IPSOS MARKET ACCESS

Introduction

2024

Ipsos Market Access
OUR FOCUS

We support clients in all aspects of market access, throughout clinical development and post-launch through to loss of exclusivity.

Built on a foundation of world-leading market research and analytical capabilities, deep global knowledge, and multi-stakeholder reach within healthcare.

We bring insight, evidence, value and strategy expertise – enhanced by the market intelligence, research and analytic capabilities of the wider Ipsos team.

Ipsos Market Access sits within the Ipsos Healthcare business unit and is positioned to leverage our insight and analytics expertise

IPSOS HEALTHCARE

CUSTOM RESEARCH

HCP and patient research across the product lifecycle (Commercial Strategy, Launch Excellence, and Performance Optimisation)

SYNDICATED RESEARCH

Syndicated Global Real-World Evidence (RWE) and other syndicated solutions utilised by clients to answer business questions

MARKET ACCESS

Helping our clients address Market Access challenges. Developing solutions and strategies to ensure the greatest access & value for their products

ADVISORY SERVICES

Guiding our clients' strategic decisions through insight, research and analytics, across the product lifecycle

CENTRES OF EXPERTISE

PRODUCT LIFECYCLE

- Commercial Strategy
- Launch Excellence
- Performance Optimisation
- **Market Access across the lifecycle**

THERAPY INSIGHTS

- Oncology
- Autoimmune
- Vaccines/Virology/Liver Diseases
- Rare Diseases
- Diabetes, Obesity & CVRM
- Respiratory
- Dermatology

MARKET KNOWLEDGE

- Biopharma Industry
- Multi-Stakeholder Access/ Engagement
- Medical Devices & Diagnostics
- Connected Health
- Patient & Consumer Health
- Animal Health
- Gx, BGx and Biosimilars

INNOVATIVE SOLUTIONS

- Data Science & Advanced Analytics
- Multi-source Data Solutions
- Digital Innovation/Social Intelligence/AI
- Qualitative Observation & Activation
- Behavioural Science
- Syndicated Real World Data & Norms

The global Market Access team have diverse experience from consulting and industry – with hubs in the US, EU and APAC

Americas Leadership

Scott Freeman

Head of US Market Access
Scott.Freeman@ipsos.com

Europe & MENA Leadership

Richard Tolley

Head of EU Market Access
Richard.Tolley@ipsos.com

Andrew Ballantyne

Vice President
Andrew.Ballantyne@ipsos.com

Asia & Oceania Leadership

Adrien Gras

Head of APAC Market Access
Adrien.Gras@ipsos.com

Global Expertise in

- Turning insight into Payer Strategy
- Turning Evidence into Value

Expertise across the team is focused around four key areas: insight, evidence, value and strategy – which defines our services

Aligned global expertise

Insight

Gathering **insight** from stakeholders or secondary sources and advising our clients

Examples:

- Due diligence
- Disease landscape
- Stakeholder profiling
- Payer insight tracking

Evidence

Understanding what **evidence** is needed to support product value and where to find this data

Examples:

- Evidence generation strategy
- Health Economic evidence
- Collecting and using Real-World Evidence

Value

Gathering and using evidence to define and communicate the **value** of a drug to payers

Examples:

- Value message development
- Focused value communication tools

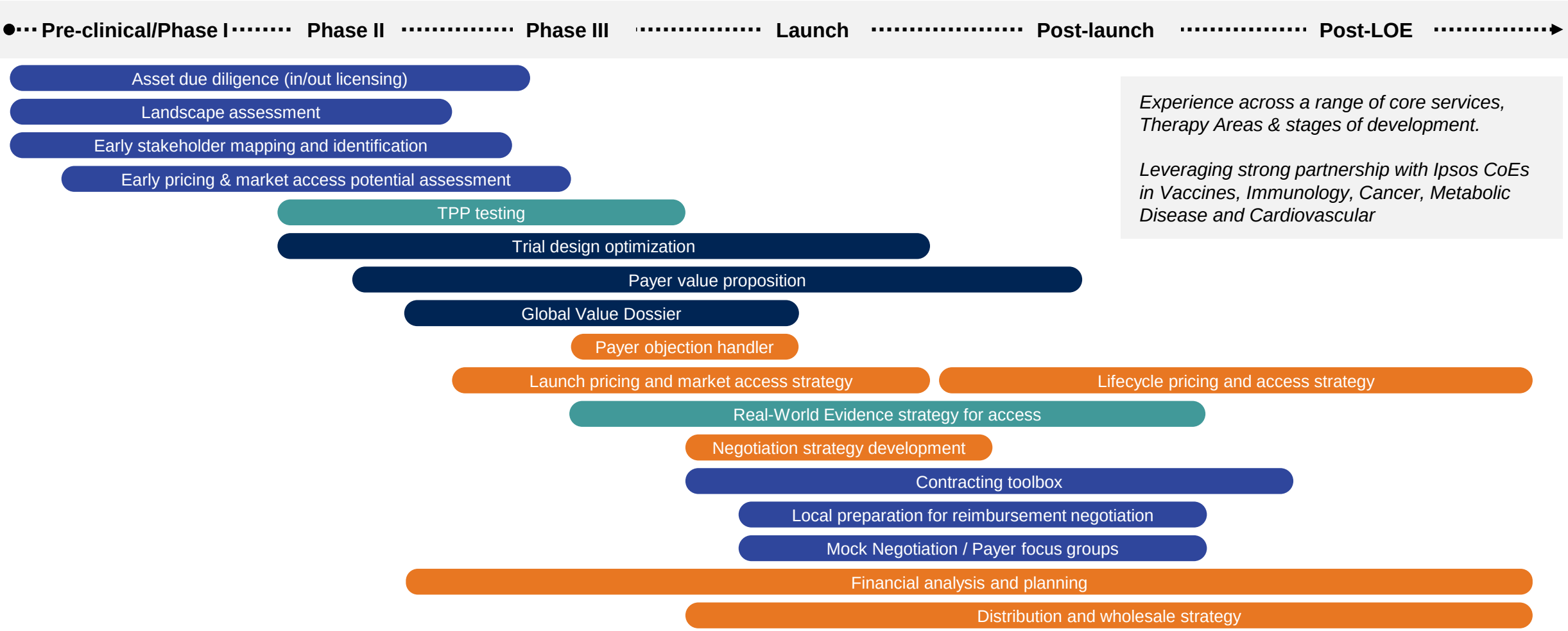
Strategy

Developing **strategies** which help clients achieve optimal pricing, reimbursement and access

Examples:

- Market Access strategy
- Pricing strategy
- Contracting strategy
- Dynamic market simulation

Ipsos Market Access can support on a range of solutions across the product lifecycle, using expertise to address client challenges



Experience across a range of core services, Therapy Areas & stages of development.

Leveraging strong partnership with Ipsos CoEs in Vaccines, Immunology, Cancer, Metabolic Disease and Cardiovascular

Some of the clients that we work with…

Case Studies

CASE STUDY:

Early Payer Landscaping and Understanding HCP Perspectives on the Future Treatment of Hidradenitis Suppurativa

In-depth Qualitative & Quantitative Interviews with Payers and HCPs

Global Pharmaceutical Company

Immunology, Dermatology

USA, EU5

Client situation

Our client wanted a flexible way to evaluate the uptake, potential pricing and access for a broad range of possible assets in Hidradenitis Suppurative (HS) in a variety of likely future market scenarios taking into account the perspective of payers and leading HCPs.

The client objectives were:

- To deepen understanding of HS as a therapy area to inform further investment decisions
- To understand how the advent of new biologic and biosimilars will change the HS treatment landscape
- To carry out early payer landscaping i.e. understand knowledge gaps, the priority given to HS as a therapy area, potential management tools to be implemented by payers as it becomes a crowded market, thoughts on patient numbers as more treatments become available
- To understand physician interest in the early stage uptake of assets, taking into account the management tools shared by payers

Ipsos solution

Ipsos proposed a step-wise approach to address client's objectives:

1. **Qualitative in-depth interviews with dermatologists** to create a detailed picture of physician objectives in HS therapy e.g. referral patterns, diagnosis and patient types
2. **Qualitative in-depth interviews with payers** (with a KOL-led educational webinar on HS prior to interviews) to understand access restrictions and potential uptake of new, advanced HS assets in an increasingly competitive landscape
3. **Advisory board with two influential KOLs** and our client's teams to understand evidence requirements to enable preferential uptake of assets and the latest scientific thinking in HS treatment
4. **Conjoint exercise via quantitative dermatologist interviews** to assess different asset profiles and launch scenarios

Business impact

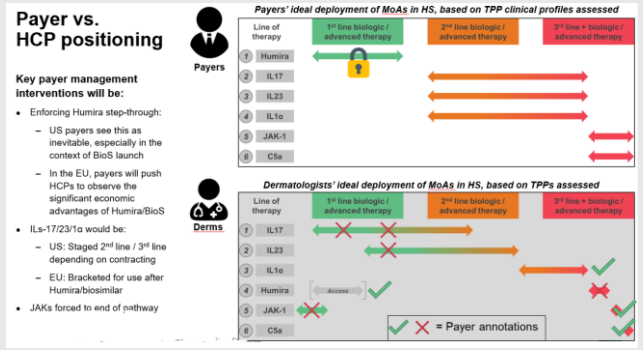
The outputs for each stage were as follows:

1. **In-depth interviews with dermatologists** provided perspective on the treatment pathway, diagnosis and patient stratification, enabling an understanding of the key drivers of preferential drug usage
2. **In-depth interviews with payers** provided insights on payer awareness and management strategies once HS becomes a crowded market, enabling our client to plan various scenarios and understand evidence requirements to differentiate new therapies
3. **Advisory board with influential KOLs** advanced our client's understanding of biologic therapy as a part of the future HS treatment landscape
4. **The conjoint exercise** led to a simulator which allowed our client to assess their assets performance in terms of market share depending on key profile attributes (e.g. safety, efficacy) and range of potential future competitors

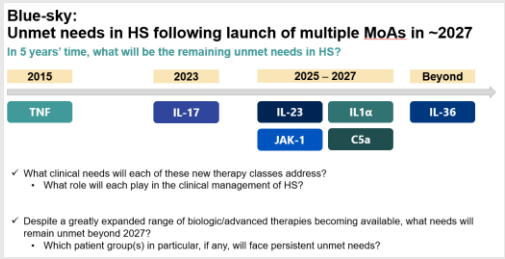
CASE STUDY:

Early Payer Landscaping and Understanding HCP Perspectives on the Future Treatment of Hidradenitis Suppurativa

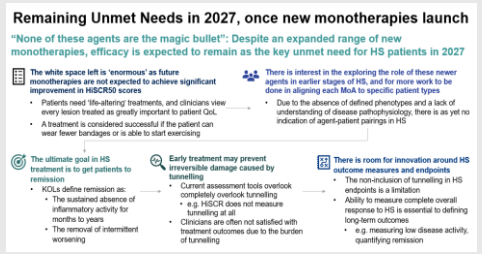
Screenshots from Project Deliverables:



- Ipsos summarised the discussions from the payer and HCP interview and presented findings as a report for the client
- Example: key payer management interventions and MoA positioning by stakeholder



- Ipsos facilitated advisory board discussion with leading KOLs to understand the latest scientific thinking and evidence requirements behind HS treatment



- Example: remaining unmet need in the future HS treatment landscape

CASE STUDY:

Understanding the originator biologics company's current activities and future defence strategies

Competitive Intelligence / Landscaping

Global pharmaceutical company

Musculoskeletal disease/osteoporosis

EU4, UK, US, Canada, Austria, Finland, Poland, Sweden

Client situation

Our sponsoring pharmaceutical company was developing a biosimilar biologics product that would compete with two distinct brands, each having unique indications of use that cover both primary and iatrogenic diseases.

The client wanted to position their new biosimilar product and ensure appropriate clinical uptake.To achieve this, they sought to understand the current commercial, medical, and promotional activities of the originator company. They also aimed to identify future defense strategies that the originator company plans to amplify ahead of the expected loss of exclusivity of their product.

As part of the comprehensive Ipsos solution - which also involved research on healthcare professionals and social intelligence analytics - Ipsos Market Access conducted a payer research to uncover insights into the promotional activities and communication of the originator biologics company.The research aimed to ascertain the payers' reaction regarding the success of these activities.

These insights were intended to provide indications of potential future defense strategies and guidance on how our client can improve the positioning of their biosimilar product.

Ipsos solution

Prior to conducting the research program, Ipsos held a 1-hour workshop with our client to align on key themes to explore, as well as sample composition in each market for the primary research component.

Based on the inputs gathered from the workshop, Ipsos developed a 15-minute online questionnaire designed to gather competitive intelligence on the originator biologics company from payers who had received communication on two originator biologic brands.

Ipsos designed a comprehensive global report that highlighted the key trends and themes that were communicated by representatives of the originator biologics company to payers. It also provided insights on regional variations and denoted differences by biologic brands. Furthermore, the report included insights on strategies employed in the past by the originator company to counter biosimilar entrants.

Based on these findings and internal expertise, Ipsos provided actionable recommendations to optimise the positioning of the client's biosimilar product within the competitive market landscape.

Business impact

Ipsos' report offered valuable insights to our client, shedding light on the activities and potential future strategies of the originator biologics company to maintain their market share and revenue following the loss of exclusivity of their product.

After contemplating the expected defensive measures that the originator biologics company might use, we advised our client on the optimal approach to leverage the potential of their biosimilar product and succeed in the competitive market.

Our recommendations offered valuable support to our client. By following our advice, the client was able to optimise the success of their biosimilar product and maintain a competitive position in the dynamic biologics market.

CASE STUDY:

Understanding the originator biologics company's current activities and future defence strategies

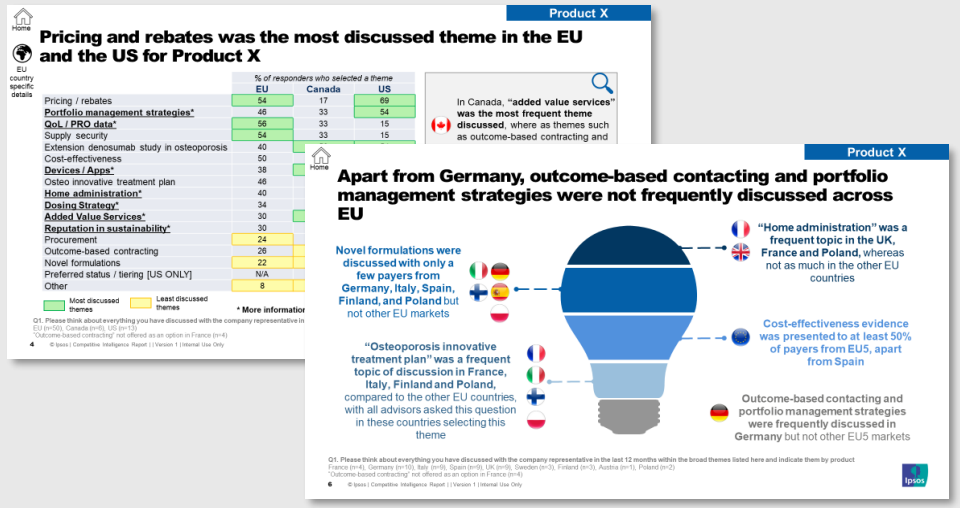
Competitive Intelligence / Landscaping

Global pharmaceutical company

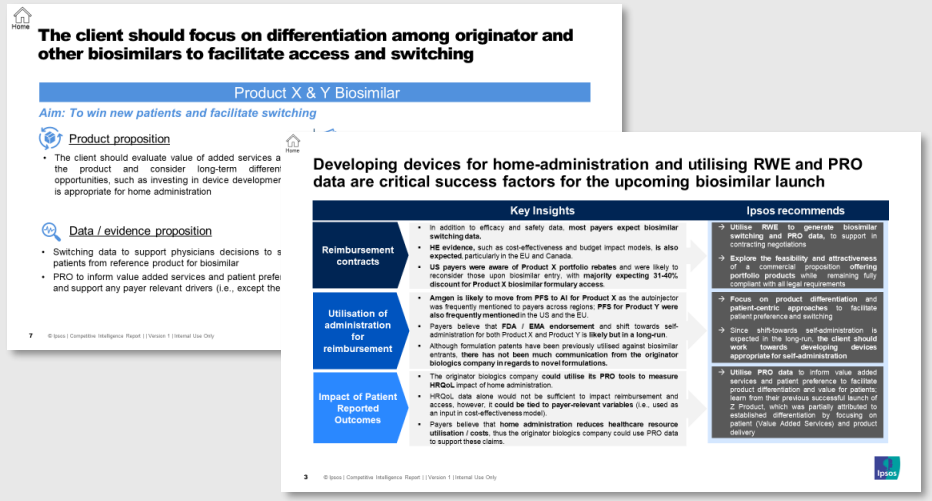
Musculoskeletal disease/osteoporosis

EU4, UK, US, Canada, Austria, Finland, Poland, Sweden

Blinded Screenshots from project deliverables:



E.g., Detailed findings slide outlining key themes discussed for Product X and regional variations



E.g., Executive summary slide outlining key insights and Ipsos recommendations

CASE STUDY:

Metastatic colorectal cancer: review of the HTA landscape to inform trial design

- Secondary research
- Pharmaceutical company
- Metastatic colorectal cancer
- EU5

Client situation

Our client was developing a third-line therapy for metastatic colorectal cancer (mCRC).

In preparation for their phase III clinical trial, they were interested in understanding the outcomes of recent HTA assessments in metastatic colorectal cancer to identify comparators and key trends that could impact reimbursement and access.

The project goals were:

- Assess which products gained reimbursement in the EU for third-line therapy mCRC.
- Explore the reasons for products to be denied reimbursement in mCRC.
- Inform on upcoming products and comparators in clinical development; chances of those upcoming products to become SoC.
- Propose a design of the clinical development programme.

Ipsos solution

Ipsos conducted a thorough review of the client's clinical trial programme and conducted in-depth secondary research on recent HTA assessments and the therapeutic landscape.

The secondary research provided a strong basis on which to build, allowing Ipsos to recommend several design options for the clients' phase III clinical trial, highlighting the potential consequences of each design.

Business impact

The results of the second research program helped our client to understand the potential access outcome for their therapy depending the trial design, and to assess how trial outcomes could be leveraged across the scope markets.

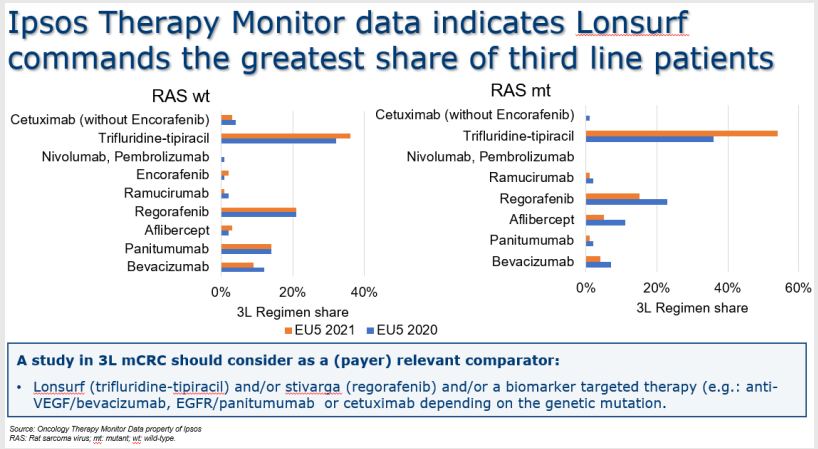
Our analysis was able to highlight:

- Unmet needs in mCRC
- The likely clinical and economic comparators for each market, considering the various SoCs
- The price potential in relation to other available treatments
- The benefits, costs, and risks of alternative trial programme designs

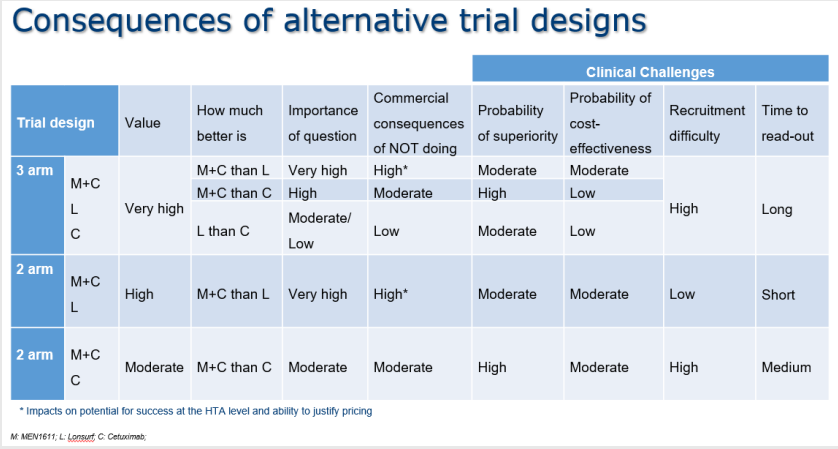
CASE STUDY:

Metastatic colorectal cancer: review of the HTA landscape to inform trial design

Blinded Screenshots from project deliverables:



- **E.g.** A final report slide displaying which therapies in 3rd line mCRC are relevant to use as comparators from a payer perspective



					Clinical Challenges			
Trial design		Value	How much better is	Importance of question	Commercial consequences of NOT doing	Probability of superiority	Probability of cost-effectiveness	Recruitment difficulty	Time to read-out
3 arm	M+C	Very high	M+C than L	Very high	High*	Moderate	Moderate	High	Long
	L		M+C than C	High	Moderate	High	Low		
	C		L than C	Moderate/ Low	Low	Moderate	Low		
2 arm	M+C	High	M+C than L	Very high	High*	Moderate	Moderate	Low	Short
	L								
2 arm	M+C	Moderate	M+C than C	Moderate	Moderate	High	Moderate	High	Medium
	C								

* Impacts on potential for success at the HTA level and ability to justify pricing

M: MEN1611; L: Lonsurf; C: Cetuximab;

- **E.g.** Detailed report slide showing the clinical and commercial consequences of alternative trial designs

CASE STUDY:

Impact of investigator-led study on lymphoma asset pricing and market access in Europe

Virtual advisory board

Pharmaceutical company

Hodgkin's Lymphoma (HL)

Denmark, EU4 (France, Germany, Italy, Spain), Turkey

Client situation

Our client was made aware of an investigator-led study in which one of their assets, currently indicated for a variety of haemato-oncological indications, was being tested as part of a new frontline treatment regimen for Hodgkin's Lymphoma (HL). Outcomes were expected to show similar efficacy but improved safety of this new regimen vs the study comparator.

Prior to the study publication, our client wished to understand the impact of the expected label extension for their asset on the product's

- Reimbursement of the product for use in this therapeutic regimen
- Use, expected to increase in countries where the study comparator represents the SoC
- Price, expected to be reduced given the expected increase in the treated patient population

Ipsos solution

Ipsos executed and moderated a 4-hour virtual advisory board meeting to allow discussion of the expected study data, and how the latter would impact the client's asset's pricing, reimbursement and use.

Ipsos recruited 6 external ex-payers, and 3 clinical experts to gauge understanding from a payer and prescriber perspective.

Advisors were split into break out groups to discuss how the data would be viewed in countries where the study comparator was SoC versus those where a different SoC is used

To gather final considerations from advisors and additional insights, Ipsos prepared a post-meeting survey (20 minutes) which enabled sharing of further advice and recommendations

Business impact

Our recommendations were used by the European Market Access Team to determine whether to submit for reimbursement in each country, and the additional evidence needed to support the study data

Our analysis was able to highlight:

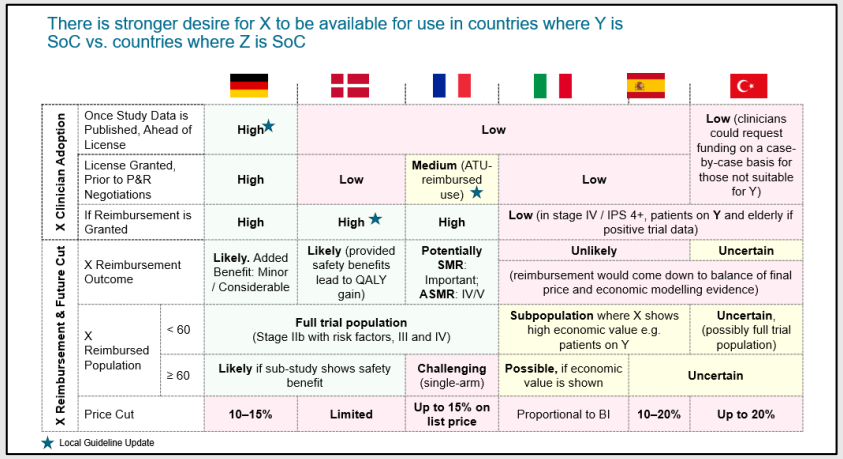
- Unmet needs in frontline HL and likely advantages that their product may offer vs. current SoCs
- The limitations of the investigator-led study and implications these may have on uptake, price and reimbursement across countries
- The likely clinical and economic comparators for each market, considering the various SoCs
- The price potential in relation to the product's current list price

CASE STUDY:

Impact of investigator-led study on lymphoma asset pricing and market access in Europe

- Virtual advisory board
- Pharmaceutical company
- Hodgkin's Lymphoma (HL)
- Denmark, EU4 (France, Germany, Italy, Spain), Turkey

Screenshots from project deliverables:

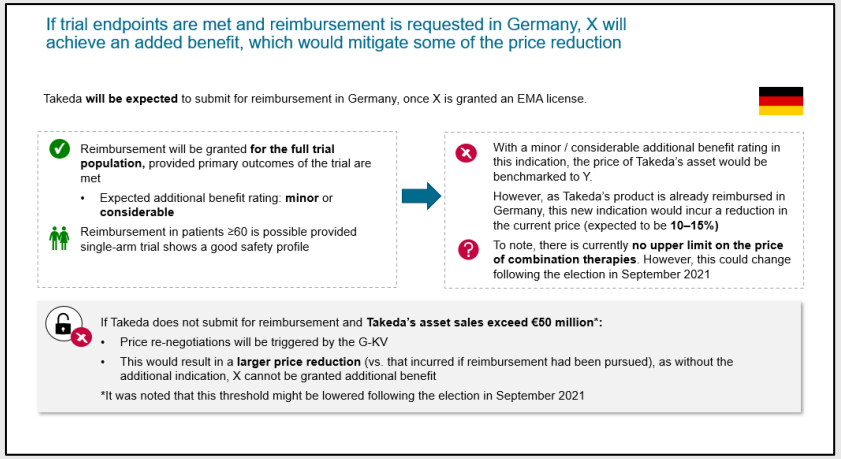


There is stronger desire for X to be available for use in countries where Y is SoC vs. countries where Z is SoC

X Clinician Adoption	Once Study Data is Published, Ahead of License		High★	Low			Low (clinicians could request funding on a case-by-case basis for those not suitable for Y)
	License Granted, Prior to P&R Negotiations		High	Low	Medium (ATU-reimbursed use) ★	Low	
	If Reimbursement is Granted		High	High ★	High	Low (in stage IV / IPS 4+, patients on Y and elderly if positive trial data)	
X Reimbursement & Future Cut	X Reimbursement Outcome		Likely. Added Benefit: Minor / Considerable	Likely (provided safety benefits lead to QALY gain)	Potentially SMR: Important; ASMR: IV/V	Unlikely	Uncertain
						(reimbursement would come down to balance of final price and economic modelling evidence)	
	X Reimbursed Population	< 60	Full trial population (Stage IIb with risk factors, III and IV)			Subpopulation where X shows high economic value e.g. patients on Y	Uncertain, (possibly full trial population)
		≥ 60	Likely if sub-study shows safety benefit		Challenging (single-arm)	Possible, if economic value is shown	Uncertain
	Price Cut		10–15%	Limited	Up to 15% on list price	Proportional to BI	10–20%	Up to 20%

★ Local Guideline Update

E.g. Executive Summary slide displaying how the study publication will affect adoption and pricing of the client's asset



If trial endpoints are met and reimbursement is requested in Germany, X will achieve an added benefit, which would mitigate some of the price reduction

Takeda **will be expected** to submit for reimbursement in Germany, once X is granted an EMA license.

- Reimbursement will be granted **for the full trial population,** provided primary outcomes of the trial are met
  - Expected additional benefit rating: **minor** or **considerable**
- Reimbursement in patients ≥60 is possible provided single-arm trial shows a good safety profile

→

- With a minor / considerable additional benefit rating in this indication, the price of Takeda's asset would be benchmarked to Y.

  However, as Takeda's product is already reimbursed in Germany, this new indication would incur a reduction in the current price (expected to be **10–15%**)
- To note, there is currently **no upper limit on the price of combination therapies**. However, this could change following the election in September 2021

If Takeda does not submit for reimbursement and **Takeda's asset sales exceed €50 million***:

- Price re-negotiations will be triggered by the G-KV
- This would result in a **larger price reduction** (vs. that incurred if reimbursement had been pursued), as without the additional indication, X cannot be granted additional benefit

*It was noted that this threshold might be lowered following the election in September 2021

E.g. Detailed report slide showing a country-specific example of how the study publication will impact pricing and reimbursement of asset

What our clients say:

> Thank you very much for the slides and the survey. They look good to me and they will be helpful for our internal discussions
>
> **Global Patient Value and Access Lead**

CASE STUDY:

Rheumatoid arthritis market access landscape assessment for the introduction of a new treatment in the EEu6

- In-depth interviews
- Type of company
- Rheumatology
- Hungary, Romania, Serbia, Slovenia, Croatia, Bulgaria

Client situation

Our client was looking to launch a new treatment for rheumatoid arthritis (RA) in six Eastern European countries. The research focussed on generating detailed insights on the route to market access in each country and translated that into an optimal launch strategy for the client. The project focused on 2 main goals:

1. To explore the pricing and reimbursement landscape for key products currently available to patients with Rheumatoid Arthritis (RA)

2. To examine local procurement processes (including tendering and contracting) and outline a clear and exhaustive map of stakeholders

Ipsos solution

To address the client's research objectives, the project was divided into two workstreams.

Initially, Ipsos performed desk research to outline a benchmark HTA evaluation and market access process that was then be tested with payers to understand if the processes outlined by national laws are implemented differently in real-world practice.

In total, 11 interviews were completed across six markets: Hungary, Romania, Serbia, Slovenia, Croatia, Bulgaria. Interviews lasted 60 minutes and involved payers at both a national and regional/local level. The inclusion criteria for the sample ensured that the entire process from dossier submission at a national level, to dispensation of the product at a pharmacy/hospital level was captured.

Business impact

Our findings were crucial in offering our client visibility of the market access process and timelines in key Eastern European markets.

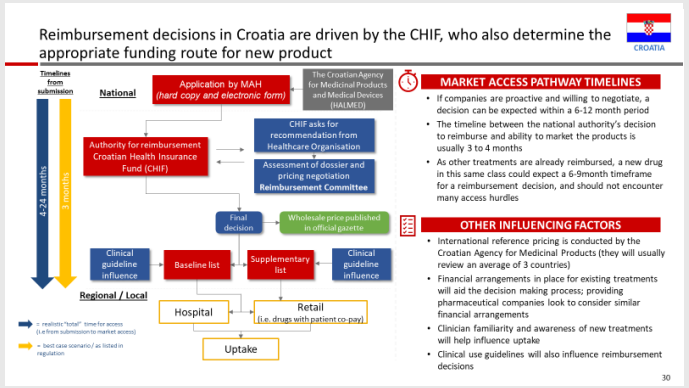
The final report had clear roadmaps and flowcharts that highlighted key stakeholders within the HTA and reimbursement process, flagging their drivers for reimbursement, their importance and their role in the decision-making process. Additionally, the report contained a pragmatic view of each country with reference to their expected timelines for reimbursement and resources for the HTA evaluation.

The output of the work allowed the client to have a comprehensive prioritisation of countries based on fastest time to positive reimbursement, financial resources, scale of market and willingness to approve a new expensive therapy in RA.

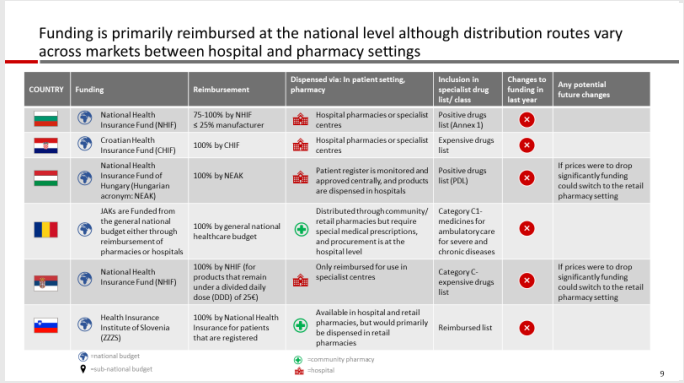
CASE STUDY:

Rheumatoid arthritis market access landscape assessment for the introduction of a new treatment in the EEu6

Blinded Screenshots from project deliverables:



- Example slide related to the HTA / market access pathway in Croatia
- Findings show that despite the fact that "official" reimbursement timelines should be 3 months long, actual reimbursement can take up to 24 months



- Example slide detailing the funding and access routes for RA medications in EEu6
- Whilst funding is primarily at the national level, distribution routes vary across markets between hospital and pharmacy settings

What our clients say:

> Thank you for taking the time to walk us through the report. It is important for us to have such a detailed view of what happens in these markets so that we can align our strategy from a global perspective.
>
> **Head of Health Economics and Market Access**

Case study: Due diligence on paediatric drug development company

1 OUR CLIENT'S NEED

To provide a due diligence assessment of the target company's product portfolio, and identify the areas of risk associated with the development of drugs through paediatric regulations.

IPSOS' SOLUTION 2

Ipsos focused on two of the lead products under consideration. The due diligence assessment drilled into the regulatory pathway, regulatory risk, clinical development and market risk.

3 INSIGHTS/RECOMMENDATIONS

Ipsos assisted an investment company who were considering an opportunity in the field of paediatric drug repositioning/ licensing.

Our client required an independent due diligence assessment in order to make a more informed investment decision.

THE BUSINESS IMPACT 4

Ipsos enabled the client to make a more informed investment decision, and helped determine the level of investment they wished to make in the company.

Case study: Due diligence

1 OUR CLIENT'S NEED

To provide the client with a clear overview, together with detailed insight into the potential investment, highlighting the positive elements of the business and the business model and isolating the risks for further investigation/management.

To conduct a due diligence of a French pharmaceutical company and its current and future product portfolio for an investment client that was looking to make a substantial investment for a period of five to seven years.

"I wanted to thank you very much for all the work you have put into this project, especially given the difficult timing. My senior colleagues were very impressed with the quality of your analysis and unanimously applauded our choice of Ipsos for this project… we would be delighted to work with you again."
– Client project lead

IPSOS' SOLUTION 2

Ipsos performed a systematic review of the company and its commercial capability over the medium term. A number of product areas were investigated through an in-depth primary research. The due diligence assessed the capabilities of the company and its partners to achieve a challenging business plan with its new, recently launched product as well as planned future launches.

Ipsos provided a clear recommendation on the investment opportunity and the challenges the business would benefit from addressing in the short-term.

3 INSIGHTS/RECOMMENDATIONS

THE BUSINESS IMPACT 4

Case study: Driving informed investment decisions for a new treatment

1 OUR CLIENT'S NEED

Before making an in-licensing decision for a new drug targeting primary biliary cirrhosis and non-alcoholic steatohepatitis, our client wanted to assess the commercial opportunity for the treatment.

To assess the size of the target population, the competitive landscape and the target product profile.

To evaluate the willingness to pay for new treatments, potential price opportunity, diagnosis and treatment rates, target treatment population size and likely market share.

To obtain actionable recommendations and a revenue forecast model to inform its decision.

2 IPSOS' SOLUTION

Ipsos carried out desk research to collect information on disease prevalence, diagnosis, treatment guidelines and the pricing and reimbursement landscape in EU5 and USA. We then used this information to develop primary research materials (i.e., pre-reading and discussion guide) and interviewed KOLs, physicians and payers in scope markets. This information was used to inform a forecast model based on realistic assumptions of market performance.

"Thanks for your excellent work to conduct this project successfully.

It is a remarkable achievement given the objectives and the timelines."

– Disease Area Lead, Europe

3 INSIGHTS/RECOMMENDATIONS

Our final forecast model and report covered multiple scenarios for the drug we assessed.

This enabled our client to make an informed investment decision on whether to acquire the asset.

4 THE BUSINESS IMPACT

Contact us for further information and to discuss your needs

Richard Tolley

Managing Director, Market Access Europe

Richard.Tolley@ipsos.com

Andrew Ballantyne

Vice President, Market Access

Andrew.Ballantyne@ipsos.com