

Life Sciences

Oncology biotech gains robust Product Development & Commercialization process through Guidehouse's objective analysis

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CHALLENGE

Facing an intensely competitive global oncology market, the leadership team of a global biotech company required a strategy to inform efficient and coordinated decision-making regarding its rapidly maturing portfolio.

At the time, total revenues for the global oncology market were expected to exceed \$150 billion in 2020 and grow to over \$240 billion by **2025**. Meanwhile, the frequency of launches for many oncology therapeutics had increased over the last 10 years, driven by an improved understanding of disease biology and higher levels of competition. Still, few companies achieved their sales projections in the ever-tighter market.

With a solid financial base from out-licensed products, the biotech had a dozen pipeline products, spanning multiple tumor types, mechanisms of action, and potential indications. The leadership team aimed to launch and commercialize at least two new products before 2025. However, because the company was growing its early pipeline while simultaneously advancing assets into later stages of development, the leadership team expressed concerns about seamlessly executing against both of these objectives. As such, they sought to put clear structures in place to inform critical portfolio prioritization decision-making.

In this context, the leadership team enlisted Guidehouse's extended experience supporting global companies to assess and make recommendations for optimizing the biotech's product development and commercialization (PD&C) process – from preclinical work through development, launch, and beyond.

SOLUTION

Guidehouse conducted a rigorous and objective strategic assessment of the biotech's existing PD&C process. Based on the results, the team prepared recommendations for a fit-for-purpose, future-proof, and scalable PD&C model to enable and inform critical decision-making, while preserving rapid and quality execution excellence.

Guidehouse performed an organizational diagnostic to understand existing processes, governance structures, and capabilities in order to identify and assess critical business challenges. Team structures, roles and responsibilities, key operating processes, and the governance model were evaluated through over 25 stakeholder interviews across development and commercialization functions from the biotech, leading to several insights.

First, in the organization, products historically were managed individually, and not in relation to the portfolio. This meant investment prioritization decisions were limited. As the portfolio matures and the early pipeline expands, and managing the pipeline at the portfolio level would be important to accommodate a larger number of assets.

About Guidehouse

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Second, the company lacked structure in decision-making processes. Different governance committees often met to discuss the same topics and make the same types of decisions with regard to investments, project strategy, and related issues, and sometimes made key decisions during “water cooler” meetings. This informal structure resulted in misalignment within the organization and an inefficient use of resources across it, among other obstacles. Product teams over-relied on the undefined governance structures to devise and manage the execution of compound strategies, which also would be unsustainable at scale. By formalizing governance structures, decision-making processes, and developing strategic planning materials, the product teams would be more integrated and empowered to strategically develop compound plans, get endorsement from governance, and then execute independently.

Leveraging these critical insights combined with detailed assessment and analysis, Guidehouse developed an integrated PD&C process in order to:

- Create a standardized process with clear decision points and requirements for each decision.
- Ensure governance structures and roles are dynamic, fit for purpose, and drive rapid and informed decision-making responsibilities.
- Evolve the process for developing strategic PD&C plans for compounds from preclinical development through lifecycle management.
- Enhance and formalize portfolio management capabilities and processes to enable governance decision-making on investment and resource prioritization.

Guidehouse also performed robust benchmarking analysis of oncology companies of all sizes and oncology divisions within large pharmaceutical companies to ascertain industry best practices for PD&C and associated governance principles.

Based on the above insights and in-house biotech expertise, the end result was an integrated and deployable PD&C process that included a clear governance structure, planning strategy, and implementation support.

“Guidehouse provided great expertise and benchmarks in supporting the design of a PD&C process, allowing the team to develop a process targeted to our needs,” said the biotech’s Vice President of Commercialization.

This solution was designed to enable the biotech to manage, sustain, and continue to grow its maturing portfolio. Highlights of the solution’s key elements include:

- **An evolved PD&C process** links to decision-making points for major investments and points of strategic alignment for product teams and governance.
- **A formalized governance model** reduces overlaps in decision-making and articulates responsibilities for strategic support, product team oversight, and investment decision-making, all of which link directly to the process.
- **Comprehensive product plans** integrate functional and cross-functional strategies from preclinical development through launch and lifecycle management, while a novel prioritization scoring and analysis framework facilitates investment decision-making.

IMPACT

The evolved PD&C process will future proof the organization as its portfolio continues to expand and mature. Equipped with this new process, governance structures, and capabilities, the biotech’s team is better equipped and prepared to make complex, coordinated, and informed investment decisions, strategically plan PD&C at the product and portfolio level, and continue executing on key activities with speed and quality. These advances have enabled the organization to be more agile and competitive in the fast-evolving oncology marketplace.

“Guidehouse helped design a fit-for-purpose PD&C process that allowed greater synergy between clinical development and commercialization functions to ensure greater value for the company,” said the biotech’s Chief Operating Officer.

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