



Market Access Strategy and Planning: Succeeding in the Age of Value-based Reimbursement

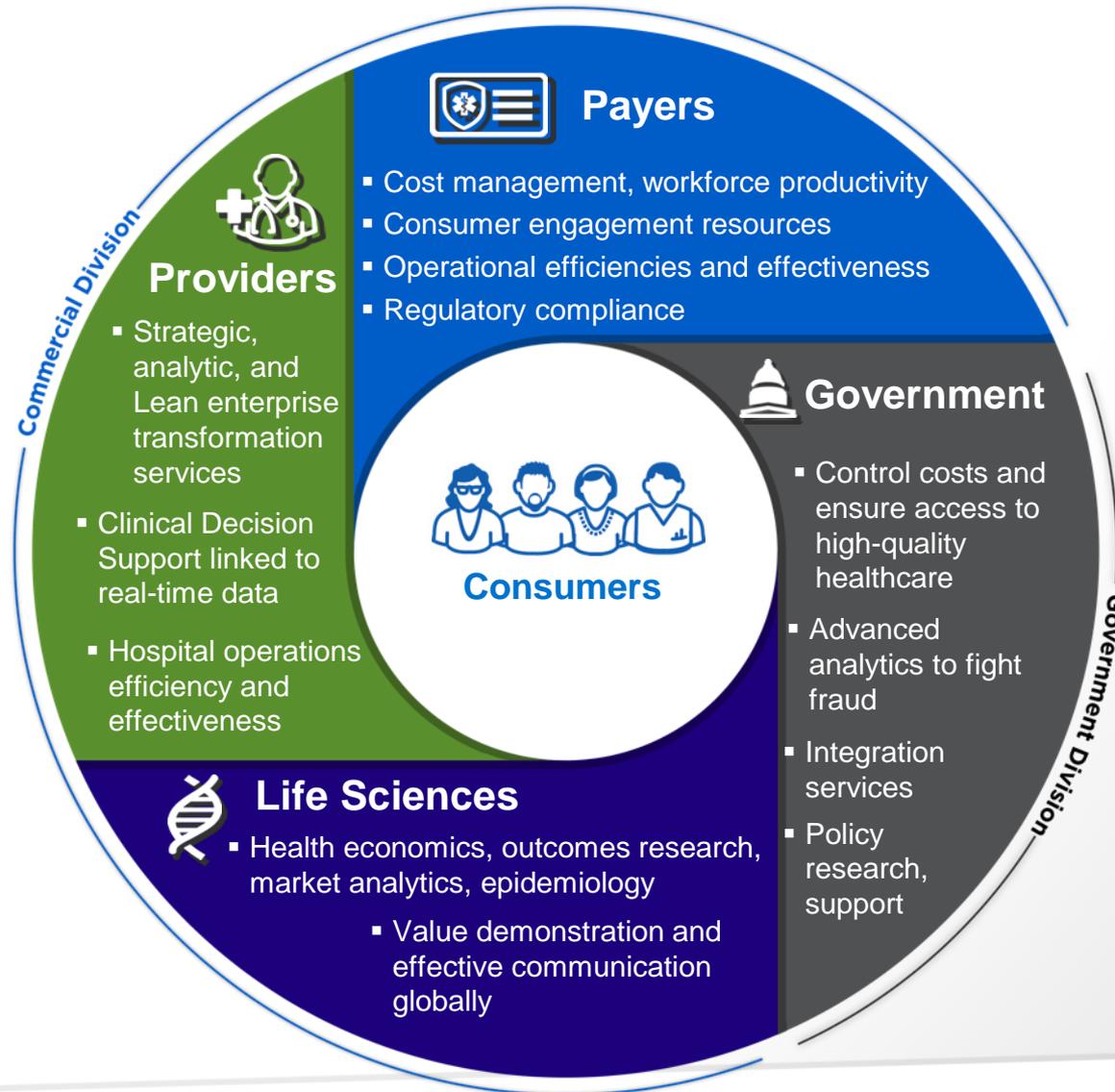
Presented by: Michael J. Lacey, Senior Director, Strategic Consulting (Life Sciences)
Date: March 01, 2017

Agenda

- Truven Health Analytics Background
- Factors Driving Value-based Reimbursement Trends
- Evolving Payer Requirements and Patient Engagement
- Alternative Payment Models and Value Frameworks
- Adapting Market Access Strategies for Success
- Discussion

A Quick Refresher on Truven Health Analytics...

ABOUT TRUVEN HEALTH ANALYTICS



Our Expertise to Link Data Supports Studies of Increased Complexity



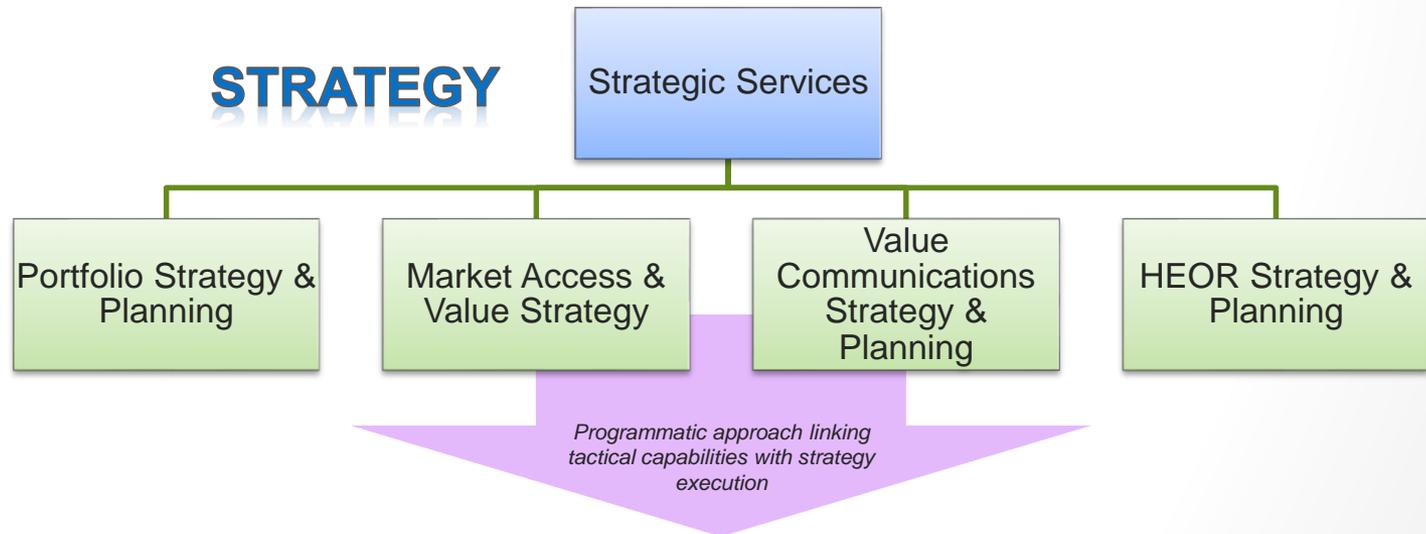
Serving Payers, Governments, Providers, and Life Sciences

9,000 Customers

2,300 Employees

Working in 50 U.S. states and more than 90 countries

Strategic Consulting and HEOR Research



TACTICS



Factors Driving Value-based Reimbursement Trends

Situation Summary

New realities in global payer environment are driving change

- Globally regulatory bodies are no longer the only critical driver of market access
 - Budget limits due to the ongoing Global financial crisis are driving rapid change in procurement practices.
- The US market is rapidly consolidating into larger provider-based accountable care organizations (ACOs) and payer groups.
 - Insurers, hospitals, ambulatory surgery centers (ASCs), and large physician groups are aligning economic incentives to take advantage of bundled payment and shared savings programs.
 - Macro-economic forces will drive continued evolution into value-based care reimbursement models and increased patient-engagement going forward.
- Outside the US, this process is rapidly moving from pharma focus to pharma and device focus.

Situation Summary (continued)

Payers are driven by business imperatives and political pressure to constrain budget growth

- Health Technology Assessments to limit access are in place globally and gaining momentum in the US
 - Level of review of medical devices and procedures increasing to pharma levels outside of the US and evolving in US
- ISPOR is sponsoring “The Initiative on US Value Frameworks”
 - Initiative was created to inform the shift towards a value-driven health care system by promoting the development and application of high-quality, unbiased value-assessment frameworks.
 - Multiple US value frameworks have been proposed –
 - *”2016 is the year of the value framework”*
 - ISPOR group has assessed that these emerging frameworks vary widely and can lead to variable evaluations of treatments.
 - Defining value in the context of the decision problem continues to be a vexing and unresolved issue.

Situation Summary (continued)

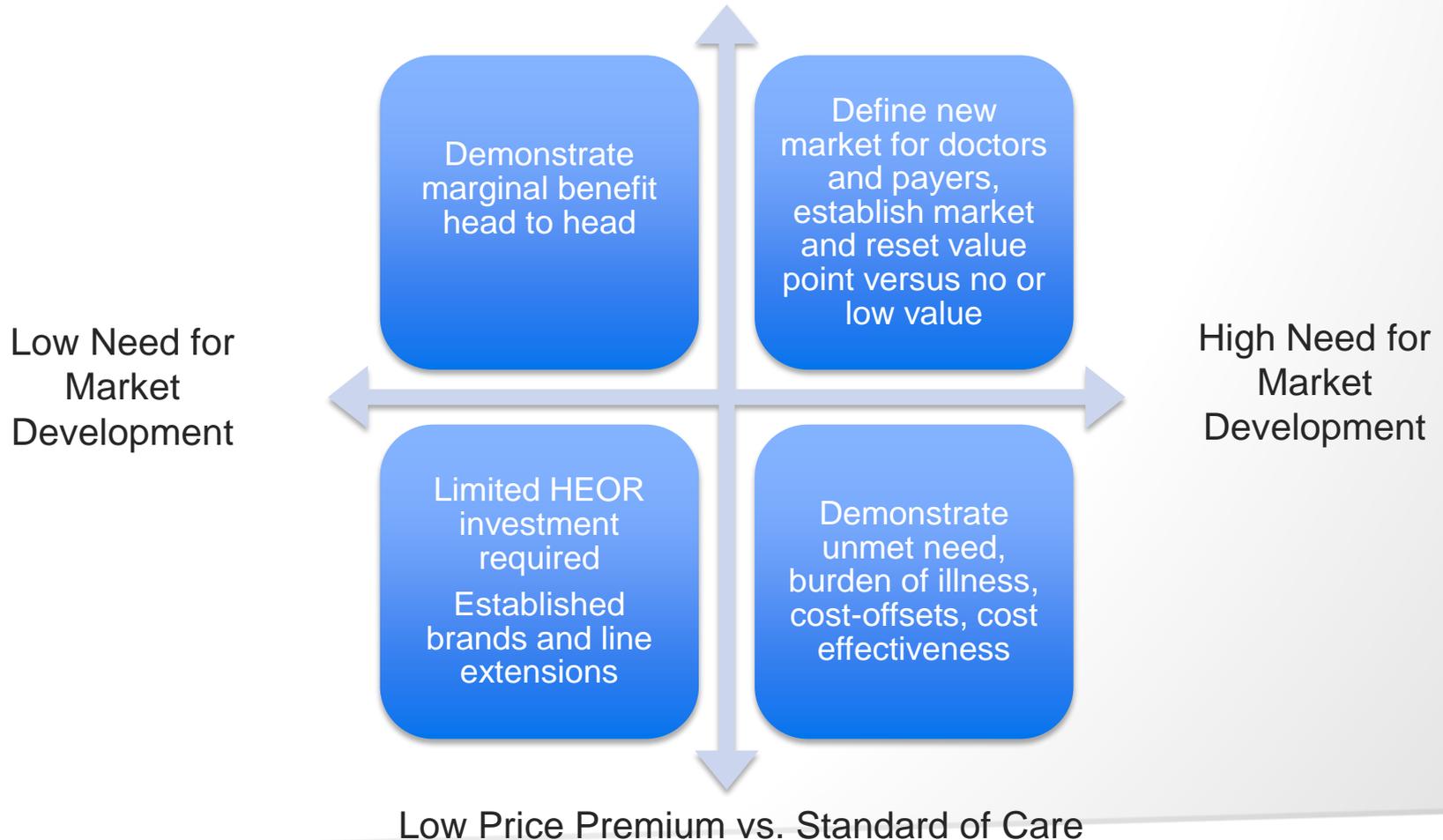
Payers are driven by business imperatives and political pressure to constrain budget growth

- Demand for scientifically valid and peer-reviewed studies demonstrating clinical and economic value increasing to set coverage and price:
 - Focused on products seeking new reimbursement (i.e., premium price compared to local standard of care)
 - Larger well-controlled comparative studies
 - Data on local populations, with locally relevant comparators, adapted to local context
 - Proxy measures of efficacy being displaced by demand for real-world effectiveness and proof of economic cost-offset
- Influencing economically driven decision makers requires:
 - Clearly incorporating “voice of the payer” into R&D and commercialization plans
 - Collecting the relevant clinical and economic data on the right populations to create best conditions for market access

New Technology Product Mix is Evolving

Capturing value for new strategic products (i.e., innovative pharma, drug/device combinations, interactive monitoring) will require comparative data and substantial investment in market development.

High Price Premium vs. Standard of Care



New Technologies Increasingly Span Markets

Drugs & Devices Are Different!

PHARMA

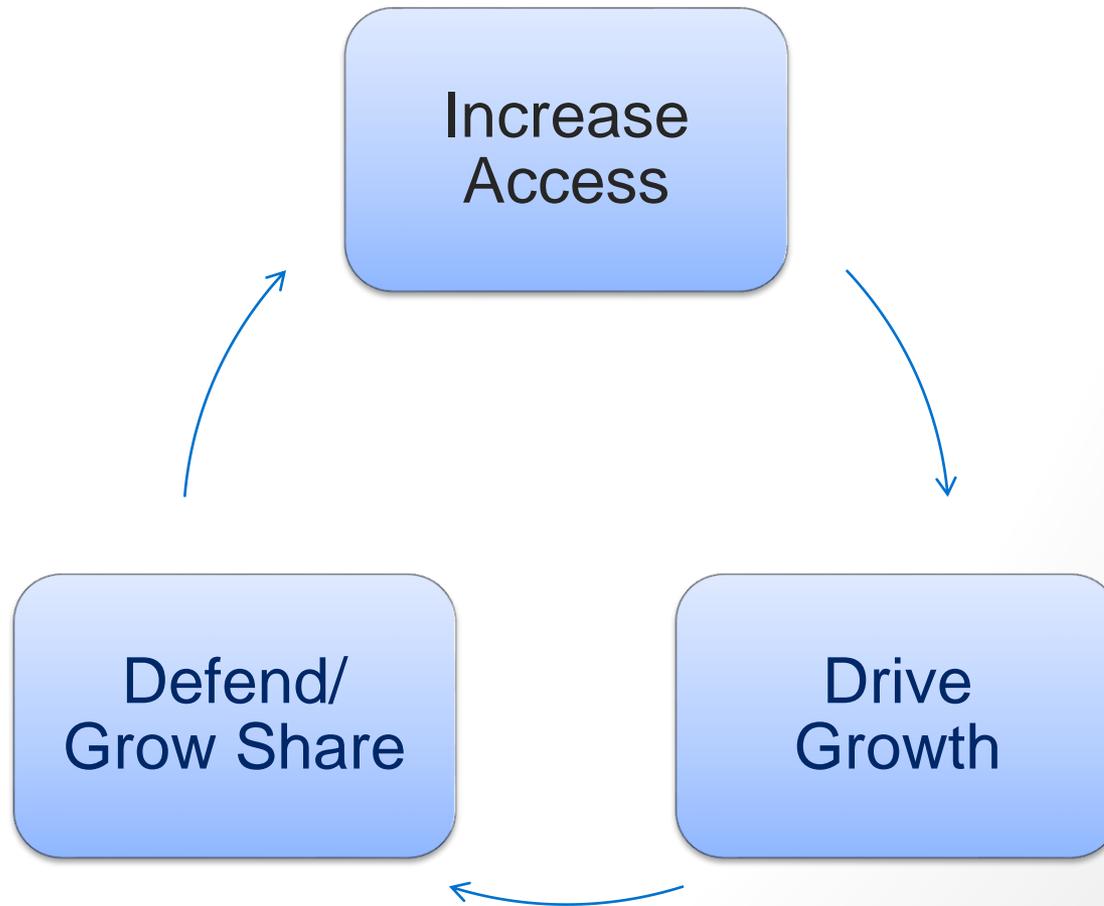
- Systemic effects
- High risk/ high reward
- High development cost
- Large market opportunities
- Long-term protection
- Few iterations

DEVICES

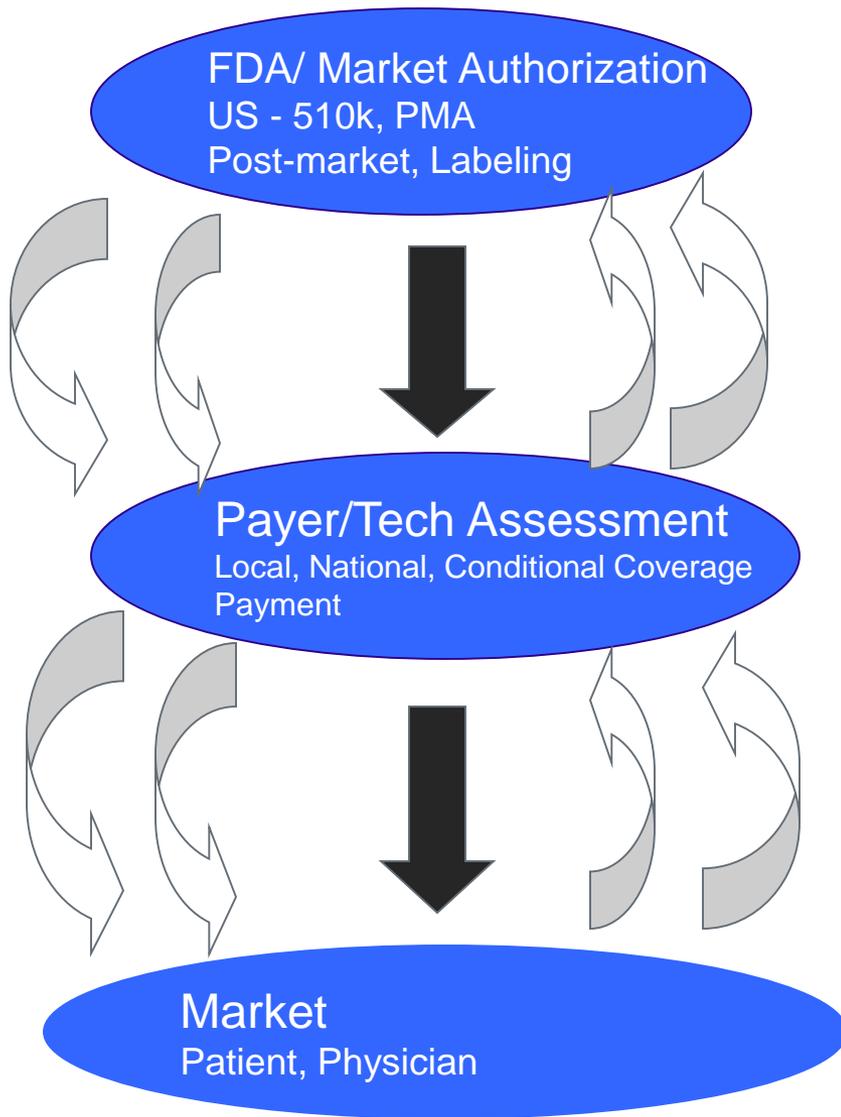
- Local effect, physician skill
- High hit rates
- Moderate development costs
- Small to mid-sized markets
- Incremental products
- No long-term IP protection

Why Do Life Sciences Firms Need Enhanced Market Access & Value Demonstration Capabilities?

In God We Trust – all others bring data – Edward Deming.



Fragmenting Paths to Sustained Market Access



Innovator

↑ Risk

↓ Hit rate

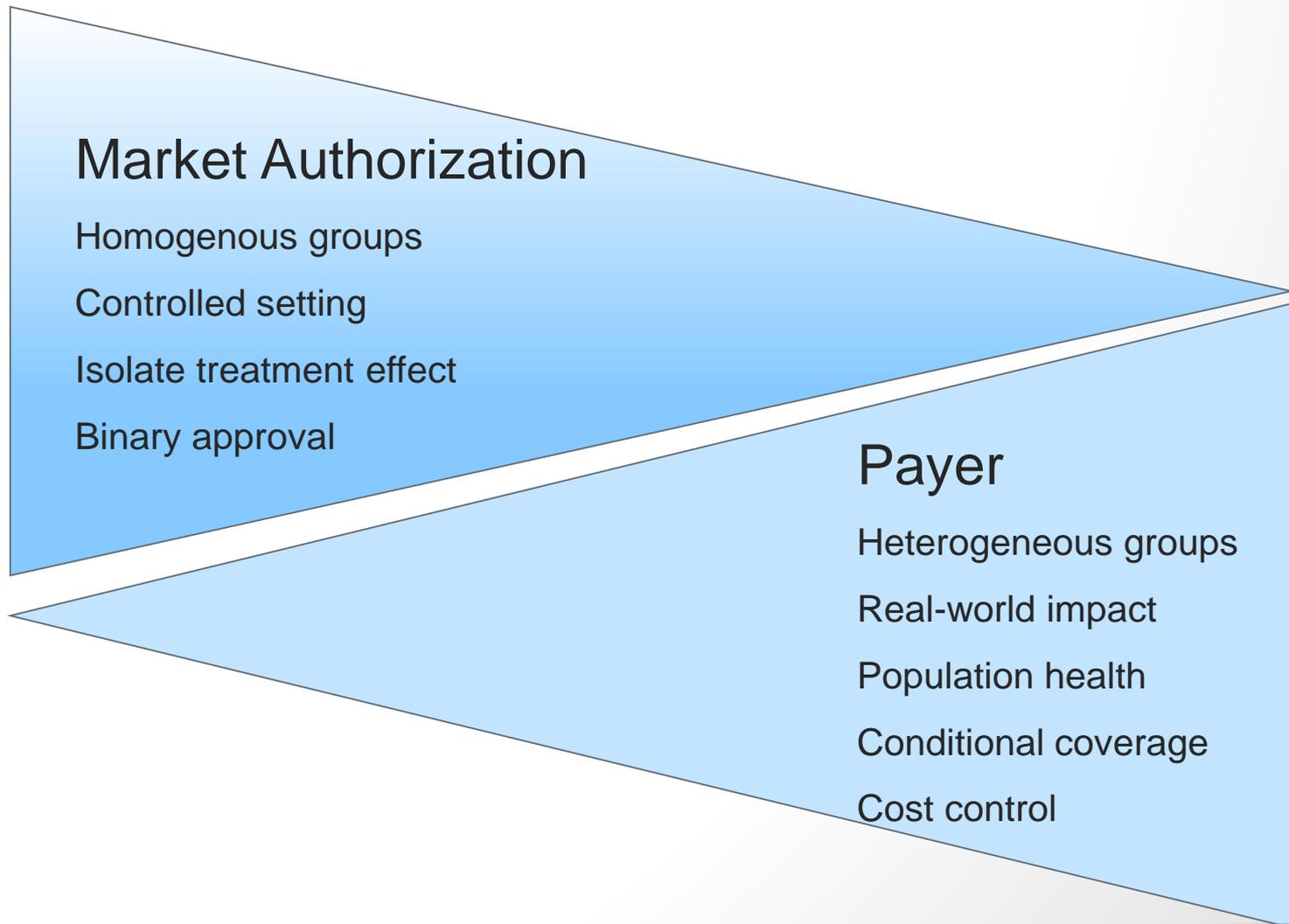
↓ Capital access

Investor

↑ Cost of capital

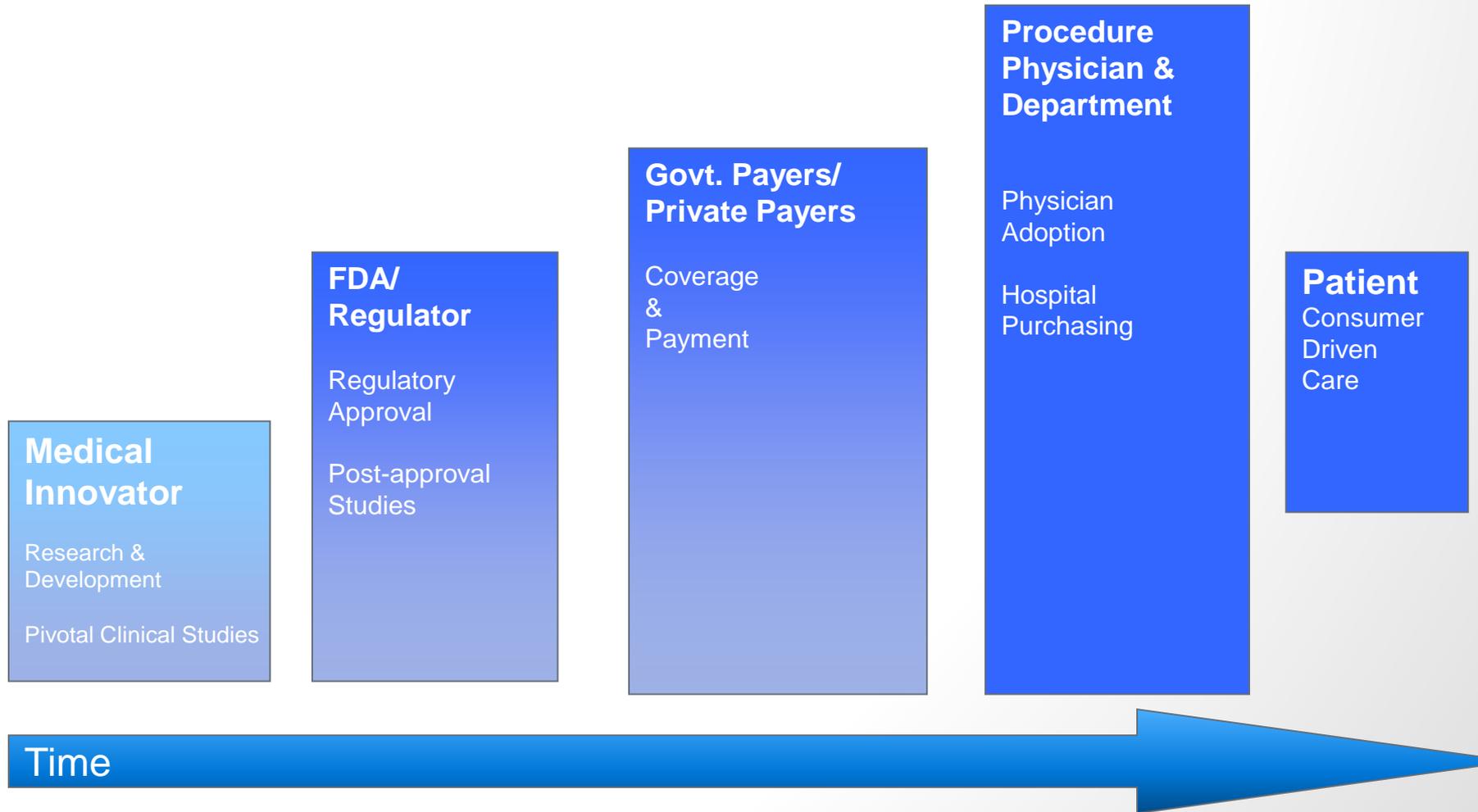
↓ Investment

Diverging Regulator and Payer Perspectives: *Requirements for success are a moving target*



Increasing Hurdles to Global Markets:

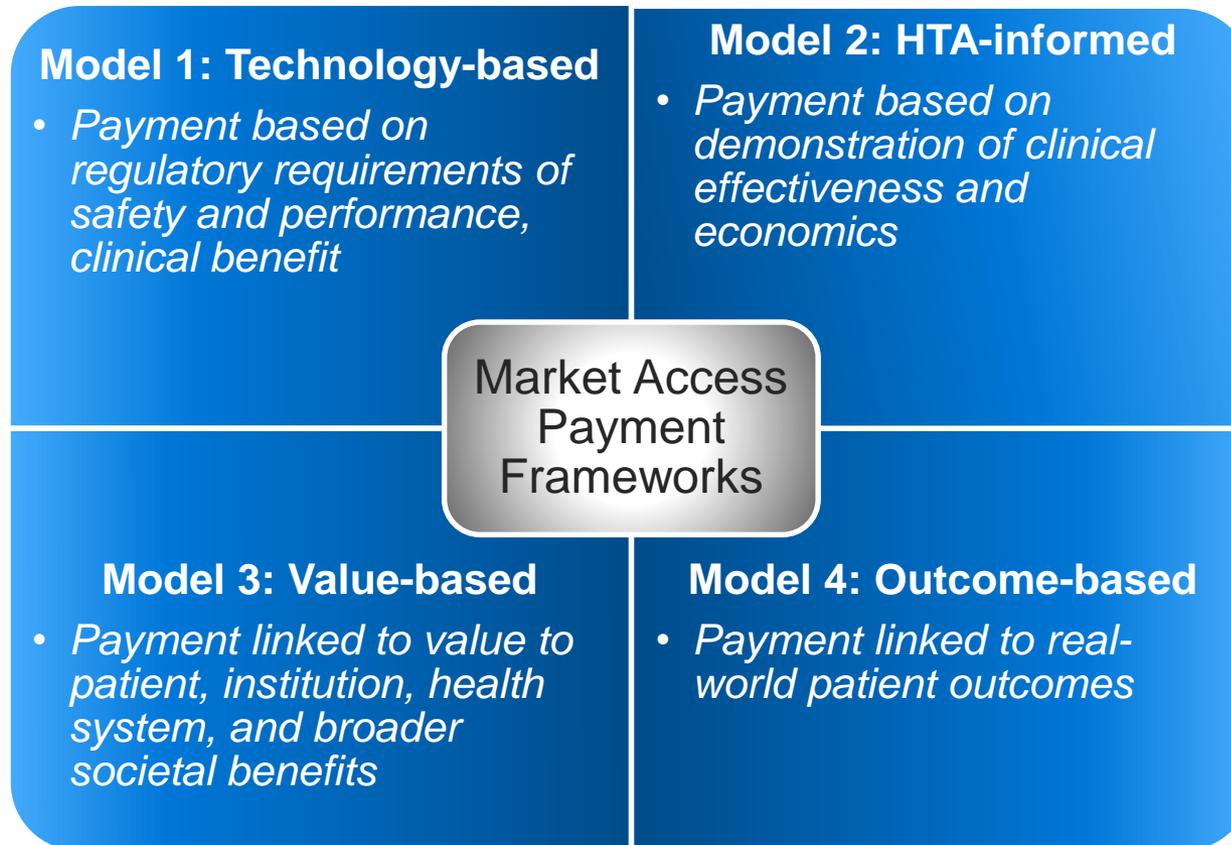
Impact on Timely Patient Access to Cost-effective Care



Alternative Payment Models and Value Frameworks

Global Health Technology Payment Frameworks

Paying for Value in Health Care



Drivers of change¹

- Technology Advancement
- Financial crisis
- Ageing population
- Quality of care
- Equity

Change Already Happening In the US: Government (CMS) has set a target to move from current 80% technology-based and fee-for-service payment in 2016 to 50% Alternative Pay for Value Models in 2018²

¹ Porter, ME. What is value in health care? N Engl J Med 2010;363:26

²Centers for Medicare and Medicaid Services. *Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume.* <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html>. Accessed June 1, 2016

Model 1: Technology-based Payment

Payment Based on:	Evidence Requirements	Payer Considerations	Key Levers to Activate Business Growth
Regulatory requirements of safety and performance, clinical benefit	<ul style="list-style-type: none"> CE marking 	<ul style="list-style-type: none"> Fee-for-service Procedure-based prospective payment schemes (e.g., DRG – tariffs) Positive list Innovation payments Premium reimbursement 	<ul style="list-style-type: none"> Gain market share using value communication tools to support physician preference and economic story Post-launch evidence generation to gain inclusion in care pathways Seek premium reimbursement



Model 2: HTA-informed

France, Germany, United Kingdom

Payment Based on:	Evidence Requirements	Payer Considerations	Key Levers to Activate Business Growth
Demonstration of clinical effectiveness and economics	<ul style="list-style-type: none"> EU legislation 	<ul style="list-style-type: none"> HTA to inform decision on reimbursement, pricing Does technology address priority unmet need? What is the budget impact? 	<ul style="list-style-type: none"> Develop robust evidence-generation plan to optimize market access to improve revenue, market share, and price positioning Establish credible burden of illness, unmet need, sources of local cost data for cost-effectiveness and budget-impact Ensure value communication tools are designed to secure local reimbursement



Model 3: Value-based

Payment Linked to:	Evidence Requirements	Payer Considerations	Key Levers to Activate Business Growth
Value to patient, institution, health system, and broader societal benefits	<ul style="list-style-type: none"> ▪ EU legislation ▪ Demonstrate benefits of product value ▪ Confirm value demonstration in real life 	<ul style="list-style-type: none"> ▪ What is the willingness to pay for product value? ▪ What is the overall economic value delivered relative to price? ▪ Is it worth investing in new technology? 	<ul style="list-style-type: none"> ▪ Assess readiness to enter into contractual value-based agreements ▪ Integration of reimbursement, health economics, HTA, Pricing and Tendering teams



Model 4: Outcome-based

Payment Linked to:	Evidence Requirements	Payer Considerations	Key Levers to Activate Business Growth
Real-world patient outcomes	Post-market negotiation	<ul style="list-style-type: none"> Does a negotiated contract with post hoc adjustment make business sense? Can utilization and outcomes measurement be implemented? 	<ul style="list-style-type: none"> Develop appropriate real-world evidence (RWE) studies to support value claims Willingness to invest in structural set up to facilitate collection of data Develop business case for establishing a patient outcome based model



ISPOR Value Frameworks Overview

- ISPOR has identified:
 - a “need for a set of standards that are robust, transparent, methodologically sound, and that involve the input of all key stakeholders to guide the development of value assessment frameworks for health care decision making.”
- Meeting was designed to convene stakeholders across all segments of health care to generate input and help guide the scope of work for the Initiative’s Special Task Force.
- More than 250 health care stakeholders attended the conference

<http://press.ispor.org/index.php/ispors-initiative-on-us-value-assessment-frameworks-conference-draws-key-health-care-stakeholders-and-thought-leaders/>

Value Framework Comparison

Table 1: Overview of Value Assessment Frameworks

	ACC-AHA	ASCO 2.0	<u>DrugAbacus</u>	ICER	NCCN
Target Audience	Physician/patient	Physician/patient	Payers, policy makers, physician/patient	Payers, policy makers, physician/patient	Physician/patient
Services Addressed	Treatments, primarily drugs	Drug regimens	Drugs	Primarily drugs, has been extended to devices and delivery system programs	Treatment regimens, primarily drugs
Conditions Addressed	Cardiovascular	Oncologic	Oncologic	All conditions, particular focus on new drugs anticipated to be high impact	Oncologic
What is the "Value" Output?	Level of value assessment (high, medium, low, uncertain, not assessed)	Numerical net health benefit score; drug regimen cost	Value-based price	Value-based price benchmark; assessment of care value (high/intermediate/low)	Score (1-5) for each of 5 evidence blocks: efficacy, safety, quality of evidence, consistency of evidence, affordability
Evaluations to Date	1 guideline includes concept, but makes no assessment	10 examples using <u>initial</u> draft framework; 4 examples using updated framework	Tool includes 54 drugs approved from 2001-15	8 topics have been completed; 5 are in process	12 guidelines include evidence blocks
Selection Process for Future Evaluations	As guidelines are updated, value assessments will be added	Undetermined at this time	Will eventually include other cancer drugs and other indications	Selected by ICER and three advisory boards informed by horizon scan and payer input ⁹	As clinical practice guidelines are updated, evidence blocks will be added

- Though not a presenter – the National Pharmaceutical Council (NPC) has developed a summary comparison and critique of the various frameworks.
- <http://www.npcnow.org/publication/current-landscape-value-assessment-frameworks>

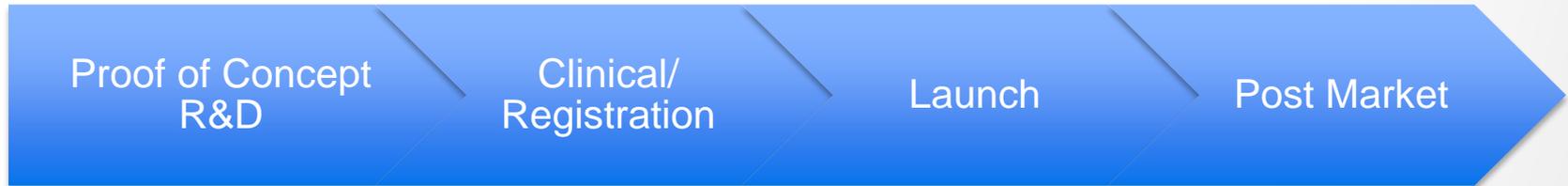
Value Framework Workshop – Key conclusions

- All frameworks hinge on a common issue of lack of high-quality rigorous data needed at the point of decision.
- Strategic planning, evidence generation and communication of high-quality, rigorous evidence of clinical and economic value at the point of decision can help manage downside market access risk.
- Value frameworks will need to incorporate the **“voice of the patient”** both within the physician/ patient shared-decision making context and the broader payer context.

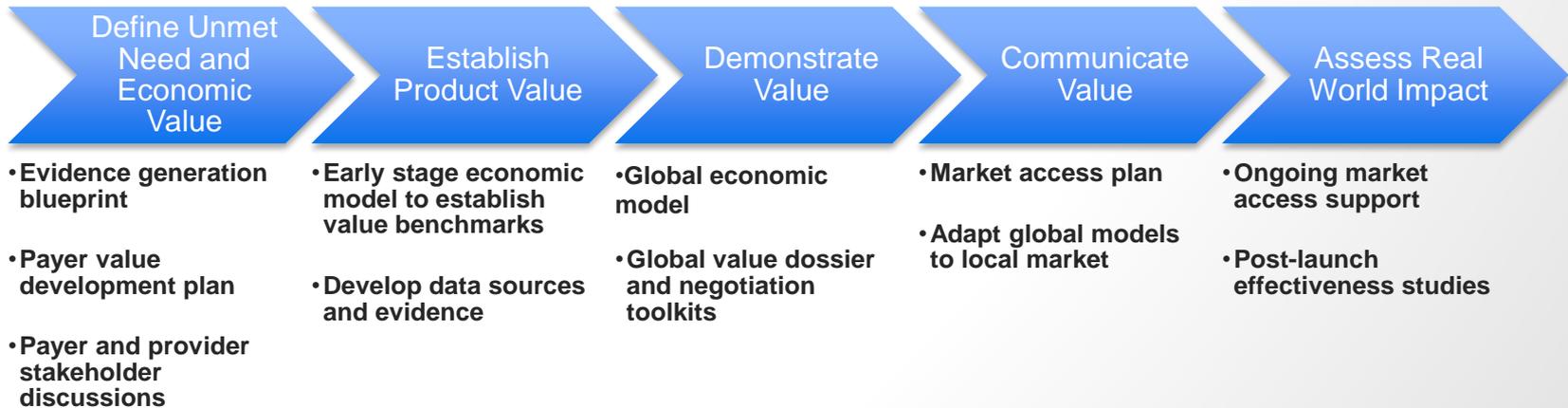
Adapting Market Access Strategies for Success

“Gold Standard” Market Access Process

Development Stage



Market Access Process



HEOR and Market Access Teams

Collaboration to drive strategy, generate evidence and communicate product value to stakeholders

HEOR groups are responsible for generating the evidence to obtain access

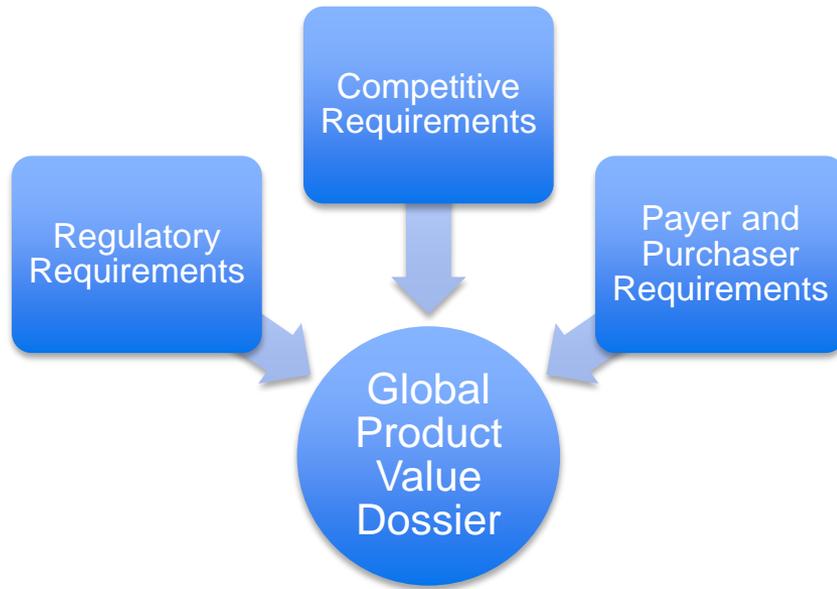
- Outcomes Research - Scientific discipline seeking to demonstrate effectiveness of interventions to the patient and health care system.
- Health Economics – quantifying value for money (value-based pricing) of alternative intervention strategies to a given stakeholder.
- Develop value dossier and global economic models

Market Access groups package material to gain access, negotiation with payers

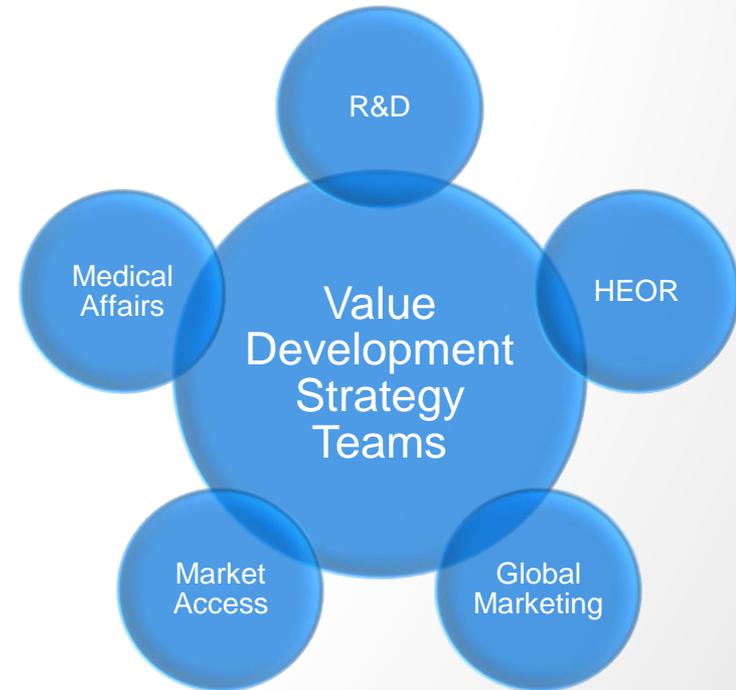
- Define value-based positioning by stakeholder
- Establish relationships and market requirements with payers.
- Adapt global value dossiers and HEOR models and insights to specific environment
- Negotiate to gain reimbursement authorization and payment

Global Value Strategy Planning Teams

Empowered cross-functional product-value planning teams need to address new realities in global life sciences markets.



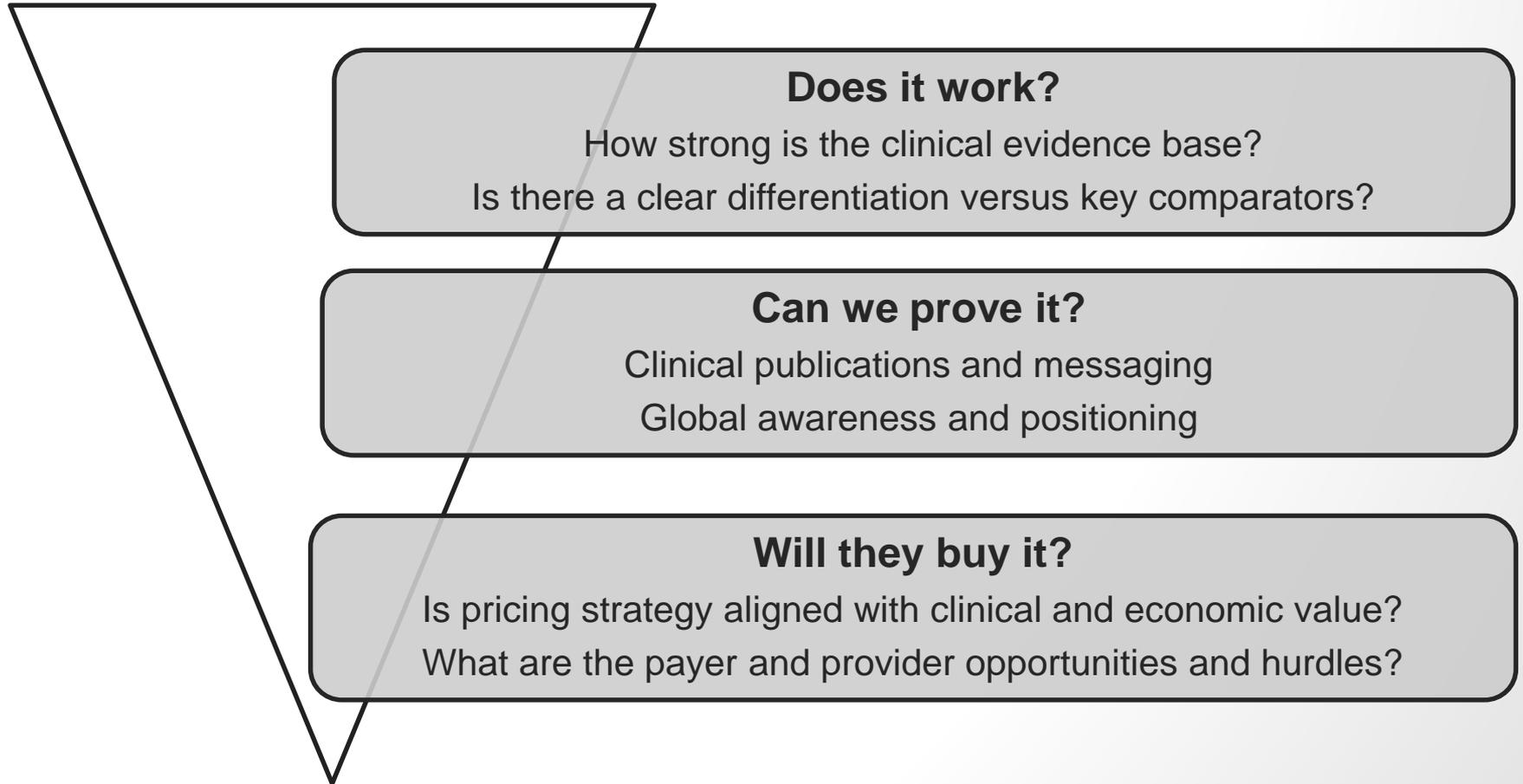
Broaden R&D and Regulatory objectives to address all three sets of market requirements across lifecycle.



- Senior Leadership Team Council to drive overall strategy and resourcing
- Franchise or product teams to drive product strategy and implementation

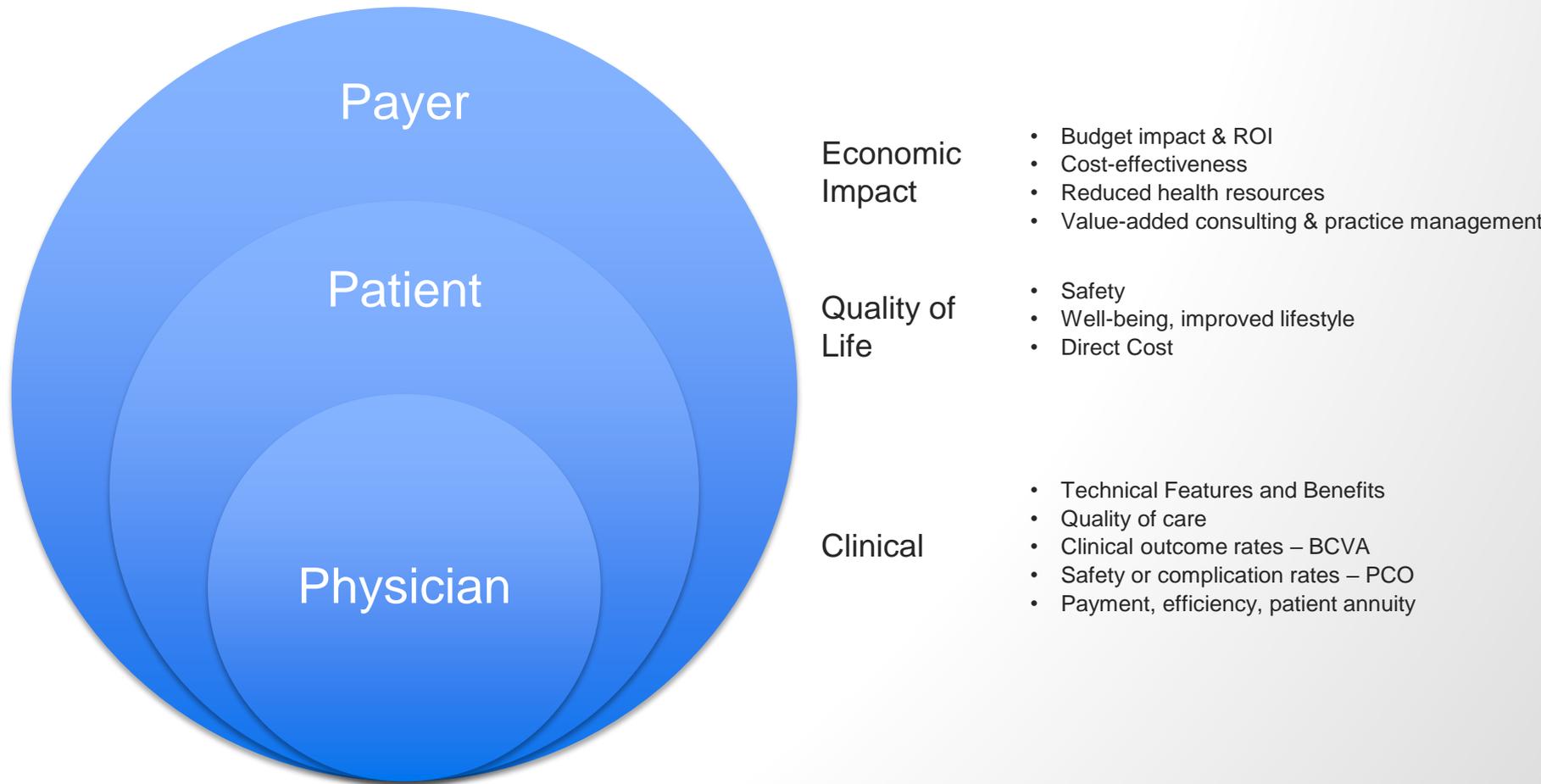
Pro-forma Product Planning Triage Process:

Strategic HEOR Product Evaluation to Assess Value-based Positioning



Evolution to Address Needs of Stakeholders in the New Global Market

Broaden value demonstration to remain partner of choice.

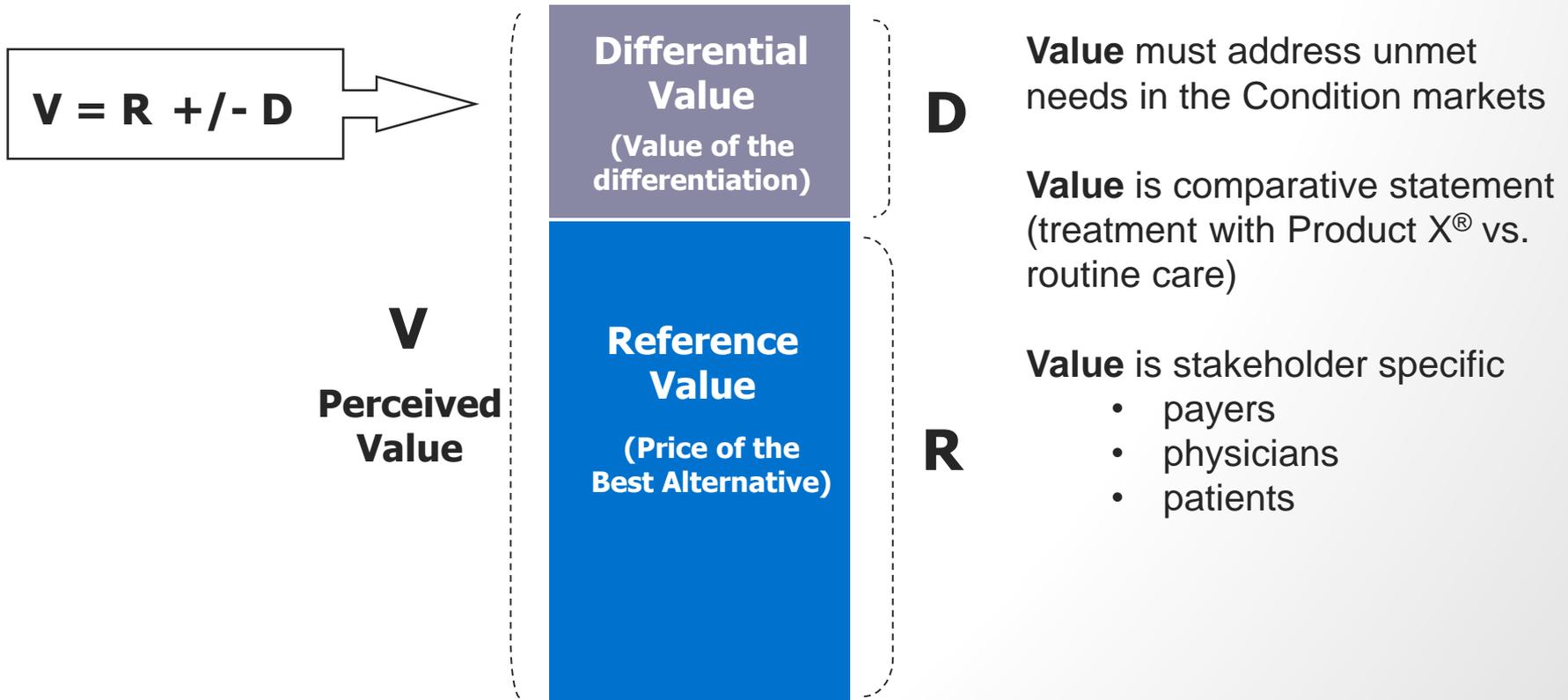


Critical to Triage Evidence Development Resources

- Leading companies have developed triage process to guide R&D and post market evidence development spend.
 - Fully integrated into investment decision and life-cycle business model to ensure funding at a program level
 - Sample criteria include
 - Is the product a breakthrough?
 - Is the product of strategic importance?
 - Is the target price and volume estimate likely to raise payer hurdles?
 - Is reimbursement adequate to fund the new technology?
 - Does our plan address the needs of the our four major stakeholder groups – physicians, regulatory, payers, and patients?
 - Does technology support suite of leading technologies and can evidence be used to maintain market dominance by erecting barriers to entry?
- Iterative products without clear value differentiation don't receive marginal investment – pricing and volume expectations are adjusted accordingly.

The HEOR strategy must address each stakeholder's perception of value, which underpins treatment and coverage decisions

The perceived value to a *stakeholder* is based on*....



▪ Holden R, et al. Elements of Pricing.

Discussion



More Than Data. **Answers.**

Thank you.

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