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# Got value? Determine it. Demonstrate it. Communicate it. Realise it

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Received (in revised form): 10th March, 2008

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## **Abstract**

Many healthcare systems are in crisis due to rising costs, rising demand and inadequate funding. Consequently, healthcare decision makers are increasingly demanding that costs for new health technologies be justified with scientifically rigorous evidence. This is particularly true for biotechnology products, which tend to be more expensive, require more handling and have more uses/indications beyond that which is experienced for traditional pharmaceutical products. Given today's demands for demonstrating value in medicine, health economics and outcomes research (HEOR) techniques are now in focus, and increasingly linked to brand strategy. To facilitate this process, a Value Development Plan

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(VDP)<sup>TM</sup> is warranted; a process by which to identify, demonstrate, communicate and realise the value of a product; similar and running parallel to a clinical development plan. There are four key steps in building a VDP. Briefly, these include the following:

1. *Value determination* – benchmarks available alternatives in a therapy area based on clinical/economic value.
2. *Value demonstration* – identifies tactical outcomes research and economic model projects to demonstrate the clinical and economic elements, respectively, of the target value proposition.
3. *Value communication* – helps to inform and define the value communication strategy and tactics for relevant audiences.
4. *Value realisation* – defines price ranges for products based on demonstrated value and addresses reimbursement and seamless market access.

*Journal of Commercial Biotechnology* (2008) **14**, 299–306. doi:10.1057/jcb.2008.7;  
published online 15 April 2008

**Keywords:** *value development, market access, health economics, technology assessment, outcomes research*

## INTRODUCTION

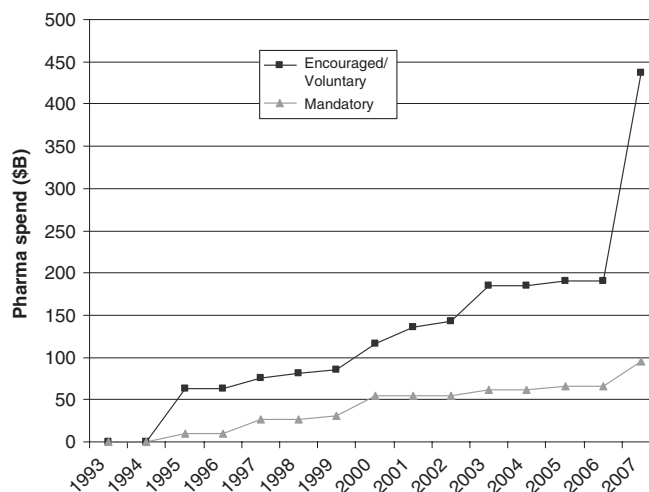
A Kaiser Family Foundation Survey<sup>1</sup> published in 2005 showed that more than one in four Americans are faltering under the burden of healthcare costs. Just six months later, in a February 2006 article entitled ‘A Cancer Drug Shows Promise, at a Price That Many Can’t Pay’, *The New York Times* published the monthly costs of some of the new biologics that treat cancer which were as high as \$9,600 per month.<sup>2</sup> While patients rarely pay anywhere close to that amount for their treatment, the concern about the costs of biologics has been growing. Payers are likewise focused on this issue, even though pharmaceutical budgets continue to represent a small per cent of the total healthcare budget. In reference to the cost of one of the new oncology agents, a payer was quoted as asking, ‘Are we going to bankrupt ourselves buying this oncology drug so we won’t be around to treat other people?’<sup>3</sup> This concern is being fuelled by the growth of biotechnology products, especially in oncology.

Given today’s demands for demonstrated value in medicine, health economics and outcomes research, or HEOR, professionals and brand strategists are joining in an unlikely

pairing. This surprising marriage comes at a time when the pharmaceutical, biotechnology, diagnostics and device marketplaces are growing increasingly competitive and complicated. With payers working harder than ever to minimise the budget impact of new medical technologies, the industry’s need for comprehensive and coordinated market access strategies has never been greater.

To achieve unfettered access to today’s healthcare systems requires that medical technologies and products possess documented and sustainable value – it is this commercialisation value of technology which is the culmination of market, economic and financial value, where market and economic value encompass the inherent social value of the medical technology.

Demonstrations of product value may take shape in many dimensions or facets, including safety, tolerability, clinical efficacy and effectiveness under actual conditions of use; price relative to alternative therapeutic options and approaches; relative cost-effectiveness; patient reported quality of life, activities of daily living and functionality; patient compliance; physician, patient and payer perceptions and acceptance; and finally reimbursement.



**Figure 1:** Economic evaluation on the rise.<sup>4</sup> Economic evaluation now affects more than \$400bn of annual global pharmaceutical sales, requiring an ‘evidence-based’ approach to demonstrate value

## THE CHANGING HEALTHCARE ENVIRONMENT

There are at least five substantial changes occurring in the healthcare environment that are resulting in an expanded focus on the issue of value. These include:

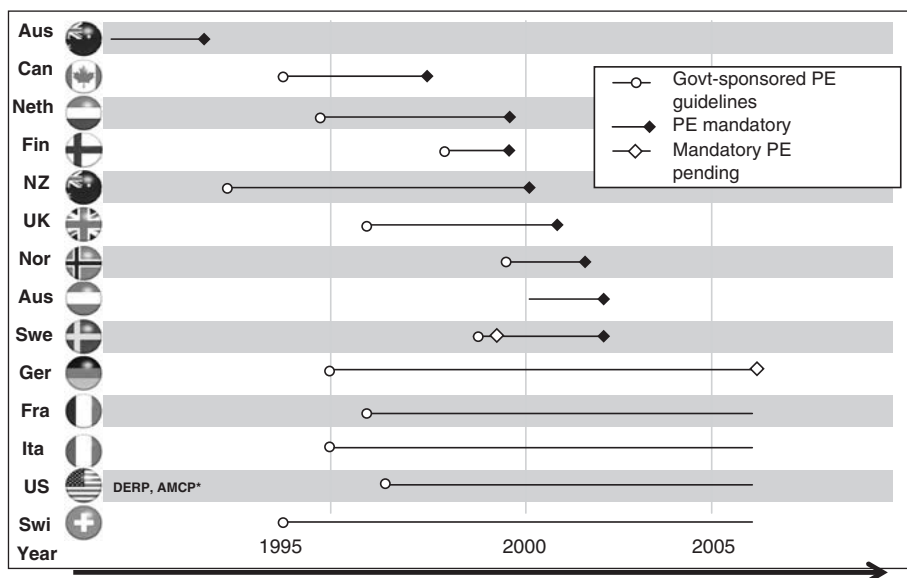
1. *Pharmaceutical costs* – The perception of escalating drug costs in the United States, along with the reality of more high priced drugs, especially in oncology, is leading a call to action by payers and employers. While the long-term health outcomes are still unclear, these parties are exploring various options.
2. *CMS entry into the value debate* – With the introduction of the Medicare Part D drug benefit, the Centers for Medicare and Medicaid Services (CMS) now has the ability to become an active participant in the ‘value for money’ dialogue. Private organisations are hoping that CMS will take the lead, as this may reduce threats of litigation from implementing limits on coverage, especially for drugs that have the potential to be life saving.
3. *European actions* – Europe is decentralising budget responsibility, which expands the audiences for value. In addition, European

payers are participating in innovative contracting relationships that impact product value.

4. *BRIC countries and HTA* – New countries, such as Brazil, Russia, India and China (the BRIC countries), are emerging as potential key markets and will be confronting Health Technology Assessment (HTA) – where the value proposition (the value for money) of new healthcare technologies is evaluated – as they develop their healthcare infrastructures.
5. *HEOR’s expanded role* – HEOR groups, like all others within the pharmaceutical and biotechnology industry, are now required to justify their budgets, as well as their very existence. These groups are increasingly successful in providing brand teams with well-documented demonstrations of value that support the commercial plan and communicate value in ways that are understandable and useable for decision-making.

## NEED FOR ARTICULATING VALUE

Value is informed by the market. Medicine is global, but reimbursement is local and market responsiveness ultimately dictates perceptions



**Figure 2:** PE in formulary and reimbursement decision-making (1990–present). \*Key entities in the US discussion – Academy of Managed Care Pharmacy (AMCP); Drug Effectiveness Review Project (DERP)

of value. HTA is more relevant than ever, as Figure 1 indicates.

Nearly \$400bn of global pharmaceutical sales are subject to these evaluations of product value. A new therapy must either increase a definable and valuable clinical (including quality of life) outcome at an acceptable increase in total costs, or decrease other costs associated with the illness, commonly called ‘cost offset’. The practice of health economics, or the more modern designation of HEOR, evaluates the costs associated with health technologies, while outcomes research assesses outcomes from the perspective of key audiences.

HTA and Pharmacoeconomic Evaluation (PE) may just be picking up speed in the United States, but its activity in Europe has been more pronounced over the last decade, as illustrated in Figure 2.

### AN EXPANDING ROLE FOR HEOR EXPERTS

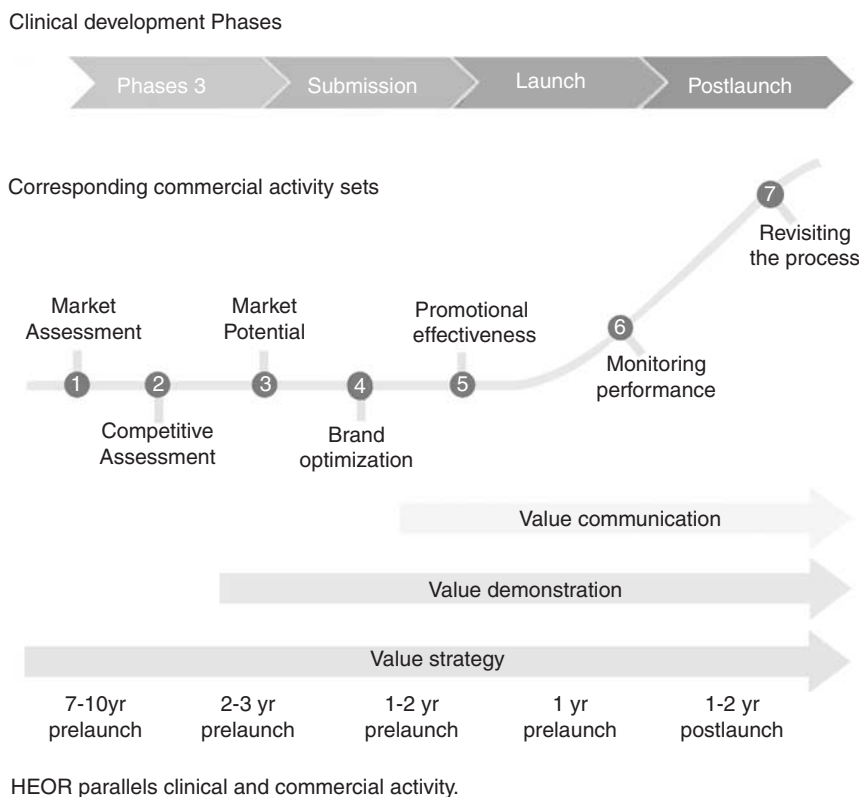
For the past 20 years, health economists’ and outcomes researchers’ contributions have been

seen as commercially irrelevant. In this era of pricing pressures and market access barriers, however, pharmaceutical and biotechnology companies have come to appreciate the importance of demonstrating and articulating the value of their products. The time has come to transform HEOR studies from academic exercises into key components of the commercialisation strategy.

The first part of this transformation is to become process-oriented: HEOR professionals are increasingly becoming involved in commercial development planning – beginning with product proof of concept (see Figure 3).

Second is skills-oriented: HEOR professionals have been learning to communicate their findings in concrete, business-oriented terms and to expand their messages to multiple audiences.

As the importance of demonstrating value becomes paramount, HEOR professionals will take an ever-larger role in aiding sales and marketing personnel in reaching individuals who make value-based decisions about products. Most major pharmaceutical companies have set



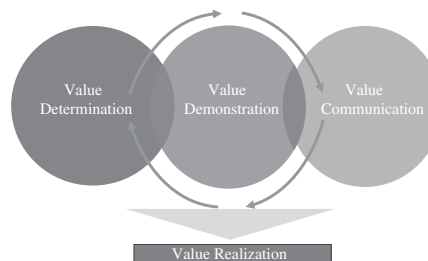
**Figure 3:** HEOR parallels clinical and commercial activity

up specialised sales forces to reach these decision makers and influencers, and health economists are generally required to support these sales forces through the development of value messages and sales material.

Ultimately, for their products’ value to be realised, companies must systematically work through a value development planning process – a strategic exercise of first deciding what the potential value proposition is, proving it through appropriate research and then communicating the documented value in a way that resonates with both internal and external audiences.

### VALUE DEVELOPMENT PLANNING

Value development planning specifies the potential elements of a product’s value proposition with tactical recommendations to



**Figure 4:** Value development plan in motion

build evidence and communicate effectively with all healthcare stakeholders. The strategies are evidence-based, drawn from a rigorous and refined process that includes value strategy summits with key internal stakeholders and in-depth research with payers, prescribers and peer-reviewed literature and critically rests upon the research experience and expertise of HEOR professionals.

## The Value Development Plan

This process is referred to as the ‘Value Development Plan (VDP)<sup>TM</sup>’, which parallels the clinical development plan and is often coupled with a medical communications plan. This strategy document defines the core value proposition for a product, which can then be adapted for all regions and countries globally. The VDP includes tactical recommendations for building evidence and communicating effectively with stakeholders (see Figure 4).

To be useful, a VDP must be comprehensive, clear and well supported with evidence. The underlying argument must be logical and compelling, as its purpose is to persuade. The objective of a VDP is to provide all members of a brand team with a clear, evidence-based set of tactics for determining, demonstrating, communicating and realising product value to support the brand team’s global marketing strategy. The result of a VDP is a working document that is endorsed by the full brand/product team and that specifies exactly what HEOR is to deliver.

The development of a VDP requires maintaining a fair balance between product advocacy to stakeholders and an accurate representation of the science supporting the

product. Part of the process in developing these strategies is to identify and link available supporting evidence to each element of the VDP and detect information gaps that should be filled through additional studies. This is a way to ‘take stock’ of where a product lies on the value continuum and access the potential ROI of designing new studies or projects to further determine and demonstrate the product’s value. The VDP is a living document, guiding decision makers on choosing which additional studies to fund and serving as a repository for new information as it becomes available.

As Table 1 demonstrates, each stage of the VDP has a specific set of objectives, all of which were addressed in the monoclonal antibody value development case study described below.

### Case study 1: Monoclonal antibody value development exercise

IMS created a VDP for one of the world’s leading biotechnology company’s monoclonal antibody in early stage development for treatment of lymphoma. The purpose was to identify sources of value for the product in the United States and European Union for

**Table 1:** Objectives for a VDP

<p><i>Value determination:</i></p> <ol style="list-style-type: none"> <li>1. Benchmark the available alternatives in the relevant therapy areas in terms of their clinical, economic value and patient-reported value</li> <li>2. Identify elements of the clinical profile that may be perceived to add value by stakeholders in the marketplace</li> <li>3. Articulate the ‘target value proposition’ based on available data and stakeholder views</li> </ol>
<p><i>Value demonstration:</i></p> <ol style="list-style-type: none"> <li>1. Recommend tactical outcomes research projects to demonstrate the clinical and humanistic elements of the target value proposition</li> <li>2. Recommend tactical economic models to demonstrate the economic elements of the target value proposition</li> </ol>
<p><i>Value communication:</i></p> <ol style="list-style-type: none"> <li>1. Define the value communications plan</li> <li>2. Outline the strategy for each relevant audience, including target clinical and other professional conferences, detail pieces, health promotion and other forms of value communications focused on using value to overcome potential barriers to access</li> </ol>
<p><i>Value realisation:</i></p> <ol style="list-style-type: none"> <li>1. Identify the net cost range that can be supported by demonstrations of value or willingness to pay (if it is a new product)</li> <li>2. Identify methods for overcoming actual barriers in the market due to cost (if it is an already-launched product)</li> </ol>

different stakeholders, including payers, physicians and government regulatory bodies. Chief among the ultimate outputs from the VDP were the following.

A global environmental analysis was conducted to gain a firm understanding of the published literature in this particular lymphoma sub-area. This involved an extensive literature review, as well as a series of interviews with US-based managed care payers, US and EU haematologist-oncologists, and EU reimbursement experts. This resulted in a solid understanding of the reimbursement hurdles in each environment and initial responses to the product profile and how it might be used clinically.

The global environmental analysis was followed by the development of a cost-effectiveness model which helped to demonstrate the product's economic value, which was then used both for internal pricing and market segmented forecasting and scenario testing as well as becoming the foundation for scientific demonstrations of the product's value specifically to payer audiences in either reimbursement evaluation situations (HTA in the EU) or coverage negotiations (US).

A global value dossier was created to communicate the value to payers in the US and reimbursement officials in individual EU countries. In order to communicate the product's value to physicians, a manuscript was developed documenting the change in the oncology treatment paradigm, showing a shift away from cytotoxics towards greater use of biologics.

## VALUE COMMUNICATIONS UP CLOSE

Value communications is a new frontier within the HEOR discipline that provides a vehicle by which HEOR can move from a purely research focus to the broader packaging of information that is supported by research but delivered in ways that are useful to disparate audiences. The goal of formalising

and pursuing value communications is to move HEOR from what is often viewed as an academic exercise to the forefront of commercial development and product commercial potential.

Value communications is an umbrella term that covers the following three areas: scientific communications, business communications and health promotion. The purpose of value communications is to translate the studies identified in the VDP from academic exercises into key components of the commercial development for products. Because HEOR professionals often 'speak a different language' than brand teams, the value of medicine (or a molecule or product in the case of biotechnology) is not always obvious and must be demonstrated. Value communications bridges the gap in understanding between outcomes research and marketing teams, brand teams and other stakeholders – helping to more effectively communicate HEOR study results and findings to both internal and external audiences in a straight-forward, comprehensible manner.

## Value communication examples

There are a number of ways to communicate with healthcare stakeholders. Some examples of where value communications can be beneficial include:

- *Internal audiences*
  - value slide decks that training departments can use and incorporate in their materials;
  - copy for intranet and email value-focused communications.
- *External audiences*
  - *Payers* – creation of value-related content for an existing dossier (eg Academy of Managed Care Pharmacy) and formulary kit, as well as value articles for leading journals.
  - *Patients* – delivery of value messaging in health promotion materials, such as brochures and booklets.



- *Providers* – fostering of lunch-and-learns, detail aids, continuing medical education (CME) programmes and symposia.
- *Employers* – sponsoring of an employer education programme.

While this is a small sample of the medium available to communicate the value of healthcare intervention, the key point is that internal and external audiences must appreciate this value, even if it translates into increased healthcare costs. The following case study highlights the frontier of value communications via a real-world application in an example organisation.

## Case study 2: An innovative approach to patient education

### Overview

One of the world's largest research-based biomedical and pharmaceutical companies conducted a national survey study of medication use in patients with the condition of interest. The study led to key findings in several areas, including reasons and predictors for discontinuation, patient knowledge, attitudes and behaviour, treatment satisfaction, and quality of life.

The client's marketing group requested that IMS develop a patient education piece to be included with medication samples that would address patient non-adherence with the product class.

### Strategy/tactics

IMS created innovative messaging based upon its adherence and communications expertise and knowledge from the study to drive content for the booklet. Content and

framework, as well as design elements of the piece, were tested through qualitative research with both patients and physicians.

Testing showed the content to be 'honest' and 'easy to understand', while the messaging proved to engage, educate and impact the target audience.

### Results

The evidence-based, adherence-focused messaging helped to differentiate the client's product from competitors and appealed to both patients and physicians.

## CONCLUSIONS

These case studies, and the VDP process described in this paper, illustrate the value of the modern HEOR professional in guiding product development and the marketing strategy, especially to key payer audiences, where evidence-based decisions and value-based pricing are becoming the rule rather than the exception. Armed with a rigorously and fully researched VDP, HEOR professionals can help healthcare manufacturers guide the activities necessary to realise the potential value inherent in the new medical technology.

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