?

Michael Phalen

November 19, 2024

Introduction

Michael Phalen

Chairman, RQR Advisors

Executive Vice President, Group President, Boston Scientific (Retired)

Experience:

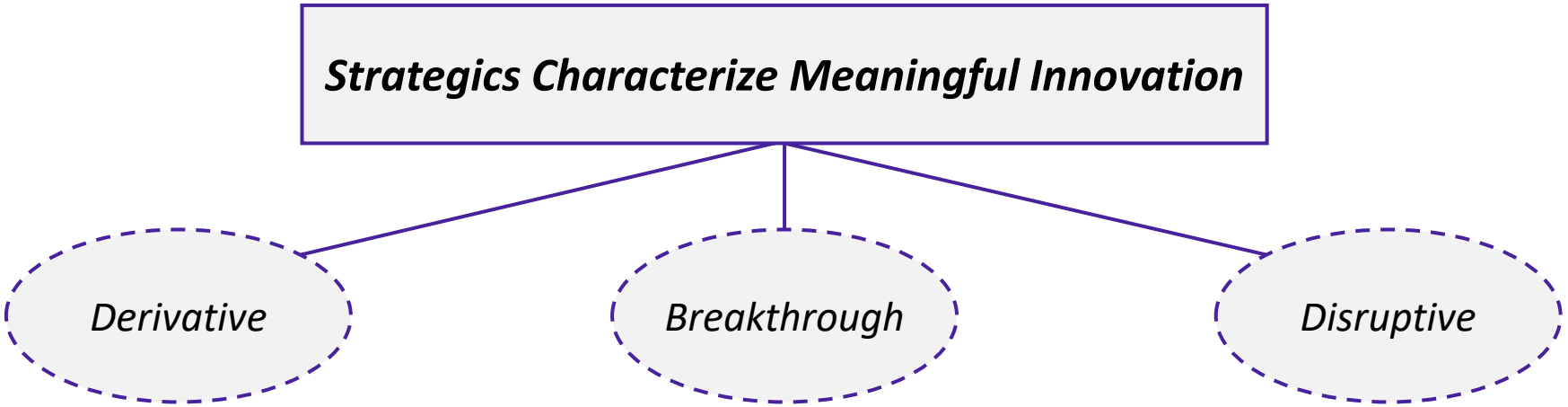
- Global President, Boston Scientific Endoscopy
- President, Boston Scientific International
- Group President, Boston Scientific MedSurg (Endoscopy, Urology Women's Health, Neuromodulation
- Chair, MassMEDIC
- Advamed Board of Directors

Meaningful Innovation Fuels New Growth

Primary Sources of Meaningful Innovation:

Organic New Product Development

Mergers & Acquisitions



Meaningful Innovation from Tuck-In Acquisitions

Medtronic

"We are very focused on ***tuck-in acquisitions*** ... [and] most of what we do is ***early stage*** ... where things are still in development or maybe finished development, but not yet commercialized. Then we can use our ***expertise ... to help get it through final regulatory approval, reimbursement, and then ultimately, take it commercially around the world.”***

Karen Parkhill, Former CFO and EVP, Medtronic

Boston Scientific

"We've acquired…. over 40 companies or so over the past 10 years [and] the majority of these ***tuck-in M&As*** have really improved our innovation cadence and our weighted average ***market growth rate.”***

Mike Mahoney, CEO, Boston Scientific

stryker

"over time, obviously, the larger volume of our deals are going to be ***smaller tuck-ins."***

Kevin Lobo, CEO, Stryker

"Companies ranging from Abbott to AngioDynamics to Boston Scientific and Integra have shown that you can do meaningful deals for a ***sub-$100M*** price tag.”

CEO, Merit Medical

$47B+ in Medtech M&A Transactions in 2023, with Increasing Focus on Pre-Commercial Tuck-Ins

Which Ideas Do Strategics Pursue and Why?

Ideal Meaningful Innovation Has…

- Significant Defined Unmet Clinical Need(s)
- Clear Defined Growth Market Vertical
- Recognized Market Share Product
- Recognized Market Development Product
- Well Defined Call Point
- Limited Patient Referral Pathway
- Rapid Adoption Curve
- Strong Intellectual Property Position
- Deep Market Vertical Understanding
- Strong Proof of Concept
- Defined / Understood Mode of Action
- Working Prototypes
- Compelling, Bench, Animal, Human & Economic Data
- Well Defined Coding, Coverage & Payment Strategy
- Designed for Manufacturability
- Robust Documentation QMS

High Commercial Viability

The Calculus of Market and Product Viability = Commercial Viability

Market Viability

- Product Marketing
- Product Positioning
- Product Pricing/Promotion
- Economics
- Commercial Ethos
- Competitive Environment
- Intellectual Property

Product Viability

- Product Development
- Manufacturing
- Clinical Data
- Regulatory
- Quality

Strategics Foundational Questions

- Does the Technology Work?
- Can You Prove It?
- Will the Market Believe You?
- Can You Make Money With It?

Commercial Viability Touches Product Viability, Market Viability and Strategics Foundational Questions

Traditional Medtech Funding Milestones

Does The Technology Work?

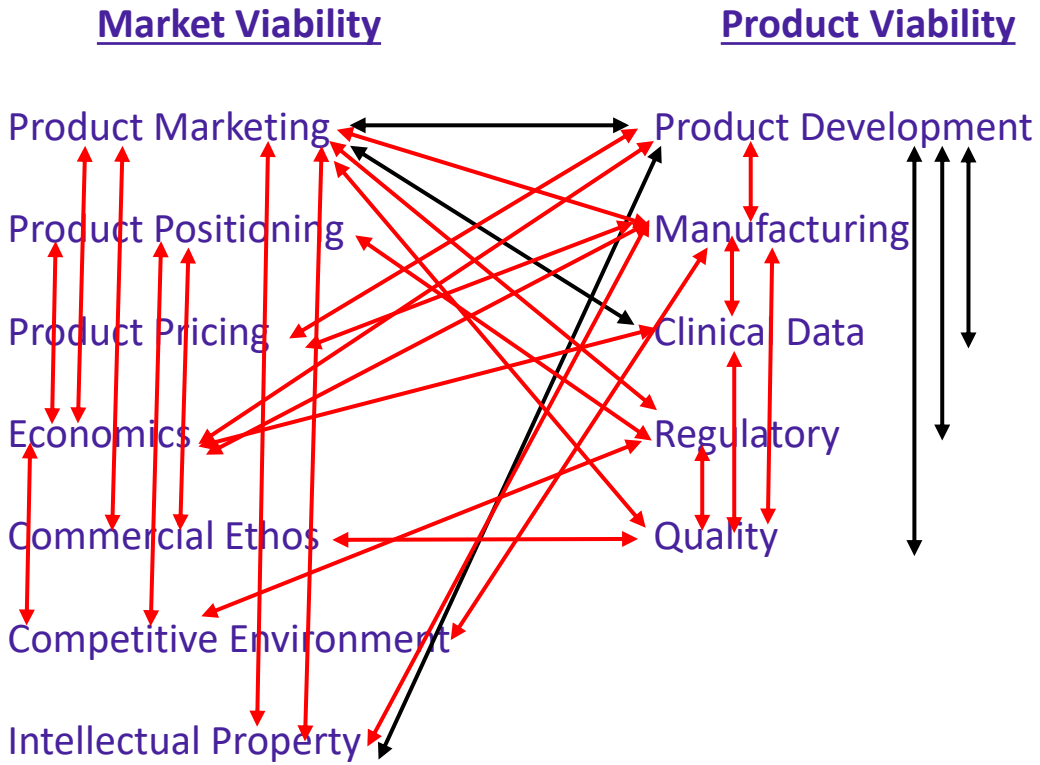
Can We Prove It?

Will The Market Believe Us?

Can We Make Money With It?

Commercial Viability Is Foundational to Investment/Acquisition

Pre-seed	Seed	Series A	Series B	Series C
Proof of Concept	Preclinical Study	First in Human	FDA Approval	Commercial



Strategics Foundational Questions

- Does the Technology Work?
- Can You Prove It?
- Will the Market Believe You?
- Can You Make Money With It?

Cross Functional Dynamics Increase Exponentially Through Funding Milestones

Summation and Conclusion

Why Would A Strategic Acquire Me?

- Delivered Meaningful Innovation That Solves A Real Need
- Demonstrated Understanding of Market Viability For Your Product
- Produced Compelling Product Viability Evidence
- Executed Continuous Cross Functional Engagement Between Market and Product Viability Workstreams
- Realized A High Commercial Viability Product

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Product Innovation:
Understand and Anticipate the Market

Kevin Henseler, M.D.

November 19, 2024

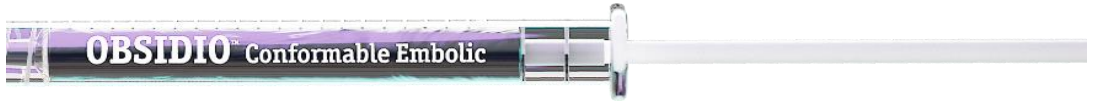
Introduction

Kevin Henseler, MD FACR

20+ years Practicing Interventional Radiologist

Obsidio Embolic: Early Phase Product Design Through 510(k) and Sale to Boston Scientific

- From Bench to 510(k) – **~18 Months**
- 510(k) to Sale – **~1 Month**
- Investor ROI at Exit – **~8.0x**



Boston Scientific

Introduction

Kevin Henseler, MD FACR

20+ years Practicing Interventional Radiologist

Strategic Advisory Board:

Pulmonary Implantable Device

- Early design/animal work to 510(k) ~ 18 Months
- Currently undergoing Human Trials

Gel Embolic Company

- Early design & testing – Current

Board of Directors:

~3rd Largest Private Practice Radiology Group in the US

- 185+ Radiologists
- Primary provider for health systems with revenue >$20Bn USD

Medical Advisory Board:

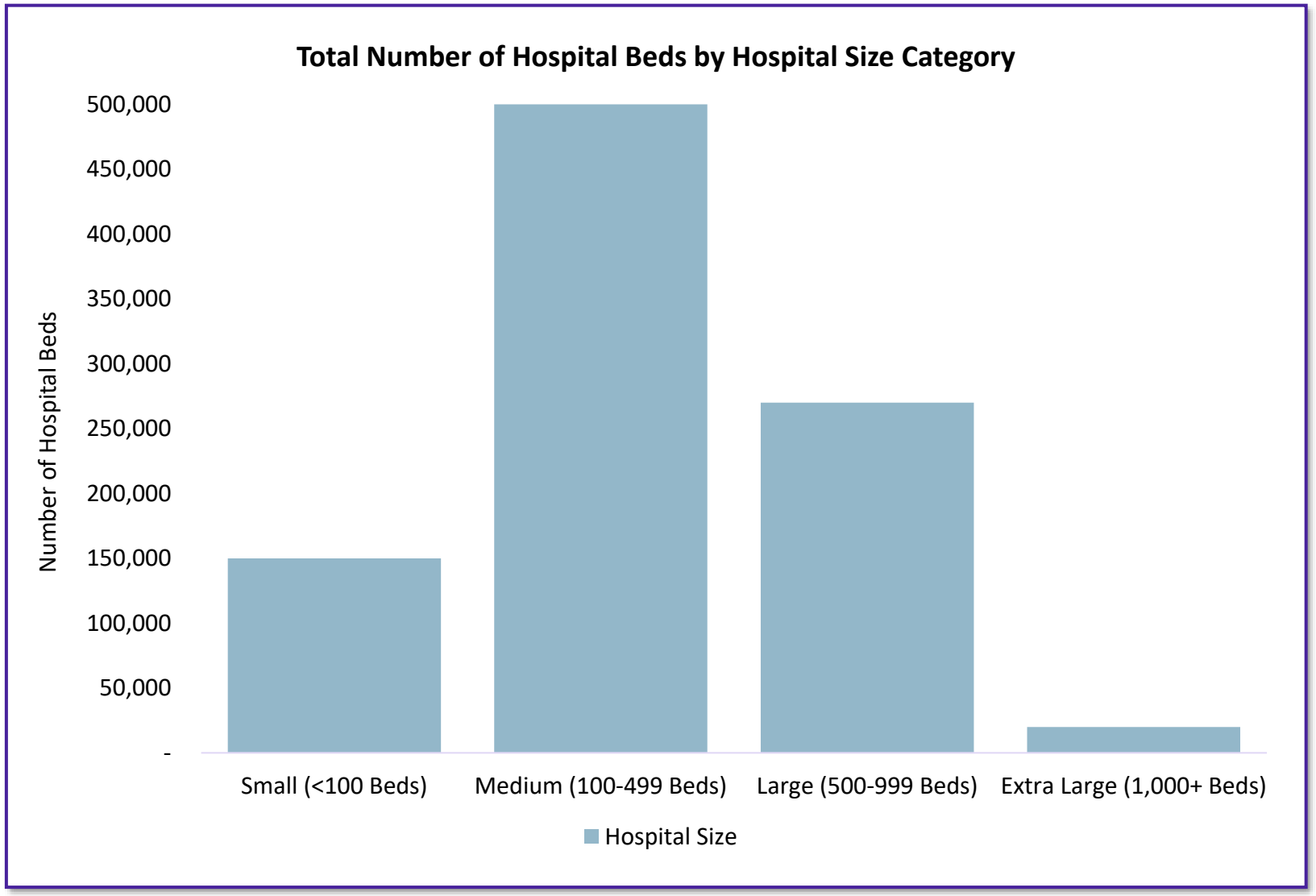
Interventional Oncology, Embolic Devices

- Boston Scientific (<10% are private practice physicians)

Preclinical Advisement:

10+ Companies / Products

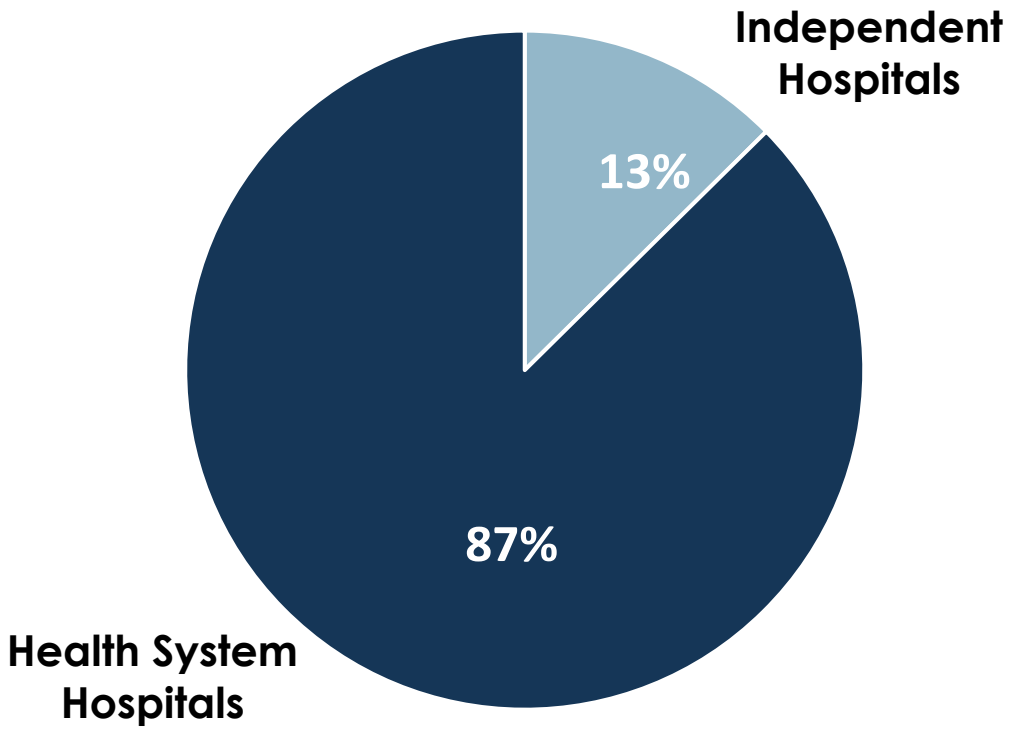
US Hospital Market



The vast majority of healthcare takes place outside of the highest profile hospitals and occurs in smaller community or regional hospitals.

US Hospital Market

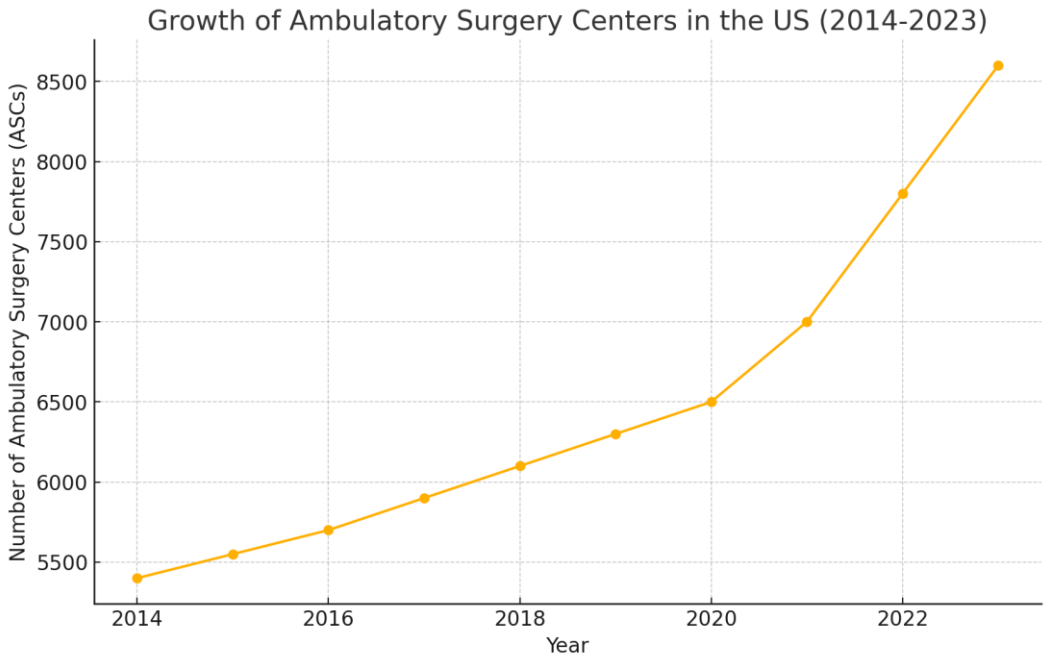
Distribution of Hospital Beds by Health System Affiliation

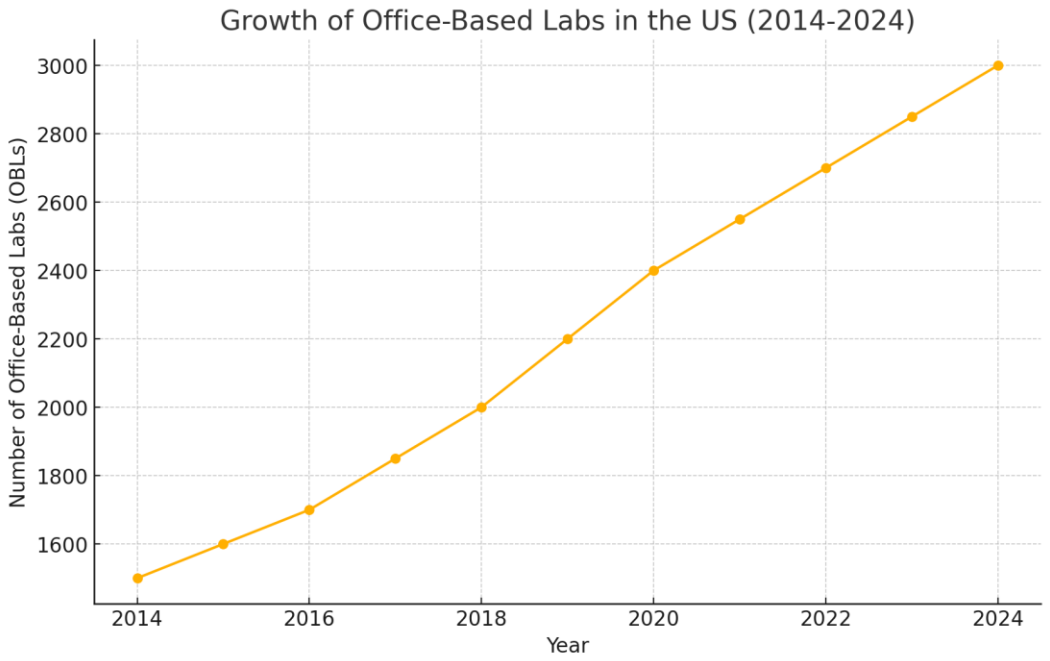


Most Hospital Beds are part of a Health System.

System Value Analysis Committees direct product introduction into the local markets, and drive product success.

US Ambulatory market

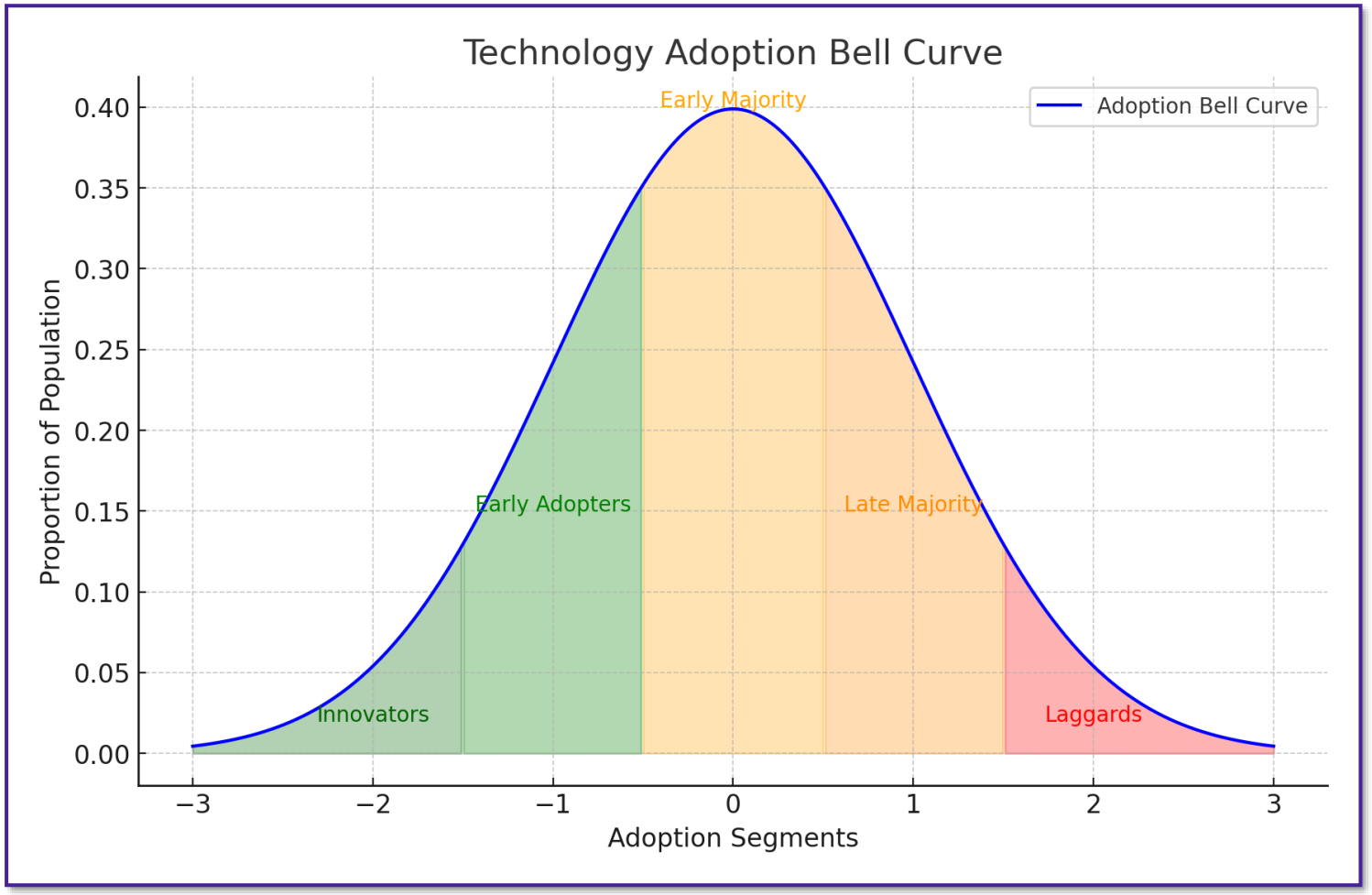




More care is being delivered outside of hospital settings.

Facilities often privately owned and for profit, adding complexity.

From Innovators to the Majority: Planning



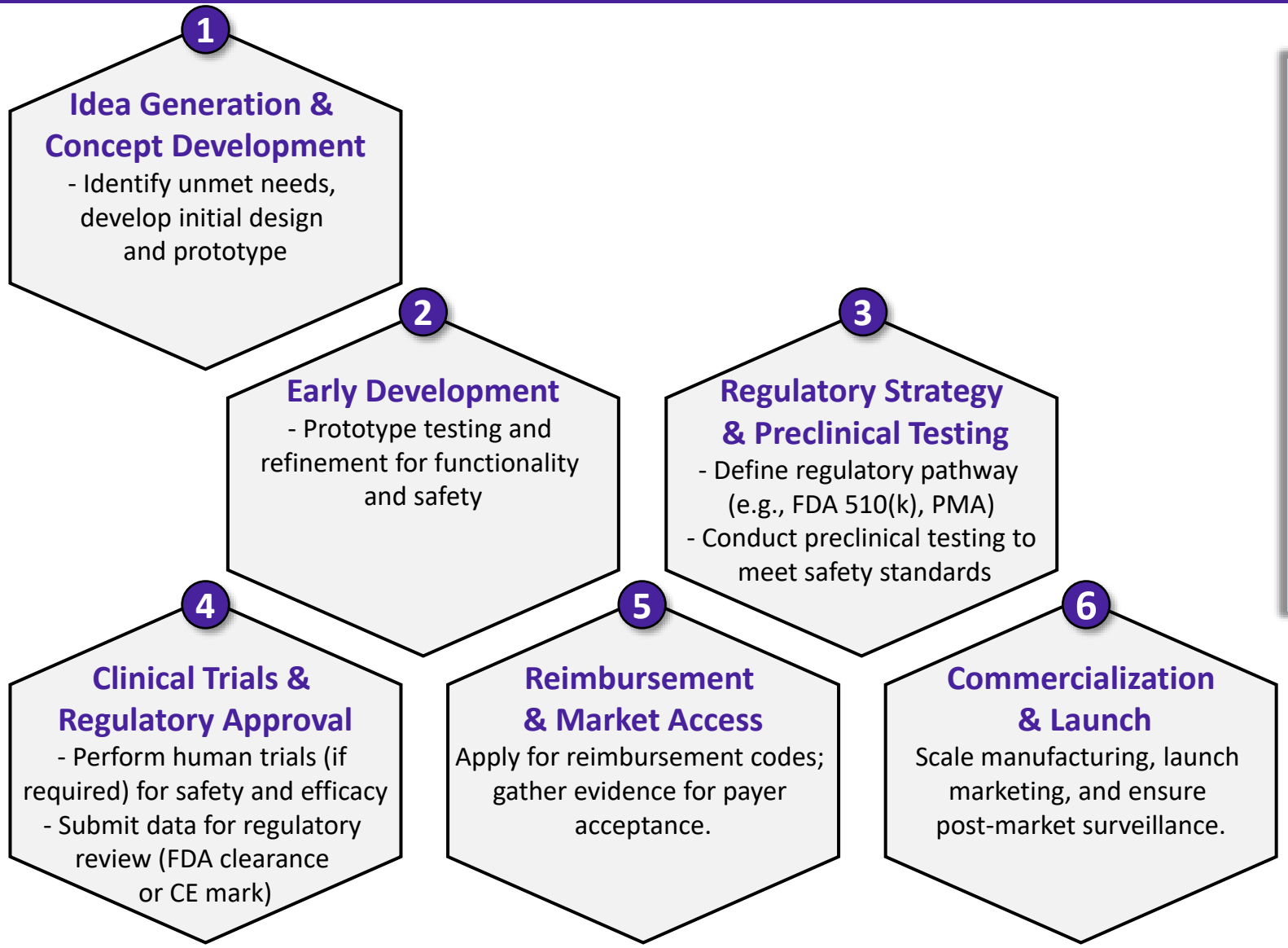
Important factors influencing the introduction of a new technology:

- **learning curve**
- **time efficiency**
- **space constraints**
- **competing product baskets**
- **financial incentives**

The *time* and *capital* it takes to reach the 2nd half of adopters

Factors Influencing Commercial Viability

Efficient Innovation is not Linear



At Stage 1&2:
Must Know & Understand:

- **Time needed for each step**
- **Cost and requirements of each**
- **Likelihood of success at each step**
- **Impediments to successful commercialization & launch**

Cross-Functional Expertise Needed at Each Stage

Summation and Conclusion

- Smaller regional and community hospitals dominate U.S. market
- Most hospital beds are part of a Health System with System Value Analysis Committees
- More care being delivered in private, non-hospital settings
- Must understand the learning curve, time & capital needed for new technology adoption
- Consider commercial viability at each stage of innovation

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Marketing & Regulatory Claims:

Aligning the FDA Strategy with Commercial Opportunity

Laurie Lewandowski & London Krueger

November 19, 2024

Introduction

London Krueger

30+ years International Marketing, Commercialization and Business Development with large Strategics, mid and small sized companies going beyond their home markets

Experience:

- International Product Manager, Market Manager and Group Manager for U.S. large strategics
- Commercialization and channel management (U.S. and International)
- Business development, marketing strategies, upstream product development
- Portfolio management and optimization

Introduction

Laurie Lewandowski

30+ years with Quality and Regulatory

Experience:

- Class I, II and III medical devices
- Experience with small, medium, large and the strategic companies
- Experience with quality systems, quality assurance, regulatory strategies and submissions and advertising and promotion

The “4 P’s” of Marketing

1 Product

- What is it?
- What problem does it solve?
- What value does it have to each user group/ stakeholder?

2 Placement

- Who will sell it?
- What sales channel will it use – New or existing?
- How will it be sold – workflow?

3 Pricing

- What is the current competitor pricing – think big picture
- COGS
- Reimbursement strategy
- Pricing strategy

4 Promotion

- What are the “must haves” in claims to promote successfully?

Should Answer These Questions Early to Confirm Market Viability

Portfolio

Where does this fit?

Who stands to gain the most, lose the most?

Sales channel

Value to shareholders

Goodwill factor

USA Regulatory Device Classifications

Class I

- Low Risk Devices
- Most need no submissions
- Types of devices
  - Stethoscopes
  - Thermometers
  - Bandages
  - Drainage Catheters

Class II

- Moderate Risk Devices
- Most need Premarket Notification (510(k))
- Types of devices
  - PICC lines
  - Bronchoscopes
  - Shoulder Replacements

Class III

- Highest Risk Devices
- Support or sustain life
- Subject to Premarket Approval (PMA)
- Types of devices
  - Pacemakers
  - Stents
  - Lens (eye) Replacement
  - Orthopedic – weight bearing / prothesis

US Regulatory Submission Types

510(k) Premarket Notification

- Majority of submissions
- Demonstrate Substantial Equivalence to a predicate

De Novo

- No identified predicate
- Not class III
- New devices are automatically class III until a de novo is granted

Premarket Approval PMA

- Require clinical study
- Require pre-market audit

U.S. Regulatory Submissions
(FY2023 and FY 2024 as of 6/30/2024)

510(k)

	2023	2024
# Received by FDA	3,883	2,517
# Accepted on First Review	3,020	2,200

De Novo

	2023	2024
# Received by FDA	96	52
# Accepted on First Review	65	44

PMAs

	2023	2024
# Received by FDA	73	51
# Accepted on First Review	64	42

The Importance of Claims

Key Questions

Indication for Use

What is the product intended to do for the patient / user?

Claim

What does Marketing want to say about the device?

What is new / novel about the device?

Testing needed to determine if the device is safe and effective

The answers drive the marketing, regulatory, product development, clinical and reimbursement strategy and thus nearly all aspects of Commercial Viability

Marketing Claims

Marketing Claims

Competition

- Who are they really
- What are they claiming
- How does the market perceive and use the competitor product/s

Value of a Claim vs. Risk and Cost (€ & Time)

- Value of the claim to each user group/ stakeholder
- Cost to achieve the claim
- Speed to market
- Exclusivity and longevity of the claim – barrier to entry
- Beyond incremental improvements
- Should consider reimbursement strategies

Market Acceptance of the Claim

- Will they believe it
- What proof do they need
- Ascertain true cost of minimum required support to claim

Cross-functional Expertise Needed to Achieve Commercial Viability

Claims Lead to Regulatory Strategy

Marketing Desired Statements:

Statistically Sound Data Required

- Design verification
- Design Validation
- Pre-Clinical or
- Clinical

Regulatory includes data to support claims in the submission

Advertising and Promotional Materials Align with Submitted Data

Words that Drive Data

- Outperforms
- Exceeds
- Superior
- Lowest profile
- Least
- Surpasses
- Faster
- Unmatched
- Most
- Optimal

Understanding the Different Stakeholders

Patient

Patient being treated by physicians, nurses, etc.

Physician

Treating doctor

Nurse

Support staff and follow-up

Technician

Support staff

Hospital Administrator

HR and Operations, Decision Makers on new Technology

Purchasing

Contracts, cost containment

Staff

Room cleaning, sterilization, equipment processing, storage

User

Physician, nurse, technician

Critical Component of Commercial Viability

Claims Matrix

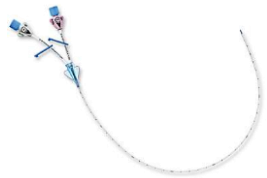
Stakeholder / Benefactor	Claim	Post Market Benefit / Marketing Statements	Evidence to Support
Physician	EP Mapping System A single solution for Electrophysiologists, Intracardiac Stimulator, EP Recording and an Electroanatomical Mapping System all in one.	Simplification, one interface, one keyboard, one mouse	Design Validation
Hospital Administration / Staff	EP Mapping System A single solution for Electrophysiologists, Intracardiac Stimulator, EP Recording and an Electroanatomical Mapping System all in one.	Reduced accessory re-orders / reduced inventory / reduced storage space	Accessory list comparison
Patient, Physician, Nurse, Technician, Clinic Staff	Steerable Lung Biopsy Needle Unidirectional steering capable of 360-degree rotation and 70-degree articulation	Flexible shaft design and articulation enable device to navigate reach all segments of the lungs.	Design Verification Publications
Patient, User	Coated PICC Reduced Thrombus formation	Less thrombus → fewer replacements	Blood Loop Study

Examples

	Indication:	Claim:	This Allows…
 **QXMédical Boosting Catheter**	Indication for injection of procedural fluids	Only guide extension catheter with that indication ***(So What… They all do it)***	**This allow sales to lock out competition on tenders and contracts in some cases**
 **CSI Diamondback Orbital Atherectomy System**	Indication for severely calcified lesions	Orbiting crown enables simultaneous modification of both intimal and medial calcium for **optimal** stent delivery, expansion and apposition in severely calcified lesions.	**This allows them to attack, head-on, any competitor claiming to remove calcium in intimal and medial tissue.**
 **Medtronic Guardian CGMS**	Predictive alerts up to 60 seconds in advance	**Sensor sends predictive alarms when patient is outside normal range, addressing nighttime low blood glucose levels**	**Market research revealed that this was the #1 feature** that parents of T1 diabetic children(largest initial market) most valued, significantly out pacing the other features

Advertising and Promotion → Market Differentiator → Commercial Viability

Examples

	Indicator:	Claim:	This Allows…
 **Zeus PICC**	Indication for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media,	Reduced thrombosis formation on the device	**This allows the marketing to promote reduced thrombus**
 **AEQUALIS FLEX REVIVE Shoulder System**	Indication for replacement of the shoulder joint to reduce pain and improve shoulder mobility	Address unique anatomies and **convertible** between anatomic and reversed configurations	**This allows the use of one device for shoulder replacement and the same device for revisions**
 **Shockwave Javelin**	Indication for lithotripsy-enabled modification and crossing of calcified lesions in the peripheral vasculature, prior to final treatment	It's all about speed **same great treatment in half the time**	**This allows marketing to address the time needed for treatment (physician, staff and room time)**

Advertising and Promotion → Market Differentiator → Commercial Viability

Conclusion

Marketing & Regulatory Critical Components Of Commercial Viability

- Understand the “4 P’s”
- Assess the portfolio alignment
- Develop the claims and test plan to support them early on
- Consider the stakeholders
- Construct a claims matrix

How Do I Get Paid?:
Unlocking The Coding, Coverage and Reimbursement Mystery

Jay Stracke

November 20, 2024

Introduction – Jay Stracke

Jay Stracke

Health Care Finance, Economics and Policy Specialist > 30 yrs. experience

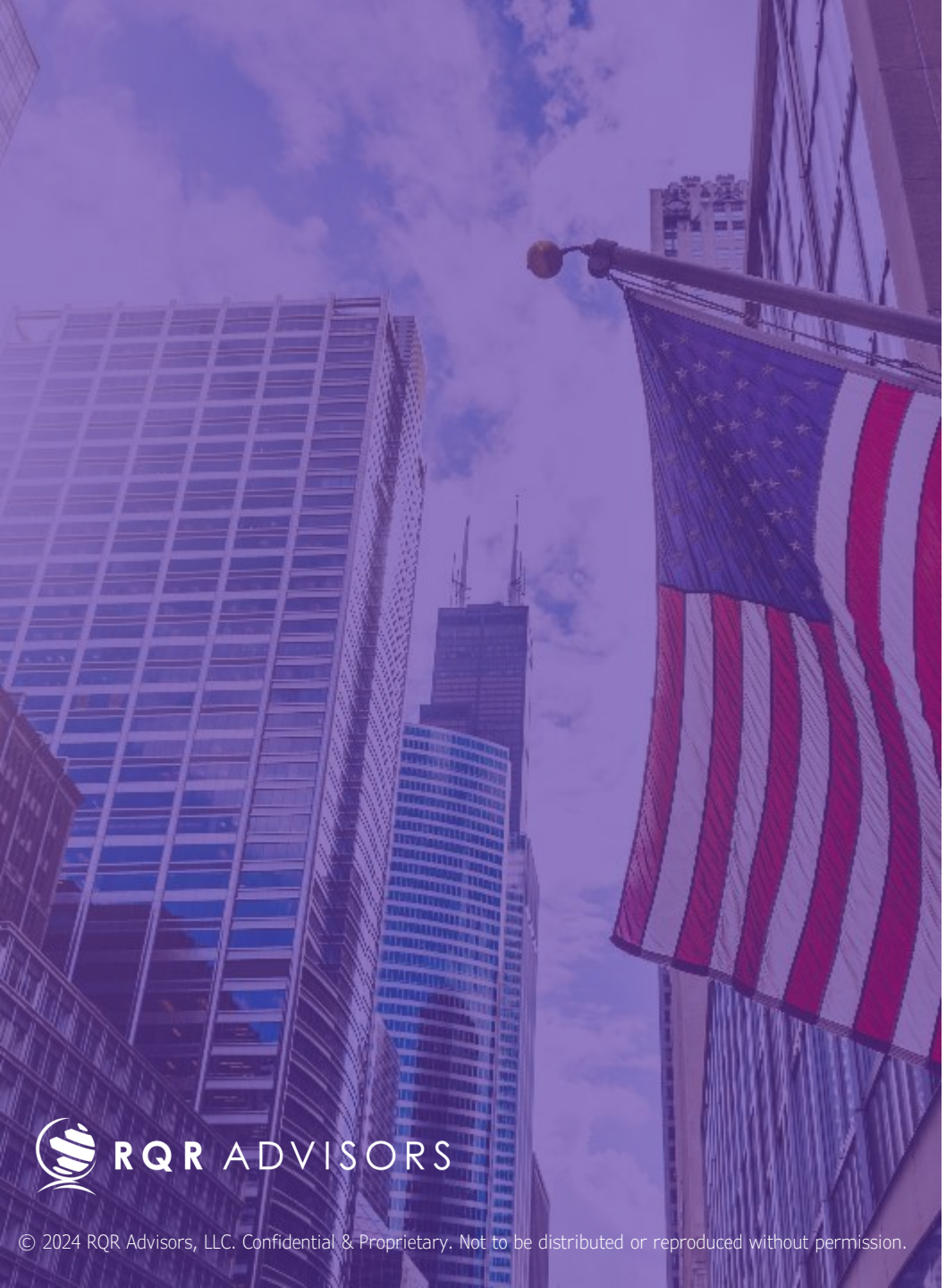
Experience:

Federal Government

- *Staff to Secretary of Dept of Health*
- *CMS, Medicare Advantage startup team*
- *Medicare trust fund budget analyst*

Medical Technology Companies

- *Led Global and US Health Economics teams for large and small companies*
- *Private consulting practice, new technologies*



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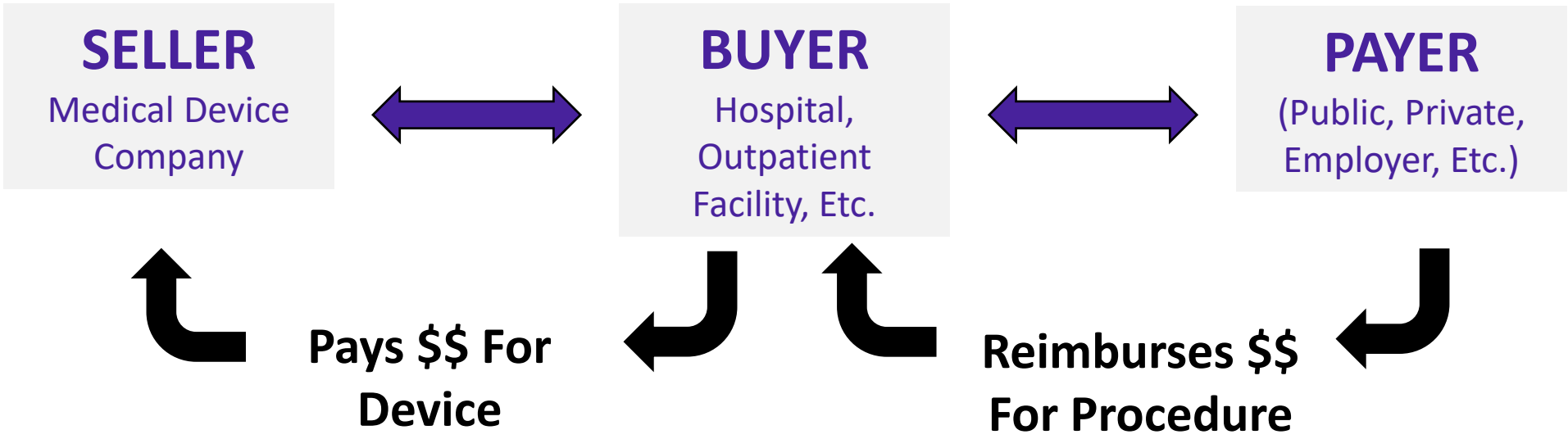
Discussion Outline

- Govt. vs Private Payers
- The Payer Business Model
- Commercial Viability
- New Technology Planning

Basic Money Flow?

ALL STAKEHOLDERS ARE BUSINESSES? *(except Govt Payers)*



Medical device companies must know if, and how insurance plans will reimburse providers for procedures that use your device?

Government Payers

MEDICARE

1.45% Income Tax
+ $175 month per member

66 Million People
(age 65+ or disabled) & paid Medicare income tax for at least 10 years)

Comprehensive Benefits
Minor copays

No Budget

Two Options
(annual decision)

1. TRADITIONAL MEDICARE

Go to any provider

No prior authorization for services

2. MEDICARE ADVANTAGE

Sign up with private health plan

Get all Medicare benefits +

Go to smaller network of providers

Follow private health plan rules

Private Payers

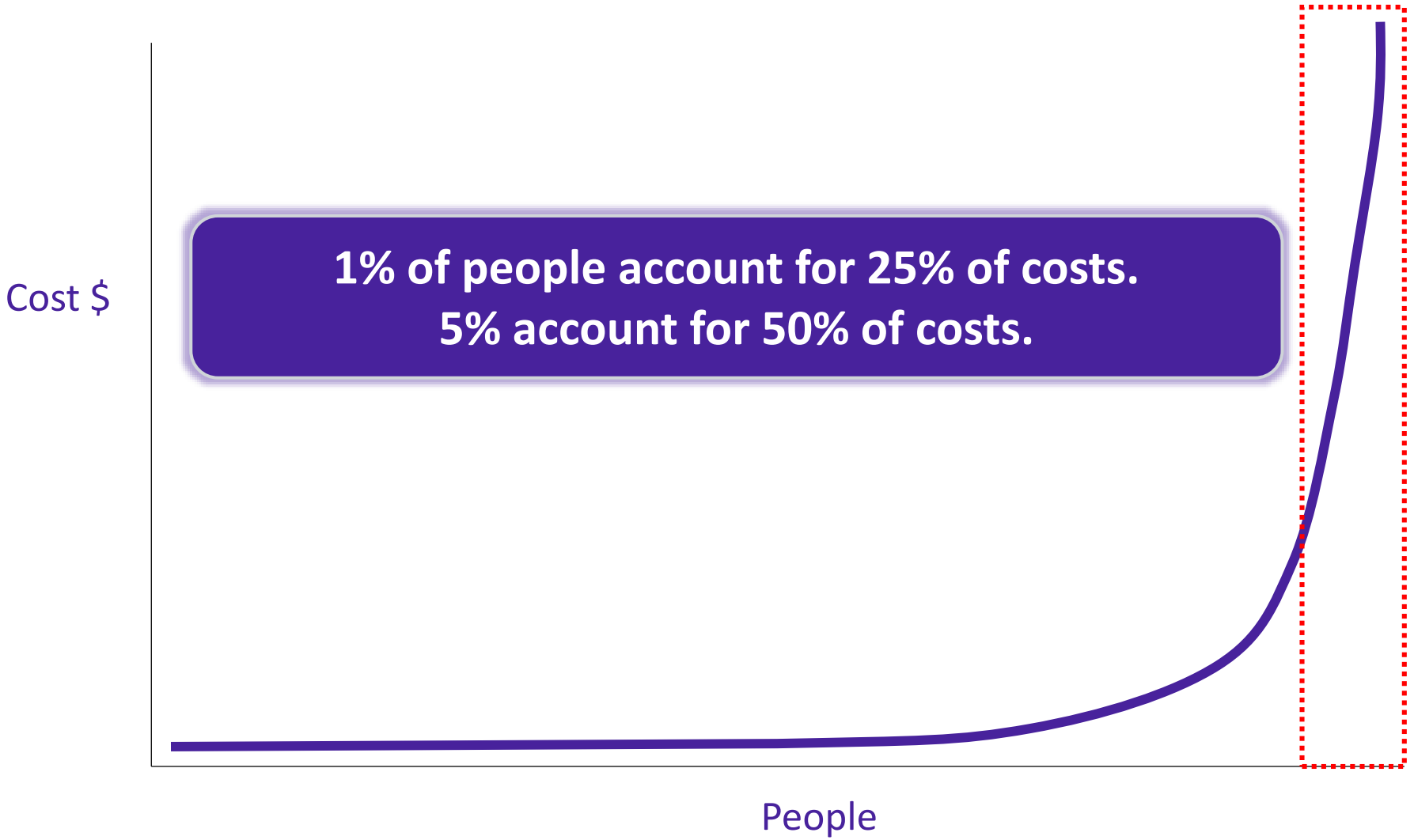
- Very large companies (top 5 - 80% of market)
- Volume business; ~ 13 percent gross margin, 2-3% profit
- They do have a budget! AND shareholders!
- Tough negotiators – but pay providers more in some cases

If you have a commercially viable product (i.e. have done your homework), most reimbursement work you need to do will be with Medicare

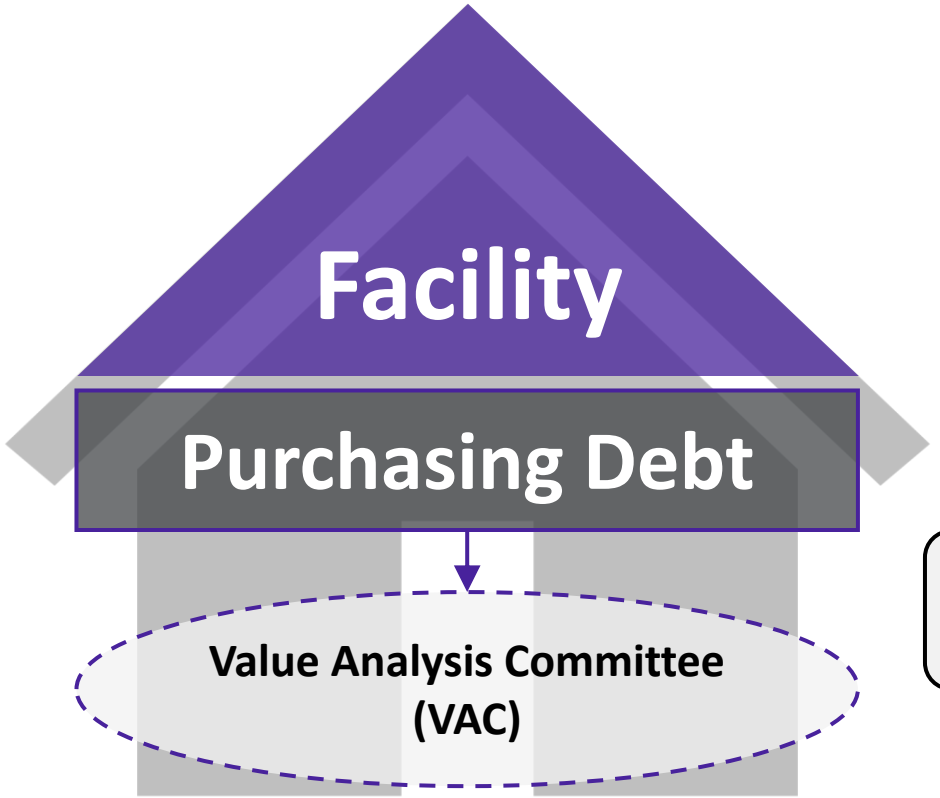
Basic business model

- Product = health plan (package of covered benefits)
- Primary customers = employer groups
- Annual product release.
- Sign up members (hope there are lots of them and they are healthy)
- Monitor cost and influence where possible– hope they hit earnings!

Basic Law of Insurance



Buyers – What's on their mind?



Physician preference item or a real differentiator?

What's the lowest price?

Really necessary?

WILL WE GET REIMBURSED FROM INSURANCE COMPANIES?

Does it work? Evidence?

Other companies have something similar? Compare?

Impact compliance with existing agreements?

Require us to work with more vendors?

Very Complex Reimbursement Systems

Fee-For-Service Based

1. Physician Services / In-Clinic
2. Acute Care (Inpatient) Hospital
3. Outpatient Hospital
4. Outpatient (Non-Hospital)
5. Skilled Nursing Facility
6. Home Health Care
7. Durable Medical Equipment
8. Long Term Care

Performance Based Adjustments

A. Value Based Purchasing Modifiers

B. Hospital Readmission Reduction

C. Physician Merit Incentives Payment

D. Shared Risk and Savings Programs

New Technology Supplements

I. New or Improved fee-for-service payments

II. New Technology Add-on Payment (NTAP)**

III. New Technology DRG, APC

IV. Transitional Coverage Emerging Technology (TCET)

Basic Components of Reimbursement

COVERAGE + CODING + PAYMENT = REIMBURSEMENT

1. ***Is it a covered procedure (insured under patient's health plan)?***

2. ***Are appropriate billing code(s) in place to track procedure and submit a claim for payment?***

3. ***Are existing payment rates adequate to cover costs of new technology?***

All 3 required for reimbursement

1. COVERAGE

Payers	Source	Criteria	Decision Makers	Key Influences	Oversight	Data
Public	Laws, Regs Natl and local coverage decision policies	reasonable and necessary (not cost)	CMS Coverage Group, State Medicaid Agencies	MedCAC, Regional medical directors, published evidence, KOLs	Claims review, post payment audits	Published evidence; clinical trials raw data
Private	payer-employer Contract, corporate and health plan policies	medical necessity, cost, other	Chief Medical Officer, Utilization Review, Claims Review	MedCAC, BCBS TEC, HTAs (ECRI, Hayes), published evidence, treating physicians in network	Prior auth; claims review, post payment audits	HTAs, published evidence, some cost?

High volume, is not delivering expected outcomes, and/or is a significant cost outlier – Proceed with Caution

2. CODING: Types of Billing Codes

	Defines	Owner	Decision Maker(s)	Stakeholders	Process	Tracks to Payment
CPT	Physician Procedure (permanent, temporary)	AMA	CPT Editorial Panel	Physician specialty societies	2-3 yrs +.	Physician Fee Schedule
HCPCS	Outpatient Facility Procedure, (+ Drugs, Biologics, Misc.)	CMS	CMS	Physician experts, payers	1-2 yr.	APC
ICD-10 PCS	Inpatient Hospital Procedure	CMS	ICD-10 C&M Committee	CMS, AHA	1-2 yrs	DRG
ICD-10 CM (Intl)	Patient Diagnosis	CDC, NHCS	CDC, Intl Stds	CDC	2+ yrs	DRG
C-Code	Medical Device *(if used in outpatient)*	CMS	CMS	CMS	6 month.	NONE Tracking only

Codes are used to track and bill for procedures. Each one involves a separate process, data and stakeholder alignment

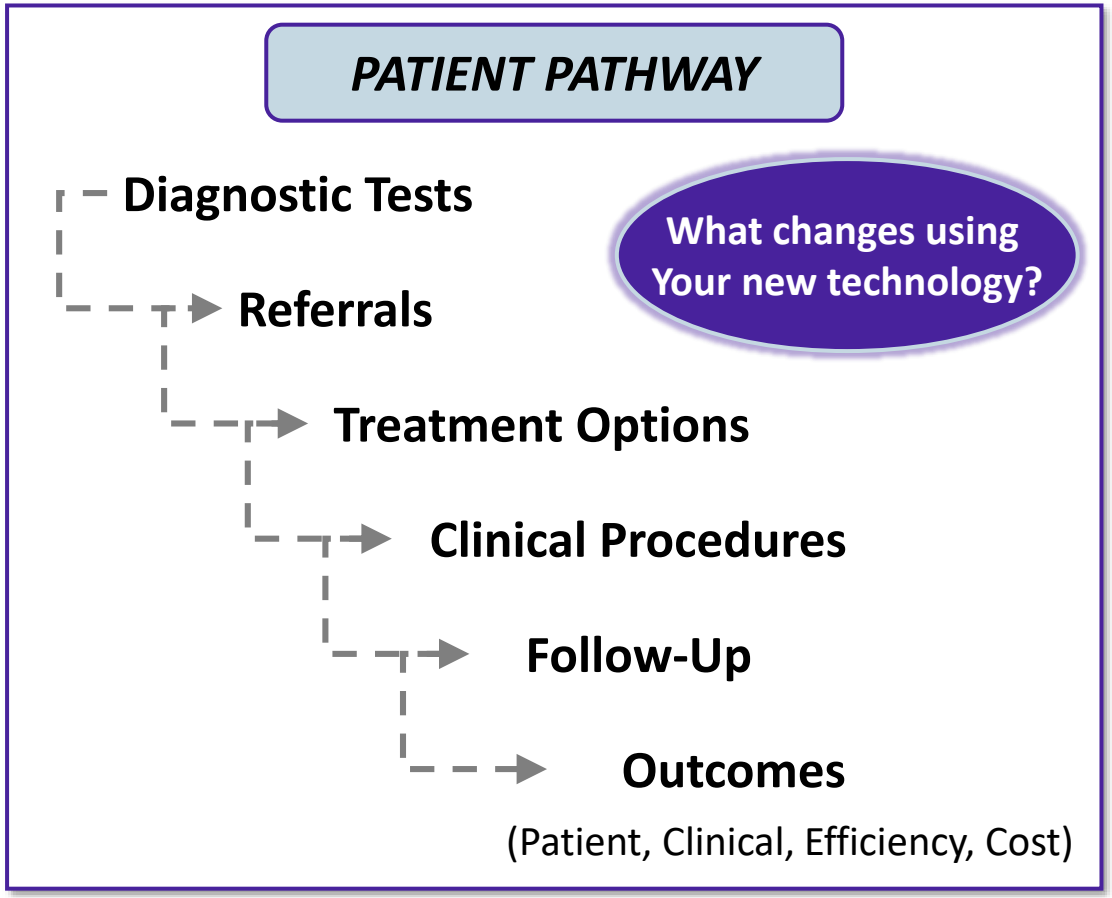
3. PAYMENTS: Prospective fees + Performance Adjustments

	Defines	Data	Payments
Physician Fees	Individual payment for each CPT code (fee schedule). Lots of rules.	Physician Surveys: Physician work, practice expensive, malpractice insurance	Common to have multiple fees per procedure (with discounts). Lots of rule.
Outpatient	Bundled payment. Ambulatory Payment Classification (APCs)	Cost (hospital charges). *Cost of medical device tracked separately**	One or more APCs paid per procedure. Small items bundled.
Inpatient Hospital	Diagnosis Related Group (DRG)	Cost (hospital charges), patient conditions	One DRG payment per admission.
Performance Based Payments	Variety of performance incentives in place. Can result in pay adjustments.	Reporting. compliance, relative performance to peers, some risk sharing on cost of care.	Typically end of year bonus pools, or fee-based adjustments. Some risk sharing.

Health insurance payment mechanisms are cost based. If your device does not increase costs for providers, the payment rate will not be higher.

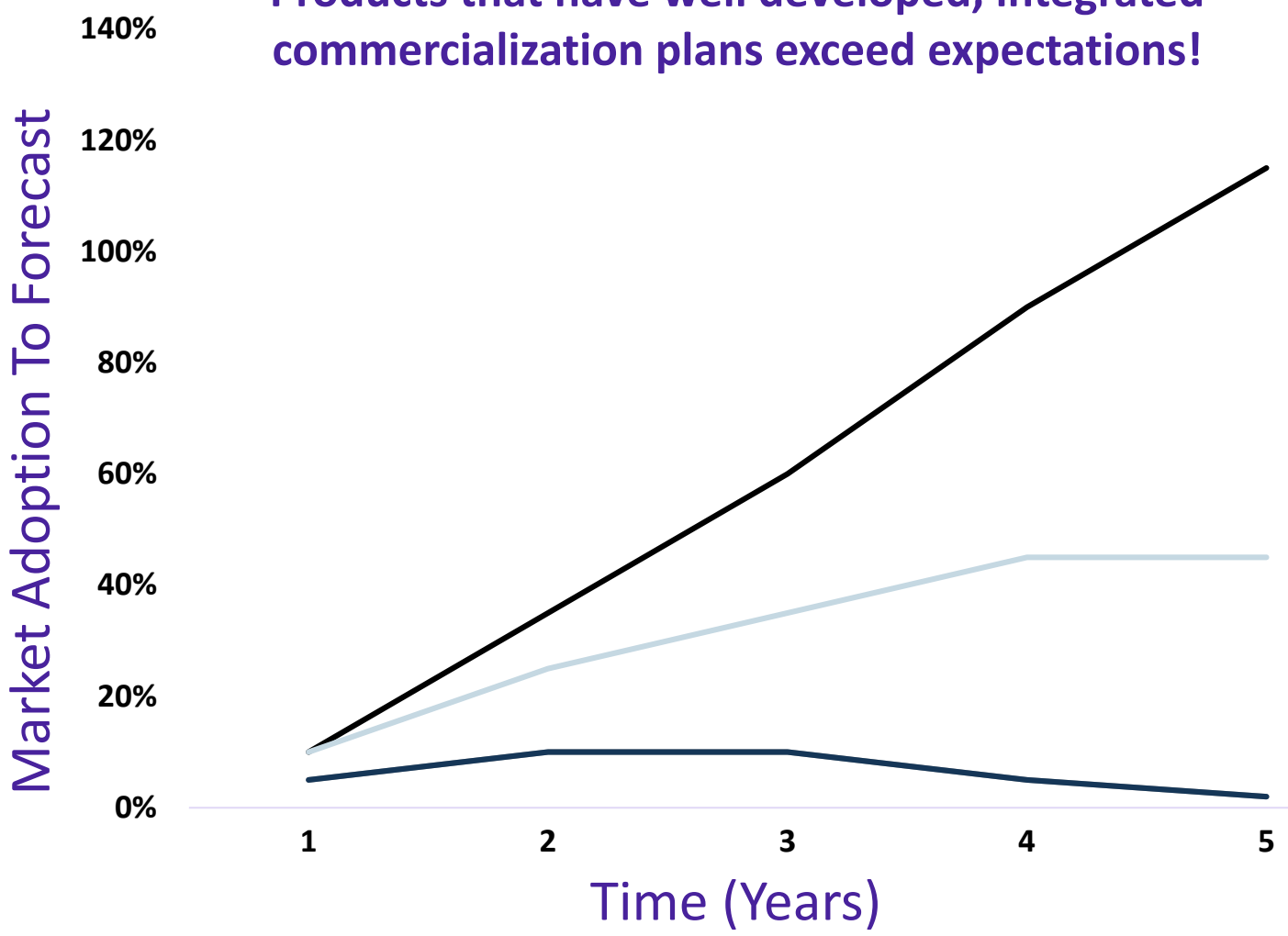
Key Questions *(early phase)*

1. What is it and what does it do?
2. What is the problem / unmet need?
3. New or ‘me too’?
4. Who will use it?
5. Where will it be used?
6. Intended benefits?
7. Target outcomes?



Reimbursement can make or break your forecast

Products that have well developed, integrated commercialization plans exceed expectations!



Above Average Reimbursement

- *Clear plan and evidence-based value messages*

Some Reimbursement

- *Weak plan, reactive strategies, learn as you go*

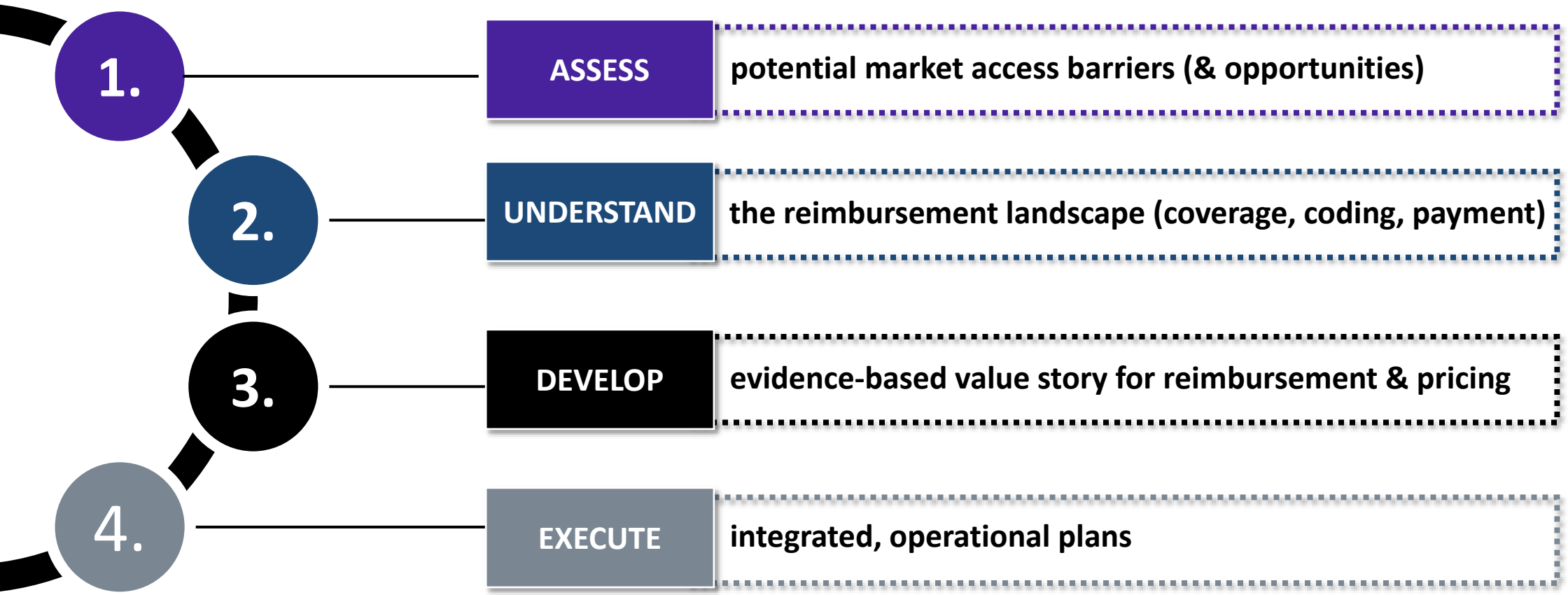
Poor Reimbursement

- *No Solutions*

Do You Need Economic Data?

1. If there's **SOLID** evidence, use it. Otherwise, don't rely on it.
2. Focus on **DIFFERENCES** in cost or revenue (compare to std of care)
3. Short term is **MUCH** better than long term.
4. Economic research is **MODEL BASED**, not a clinical study endpoint.
5. Payers have a gold mine of retrospective data. **USE IT**.
6. Everyone has a perspective. And **ONLY** theirs matters!

Reimbursement & Health Economics Planning



Reimbursement and health economics needs to be an integral part of developing a product commercialization plan!

RQR ADVISORS

Founder Law & Economics:
Practical Tools for Value Creation

James Joslin

November 20, 2024

Introduction

James Joslin

General Counsel & Secretary, RQR Advisors

Experience:

- 28 years practicing law and advising companies around the globe
- ***Kirkland & Ellis LLP***, partner in 3,000+ lawyer international law firm, with life science, IP, private equity, and litigation responsibilities
- ***Honeywell International Inc.,*** general counsel of $2B+ business unit; chief litigation counsel for $17B+ business group
- ***Abbott Labs,*** member of legal team responsible for portfolio of life science products and technologies

“What Could Possibly Go Wrong?”

-- Eddie (the Enthusiastic) Entrepreneur

Answer:

. . . EVERYTHING!!!

BUT IT DOESN'T HAVE TO

First Things First: The Shareholder Agreement and Cap Table

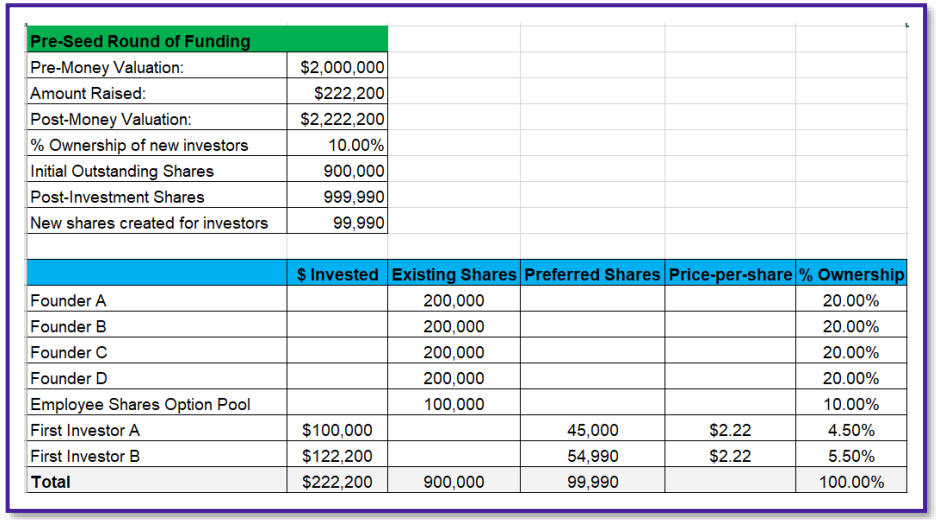
A capitalization table ("cap table") tracks who owns how much of a company

- How much equity does each founder own?
- Who owns what types of equity?
- What is the valuation?

A powerful planning tool for future capital raises

- Run "what-if" scenarios for future financing rounds
- Evaluate impact of issuing convertible debt, warrants, etc.
- Analyze potential exit scenarios

Example Cap Table



Pre-Seed Round of Funding	
Pre-Money Valuation:	$2,000,000
Amount Raised:	$222,200
Post-Money Valuation:	$2,222,200
% Ownership of new investors	10.00%
Initial Outstanding Shares	900,000
Post-Investment Shares	999,990
New shares created for investors	99,990

	$ Invested	Existing Shares	Preferred Shares	Price-per-share	% Ownership
Founder A		200,000			20.00%
Founder B		200,000			20.00%
Founder C		200,000			20.00%
Founder D		200,000			20.00%
Employee Shares Option Pool		100,000			10.00%
First Investor A	$100,000		45,000	$2.22	4.50%
First Investor B	$122,200		54,990	$2.22	5.50%
Total	$222,200	900,000	99,990		100.00%

The Shareholder Agreement

"A (Flexible) Contract"

Who Is On The Cap Table?

Examples of Shareholders

- Founders
- Government / University Funds
- Friends & Family
- High Net-Worth Individuals
- Family Offices
- Venture Capital
- Strategic Companies

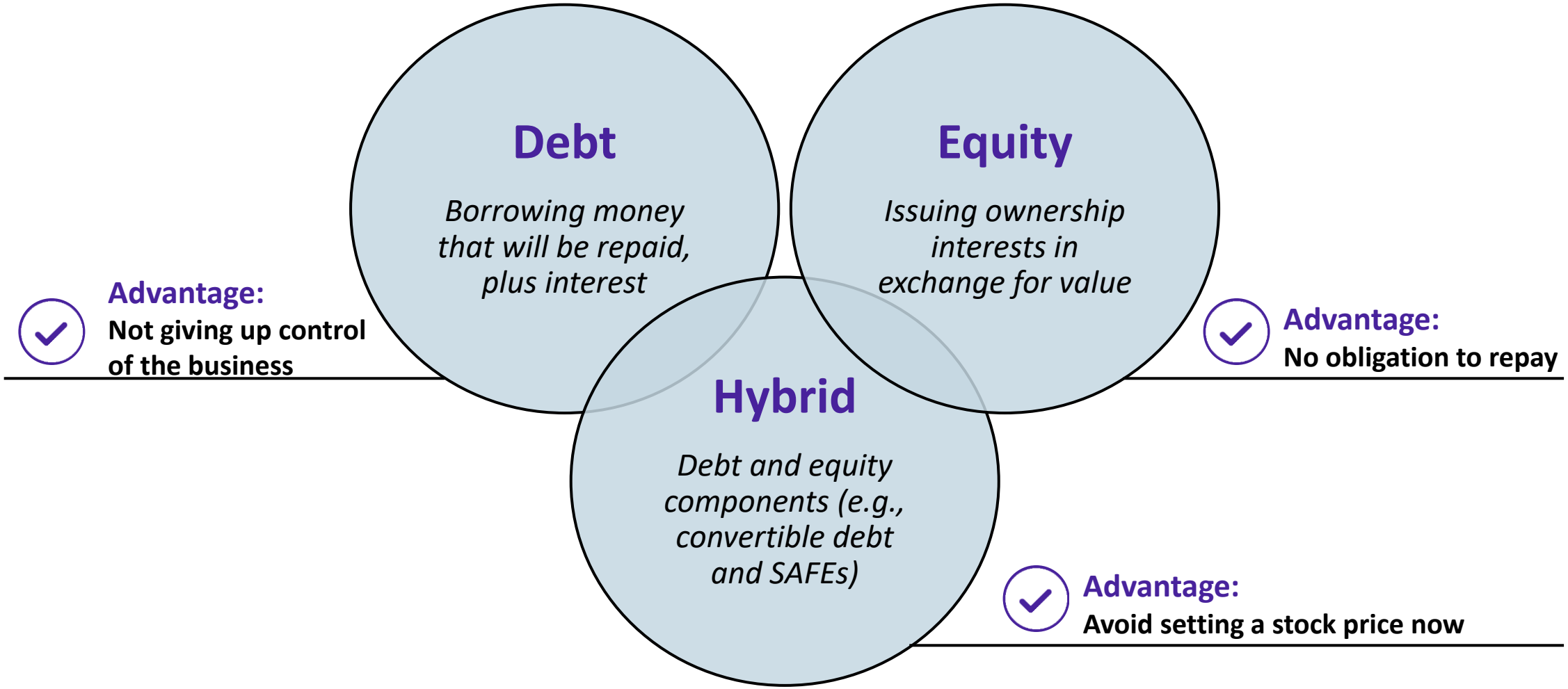
Example Cap Table

Stockholder (A)	Common Stock (B)	Series Seed-1 Preferred Stock (B)	Series Seed-2 Preferred Stock (B)	Series A Preferred Stock (B)	Total Shares	Fully-Diluted %
Founder A	1,000,000	-	-	-	1,000,000	23.63%
Founder B	1,000,000	-	-	-	1,000,000	23.63%
Angel Investor A	-	150,000	-	-	150,000	3.54%
Angel Investor B	-	-	450,000	-	450,000	10.63%
VC Investor	-	-	-	544,186	544,186	12.86%
Institutional Investor	-	-	-	302,325	302,325	7.14%
Other Investor				241,860	241,860	5.71%
SPV	-	-	-	120,930	120,930	2.86%
Option Pool (C)						
Options Issued	-	-	-	-	-	0.00%
Shares Available	423,256	-	-	-	423,256	10.00%
Totals	**2,423,256**	**150,000**	**450,000**	**1,209,301**	**4,232,557**	**100.00%**

(D)

Series A Financing Details		
Pre-Money Valuation	$	5,000,000.00
Pre-Money Capitalization		3,023,256
Investment	$	2,000,000.00
Post-Money Valuation	$	7,000,000.00
Series A Price per Share	**$**	**1.65385**

How Should We Finance the Company?



Valuation and Price-Per-Share

"Valuation"

The value an investor ascribes to the company

- ***Pre-Money Valuation** = Value of the company, prior to investment*
- ***Post-Money Valuation**= Pre-Money Valuation + Investment*

"PPS"

The price an investor is paying to purchase the stock

Investors issued shares of stock based on amount of their investment

Who Is On Your (Advisory) Board?

Diversity is key!

- Your board should reflect the range of stakeholders
- Diverse boards comprised of a variety of ages, ethnicities, genders, skills, experiences, competencies, philosophies, education, races, religions, etc.

Experienced Leaders

- As executives at small or large companies or leaders in finance, academia, etc.

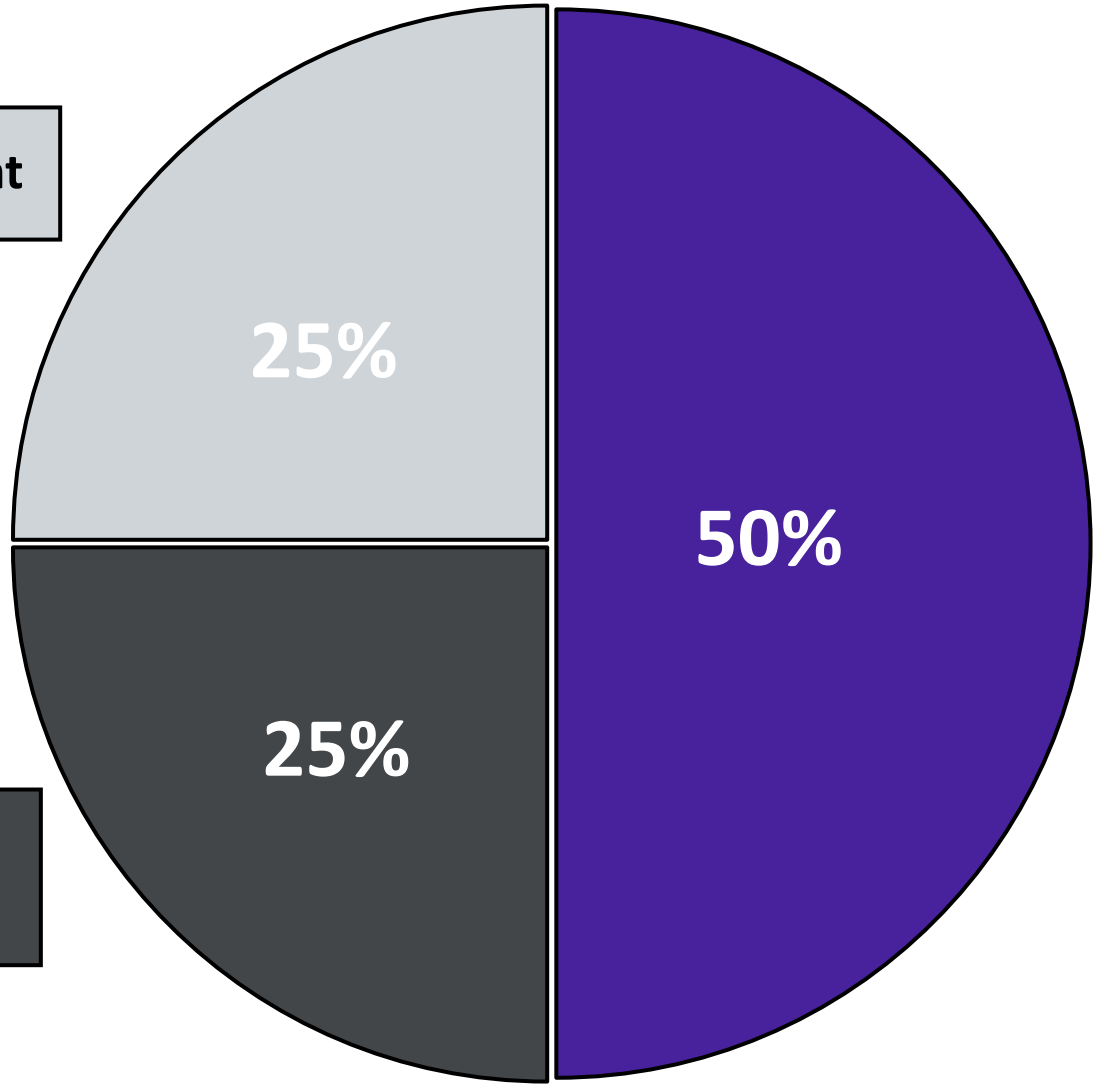
Strong networks

- Ability to fundraise, make introductions, etc.

Committed to the company

- Shown in various ways, such as regular meeting attendance, financial support, etc.

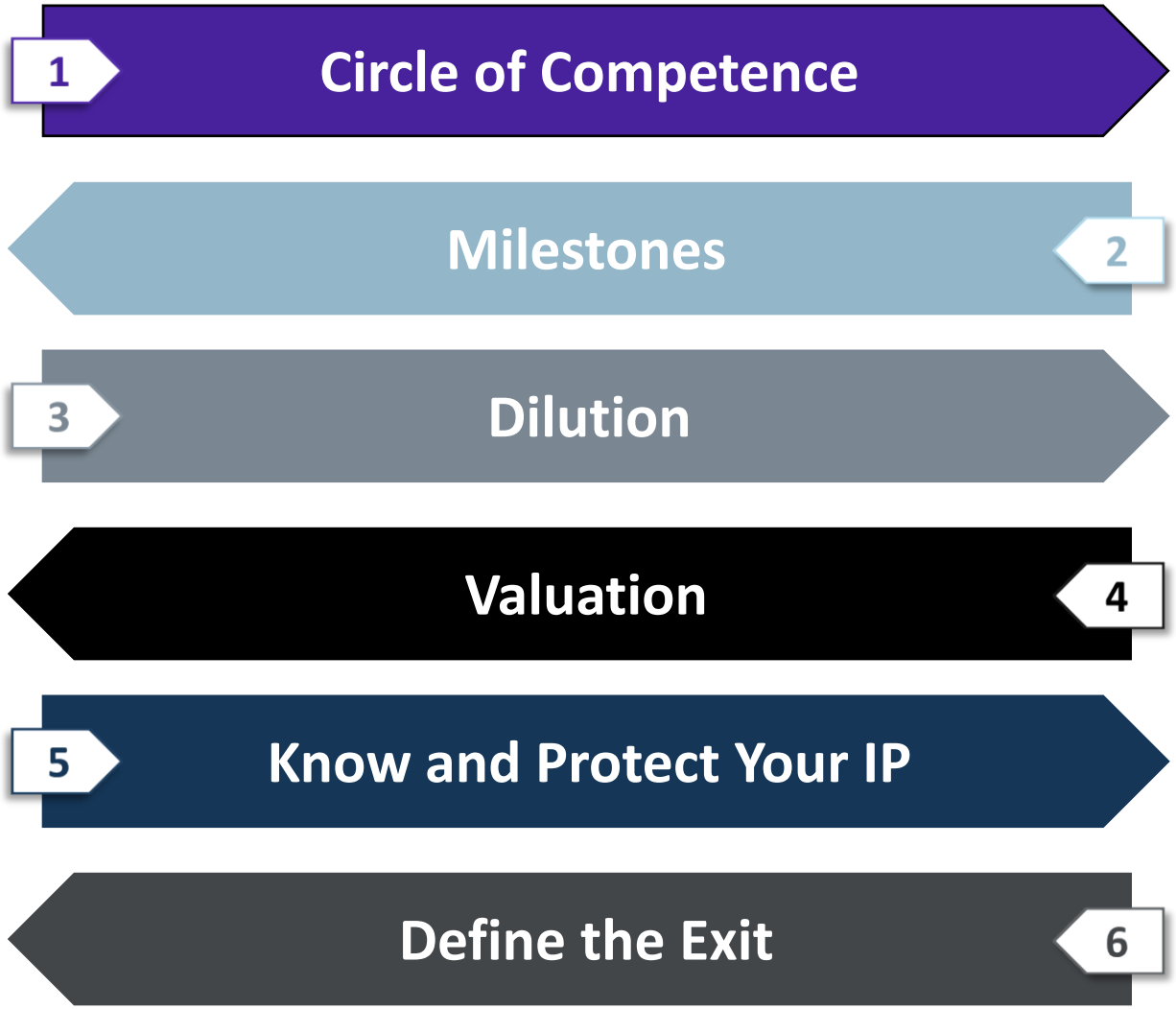
CEO Roles & Responsibilities



The “Investment Case” (NOT “Pitch Deck”) Essentials

- Our invention/technology solves a ***compelling unmet need***
- We’ve ***hit our milestones*** with efficient use of human and financial capital
- We’ve ***protected our invention*** with ***robust IP*** and created significant ***barriers to entry***
- We need ***€ XXX*** to reach our ***next value creation milestone***
- We anticipate XXX ***additional value creation milestones***
- We have an ***exit plan (“strategic value” / ”portfolio alignment”)***

Founder Financial Essentials



Founder Financial Essential #1

1. Circle of Competence
2. Milestones
3. Dilution
4. Valuation
5. Know and Protect Your IP
6. Define the Exit

Circle of Competence

Understand your circle of competence first. Respect the **importance of outside expertise** and the value they create.

Founder Financial Essential #2

Milestones

Understand what the next value creation milestone is. Respect **the importance of overfunding** and the value it will preserve versus being underfunded.

Founder Financial Essential #3

Dilution

Focus on **creating value versus arguing a percentage** of ownership. Wealth is not measured with a percent; it is measured with currency. Do not confuse the two.

Founder Financial Incentive #4

Valuation

Understand the investor perspective. An investor expects a **defined multiple of invested capital** and their ownership percentage should reflect exit value.

Founder Financial Incentive #5

Know and Protect your IP

Cover your invention, its applications and extensions, and obtain guidance on your freedom to practice.

Founder Financial Incentive #6

Define the Exit

Be able to communicate to investors the exit. They already understand the risk, they want to know the **when, why, and how much**.

Founder Financial Essentials