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INTEGRATION OF HEOR INTO GLOBAL PUBLICATION PLANS

*Communicating safety, efficacy, and value
of a health care intervention through an
integrated publication plan*

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WHITE PAPER
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Introduction

Communicating the results of health economics and outcomes research (HEOR) is a key element of a publication plan. It provides peer-reviewed evidence that supports the adoption of approaches to improve outcomes and control costs by decision makers. HEOR encompasses aspects such as real-world effectiveness, quality of life, and cost effectiveness,¹ along with clinical efficacy and safety (Table 1). Most importantly, HEOR helps derive the value of an intervention.

Traditional Approach to Decision-Making

Traditionally, decision-making was driven by the efficacy and safety of interventions. Accordingly, publication plans tended to focus on communicating the results of “standard” clinical trials aimed specifically at assessing efficacy and safety.² In the current value-driven health care system, pharmaceutical and medical device companies need to provide interventions that show a real, measurable value to stakeholders. Thus, a definite shift in traditional publication planning practices is evident by the greater emphasis on positioning the patients at the center of health care decisions,² by a large number of clinical trials including patient-reported outcomes (PRO) measures.

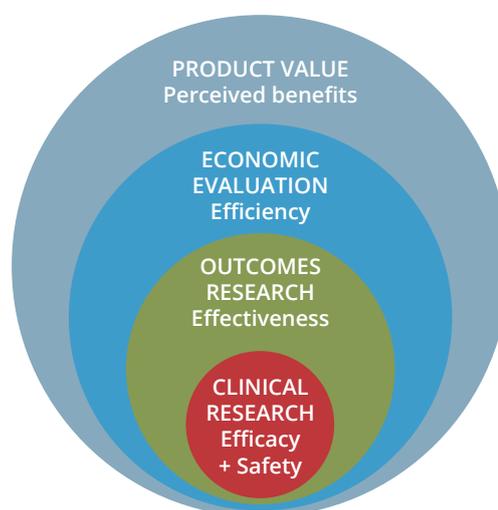
▼ **Table 1. HEOR Concepts⁴**

Efficacy	How well a drug works under ideal circumstances
Effectiveness	How well a drug works in normal clinical practice
Efficiency	How cost effective is the drug in normal clinical practice
Equity	How fair is the distribution of healthcare among individuals or groups
Value	What are the perceived or derived functional benefits of an intervention

New Approach to Decision-Making

Outcomes research plays an increasingly important role in health care decisions: HEOR can provide data on specific populations and interventions, treatment combinations, and diagnostics, in addition to the traditional clinical development information (efficacy, safety, and quality). Cost-effectiveness research (CER) and economic evaluations help establish a correlation between adherence to interventions and clinical outcomes as well as total costs (direct and indirect) and assess the relative risks and benefits of alternative approaches.⁵

▼ **Figure 1. Value of a Product**



The manufacturers’ clinical and commercial teams must collaborate early in the clinical development process to define the **value** of a product, facilitate its appropriate use, and address patient access concerns.⁶ HEOR teams may be incorporated within the R&D department (where they can easily commission research and clinical trial-type studies),⁷ the Medical Affairs department (that manages key thought-leader relationships, presents educational information, answers off-label questions from health care providers, and publishes trial data),⁸ or the Market Access group, which has a primarily commercial function (where they can commission real-world evidence-based studies). Regardless of its position on the organogram, it is important that the HEOR team be an integral part of the clinical trial and publication planning process (Figure 1).

An integrated publication plan supports dynamic decision-making based on evidence published at

various stages of drug development. It also ensures adequate dissemination of clinical and HEOR data to various stakeholders for creating awareness of the “value” of an intervention. Developing a fully integrated plan warrants the inclusion of stakeholders across R&D, medical, and commercial teams (Figure 2).

Distinguishing Between Clinical Trial Outcomes and HEOR Analyses

Clinical research, outcomes research, and economic evaluations are closely interrelated. Therefore, the traditional publication plan should be supplemented with a broad range of theoretical contributions, empirical studies, analyses of health policy, and explanation of HEOR models with a focus on value.⁹ Table 2 lists the characteristics of clinical and HEOR publications that can guide an integrated HEOR publication plan.

▼ **Figure 2. Stakeholders in HEOR Publication Planning**

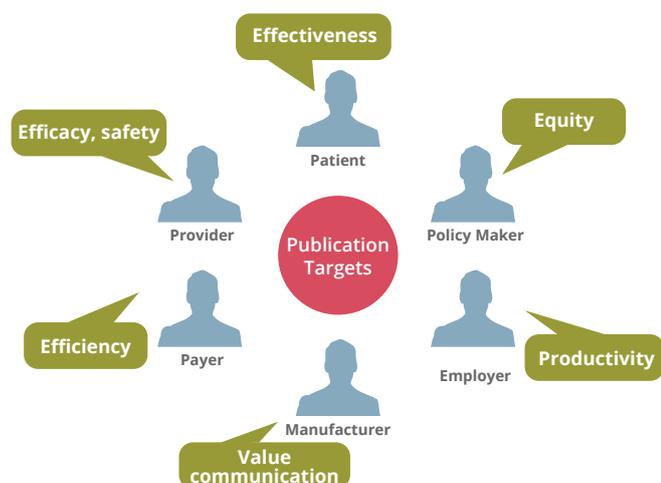


▼ **Table 2. Characteristics of Clinical and HEOR Publications**

	Clinical	HEOR
Process	Publications planned to coordinate with completion of trials; analysis and results predominantly driven by R&D and Medical Affairs teams.	Publications aimed at dissemination of information at various stages of the product lifecycle for communicating product value relevant to different stakeholders.
Audience	Target the scientific community and health care practitioners (providers).	Target various stakeholders beyond health care practitioners, the gold standard in the past (Figure 3).
Data	Data derived from studies conducted in controlled environments focusing on safety and efficacy and possibly including patient-reported outcomes (PROs). These studies are primarily conducted to support product registration.	Data derived from real-world sources* in addition to clinical trials. HEOR publications also include health policy analysis, behavioral analysis, economic evaluations, and systematic reviews and meta-analyses of multiple randomized controlled trials (RCTs).
Style	Clinical and outcomes research publications are structured similarly when developed from clinical trial study data.	Content and style differ depending on the perspective of the analysis (societal or individual), target audience, and timing of publication (phase of product lifecycle).
Journals	Target medical and therapeutic area-specific scientific journals.	Target therapeutic area-specific as well as HEOR-specific journals. Journal choice is driven by the content (clinical and/or economic) and target audience.

*Examples of real-world data sources: Administrative medical and pharmacy claims (e.g., Truven Health MarketScan® Research Database), clinical databases (e.g., Premier Healthcare Database), survey data (e.g., National Health and Wellness Survey), patient registries (e.g., North American Research Committee on Multiple Sclerosis), prescription sales datasets (e.g., IMS), epidemiology datasets (e.g., Kantar Health), electronic medical records, and patient-reported outcomes

▼ **Figure 3. Target Audience Perspective**



Changing HEOR Publication Landscape

An upward trend in HEOR publications was observed in an analysis of >33,000 HEOR articles published between 1969 and 2010 in economics, HEOR, and clinical journals.¹⁰ A distinct geographical disparity was noted, with predominance in developed countries (UK, Canada, USA, and the Netherlands) and a lower number of publications in the Middle East.¹⁰

▼ **Table 3. Most Common HEOR Publication Topics**

Sr. No.	Topic
1	Health and its value
2	Efficiency and equity
3	Determinants of health and ill-health
4	Public health
5	Health and the economy
6	Health statistics and econometrics
7	Demand for health and health care
8	Medical insurance
9	Supply of health services
10	Human resources
11	Markets in health care
12	Economic evaluation

Another analysis revealed that non-HEOR journals publish a significant proportion of articles on select HEOR topics (up to 50% or more, depending on the topic).¹⁰ Because of the inter-disciplinary nature of

the articles, a majority of HEOR articles appeared in clinical journals, such as JAMA, NEJM, and BMJ, as well as in HEOR journals, such as the Journal of Health Economics, Journal of Public Economics, and RAND Journal of Economics. Furthermore, there was a growing trend toward multi-disciplinary authorship. **Table 3** presents the most commonly featured topics in HEOR publications (in HEOR-specific and non-HEOR journals) in order of frequency.¹¹

Turning HEOR “Language” into Practical Prose: The CACTUS Approach

At CACTUS, we assist our clients to disseminate not only the efficacy and safety of an intervention but also the value proposition to all appropriate stakeholders. To this end, the value of an intervention that can be integrated early in the product development cycle in order to achieve well-planned, timely, strategic communications needs to be defined (**Figure 4**).

Define the Problem – Phase I-II

Based on the results of needs assessments and gap analyses, publications are planned to provide a thorough understanding of both the disease burden, based on real-world data, and management and delivery of care.

Identify the Unmet Need – Phase II-III

Publications in this phase are designed to create common understanding of patient flow to identify where value is being lost, where new value can be created, and how the company can best capture that value. They also discuss various topics to convey the results of effectiveness of an intervention from RCTs as well as existing treatment guidelines and patterns to provide an insight into the unmet needs in a target population.

Offer Solution (Intervention) – Late Phase III

Specific opportunities vary by product, product type, and product lifecycle stage, but value drivers can be found in treatment patterns, efficacy, dosage regimens, length of therapy, active side-effect management, compliance and adherence, comprehensive patient education and services, convenience aspects of care, and access and affordability. Publications in this phase target key

▼ **Figure 4. Integrated Publication Plan**



value-creation opportunities across all stakeholders to fulfill the identified unmet need with the proposed intervention. These studies discuss the clinical and cost effectiveness as well as cost benefit of introduction of an intervention in the existing disease-management pathway.

Update with Continuous Real-World Evidence – Phase IV

Publications in this phase provide economic and humanistic data from real-world sources to provide a proof of clinical and cost effectiveness to various stakeholders, thus enabling the feedback loop of re-assessment for decision-making to achieve optimal efficiency in the distribution of health care.

Summary

- HEOR data are indispensable for evidence-based decision-making for improved health outcomes and efficient apportioning of health care resources.
- In an evolving value-driven, patient-centric system, manufacturers are required to provide evidence that supports a tangible value of an intervention to stakeholders.
- Inputs from research, medical, and commercial functions are pivotal for conceptualization of the optimal product value proposition.
- Communicating clinical and HEOR data is integral to creating awareness of product value.
- Integrated clinical and HEOR publication planning teams facilitate an effective opportunity for distribution of compelling evidence to a diverse target audience.

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About the Authors...

Kim Pepitone, BA, CMPP
Scientific Director

Kim is responsible for providing scientific direction and oversight for medical publications and communications projects. Kim also provides professional training for CACTUS staff worldwide to ensure currency with all professional standards and guidelines regarding medical publication practices. Prior to joining CACTUS, Kim was Senior Director, Knowledge Management, at the International Society for Medical Publication Professionals (ISMPP), with responsibility for professional education programming.

Kim was also integrally involved in the development and launch of the Certified Medical Publication Professional (CMPP) program, and was among the first to be awarded the professional certification. Early in her career, Kim held the position of Managing Editor of the journal *Cardiovascular Medicine*. She has over 20 years of experience in medical communications and publication agencies, where she has held senior-level positions in firms such as Excerpta Medica, ProHealth (medical education division of Draftfcb Healthcare), and Access Communications (managed markets focused). She also holds the position of Adjunct Associate Professor, University of the Sciences in Philadelphia, where she teaches a graduate level course on publication planning.

Kim has authored articles on medical publications and the Sunshine Act and has presented at the annual meetings of ISMPP, the American Medical Writers Association, The International Publication Planning Association, and the Drug Information Association.

Kim has extensive publication planning and execution experience in several therapy areas including oncology, neuroscience, hematology, immunology, and cardiology.

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Dr. Lamror is a clinical doctor with a Masters in Public Health from Johns Hopkins Bloomberg School of Public Health. She has more than 9 years of experience in the health care and HEOR industry. Having worked with providers, public health organizations, pharmaceutical organizations, medical devices, and service providers, her experience includes development of deliverables from payers, providers, and social perspectives.

Her expertise includes synthesizing evidence for burden of disease (clinical, economic, and humanistic outcomes), disease landscaping, competitor profiling, PRO measures, pharmacoeconomic models, Health Technology Assessment (HTA) dossier development, claims database analyses, clinical trial analytics, systematic literature reviews, meta-analyses, white papers, and chart reviews. She has experience across therapy areas (respiratory, immunology, cardiovascular, oncology, and infectious diseases). As Associate Scientific Director - HEOR at CACTUS, Dr. Lamror oversees the work of a team of experienced HEOR writers, analysts, and editors. She is responsible for conceptualization, execution, delivery, and training on end-to-end solutions for HEOR and Market Access, as per client specifications in the pharmaceuticals, medical devices, and healthcare domain. She is also responsible for content and face validation of all HEOR deliverables: qualitative, quantitative, and technological solutions, and for working on hybrid delivery models for providing clients support and guidance on HEOR deliverables and market access strategy.

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