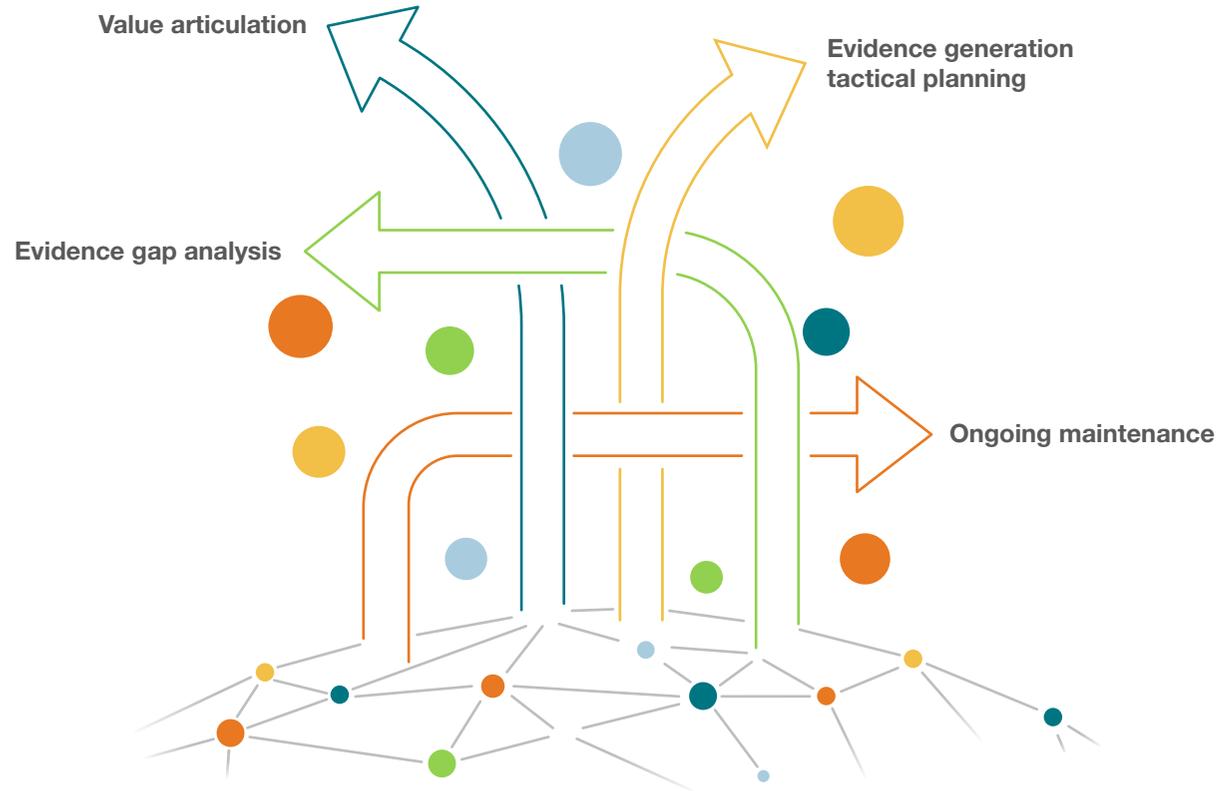




Evidence gap analysis: Four areas of intersection where real-world evidence and market access strategy should come together

- Introduction
- Four areas of intersection
- #1: Value articulation
- #2: Evidence generation tactical planning
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Introduction

Can we bring together **market access** and **HEOR** to support a product across the lifecycle?

Bridging the divide between market access and HEOR teams can make the difference in how well or quickly you move your commercialization plans forward. Or if those plans ever materialize.

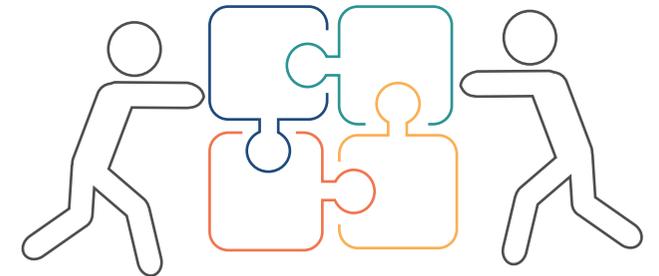
The business objectives of market access and HEOR teams are different, but should be highly complementary, ensuring the success of both groups and an effective commercialization strategy for the product.

On the one hand, market access experts use a variety of tools, research and methods to assess a marketplace to determine readiness for launch of a new product and ensure the product has optimal access for the end users or patients.

For their part, HEOR teams focus on using advanced analytic techniques, large and novel data sources to explore the current state of care within a therapeutic area, and then the comparative effect of the product after launch.

These two areas should interact throughout the product lifecycle with a continuous feedback loop between the two groups on the evolving evidence needs of the product.

This white paper frames the evidence gap analysis story through “four areas of intersection.”





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Yes, we can bring together market access and HEOR...with a little planning and due diligence...as expressed in these four areas of intersection:



1. Value articulation

What is our value story and what evidence will we need to support it?



2. Evidence generation tactical planning

Who is responsible? When is it needed? What workstreams will it support?



3. Evidence gap analysis

Where are we today?



4. Ongoing maintenance

Who will keep the strategy and plan evergreen?



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Intersection #1: Value articulation

Articulation of value will be considered across the development lifecycle

It is important to consider the value of a new technology or drug throughout the development lifecycle. All of the following questions can help articulate value and require a deep understanding of the evidence available (and NOT available) at launch:



Idea

- What is the expected level of effort/risk for gaining reimbursement?
- What are the value/cost drivers associated with the intended primary use(s) of the product?
- What is the level of evidence generation that will need to be put forth to achieve either parity or differentiation?



Pre-launch

- What is the plan (goal, steps and timeline) to optimize reimbursement and access and mitigate risks?
- What are the evidence requirements in order to demonstrate value from a payer/purchaser perspective?



Commercialization

- Are the reimbursement strategy & plan on track?
- How do we articulate the final value story?



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Intersection #2: Evidence generation tactical planning

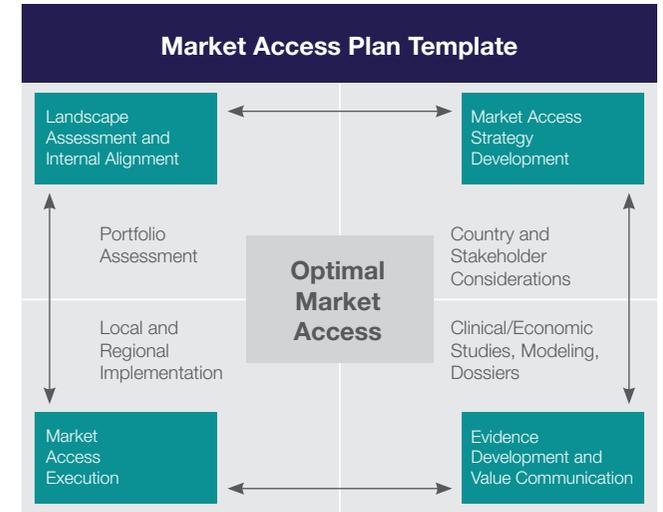
A planning tool can help organize different workstreams and cross-functional teams

A clear plan to optimize market access provides everyone a transparent roadmap for strategy development, planning and execution.

A planning tool can have a detailed base which can be used to:

- customize specific plan elements
- specify the expected start and end dates
- identify team leads for organizational purposes

Activities comprise landscape assessment, HEOR, pricing, access, value propositions, market entry, local engagements and global alignment.





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Intersection #3: Evidence gap analysis

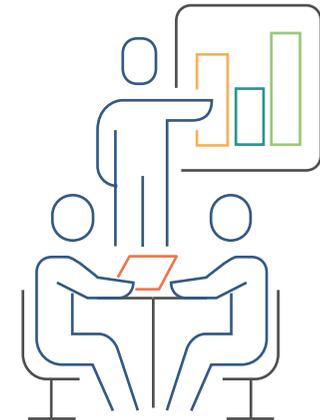
HEOR gap analysis: Evidence to demonstrate value and influence market access

An HEOR gap analysis gathers in one place all the evidence for a new technology or drug and its main competitors. Ideally, this is done prior to launch or soon thereafter.

- First, market access, HEOR and the clinical teams should meet to discuss where the product is likely to succeed and where there are potential threats moving forward. These areas should be further explored, finding key attributes that can be measured in an understandable manner.
- Next, conducting a literature review provides a complete understanding of the available evidence for the new technology or drug, and its main competitors.

- Finally, assessing the gaps in evidence and completing an evidence grid, provide a color-coded, high-level chart where the teams can easily see where the product is clearly winning and where more information may be needed.

Taken together, this evidence gap analysis, along with a plan for future evidence generation, will help support successful commercialization.





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Intersection #3: Evidence gap analysis

HEOR gap analysis: Evidence to demonstrate value and influence market access

Flow:

- Data is extracted, mapped against the evidence grid and evaluated, based on the merit that a payer or decision maker may give it.
- Areas of relative strength and weaknesses should be classified, and quality of existing evidence for reimbursement should be evaluated.
- A detailed grid with summary data and a grid highlighting the gap analysis with heat map should be provided.

| | Comparator 1 | Comparator 2 |
|---------------------------|--------------|--------------|
| Clinical trials | | |
| Efficacy | | |
| Safety | | |
| Patient-reported outcomes | | |
| Real-world evidence | | |
| Efficacy | | |
| Safety | | |
| Patient-reported outcomes | | |
| Healthcare utilization | | |
| Healthcare costs | | |
| Models | | |
| Incremental QALYs or LYG | | |
| ICER | | |



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Intersection #4: Ongoing maintenance

Successful implementation relies on continuous maintenance pre- and post-commercialization

As you continue to pursue new research and achieve new access status, it is important to revisit the plan. The competitive landscape is continually evolving. New strengths and weaknesses should be articulated, placed into the gap analysis and inserted into the next cycle of planning to ensure optimal placement is achieved and maintained.

Ongoing evidence assessment

Identify new evidence that either strengthens or challenges your value story.



Coverage and reimbursement

Monitor payer coverage and reimbursement to identify where additional evidence may improve market access.



Value message effectiveness

Assess whether the value story still resonates with payers/clinicians.

Competitive intelligence

Scrutinize how competitors are responding to your value story, both from message recall and evidence generation.



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Summary



→ Start with the end in sight

- First, think broadly about what value your product brings.
- Next, assess what evidence will support that value (Will your product demonstrate unique value? Is it a “me-too”?).
- Lay out specific steps along product development process, and assign tasks with deadline to cross-functional partners.



Involve all of the cross-functional team

- It is essential to align on the roles and responsibilities early in product development process.
- Planning tool can help to organize steps, timelines and responsible team.



Continually assess the evidence plan

- Your plan will only be successful if it evolves with changes in the competitor landscape, payer perspectives, product development, etc.
- The evidence plan doesn't stop with launch - keep assessing your evidence needs to be responsive to the environment.

Let's start the conversation!

Reach out to your Ipsos account contact or:

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Ipsos' Healthcare Service Line partners with pharmaceutical, biotech and medical device manufacturers to inspire better healthcare. Operating in 50+ markets, our 1,000+ experts support key business decisions for our clients throughout the commercial lifecycle, from early-stage strategy, to launch, to performance optimization. We do this through a uniquely integrated combination of therapeutic and market expertise, gold standard real-world evidence and market-leading custom research approaches – all underpinned by a global footprint and unprecedented access to today's healthcare stakeholders.

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