Unlock your Value Proposition

By integrating value assessment into your portfolio strategy & clinical development journey, we help you pick the winners & get them to patients

Value and Impact Strategic Trends Assessment (VISTA)

So, a more integrated approach is needed, with Medical Affairs strategy playing a key, cross-functional role in value creation throughout the development cycle

Portfolio prioritization and value assessment

- Is there an unmet need in key markets for a new product?
- Is the burden of illness recognized? Is further work needed to fully define?
- Are the key markets identified and how big is the opportunity?
- How will the product be differentiated?
- What are the potential barriers to adoption?

Clinical trial shaping

- Are the active comparators in your trial appropriate across key launch markets?
- Are outcome measures relevant and meaningful for patients, as well as regulatory bodies?
- Are patient-reported outcomes validated and acceptable for HTA assessment bodies in key markets?
- Has a robust evidence generation plan been created to maximize opportunities?

Preparing for access and launch

- Does the proposed product label align with the value story and evidence being submitted in key markets?
- Are the planned publications and communications aligned with the access strategy?
- Do any of the key markets have special communication requirements?
- What would the value story look like for different target profiles?
- Has the landscape changed since the early stages of your value story concept and design?

Uptake and maintained life-cycle access

- Has the product been approved at national and local level and is reimbursement in line with expectations?
- Are the data publications appropriate to maintain access?
- Are real-world data being collected and utilized to demonstrate sustained value?
- Is the value proposition delivering on the promise to patients and payers?

- Eliminates silos providing end-to-end visibility through an integrated offering, led by senior in-house specialists with diverse and deep expertise
- Under unified leadership, we deliver evidence-based, patient-focused solutions that optimize audience engagement and improve access

Value-based strategy: We offer a framework for applying an integrated value optimization approach across the entire lifecycle

VISTA

Value and Impact Strategic Trends Assessment

Pharma pain points

Phase 2	Phase 3	Launch	LCM
• Multiple portfolio assets to prioritize • Picking the winners • Assessment of clinical development plans • In-licensing due diligence assessment • Value forecast → ROI	• Right outcomes in pivotal studies • Competitive TPP • Inclusion of right PROs • Country/regional variability in treatment pathways • Timely RWE plans	• Changing competitor landscape • Regulator pushback on endpoints • Evidence gaps • Timing of launch impact • Reimbursements delays • Price discounts	• Delays in access and uptake • New indication timing • Field training • Price erosion – 2nd indication • Variation in stakeholder perception of value

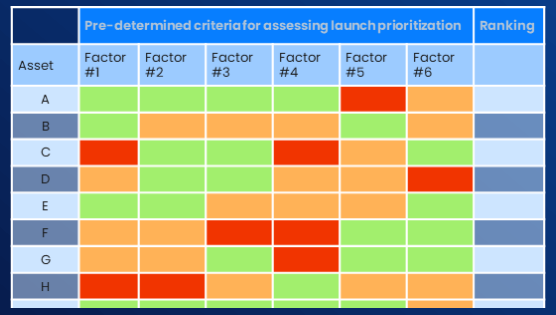
Prime solutions

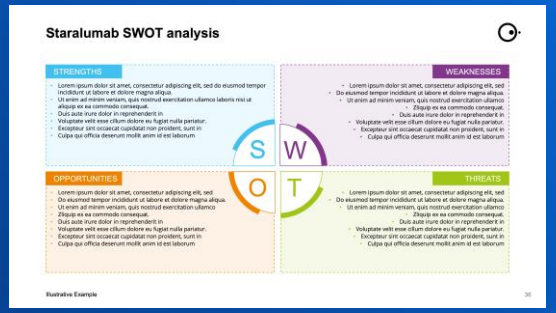
Decision 1	Decision 2	Decision 3
Emerging portfolio teams	**Clinical Development teams**	**Market Access and Commercial**
Portfolio prioritization + value assessment	Clinical program for value optimization	Value strategy for launch and LCM
Value assessment framework	Landscape analysis and analog research Clinical outcomes assessment Integrated evidence planning	Scenario analysis Payer insights research Patient preference research

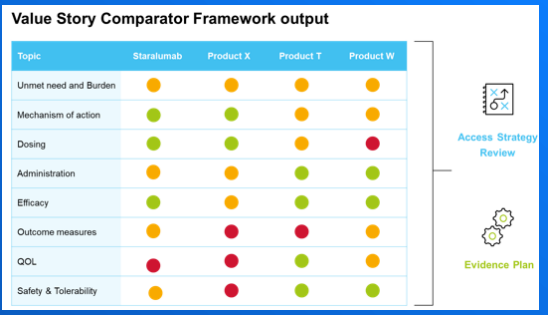
LCM, life cycle management; PRO, patient-reported outcome; ROI, return on investment; RWE, real-world evidence; TPP, target product profile.

Value assessment framework

Our framework to rapidly assess the opportunity of an asset and inform internal strategic decisions on portfolio prioritization (e.g. clinical trial design, Go/No-go investment decisions, pricing strategy, integrated evidence generation plans)







We work with you to identify critical success factors relevant to your asset's development stage, such as market size, competitor landscape, clinical differentiation, and reimbursement potential

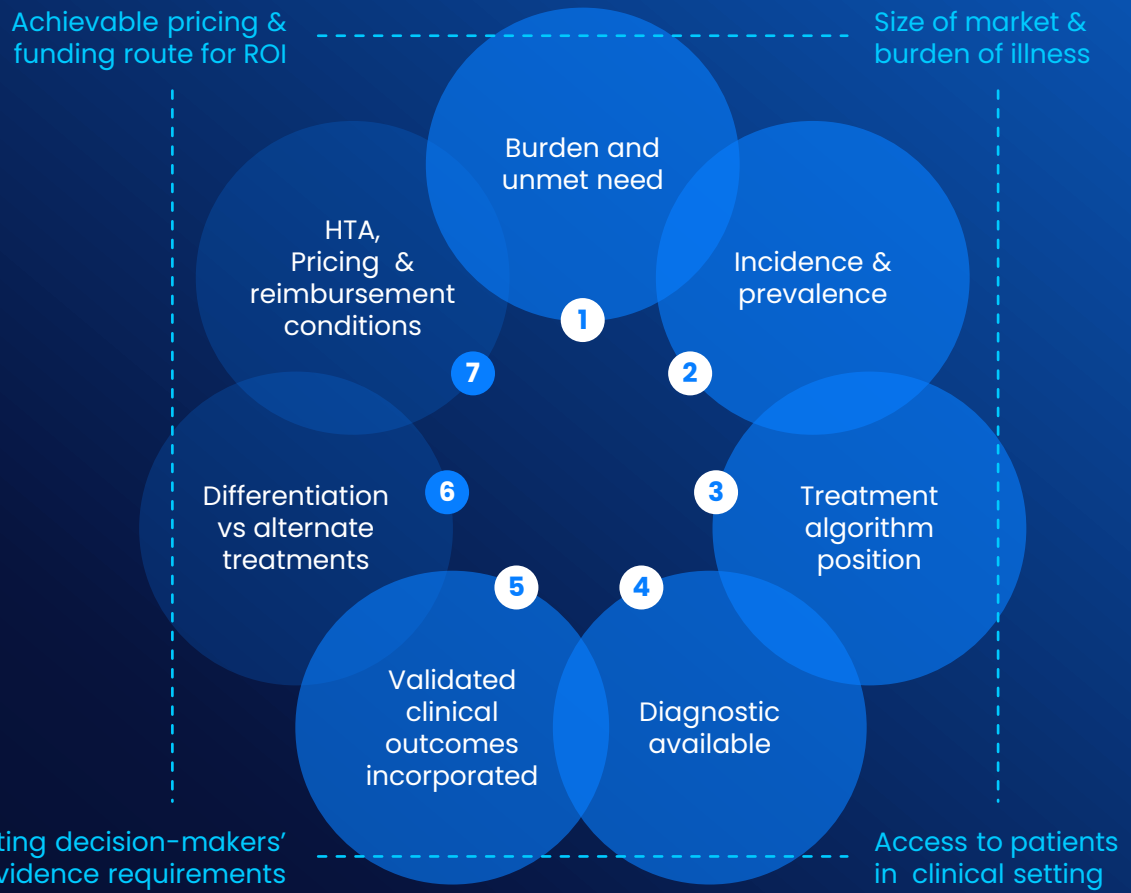
We utilize a combination of primary research (e.g. surveying local affiliates) and secondary research (ranging from TPP and market research, to industry reports, congress reports, and company press releases)

The research is used to generate for each asset, a comprehensive SWOT with competitor & environment analysis, which inputs into the value assessment framework

The output is a comprehensive value assessment, enabling decision-making on asset investment & prioritization, value story development, and evidence generation strategies

We have experience supporting portfolio investment decisions by considering multiple factors which drive value

Key assets and value drivers to be aligned with company priorities



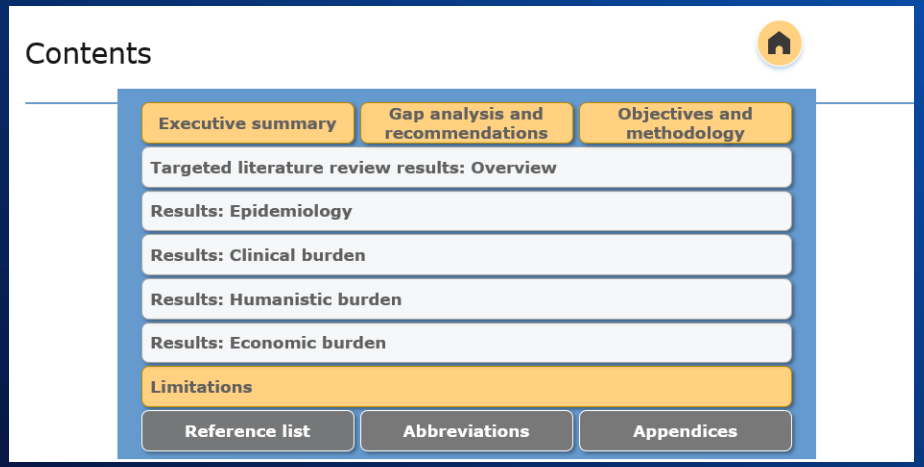
Criteria for early value assessment (examples)

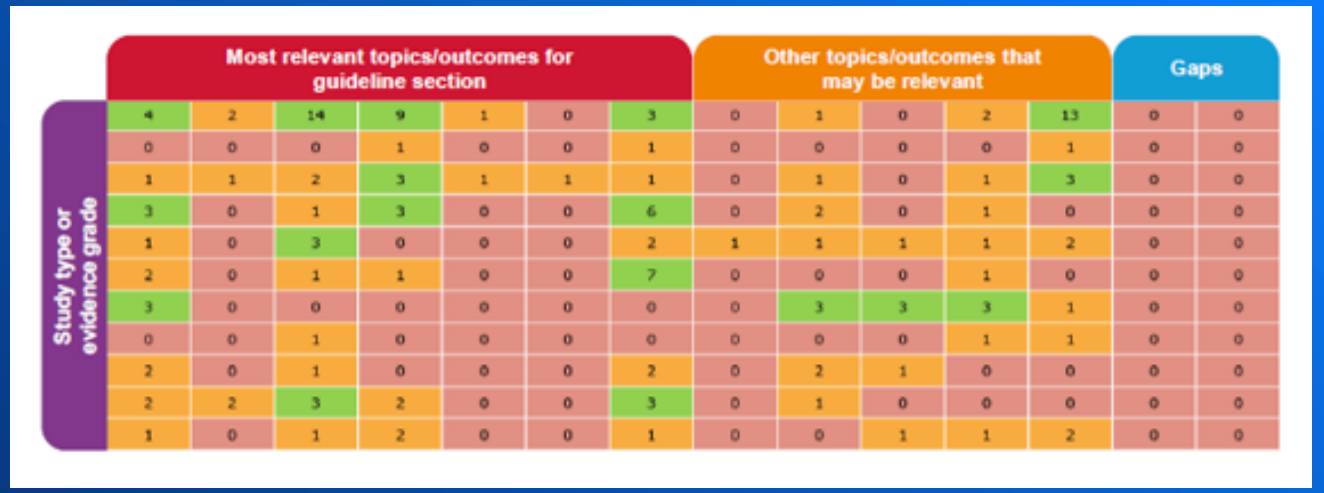
Development Asset	#1 Is burden of disease and unmet need identified?	#2 Is target population identifiable?	#3 Is position in Tx guidelines clear?	#4 Is diagnostic available in routine practice?	#5 Are primary outcomes and PROS validated?	#6 Are other assets in development for indication?	Need for additional validation
A							
B							
C							
D							
E							
F							

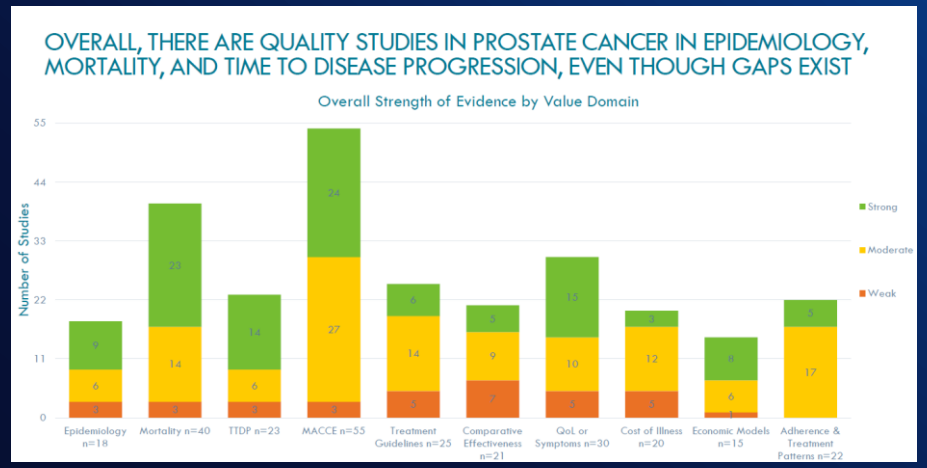
Illustrative worksheet Meets criteria Some gaps Significant gaps

Incorporating burden and unmet need assessment early will ensure a platform for value creation

Structured and pragmatic approach to evidence review





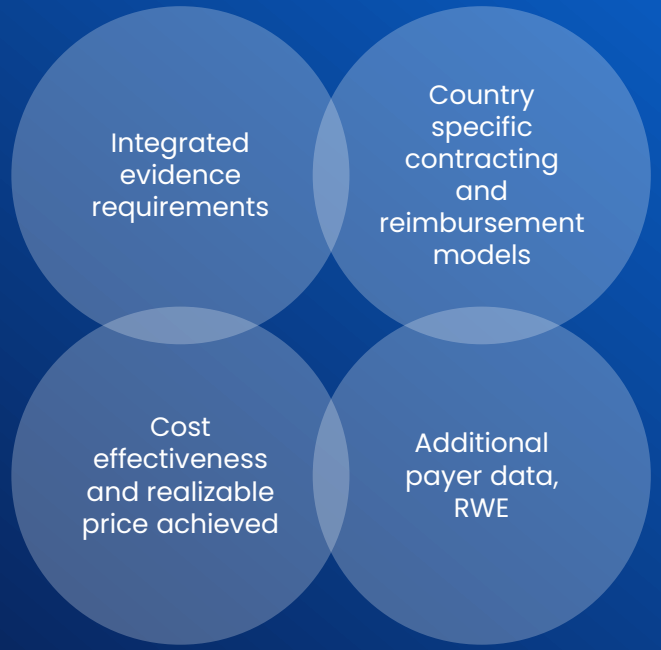


Understanding the established burden and levels of evidence will help prioritize additional requirements for **integrated evidence planning**

An integrated approach to value assessment to drive optimal ROI

Medical Affairs

HEOR and Market Access



Commercial

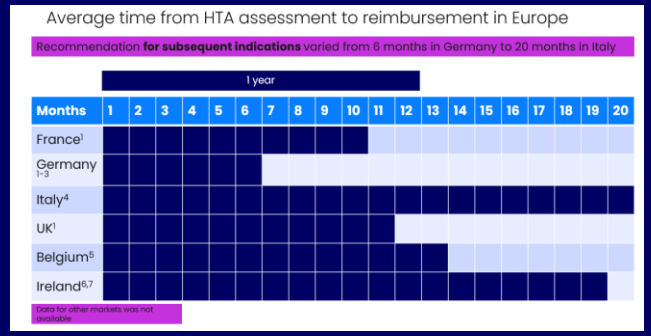
Landscape analysis

A comprehensive review of the landscape across relevant markets, to capture Market Access challenges that can impact commercialization and ROI

KEY OUTPUTS

Country	National HTA outcomes	Influence	Payer decisions on pricing and coverage
Australia	PBAC Archetype: Cost effectiveness	Binding	The Federal Government Minister for Health agrees with manufacturer on price, other payers may act at regional and/or local level Archetype: Budget optimisation
USA	ICER Archetype: Cost effectiveness	Non-binding	Multiple payers exist across **public** (e.g. Medicare/Medicaid) and **private** sectors (e.g. managed care and employer-based insurance organisations) Archetype: Patient centric (out of pocket) & budget optimisation*
France	HAS Archetype: Comparative effectiveness and cost-effectiveness hybrid	Non-binding	Drug price setting is established by CEPS. The reimbursement rate is fixed by a decision from UNCAM Archetype: Comparative clinical effectiveness
Germany	G-BA Archetype: Comparative effectiveness	Binding	SHI GKV-SV negotiates prices with pharmaceutical companies dependent on outcome of the early benefit assessment conducted by the G-BA. Archetype: Comparative clinical effectiveness
England	NICE Archetype: Cost effectiveness	Binding	NHS England Archetype: Budget optimisation

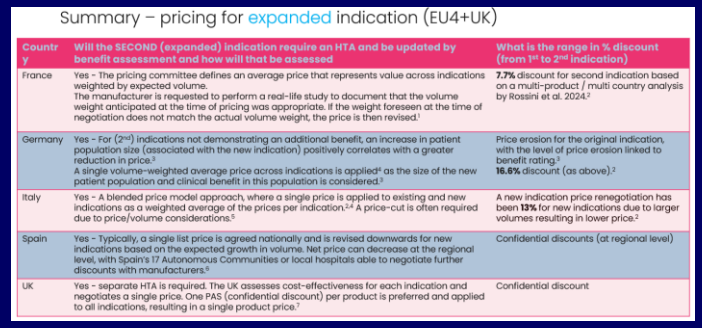
Identification of payer and HTA archetypes



Review of time between market authorization, reimbursement, and market access

Situational summary	• Regulatory, competitive landscape, access or reimbursement/coverage status
Device / digital / connectivity	• Perceptions on devices, digital applications and/or application connectivity to self-administered injectables, e.g., improvement on adherence
Sustainability	• Are there sustainability initiatives associated with self-administered injectables?
Medical benefit versus pharmacy benefit	• What are the implications of having an HCP-administered product (medical benefit) to self-administered product (pharmacy benefit)? • Do health insurance providers (by number of lives covered) differ in their approach?
Innovative contracting	• Are innovative contracts in place for selected analogues? Potential link to adherence monitoring • Are there potential cost savings associated with self-administered injectables (at home)?

Review of patient access mechanisms



Review of asset pricing in original vs expanded indications

Analogue research

We research analogues in other therapy areas to generate detailed insights into country hurdles, clinical trial design, price potential & access strategy

Key considerations:

- **Evidence** package including specific data supporting the market access strategy, including economic, clinical, quality of life, patient-reported outcomes and real-world data
- **Time** between market authorization, reimbursement, and market access (at the national, regional/state, and plan level)
- **Price** including list price, reimbursement, and co-pay at launch. Understand price evolution and provide insights on pricing, discounting and contract arrangements
- **Budget impact** of the analogue in 'real world' treatment setting and assessment of relevant technology appraisals (NICE, IQWIG)
- Determine the **funding flow** and key decision-makers

Illustrative outputs:

MOA/ molecular target	Treatment algorithm position
Clinical comparator	Price comparator
Duration of therapy	Time to reimbursement (days)
Standard of care	Reimbursed population at launch
Indications	Current reimbursed population
Why approved and marketed	Assessment rating

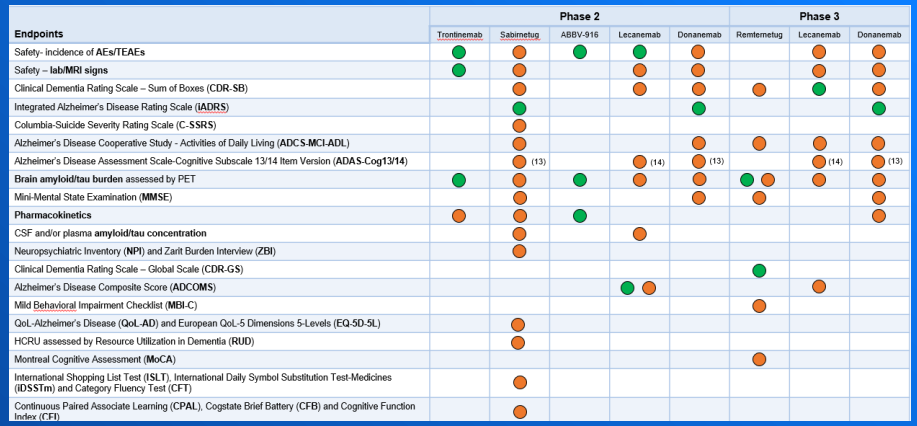
Clinical outcomes assessment

We guide your outcomes selection to ensure robust evidence which demonstrates value and meets market and regulatory demands

The importance of a strategy for demonstrating value throughout R&D program

Guiding development: Understanding the clinical outcomes landscape informs trial design, endpoint selection, and the evidence needed for regulatory/HTA success

Differentiated value: The clinical outcomes assessment will ensure meaningful outcomes for patients, clinicians, and payers, demonstrating product differentiation from early development



Endpoints	Phase 2					Phase 3		
	Trontinemab	Sabirnetug	ABBV-916	Lecanemab	Donanemab	Remternetug	Lecanemab	Donanemab
Safety- incidence of **AEs/TEAEs**	●	●	●	●	●		●	●
Safety – **lab/MRI signs**	●	●		●	●		●	●
Clinical Dementia Rating Scale – Sum of Boxes (**CDR-SB**)		●		●	●	●	●	●
Integrated Alzheimer's Disease Rating Scale (**iADRS**)		●			●			●
Columbia-Suicide Severity Rating Scale (**C-SSRS**)		●						
Alzheimer's Disease Cooperative Study - Activities of Daily Living (**ADCS-MCI-ADL**)		●			●	●	●	●
Alzheimer's Disease Assessment Scale-Cognitive Subscale 13/14 Item Version (**ADAS-Cog13/14**)		● (13)		● (14)	● (13)		● (14)	● (13)
Brain amyloid/tau burden assessed by PET	●	●	●	●	●	● ●	●	●
Mini-Mental State Examination (**MMSE**)		●			●	●		●
Pharmacokinetics	●	●	●					●
CSF and/or plasma **amyloid/tau concentration**		●		●				
Neuropsychiatric Inventory (**NPI**) and Zarit Burden Interview (**ZBI**)		●						
Clinical Dementia Rating Scale – Global Scale (**CDR-GS**)						●		
Alzheimer's Disease Composite Score (**ADCOMS**)				● ●			●	
Mild Behavioral Impairment Checklist (**MBI-C**)						●		
QoL-Alzheimer's Disease (**QoL-AD**) and European QoL-5 Dimensions 5-Levels (**EQ-5D-5L**)		●						
HCRU assessed by Resource Utilization in Dementia (**RUD**)		●						
Montreal Cognitive Assessment (**MoCA**)						●		
International Shopping List Test (**ISLT**), International Daily Symbol Substitution Test-Medicines (**IDSSTm**) and Category Fluency Test (**CFT**)		●						
Continuous Paired Associate Learning (**CPAL**), Cogstate Brief Battery (CFB) and Cognitive Function Index (**CFI**)		●						

Our Approach: Evidence-Driven COA Selection & Validation

1. Landscape analysis

We analyze competitor outcomes strategies, historical precedents with regulators/payers, and systematically search trial databases and literature for relevant outcomes and performance data

2. Instrument evaluation & evidence gap analysis

We assess if the chosen outcome is validated for the target population and identify any gaps in psychometric evidence or real-world validation. This includes "minimal clinically important difference" (MCID) evidence

3. Robust evidence generation

We provide strategic consultancy to address evidence gaps. Our services include designing tailored validation studies (qualitative, quantitative, RWE) and defining the clinical relevance of outcomes/scores to ensure instruments meet payer, regulatory, and clinical requirements

Scenario analysis

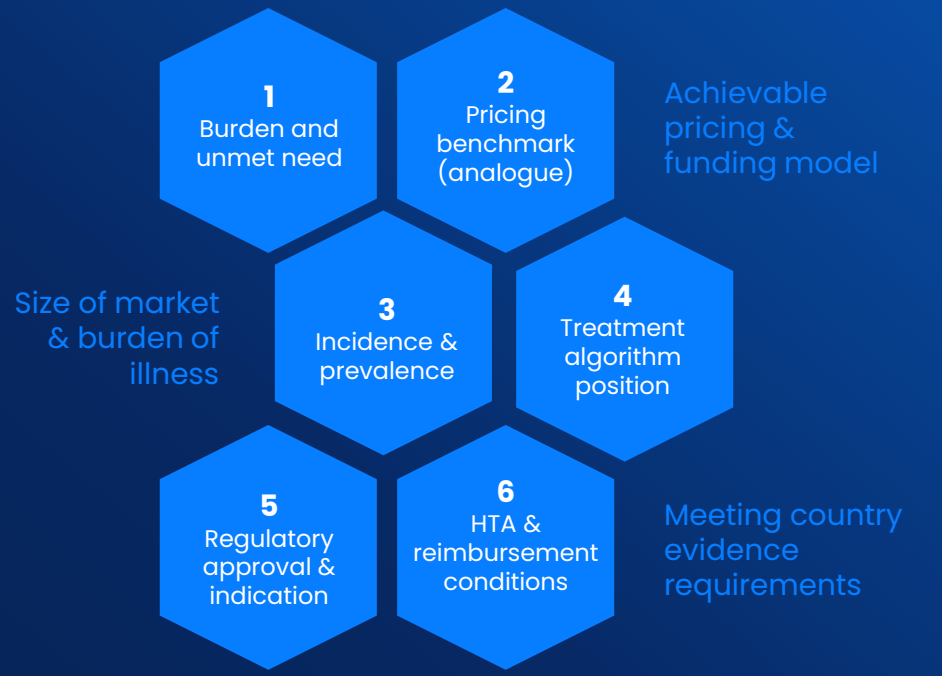
Utilizing cross-functional expertise, market insights, and analogue research, we generate a dashboard of factors influencing successful launch for alternate scenarios. This can be validated with external stakeholders, including payers & KOLs

Examine **scenarios** that are likely to be accepted in each country

Time to reimbursement and other **market factors** are accounted for, and **country-specific payer insights** are interpreted to inform the market access strategy

Price recommendations per country include a **launch price corridor** accounting for international price referencing

Final strategic recommendations consider specific **local challenges to implementation** and **risk mitigation** tactics



Scenario 1	Pre-determined criteria for assessing launch prioritization						Ranking
Country	Factor #1	Factor #2	Factor #3	Factor #4	Factor #5	Factor #6	
A							
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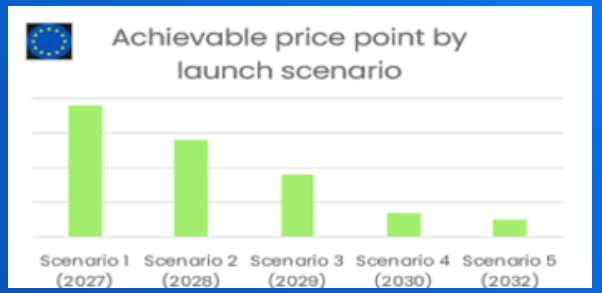

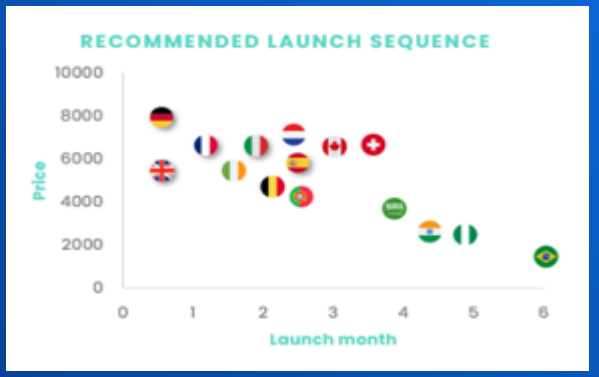

Payer insights research

Payer research enables testing of pricing scenarios, launch sequencing, and overall value perception of current and future treatments

Stakeholder identification

Illustrative payer types, in example markets:

Example countries	Suggested payer sample
UK	1 x National former NICE or SMC; or pricing specialist 2 x Regional (CCG member, Medicines Management or Regional Medicine Committee member)
FR	1 x National: Former member of CEPS 2 x Regional: Hospital Formulary Committee Member (COMEDIMS)
US	1 x Commercial Managed Care (PBMs, IDNs) Pharmacy and medical directors from national and regional health plans 2 x Commercial plan pharmacy and medical directors who cover some Medicare lives
DE	1 x Former advisor to GBA/GKV; or national pricing expert 2 x Regional (senior members of KK or KV)
BR	1-2 x regional and local payers that influence the decision-making process and will also influence prices in their states or in the formulary 1-2 x hospital payers from large hospitals (private and public) from larger cities, as they are considered reference hospitals to the country 1-2 x payers from private Health Maintenance Organisations
JP, TW	Representatives from Japan and Taiwan (developed markets in APAC). For example, 2x payers from the The National Health Insurance (NHI) in Taiwan and 2x payer advising KOLs

Recruitment criteria includes payers, payer advisers, or experts in the assessment/approval of relevant therapies holding budgetary responsibility

Insights research via interviews

Payer interviews cover all pricing and launch scenarios, to provide comprehensive insights on value perception across markets

Virtual advisory panel

Building on research findings, a panel will:

- Assess reaction to the proposed strategy
- Identify further evidence requirements to support pricing
- Assess the potential for innovative contracting or outcome-based agreements

Output:

robust, validated insights on value perception, to inform pricing & launch strategy

Thank you

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