PRICING RESEARCH & CONTRACTING STRATEGY

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Client Need > Assess and validate portfolio with respect to early stage planning and P&R implications for a single product with broad applicability

Assess the current and future clinical and commercial landscape for one product in multiple disease areas

Identify areas of opportunities and threats within each disease area

Assist in strategy development with regard to clinical and commercial planning to maximize product value and return on investment

Clinical Landscape

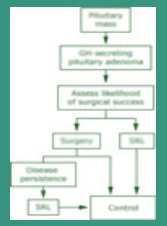
Conduct analysis of the current and future clinical landscapes, covering the following topics for each indication:

- Disease Overview
- Epidemiology
- Economic & Humanistic Burden of Illness
- Diagnosis and Treatment Algorithm
- Current Treatments with Corresponding Clinical Trial Information
- Unmet Needs

Current Treatments

Class	Key Product	Strengths/ Weaknesses
Class 1	Comparator 1	• Strength • Weakness
	Comparator 2	• Strength • Weakness

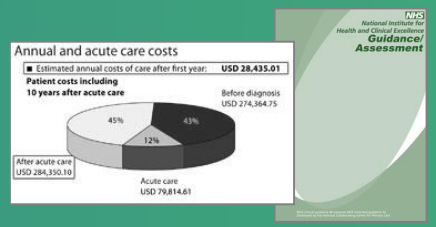
Treatment Algorithm



Pricing & Reimbursement

Assess the current and future economic landscape in key markets with regard to the following themes:

- Clinical and health economic value drivers
- Treatment guidelines, health technology assessments
- Themes surrounding market access and restrictions
- Pricing for key competitors
- Willingness to pay for new innovations



Market Overview

Understand the magnitude of the risks and opportunities for each indication with special attention to the areas below:

- Current trends
- Market size
- Risks and barriers to market entry
- Current and future competitive landscape

Key Emerging Treatments

Class	Key Product	Development Stage	Competitive Implications
Class 1	ABC-320	Phase I/II	• New MOA • Long acting
Class 2	XYZ-111	Phase III	• Oral therapy • High affinity
Class 3	MNO-529	Phase IV	• Extends survival 30%

SWOT Analyses

Identify **S**trengths, **W**eaknesses, **O**pportunities, and **T**hreats with regard to the placement of the product within each indication to summarize findings and highlight opportunities

SWOT Analysis: Indication 3

SWOT Analysis: Indication 2

SWOT Analysis: Indication 1

Recommendations:	
Indication 1	Very large market, but crowded pipeline; Interesting opportunity
Indication 2	Maximum ROI potential; large unmet need, no competition
Indication 3	Low priority; Saturated market with low unmet need

Strengths	**Weaknesses**
• Convenient treatment schedule	• Difficult administration
Opportunities	**Threats**
• Broad market potential	• Uncertain clinical benefit

EARLY VALUE & PRICING STRATEGY

Client Need > Strategic guidance on the pricing and reimbursement related assumptions for the Target Product Profile(s) in early stage portfolio

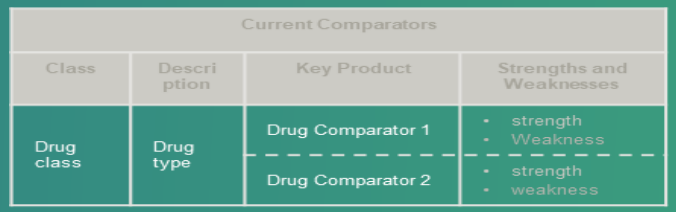
Determine overall value proposition to optimize market access and price considering the impact of market specific cost containment measures and the perceived value of key competitors

Understand current and future disease landscape as well as the needs and objectives of decision makers in each market

Assess completeness of each TPP (ie. is TPP addressing value drivers, additional info required at launch, etc.)

Reference

- Presents the current / future clinical and reimbursement landscape
- Establishes the leading current comparators and future competition for the TPP
- Incorporates company's internal information and internal expertise / research

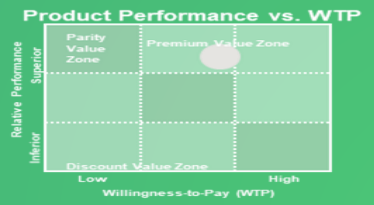


Willingness to Pay (WTP)

- Evaluates the therapeutic area to determine the overall WTP and the key drivers that push WTP higher or lower
- Incorporates Certara internal expertise validated by payers

Product Performance

- Establishes the key attributes including efficacy, safety, innovation, and health economics
- Evaluate the target product profile against attributes and comparators
- Provides a gap analysis and product value proposition
- Incorporates Certara internal expertise validated by thought leaders and payers



PRICING STRATEGY

Client Need > Pricing research to quantify the value placed on certain enhancements of in-market product and determine the pricing implications

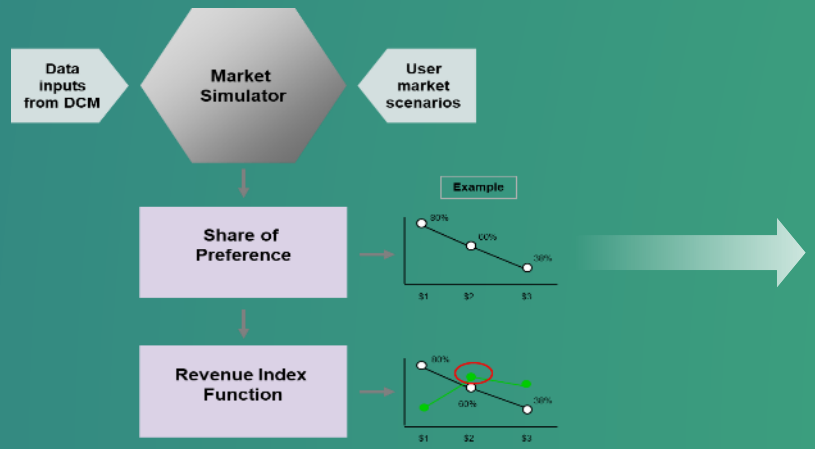
Understand value placed on the product improvements (enhanced labeling, US/Canada API source, packaging, screening measures beyond current industry standards)

Simulate share of preference and optimal price and how these values change under different scenarios

Following analysis via both in-direct, algorithmic and direct methodologies the company was able to command substantial price enhancement

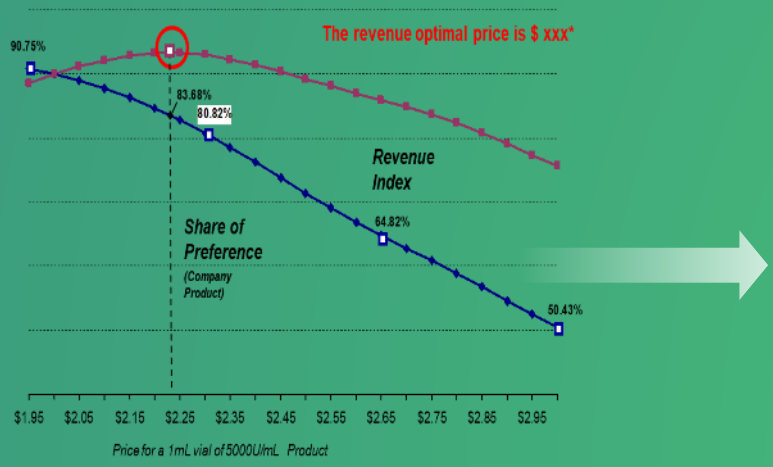
Questionnaire Research to define the Value of Product Attributes

- Employing discrete choice modeling to indirectly determine the value of product attributes and the revenue-optimal price



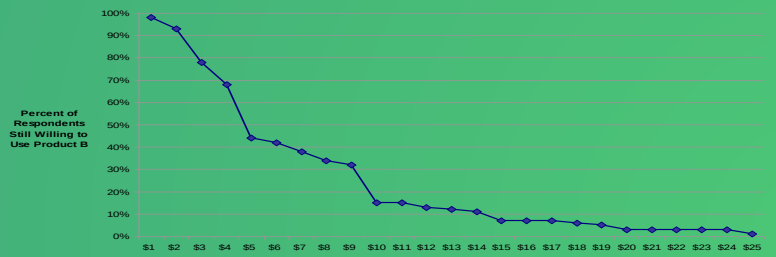
SAS-driven Market and Price Simulations

- Assessing Impact of preference of each product improvement



Substantiate quantitative pricing models with direct methods

- Confirmation with direct questions on treatment utilization, key purchase influencers, contracting with GPOs and reaction to product profile, expected price and product switching
- Assessing i.a. purchasing probability at different price points and rating pf purchasing decision influencers by strength of influence



Scenario 1 | Scenario 2

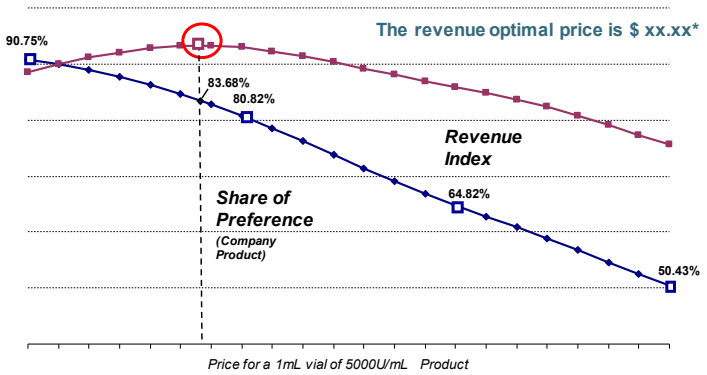
Scenario 2: Company, all product enhancements; Comparator X, improved screening
Revenue Optimal Price: $x.xx

- This simulation assesses the market share of preference for the Company and Comparator X defined in the Scenario Key below
- Unlike Scenario 1, Scenario 2 assumes that Comparator X is also exceeding FDA, USP, and EUP screening requirements
- In this scenario, the Comparator product price is held at a constant at $xx.xx
- The revenue optimal price can be found where the revenue index curve peaks; for this scenario the peak corresponds to **$xx.xx**

Scenario Key

Brand	Product A	Product B
API Source	US/Canada	UK
Labeling	Enhanced Company labeling	Current APP labeling
Packaging	Glass vial	Plastic vial
Screening	Exceeds FDA, USP, and EUP requirements	Exceeds FDA, USP, and EUP requirements
Price	Tested at all prices between $xx.xx-$xx.xx	$xx.xx

BXTR Revenue Index (Price x Share of Preference)		
$xx.xx	$xx.xx	$xx.xx
X	X	x

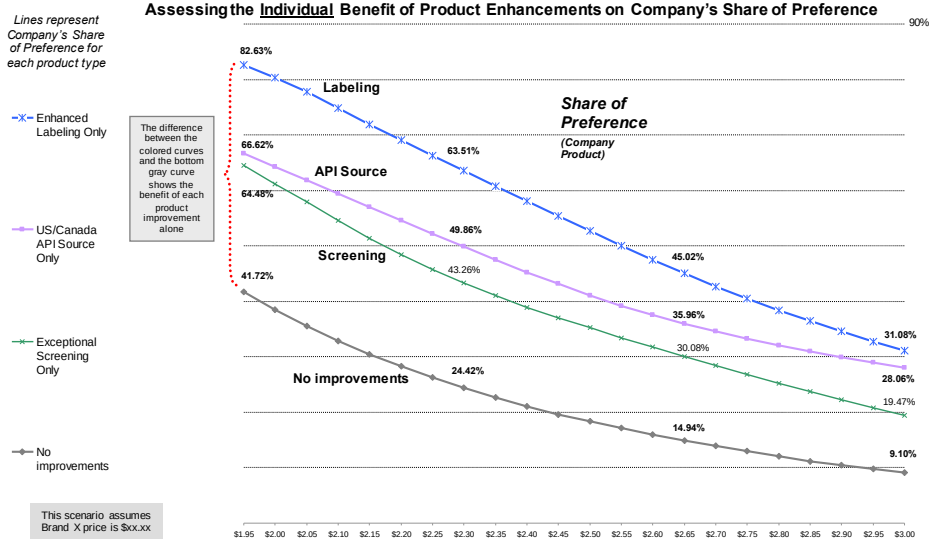


Price points tested in discrete choice questionnaire
Peak of the Revenue Index Function

*Profit optimal price may be calculated when accounting for all fixed and variable costs

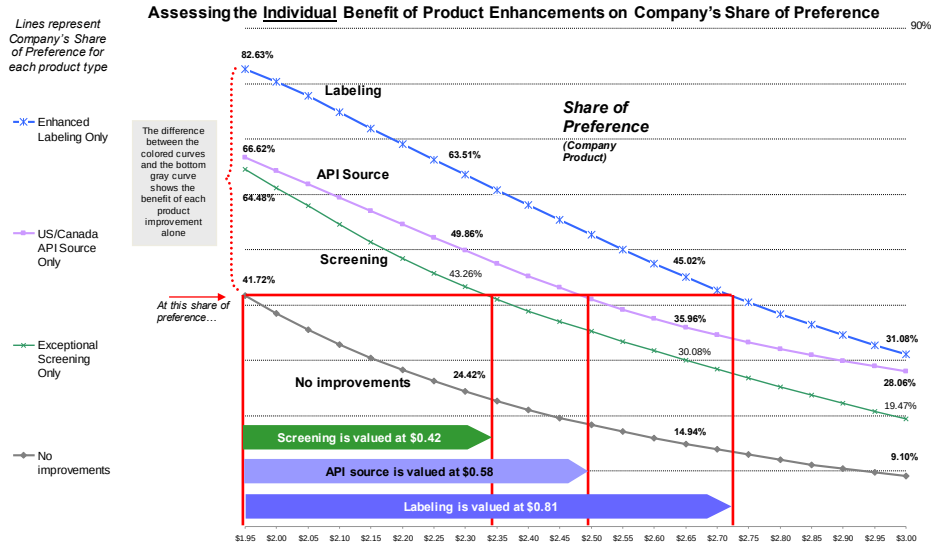
Attribute Value | Relative Importance | Share of Preference | Monetary Value

The graph shows the share of preference (in-market including xxx) for Company's product with each of the proposed enhancements



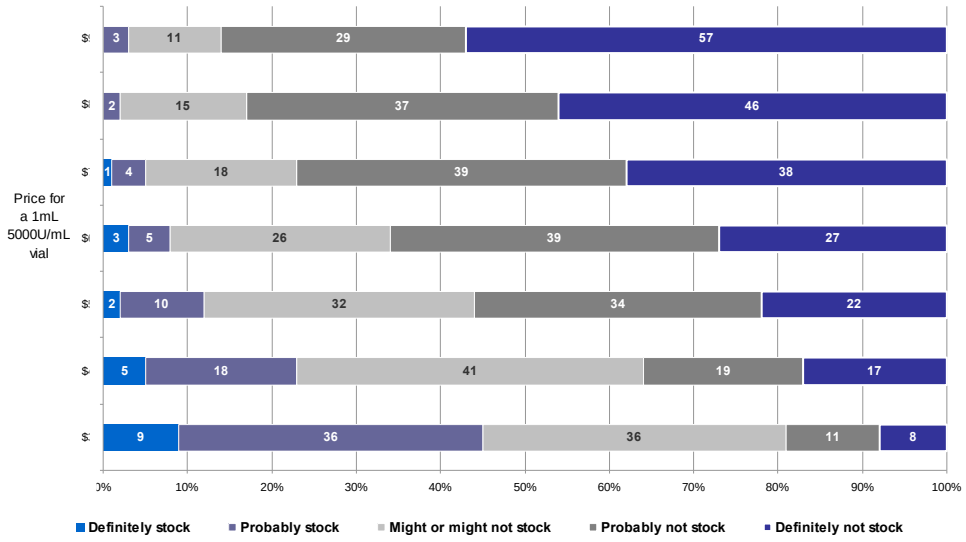
Attribute Value | Relative Importance | Share of Preference | Monetary Value

By intersecting the curves on this graph, we can estimate the dollar-value associated with each individual product enhancement



DIRECT METHODS | RESPONSE TO PRICE POINTS

At $x/vial, 19% of respondents report they will probably or definitely NOT stock Product B; at $y this number rises to 66% and at $z it rises to 86%



PRICING RESEARCH & CONTRACTING STRATEGY

1 DESCRIPTION

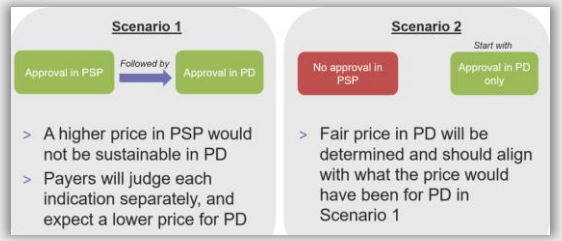
Certara US teams were approached by a late-stage biopharmaceutical company with in-licensed rights to a product which is in Phase II for two indications, Progressive Supranuclear Palsy (PSP) and Parkinson's Disease (PD). The company was looking to initiate Phase III trials soon and hoping for a fast-track designation for PD and orphan indication status in PSP

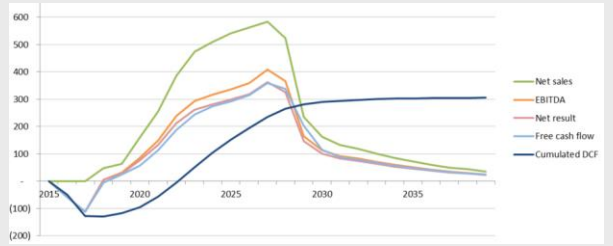
2 KEY OBJECTIVE

Refine product positioning and clinical approach and to assess the price potential of both, PSP and PD, or PD only

4 Certara METHODOLOGY

Our approach was rooted in an in-depth secondary analysis of treatment landscapes followed by multi-step primary research with KOLs and payers. We sought to first identify relevant patient segments/positioning options and possible endpoints and refresh the competitive landscape. We then tested possible positioning options and endpoints to include with KOLs. Our teams validated the relevance of patient segments & endpoints, and we pressure-tested price/reimbursement potential with payers. We synthesize all recommendations for a phase III study design and update product valuation through an NPV analysis





5 RESULTS

We employed a traditional market research methodology added by qualitative data from KOL and payer interviews to support a product value and NPV assessment. This generated significant impact as challenges regarding pre-conceived notions about the product were overcome by formulating a clear value proposition that differentiates the product in a competitive market space. This is an instance where Certara was critical in shaping the clinical and commercial strategy for a smaller-sized biotech company, speaking to our teams strategic capabilities to optimize commercial success

PRICING RESEARCH & CONTRACTING STRATEGY

1 DESCRIPTION

A pharma client required evidence-based pricing and access assumptions for its internal valuation model to inform the term sheet

2 KEY OBJECTIVE

Provide a solid rationale for pricing and access assumptions in US and EU5 for a new oncology product in development

3 Certara METHODOLOGY

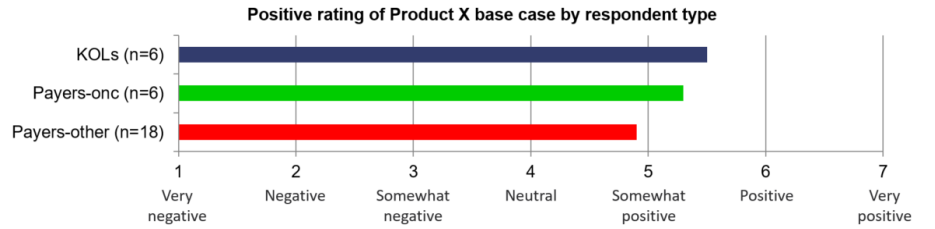
In-depth interviews with 30 KOLs and payers in 6 countries including US, FR, DE, ES, IT, and UK

4 RESULTS

- Identified value drivers and clinical and outcomes studies that will meet Health Technology Assessment needs and drive value
- Mapped how the payment dynamics in each market will affect access to the product
- Developed a high-level access strategy
- Defined a price window for the product and the impact of achievement of endpoints on willingness to pay
- Price recommendation by market

5 DELIVERABLE

Assessment of the product by respondent group identified different priorities among stakeholders



Key findings on initial reaction to Product X base case by respondent type in US and EU5

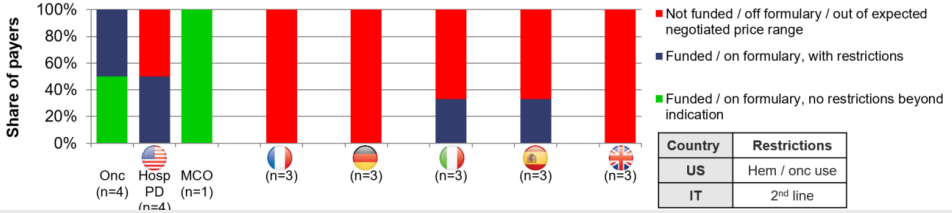
KOLs (n=6)	Payers-Onc (n=6)	Payers (n=18)
• Increase in toxicity does not translate into increased mortality • Manageable and worth the improved outcomes • Increase in infections to be expected	• Increase in toxicity does not translate into increased mortality • Benefit is worth risk • Infection and recovery time is fairly equivalent from their perspective	• Concerns over increased infections and recovery time especially in this patient population • Requires greater patient support which will lead to greater costs

Since funding was not recommended in the EU at price points tested, recommendations were provided for additional data to support funding

Price testing findings for Product X by payers (n=24)

Expected price per cycle	Oncologists: $33,500 Hospital PD: $5,000 MCO Payer: $12,000	FR, DE: €6,500 IT: €14,700 ES: €10,000 UK: £4,000
Majority access recommendation at expected price	On formulary with no restrictions beyond indication	Funded with no restrictions beyond indication

Recommendation for Product X at a price of $30,000 (€28,000, £20,000) per induction cycle



Country	Restrictions
US	Hem / onc use
IT	2nd line

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PRICING RESEARCH & CONTRACTING STRATEGY

1 DESCRIPTION

A client approached Certara to develop a pricing and contracting strategy for a new product to ensure launch success as a critical successor to an already accomplished product line

2 KEY OBJECTIVE

Develop an evidence-based integrated pricing and contracting strategy and assist in communicating the strategy across and up the organization

3 Certara METHODOLOGY

- Integrated qualitative-quantitative research with 45 payers, 325 physicians, and 425 patients, minimizing the use of arbitrary discounting factors
- The net revenue simulator was customized to include variable clinical and economic parameters and accounted for changing competitive scenarios

4 RESULTS & DELIVERABLE

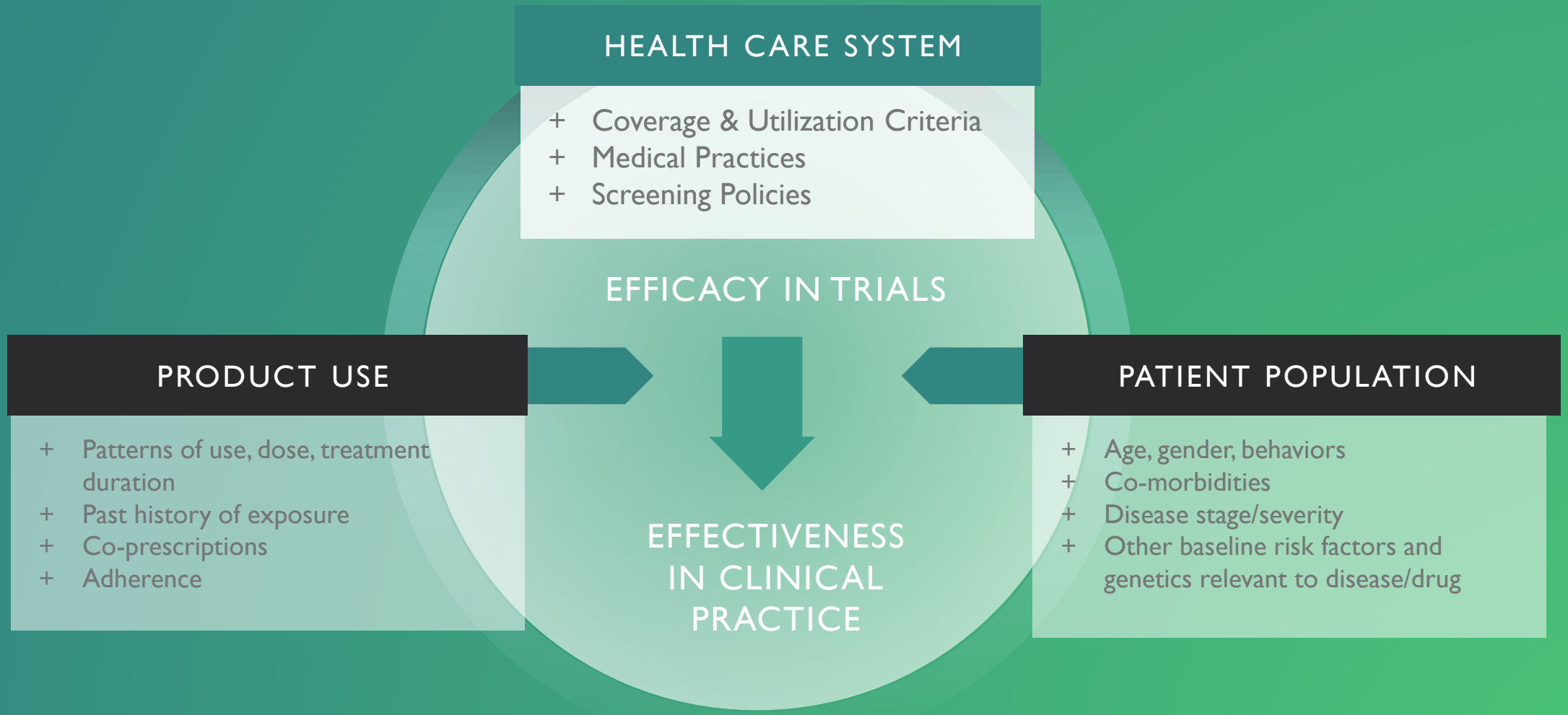
- Product exceeded unrestricted access goals for commercial and Medicare lives within 6 months of launch as quoted by senior management in investor calls
- Awarded a launch segmentation of managed care payers to further refine contracting recommendations using payer characteristics and likely launch access
- Subsequently, a project to update the contracting strategy was initiated
- A project for launch pricing and contracting research and strategy for other internally developed assets was awarded

Design

Deliverables

INNOVATIVE CONTRACTING WITH RWE

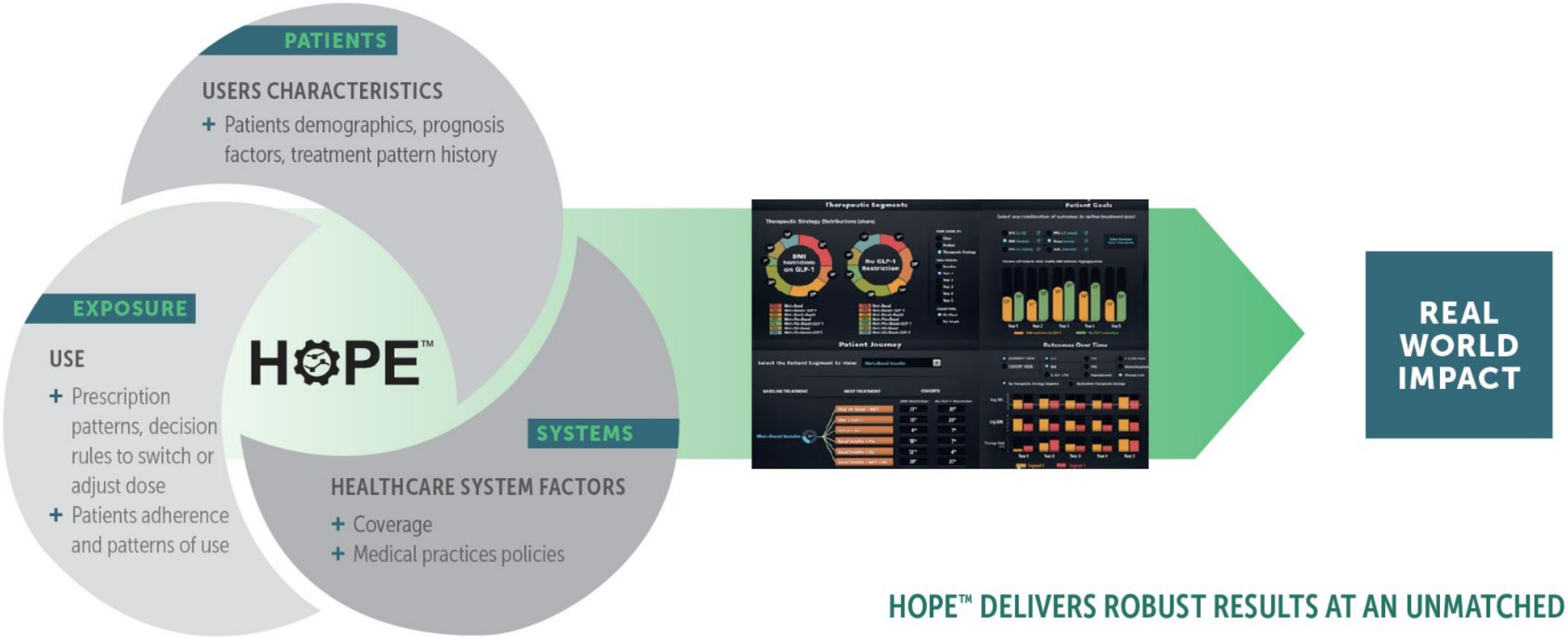
*WHAT IS YOUR PRODUCT'S **REAL WORLD IMPACT**?*



USING OUR PROVEN FRAMEWORK FOR **PAYER VALUE TRANSLATION**

OUTCOMES PERFORMANCE SIMULATION

Introducing HOPE™: The industry's first dynamic and versatile tool dedicated to building predictive models for real world effectiveness



HOPE™ DELIVERS ROBUST RESULTS AT AN UNMATCHED SPEED

CERTARA | EVIDENCE & ACCESS

DECISION-ANALYTICS FOR CONTRACTING

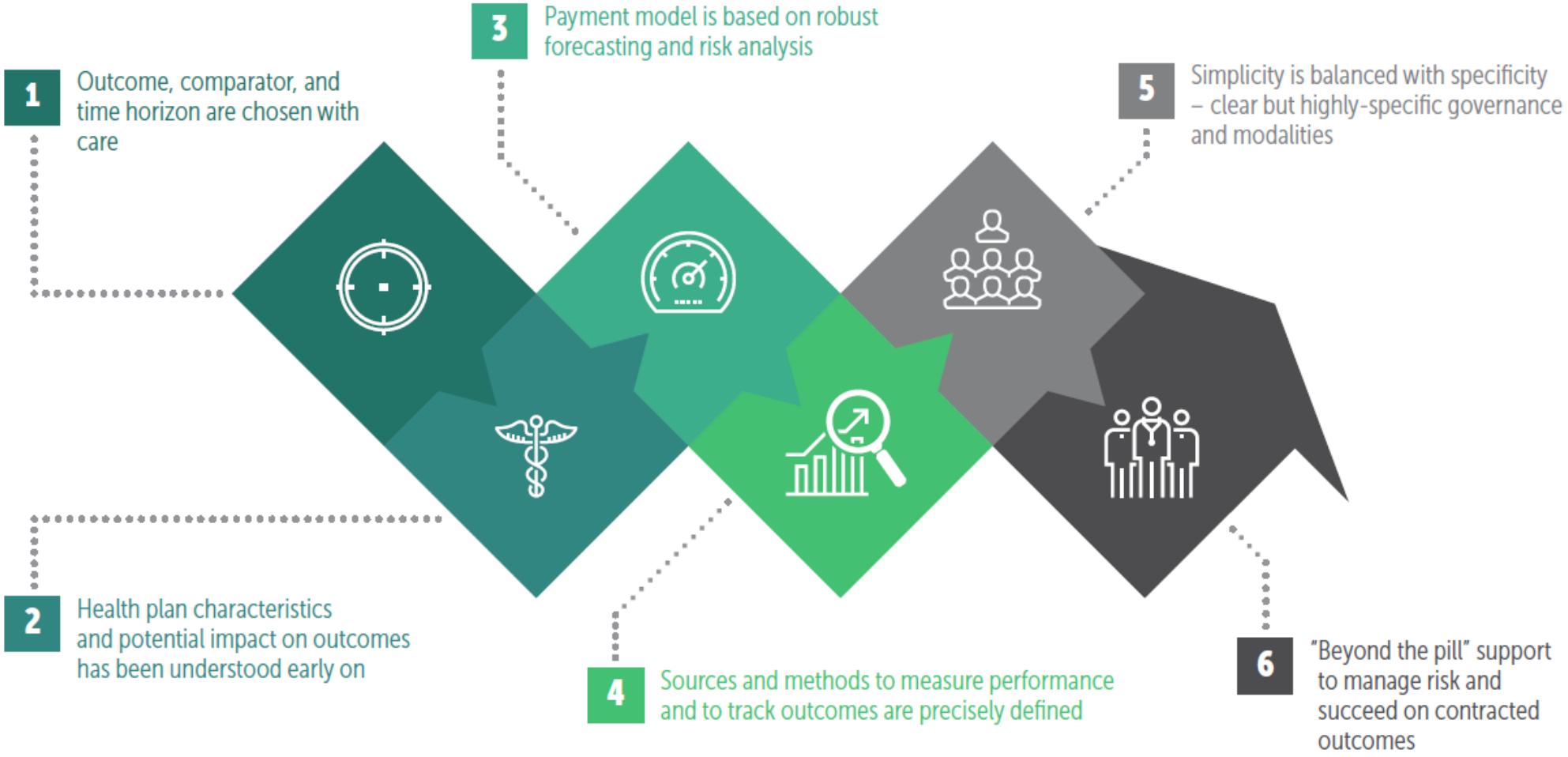
Across all health systems, payers and reimbursement authorities are urging the adoption of performance-based contracting.

What if you would be able to identify the sources and quantify the impact of uncertainty around outcomes-based agreements?

Our proprietary technologies enable us to:

+ Test highly complex scenarios to optimize your plan design and inform payer negotiations and contracting
+ Understand what outcome, comparator and time horizon to select
+ Define the best methods to measure performance and opt for the most appropriate payment models

SIX CRITICAL COMPONENTS OF SUCCESSFUL AGREEMENTS



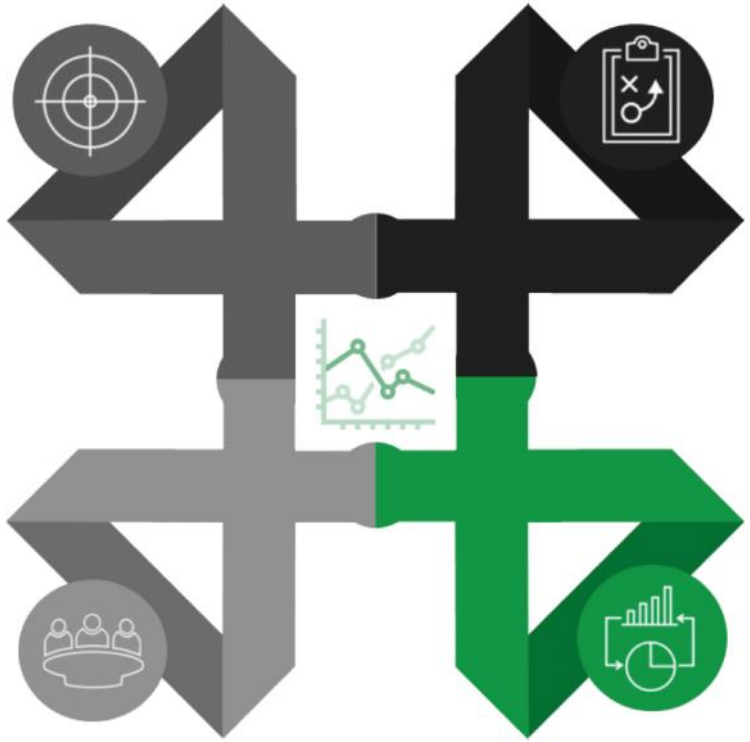
DECISION-ANALYTICS FOR CONTRACTING

Definition of the Contracting Approach

- Evalution of payers/health system position regarding different types of innovative agreements
- Clearly set out the benefits of the OBA for the respective payers
- Setting expectations in terms of improved access, lower base rebates, increased customer confidence in products, payer relationship building

Implementation & Adjudication

- Selection of data sources and methods most adequate to monitor real-world performance
- Developing plans to adjudicate results and trigger payments and define exceptional events that should lead to renegotiation
- Analysis of re-insurance modalities
- Decision of governance to ensure the long-term success of the agreement



Selection of the Right Design

- Investigation of outcomes interesting to respective payer(s)
- Assessment of which outcomes can be monitored
- Selection of time horizon and most adequate type of agreement
- Consideration of legal issues such as impact on Medicaid best price, Medicare Part D payment rates

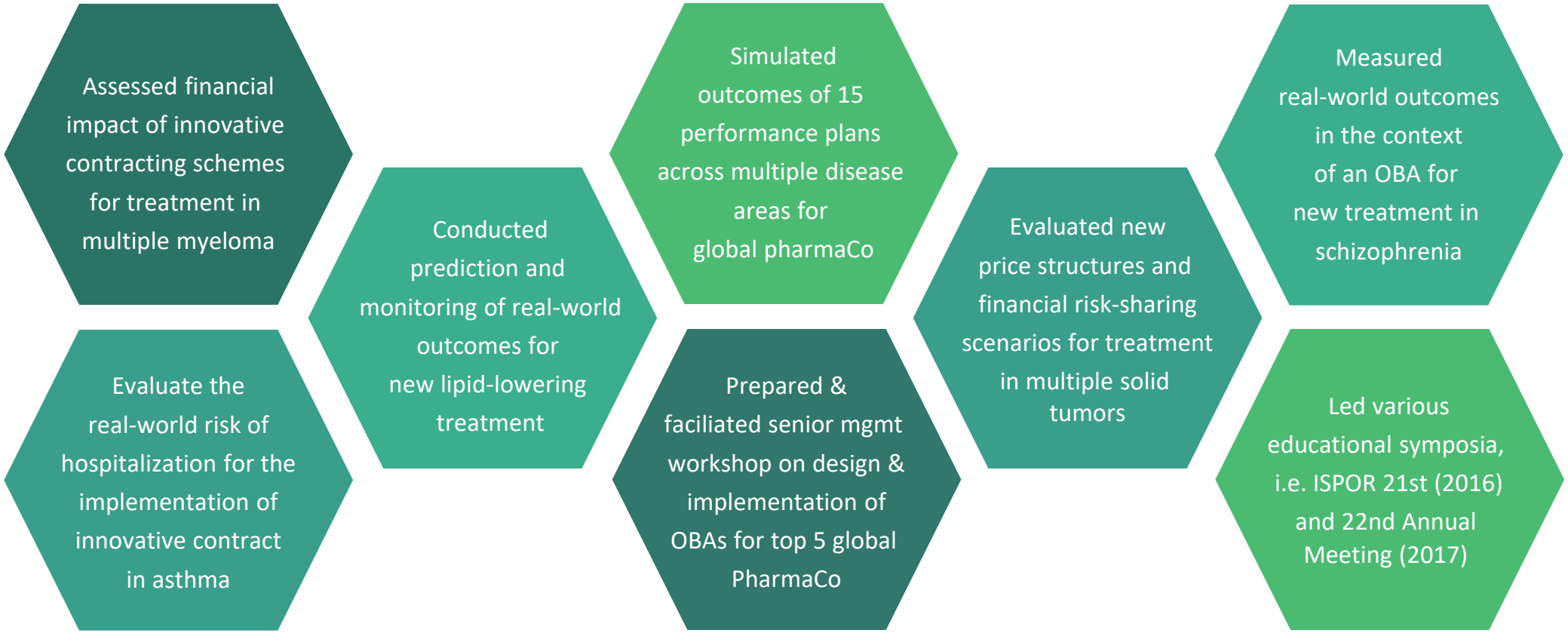
Testing & Refining Deal Modalities

- Definition of key factors that could influence the outcomes/risk
- Simulation of the expected performance in the real-world for the selected outcomes in the population covered by the plan
- Modelling of the expected financial impact compared to traditional pricing/rebating approaches
- Evaluation of contractual terms needed to limit risk

HOW WE HELP CLIENTS SCALE

Track Record in Performance-Based Contracting

Decision analytics for performance-based contracting

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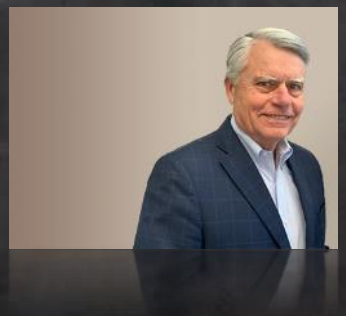
EVIDENCE & ACCESS
Impactful science from bench to market

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

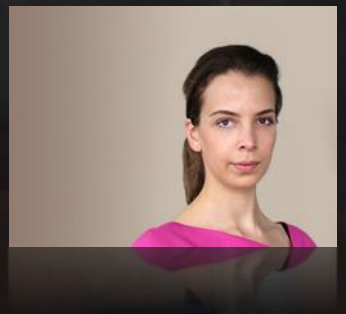


Paul Gallagher
MBA
Vice President, US Market Access Strategy

+ 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

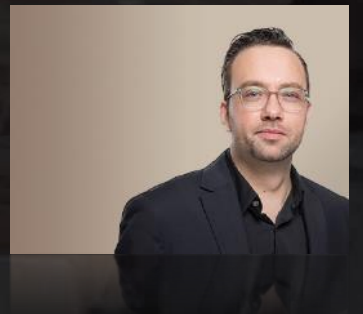


Atlanta Kassatly
MS
VP, Basecase Consulting

+ Oversees all Basecase technology engagements and app development

Michael Minshall
MPH
Senior Consultant, US HEOR

+ 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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