Commercially Driven Product Development: Delivering on the Promise of the Pipeline

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When a new pharmaceutical product fails to live up to its promise, the reason is often the lack of a commercially driven approach to product development. Commercial considerations may not be incorporated until late in the development process, resulting in indications that represent low-value opportunities or a profile without a strong value proposition.

A commercially driven development approach helps products reach their greatest economic potential. This paper will introduce the OPEN approach to commercially driven product development, which can help product development teams design products that achieve their full commercial potential while balancing technical and regulatory concerns. OPEN enables marketing, development and regulatory to make better decisions, resulting in better outcomes.

Introduction

It is a situation we see all too often: A promising pharmaceutical product, the result of an enormous investment of time and money, is rolled out to the public with great expectations, but the product fails to perform as planned.

In some cases, these failures were the result of poor launches, but many are a function of product development decisions that are not aligned with commercial opportunity and market needs. While most pharmaceutical companies involve marketing in development, commercial considerations are not always a primary driver of product development decisions, inhibiting postlaunch success.

Take the example of "Kathy Johnson," who was in charge of the oncology commercial development team at "GenSciences." The company had a new oncology asset, GEN-50, with significant scientific promise but unknown market potential.

Those leading the GEN-50 project solicited Kathy's team for input, and integrated her perspective into development. Kathy's efforts resulted in a qualified endorsement of GEN-50's potential. With commercial, clinical, regulatory and other perspectives incorporated into the process, GenSciences pushed development of GEN-50 to completion, and brought GEN-50 to market confident of commercial success.

That's when things started to go sour. Contrary to what executives had thought, GEN-50's market uptake was inconsequential, despite the company's best marketing efforts. GEN-50's clinical trials strategy, which was designed primarily with scientific feasibility and regulatory success in mind, targeted a large patient population, which, unfortunately, had limited unmet need. Despite achieving its desired indication, GenSciences had not produced data that made a compelling case to physicians or payers that GEN-50 should be used in such a broad patient population. Furthermore, GenSciences missed the opportunity to generate data for a smaller subset of patients with significant treatment needs, limiting the company's ability to position the product in a highly valuable niche patient population. In the end, GEN-50 had difficulty recouping the cost of R&D.

The company had apparently done the right thing by involving marketing in key development decisions. Yet its product failed commercially. Why?

In part, the problem was that GenScience's development approach was not commercially driven.

Although GenSciences' development leaders solicited and incorporated advice from Kathy's commercial development team, their outreach did not happen until just prior to Phase III clinical trials were initiated—long after the product profile had been formulated. Kathy's team also lacked the funding and time to conduct a proper assessment that could identify a true commercial perspective for GEN-50; without such an evaluation, she did not have the data needed to influence the development plan. Her team's take on GEN-50's commercial potential was not wrong, per se, but its efforts were hobbled by circumstance.

If Kathy's team could have produced a strong commercial analysis—and had it been fully incorporated early in the development process, prior to clinical trials—GenSciences would have seen that the opportunity for GEN-50 was not as large nor as lucrative as hoped. In addition, the company could have optimized the design of its clinical and commercial programs to pursue additional niche indications, that, despite being smaller, could have been quite valuable. GenSciences ended up taking to market a niche product, not the blockbuster executives had expected.

Meanwhile, the company had ignored other development options and potential treatments that may not have had the same level of scientific promise but greater market potential. The issues extended beyond GenSciences' marketing operations or clinical development strategy: The lack of a commercially driven approach hurt R&D operations overall as GenSciences could not invest in other pipeline molecules.

Though GenSciences is not a real firm, the example is based on actual client experiences we have seen throughout the industry. Nearly every marketing director or head of commercial operations has gone through the same drill and suffered the same frustrations as Kathy Johnson.

Companies do not intentionally or consciously pursue drug candidates with little commercial potential, of course. Instead, while a pharmaceu-

tical company may ask for input from a commercial team, this information is often not fully integrated into the development plan.

Or, to put it another way, though commercial operations help *shape* product development, rarely does commercial viability actually *drive* the process. As a result, a company's decisions will not lead to the evidence needed to realize the commercial value of the product—the company has chosen the wrong comparator, has missing endpoints or has simply chosen the wrong indications.

We have found when drug development is commercially driven—with regulatory, clinical, commercial and other entities working as partners—companies enjoy a greater rate of success, and prospects discarded during development are done so early in the process, saving money that can be invested in more-promising targets.

Lacking a commercially driven approach, product development may be based on minimizing risk rather than on maximizing commercial success. We recommend companies also explicitly include commercial goals as the basis for success, and have regulatory and clinical operations become full partners on the basis of these goals.

In pursuing a commercially driven approach, we have found that the OPEN approach to clinical development strategy (which this article will detail) can help ensure success. As a commercially driven approach, the OPEN approach can help deliver cost savings and move high-potential products to market faster than the competition.

It is important to note that a commercially driven approach does not just benefit the marketing team, but is beneficial to the entire development process. A commercially driven approach does not mean a pharmaceutical company's commercial arm takes over product development or gives top-down orders to its clinical and regulatory partners. Rather, when commercial considerations drive product development, priorities change and all entities within a pharmaceutical company can do their jobs better, more efficiently and with superior results.

What Is a "Commercially Driven" Product Development Approach?

Simply put, a commercially driven approach aims to develop molecules with the best commercial opportunity, while still taking technical and regulatory risk into account. A commercially driven approach results in a profile that supports the greatest commercial success, pushing the company to establish a winning product label that supports the optimal commercial profile while investigating clinical development alternatives for delivering that label with the least possible risk (see Figure 1). With this approach, companies can make well-informed trade-offs between commercial opportunity and risk in development and regulatory matters.

Companies need to think about a product's commercial requirements *before* considering regulatory or other criteria. Without commercial potential, a product's other attributes—regulatory, scientific or otherwise—are usually not worth investigating.

For reasons political, technical or otherwise, we do not see many companies with a commercially driven approach (even though they may believe otherwise). Instead, most companies start the process with regulatory requirements and design a development program that meets these requirements. Commercial operations within the company must then take a product that has already been "baked" and reconstitute it.

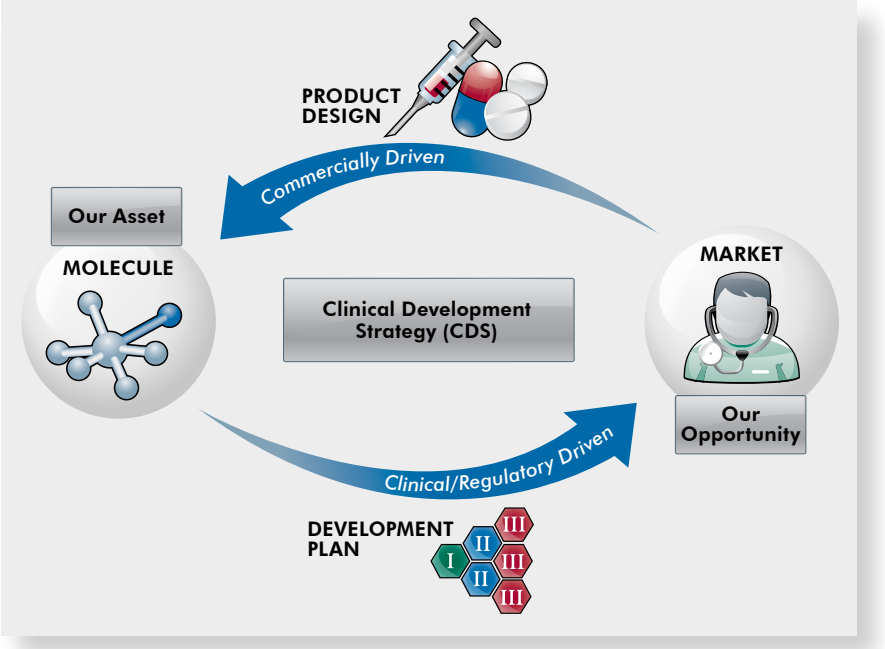

Figure 1. The product development strategy is the bridge between the molecule and opportunities within the disease landscape.

Though straightforward in theory, putting a commercially driven development approach into action is far more complex.

The target product profile is key. Ideally, this profile incorporates input from the marketing, regulatory and development arms of the company. However, the target product profile is usually focused on a product's clinical and regulatory attributes, which marketing managers can help shape but do not own—and this small distinction can undermine the product's commercial success.

Instead, we recommend producing individual profiles with commercial requirements only, translating this profile into a label and ultimately into required clinical data. This can be divided into three parts, often performed sequentially and always aligned:

- **Target Commercial Profile**: Marketing operations should "own" target commercial profiles; these profiles should include the minimum required product attributes for a commercially viable product along with additional desired attributes that can enhance the product's commercial success.
- **Target Product Label**: The company's regulatory arm should develop and "own" the product's target product label, which includes marketing attributes that can be included in the product label, as well as the clinical data required to support inclusion of these attributes in the label.
- **Target Clinical Data**: Clinical development generates and "owns" target clinical data, which includes data that can actually be generated through available science (within a reasonable level of risk) to support the target product label.

These three elements are ultimately integrated into the overall target product profile, revealing the trade-offs between conflicting priorities and allowing the team to derive the best outcome. It is critical to preserve the work done for each phase, so that the reasoning for each decision is readily available; this allows product development teams to understand the rationale for their decisions as conditions change.

These elements work best when incorporated into a proper approach to guide the company. OPEN is one such approach that can help

ensure that a pharmaceutical company's development process is commercially driven.

OPEN—**O**pportunity, **P**romise, **E**vidence, **N**avigation—allows product development in pursuit of a common vision, focused on long-term commercial success (see Figure 2).

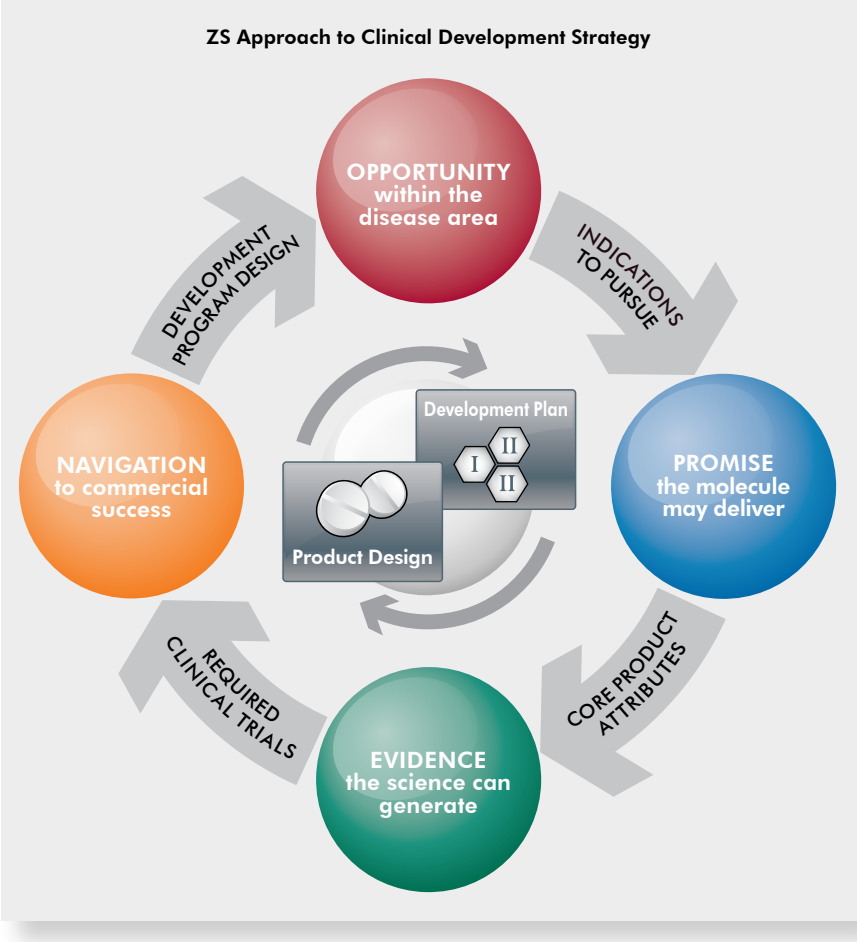

Figure 2. The OPEN approach translates commercial success factors into product development program requirements.

The initial decision in new product development lies in its specific *opportunity*, typically its target conditions and indications. Companies must also define the product's *promise*, in order to pursue each of the prioritized opportunities; it is important to consider the potential benefits to stakeholders (providers, payers, patients and regulators).

In determining the *evidence* to each stakeholder, the company's clinical trials must generate efficacy and safety data that can prove the functional benefits of the product. Finally, companies must ensure the *navigation* of the product from development to final regulatory approval and

commercial success, deciding which trials to execute, the design and sequencing of these clinical trials, and the lead and backup strategy for the product.

The best illustration of the OPEN approach is showing it in action—how GenSciences and Kathy Johnson used the OPEN approach illustrates both its power and why it is essential that commercial considerations drive pharmaceutical product development from the start of the process.

CASE STUDY

Kathy Johnson, GenSciences

Not long after the failure of GEN-50, Kathy Johnson convinced her company that product development should be commercially driven using the OPEN approach.

As she was responsible for developing commercial strategy for GenSciences' oncology portfolio, her first project using OPEN was commercial development of GEN-75, a promising treatment for prostate cancer that had potential to work in other tumor types as well. (As with GEN-50, the example of GEN-75 is fictitious but based on actual situations we have witnessed across the pharmaceutical industry.)

GEN-75's success was of vital importance to GenSciences. Not only did the company have a huge opportunity to claim market leadership, but it needed a commercial success badly and could not afford wasting millions of dollars on inferior indications, as it had for GEN-50, its previous oncology "breakthrough."

To ensure that the development process was commercially driven, Kathy and the commercial team first focused on GEN-75's **opportunity**. Using primary and secondary market research, Kathy and her team identified several potential prostate cancer indications for which GEN-75 should be tested. For each indication, GEN-75's opportunity was tremendous—the indications had both high unmet need and sizable patient populations. Kathy leveraged this research when working with her clinical colleagues, and helped develop three priority indications for the product team to target in development.

After Phase I clinical trials were complete, Kathy considered the **promise** of a new prostate cancer treatment for the most important stakeholders: providers, payers, patients and regulators. Based on its research,

Kathy's team knew that both urologists and oncologists would contribute to the product's success or failure. Additional customer research helped identify the value proposition that GEN-75 needed to meet the needs of each stakeholder. Kathy's team also uncovered a surprising fact: Payers were playing a greater role in product use for indications that involved less-severe patients. Combined with regulatory findings, these needs and market idiosyncrasies defined the endpoints and comparators to be included in Phase II clinical trials.

As Phase II clinical trials progressed, it was important the trials delivered **evidence** that fulfilled the product's promise. Kathy's team conducted attribute analysis to determine the levels of efficacy, safety, dosing and health economics required to successfully launch GEN-75, and used the analysis to develop a target commercial profile (TCP) for GEN-75 that defined optimal requirements for commercial success. Kathy then worked with her regulatory and clinical peers to develop a target product label and clinical data to support the TCP.

As it developed the target product label and target clinical data, the product strategy team identified significant clinical and regulatory risk—they were unsure if they could deliver marketing's requests for certain elements of the target product profile. And there was uncertainty regarding how well the product would perform in Phase II clinical trials. So upon the release of Phase II data—and considering budget limitations—GenSciences would have to decide whether to initiate Phase III trials for all three prioritized indications or to focus on those with the lowest risk.

Kathy knew the size of the patient population for the lowest-risk indication was extremely small. So using customer research and leveraging decision analysis, her team demonstrated how to best **navigate** the Phase III clinical trials program and guide GEN-75 toward launch. The analysis showed that pursuing two of the three indications improved the commercial value of the product; this also would mitigate some of the risk associated with clinical development in each indication. As a result, Kathy's marketing team worked with the product's clinical team on a plan to develop GEN-75 in two prostate cancer indications. This not only benefited the asset's commercial value, but allowed GenSciences to prioritize its development efforts.

Ultimately, her analysis helped lead management to increase its investment in GEN-75's development. GenSciences successfully launched GEN-75 with two prostate cancer indications to the accolades of both the medical community and Wall Street, while helping solidify GenSciences' long-term viability as an independent entity.

Compare Kathy's experience with the two different oncology prospects. In the case of GEN-50, the company charged ahead with product development without using a commercially driven approach or truly considering the commercial potential of the product. The company was blind to the fact that GEN-50 had little commercial promise until it had spent millions of dollars on development.

But with GEN-75, GenSciences not only saw clear economic potential for the molecule in development, it prioritized which indications to pursue and designed the product to meet the needs of key stakeholders A commercially driven approach using OPEN did not guarantee success for GEN-75, but it did ensure that GenSciences was following the path most likely to succeed.

Conclusion

The pharmaceutical industry needs to combine its pursuit of improved pipeline productivity and market success with better decision-making in product development. The stakes for pharmaceutical companies are tremendously high—neglecting commercial considerations *early in the process* can compromise a new product's success or cause misallocation of scarce investment dollars.

Companies need focused, efficient and effective investments in the opportunities that match the company's goals. A comprehensive disease area strategy to guide research, aligned with improved commercial development strategy to drive development, can improve an organization's decisions.

What makes these issues particularly urgent is that new product development is getting harder, not easier. Markets are becoming microspecific as products address smaller, targeted patient populations. Personalized medicine and other trends are eroding the mass market as we know it today; products are likely to be riskier and less lucrative. Meanwhile, companies must confront public concerns on rising health-care costs, increased scrutiny from regulators and a Wall Street intolerant of failure.

These are not temporary market conditions, but long-term structural issues every pharmaceutical company must deal with. Bottom line, a commercially driven development approach is not only desirable, but necessary. The industry can no longer afford to pour billions into developing products that are not commercially viable.

Yet, even in this difficult environment, there remain excellent opportunities for pharmaceutical companies. Innovative, forward-looking companies can turn these tough market conditions to their own advantage. Enterprises that adopt a true commercially driven development approach will be rewarded with greater productivity, fewer product failures and more success than the competition.

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