

HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS



A large, abstract background graphic consisting of a series of overlapping, semi-transparent triangles in shades of gray and white, creating a sense of depth and perspective.

CERTARA®

EVIDENCE & ACCESS

As the US healthcare system becomes more value-driven, manufacturers must differentiate products to be in favorable market access positions with payers and providers

We engage with key stakeholders and use analytics-based approaches to develop targeted and strong product value stories for early-stage products through commercial launch.

The FDA is encouraging manufacturers to explore novel endpoints and clinical trial designs

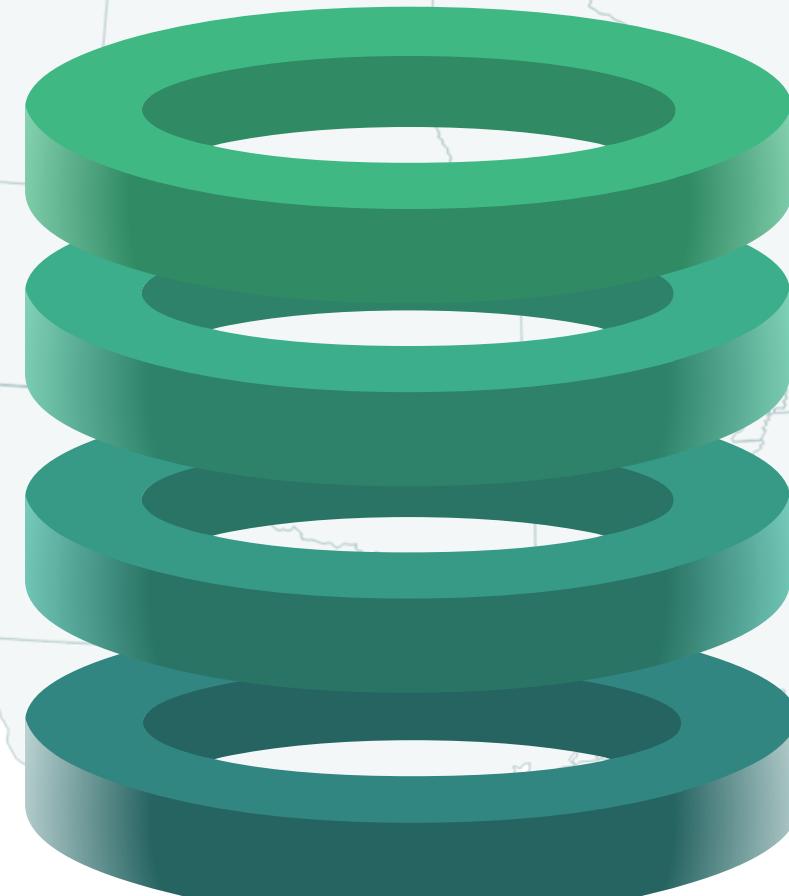
Certara has a track record in developing and validating new clinical endpoints, allowing manufacturers to be recognized as leading market innovators.

In an insurance environment strongly driven by budget concerns, manufacturers must pressure-test multiple pricing strategies prior to launch

We leverage our vast payer network to assess the best pricing scenario that will lead to optimal reimbursement across all payers.

There is an increasing trend for US healthcare stakeholders to utilize treatment patterns and guidelines (e.g. NCCN) in clinical practice

Through KOL engagement, we provide manufacturers with a full picture of treatment patterns and strengthen value propositions with clinical relevance.





HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS

1

DESCRIPTION

A large pharma company, for a new division, requested a strategic segmentation of accountable care organizations and other at-risk provider entities

2

KEY OBJECTIVE

Develop a segmentation of ACOs, integrated delivery networks and patient centered medical homes that aimed to inform a new division of account managers of organizations and areas where the greatest opportunities for success reside

3

Certara METHODOLOGY

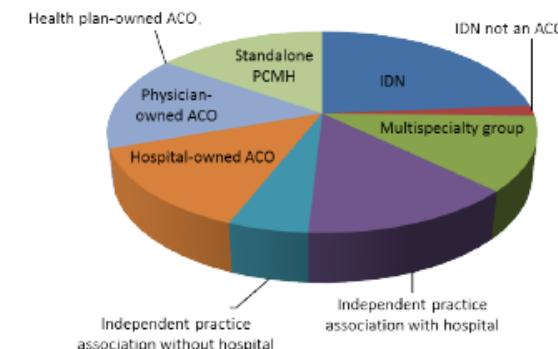
In-depth interviews with 59 ACO decision-makers, both payers and providers

4

RESULTS & DELIVERABLE

- Metrics and levels were developed from the research aligning to level of opportunity
- Since the ACO market continues to evolve rapidly, a dashboard was encoded into reporting software so the account managers can keep the segments current based on field intelligence
- A strategic market access plan was awarded as a result of this work

Panel distribution for ACO segmentation (n=59)



Distribution of roles and representation in the panel (n=59)

Role	Number
Payors	10
Providers	30
• Physician group	19
• Hospital	19
Total	59



HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS

1

DESCRIPTION

Client requested a customer-facing presentation to engage payers on health insurance exchanges

2

KEY OBJECTIVE

- Educate payer customers on regulations and potential effects on managed care, thereby providing an opportunity for discussion on the exchanges
- Provide an independent perspective of the opportunities and challenges health plans face with implementation of Marketplaces
- Provide an updated view of Marketplaces with early enrollment experience

3

Certara METHODOLOGY

Secondary research and graphic design

4

RESULTS & DELIVERABLE

- Account managers used the presentation with customers
- Presentation has also been used as an internal training tool
- As new information was released, regulations evolved, and the implementation proceeded, several updates to the presentation were requested and fulfilled

Most enrollees will be in a federal Marketplace now that 34 states will be using a federally driven system

State decisions on Marketplaces

State decisions on Marketplace creation
October 2013¹



■ State-based Marketplace and Moving Forward with the Medicaid expansion (16 States including DC)

■ State-based Marketplace and Not Moving Forward with the Medicaid expansion (1 State)

■ Federally-Facilitated or Partnership Marketplace and Moving Forward with the Medicaid Expansion (10 States)

■ Federally-Facilitated or Partnership Marketplace and Not Moving Forward with the Medicaid Expansion (24 States)

Opportunities

Large national plans have the advantage in administering or working with the federal government

Challenges

States may change model after experience in first year



HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS

1

DESCRIPTION

A client requested a characterization of payers' pricing and access strategies through 2020 for current and pipeline products covered under the pharmacy and medical benefits in an effort to inform their business development assessments and strategies

2

KEY OBJECTIVE

Identify strategies that payers may adopt in a competitive category as the market evolves and create a comprehensive landscape with an estimate of the likelihood of adoption of strategies by year

3

Certara METHODOLOGY

Conduct in-depth interviews with nine US medical and pharmacy directors who are members of formulary committees and have responsibility for 60 million commercial lives

4

RESULTS & DELIVERABLE

- Identified current access management strategies in use by plans in the category
- Identified specific management strategies that payers expect to adopt in the future in both the medical and pharmacy benefits and timeframe for adoption
- Identified impact of scenarios such as price increases, entry of generics, and pipeline products on future management strategy
- Identified expected prices for pipeline agents and evidence needed for premium pricing

In the category assessed, increasing treatment options with few innovations will lead to decreased payer willingness-to-pay and more restrictions

Trend and drivers of willingness-to-pay through 2020





HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS

1

DESCRIPTION

A large biotechnology company requested initial research to understand the impact to specialists of key provisions of the Affordable Care Act

2

KEY OBJECTIVES

- Conduct exploratory research to understand the current and anticipated impact of healthcare reform provisions on providers and their treatment of patients
- Identify hypotheses for further testing in a larger scale research project

3

Certara METHODOLOGY

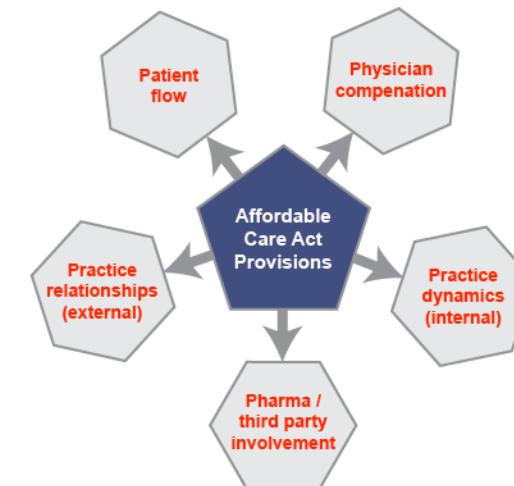
In-depth interviews with fifteen specialists and five practice managers from multiple settings

4

DELIVERABLE

Exploratory research with neurologists was organized into likely domains of impact according to provisions of the Affordable Care Act

Organization schematic of exploratory specialist research





HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS

1

DESCRIPTION

A large pharma company requested strategies to take advantage of opportunities and address potential gaps over the next 10 years in the metabolic space

2

KEY OBJECTIVE

Characterize management of metabolic portfolios among ten key pharmaceutical companies with R&D programs in discovery and development of new agents and/or delivery systems to treat metabolic disorders

3

Certara METHODOLOGY

- Primary research through telephone interview of US and EU KOLs (n=7), external commercial/R&D/BD executives (n=32) and client commercial/R&D executives for an assessment of the competitive situation, identification of attributes leading to long term success and rating of portfolios
- Primary research through an online survey of 14 business development external execs to prioritize attributes and rate companies

4

RESULTS & DELIVERABLE

- Ranking of metabolic companies and key strengths and weakness of client
- Identification of competitors that will challenge client's portfolio

Top attributes selected by respondents were used to rank the metabolic companies

Ratings of applicability of key attributes for long-term success in metabolism

Attribute	Company (only 3 "H" ratings / key attribute)										
	GS	SA	TK	PF	MK	NN	BM	LY	NO	RO	AZ
Defined & clear strategic vision in metabolism	M	H	M	L	L	H	M	H	L	L	L
Alignment across research and commercial organizations	H	M	L	M	M	M	M	H	H	M	L
Commercial / marketing											
• Core competency in commercial development and marketing execution	H	H	L	H	L	L	L	M	M	L	M
• Responsive to changing market conditions											
Strong relationships with KOLs	M	H	L	M	M	M	M	H	H	L	L
Research											
• Core competency in metabolic clinical res.	H	H	L	M	M	M	L	H	M	L	L
• Excellence in clinical trial design											
• Superior scale in Phase III research resources											
Score	13	14	6	10	8	10	8	14	11	6	6
Ranking	3	1	9	5	7	5	7	1	4	9	9

H = highest scores in applicability of attribute; M = mid-range scores; L = lowest



HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS

1

DESCRIPTION

Based on changes in the product payer mix and pressure from competition and payers, a client requested a forward looking strategy, including segmentation, for its US payer-focused marketing efforts

2

KEY OBJECTIVE

Develop an evidence-based segmentation to efficiently deploy managed market account managers and align communication tools and support programs to gain access

3

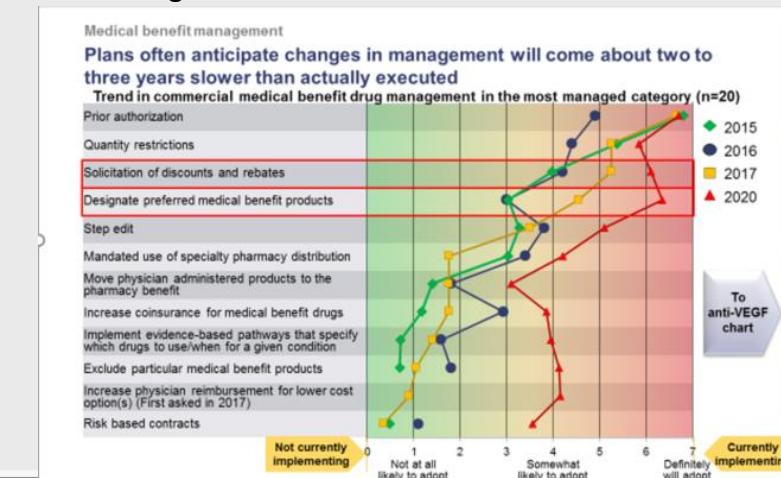
Certara METHODOLOGY

- In-depth interviews with 30 US medical and pharmacy directors who are members of formulary and/or medical policy committees

4

RESULTS & DELIVERABLE

- Metrics and levels were developed from the landscape research aligning to level of opportunity/risk for the asset
- The landscape was presented to the client's NAM team and leadership and segment-level business plans were developed
- In subsequent projects, metrics and levels regarding payer management identified in the original project have been time-trended to pinpoint changes resulting from the client's, competitor, and managed care actions
- The deliverables included a landscape of medical benefit drugs and the therapeutic category, and a payer segmentation based on access management strategies





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Case study – physician-administered landscape

For a physician-administered and complex distribution product, explored the landscape of potential generic competition from the perspective of all stakeholders in the delivery chain

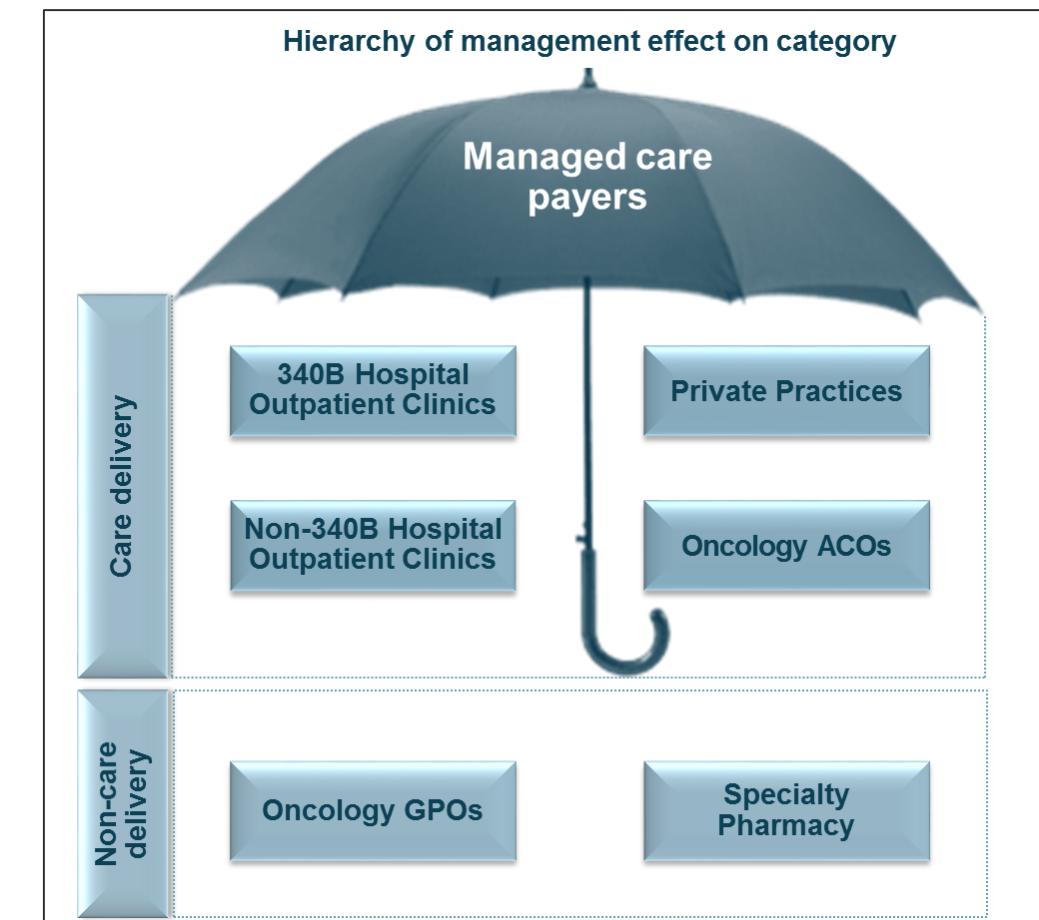
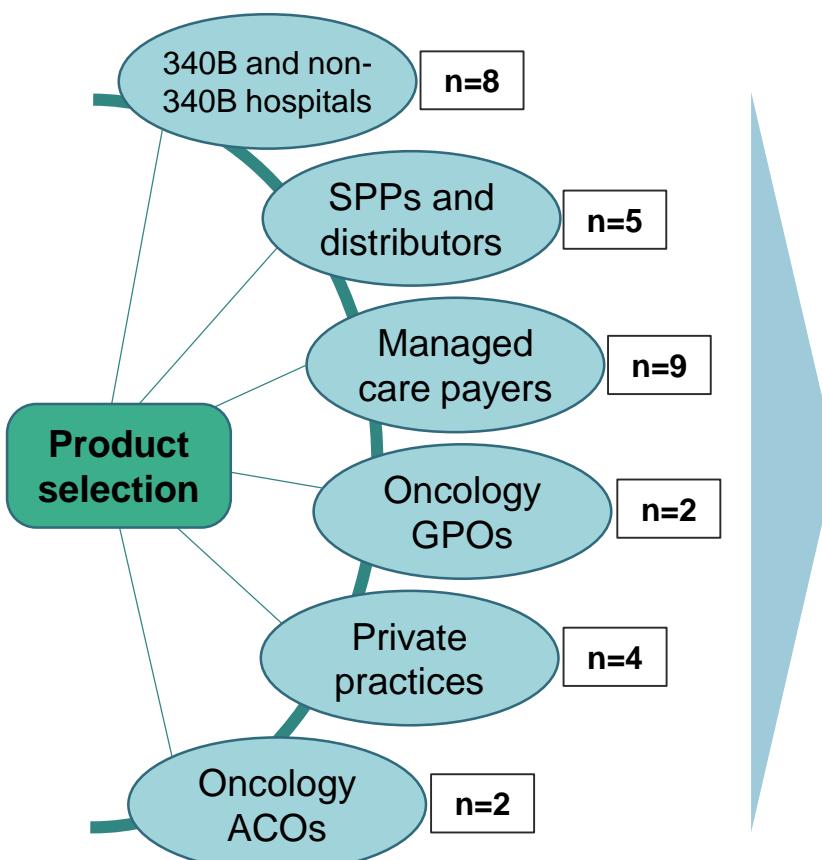
- ▶ Situation: Client requested evidence-based updates to the forecast for a physician-administered product as a result of potential generic competition
- ▶ Key objectives:
 - Investigate payer reactions and potential access of generic competitors to a physician-administered drug and the effect on the innovator brand
 - Understand qualitatively the likely effects of these new entrants on the overall access to the brand and deliver assumptions for the brand forecast
 - Assess current strategies to minimize generic erosion and recommend new ones considering the market evolution
- ▶ Methodology: In-depth telephone interviews with managed care payers, GPO trade relations professionals, SPP representatives, hospital outpatient clinics (340B and non-340B), private practices, and oncology ACOs
- ▶ Topics covered: relative strength in contracting among stakeholders in the distribution chain, drivers of decision making from acquisition cost to margin / recovery, medical to pharmacy benefit management strategies and implementation, 340B rebate and recovery impacts



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Case study – physician administered landscape

Compass detailed the interactions among stakeholders in the buying and distribution chain to establish a hierarchy of product selection influence





HEALTH SYSTEMS EVOLUTION & MARKET SCENARIO PLAYBOOKS

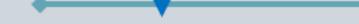
Case study – physician administered landscape

Purchasing decision making was then explored from the perspective of the differing views: acquisition cost, recovery, and margin

Purchasing decisions

Purchasers utilizing buy and bill reimbursement make decisions on either lowest cost or highest margin

Purchasing decision making rationale

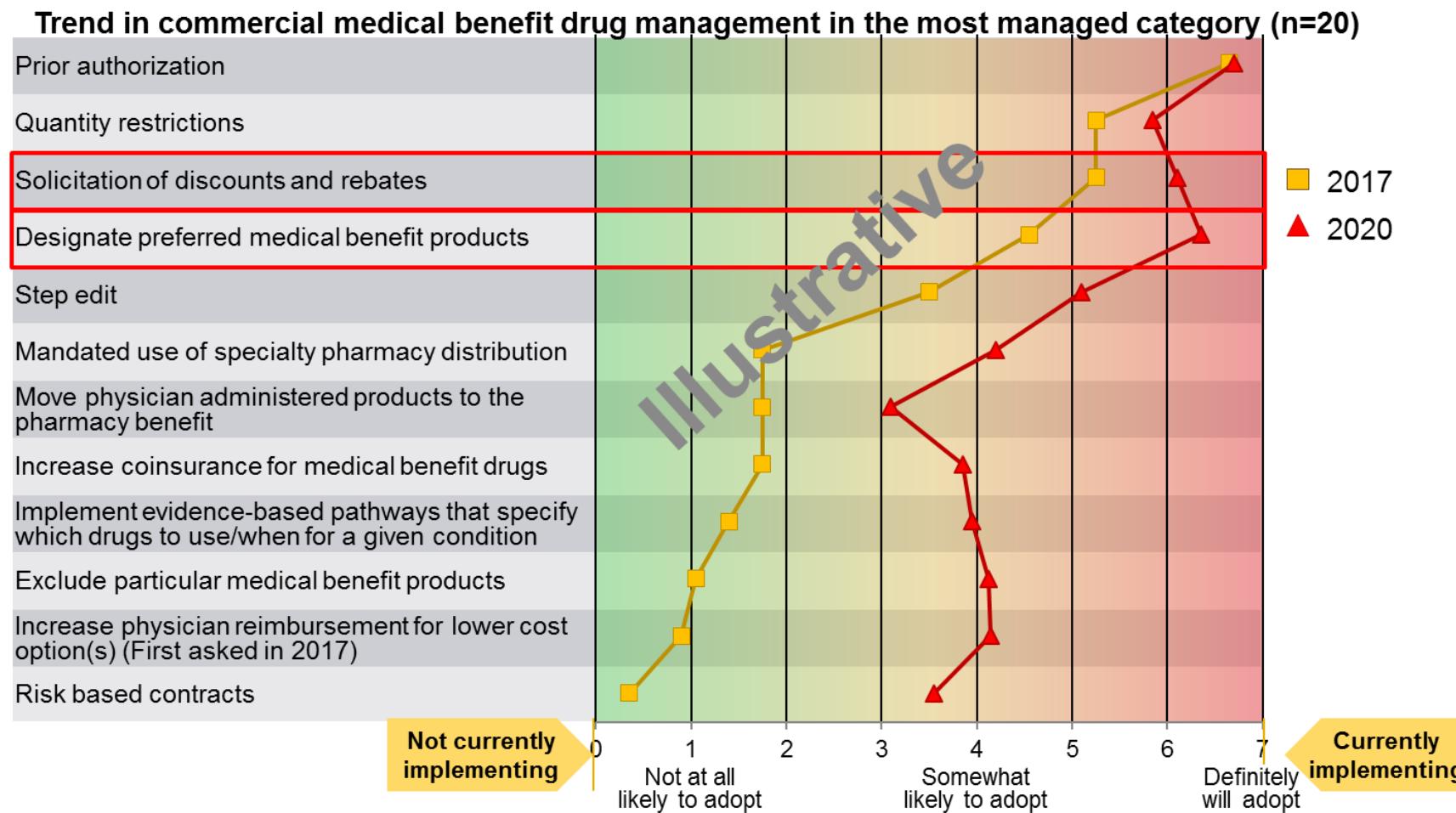
	340B hospital outpatient	Non-340B hospital outpatient	Private practices and ACOs
Purchasing decision	Lowest acquisition cost 	Highest margin 	Lowest acquisition cost 



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Case study – physician administered landscape

Trends in medical benefit drug management by managed care plans including movement to the pharmacy benefit were identified and tracked





EVIDENCE & ACCESS

Impactful science from
bench to market

MEET OUR SENIOR US TEAM

**Roman Casciano**

MSc BSc
SVP, Certara Evidence & Access

- + 25+ years of market access and HEOR leadership
- + Co-Founder Analytica Int

**Paul Gallagher**

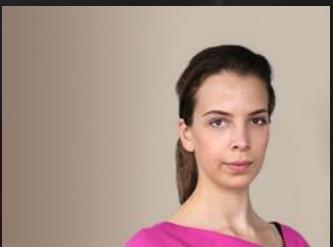
MBA
Vice President, US Market Access Strategy

- + Launched products into over 65 markets as head of a global marketing organization
- + Founder of Compass

**Edward Gallagher**

MS
Senior Consultant, Pricing

- + 20+ years' of pricing experience
- + Former head of Marketing Research and Pricing and Contracting in a major pharma

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VP, Basecase Consulting

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**Michael Minshall**

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- + 20+ years' experience in outcomes research
- + Medical Device Expert
- + Ex-Lilly, IMS Health, Humana and CTI Clinical Trials

**Ulrich Neumann**

MSc MA FRSA
Senior Director, US Access & Commercial Strategy

- + 12+ years' experience in product development, marketing & policy
- + Founded several ventures, led US division of global pharma networking and research firm

**Barbara Pannone**

PhD
Senior Director, US Market Access Strategy

- + 12+ years in US and global market access
- + Has led 300+ projects assessing early stage assets & developing access strategies

**Lee Stern**

MSc
VP, BD and Sr. HEOR Consultant

- + 15+ years' experience in HEOR client engagements
- + Oversees global BD team

**Maximilian Vargas**

PhD, MBA
Senior Director, US Access and Account Management

- + Oversees projects in launch pricing, contracting, market segmentations, and due diligence
- + Experienced across all major therapeutic areas and care settings



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