

LAUNCH PLANNING & 360° REIMBURSEMENT



CERTARA. 

EVIDENCE & ACCESS



360° REIMBURSEMENT & LAUNCH PLANNING

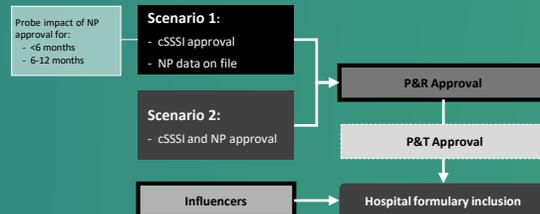
Client Need >

Build strategic imperatives for clinical and commercial planning that address access, utilization, and reimbursement potential based on the identification of hurdles and competitive landscape



Environmental Assessment & Scenario Playbooks

- Presents the current clinical and reimbursement landscape including:
 - Treatment approaches
 - Treatment satisfaction
 - Unmet needs
- Develop launch scenarios for antimicrobial

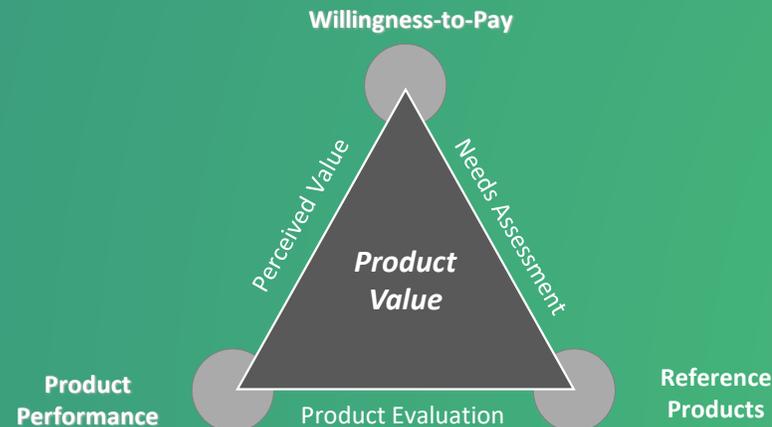


Decision-Maker Interviews

- Payer Panel consisting of top-tier decision-makers who lead and set policy for formulary access and price negotiation

Market-Specific Strategic Implications

- Offers insight on key implications and strategic recommendations to optimize P&R positioning and market access



Conclusions	
1	In either scenario, market access is not hindered due to perceived value for NP
2	Establish NP benchmark price without the NP indication except in Italy
3	Launch with cSSSI indication and robust NP data file in market 1, market 2; wait for NP indication in country x



360° REIMBURSEMENT & LAUNCH PLANNING

Client Need >

Quantitative Launch Pricing Research through different price finding methodologies seeking to identify price response and profit functions to determine the profit-maximizing price



Understand the impact of a competitor entering in the market at 50% off the current price



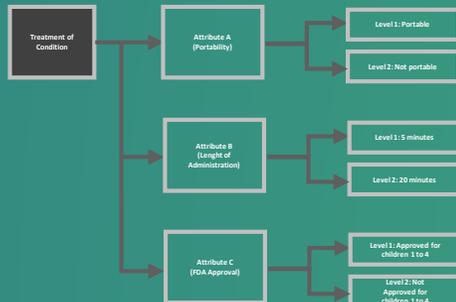
Gauge the potential share of various efficacy, toxicity, dosing frequency, and cost per cycle performance scenarios associated with the licensing of an oncologic



Derive value-based price optimization curve and price elasticity from qualitative and quantitative inputs

Attributes Validation

- Through qualitative discussions with payers and KOLs, identified the attributes, levels, and potential pricing points that have impact on physician's prescribing behavior



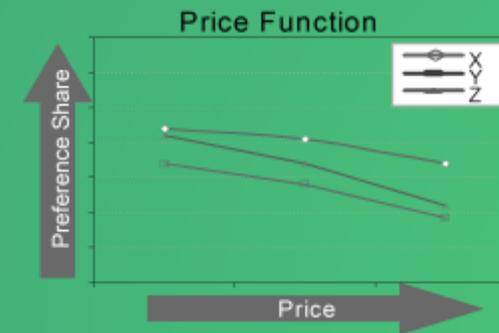
Quantitative Target Profile Substantiation

- Discrete choice modeling was applied to best understand prescribing decision-making based on behavioral response (rather than preference judgment)

Value Scenario 1			
	COMPETITOR 1	COMPETITOR 2	PRODUCT A
Product profile			15% increase
Annual cost of therapy			\$XXX
How you would allocate your next 10 patients between these products:			
Number of patients			

Market Simulation and Pricing Strategy

- For each scenario, unique demand curves were generated and incorporated into a market simulation model
- The simulator allows the client full insight into the influence of specific product attributes on price and demand





360° REIMBURSEMENT & LAUNCH PLANNING

Client Need >

Understanding the attributes and nuances of the product which attain favorable versus unfavorable reimbursement status across various markets and across key health plans



Identify the therapeutic areas where products launched with a non-reimbursement strategy are most likely to succeed



Evaluate the implications of identified product characteristics/factors on the uptake of non-reimbursed products in comparison to reimbursed competitors



Provide a strategic decision-making tool to help the client to assess future reimbursement strategies for its portfolio

Product Evaluation

- Identify and define values for the factors that are most relevant to succeed with a non-reimbursement strategy
- Conduct historic product performance analysis to identify the negative and positive factors to influence the uptake of a non-reimbursed product
- Perform correlation analysis to clearly delineate the factors most important when determining a successful non-reimbursement strategy

Opportunity Assessment Matrix

- Applying therapeutic area and macroenvironmental relevant factors and build an opportunity matrix to identify which therapeutic areas are most suitable for products launching with a non-reimbursement strategy in each country



Interactive Assessment Tools

- Strategic decision-making tools are provided to clients to perform future assessments for their pipeline when considering the launch with a non-reimbursement strategy in each individual plan analyzed

Factor	Weight	Influence			Score
		Positive	Neutral	Negative	
Prevalent population	0.15	4	3	1	30
Elderly population	0.15	4	3	1	30
Costumed population	0.15	4	3	1	30
Prevalent market	0.15	4	3	1	30
Market accessibility	0.15	4	3	1	30
Existence of disease	0.15	4	3	1	30
Healthcare expenditure	0.15	4	3	1	30
Healthcare access	0.15	4	3	1	30
Public health status	0.15	4	3	1	30
Consumer awareness	0.15	4	3	1	30
Global market of interest	0.15	4	3	1	30
OTC availability presentation	0.15	4	3	1	30
Regulatory environment	0.15	4	3	1	30





LAUCH PLANNING & 360° REIMBURSEMENT

1

DESCRIPTION

A small-sized biopharmaceutical company with a focus on antivirals for immunocompromised patients approached the Certara US team. They had developed a Phase II pipeline agent for treatment of adenovirus in allogeneic stem cell transplant recipients. However, their product development strategy faced a major challenge: there currently is a major gap in multicenter studies of incidence and management of adenovirus infection in allogeneic hematopoietic cell transplant (allo-HCT) recipients

2

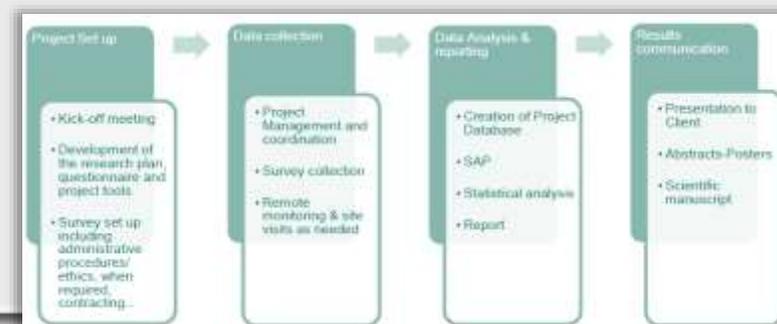
KEY OBJECTIVE

Answer a number of critical questions for product success to characterize the incidence and management of adenovirus infections in pediatric and adult HCT recipients in the US

3

Certara METHODOLOGY

The Certara teams conducted multi-center electronic physician surveys to identify practice patterns and collect aggregated data on the incidence of adenovirus. Physicians and centers performing allo-HCTs were identified through the Center for International Blood and Marrow Transplant Research (CIBMTR) database, and other resources; recruitment was achieved via targeted personal engagement, project overviews were held via teleconference, and in-person meetings. Certara worked closely with the client to develop a secure, electronic survey platform and a statistical analysis plan for the data interpretation. This allowed us to produce a full technical report and subsequent materials for publication of the research results



4

RESULTS

The project demonstrates Certara’s ability to take a customized approach on highly complex path-to-market challenges, and leverage strong client relationships to tailor content that creates unique value and positively impacts external stakeholders. The client chose Certara given our extensive expertise in rigorous primary research processes (e.g. physician procedures, recruitment, contracting, fees, IRB process) and our ability to navigate a complex US system with an advanced approach to capture physician insight. The results of the research led to a transformation in the client’s value proposition, but also provided their key stakeholders (transplant physicians) with helpful insights about patient management. For example, many of them thanked the Certara teams they engaged with for the opportunity to compare how their center performs on a national level. Our engagement with this client led to a multi-year partnership involving US and ex-US markets



LAUNCH PLANNING & 360° REIMBURSEMENT

1

DESCRIPTION

A large pharma company approached Certara to develop a plan to derive evidence-based strategies to proactively ensure franchise success through an evolving market

2

KEY OBJECTIVE

Achieve franchise profitability goals through 2015 as the market and client's franchise face challenges from new competitors, patent expirations, and changes in care delivery models

3

Certara METHODOLOGY

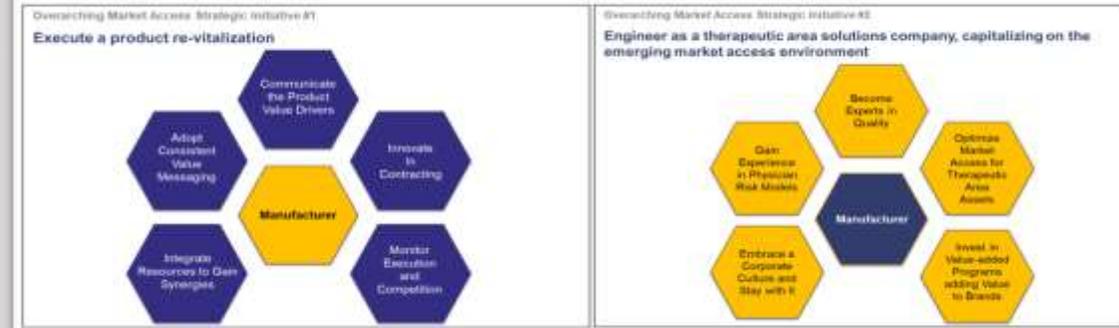
- Comprehensive secondary research and gap analysis informed the research plan
- Primary research of internal stakeholders (n=18) and payer customers (n=22) provided intelligence for an updated market access landscape
- Using additional internal expertise collected through an account team survey (n=62) and war game exercises (n=40), a strategic market access plan was developed

4

RESULTS & DELIVERABLES

- Recommendations in the Strategic Market Access Plan have been executed
- Client's principal product has retained market leadership in most plans and geographies through the launch of a successor compound

Actionable strategic recommendations from the Strat-MAP





LAUCH PLANNING & 360° REIMBURSEMENT

1 DESCRIPTION

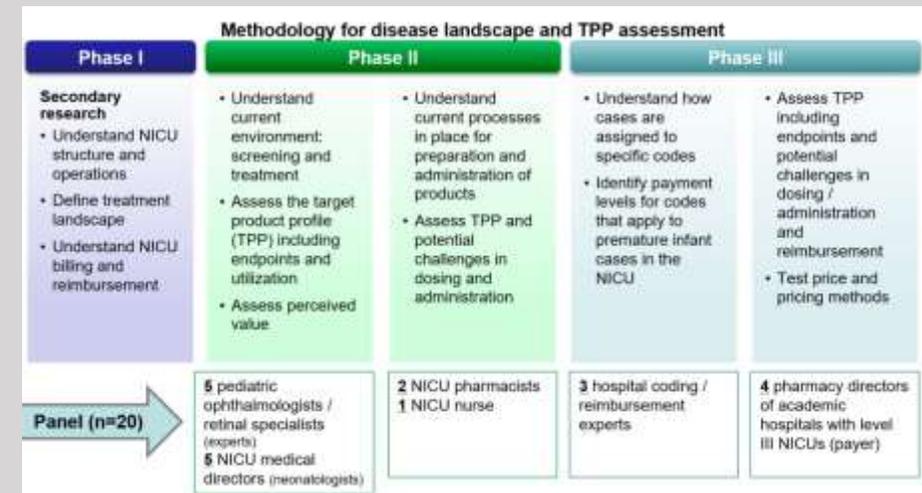
A client requested evidence-based guidance of the current landscape and target product profile to identify the value drivers and advance the asset in product development

2 KEY OBJECTIVE

- Understand current patient journey and treatment landscape
- Review process of novel therapies within the neonatal intensive care unit (NICU) and the billing and reimbursement process in the NICU
- Assess the clinical research designs of a novel treatment of an orphan disease to assist in guiding the commercial development and clinical teams

3 Certara METHODOLOGY

- In-depth interviews with 20 respondents in the US including pediatric ophthalmologists, retinal specialists, NICU medical directors, NICU nurse managers, NICU pharmacists, hospital coding/reimbursement experts, and payers



4 RESULTS

- Description of types of NICUs in US, key decision makers, adoption of new treatments and their fit into current processes
- Map of reimbursement process within the hospital and NICU by payer type
- Patient journey including patient characteristics, screening, treatment and outcomes of this rare disease
- Comprehensive product assessment by respondents and expected utilization by HCPs
- Development of a cost model and price recommendation
- Findings were used by the client to plan the Phase III clinical trial



LAUNCH PLANNING & 360° REIMBURSEMENT

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4 RESULTS & DELIVERABLES

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Many of the recommendations in the Strategic Market Access Plan have been executed

Actionable strategic recommendations from the Strat-MAP

Overarching Market Access Strategic Initiative #1 Execute A Product Re-Vitalization



Overarching Market Access Strategic Initiative #2 Engineer as a therapeutic area solutions company, capitalizing on the emerging market access environment



The logo for CERTARA, featuring the word "CERTARA" in a bold, red, sans-serif font. To the right of the text is a circular icon composed of two overlapping rings, one yellow and one orange, with a small gap at the top. A thin white horizontal line is positioned below the text.

CERTARA

EVIDENCE & ACCESS

Impactful science from
bench to market

WE ARE CERTARA[®]



90% of all novel drugs approved by the U.S. FDA in the past three years were supported by Certara software or services



850+

Employees including

250+

PhD, PharmD, and MD consultants



110+

Global regulatory submissions written and approved in the last three years from a team of

250+

Regulatory science consultants



Certara software is used by major regulatory agencies and considered a "gold standard" by the U.S. FDA

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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Please get in touch with our US team for any questions, consultations or RFP: Email ulrich.neumann@certara.com or call our New York head office directly at **+1 646 887 6540**