WHITE PAPER

HEOR, a trusted strategic partner: Rebranding a vital discipline

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Health economics and outcomes research (HEOR) professionals have spent decades applying their skills, experience and expertise to help solve some of healthcare's thorniest challenges—but many still suspect they aren't seen as essential strategic partners to life sciences companies, policymakers and other critical stakeholders. Some even worry that rather than being invited to participate in key discussions, they are cast aside and viewed as technocratic naysayers who block innovation. This is exacerbated by an understandable tendency to retreat into the safe space of technical silos and productized evidence solutions.

To explore how HEOR teams can challenge and evolve how they're perceived, the role they play within the healthcare ecosystem, and how they can continue to increase their impact and deliver more value, ZS convened a panel of 12 thought leaders. They examined the state of HEOR today and how it can become recognized as the indispensable partner it is. Perhaps the most important theme the panelists discussed is how HEOR can showcase its strategic value by becoming more involved earlier in the R&D process. They agreed HEOR has the tools and expertise to help R&D teams make better pipeline and investment decisions, which will help address longstanding affordability challenges in healthcare.

The state of HEOR today

While each expert brought a unique perspective to the conversation, they agreed that for HEOR to be viewed as an essential strategic partner rather than as a support function, it must confront today's challenges with greater flexibility and a broad skillset. According to the panel, the most pressing problems HEOR should tackle relate to equitable pricing, emerging markets, demographic changes and health system capacity. It must also build stronger relationships with both internal and external stakeholders such as clinical development teams, payers and governments. Developing solutions for these complex, ecosystem-related issues will allow HEOR to help patients all over the world. Panelists specifically discussed:

Improving payer relationships: A number of enduring issues have created an arms-length relationship between pharma and payers that stifles collaboration and causes R&D to focus on areas that aren't priorities for healthcare systems. Not surprisingly, innovation can be difficult in this environment.

Governments and payers face pressures that should lead to more strategic partnerships with life sciences as these stakeholders start taking a more holistic view of disease in an effort to jointly manage care pathways as efficiently as possible. This shift will result in larger roles for some pharma companies, bigger access challenges for others and eventual industry consolidation.

Focusing on strategic partnerships while taking a holistic view of disease could also affect the value assessments led by HEOR. Potential positive developments include:

- Transitioning away from single technology appraisals (STAs) to assessments that consider whole pathways
- Deeper dialogues between payers and the industry, rather than the transactional submission of dossiers, as both parties aim to maximize the value of products and services they provide
- More integrated processes between regulation and reimbursement. For example, better aligning the evidence required by various agencies and the timeframes in which it must be submitted could improve the quality of evidence. This would be helpful for value assessments and could streamline demands on pharma while reducing overall R&D costs.

It will be vital for HEOR leaders to reimagine value assessment processes and the relationships between payers and pharma as it plays its role in helping build a sustainable life sciences sector.

Healthcare capacity planning: Economic pressures are far from the only challenges healthcare systems face. In developing countries, physician density and other measures of capacity are growing more slowly than the aging population, leading to a rapid demand increase. And in low income and lower-middle income countries, the World Health Organization estimates a projected shortfall of 10 million healthcare workers by 2030, mostly due to underinvestment.

Addressing this shortfall will require a more coordinated, system-level approach to healthcare planning. For example:

- Governments, payers and providers will need to give clearer signals to the industry on what products they value and want to see developed. They could financially incentivize the development of products that are less workforce intensive, for instance.
- Life sciences companies will need to respond to these signals while potentially creating more sophisticated measures of value than traditional cost effectiveness.
- HEOR teams will need to work with governments to develop new approaches and endpoints that explicitly consider the impact of workforce efficiency as part of the value assessment framework.

Pricing: Affordability and willingness to pay are major challenges across the globe, and these factors are changing incentives for conducting R&D. In Western markets, healthcare innovation is increasingly viewed as unaffordable, with efforts to reduce costs leading to legislation such as the U.S. Inflation Reduction Act of 2022 (IRA), which authorizes the Department of Health and Human Services to negotiate drug prices under Medicare. Meanwhile, countries such as Germany are increasing mandatory discounts while Canada's Patented Medicine Prices Review Board has updated its approach to excessive pricing.

These policies risk setting the wrong incentives for the industry and could significantly reduce or redirect R&D investment. For example, in the U.S., a significant percentage of health plan spending is allocated for specialty medicines for a relatively small percentage of patients. The IRA could exacerbate this gulf by providing exceptions for biologics and rare disease treatments, while introducing negotiations for products primarily used to treat older people and those with chronic conditions. At the same time, the IRA threatens innovation in the rare disease space by introducing measures that limit commercial potential through focusing negotiations on the first approved indication. It's also unclear how value will be recognized within the IRA process.

> **"The Inflation Reduction Act might be setting the wrong incentives if society's biggest challenges are aging populations living with chronic diseases."**
>
> – Panelist

New price controls will create additional demands on HEOR teams to support reimbursement processes and demonstrate the value of in-line and pipeline assets.

It will be even more important to ensure R&D decision-making improves so that price pressures don't lead to less innovation. The panel emphasized that by employing their expertise and modeling tools earlier in the R&D decision-making process, HEOR can help lower the cost of drug development by quantifying uncertainty, reducing risk and driving better and earlier decisions around evidence development.

Emerging markets: With so many challenges in traditional markets, life sciences companies are hopeful that purchasing power and willingness to pay are increasing in emerging markets such as India and China. While markets like these could help offset tightening budgets in Western countries, emerging markets with large populations present their own challenges. The overall gross domestic product (GDP) of China and India is sizable, but per capita GDP is smaller than in Europe or the U.S.—meaning the same levels of pricing aren't feasible. What's more, healthcare systems and infrastructure vary greatly across markets. India, for example, has a high level of self-pay funding.

Emerging markets are adopting the value-assessment practices—often called health technology assessments, or HTAs, in Europe—of advanced countries. HTAs will challenge HEOR teams in these markets to follow sophisticated processes with limited resources. Their success is critical, as fairly and systematically tiered pricing among global markets, along with equitable access and financing within countries, will be key to improving global health equity and making R&D investments sustainable. With their blend of technical and commercial skills, HEOR teams are positioned to support the development of global policy around pricing.

How to ensure HEOR is seen as a strategic partner

As HEOR engages with policymakers amid systemic market challenges, HEOR teams will need to become more strategic and work to align global incentives to develop and shape better R&D investments, panelists said. HEOR has had a significant policy impact over the years, having helped establish HTA principles and critical processes. As the latter have become more commoditized, academics focused on publishing work in established journals. Meanwhile, other HEOR professionals often function reactively by responding to evidence requirements.

The tools available to HEOR professionals are more relevant than ever for broad policy setting, which requires difficult decisions on value, equity and investment priorities to be made in a credible, evidence-based manner. HEOR should:

- Work with governments and payers to design system incentives that lead to prudent and needed R&D investments.
- Use its tools to improve the early-stage value assessment process and determine which evidence is needed to support value claims.
- Establish methodologies for fair, tiered pricing between countries to improve access and overall funding of innovation.
- Develop strategic value frameworks and health economic models that help policymakers simulate the results of different choices across pathways and populations.
- Engage in welfare and development economics challenges beyond health. These could include supporting investment decisions involving social drivers of health, such as housing.

"HEOR will need to become more strategic in the face of systemic market challenges and realigned global incentives."

– Panelist

Helping pharma improve decision-making across the product life cycle

Few industries invest more in R&D than pharma, but despite huge outlays, life sciences companies often wait until late in the development cycle to understand the true value of their products. Similar issues occur when external assets and companies are acquired before their potential value and related risk are fully understood.

This failure to properly assess products and assets can reduce returns and dampen incentives to continue investing in R&D, while at the same time inflating the costs of successful products. HEOR professionals can help pharma assess and make better decisions. HEOR also can use established models to quantify risk and determine the value of additional research that could help companies create properly sized trials and improve trial design. It's easier for pharma companies to decide which potential products are worthy of continued investment when they have evidence-based input from HEOR teams. For HEOR teams to maximize their impact, however, leaders across life sciences must realign the incentives they offer and welcome HEOR professionals as strategic advisors. HEOR professionals must bring high-value insights, analytics and evidence to these discussions.

How HEOR can harness technology to become a strategic partner

For HEOR teams to become strategic advisors to the C-suite, they must deftly navigate an increasingly technical landscape. HEOR professionals should adopt advanced system-modeling techniques from other fields, such as engineering and physics. It will be critical for HEOR teams to have advanced statistical, AI and machine learning (ML) knowledge so that they can understand complex relationships among broader arrays of variables.

At the same time, technology will provide the opportunity for HEOR teams to do today's work better and faster. AI and ML techniques are already being deployed to assist in evidence synthesis tasks such as conducting literature reviews. And analysis and report writing may soon be automated by natural language AI models, while the new activities of HEOR teams will also need to leverage these technologies from the outset. These advancements will free up HEOR leaders and teams to focus on their role as strategic advisors and trusted partners.

To excel as an advisor and partner, HEOR professionals will need to become:

- More flexible to the increasingly heterogenous questions at hand
- More comfortable challenging the questions being asked, to ensure they're the right ones
- Closer to customers to ensure they gain access to important insights that are necessary to align needs, plans and expectations
- Adept at dealing with uncertainty
- More connected to people and ideas outside of HEOR

With all of that said, HEOR can, and should, retain the fundamental characteristics that have served it well, including transparency, academic credibility and a methodological approach to analysis.

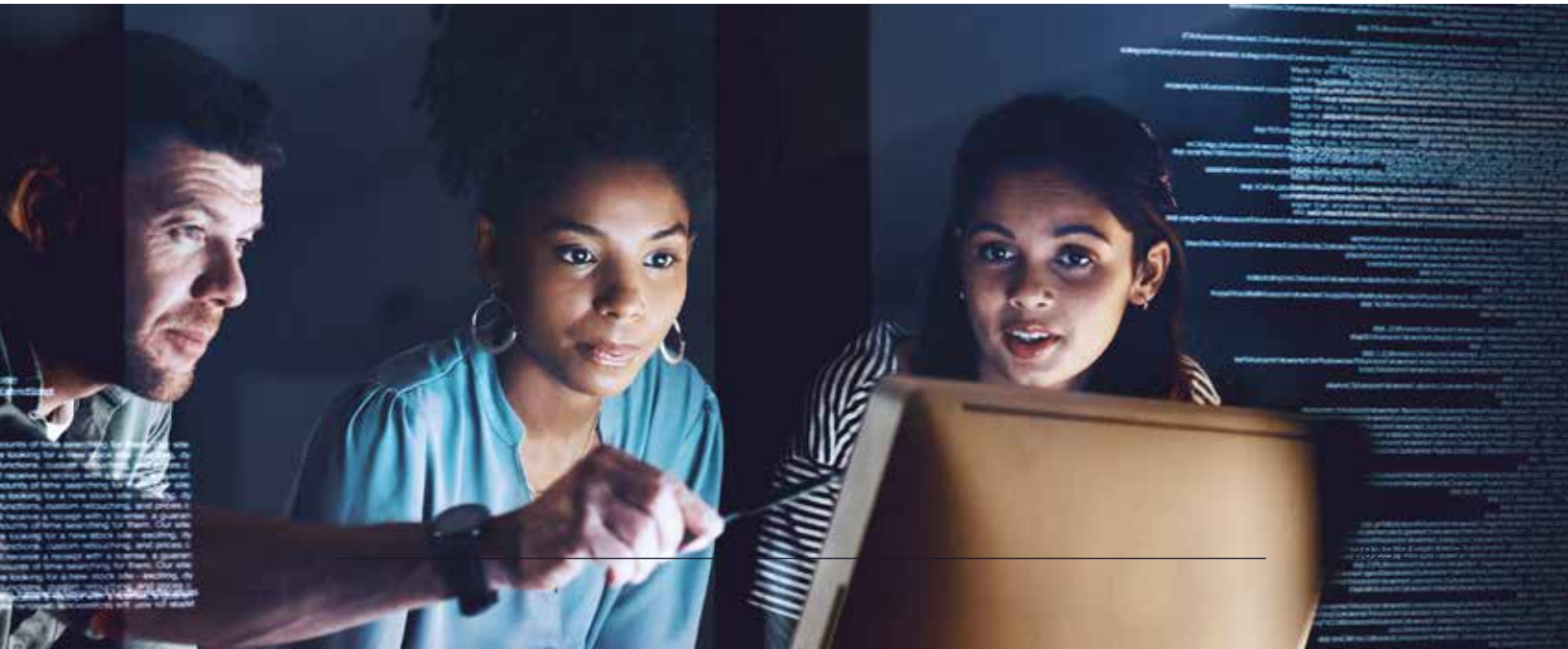
Why HEOR should help produce flexible disease models and value frameworks

Developing and using disease models and value frameworks is critical for HEOR teams, but they will need to change to adjust for a new environment. We're seeing this in Germany with its disease management program for diabetes. More complex disease models that include a wide variety of pharmaceutical and non-pharmaceutical treatments, as well as diagnostics tools and digital interventions, will require a shift away from evaluating a single technology or therapy in isolation.

New disease models will need to enable payers and policymakers to design end-to-end care systems. While building a disease model from scratch for every decision required is unfeasible, new paradigms around the use of open source or payer-owned models can be helpful. These new disease models should be underpinned by a data and evidence ecosystem that allows the models to examine the entire landscape, including relevant disease states, endpoints and products.

Along with new disease models, broader value frameworks are needed. Stakeholders will increasingly weigh investments in healthcare against other potential investments in social utility, making it necessary to capture and compare a therapy's total impact. For example, if a therapy is developed for children with muscular dystrophy, broader value frameworks can analyze the economic impact of a parent working instead of caregiving. This analysis is in addition to the benefits the therapy could have for the child. Broader value frameworks could even look at resources saved by families and public services if a child is able to attend a traditional school rather than a school that offers special services.

Building the ideal framework may seem daunting, but the panelists agreed it's unnecessary to develop new value frameworks. Instead of endlessly searching for the perfect framework, they discussed the importance of more broadly using existing frameworks.



Looking ahead: Challenges as HEOR evolves

The next decade will offer HEOR teams the opportunity to make progress on issues such as entrenched value assessment processes, disparate regulations across countries and misperceptions around the HEOR brand. On the upside, these challenges present HEOR professionals with the chance to make our case as an indispensable strategic partner.

Entrenched value assessment processes: Much of the HEOR community is committed to national-level STAs, as highlighted by Europe's EUNetHTA joint clinical assessment process that continues to offer member states a role in setting the range of evaluation questions. While important, rigid processes can be a drag on development and innovation. unwillingness by regulatory and reimbursement bodies to accept new tools and techniques—such as the use of AI and ML in evidence synthesis and outcomes research—will negatively affect investments in them. It's important for HEOR professionals to advocate and consider how it can influence its environment to open doors for innovation. We must do our part to ensure the value assessment process becomes more flexible.

Differing regulations: Variation in the structure of national health systems and differences in national government policy could lead to fragmentation in how the HEOR discipline develops. Bodies representing HEOR should communicate a compelling vision of what HEOR can be and the role it can play to national, regional and local stakeholders.

The HEOR brand: In some quarters, HEOR is perceived as a commoditized, technocratic function—and this could serve as a barrier to the profession's goal of being a true strategic partner to the C-suite. Too many stakeholders don't fully understand the skills HEOR practitioners bring to the table. For example, some in R&D view HEOR as mainly a commercial function. Even the name "HEOR" could have limited relevance to a broader set of payer and policy stakeholders outside life sciences.

While not all HEOR professionals may be comfortable with the idea of rebranding and marketing the discipline, the good news is a full-scale marketing campaign isn't what's needed. Instead, HEOR teams should focus on demonstrating how HEOR tools and techniques can solve some of healthcare's biggest challenges, while continuing to evolve their capabilities and their understanding of the broader ecosystem. We can rebrand ourselves by becoming better known for the problems we solve rather than the methods we use.

> **"In the future, HTA bodies will need to adopt a more strategic approach to evaluation, thinking holistically about disease and pathways."**
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> – Panelist

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