PRICING RESEARCH & CONTRACTING STRATEGY
Assess and validate portfolio with respect to early stage planning and P&R implications for a single product with broad applicability

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

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

SWOT Analyses
Identify Strengths, Weaknesses, Opportunities, and Threats with regard to the placement of the product within each indication to summarize findings and highlight opportunities

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
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 (i.e. is TPP addressing value drivers, additional info required at launch, etc.)

Client Need:

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

<table>
<thead>
<tr>
<th>Current Comparators</th>
<th>Key Product</th>
<th>Strengths and Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Class</td>
<td>Drug Type</td>
<td>Drug Comparator 1</td>
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Willingness-to-Pay

- Lowest WTP
- Highest WTP

Payers’ Willingness to Pay

- High
- Medium
- Low
- Unknown
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)

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 of purchasing decision influencers by strength of influence
Scenario 2: Company, all product enhancements; Comparator X, improved screening Revenue Optimal Price: $x.xx

- This simulation assesses the market share 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 $x.xx
- The revenue optimal price can be found where the revenue index curve peaks; for this scenario the peak corresponds to $x.xx

<table>
<thead>
<tr>
<th>Scenario Key</th>
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<tbody>
<tr>
<td>Product</td>
<td>Product B</td>
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<tr>
<td>API Source</td>
<td>US-Canada</td>
<td>API Source Only</td>
</tr>
<tr>
<td>Quality</td>
<td>US-Canada</td>
<td>API Source Only</td>
</tr>
<tr>
<td>Packaging</td>
<td>Glass vial</td>
<td>Plastic vial</td>
</tr>
<tr>
<td>Screening</td>
<td>Economic FDA</td>
<td>Economic EUP</td>
</tr>
<tr>
<td>Price</td>
<td>Total at all price regions</td>
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*The revenue optimal price is $x.xx*

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Attribute Value: Assessing the Individual Benefit of Product Enhancements on Company’s Share of Preference

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

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Likelihood to Stock Product B at Given 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%

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*Profit optimal price may be calculated when accounting for all fixed and variable costs*
Refine product positioning and clinical approach and to assess the price potential of both, PSP and PD, or PD only.

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

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.

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

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

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

- 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

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

- KOLs (n=6)
  - Increase in toxicity does not translate into increased mortality
  - Manageable and worth the improved outcomes
  - Increase in infections to be expected

- Payers-Ons (n=6)
  - Increase in toxicity does not translate into increased mortality
  - Benefit is worth risk
  - Infection and recovery time is fairly equivalent from their perspective

- Payers (n=18)
  - 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.

Expected price per cycle
- Oncologist: $35,500
- Hospital Pd: $5,000
- MCO Payer: $12,000

On formulary with no restrictions beyond indication

Funded with no restrictions beyond indication

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

Share of payers
- Onc (n=4)
- MCO (n=1)
- Pd (n=1)

Country Restrictions
- US
- IT
- 2nd line

Certara METHODOLOGY

DEVELOPMENT OF PRECISION MEDICINE STRATEGY
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.

**DESCRIPTION**

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

**KEY OBJECTIVE**

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.

**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**

- Phase I: Planning and pilot
- Phase II: Payor research
- Phase III: Physician research
- Phase IV: Patient research
- Phase V: Modeling and reporting

**Deliverables**

- Research plan
- Market access landscape
- Value messaging and sensitivity
- Price sensitivity

Integrated pricing recommendations.
WHAT IS YOUR PRODUCT’S REAL WORLD IMPACT?

USING OUR PROVEN FRAMEWORK FOR PAYER VALUE TRANSLATION

HEALTH CARE SYSTEM
- Coverage & Utilization Criteria
- Medical Practices
- Screening Policies

Efficacy in Trials

Effectiveness in Clinical Practice

Product Use
- Patterns of use, dose, treatment duration
- Past history of exposure
- Co-prescriptions
- Adherence

Patient Population
- Age, gender, behaviors
- Co-morbidities
- Disease stage/severity
- Other baseline risk factors and genetics relevant to disease/drug
Introducing HOPE™: The industry’s first dynamic and versatile tool dedicated to building predictive models for real world effectiveness.
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

1. Outcome, comparator, and time horizon are chosen with care.

2. Health plan characteristics and potential impact on outcomes have been understood early on.

3. Payment model is based on robust forecasting and risk analysis.

4. Sources and methods to measure performance and to track outcomes are precisely defined.

5. Simplicity is balanced with specificity – clear but highly-specific governance and modalities.

6. "Beyond the pill" support to manage risk and succeed on contracted outcomes.
**Definition of the Contracting Approach**
- Evaluation 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
Track Record in Performance-Based Contracting

Decision analytics for performance-based contracting

- Assessed financial impact of innovative contracting schemes for treatment in multiple myeloma
- Conducted prediction and monitoring of real-world outcomes for new lipid-lowering treatment
- Simulated outcomes of 15 performance plans across multiple disease areas for global pharmaCo
- Prepared & facilitated senior mgmt workshop on design & implementation of OBAs for top 5 global PharmaCo
- Evaluated new price structures and financial risk-sharing scenarios for treatment in multiple solid tumors
- Measured real-world outcomes in the context of an OBA for new treatment in schizophrenia
- Led various educational symposia, i.e. ISPOR 21st (2016) and 22nd Annual Meeting (2017)
Impactful science from bench to market
MEET OUR SENIOR US TEAM

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MSc BSc
SVP, Certara Evidence & Access
+ 25+ years of market access and HEOR leadership
+ Co-Founder Analytica Int

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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
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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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Barbara Pannone
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Maximilian Vargas
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