

Health Economics and Outcomes Research (HEOR)

What is it?

It is clinical and health economic research that focuses on net health outcome endpoints for one intervention compared to an alternative intervention. Traditionally the study design includes economic endpoints, but sometimes HEOR studies are designed to just capture patient outcome components of an intervention. HEOR is not simply a study to determine a product's efficacy or safety but rather the impact on net health outcomes (effectiveness) such as morbidity and mortality, and at what cost compared to alternative interventions.

Why do it?

HEOR information helps healthcare decision makers understand the impact of a medical intervention on a patient's overall health. Healthcare decisions makers are increasingly relying on HEOR to fully understand a products value and its potential impact in real-world clinical practice. HEOR answers health authority questions about a product's value such as; What is the economic burden of a disease within the healthcare system?; Does the new intervention merit funding?; What are the economic implications of its use?; How do the incremental costs compare with the anticipated benefits for specific patient groups?; Is the intervention used appropriately versus available alternatives?; What happens to patients in the long-run with the intervention versus alternatives?

When should it be done?

HEOR can benefit brand strategy from preclinical through the post launch phase of a product's life cycle. The decision to engage into HEOR depends on the product and its healthcare market environment. However, due to existing pay for performance reimbursement models found within the private payer market, and now with Medicare embracing pay for performance models, HEOR is gaining steam in the United States. Therefore, many manufacturers are incorporating HEOR at the proof of concept stage in order to demonstrate the product's value to gain coverage, and adequate reimbursement.

Evolution of HEOR

HEOR has been conducted by single-payer systems such as the United Kingdom for many years. However, HEOR is evolving from academics to address more practical business needs for new payers in the United States, ones without health economics expertise. Therefore, HEOR findings must be communicated in a concrete, business-oriented fashion to reach multiple audiences with differing perspectives.

“The comparative effectiveness research (CER) movement burst on the scene in the US with the passage of the American Recovery & Reinvestment Act of 2009, which allocated \$1.1 billion in funding to this type of research. This legislation initiated a great

deal of activity on the part of researchers, policymakers, health insurers, life science companies, and other stakeholders interested in providing definition to CER and influencing the trajectory of the movement.” – April 2012 ISPOR Connections, pg. 11

The recent public funding initiatives along with the practical motivation of payers/buyers have given rise to more “real world” focused HEOR in the United States.

Systematic Value-Development Plan

To help in the evolution from academics to business, there should be a systematic development and implementation process for value-demonstration. This is a strategic exercise to determine the value of a product, then proving that value through appropriate research and communicating the documented value in a way that resonates with internal and external audiences.

Essentially, the value-development plan is a strategy document that includes a clear set of evidence-based recommendations, on how the product’s value will be determined, demonstrated, communicated and realized in the market.

Steps to develop HEOR plan

1. Conduct an environmental assessment; this entails reviewing the marketing plan, latest market research on the product, market projections, competitor profiles, etc.
2. Gather input from key internal staff on their expectations for the product and its perceived value, the challenges they foresee and their expectations of HEOR
3. Interview key external stakeholders e.g., payers, hospitals, employers, patients, and physicians, on their needs, expectations and perceptions of treatment in the disease area.
4. Based on this research, benchmark the product against the alternatives, identify elements in the clinical profile that may be perceived to add value and articulate the target value proposition.
5. Craft a value strategy and accompanying tactics. The strategy should specify all the ways that value demonstration could support the marketing strategy to articulate the product’s value proposition and message. It should identify the HEOR studies needed in order to develop supporting documentation for each of those messages, by audience. The result is a working document endorsed by the full brand/product team specifying exactly what the HEOR is to deliver.