

Complexity of the US Market

Accessing the US market in an integrated way:
clinical trials, regulatory strategy and
reimbursement



US medical product ecosystem

Regulatory considerations and
business strategy

Getting the right focus on health
economics and reimbursement

Approaches to integration

Impact of evidence

US medical product ecosystem

Regulatory considerations and business strategy

Getting the right focus on health economics and reimbursement

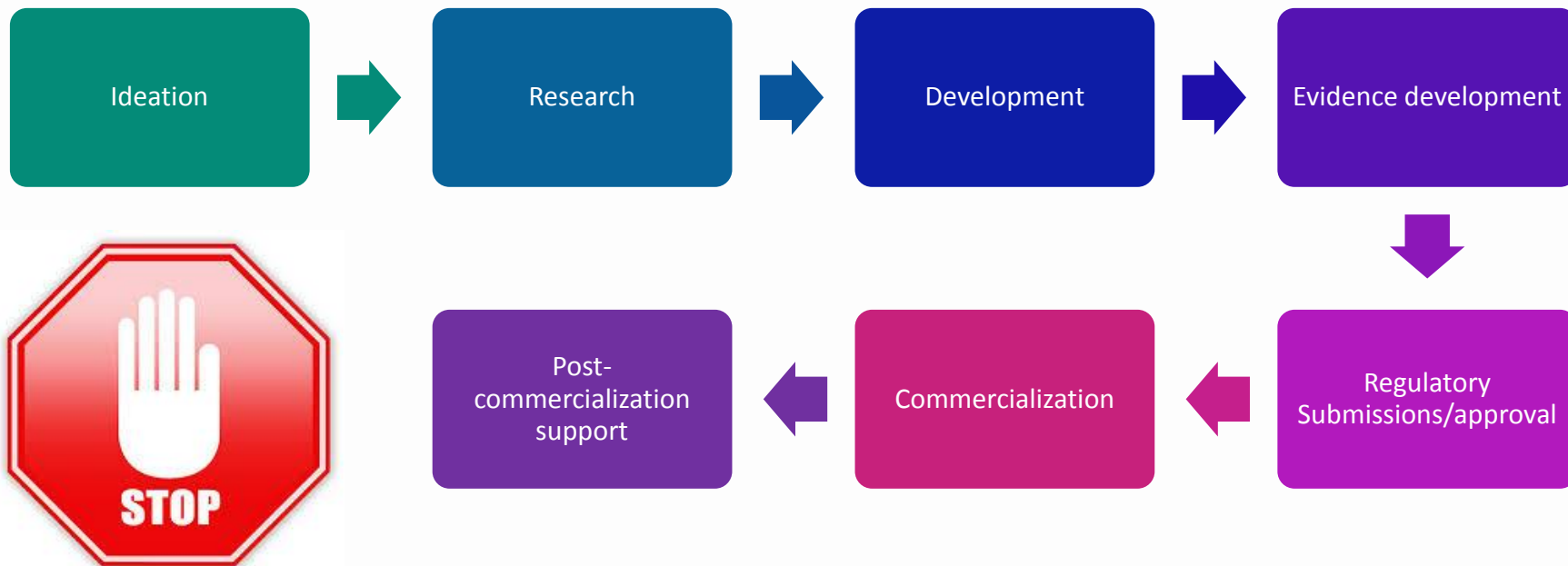
Approaches to integration

Impact of evidence



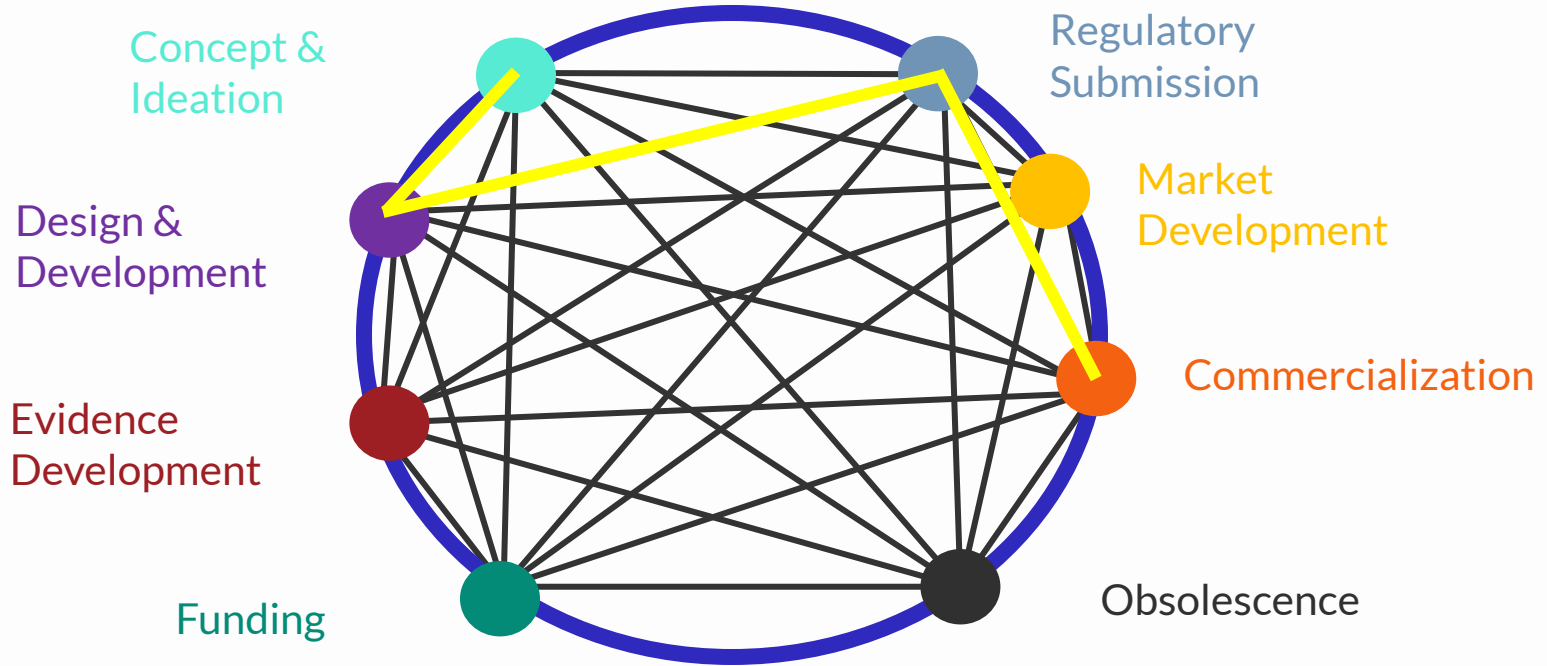
Medical product development in the US

Most manufacturers plan in a linear fashion.....



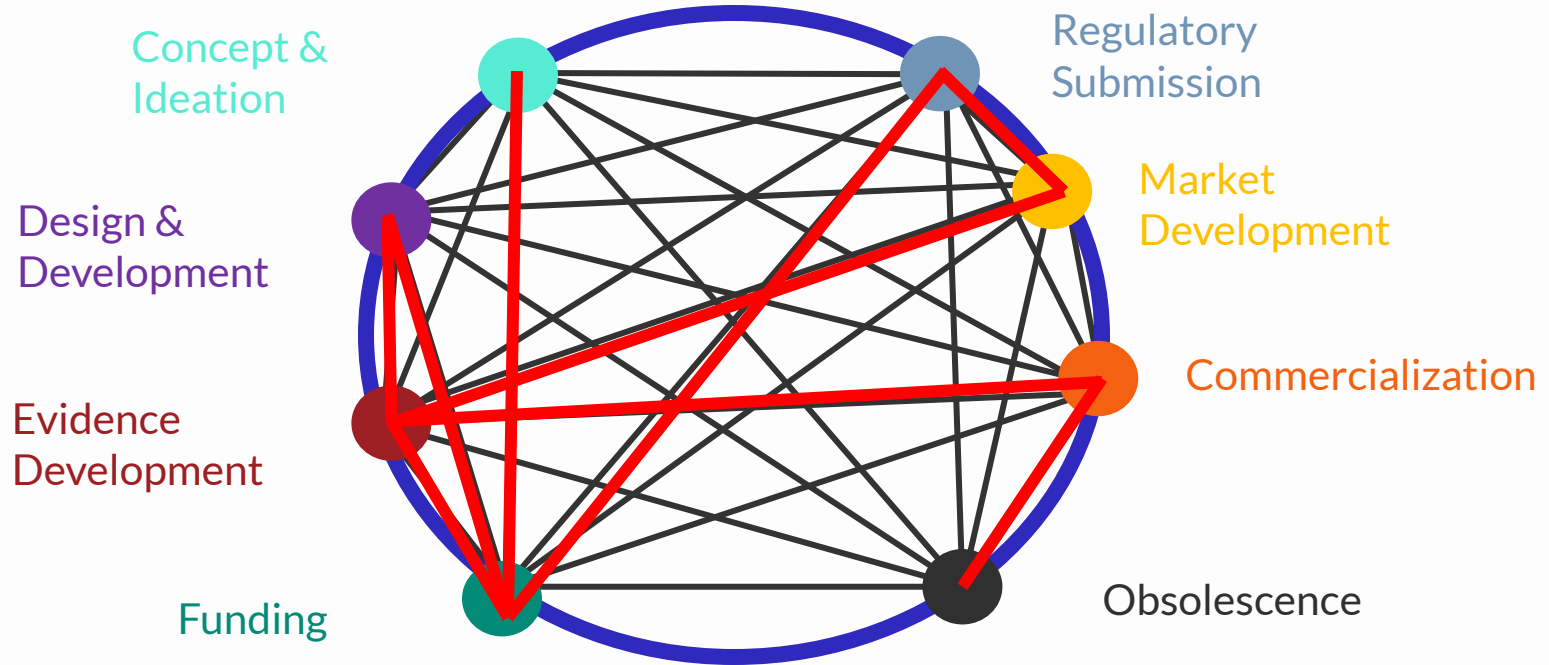
Medical product development in the US

...but actual development is interconnected and iterative



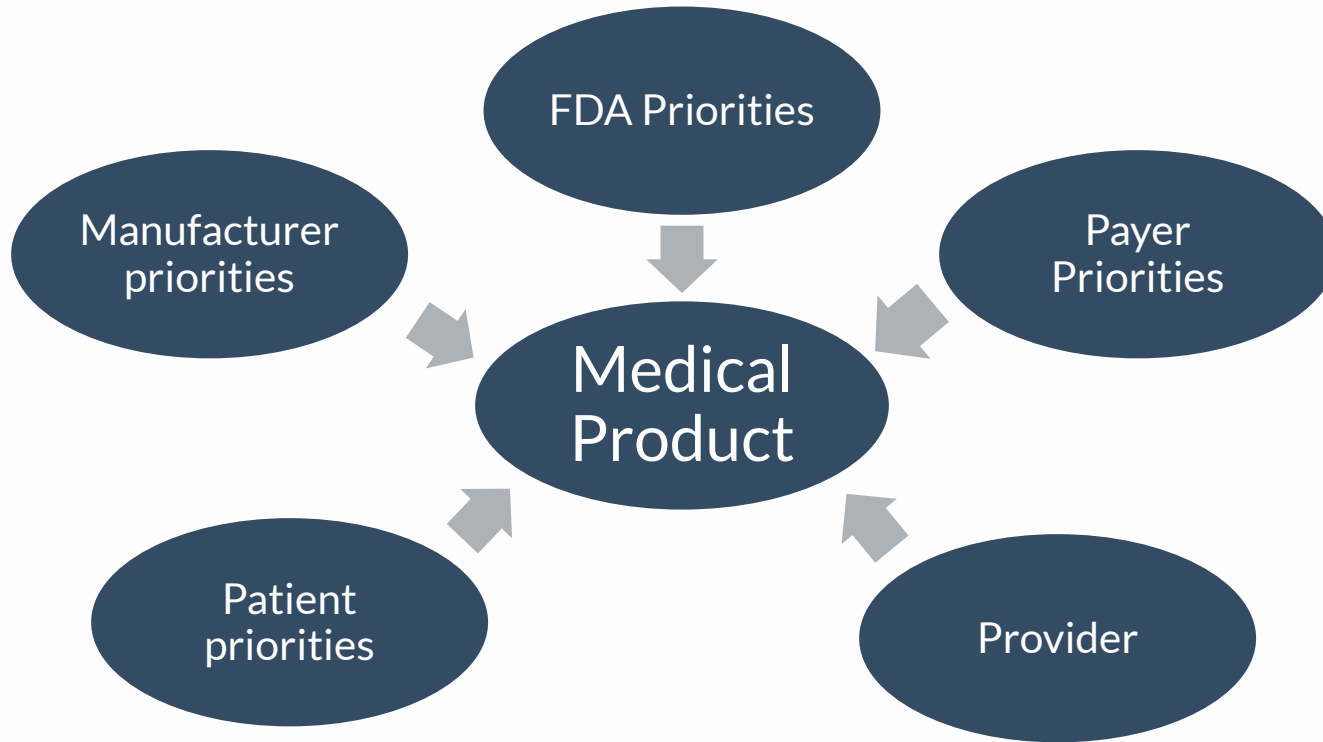
Medical product development in the US

...but actual development is interconnected and iterative



Factors impacting complexity

Conflicting priorities



Why tackle the US market

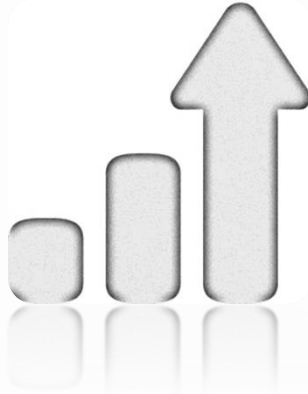
\$10,345

average spent
per person

\$3.3 trillion

spent on healthcare

27% increase in aging
population by 2050



Reclassification

of devices driven by the MDR

Increased

clinical evidence
requirements by the MDR



US medical product ecosystem

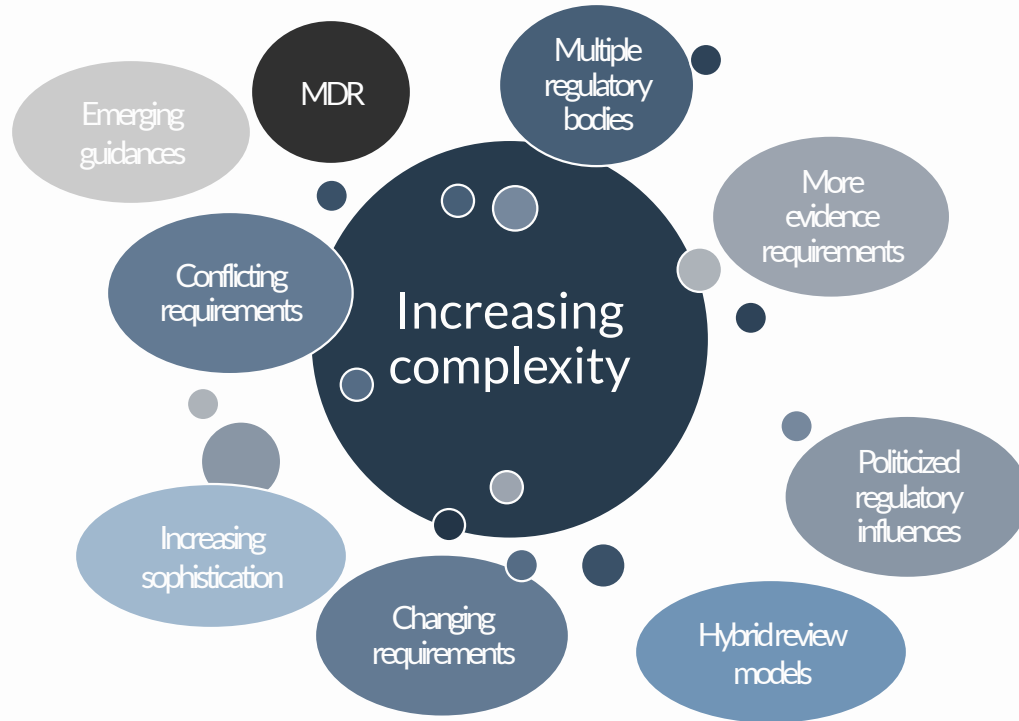
Regulatory considerations and
business strategy

Getting the right focus on health
economics and reimbursement

Approaches to integration

Impact of evidence

Regulatory environment



Business success, product development & regulatory considerations

Product development in a regulated ecosystem has complexities that impact business goals



- Without regulatory approval, sales are not possible
- Some geographies have favorable regulatory pathways but poor market size
- EU is not necessarily fastest path to market post-MDR implementation
- Regulatory pathway can impact reimbursement and hence end user attractiveness

Navigating forward





US medical product ecosystem

Regulatory considerations and
business strategy

Getting the right focus on health
economics and reimbursement

Approaches to integration

Impact of evidence

Clinical vs. Economic Value Analysis

Fundamental difference in stakeholder viewpoints drive fundamental differences in behaviors

Clinical Effectiveness

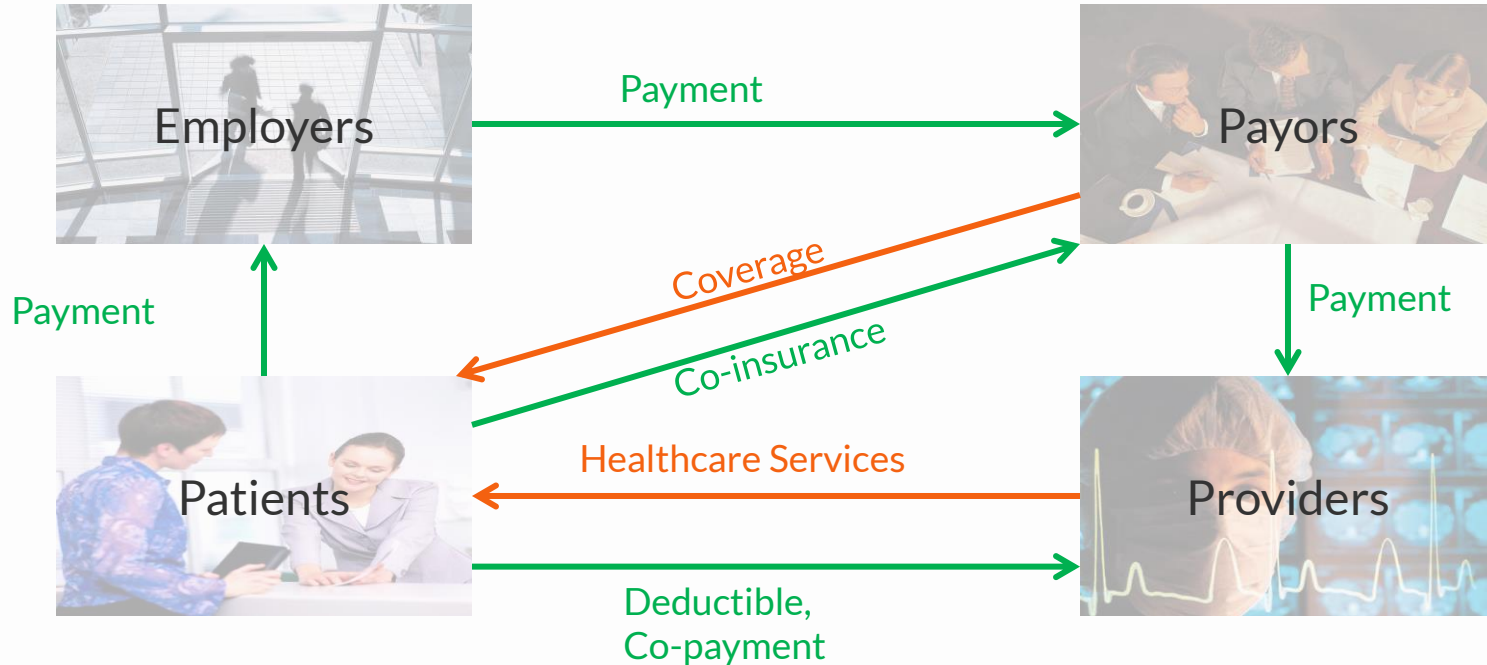
- How well does the course of action **work** (device, procedure, etc.) compared to the standard of care? What alternatives are available?

Cost Effectiveness

- How much does this course of action **cost** compared to standard practice?

Healthcare delivery system interactions

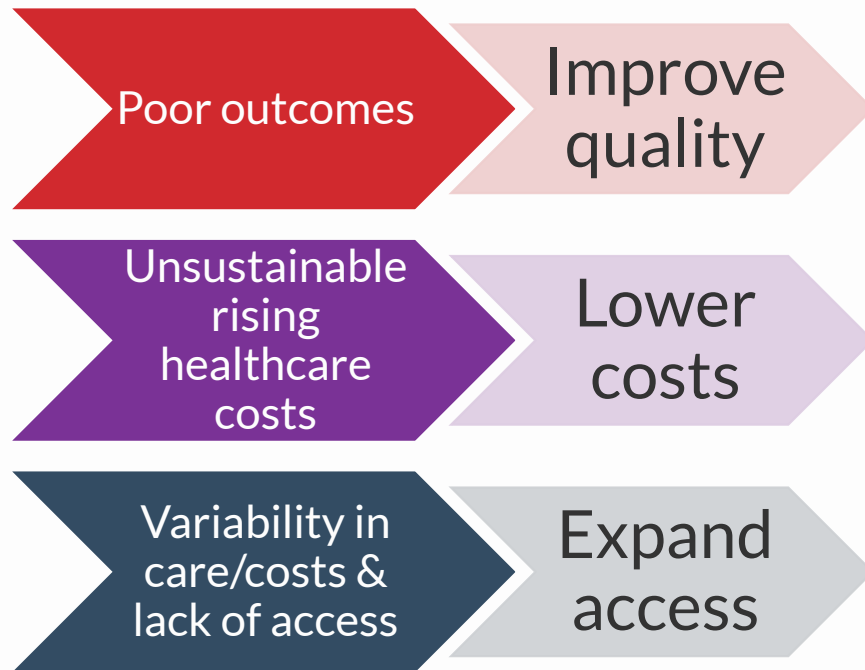
Fee for service, volume based payment drivers behavior



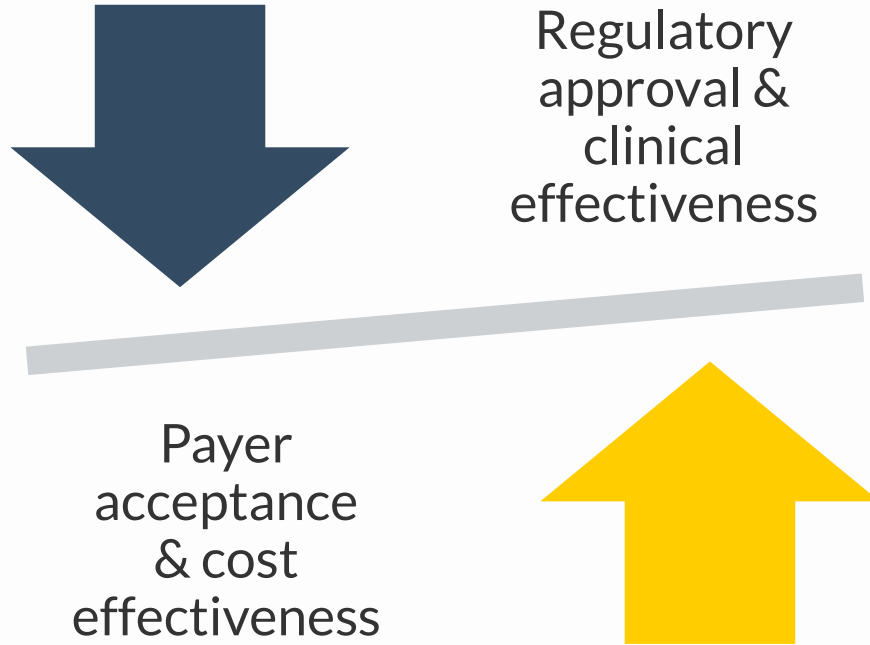
Value-driven healthcare

Shortcomings in the system are driving change

Underperformance in 3 key areas is driving change in the healthcare delivery system



Evidence in value-driven healthcare

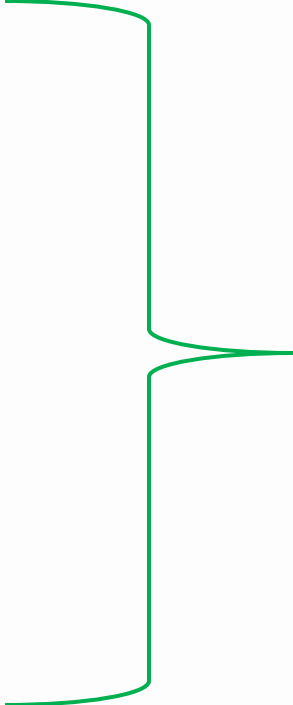


Whatever the goal, evidence is now required.

Evidence Strategies

Obtaining payment requires objective evidence

- Prospective studies
- Retrospective studies
- Chart abstractions
- Claims data review
- Literature review
- Objective economic models



Options to
optimize
payment



US medical product ecosystem

Regulatory considerations and business strategy

Getting the right focus on health economics and reimbursement

Approaches to integration

Impact of evidence

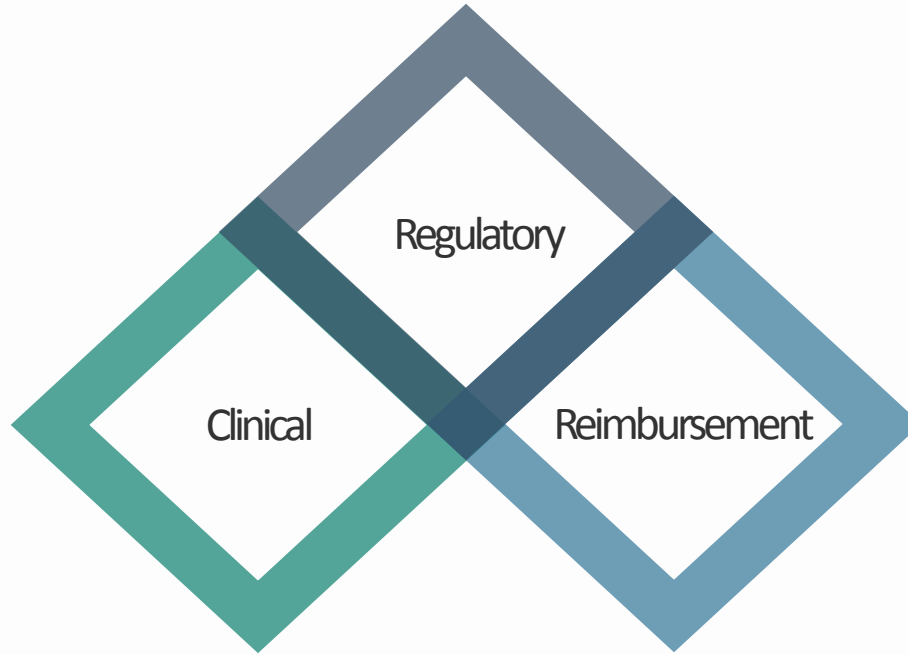
Classic Strategy Development

Traditional strategic planning follows traditional development pathways leading to discrete strategic plans



The elegance of integration

inform and iterate



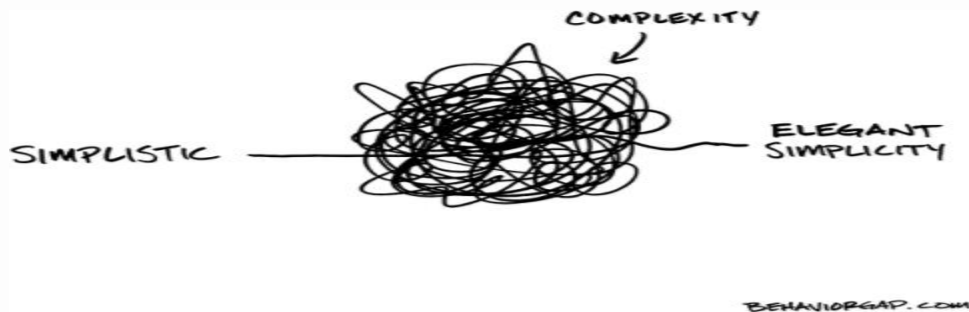
Iteration and refinement

Use decision outcomes and evidence to refine tactics



Key take-away information

- Integration only happens through **intention**
- Start integration at the outset
- Smart development is **not linear**
- Decisiveness is important, **flexibility is crucial**





US medical product ecosystem

Regulatory considerations and
business strategy

Getting the right focus on health
economics and reimbursement

Approaches to integration

Impact of evidence

Case Study

Delayed achievement of success



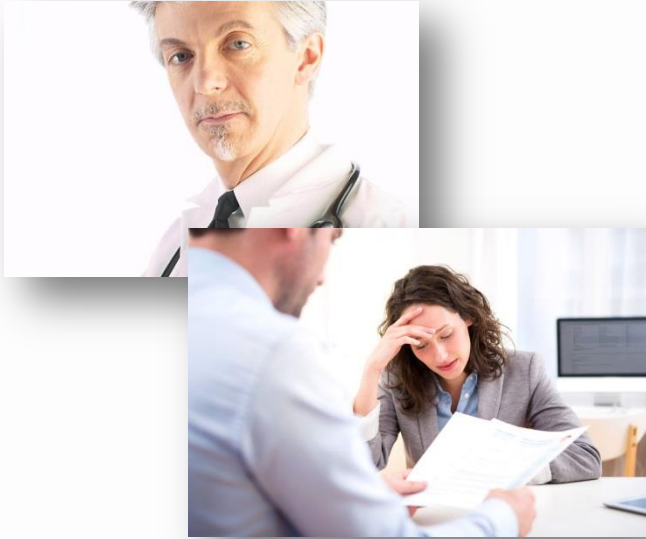
Background:

- Carpel tunnel indication
- Novel/disruptive surgical tool
- Ultrasound guided
- Hospital setting with DRG
- Easier, safer procedure, reduced recovery time
- Linear development process and rapid FDA approval
- Well capitalized through approval

Implications

Results:

- Poor market adoption
- Delayed international push
- Disappointed investors
- Time and money wasted on office based concept



Background factors

Examining the market situation

Stakeholder assessment indicated

- Elegant solution that cost surgeons money
- Payers interested but no clinical or health economic data
- Patients have much to gain but have little influence

Correction steps

Solution:

- Employ gorilla sales emphasis to gain some revenue
- Develop comprehensive evidence based health economic story
 - Efficiency
 - Less complications
 - Lower payer costs

Long term outlook

Retooling the strategy

Solutions on the horizon:

- Explore office based procedure
- Begin consumer based campaign



Case Study

Higher success rate



Background:

- Novel Atrial Fibrillation Technology
- Done in concert with CABG procedure
- Standard of care: ablation
 - frequently have to redo procedure
- Results in huge reduction in stroke

Creating the opportunity for success

Proactive approach

Conducted Landscape Assessment:

- Surgeons concerned about increased
 - Cost
 - Time
 - No repeat ablation procedures
- Payers concerned about increased costs



Creating the opportunity for success

Developed a strategy to determine what evidence was needed to gain traction with surgeon and payers:

- Clinical evidence
- Health economic models

Pivoting the strategy

Generating compelling data

- Real world clinical and economic data with 1 year follow up
 - Indexed hospital economic tool
 - Payment study for surgeon
 - Reduction in stroke
- Clinical mortality study
- Guideline development



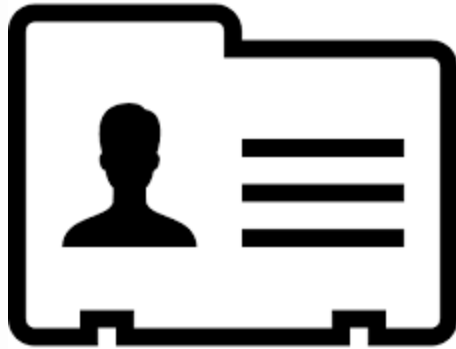
Long term outlook

- Better surgical reimbursement
- Increased market share
- Improved outcomes
- Lower payer costs



Key Takeaways

- Assess the landscape early
- Prioritize tactics
- Educate
- Values always in the eye of the beholder
- Utilize integrated thinking and consulting collaborators



Lisa Olson, B.S., MBA

lolson@rcri-inc.com

01-952-224-2259

Todd Anderson, B.A.

tanderson@rcri-inc.com

01-952-224-2254

THANK YOU

MAAKE
TERMA KASIH RAIBH MAITH AGAT
MULTUMESC
GRAZIE
MERCIO
MOCHCHAKKERAM
JUSPAXAR
OBRIGADO
MATONDO
KIITOS
SALAMAT
MOCHCHAKKERAM
KIA ORA
MULTUMESC
CHOKRANE
SALAMAT
CAM ON BAN
MERCIO
RAIBH MAITH AGAT
OBRIGADO
MOCHCHAKKERAM
ASANTE
UA TSAUG RAU KOJ
MOCHCHAKKERAM
GRAZIE
CHOKRANE
MATUR NUWUN
MATONDO
CHOKRANE
UA TSAUG RAU KOJ
DANK JE
RAIBH MAITH AGAT
SPASIBO
MAAKE
OBRIGADO
WELALIN
SPASIBO
ARIGATO
MOCHCHAKKERAM
OBRIGADO
KIITOS
DANKON
NIRRINGRAZZJAK
MOCHCHAKKERAM
VINAKA
MULTUMESC
NIRRINGRAZZJAK
MAMANA
OBRIGADO
DANK JE