EARLY VALUE ASSESSMENT & DUE DILIGENCE

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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**
- **Competitive landscape analysis**
- **Target patient population selection**
- **Early Revenue & Pricing Development**
- **Clinical development strategy**
- **Preparation and participation to investor and partnering meetings**

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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).

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	Pre-POC investment due diligence	At or post-POC optimal option selection	Portfolio review and prioritization
Project type			
Client strategic investment issue	**Biotech company** pursuing 4 early clinical programs (Parkinson's, Diabetes, NSCLC, breast cancer) **looking for new investors (VC or IPO)**	Mid-size biopharma company considering **alternative options for PhIII clinical program** and **looking for best value and financial return**	**Large biopharma** company with major R&D budget constarints requiring **pruning of part of ~130 programs** in the development pipeline
Certara support and successful solutions	• Full business case (TPP, population sizing, competitive review, price and market share estimates, R&D investments…) for each program • P&L projections and key financial metrics (NPVs. rNPVs, IRRs…) • Upside/downside business scenarios to stress-test valuations	• Clear articulation of options and evaluation of R&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	• 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
Mission outcome	Well advanced discussions for IPO	Project discontinued as no viable option was found	Clear and rational prioritization leaving budget room for in-licensing

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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

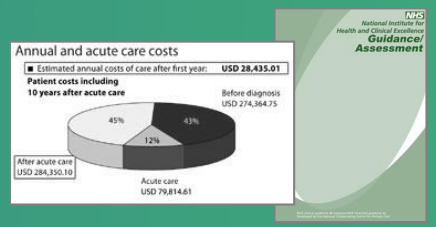
Class	Key Product	Strengths/ Weaknesses
Class 1	Comparator 1	• Strength • Weakness
	Comparator 2	• Strength • Weakness

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 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
- Convenient treatment schedule

Weaknesses
- Difficult administration

Opportunities
- Broad market potential

Threats
- Uncertain clinical benefit

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

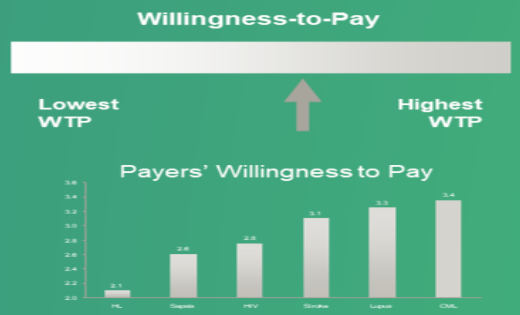
Reference

- 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

Current Comparators			
Class	Description	Key Product	Strengths and Weaknesses
Drug class	Drug type	Drug Comparator 1	• strength • Weakness
		Drug Comparator 2	• strength • weakness

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

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1 DESCRIPTION

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

2 KEY OBJECTIVE

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

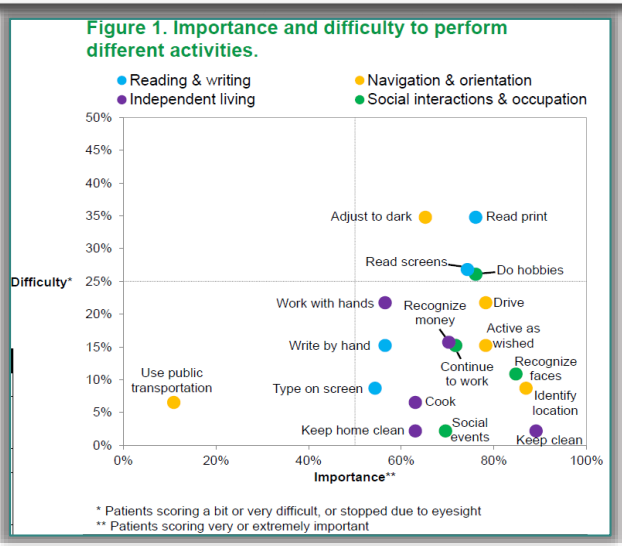
3 Certara METHODOLOGY

- Employed an analytics-driven and stakeholder research approach where the US, UK, French and Canadian teams conducted multinational, individual, structured patient, regulator, KOL, physician and payer interviews
- 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 patientsa

4 RESULTS

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

Figure 1. Importance and difficulty to perform different activities.



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1 DESCRIPTION

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

2 KEY OBJECTIVE

Identify the most promising indications which we defined as 5 “gateway” (high feasibility) and 5 “value” (high return on investment) indications for pre-clinical and clinical development of the lentiviral technology

4 Certara METHODOLOGY

Given the complexity and breath of the project, we suggested a multi-step secondary research approach. Our teams compiled a list of over 200 indications in which transient RNA expression can lead to a therapeutic effect; each indication was then assessed on eligible population, severity and unmet need, and feasibility of clinical proof of concept. We selected the top 25 “gateway” and “value” indications and then further evaluated for feasibility using a set of 9 sub-criteria and competitive intensity. A Target Product Profile (TPP) was created for each final selected indication, comparing the lentiviral product to the most relevant comparator, including development of the most impact value proposition in each instance

5 RESULTS

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 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

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1 DESCRIPTION

A pharma client requested evidence-based priorities and target product profile characteristics to guide the priorities for their dermatology portfolio

2 KEY OBJECTIVE

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

3 Certara METHODOLOGY

- In-depth interviews with ten US commercial and Medicare payers

4 RESULTS & DELIVERABLE

- Identified efficacy / safety endpoints and additional economic data that would drive value to payers
- Comprehensive assessment of each product concept by payers
- Defined a price range for each product concept and expected formulary access
- Assessed payers' future priorities in managing and funding treatments for patients in this therapeutic category and identified how this will affect access to the products tested
- Identified products to prioritize based on payer assessment

Assessment of efficacy, safety and cost attributes identified efficacy attributes as the key value drivers for payers in the category

Weight of category importance (n=10)

Category	Relative weight
Efficacy	38
Safety / tolerability	27
Cost	22
Dosage and administration	6

Top weighted value drivers in efficacy, safety/ tolerability, and cost for treatments for plaque psoriasis (n=10)

Top attributes	Relative weight
Change from baseline in Psoriasis Area and Severity Index (PASI)	8.7
Increase in percent of patients achieving complete remission	7.1
Reduction in Body Surface Area (BSA) affected with psoriasis	6.2
Cost to plan	5.2
Maintenance of effect	5.0
Minimal respiratory infections	4.3

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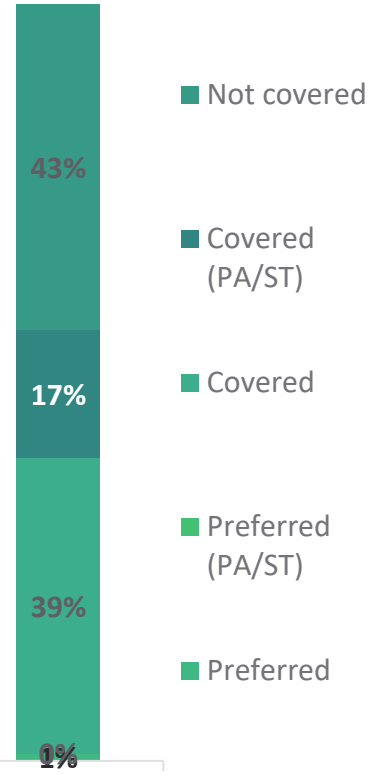
Recent 505(b)(2) Projects: Case Study 3 – Women's Health

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)



Source: MMIT, Mar '19

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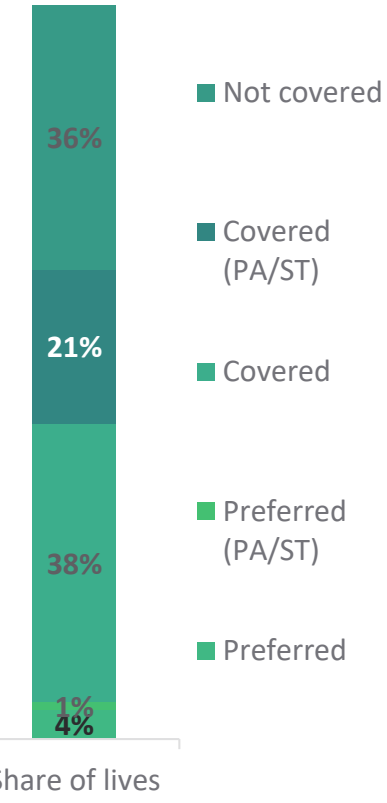
Recent 505(b)(2) Projects: Case Study 2 – Ophthalmic

Validated the planned launch price of a 505(b)(2) ophthalmic. Formulary access appears encouraging after the Jan 2019 launch

- **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

Commercial access of an ophthalmologic, share of lives (2019)



Source: MMIT, Mar '19

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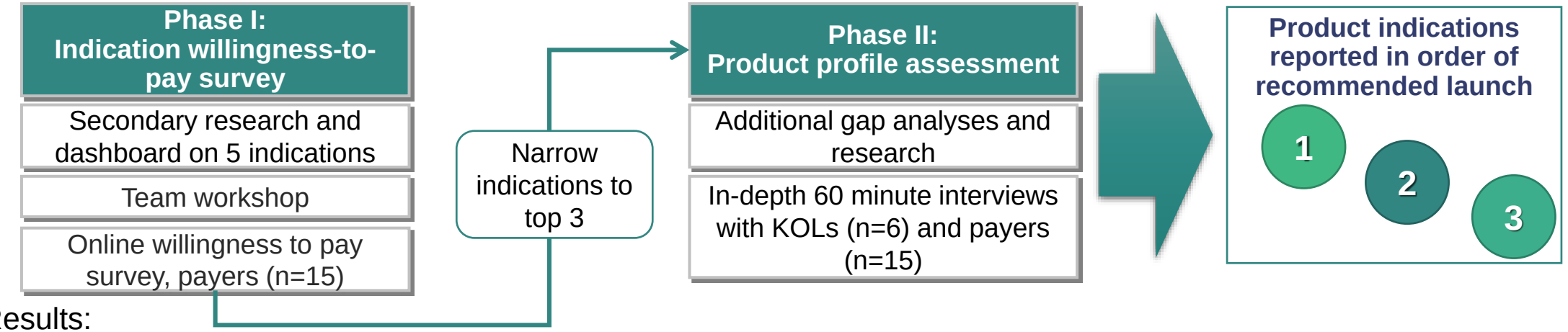
Case study – Indication prioritization

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

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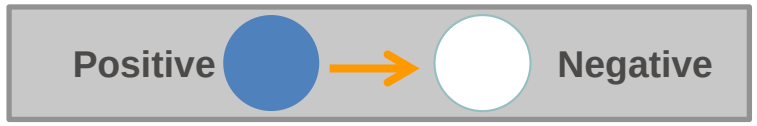
Case study – Indication prioritization

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

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



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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

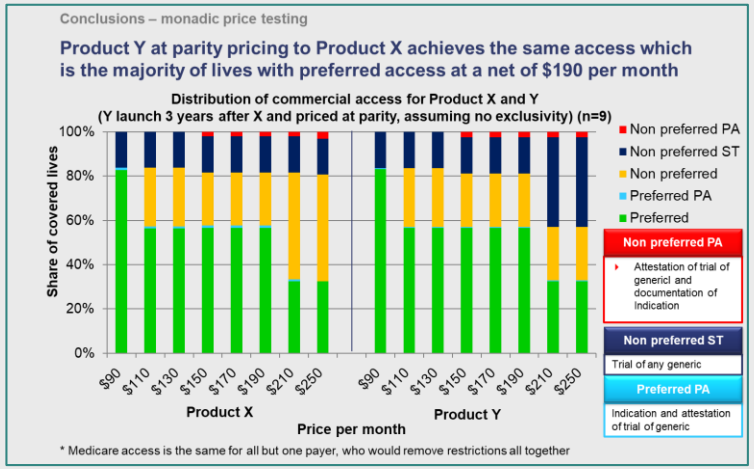
- Provide an evidence-based assessment of pricing and access of two assets
- Deliver quantitative estimate of utilization of each asset among neurologists and headache specialists in the acute treatment of migraine
- Discount the utilization based on evidence of patients' acceptance and copay sensitivity

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

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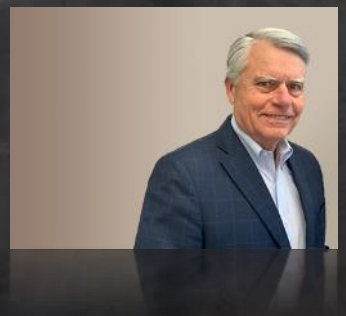
Impactful science from bench to market

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

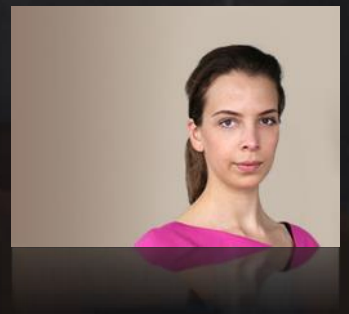


Paul Gallagher
MBA
Vice President, US Market Access Strategy

+ 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

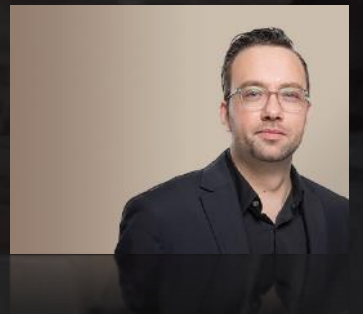


Atlanta Kassatly
MS
VP, Basecase Consulting

+ 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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