Building Effective Health Economic Outcomes Research (HEOR) Teams
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Published April 2016
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Research Objectives and Methodology

Health economics and outcomes research (HEOR) is a discipline that is used to complement traditional clinical development information to guide decision-makers regarding patient access to specific drugs and services.¹ HEOR is seen as part of the wider market access discipline (see Figure 1, page 4), where market access integrates pricing and reimbursement, policy/corporate affairs and patient advocacy alongside HEOR.² This report looks at companies’ HEOR teams in light of increasing demands from payers that manufacturers demonstrate the value of their products. Key questions explored in this report include:

- What is the strategic importance of HEOR?
- How do HEOR teams help to achieve market access?
- At what stage of a product’s development does the HEOR team become involved?
- How are companies organising HEOR teams?
- What training and support is available to HEOR teams?
- How are HEOR teams’ performances managed and incentivised?


Investing in HEOR

Over time companies have been developing and integrating market access into their global, regional and country strategies. Companies have been increasing resources for HEOR, with the majority of firms in the US anticipating increased budgets in the future. A Vice President, Market Access, Health Policy and Medical Affairs within a top 10 vaccine manufacturer notes that “we’ve increased the budget for HEOR, we’ve had to invest more.” Senior HEOR Manager notes that, “the budget allocated [to HEOR] projects has increased over the last three years, and increased quite dramatically.” He goes on to say that, “If budget is needed, for something considered to be important, it will be found from somewhere [even if this means] a cut from somewhere [else].”

A Director of Medical Policy-Access Research and Pricing at a top 10 global pharmaceutical manufacturer suggests that in the company where she works the strategic importance of HEOR is recognised. She says, “the function is critical and well recognised [within the company].” HEOR she says, “has seen an increase in budget over the last five to eight years.” That, in part, reflects externally driven factors such as a fee for Pharmaceutical Benefit Advisory Committee (PBAC) submissions. Despite the increasing budget, she says that “it’s still very tight”, so the focus is on making a commercial case for HEOR spend, particularly for additional studies.

Development of dedicated HEOR teams

By 2015, up to half of all global pharmaceutical companies had developed dedicated groups for HEOR (see Box 1 for an example). As a Senior Vice President, Global Regulation, Healthcare Policy and Corporate Affairs within a top 50 global pharmaceutical manufacturer explains “we centrally provide input and core development [of HEOR activities]”, which includes “building the core value dossier and building the necessary activities around it”.

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Early involvement of HEOR

Although involvement differs in practice, some companies will include HEOR to provide insights on very early trial design (Phase I). Others will discuss HEOR requirements at Phase II. A Senior Vice President, Global Regulation, Healthcare Policy and Corporate Affairs within a top 50 global pharmaceutical company suggests that, “HEOR needs to be involved particularly at Phase II.” This helps companies make the most of opportunities for engagement with key agencies, both regulators and HTA agencies, because, “we’re going for European Medicines Agency and health technology assessment scientific advice now.” The logic follows that if a company seeks input early from the regulator and the HTA agencies, HEOR staff need to be involved alongside those responsible for the clinical development plan.

A Senior Director, Global Outcomes & Epidemiology reinforces the importance of early involvement. He says, “We definitely want to get involved early, definitely at Phase III, but I prefer [to get involved] at Phase II.” He goes on to note that, “Any time that there is a target product plan, the reality is, that is a commercial document. It’s a statement of what the company would like the product to be able to do. Clinical trials will provide much of the evidence to support it, but there are always gaps, and outcomes research helps identify the gaps, and the research needed to fill those gaps.”

“Phase III discussion with HEOR on additional endpoints, particularly patient-reported outcomes, was the peak [for HEOR involvement throughout the product life cycle] a couple of years ago,” according to a Senior Vice President, Global Regulation, Healthcare Policy and Corporate Affairs within a top 50 pharmaceutical firm. He noted “That is changing, as we move away from the traditional model into the new model of exploratory trials.” Now he says, “[HEOR] needs to be involved right from the beginning [of clinical study development].”

A Director of Medical Policy-Access Research and Pricing describes the approach to planning HEOR team involvement early in the life cycle. She says, “We have a yearly priority process [for HEOR team input].” Such a horizon scanning and planning process enables the HEOR team to “understand from Phase IIa or b
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