

# GAINING A CRITICAL ADVANTAGE WITH STAKEHOLDER RESEARCH

## The Importance of Earlier Intelligence to Understand the True Value of Your Product

*Yvonne Spark, Consultant, Covance Market Access Services*

In the initial stages of drug development, it is natural to focus on a compound's novel mechanism of action and potential implications in a therapeutic area. But with ever increasing complexities surrounding global reimbursement requirements and greater barriers to market acceptance, biopharmaceutical developers must gain a deeper understanding of the current landscape surrounding their therapy's healthcare marketplace. Developers need market insight to avoid the risk of advancing a product that the market simply does not want, while simultaneously recognizing the full value of their asset to maximize market uptake.

This is why best-in-class companies, both small and large, are increasingly turning to early stakeholder research to guide their development strategy, inform crucial decision points and increase their commercial potential.

### The Impact of Earlier Evidence

Stakeholder research illuminates the perspectives of payers and prescribers to understand the route to market and identify potential barriers. Traditionally, this research is performed as a product approaches market launch. But in today's fast-paced environment, there is a significant risk that this knowledge may be too little, too late. Even though analysis can be valuable at any point in the development continuum, conducting research earlier in the process offers several benefits:

#### 1. Guiding initial go/no-go decisions

With high development costs and historically low adoption rates of new products, companies—and individuals—must ask the simple, stark question of whether or not a drug has commercial potential in the real world. When a promising molecule enters clinical development, stakeholder research can examine the market landscape to determine if it makes economic sense to move the product forward. Key questions include:

- ▶ Will our product be able to compete with treatments that will be on the market at launch?
- ▶ Is there sufficient unmet need within the target therapy area to warrant launching a new product?
- ▶ Does our product have the potential to meet that unmet need?
- ▶ What does the current/future treatment landscape look like and where best might our product be positioned?

Here, it is critical to understand competitors' current and future treatments, their respective efficacy and real-world clinical practices to start making evidence-based comparisons, define chief differentiators and determine a market need.

## 2. Illuminating the development pathway

Given the difference in skill sets between drug development specialists and drug commercialization specialists, projects are often passed from one group to the next as the company races to get products to market. From the development side, the product may be safe and effective, but in today's competitive economic environment, that is simply not enough.

If the product doesn't display what the market wants to see, for example differentiating endpoints versus relevant comparators, it could impact reimbursement or end up as a "me-too" product on the prescriber's shelf. Stakeholder research at this stage can help answer questions such as:

- ▶ What comparator should we use for our clinical trial?
- ▶ Will our proposed clinical development program be likely to support reimbursement and market access?

Stakeholder research may also identify future trends, such as companion diagnostics, that may help treatments reach a larger market more effectively. By identifying a niche in the market or an opportunity to fill an unmet need, developers can then position their product to meet these specific requirements and focus on gathering the data needed to showcase differentiating features.

## 3. Revealing and communicating the value of your asset

Once stakeholder research has helped shape a product strategy and built a strong foundation of knowledge, sponsors can also start to gain greater awareness of the market landscape and increase their chances for commercial success. Crucial information can be gathered by asking:

- ▶ What is the most appropriate route to market for our product?
- ▶ Will stakeholders be likely to recommend reimbursement for/prescribe our product?
- ▶ By the time our product launches, what market access challenges will it face?
- ▶ Which of our product's attributes differentiate it from competitors, and how can we effectively communicate its value?
- ▶ How should we price our product?

Answering these questions earlier in the drug development lifecycle builds more proactive planning into the process to better anticipate and mitigate issues before they affect end-user adoption and impact commercial potential.

## Identifying Strategic Stakeholders

Depending on the therapy and its target market, a variety of stakeholders can be called upon to assess therapeutic needs and the market access pathway. A consultative approach between the market access team and the biopharmaceutical sponsor helps determine exactly what types of stakeholders will provide relevant insights that address potential issues with the product.

While the roles may overlap, stakeholders can include key opinion leaders, clinicians and prescribers, health economists, hospital payers, third-party payers and even health technology assessors. This mix of perspectives also considers stakeholder needs at national, regional and local levels to represent a complete outlook on the landscape ahead.

## Developing the Right Questions for the Right Markets

Each product has its own set of concerns that are addressed by specific questions to determine how it would be perceived in both local and global markets. By asking the right questions to the right people in the right markets, real-world data gathering can help build an understanding of the mindset of stakeholders and how they make decisions—thus forming the essential attributes that build into a successful market access strategy. Common talking points can include:

- ▶ Existing market knowledge and the perceived issues within the therapeutic area(s)
- ▶ Current therapies, prescribing pathways and policies/guidelines that affect patient management
- ▶ Expected efficacy, possible therapy combinations and labeling strategies

## Translating Research into Actionable Plans

Findings from stakeholder research can guide strategic recommendations for the clinical profile, such as efficacy and safety endpoints in the prospective trial design along with the length of the trial and patient characteristics. Knowledge gained in the research can also determine whether additional data points are needed, for example, through observational trials.

Stakeholder research also fuels the commercial plan by outlining the markets to target and mapping potential reimbursement pathways to address increasingly restrictive healthcare systems. By defining meaningful product attributes, a foundation is formed to start developing a robust value statement that resonates with stakeholders making purchasing and prescribing decisions.

## Enhancing Value with Stakeholder Research

Given the vast resources required to take a drug to market, developers are constantly exploring their options to avoid potential pitfalls and increase returns. The data-driven, evidence-based narrative developed from stakeholder research provides a very clear benefit by:

- ▶ Identifying unmet needs to open up new markets
- ▶ Providing earlier insights in patient management pathways
- ▶ Detailing potential market access hurdles and requirements
- ▶ Positioning a product to capitalize on true market needs

As global market economies continue to evolve, so do stakeholders' priorities and needs. That's why stakeholder research continues to play an important role in helping drug developers understand the true value of their assets so they can make tangible differences in development, capitalize on market opportunities and maximize their commercial potential.

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The Americas + 1.888.COVANCE + 1.609.452.4440  
Europe / Africa + 00.800.2682.2682 Asia Pacific + 800.6568.3000

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