Strategic Evidence Generation Planning for Optimal Product Positioning

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In this turbulent global economy, fraught with increasing regulatory requirements and impending legislative changes, obtaining optimal product positioning and market uptake requires thoughtful planning and a fresh perspective. The crowded therapeutic marketplace has driven the need for product differentiation and comparative assessment, and formulary decision makers and payers are demanding greater quantities of evidence with an increasing level of scientific rigor. It is now more critical than ever that pharmaceutical and medical device manufacturers seek to answer the tough questions that will define product value. These questions may include, but are not limited to:

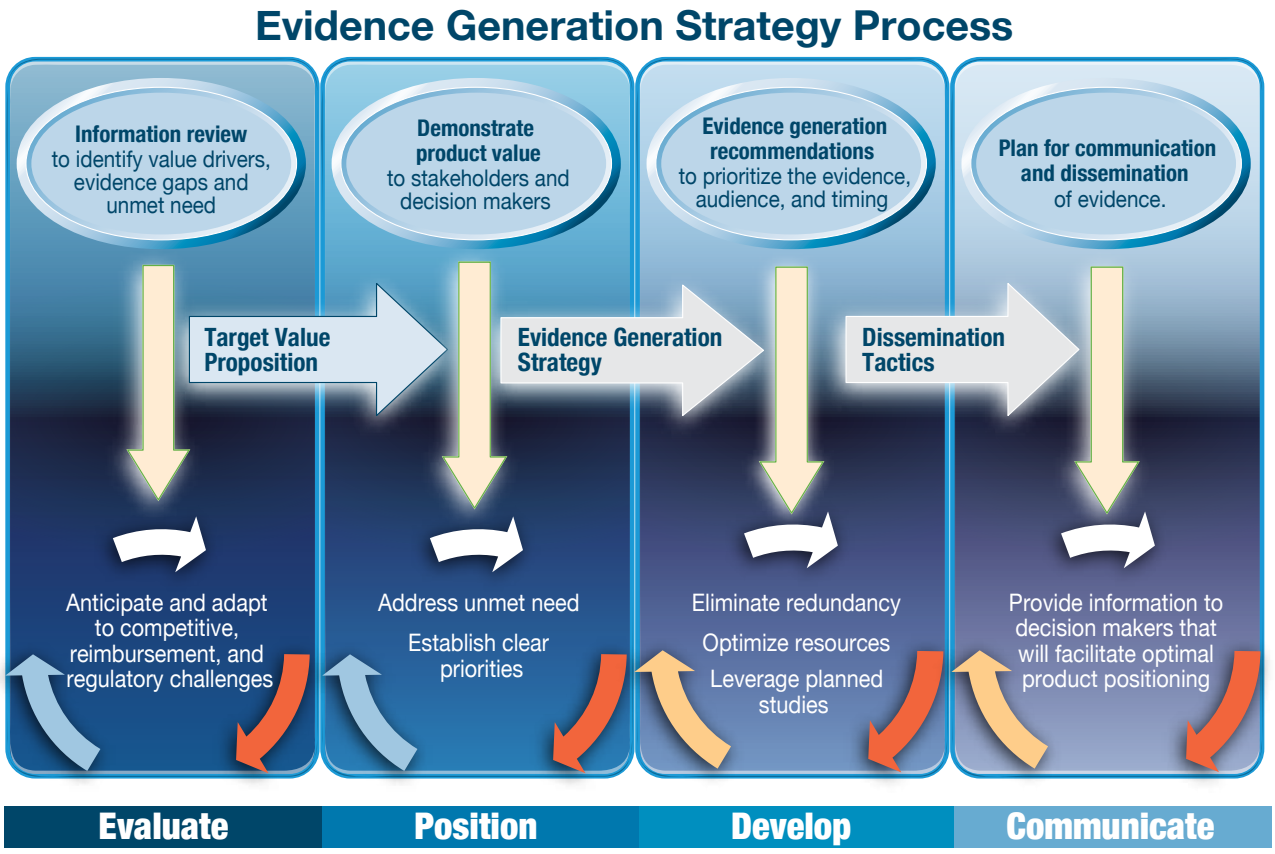
- Do you understand the unmet need in the marketplace, and are you leveraging the clinical endpoints and appropriate evidence to address it?
- What are the critical thresholds for evidence that must be met to enable decision making?
- Are you aware of the competitive, regulatory, and reimbursement environments, both present and future, and is your product development strategy designed accordingly?
- Do you understand the evidence-based value profile required by all relevant customer groups for optimal product positioning?
- Do your product development/commercialization plans mitigate risk while also ensuring maximal market adoption?

Although often complex and challenging in the face of resource limitations, effectively answering these questions requires a comprehensive, multi-year, multidimensional strategy to document and communicate evidence of product value. Employing a strategic evidence generation approach will facilitate coverage, reimbursement, and adoption by ensuring that the ***right value-based evidence*** is communicated to the ***right audience*** at the ***right time***.

Strategic evidence generation, as an approach, is a results-oriented process that assures available data are fully leveraged, new research projects are carefully designed to build a unified body of evidence, and information is effectively communicated to key decision-makers. It is most effective when a systematic, standardized, and repeatable process is in place, and when properly implemented, it will result in efficient demonstration of product value. Typically, this approach will include the following four key steps:

- Identify, summarize, and evaluate the available evidence, the marketplace (i.e., standards of care, comparator treatments, key stakeholders, etc.), and competitive challenges to identify evidence gaps and unmet need.
- Determine the target value proposition that addresses unmet need and describes (or demonstrates) product value to internal stakeholders and external decision makers.
- Identify and prioritize the evidence required to support the target value proposition, define the

Graphic 1: Strategic Evidence Generation Planning Process



resources needed, and outline a timeline for evidence generation.

- Outline a publication plan and communication strategy to ensure that the ***right evidence*** reaches the ***right audience*** at the ***right time***.

Opportunities for Strategic Evidence Generation as an Approach

Central to effective strategic evidence generation is the need to first understand the characteristics and target indications of the product, and its place and progression through the development lifecycle. Generally speaking, this approach may be applied to pharmaceutical, medical device, or diagnostic products spanning the entire product development lifecycle.

- **Early stage preclinical development:** A strategic evidence generation approach may be employed as a vehicle to set the stage for go/no-go due diligence decisions, prioritize information gathering on disease burden and competitive landscape, and inform the product value story as well as the clinical trial study design and implementation.
- **Mid-phase clinical development (successful proof of concept):** This approach can be used to define and prioritize evidence generation tasks, align internal stakeholder audiences, as well as describe tactics to address competitive, regulatory, and market access hurdles.
- **Marketed products:** Strategic evidence generation may be used to leverage or expand upon existing evidence, revitalize an underperforming product (increase market uptake), or respond to new competitive challenges, new information, or changing market dynamics.

Why is Strategy Important for the Generation of Evidence?

The delivery of the right evidence to the right audience at the right time empowers evidence-based coverage decisions that foster ***optimal product positioning***. The design of a comprehensive evidence generation strategy enables one to understand and adapt to the changing world economy, healthcare legislation, and regulatory and reimbursement policies, thereby ***anticipating competitive challenges*** and changes in market dynamics.

Strategic evidence generation is foundational and will serve to establish clear priorities and ***maximize efficiency*** of product development by eliminating redundancy and streamlining efforts across internal groups, thereby optimizing resource allocation and providing

Table 1. Product Challenges and Evidence Generation Opportunities by Phase

PRODUCT	POTENTIAL CHALLENGE	EVIDENCE GENERATION STRATEGY OPPORTUNITY
Early Stage – Preclinical Development		
In **Preclinical** or **Phase I** trials – very little known about the product and the marketplace	Making an informed decision for allocating resources for further product development	• Enable go/no-go due diligence decisions • Prioritize information gathering on disease burden and competitive landscape • Inform product value story and clinical trial study design and implementation
Mid-phase Clinical Development – Successful Proof of Concept		
In **Phase II** or **early Phase III** – may have multiple indications, submission dates, target countries/ markets, etc.	• New data/trials required for Food and Drug Administration (FDA), European Medicines Agency (EMA), or other regulatory agencies - delaying submission and providing opportunity for change in competitive landscape • Entering a crowded, competitive, and controversial market • Obtaining optimal positioning and market uptake when internal competitors exist	• Navigate competitive, regulatory, and market access hurdles • Define evidence generation tasks to position and support product launch • Leverage clinical trials and other studies in progress • Identify and establish payer/stakeholder audiences and internal priorities for launch
Approved and Marketed		
Phase IIIb/IV, or **Phase III** trials underway for a new indication or formulation	• Payer resistance if currently available formulations or comparators are well established, and available at a low cost • Underperforming product or competitor product • Crowded marketplace; available generics • Effectively communicating improvements in compliance and associated cost savings	• Define evidence generation tasks, including real-world evidence, to ensure optimal positioning and market uptake alongside other formulations and products in company portfolio • Leverage body of existing evidence, and any clinical trials or studies in progress • Integrate new evidence into current marketing strategy • Respond to competitive challenges and changing market dynamics

opportunities to leverage planned studies and available resources. This approach also focuses and informs decision making for early stage products in development.

Considerations for Effective Strategic Evidence Planning

The key elements of an effective strategic evidence generation plan are 1) senior scientific expertise, 2) a proven approach, 3) solutions-oriented, communication-focused recommendations, and 4) an emphasis on the evidence. Scientific expertise should include both therapeutic and methodology expertise (e.g., epidemiology, market access, modeling, outcomes research), in addition to an established understanding of regulatory agencies and formulary decision makers, such as health technology assessment agencies (HTAs) and payers. Any truly valuable evidence plan will succeed in aligning internal teams and ensure that all groups are communicating and leveraging the work that others are doing. Transparent working relationships with vendors (e.g., partnership is desirable in lieu of standard contract service), and strict adherence to timelines and deadlines are also critical elements.

Once completed, the plan should emphasize the ability to demonstrate effectiveness, manage safety risks, and document product value. In order to accomplish this, it is imperative that evidence development recommendations are not solely driven by capabilities or available resources, but instead are solution-oriented, evidence-driven, communication-focused, and effectively aligned with messages and audiences.

When implemented properly, a strategic approach to evidence generation provides a comprehensive, multi-year strategy across the product lifecycle to document and communicate evidence of product value. This systematic approach allows for thoughtful planning of evidence generation and associated resource allocation to optimize product positioning. In others words, an evidence generation strategy provides the ability to generate the ***right value-based evidence,*** for the ***right audience,*** at the ***right time.*** ■

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