

*ClinicalOptimizer* →



# Optimizing Clinical Strategy to Drive Lifetime Brand Value

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Pharmacos increasingly find themselves launching drugs into crowded markets, while facing regulators and payors that demand greater evidence of healthcare value. Further, it's becoming increasingly difficult and costly to get new products approved, increasing the importance of maximizing the value of in-line assets. In this context, developing a robust and sustained clinical program that continuously builds the clinical profile of a brand throughout its lifecycle has become critical to commercial success. With great risk and value at stake – both in investments and for top-line growth – a product's clinical strategy can determine whether the brand will be mediocre or a blockbuster, and can turn a \$1 billion-2 billion drug into a \$3 billion-4 billion drug.

Most successful brands will invest heavily to develop a compelling clinical strategy in support of approval and launch, but few consistently maintain that level of focus and rigorous strategic planning for the several years post-launch. As a result, many brands are left with minimal or insufficiently compelling new data post-launch to support increased use. In the past this has resulted in sub-optimization of lifetime brand value. Today the consequences can be much greater as payors' willingness to reimburse these products depends on meeting an ever higher bar for proving outcomes and clinical value pre- and post-launch.

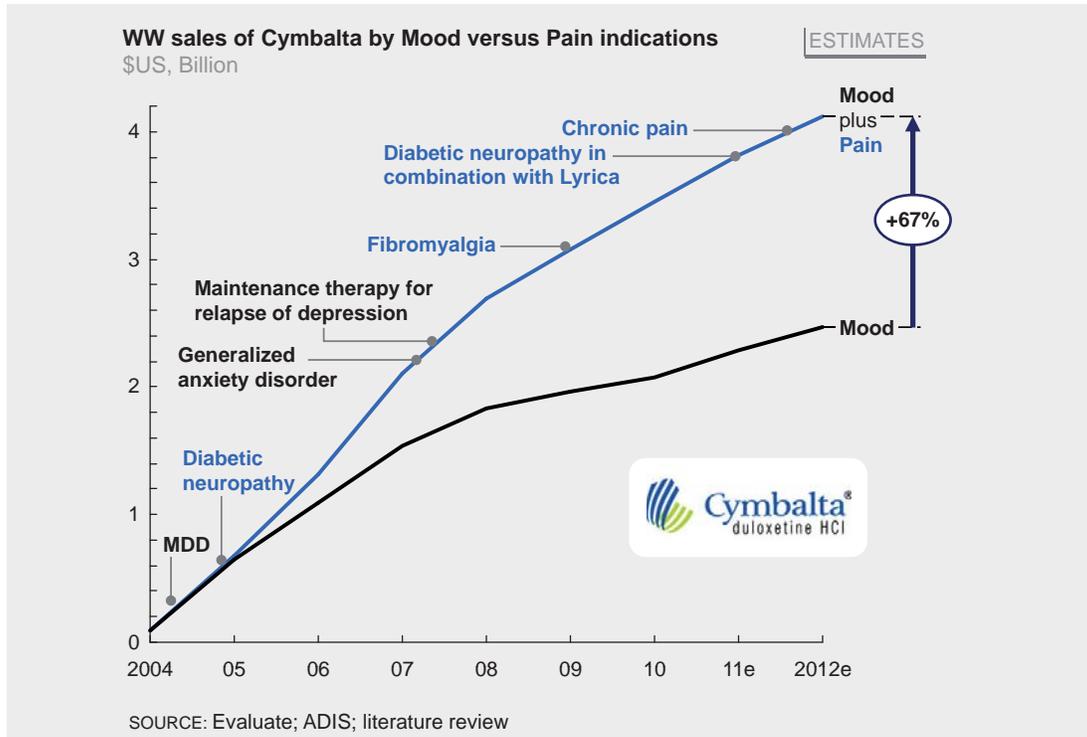
This article will argue that more can be done to develop robust clinical strategies earlier in a product's lifecycle (early-stage lifecycle management) to generate a sustained progression of data throughout the brand's lifetime

### *A Strategic Progression Of Clinical Data Drives Value*

While a lot of management attention is rightfully dedicated to getting a new drug approved and launched, the majority of value creation arguably depends on lifecycle initiatives that build and expand the clinical profile of the brand. A strategic and sustained release of clinical data (e.g., to support broader use, new indications, pharmacoeconomic benefit) can significantly enhance and extend lifetime brand value, and payors are increasingly demanding such evidence of healthcare value to justify reimbursement.

Take the historical example of Cymbalta, which launched in the crowded and competitive depression market and might have been destined to a mediocre end as just another SNRI for mood disorder. A strategic clinical program, however, generated a progression of clinical data in the years immediately post-launch that created a market for co-morbid pain and major depressive disorder (MDD). Through continued label expansion from depression to diabetic neuropathy and then more broadly in pain, Cymbalta experienced accelerated uptake and top-line growth as early as the first year post-launch, ultimately resulting in an increase in peak sales of nearly 70 percent and creating an estimated \$7 billion in cumulative value between 2005 and 2012 (Exhibit 1). Of note, the sequencing of indications (first mood, then pain) was critical to ensuring favorable reimbursement for Cymbalta, as the market for mood treatments faced less payor management than the pain market at the time.

Exhibit 1



### *Developing An Early-Stage Clinical Strategy Is Difficult*

Most clinical strategies include plans to invest in new indications, phase 4 studies, and other trials. In our experience, these initiatives often fail to reach their full potential because of several key challenges to developing and executing against a robust clinical strategy:

- **Ownership over clinical strategy and lifecycle management is not always clear**, especially in the period after launch and before loss of exclusivity approaches
- Brand teams often struggle to identify **which clinical opportunities will best “unlock” brand value** in the market
- Development teams often **lack full visibility into what is required to ensure commercial success**
- **Assessing and balancing the trade-offs of risk and reward is challenging**, and near-term P&L pressures tend to trump longer-term investments
- **Cross-functional alignment** between Commercial, R&D, Clinical/Medical, Finance, etc., and across geographies/regions is difficult to obtain and maintain

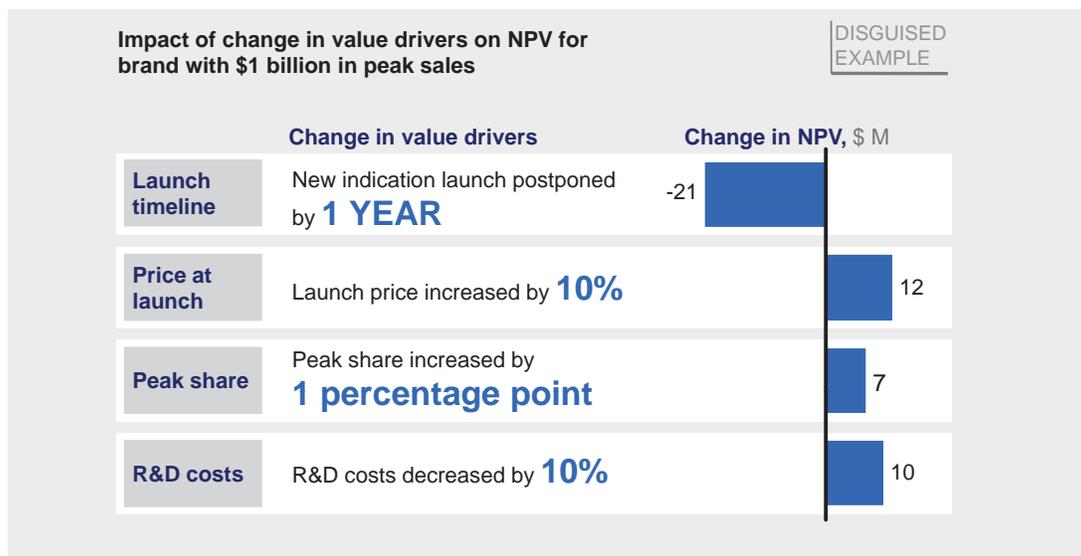
## Four Success Factors For Early-Stage Clinical Strategies

Looking across successful early-stage clinical plans, we see four key success factors:

### 1. START PLANNING AS EARLY AS POSSIBLE

Planning to generate a strategic progression of clinical data throughout the brand's lifecycle should begin as early as phase 2 and continue post-launch. This includes assessing the degree of intrinsic differentiation of the product, developing a plan to build a differentiated clinical profile that is valued by key stakeholders, and determining the optimal sequence for new indications (e.g., to maximize reimbursement). "Time is money" and many brands have lost both time and money by delaying focus on a clinical strategy. In fact, we have found that postponing the clinical development plan for a new indication by just 1 year would cost a company more value than could be obtained through hefty increases in launch price, reduction of R&D costs, or increases of peak share points (Exhibit 2).

Exhibit 2



### 2. FOCUS ON WHAT REALLY DRIVES VALUE IN THE MARKET

In our experience, about 10 to 20 percent of clinical spend is wasted on efforts that are not valued by key stakeholders. To reduce this, pharma needs to focus on what really drives treatment decisions and what new data would be viewed as clinically meaningful for prescribers and value-creating for economic stakeholders. Doing this well requires rigorous analysis, including assessment of the critical drivers of behavior for each stakeholder, stakeholder perception mapping, detailed comparison of competitor labels and clinical data, and a granular understanding of real-world data on treatment decisions and outcomes.

Analysis begins with a careful assessment of the critical factors that drive prescriber, payor, and patient behavior. Stakeholder perception mapping facilitates understanding of how competitors are perceived by each stakeholder against the most critical factors, which can help identify unmet needs that if suddenly met would drive real change in stakeholder behavior. Detailed comparison of competitor labels and clinical data

uses competitive intelligence to further inform which efficacy and safety endpoints matter most, and maps each of the brands against them. The combination of these analyses allows teams to identify what drives stakeholder behavior, how competitors stack up against those factors, and what degree of improvement would be required in future trials to represent true clinical value.

Analysis of real-world data provides value both pre- and post-launch. With products as early as phase 2, real-world data can inform understanding of disease, unmet needs, treatment gaps, and disease progression. Similarly, analysis of real-world data for competitive in-market treatments can further shape product development by informing trial design, trial prioritization, dosing, etc. Pre- and post-launch, understanding of treatment decisions, outcomes, safety, patient sub-populations, and comparative value will increasingly become critical to brand success as payors, regulators, and physicians will demand that brands demonstrate value in the real-world setting to justify premium reimbursements (e.g., AMNOG requirements in Germany) and potentially to serve as the means for value-based pricing. As a result of these developments, winning companies are developing strategic partnerships (e.g., AstraZeneca with Wellpoint's Healthcare unit and Sanofi with Medco's UBC unit) to build distinctive real-world research capabilities.

### **3. ARTICULATE CLEAR STRATEGIC GOALS FOR BUILDING OUT THE CLINICAL PROFILE**

Based on a detailed understanding of what drives value in the market and how brands compare against those drivers, planners need to articulate a clear and focused set of strategic goals along four potential dimensions to build out the brand's clinical profile.

**Close competitive gaps** by mitigating safety concerns (e.g., through long-term safety data, reversibility of side effects, ease of treating side effects); demonstrating non-inferiority for key efficacy endpoints; or reaching par on ease of administration or adherence through formulation (e.g., dosing frequency, device ease of use).

**Differentiate in existing markets** by moving earlier in the treatment paradigm (e.g., through studies in naïve patients or through switch or combination studies); generating health economics data, potentially through partnerships with payors; or considering active comparator or head-to-head studies for a select set of efficacy or safety parameters.

**Grow existing markets** by assuming a market leadership position and redefining clinical endpoints (e.g., moving from surrogate markers to clinical outcomes that matter to key stakeholders) or demonstrating improvement in patient sub-populations (e.g., defined by age, disease severity, co-morbidity) that have not been explicitly studied before.

**Expand into new markets** by entering new indications or geographies (e.g., leveraging population-specific data in underserved regions) that can significantly accelerate growth and potentially avoid high competitive intensity in the primary markets. As discussed in the Cymbalta case example, sequencing of new indications and new markets must be carefully assessed and strategically designed to optimize value and reimbursement.

Strategic approaches will widely vary depending on the degree of intrinsic differentiation of a product relative to current and future competitors, but clear articulation of the strategic goals of the clinical program will drive organizational alignment around top opportunities.

#### 4. PRIORITIZE AND MAKE DELIBERATE TRADE-OFFS

The number of trade-offs inherent in developing a clinical strategy in a resource-constrained environment are substantial. Examples of key trade-offs to consider include:

- Timing of topline impact: near-term vs. long-term
- Resources and risk tolerance: potential for revenue upside vs. cost and risk of programs
- Geographic lens: maximizing global brand value vs. tailoring to specific regions
- Competitive positioning: “offensive” vs. “defensive” strategic priorities.

Prioritizing potential opportunities and taking calculated risks are essential elements of a successful clinical strategy. Successful teams will make and communicate explicit trade-offs along each of these dimensions, supported by robust analytics and cross-functional collaboration.

#### *Questions To Consider*

Developing a robust clinical strategy for your pipeline and in-line brands will drive their lifetime brand value. It will impact regulatory approval, the level of reimbursement payors approve, the willingness of prescribers to change their behavior and the ability of your brand to differentiate against incumbent and future competitors. We leave you with several questions to consider and we would welcome the opportunity to discuss any of the above points (or McKinsey’s proprietary Clinical Optimizer toolkit) in further detail with you.

- Have you started developing the long-term post-launch clinical strategy (e.g., launch sequence of new indications) for your most promising phase II compounds?
- How fully do you understand what drives treatment decisions and what new data / outcomes would be viewed as clinically meaningful and differentiated?
- What are you doing to ensure that your top brands have the most compelling clinical profile to demonstrate value and secure favorable reimbursement?
- Have you identified the most promising opportunities to build your brand’s clinical profile? How well positioned are you to leverage insights from real world data?
- How are you trading-off risks and prioritizing investments in clinical trials?
- Does your organization have a clear owner of clinical strategy throughout the lifecycle (e.g., pre-launch, post-launch)? How well aligned are the key leaders of your organization (e.g., commercial, R&D, clinical / medical, finance, regions)?

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