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An Evolving Lens: The Intersection of Real World Evidence, Payer Policy and Reimbursement

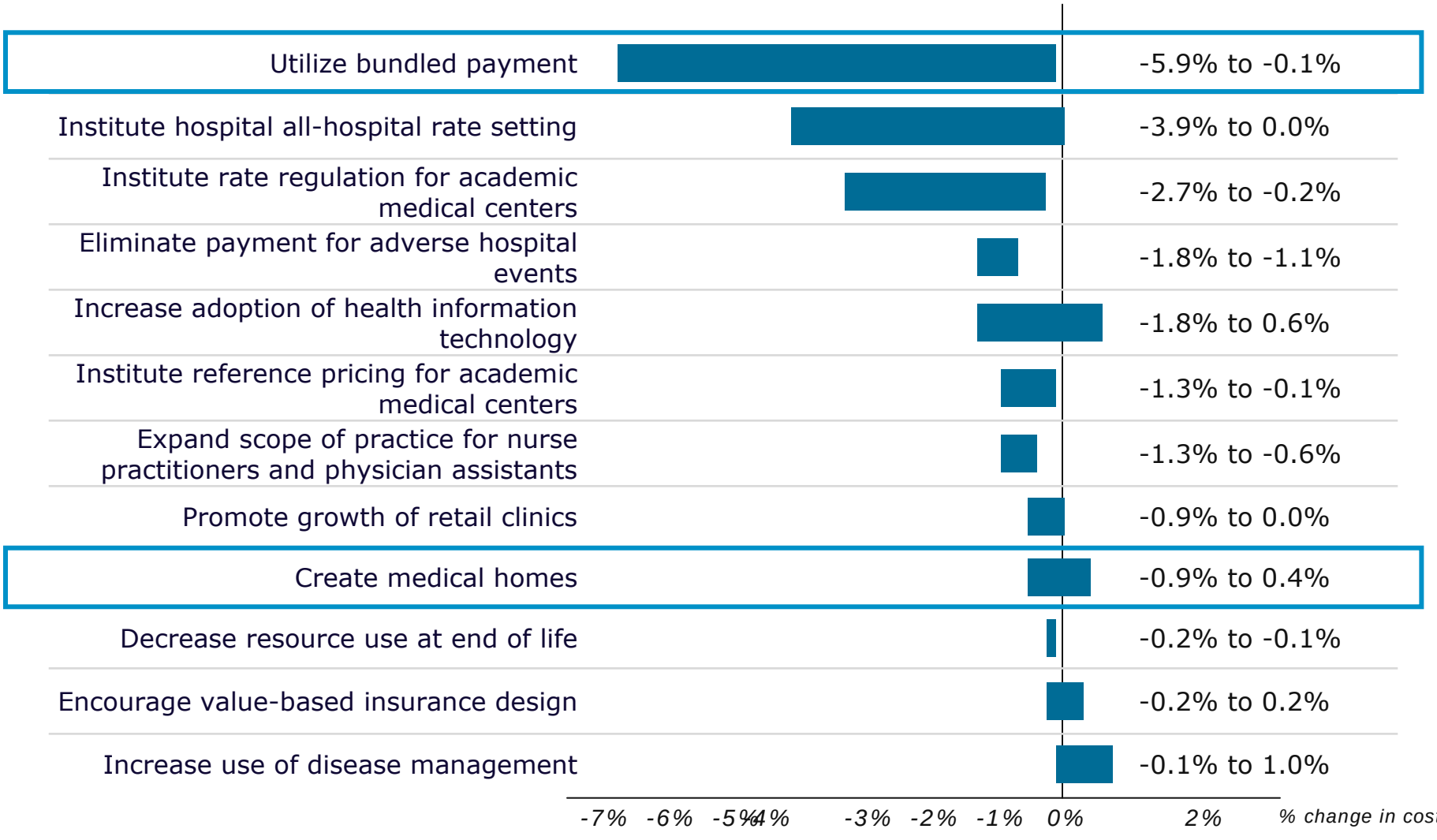
SLA PHT Spring Meeting 2014

Mitch DeKoven, MHSA, Principal – Health Economics and Outcomes Research, IMS Health

Agenda

- **Hallmarks of payment reform**
- The birth of real world evidence
- Intersection: case studies

The most promising strategies require a move away from the current fee-for-service model



Source: Eibner CE, Hussey PS, Ridgely MS, McGlynn EA. *Controlling Health Care Spending in Massachusetts: An Analysis of Options*. Santa Monica: RAND, 2009.

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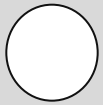
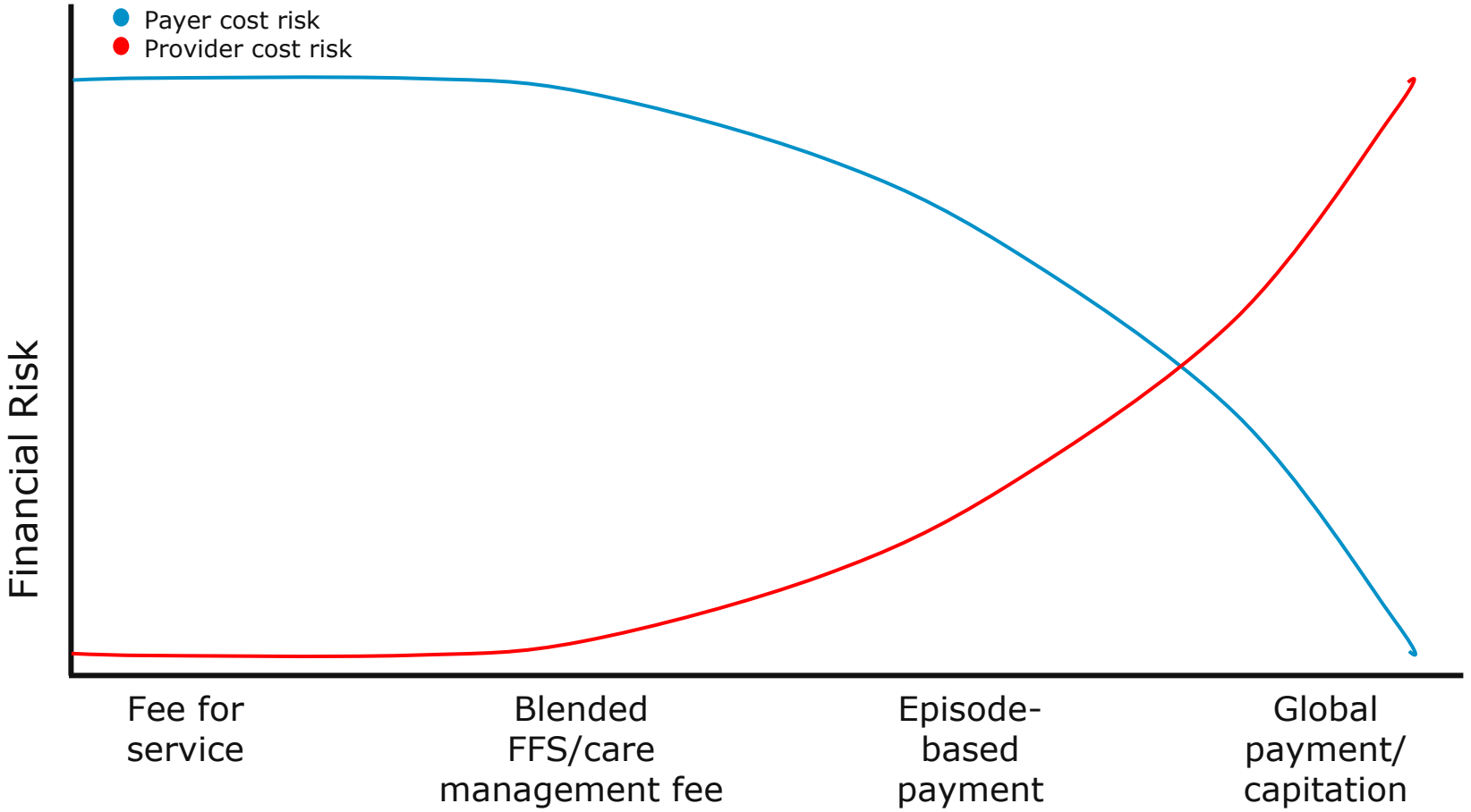
Multiple payment models are possible, with substantial implications for provider economics, risk, and incentives

	Current FFS payment	Enhanced FFS payments	Blended FFS / care mgmt fee	Episode-based payment	Global payment / capitation
Description	Payment for each unit of service provided	Enhanced FFS payments to support coordination and management	Monthly payment for patients to compensate for non-encounter-based activities	Single payment covers all products and services associated with episode of care	Single monthly risk-adjusted payment per enrolled patient for all services
Impact on Practice	N/A	All upside for the practice	Partial capitation for some activities, but underlying FFS model remains largely intact	Capitation element reduces incentive to oversupply services *per episode*	Transforms current FFS-based model into one in which provider holds significant risk
					

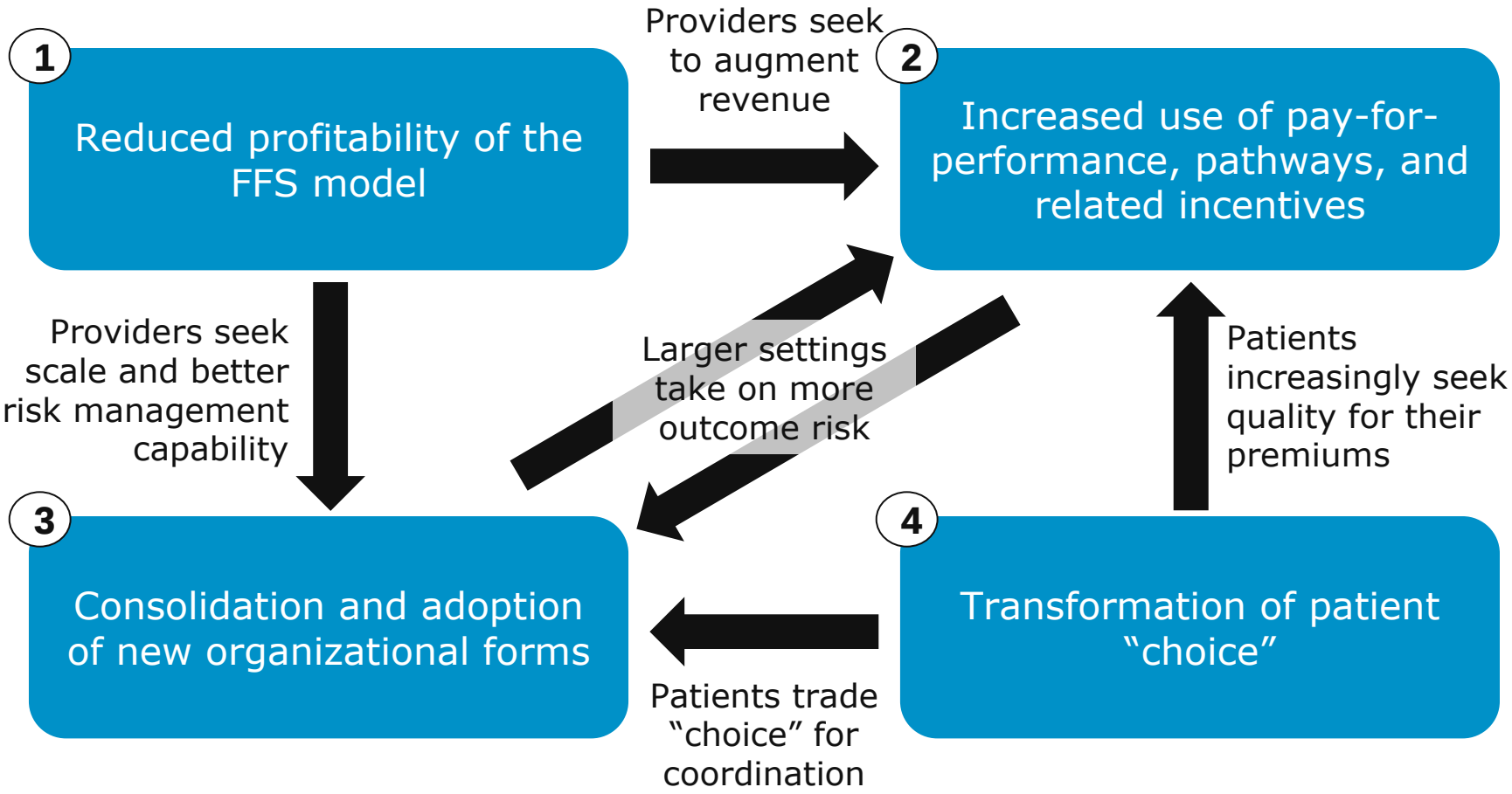
Impact on existing practice revenue model Low ◯ ⟷ ● High

Movement away from the FFS model involves transferring more risk to providers



Source: Averill RF, Goldfield NI, Vertrees JC, et al. Achieving cost control, care coordination, and quality improvement through incremental payment system reform. *J Ambul Care Manage*. 2010;33(1):2-23; IMS research.

Our research suggests that there are four "hallmarks" that will characterize the transformation of the prevailing payment model in US



The first hallmark is the reduction of the profitability of the prevailing FFS model

1 Reduced profitability of the FFS model

- Reduced reimbursement rates (ASP+4%, etc.)
- Elimination of payments for readmissions
- Growing experimentation with episode-based payments and capitation forms
- Reduced volume of ASP-reimbursable business
- Mandatory vendor imposition

Faced with margin and cash flow pressure, providers will seek to augment practice revenue

2 Increased use of pay-for-performance, pathways, and related incentives

- Increased use of pathways with compensation tied to adherence
- Differential payments based on adherence performance
- Rising share of physician compensation based on quality or adherence performance
- Transition from process to outcomes measures

Quality, Pathways, and Pay-for-Performance initiatives create opportunities for providers to augment revenue while reducing variation in treatment

As part of the effort to shift the US system away from paying for volume, a range of initiatives have been introduced to incentivize the achievement of specific quality and outcomes objectives

Pay-for-Performance (P4P)

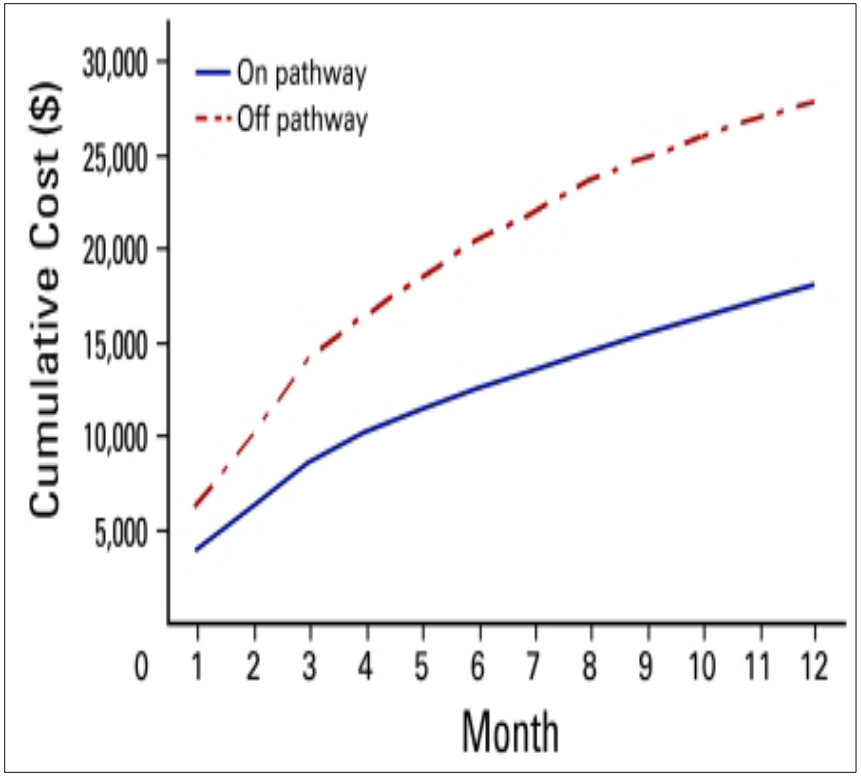
- Pay-for-performance (P4P) programs offer financial incentives to health care providers who achieve, improve, or exceed their performance on specified process benchmarks
- Performance measures include structure, process, and outcomes
- Payments may be made at the individual, group, or institutional level

Pathways

- Pathways are designed to decrease variability in treatments, improve quality of care and decrease costs
- Pathways present a narrow, standardized pool of treatment choices based on clinical evidence
- Physicians rewarded for adherence to treatment "on-pathway"

Pathways programs have successfully reduced costs and treatment variation, while generating good physician participation with only modest incentives

Cost of treatment "on-pathway" vs. "off-pathway"



- Pathways reduce costs through reduced variance from optimal treatment strategies
- Lowered risk of denied or delayed reimbursement reduce providers' administrative costs
- Pathway adoption can contribute to cost-savings of 20%-35% per year
- Physicians have been successfully incentivized to prescribe on-pathway drugs through a $5,000 incentive bonus if a 70%–80% compliance level is met at year end

Source: Cost Effectiveness of Evidence-Based Treatment Guidelines for the Treatment of Non–Small-Cell Lung Cancer in the Community Setting; *J Oncol Pract.* 2010 January; 6(1): 12–18; Citi research

Additionally, providers will continue to consolidate in order to achieve greater scale and to better manage risk

3 Consolidation and adoption of new organizational forms

- Continuing consolidation of smaller practices into larger groups
- Continued hospital consolidation and purchase of practices
- Expansion of accountable care organizations

Providers have also sought to offset declining margins through consolidation and new organizational forms

Consolidation and New Organizational Forms

In response to reforms and the evolving healthcare environment, providers are consolidating and taking on new organizational forms to meet the demands of shifting risk and emergence of new payment models

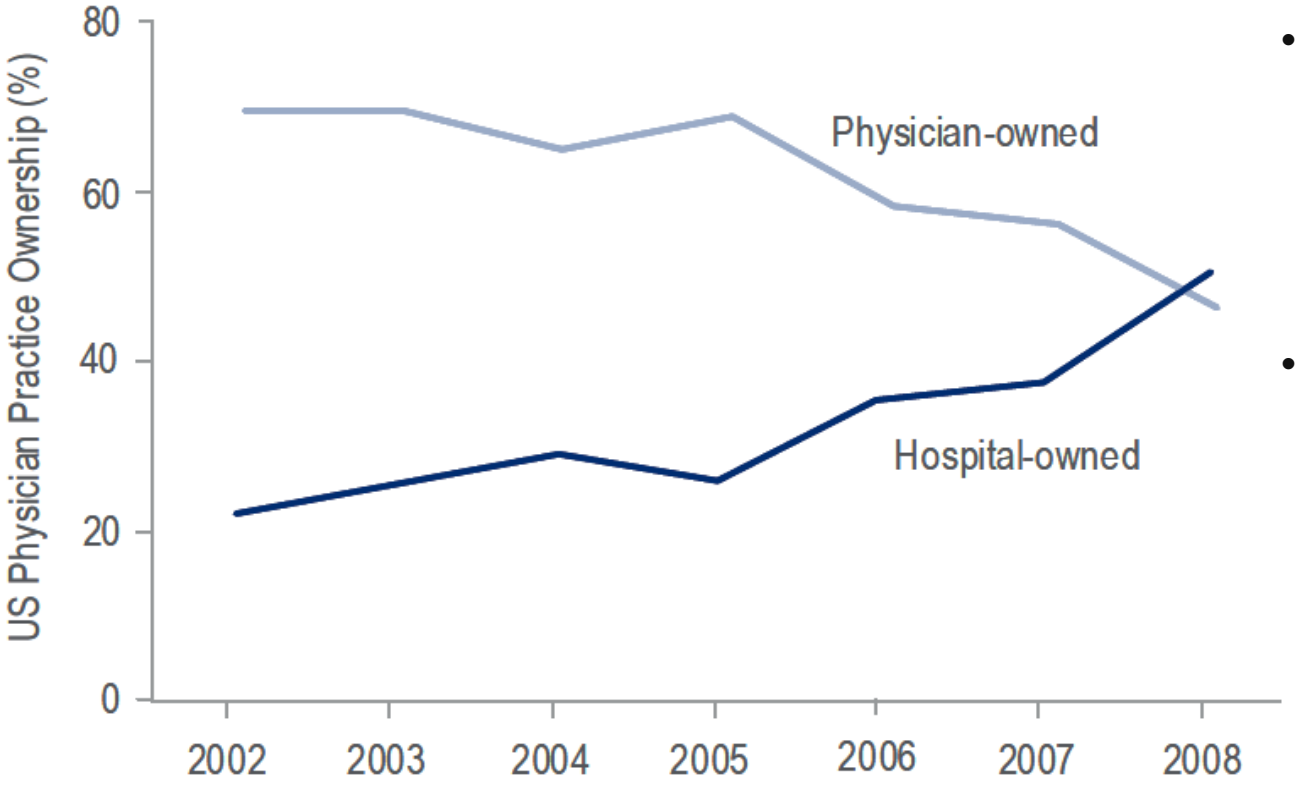
Provider Consolidation

- Significant consolidation has occurred in recent years: hospitals are merging and acquiring practices and physicians increasingly likely to be employed by a hospital or payer
- Within a hospital system, a clinician has no direct economic benefit associated with selection and administration of treatment intervention

Accountable Care Organizations

- In an ACO, provider groups accept responsibility for the cost and quality of care delivered to a specific population of patients, fostering coordinated care anchored by primary care physicians
- Payments initially maintain the FFS model, but layer on an asymmetric shared savings program (SSP); may shift to partial/full capitation and P4P

Deteriorating practice economics, administrative burdens, and superior compensation drives migration of community physicians to hospital and managed care employment



- The majority of US physicians are now employed or affiliated with a hospital group or an insurer
- Between 2010-2011, there was a 40.6% increase in practice mergers and hospital acquisition combined

Source: Citi Research, Physician Compensation and Production Survey, Medical Group Association, 2003-2009

Continued cost pressure on patients facilitates a transformation in choice, leading to thinner benefits and acceptance of higher "control"

4 Transformation of patient "choice"

- Growth in OOP burdens and premiums continue to crowd out wage growth
- Restrictions on copay cards and other programs heightens patient cost sensitivity
- Patients willing to exchange "choice" for lower cost benefits
- Exchange-based benefits introduce lower cost options
- Patient demand for lower cost options drives innovation and competition in commercial market

The patient response to changes in healthcare delivery and benefit designs will play a crucial role in the success of payment reform

There is an important question about the tradeoff between care coordination and patient choice, and healthcare insurance exchanges (HIX) will facilitate the consumer ability to make informed choices

Choice vs. Cost

Coordination of care ⟷ **Patient choice**

- Historically patients have been unwilling to forego "choice" in return for only modest savings
- Coordinated care leads to better outcomes at lower costs, but it also conflicts with the notion of unfettered patient choice of provider at the point of service

Impact of HIX

- The availability of various exchange plan options will allow patients to purchase lower cost options with thinner coverage
- As employees are pushed to the exchanges, greater innovation and competition is expected
- HIX increases transparency of OOP max, deductibles, and other costs, as well as provider quality

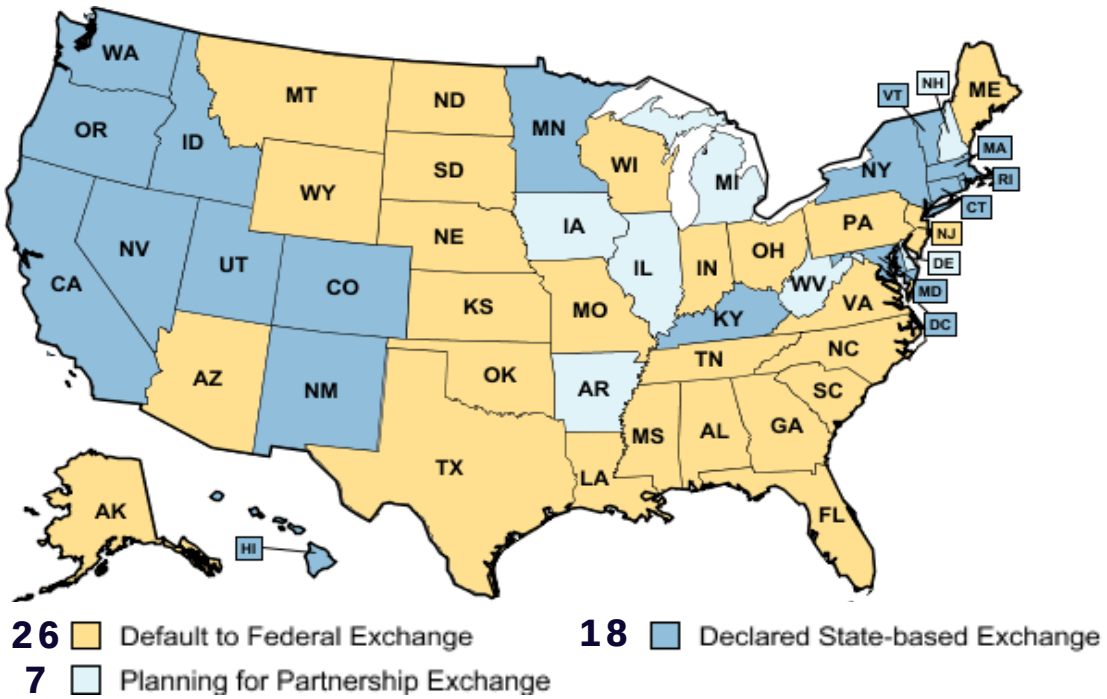
"ACO is just another way to say HMO without having to say HMO." - **Health Economist**

Exchanges and other factors will transform the insurance landscape

Healthcare Exchanges

- Individuals shopping for coverage increasingly select thinner benefit designs and CDHPs, or trade "choice" for lower costs
- Transparency provides buyers with clear data on cost and quality
- Patients may forego "choice," opting into higher-control settings, including HMOs and ACOs

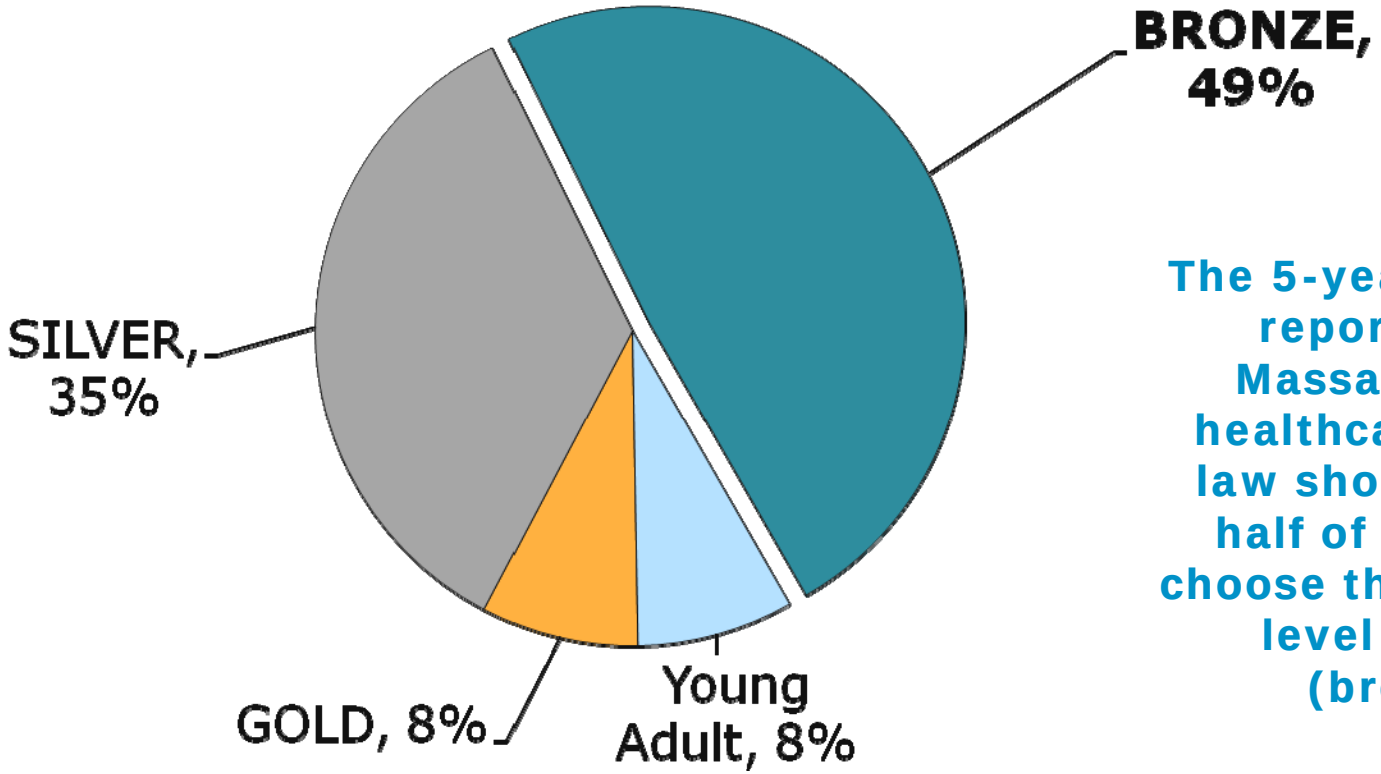
HIX State Participation



Source: Kaiser Family Foundation

Experience from Massachusetts suggests beneficiaries will adopt lower cost, thinner coverage

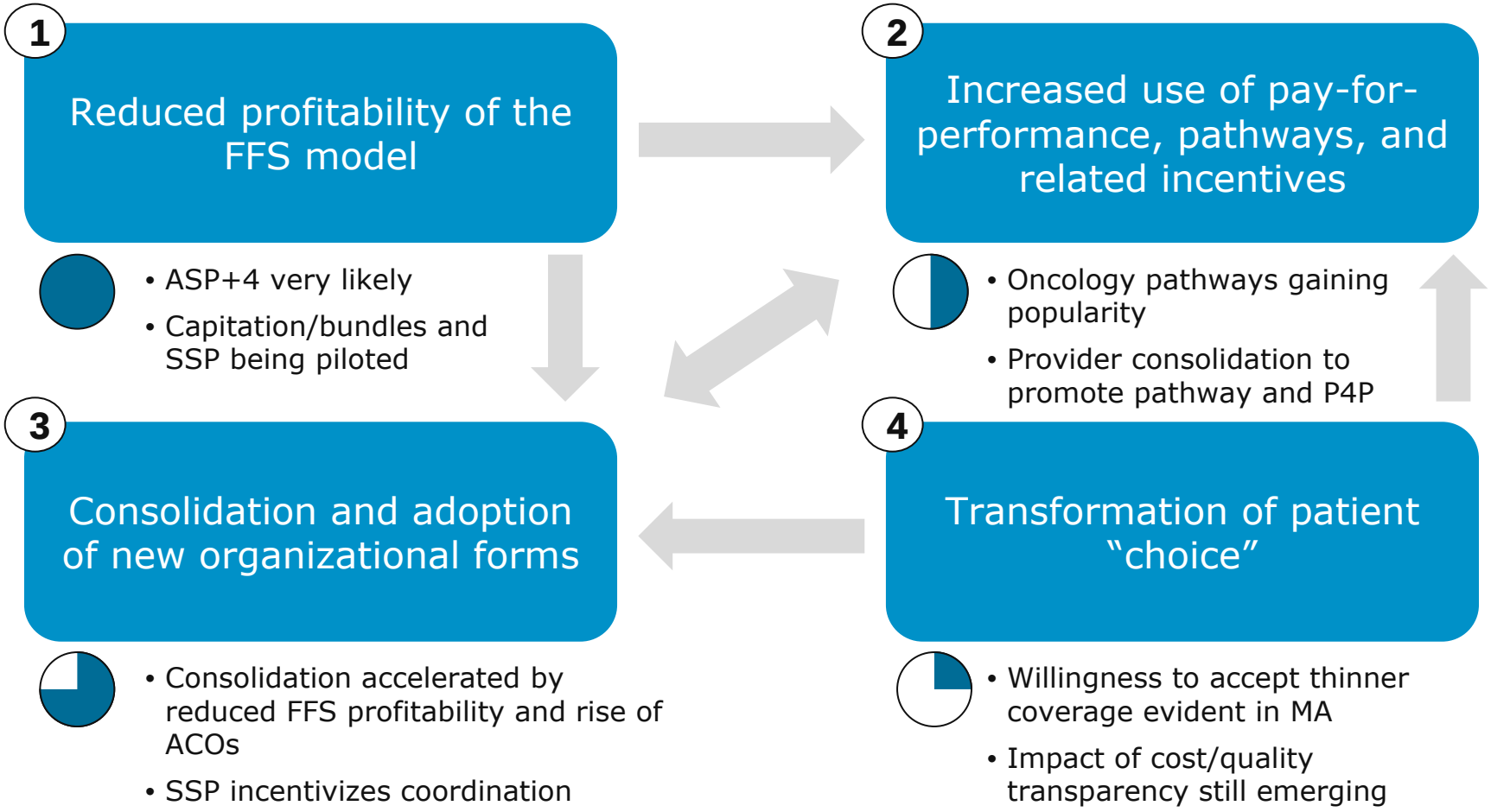
MA Commonwealth Choice Members By Benefit Level (Aug 2011)



The 5-year progress report of the Massachusetts healthcare reform law shows almost half of members choose the minimum level benefit (bronze)

Source: Massachusetts Healthcare Reform: A Five-year Progress Report, BCBS Foundation of MA, Nov 2011

The process of payment model transformation has begun – stay tuned

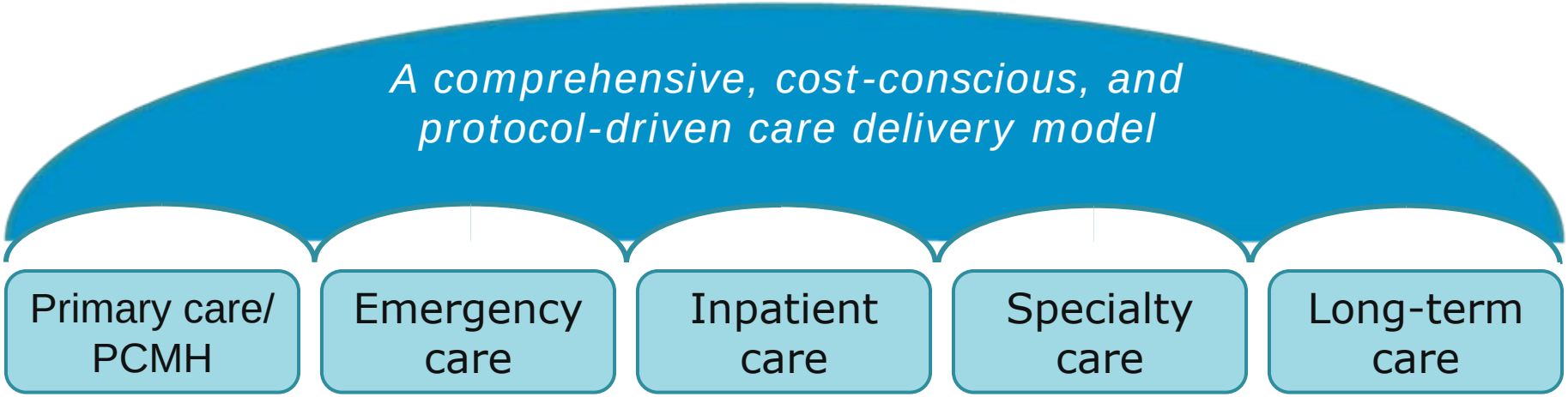


Status: No progress ◯ ⟷ ● Fully underway

The most far-reaching effects of the Affordable Care Act will come from 1) expansion of coverage and 2) payment reforms

	What is it?	Mfr Implications?
Coverage Expansion	• Enrollment of the uninsured in health plans offered through state exchanges • Expansion of Medicaid	• Increased demand • Increased payer management • Lower profit margins
Payment Reforms	• Avoidable Readmission Penalties • Value-based Purchasing Program • Penalties for Hospital Acquired Conditions • ACO Shared Savings Program • Bundled payment pilots	• Emergence of integrated providers • Focus on cost and quality in all settings of care • Financial risk shifts from payers to providers

Pay-for-performance reforms are driving formation of comprehensive provider networks that are cost-sensitive, protocol-driven, and paid on quality



Under reform, the new provider needs to have:

- **Comprehensive network and care coordination** to manage total patient care across settings
- **Protocols** embodying best practices to guide physician decision making
- **Infrastructure** to accept and distribute payment on behalf of multiple providers
- **HIT** to enable physicians to manage patients and report on outcomes

To optimize payments under reforms, a central provider must be able to 1) ensure quality across settings of care, 2) control costs, and 3) accept reimbursements on behalf of multiple providers

The ACO model, broadly defined, already covers about one-in-seven US lives, and the growth curve is steep

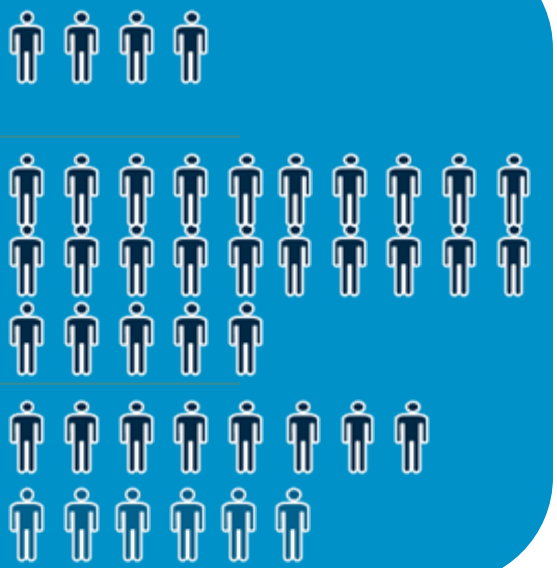
Its estimated that 37-43 million lives, or 14% of the population, already receive care through ACOs

37 to 43 million Americans currently receive healthcare through ACOs

4M Medicare lives are in Medicare ACOs

25M Commercial lives are in Medicare ACOs

8-14M Lives are part of non-Medicare ACOs



The ACO Shared Savings Program is "training wheels" for providers to learn to coordinate care, control costs, and report on outcomes

Source: Oliver Wyman

Health Exchanges expose payers to price competition, limits on profits, and rating restrictions that will drive them to shift risk

Reform Measures

- Guaranteed Issue
- Rating Restrictions
- Price Competition on Exchanges
- Mandatory Minimum Loss Ratios
- Rising Medical Costs

Commercial Payer's Mindset:

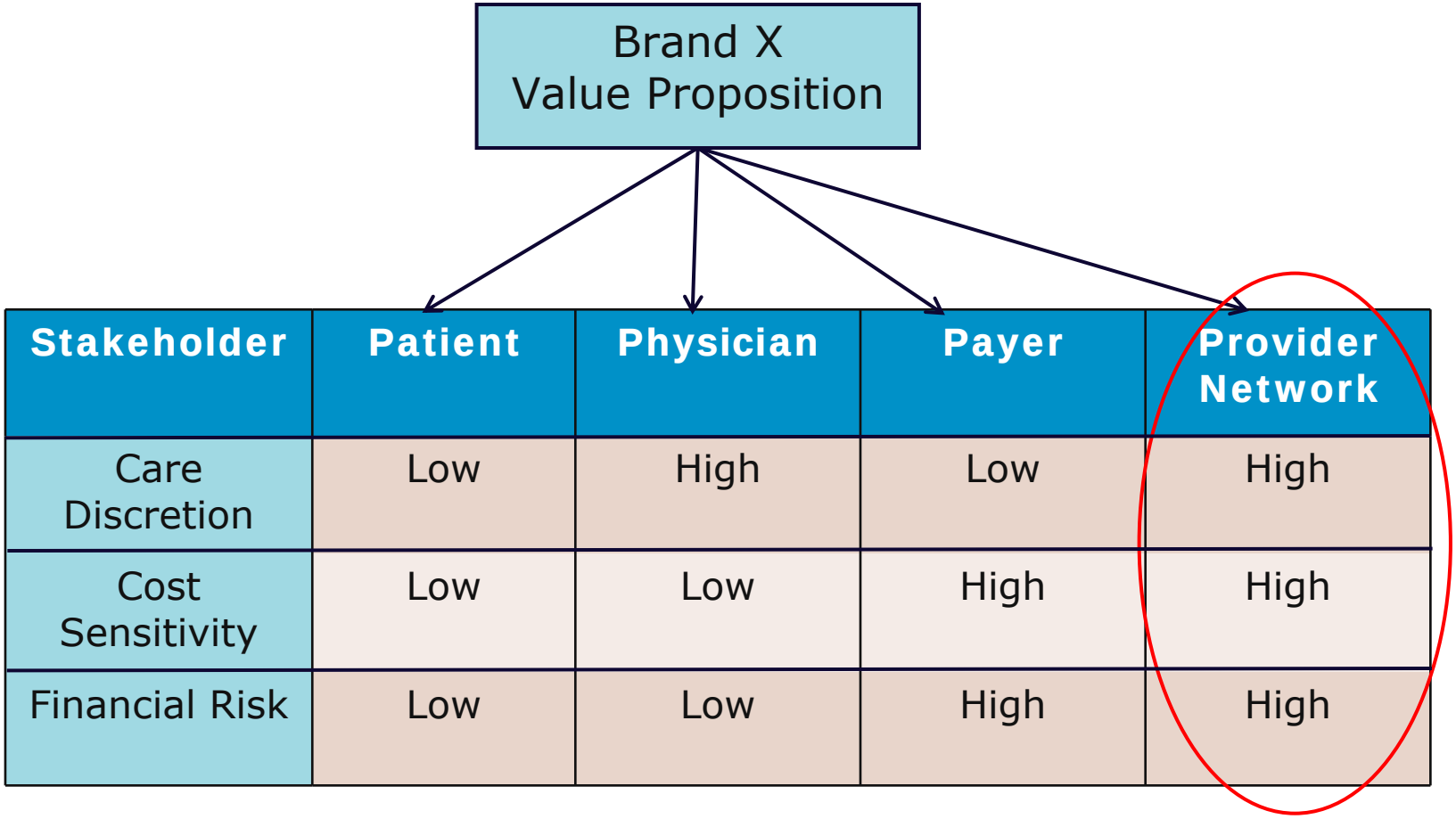
- Needs growth from Exchanges but fear risk
- Needs to establish stable, predictable costs with limited swings toward loss or profit
- Recognizes that capitation forces cost savings
- Would like to set PMPM payments and performance standards and step away from care management

In any region, evidence and endpoints must be tailored to resonate with the most sophisticated stakeholders

Stakeholder	Patient	Physician	Payer	Provider Network
Care Discretion	Low	High	Low	High
Cost Sensitivity	Low	Low	High	High
Financial Risk	Low	Low	High	High

At-risk provider networks will demand compelling clinical and economic evidence to demonstrate how new technologies improve cost-care equation

In a changing landscape, a product's value proposition must be tailored to appeal to all relevant stakeholders



Stakeholder	Patient	Physician	Payer	Provider Network
Care Discretion	Low	High	Low	High
Cost Sensitivity	Low	Low	High	High
Financial Risk	Low	Low	High	High

Promotional mix must shift toward stakeholders that control access to drugs across the care spectrum

Relevant Stakeholders

- Network P&T Committee
- Network Pharm. Director
- Care Protocol Committees
- Physicians

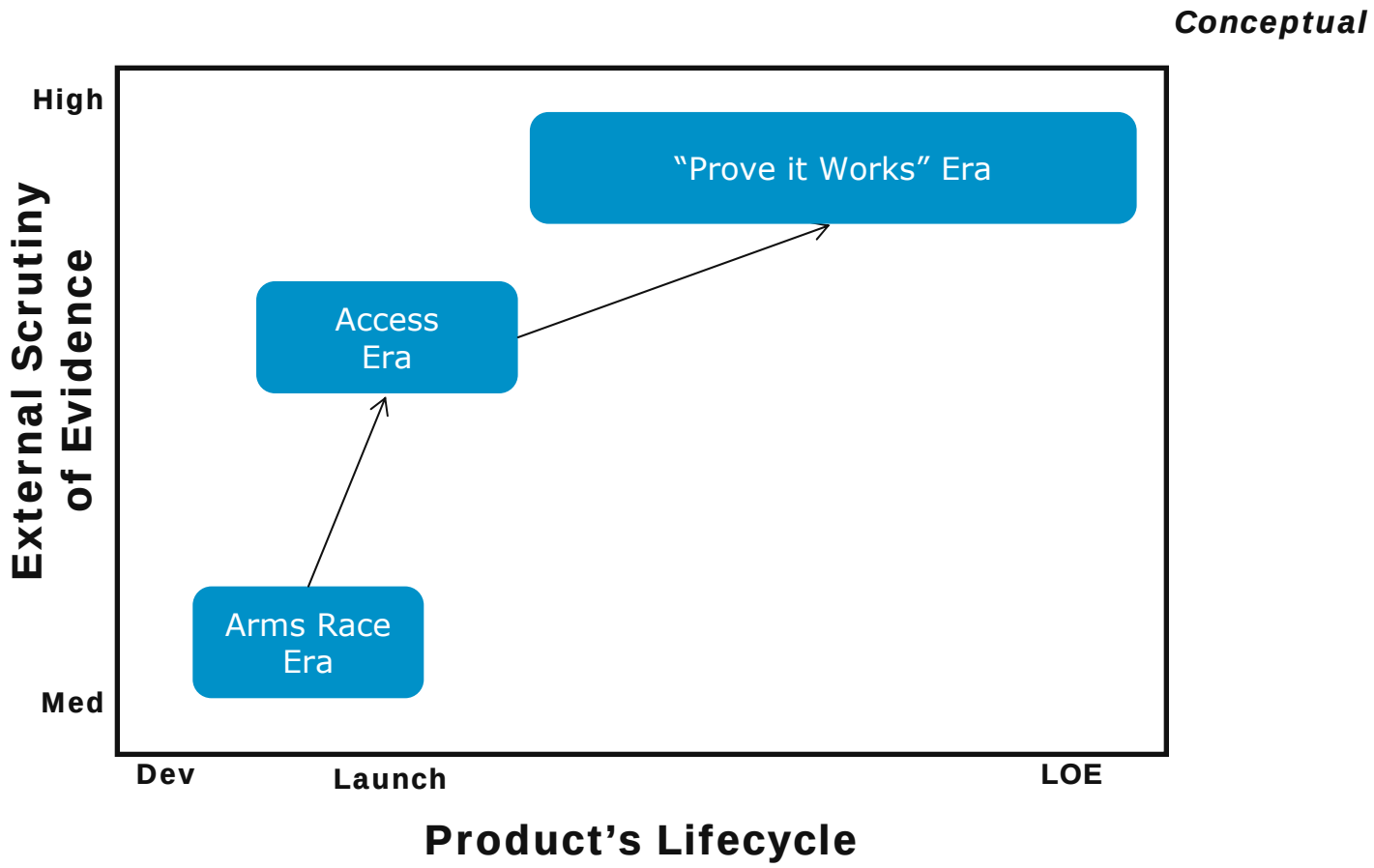
- *Challenges in this setting of care*
  - Sales Reps will face increasing barriers to access to prescribers
  - Prescribers face limited discretion under formularies and protocols
  - *Manufacturer must tailor its approach*
  - Provider Networks will be open to medical communications by MAMs about new information and data
  - KAMs need to deliver B2B value to secure access

Local market understanding will be critical to developing the right mix of field personnel to succeed in a given market

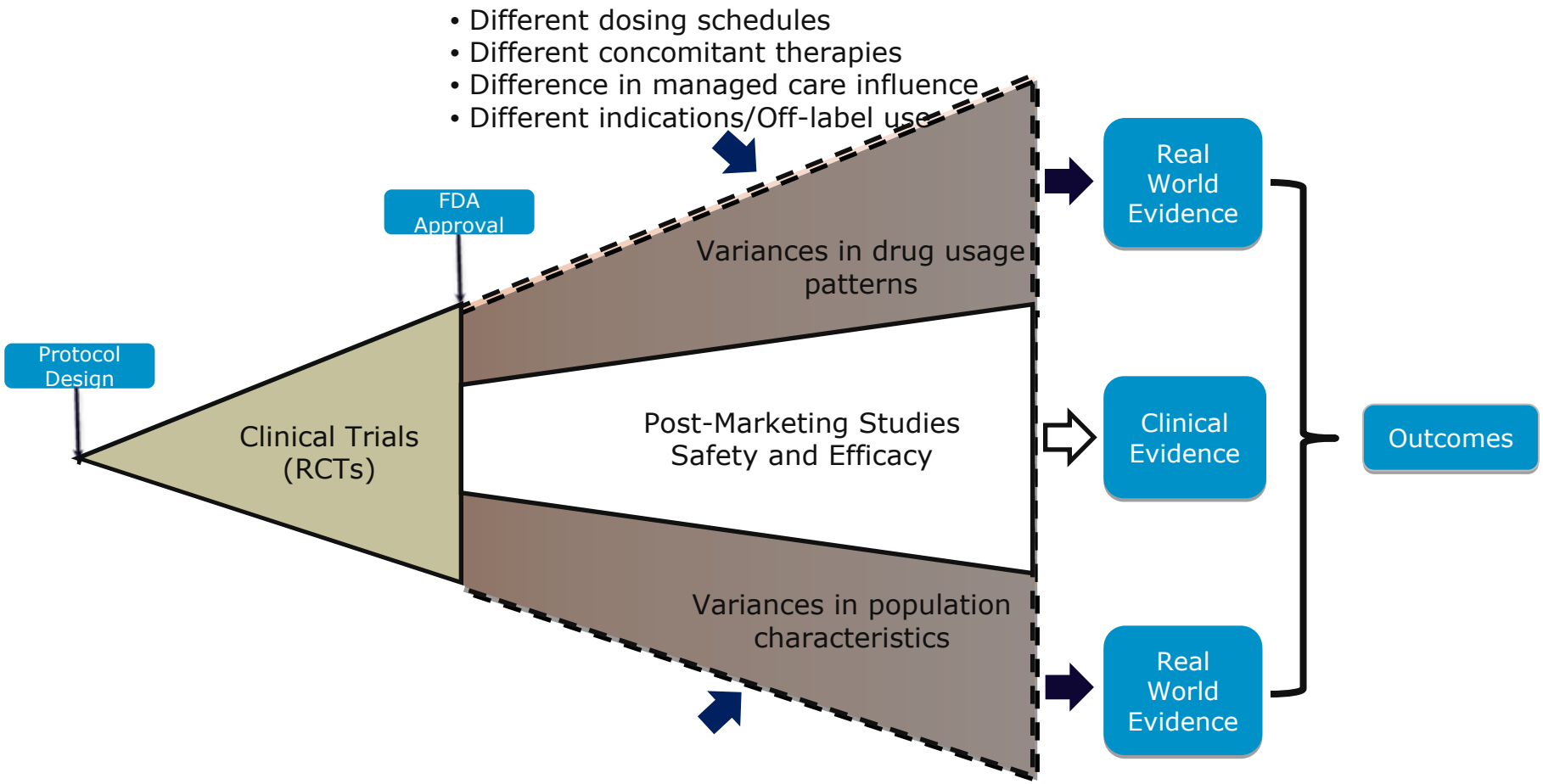
Agenda

- Hallmarks of payment reform
- **The birth of real world evidence**
- Intersection: case studies

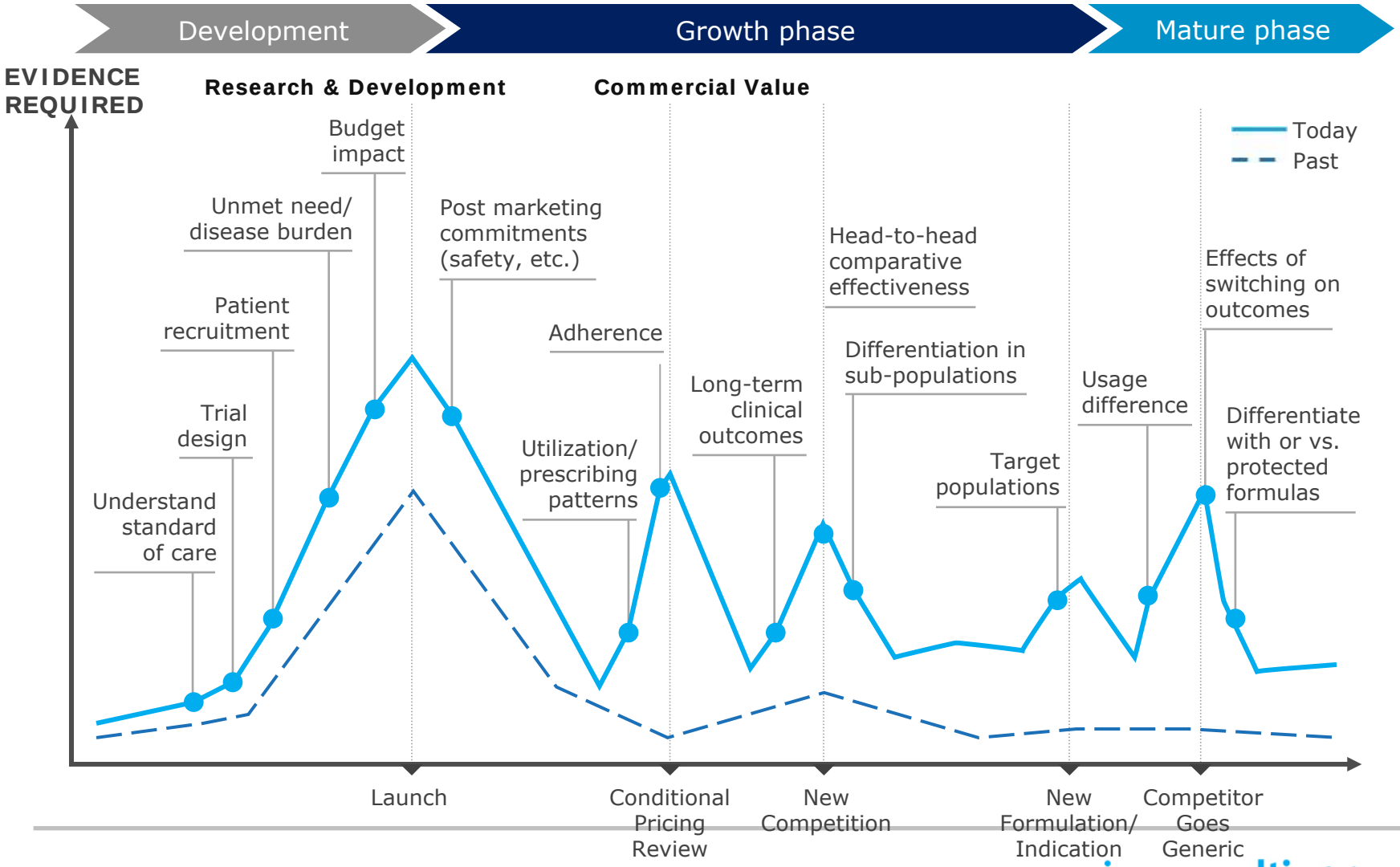
RWE is transforming the industry into a new era – The "Prove it Works" Era



This is due to the fact that RWE provides insights not possible from clinical trials



RWE extends across the product lifecycle



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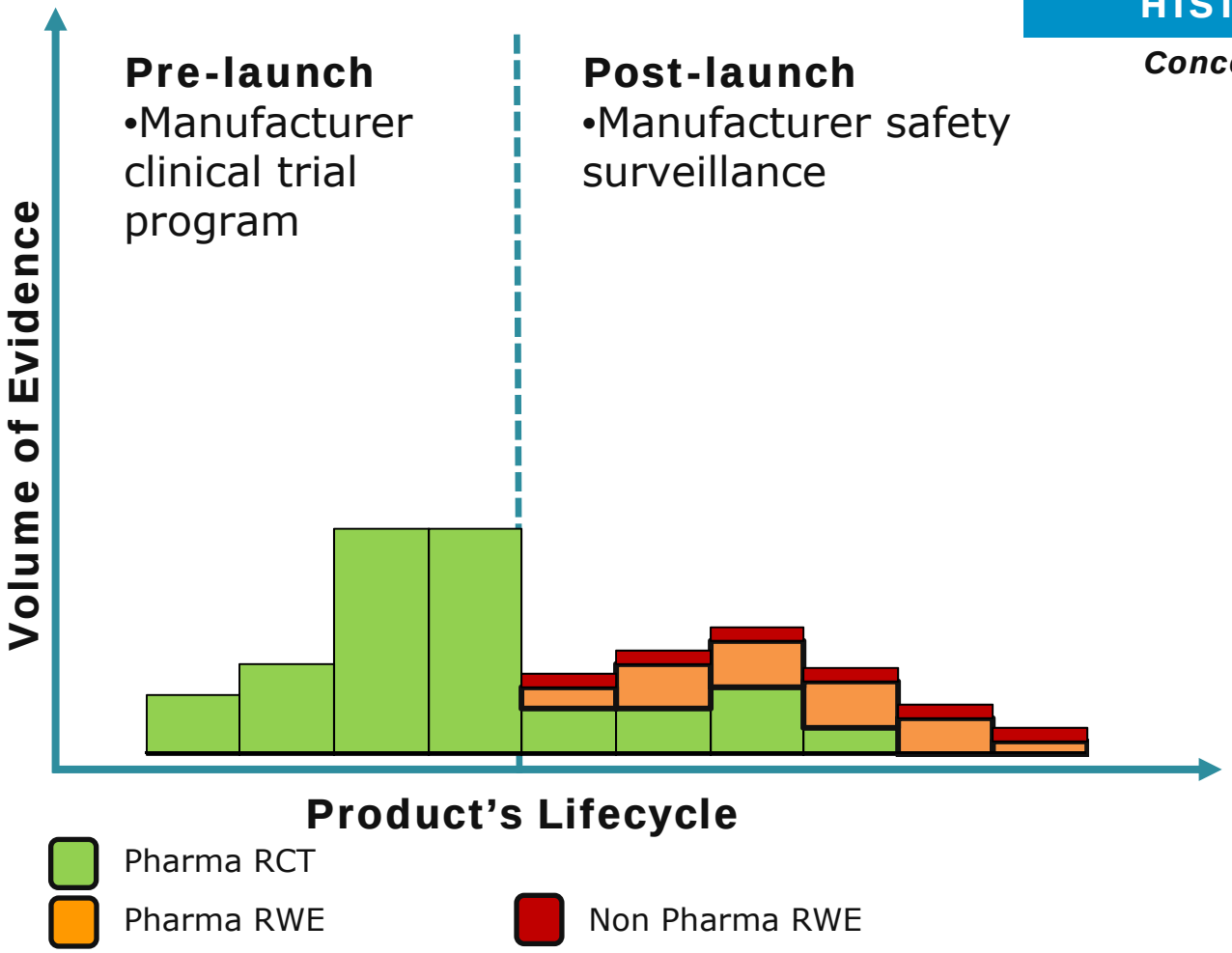
Historically Pharma were almost the exclusive custodians of data related to their products

HISTORIC

Conceptual



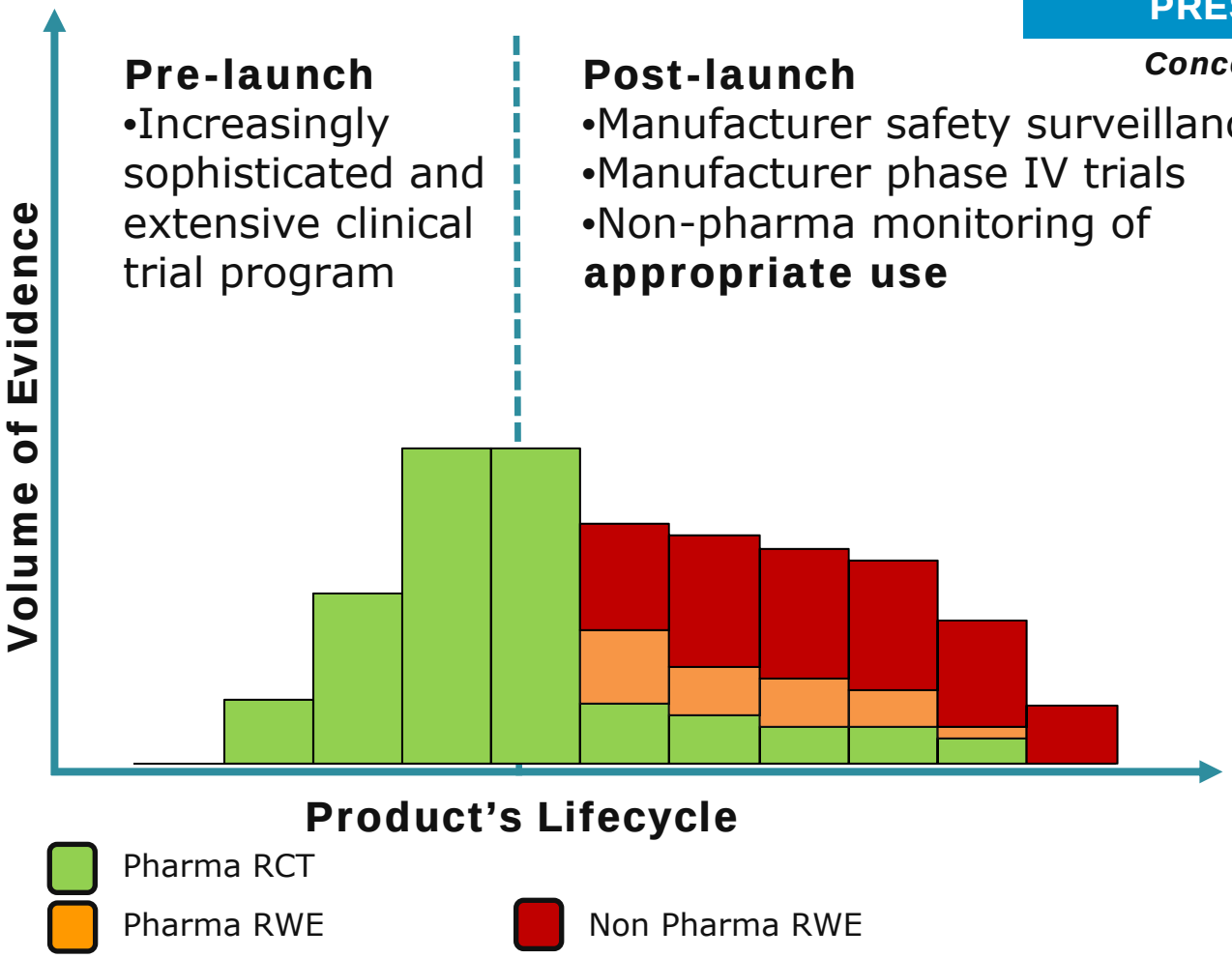
Whilst the data collected by Pharma has increased, governments/payers are generating their own data

PRESENT

Conceptual

Pre-launch
- Increasingly sophisticated and extensive clinical trial program

Post-launch
- Manufacturer safety surveillance
- Manufacturer phase IV trials
- Non-pharma monitoring of **appropriate use**



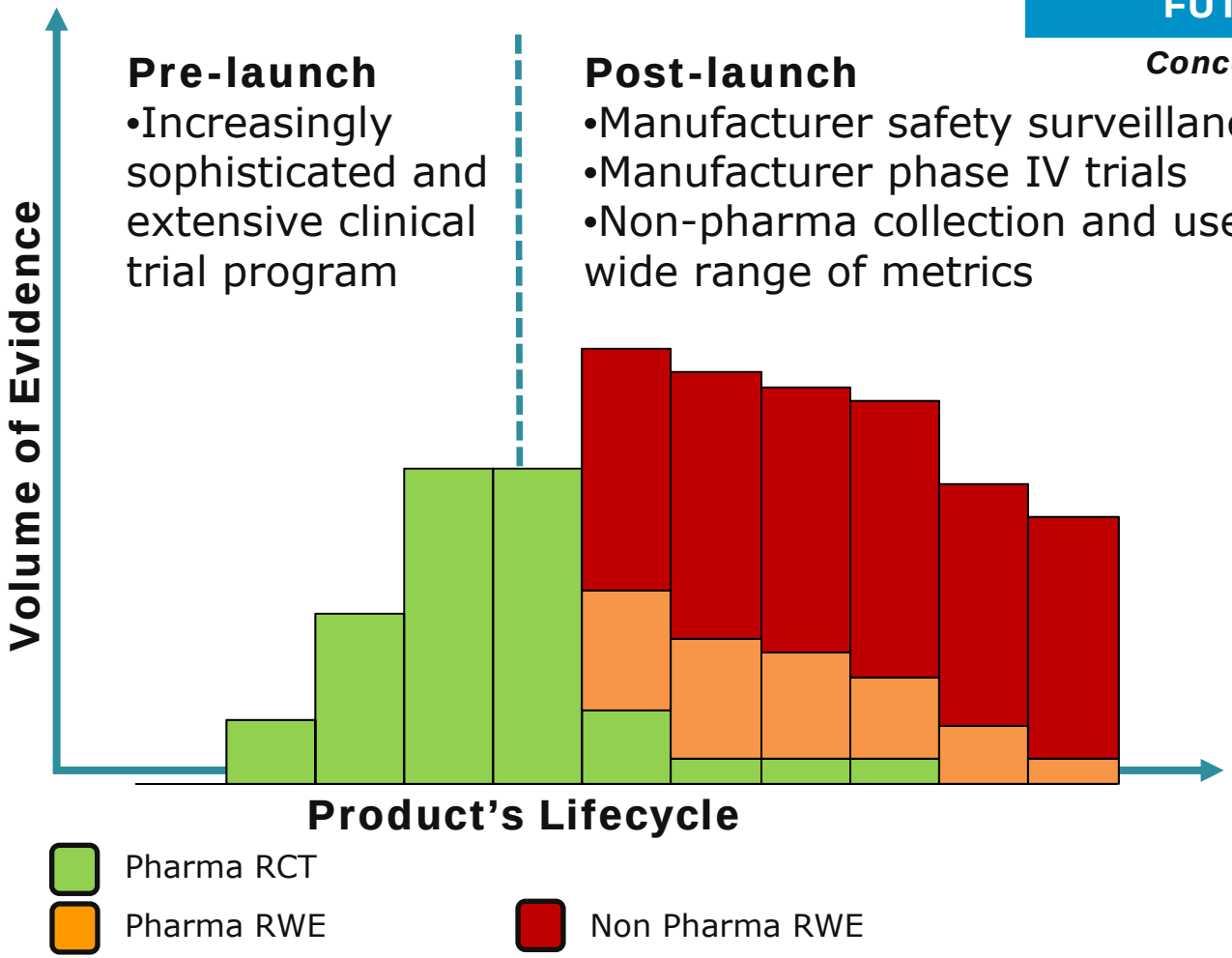
In the future, these programs will develop further to include a wide range of metrics, outpacing data collection by Pharma

FUTURE

Conceptual

Pre-launch
- Increasingly sophisticated and extensive clinical trial program

Post-launch
- Manufacturer safety surveillance
- Manufacturer phase IV trials
- Non-pharma collection and use of wide range of metrics



Third parties are offering support to stakeholders across the spectrum in terms of both analytics…

Supporting Specialized Data Needs & Integrated Assets

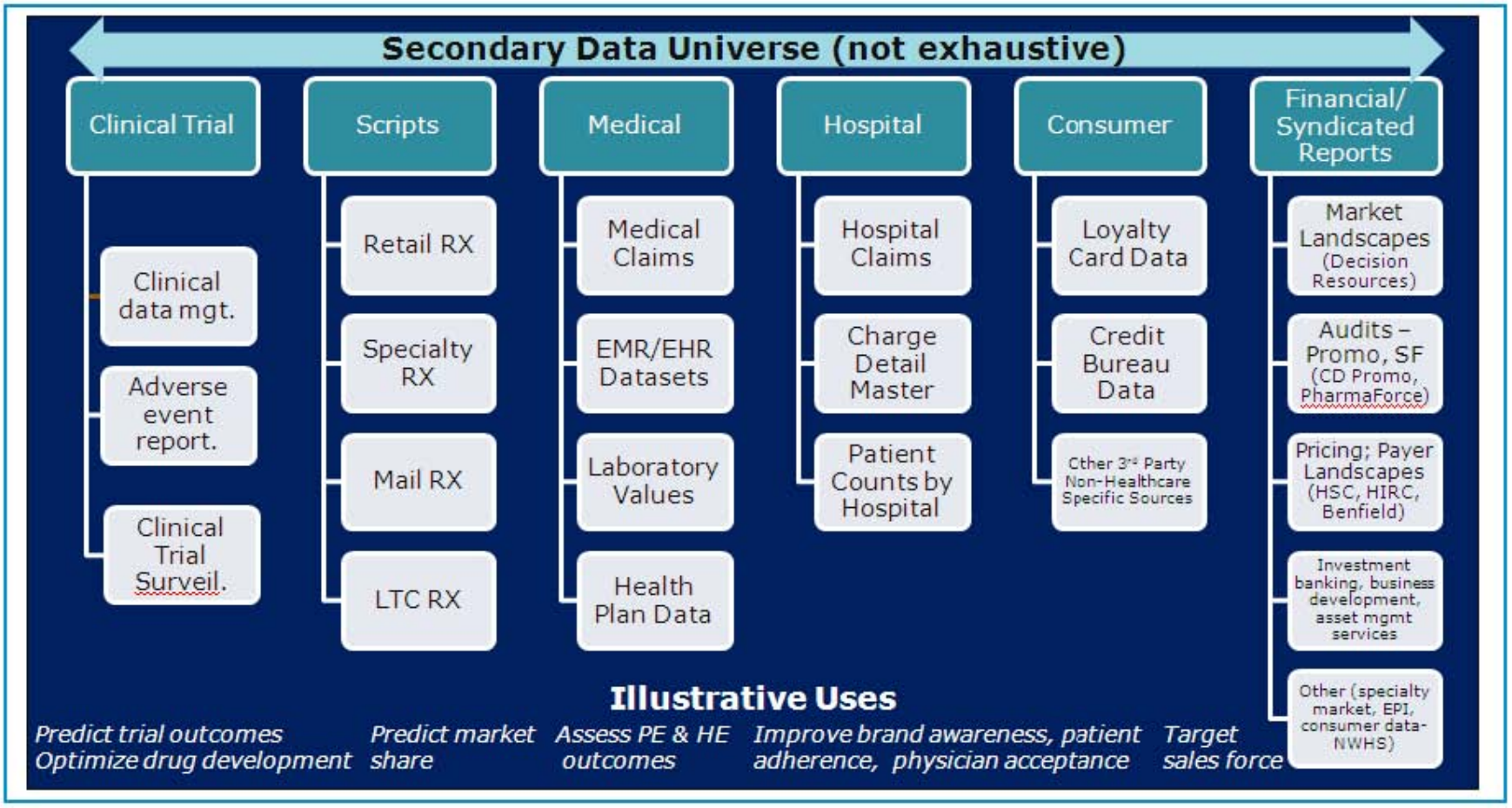
Tools To Drive Broad Dissemination

Next Generation Analytic Tools

Bundled Analytic Services

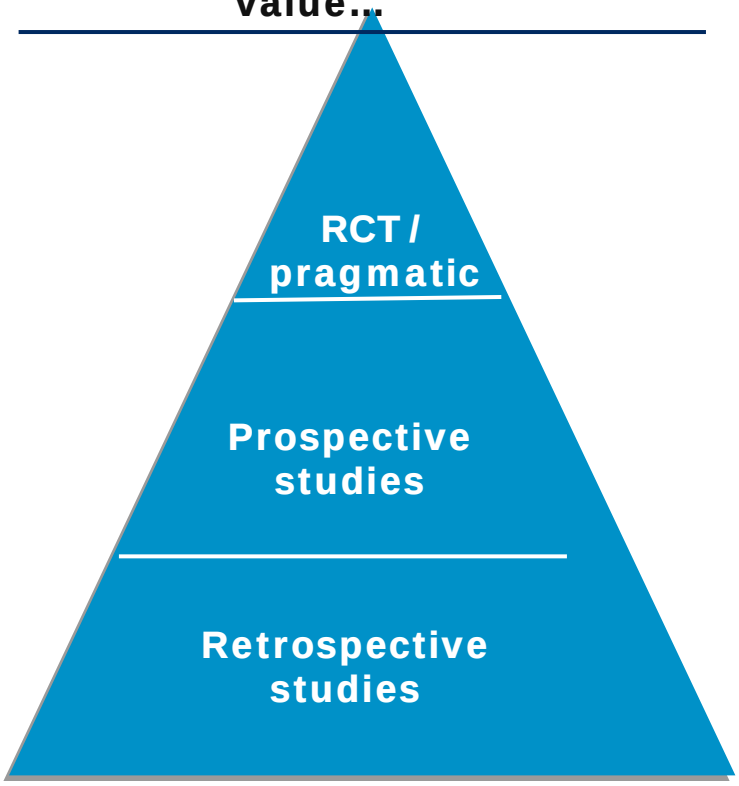
Providing Flexible Support Models

…and a vast array of available data

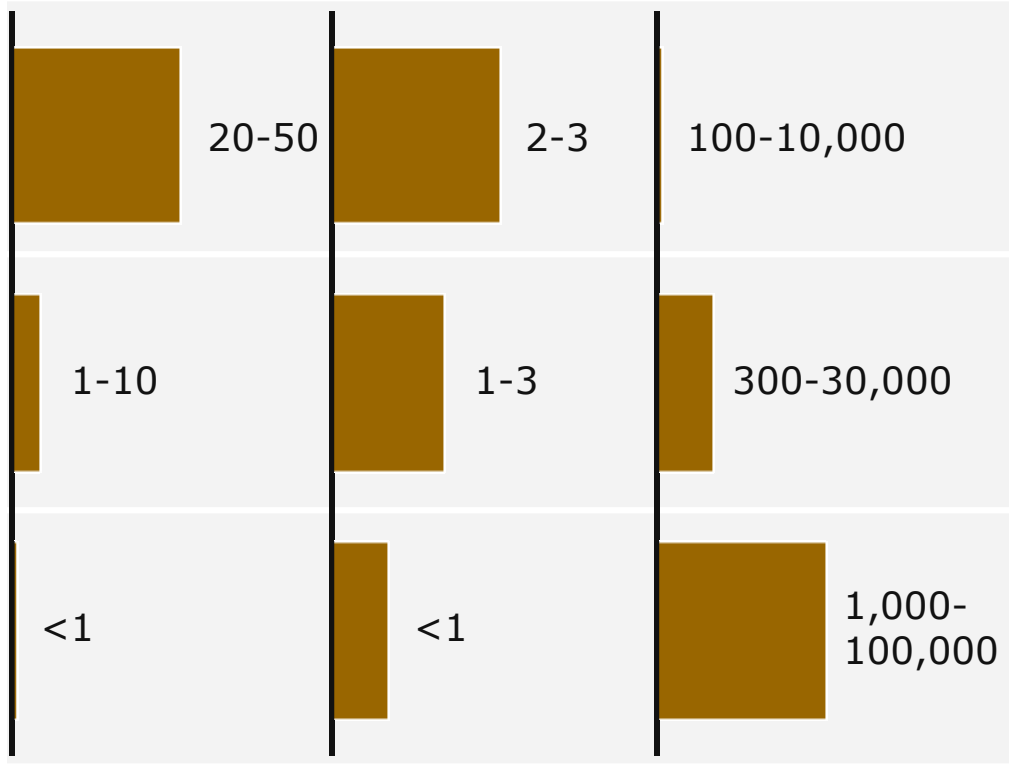


Certain types of evidence are preferred by stakeholders, but there are clear trade-offs

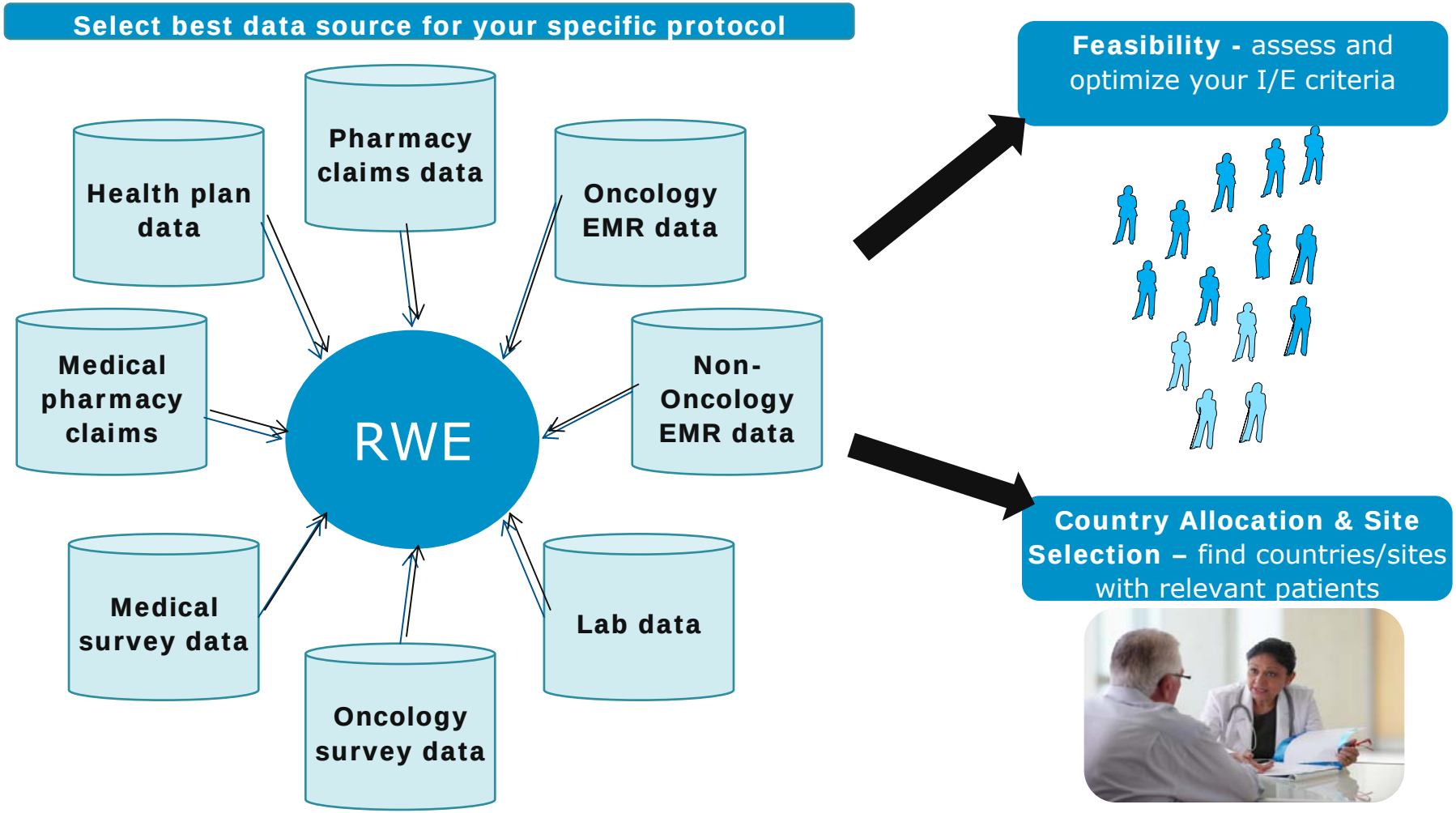
Stakeholder perception of value…



…versus development cost, time and scope

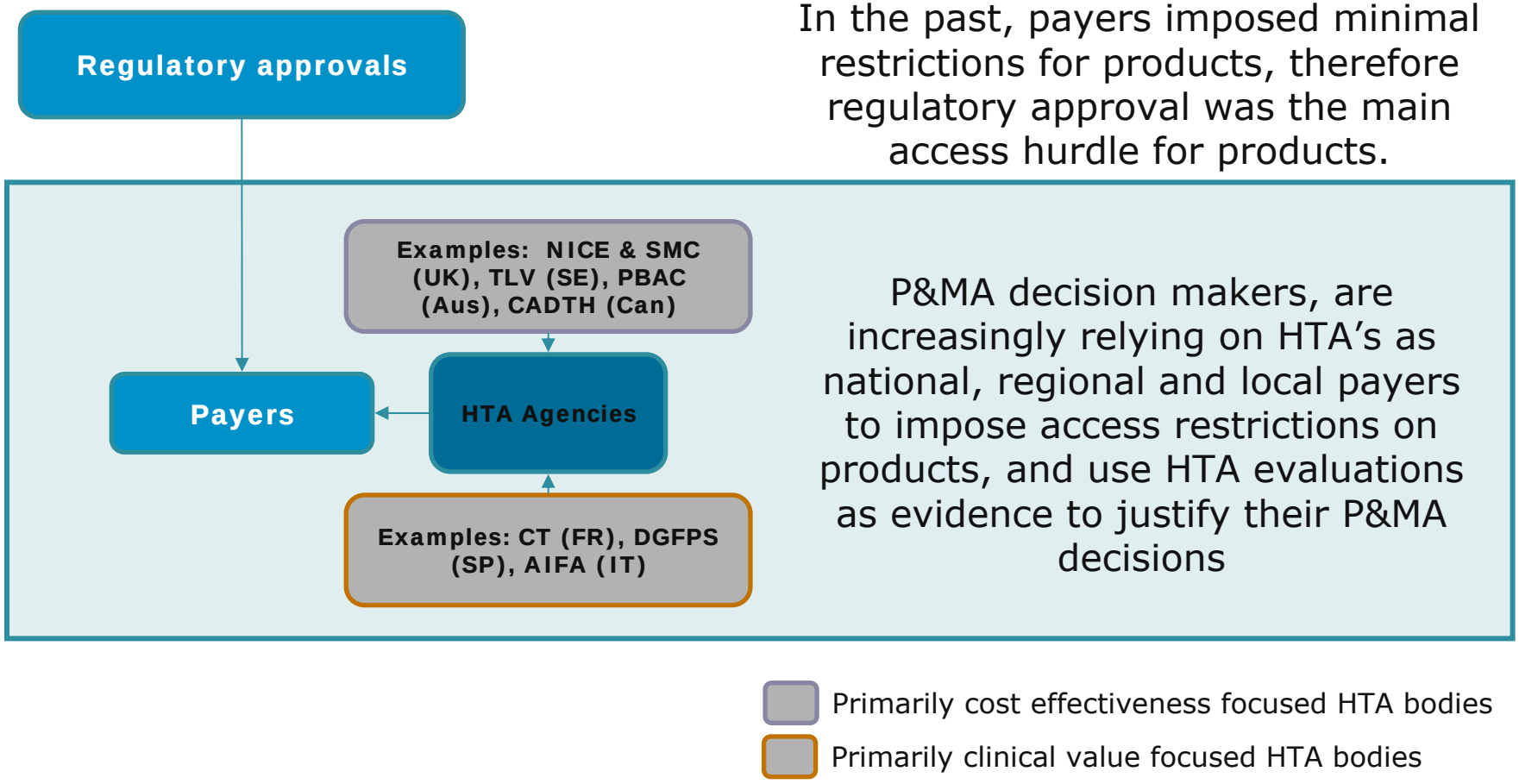


In this environment, the application of inclusion/exclusion criteria against the relevant patient population is of the utmost importance…



…as payers are using more sophisticated approaches to restrict access to products, including greater reliance on HTAs

Key stakeholders for access to pharmaceutical products



In the past, payers imposed minimal restrictions for products, therefore regulatory approval was the main access hurdle for products.

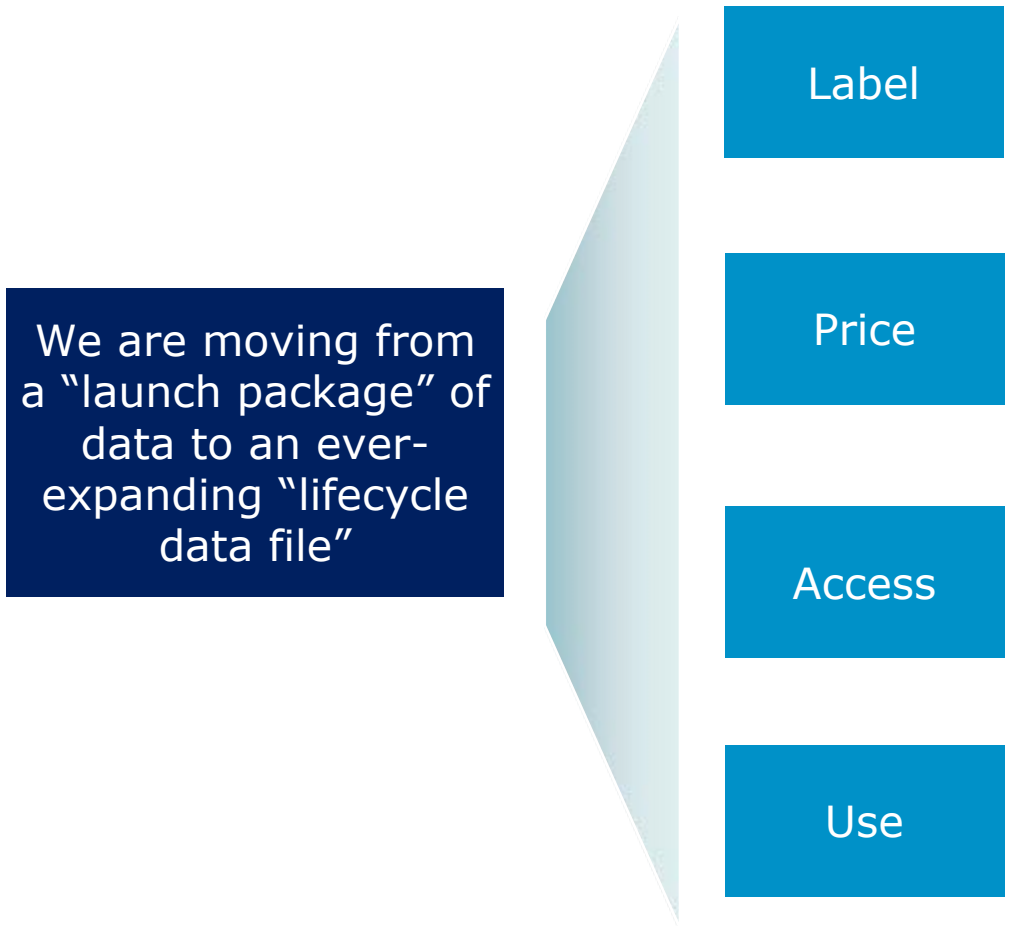
P&MA decision makers, are increasingly relying on HTA's as national, regional and local payers to impose access restrictions on products, and use HTA evaluations as evidence to justify their P&MA decisions

However, countries are at different stages in adopting real world evidence into their HTA decision making

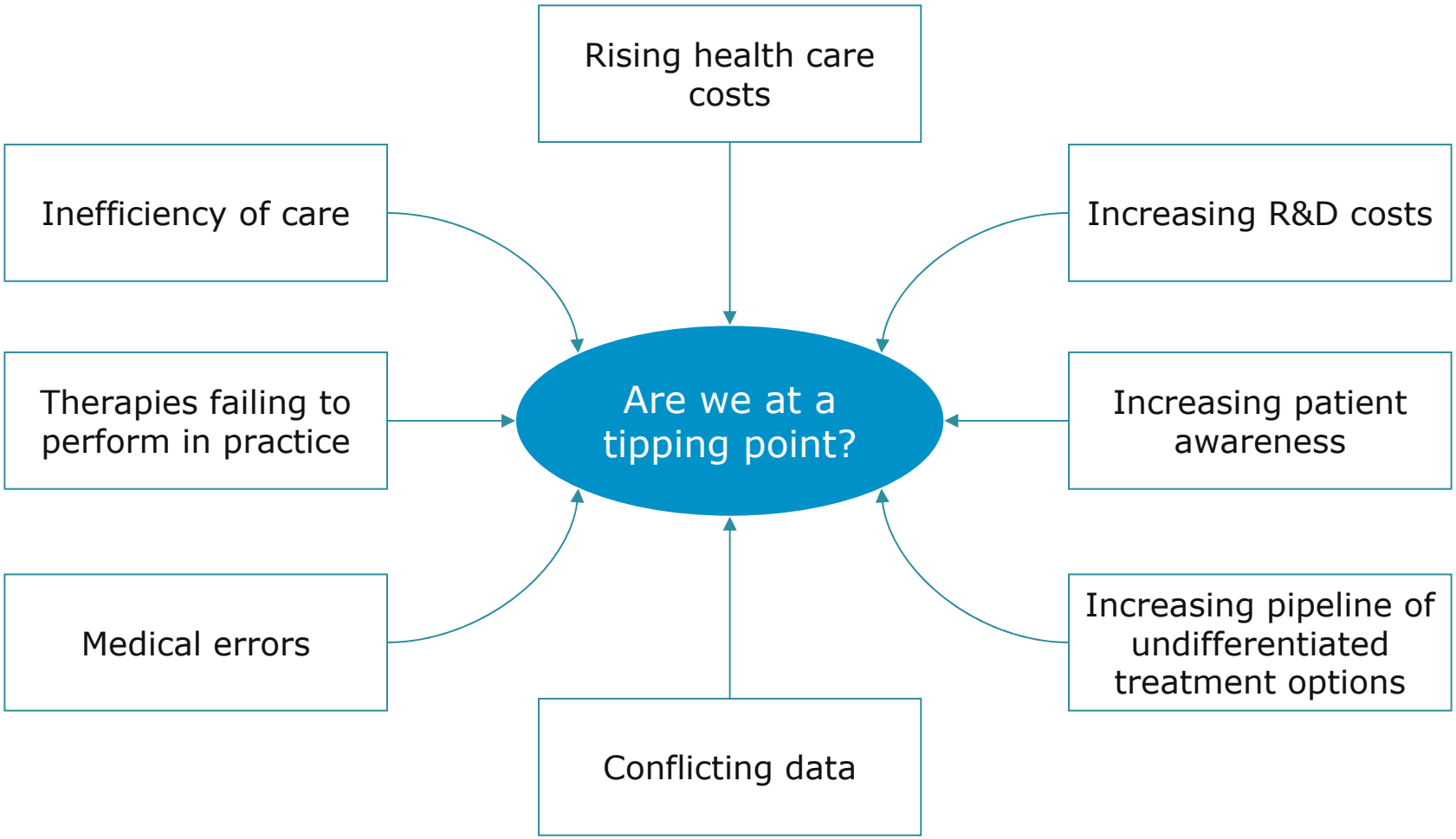
	Geographical Examples:	Label	Price	Access	Use
	• AMNOG ruling specifies that prices are to be reassessed post-launch				
	• Observational data used in post-launch decision making				
	• Drug utilisation studies specified as a condition of market access				
	• Phase IV studies potentially influencing regional payer decisions				
	• Value Based Pricing consultation will potentially reassess price post-launch				
	• Private payer attention to PCORI, private CER, FDAMA Sec 114				

No Application | Limited Application | Application

The stakes are high! A product's label, price, access and use are at continuous risk across the lifecycle…



…and stakeholders are tired of waiting



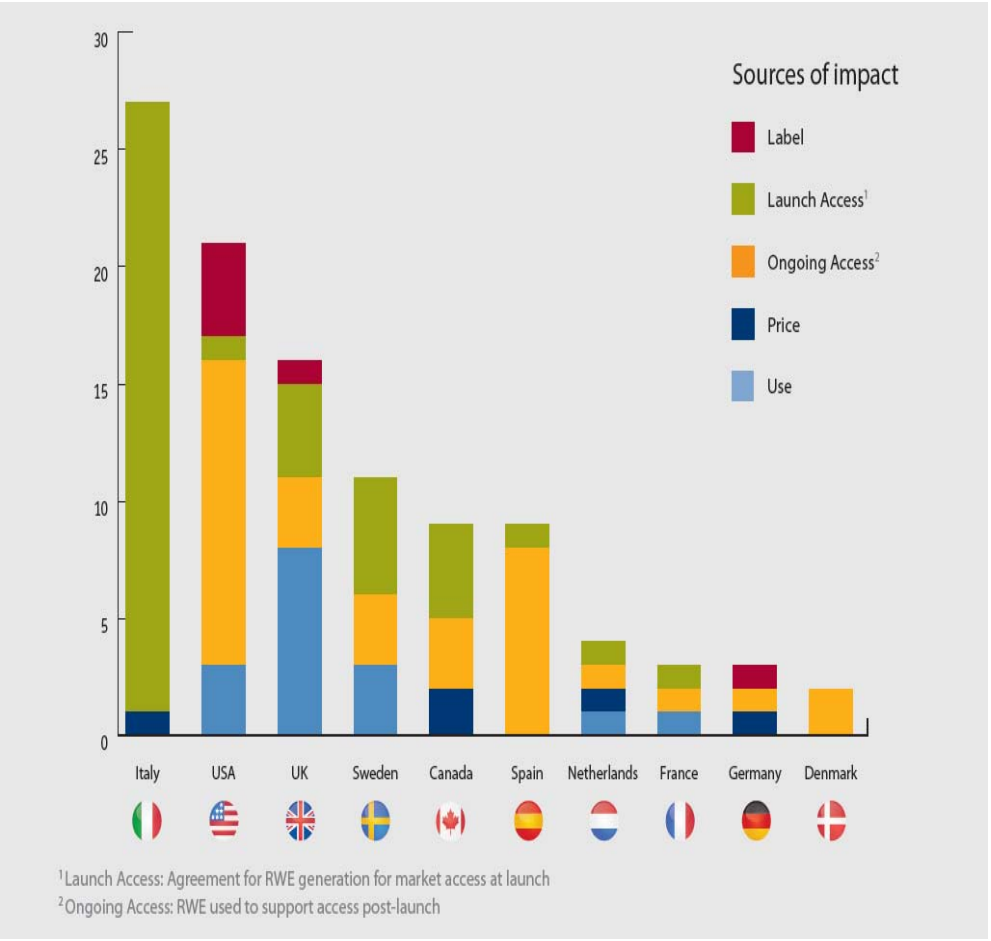
Agenda

- Hallmarks of payment reform
- The birth of real world evidence
- **Intersection: case studies**

We continue to see RWE being used much more than what you might traditionally think is the case…

Case Studies where RWE has Impacted Product Decisions

Total=104



Impact

Ongoing access

- WellPoint moved Boniva to a non-preferred tier behind a step edit requiring failure of Fosamax or Actonel after Boniva ranked lowest on an analysis of 26,000 members
- RCT evidence indicates that inhaled corticosteroids (ICS) are more efficacious than leukotriene modifiers (LM) but Healthcore's analysis of WellPoint claims showed that patients on LM had better adherence and fewer events, leading WellPoint to keep LM on a preferred tier and removing associated PA
- BCBS Hawaii tracked A1c levels for patients on Byetta versus other drugs and ultimately moved Byetta from a medical to a pharmacy benefit due to better results

Launch access

- United Healthcare agreed to reimburse the list price of Genomic Health's Oncotype Dx test for breast cancer patients for 18 months while results of the test were tracked and clinical effectiveness verified

…particularly given the increase in the number of global 'risk sharing' arrangements

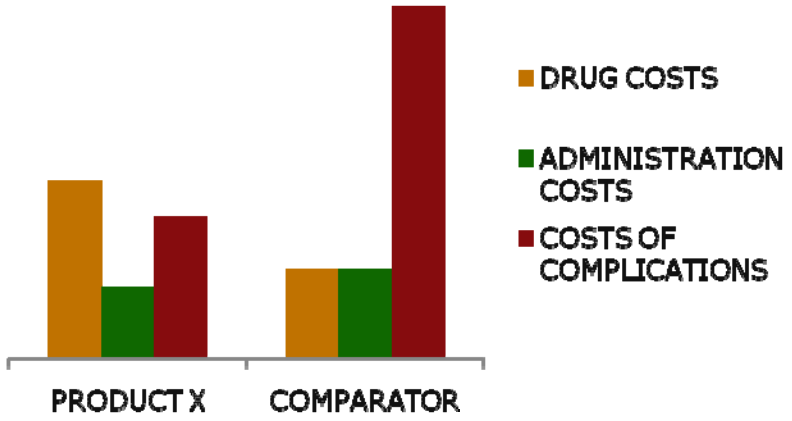
Country	Therapy Area	Brand	Brief Description
Canada	Oncology	Taxotere	Sanofi-Aventis agreed to reimbursement the cost of Taxotere to provincial payers if an agreed upon responder level had not been reached (facilitating formulary listing at launch)
France	Diabetes	Glitazone	A conditional reimbursement price for Actos was provided on the basis that additional results from clinical or observational studies would be provided; if the results of the studies were negative, the manufacturer would be required to pay back the difference for past overpayments and would apply for future price reductions
Germany	Oncology	Avastin	Roche agreed to provide full or partial reimbursement for patients in which the Avastin and Taxol combination exceeded a specific total dosage in a study designed to test whether the combination of both medicines could extend patient survival in mBC and mRCC
Italy	Oncology	Afinitor	Novartis pays back 100% of the treatment cost of Afinitor in case of treatment failure after 3 month re-evaluation
Spain	Oncology	Iressa	Iressa was granted access in one hospital only, on the basis of outcomes collected as part of a contracting pilot project between AZ and Catalonia

'Accelerated approval'

In Sweden, demonstrating real-world cost offsets preserved market access and premium pricing

Large increase in sales of CNS drug led TLV to question its price and reimbursement

Retrospective Swedish RWE Study



Showed that initiating Product X in patients with a mental health condition significantly reduced overall health care costs

TLV have, as of this day, not restricted the reimbursement or reduced the price of Product X

Thank you.

Questions?

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