



## White Paper

# Why Value Demonstration is Everyone's Business:

## A Blueprint for Change

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## Overview

Making sound investment judgments and critical decisions to drive a product's value has never been more paramount in the pharma sector than it is today.

The drive for the 'value red thread'—a consistent focus on demonstrating and generating value that is meaningful to patients, payers and healthcare systems—must now be a pre-requisite for investment decisions at every stage of drug development. In an environment defined by mounting cost pressures, working cohesively across functional teams—including research and development (R&D), clinical development, regulatory, medical affairs, market access, and commercial—with shared goals of value optimization and operational efficiency is more critical than ever.

Selecting assets that can demonstrate clear patient benefits is paramount, but the need to drive value propositions to the insurance or healthcare systems is key to success. While in the past this driver might not have been considered early in asset selection, it is now apparent that value demonstration discussions need to be factored in earlier to better target investment resource.

**To ensure long-term portfolio viability, identifying the most promising assets and demonstrating a compelling, differentiated value proposition is essential to commercial success.**

While new mechanisms of action and modes of administration can drive high scientific interest, unless these attributes can show clear differentiated value in improved patient outcomes it is unlikely that downstream there will be funds available to pay for the benefits—meaning these innovations will not make it to the patients who need them the most.

This white paper outlines opportunities for practical application of a value assessment approach to drive a cross-functional 'value red thread' mindset at every phase of portfolio development.

## Background

Demonstrating value to maximize the gain from healthcare costs is not a new phenomenon. Since the late 1990s, European bodies such as NICE (UK) and IQWiG (Germany) have been created to help put a 'value' to therapeutics and drive a structured approach to drug reimbursement decisions. These external drivers catalyzed the emergence of Market Access and health economics and outcomes research (HEOR) as formal disciplines within pharma. Over time, these functions have become increasingly integrated into launch planning, as well as pricing and access strategy, and latterly in evidence reviews and regulatory planning.

However, integration into portfolio planning and early development has remained inconsistent—often occurring too late to meaningfully shape development priorities, evidence generation or long-term commercial success.

While value assessment methods have advanced in Europe since those early days, until recently there were only limited signals that this would become an important and impactful US trend. Historically, the US system has been more fragmented, with reimbursement decisions driven largely by commercial payers rather than centralized health assessment bodies.

Yet in 2025, the pressure to demonstrate value has become universal. The US landscape has shifted significantly with the rise of outcomes-based agreements, heightened scrutiny from public and private payers, and legislative efforts aimed at lowering drug costs, such as the Inflation Reduction Act. This has accelerated the demand for robust value demonstration, including real-world evidence (RWE), budget impact and cost-effectiveness data and innovative pricing models as core components of both US and global pharmaceutical strategy.

With these global shifts, developing drugs with a clearly articulated and measurable value proposition is no longer optional.

**Demonstrating value is not just a launch requirement—it must be embedded throughout the entire product lifecycle** from early development and clinical trial design to post-launch RWE generation and lifecycle management.



## The unintentional silos

As external cost pressures have intensified, pharma companies have responded with decades of scientific advancement and a relentless drive for innovation.

R&D teams and those involved in clinical development have intentionally taken scientific advancement and discoveries of new treatments to be the key driver for investment. We have witnessed portfolios of products that have resulted in transformational therapies and significant progress in improved patient care and outcomes.

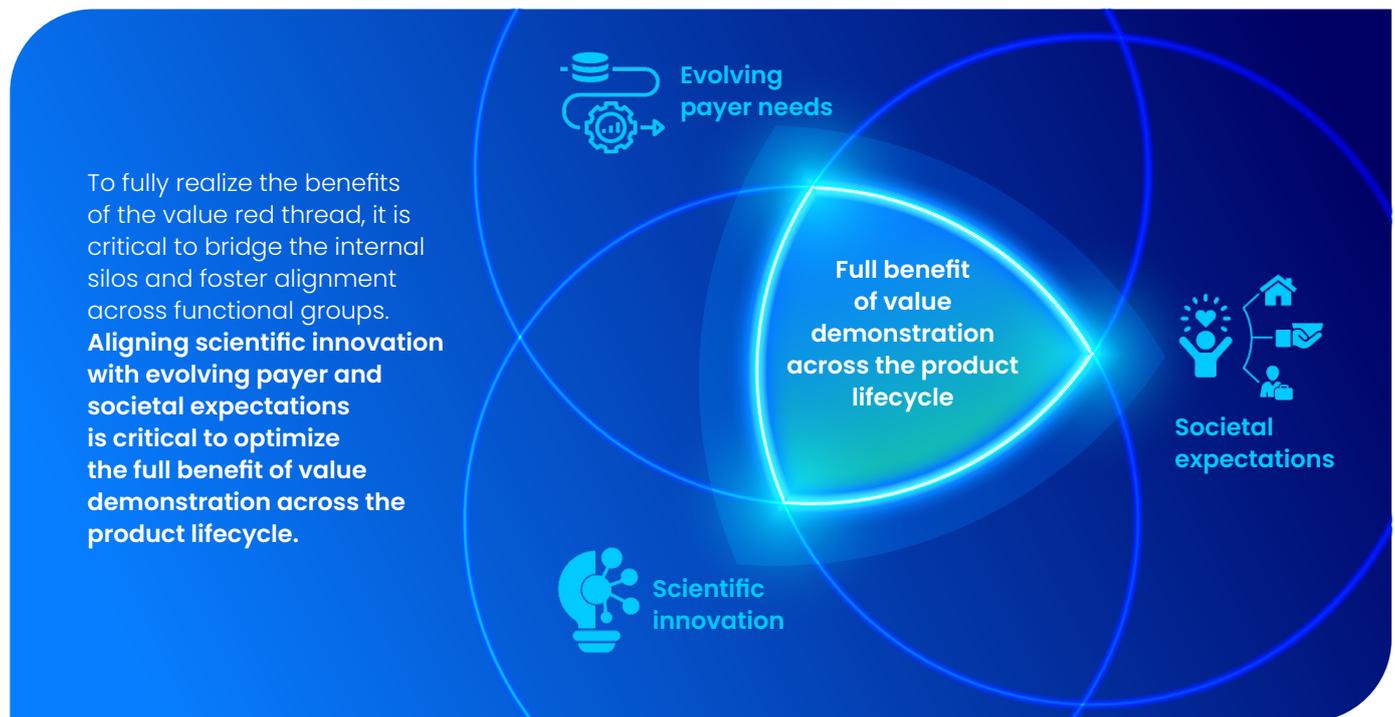
In parallel to the evolving therapeutic landscape, we have seen new internal departments emerge in Market Access, HEOR, and RWE. These functions were established to meet increasingly complex payer requirements, especially in countries where drug pricing must be justified through structured value assessment frameworks.

This internal evolution has supported the value red thread by enabling more strategic development and evidence planning which has, in some therapies, been used to drive country adoption particularly in Europe. However, despite examples of meaningful influence, the overall impact of Market Access and HEOR functions across the industry remains variable. We have seen some companies do this well, but their involvement is not always consistent or visible at the critical early stages of business and investment decision-making.

Medical Affairs teams have also been evolving in parallel to changes seen in Market Access and HEOR. Over the last two decades, these teams have moved from a support function focused on scientific communication to a strategic partner in shaping integrated evidence generation and target product profile (TPP) development. Medical Affairs increasingly contributes to clinical development decisions and plays a pivotal role in aligning scientific, market access and commercial strategies.

## Synergies without silos: A framework for shared accountability

As the steward of scientific communications and data integrity, Medical Affairs now plays a central role in developing and executing comprehensive evidence plans. These plans extend beyond traditional clinical endpoints to include RWE, patient-reported outcomes, and health economic insights—providing a much-needed holistic and patient-centric picture of a therapy's value and impact.



For those working in pharma and associated service providers, to enable this value red thread to drive both patient impact and investor return will require a shift in mindset for many organizations. This includes a willingness to collaborate in areas that have historically been considered the responsibility of a single functional group. Certainly there is a degree of discomfort where 'value' discussions are taken into some scientific and clinical development arenas, but to really shift the needle and target resource towards commercially viable assets, we would advocate for a step-change approach in integrating value assessment into product development strategy. This requires a greater emphasis on cross-functional decision making and more discipline around early alignment of critical success factors.

## A framework supporting collaboration to drive value

Engaging the right teams in the right discussions early in product development enables more structured planning and efficient use of resources. It also allows for the optimization of procurement strategies, improved efficiencies and the elimination of duplication. Too often there are significant overlaps in the work being driven by Medical, Market Access and Commercial teams, frequently running in parallel but not in sync. Whilst each function contributes to demonstrating value and differentiation, these efforts are often performed in isolation.

There is a clear opportunity to enhance impact and procurement efficiencies by aligning cross-functional activities through intentional collaboration and a shared accountability framework. A unified approach can ensure a robust, evidence-based, and differentiated value narrative is consistently delivered across stakeholders.

# Value creation

Building a value red thread into drug development requires an integrated skillset and an approach that starts early and guides key decisions. Figure 1 outlines some key questions to address at each stage to ensure value discussion stays at the forefront of investment decisions and activity prioritization.

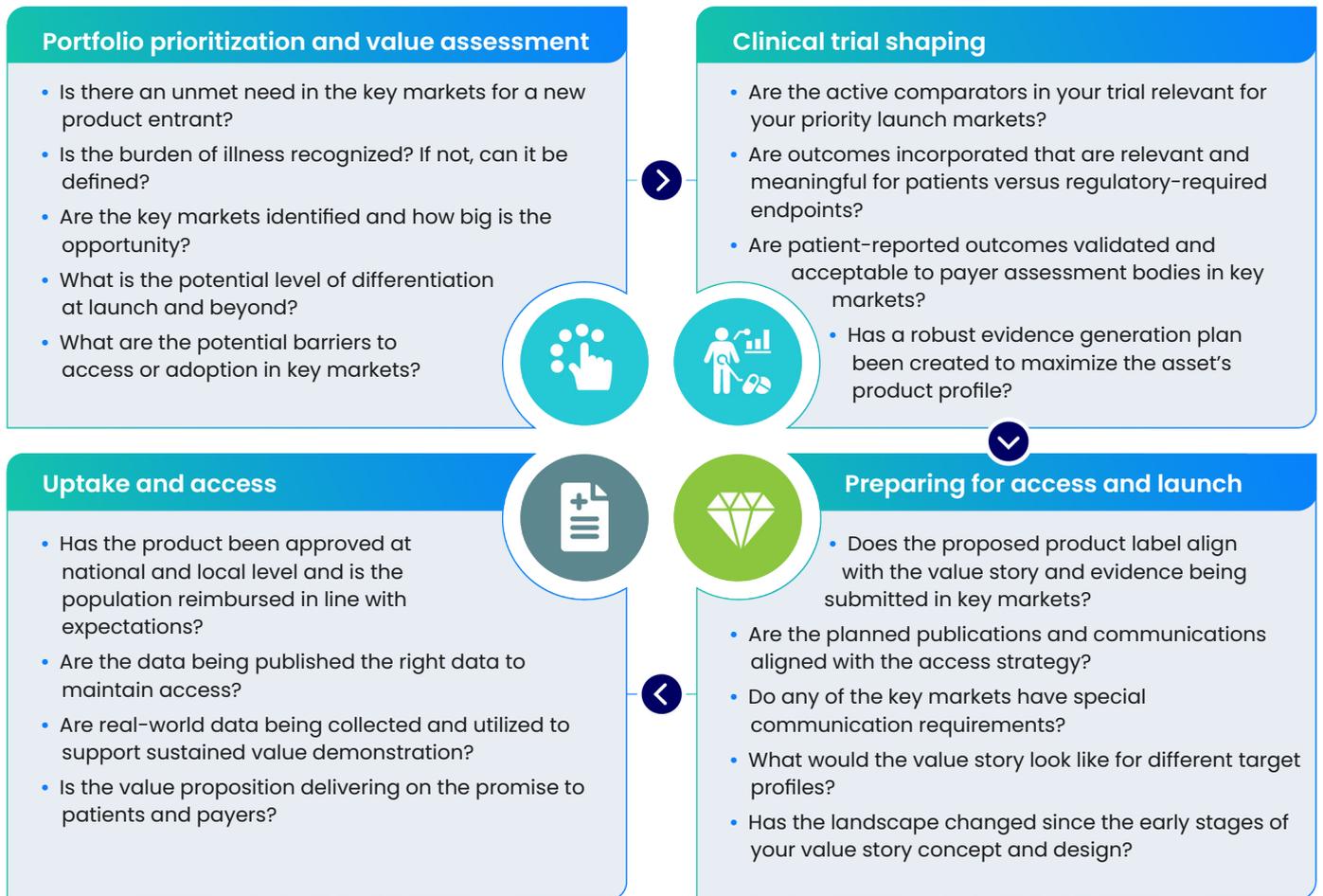


Figure 1. Questions to address in the value creation journey

## Framework step 1

### Emerging portfolio teams

#### Who to engage

Engagement is typically driven by R&D with Clinical Development, Regulatory, Medical Affairs, Market Access/HEOR, and emerging Commercial teams all contributing to the early product assessment process.

#### Why collaborate

It is essential to consider how value will be defined and delivered before investing time, people and funding, all of which are limited resources in today's industry. Clear value assessment criteria, applied early, help ensure that commercial potential and payer expectations are embedded in asset prioritization. This allows for the creation of differentiated TPPs that guide investment toward assets with strong long-term viability.

#### Value creation

Within emerging teams, it is timely to identify critical success factors relevant to your asset's development stage, such as current unmet needs, market size, competitor landscape, clinical differentiation, price and reimbursement potential. The output of a comprehensive value assessment should enable decision-making on asset investment and prioritization, value story development, and evidence-generation strategies.

## Framework step 2

# Clinical development and evidence planning

### Who to engage

Clinical development and evidence planning should be led by Clinical Development, with integrated involvement from R&D, Regulatory, Medical Affairs, Market Access/HEOR and emerging Commercial teams all collaborating early in the evidence planning process.

### Why collaborate

A differentiated value proposition depends on demonstrating outcomes that are meaningful not only for regulators but also for patients, healthcare professionals and payers. Joint planning for clinical trials and RWE programs ensures scientific rigor while addressing market relevance, regulatory requirements and reimbursement needs. This collaborative approach enables early identification of evidence gaps, inclusion of relevant patient-reported outcomes and design choices that support faster approvals and stronger, more defensible value narratives during Health Technology Assessment (HTA) and payer submissions.

### Value creation

Value can be optimized by informing trial design and selecting endpoints that satisfy both regulatory and HTA requirements. Incorporating patient-centered outcomes from the outset enables sponsors to generate data that not only secure approval but also drive equitable access and market success.

In addition to analyzing outcomes, conducting a comprehensive review of the landscape across relevant markets helps identify access-related challenges that could impact commercialization and return on investment.

Through a detailed analysis of the recently launched competitor entrants within a country landscape, the requirements for successful reimbursement and payer acceptance can be understood sufficiently to navigate country nuances. For example, are EQ-5D QOL assessments required for that therapy area? Are indirect treatment comparisons permitted where single-arm studies are a necessity?

Promoting this level of internal collaboration helps reduce redundant research efforts, ensures commercial relevance of trial outputs, and supports faster, more informed strategic decision-making.

## Framework step 3

# Value strategy for launch

### Who to engage

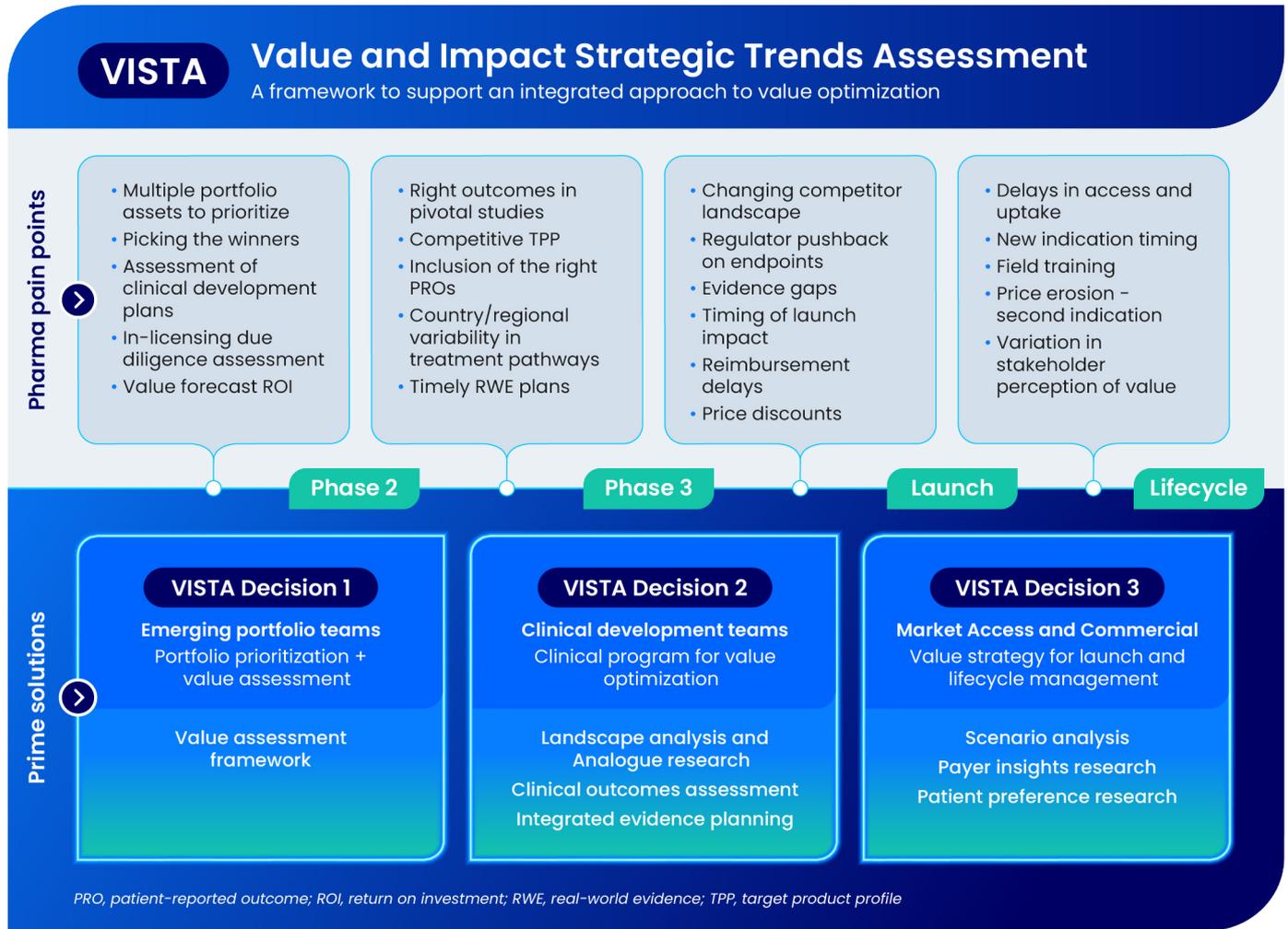
Value strategy for launch is driven by Medical Affairs and Commercial, with critical contributions from Market Access/HEOR and Regulatory.

### Why collaborate

To ensure the asset's value resonates with a diverse set of stakeholders—including payers, providers, regulators, and patients—it is essential to engage internal stakeholders who understand the nuances of each audience. Early cross-functional collaboration helps align messaging and address stakeholder-specific requirements and objections proactively, ultimately supporting smoother market entry and adoption.

### Value creation

By crafting impactful, evidence-based narratives for each key stakeholder group, the team can anticipate and mitigate access hurdles, strengthen payer negotiations, and improve clinical acceptance—thereby reducing launch delays, accelerating reimbursement, and driving faster uptake across markets.



## Conclusion

As the pharma industry navigates increasing pressures to optimize investments and contain costs, embedding the need to demonstrate value into every stage of drug development is no longer optional—it is essential. A consistent, evidence-based approach to value must guide decision-making from the earliest phases of development through to product launch and beyond.

The need to change is not new. For over two decades, external signals—from HTAs to evolving payer expectations—have pointed toward the rising importance of value demonstration. Yet internal silos and legacy ways of working have often slowed progress.

Now, with innovation accelerating and resources under greater scrutiny, success depends on early, integrated collaboration across Medical, Market Access, HEOR, Clinical Development, and Commercial teams. Those working to define and communicate value must be empowered to partner strategically across the organization. Ultimately, embedding value thinking into development and communication strategies will not only drive better patient and payer outcomes, it will determine which assets succeed in an increasingly competitive and cost-conscious landscape.

*Now is the time to shift from siloed execution to shared accountability. At Prime, we help clients make value everyone's business—from asset selection to post-launch impact. There is a need to build the 'value red thread' not as a checklist, but as a mindset embedded across functional groups, milestones, and decisions. Get in touch to see how we can help you. [info@primeglobalpeople.com](mailto:info@primeglobalpeople.com)*

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