Certara works with healthcare innovators to strategically optimize their market value in the context of financing or partnering deals. Our services include:

- **Full asset valuation**
- **Target patient population selection**
- **Clinical development strategy**
- **Competitive landscape analysis**
- **Early Revenue & Pricing Development**
- **Preparation and participation to investor and partnering meetings**
R&D investment decisions represent the largest risk taken by developers and biopharma investors. Amidst the massive uncertainties, we help companies identify the most attractive development option that will deliver the highest value in the real-world, with a reasonable cost and risk.

Investment options are compared and prioritized by our early value teams based on financial metrics of value and risk derived from real-world findings such as:

- The disease significance and adjusted patient stratification,
- The predicted relative effectiveness of the intervention(s) in real-life,
- The evaluation of the price and reimbursement potential of the program(s).
<table>
<thead>
<tr>
<th>Project type</th>
<th>Pre-POC investment due diligence</th>
<th>At or post-POC optimal option selection</th>
<th>Portfolio review and prioritization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Client strategic investment issue</strong></td>
<td>Biotech company pursuing 4 early clinical programs (Parkinson’s, Diabetes, NSCLC, breast cancer) looking for new investors (VC or IPO)</td>
<td>Mid-size biopharma company considering alternative options for PhIII clinical program and looking for best value and financial return</td>
<td>Large biopharma company with major R&amp;D budget constraints requiring pruning of part of ~130 programs in the development pipeline</td>
</tr>
<tr>
<td><strong>Certara support and successful solutions</strong></td>
<td>• Full business case (TPP, population sizing, competitive review, price and market share estimates, R&amp;D investments...) for each program • P&amp;L projections and key financial metrics (NPVs, rNPVs, IRRs...) • Upside/downside business scenarios to stress-test valuations</td>
<td>• Clear articulation of options and evaluation of R&amp;D costs • KOL and payer research in EU5 countries to assess evolution of competitive landscape, reachable price and reimbursement • Financial evaluation of each option and quantification of risk vs. reward tradeoffs</td>
<td>• Review and challenge of each target product profile • Full business case, valuation, and stress testing of each program with deeper approach in late stage • Prioritization based on risk, reward, strategic interest, and overall balance of portfolio in terms of innovation and sustainability</td>
</tr>
<tr>
<td><strong>Mission outcome</strong></td>
<td>Well advanced discussions for IPO</td>
<td>Project discontinued as no viable option was found</td>
<td>Clear and rational prioritization leaving budget room for in-licensing</td>
</tr>
</tbody>
</table>
EARLY VALUE ASSESSMENT & DUE DILIGENCE

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

Client Need >

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

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 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.)

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 Certara 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
A tier 1 pharma that has a globally marketed product for AMD and DME was planning to launch a complement to its current product with a better PK/PD profile and lower frequency of injections. However, AMD patients are entering clinical trials with increasingly better visual acuity and it becomes difficult to measure additional benefits of new drugs under existing endpoints.

**Stakeholder research to define a new endpoint in wet AMD and DME that would offer a better measure of patient visual function than the current standard of visual acuity.**

**Patient interview questionnaire was developed for investigators, leveraging available literature and external expert advice (i.e. patient representatives and KOLs).**

18 daily activities were identified and assessed according to importance and difficulty to perform among AMD or DME patients.

By establishing and validating a new endpoint, Certara provided a Tier 1 pharma client with a fundamentally stronger value proposition for its product, supporting rationale for pursuing a new direction in their upcoming trials. Our engagement demonstrates Certara’s ability to leverage traditional market research into value-driven insights that are patient-centered. In a situation when the stakes for return on investment are very high and the potential market opportunity is significant the Tier 1 pharma needed more than a vendor providing data points, engaging us for reliable decisional advice from a strategic consulting partner.
Certara was approached by a private gene therapy company specializing in the development of RNA carriers. Their therapeutic areas of interest are antivirals, cancer immunotherapies and gene cell therapies. The client had licensed a highly safe and easy-to-use lentiviral vector technology that can efficiently deliver RNAs in vitro and in vivo. However, the company had not yet identified therapeutic indications to target.

The collaboration is testimony to Certara’s partnerships with small biotech clients and/or clients with early stage-assets in defining path-to-market strategy. The project demonstrates our teams’ ability to develop value-driven recommendations through a data-driven and scientific approach, one that matters to decision-makers and investors. By systematically narrowing down a large number of therapeutic areas to a select few through a rigorous assessment, Certara was able to pave the client’s clinical development strategy, providing them with a reliable framework of existing competitive dynamics they would encounter. The client used our selection of gateway and value indications as the foundation in the next phase of their clinical development. With our help they succeeded in recruiting clinicians in the each field whom they engaged in narrowing down the target and bringing the promising technology to market.
A pharma client requested evidence-based priorities and target product profile characteristics to guide the priorities for their dermatology portfolio.

Provide a solid rationale for prioritization of dermatology product concepts in development through an assessment of clinical and economic attributes, price ranges and access.

Certara METHODOLOGY

• In-depth interviews with ten US commercial and Medicare payers.
Recent 505(b)(2) Projects: Case Study 3 – Women’s Health

In two separate evaluations, conducted diligence of the planned launch price of a women’s health 505(b)(2) and found little sensitivity at a 10% higher price. The company launched at a higher price although less than a 10% premium and is gaining access

- **Situation:** Investment firms seeking diligence of an investment in a hormonal product
- **Key objective:** Provide an evidence-based assessment of access at the planned WAC provided by the client
- **Methodologies:** In-depth, sixty minute telephone interviews with payers from regional and national health plans conducted at different time periods
  - Seven payers representing 51 million commercial and 8 million Medicare lives
  - Five payers representing 67 million commercial and 10 million Medicare lives
- **Finding and recommendation:**
  - At the planned WAC, the hormonal product achieves unrestricted access in nearly all the plans, which is maintained at a 18% higher price
  - Recommended assessing a higher launch WAC in more rigorous price testing by the asset owner
- **Actual results:**
  - Manufacturer launched the asset in 3Q 2018 at a WAC 6% higher than planned
  - Only about 40% of commercial covered lives have unrestricted access which is below peak access in the research. The asset owner data reports access at just over 50% of commercial lives
  - Growth in total prescriptions is ahead of competitive brands in the same month after launch

**Commercial access of hormonal product, share of lives (2019)**

- Not covered
- Covered (PA/ST)
- Covered
- Preferred (PA/ST)
- Preferred

**Source:** MMIT, Mar ‘19
Situation: A investment firm client engaged Certara for diligence of an investment in an ophthalmologic steroid.

Key objective: Provide an evidence-based assessment of access at the planned WAC provided by the client.

Methodology: In-depth telephone discussions with five members of the formulary committees of large US health plans and PBMs totaling 67 million commercial and 5 million Medicare lives.

Recommendation:
- At the planned WAC, the ocular steroid achieves non preferred access for the majority of covered commercial lives, but gains preferred access with a discount of 10%.
- At prices 10% above the planned WAC, access restrictions begin, particularly in Medicare.
- Certara supported the planned WAC and modest discounting.

Actual results:
- The manufacturer launched the ocular steroid in Jan. 2019 at the planned WAC and has already gained unrestricted access to 40% of commercial lives; the level of discounting, however, is not available in the public domain.
- Much of the not covered access is likely due to exclusion policies until formulary review.

Source: MMIT, Mar ‘19.
Case study – Indication prioritization

Developed a two phase methodology to narrow 5 potential indications to one product indication to pursue for development

- Situation: Client requested an opportunity assessment of an internal asset that showed clinical promise in multiple indications
- Key objective: Inform client’s commercial planning for a launch sequence of a new product in up to 5 potential indications

Results:
- Informed client on indication sequence priority
- Developed a high-level access strategy, inclusive of a value proposition and additional clinical endpoints needed
- Defined a price window for each indication and impact of achievement of endpoints on WTP
Case study – Indication prioritization

Analysis on each area of interest for Product X was investigated and compared and an indication was identified as favorable in each scenario.

<table>
<thead>
<tr>
<th>Factors</th>
<th>Indication A</th>
<th>Indication B</th>
<th>Indication C</th>
<th>comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive rating</td>
<td></td>
<td></td>
<td></td>
<td>Positive rating</td>
</tr>
<tr>
<td></td>
<td>Aligned for KOLs and payers</td>
<td>Discrepancy between KOLs and payers</td>
<td>Indication test is limited as a functional indicator</td>
<td></td>
</tr>
<tr>
<td>Efficacy profile</td>
<td>Clinically meaningful</td>
<td>Lack of comparative data, uncertainty of magnitude of effect</td>
<td>CV death and hospitalizations most meaningful vs indication</td>
<td></td>
</tr>
<tr>
<td>Safety profile</td>
<td>Some concerns about bleeding, dizziness</td>
<td>Hypotension is a concern</td>
<td>No concerns in this patient population</td>
<td></td>
</tr>
<tr>
<td>Utilization potential</td>
<td>Potential for broader use, earlier use</td>
<td>Second line</td>
<td>Limited to small share of total</td>
<td></td>
</tr>
</tbody>
</table>

Positive → Negative
**EARLY VALUE ASSESSMENT & DUE DILIGENCE**

**1 DESCRIPTION**

A long-term client approached Certara for an evidence-based assessment of pricing, access, and utilization of two pipeline assets in migraine to inform a business development objective.

**2 KEY OBJECTIVE**

- Provide an evidence-based assessment of pricing and access of two assets
- Deliver quantitative estimate of utilization of each asset among neurologists and headache specialists in the acute treatment of migraine
- Discount the utilization based on evidence of patients’ acceptance and copay sensitivity

**3 Certara METHODOLOGY**

In-depth telephone interviews were conducted with 9 payers, 10 HCPs, and 10 migraine patients followed by an online survey of 100 specialists.

**4 RESULTS & DELIVERABLE**

- Client prioritized one of the assets and is seeking a deal for US commercialization
- Delivered a topline report of the qualitative findings four weeks after kickoff, followed by a comprehensive Research Report with conclusions and recommendations three weeks later
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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