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A Quick Guide:
Leveraging Target Product Profiles to Optimize Portfolio Potential

Target product profiles (TPPs) are strategic development process tools that can be used to help enhance the development and commercialization of novel biopharmaceutical products. Incorporating a well-developed TPP into the product development decision-making process can decrease risk, accelerate approval, and help ensure product-market fit. And yet, less than 20 percent of FDA-approved products were developed using a TPP.[1]

In this guide, we discuss the critical role of TPPs in product development and offer tips and best practices for integrating these tools into and across programs to optimize portfolio potential.

Introduction

The term "TPP" is ubiquitous, and has been in use for decades. The concept was introduced in the late 1990s as an approach to improving sponsor and Agency interactions through the use of a template that could be used to summarize drug labeling concepts. In 2007, the U.S. Food and Drug Administration (FDA) codified the concept in its draft guidance, Target Product Profile – A Strategic Development Process Tool.[2] The overarching goals of the TPP are to:

- Limit the risks inherent to late-stage drug development
- Increase the probability of obtaining optimal safety and efficacy data in a timely fashion
- Minimize the overall risk of the drug development process

The guiding principle of the TPP is to begin with the end in mind, such that sponsors use their ideal version of labeling claims to guide the design, conduct, and analysis of their clinical trials.[1] When executed appropriately, the final version of the TPP should mirror the draft labeling submitted with a new drug application (NDA) or biologics license application (BLA).[1]

Using TPPs to inform development strategy

At Premier Consulting, we utilize a well-defined approach to product development strategy that is built upon three core principles:

1. **Developed with comprehensive input**, from market, commercial, and competitive insights and manufacturing and quality controls to nonclinical and clinical data, patient benefits, and regulatory requirements.

2. **Defined by trade-off decisions** related to inclusion/exclusion criteria, end point selection, formulation, dosing, and other product characteristics, as well as understanding the implications of each trade-off on the commercial potential and financial risks associated with the program.

3. **Intended to be iterative and constantly evolving** as new data and insights are generated throughout the development process.

The TPP is central to the implementation of these principles, serving as the hub for comprehensive inputs, facilitating trade-off decision-making, and helping to maximize the program's return on investment. By providing a framework that prioritizes the desired features and attributes of a product, the TPP ensures value-added differentiation and optimizes the likelihood of commercial success. It is no surprise, then, that a TPP should be created as early as possible in the development process.

Importantly, developing a TPP is not a one and done process and there is no single, industry standard template for this tool. Instead, the most effective TPPs are fit-for-purpose and, as such, their contents and applications evolve throughout the development lifecycle. The foundational document is the ***development TPP***, which typically includes information on targeted patient types, desired safety and efficacy endpoints, differentiating labeling claims, competitor claims, and the impact of each of these factors on commercial uptake. A ***labeling TPP*** builds upon the development TPP by adding data needed for full draft labeling to support negotiations with regulatory authorities. A ***quality TPP*** supplements the development TPP with product attributes that are critical to quality and manufacturing specifications. A ***target value proposition*** combines the development TPP with real-world evidence, health economics outcomes research, or other data needed to ensure access and reimbursement, thus creating a health technology assessment dossier.

Understanding the format of a development TPP

In addition to serving as a strategic framework, a TPP may also be a detailed regulatory tool, technical dossier, or due diligence tool. Consequently, there is no definitive, standard template. Instead, the format of each TPP should be designed to fit its specific purpose, whether that is guiding development, labeling, quality, or the product's target value proposition.

There is, however, a general format that basic development TPPs follow (see Figure 1). The objective of a development TPP is to inform early go/no-go decisions, strategic portfolio planning, clinical trial design, and due diligence. For maximum utility, the development TPP should include the full range of potential outcomes for the product, from describing the attributes of the product to determining how those attributes compare to competitors or the standard of care. Highlighting competitive strengths and weaknesses helps clarify and justify the commercial impact of each attribute.

	Minimally Viable Attribute	Targeted Attribute	Ideal Attribute	Competitor/SoC Attributes	Commercial Impact/ Implication/ Justification
Target Patient Population					
Indication					
Dosage Form/Strength					
Drug Product (Formulation)					
Dosage and Administration					
Efficacy (Primary Endpoint, Secondary Endpoints)					
Safety (Adverse Experiences/Tolerability)					
Warnings/Contraindications					
Drug Interactions					
Clinical Pharmacology					

The potential impact of each attribute on the overall value of the product should be evaluated through market research with targeted stakeholders, and the rationale for the trade-off choices in the development program should be documented.

For products being developed in more competitive markets, a clear understanding of the minimal requirements for commercial viability is critical.

Figure 1. Basic development TPP format

Uncovering practical challenges to using TPPs

According to an analysis conducted by Premier Consulting of all NDAs submitted between 2007 and 2015, a vast minority of applications approved by the FDA referenced a TPP:

- ~14 percent of NDAs for novel products
- ~20 percent of BLAs
- ~6 percent of all products approved via the 505(b)(2) pathway

Lower than expected utilization of TPPs may be due to:

- Limitations on, or the lack of, a structured system of governance in which decisions and decision-making criteria are clearly defined, consistently applied, and transparent to all key stakeholders
- Failure to gather comprehensive insights, which can lead to faulty assumptions or blind spots in strategy
- "Sacred Cows" – strongly held beliefs or desires that developers are unwilling to give up, when doing so would be strategically advantageous
- Concern that sharing too much information with the FDA or another health authority might create unnecessary complications

Integrating three best practices for TPP development

When developing a fit-for-purpose TPP, keep these best practices at the forefront:

1. Don't cut corners when gathering inputs and insights

Target market definition

- ☐ What indication(s) will be prioritized?
- ☐ What patients will be prioritized?
- ☐ What patient types will be prioritized?

Patient journey and stakeholder needs assessment

- ☐ What factors result in patient receiving medical treatment?
- ☐ What are the (prioitized) unmet needs of stakeholders – patients, providers, and payors – within our target market?
- ☐ Which unmet needs will motivate future behavior?

Competitive analysis

- ☐ What products will be competing in our target maket when we launch?
- ☐ How will our product be differentiated from current and future competition?

Payor/value analysis

- ☐ What benefits will our product provide?
- ☐ How will we articulate the value of these benfits to payors?
- ☐ How can we ensure that patients will have access to our product?

Figure 2. Checklist of key questions to answer

2. Apply stage-appropriate rigor

Being able to answer the key questions at any stage of development is important, but the rigor used and the amount of data and insights necessary will evolve over time. A low level of rigor can be used for high-level evaluations of opportunities, as a "gut check" for early assessments, or as a refresh on a previously made, well-informed, low-risk decision. Moderate levels of rigor are typically used to define upcoming strategic decisions, to inform strategic choices not associated with major investments, or to reassess previous decisions challenged by new data or insights. Significant rigor should be applied when seeking to make formal go/no-go decisions or pivotal decisions directly associated with significant investments or clinical milestones.

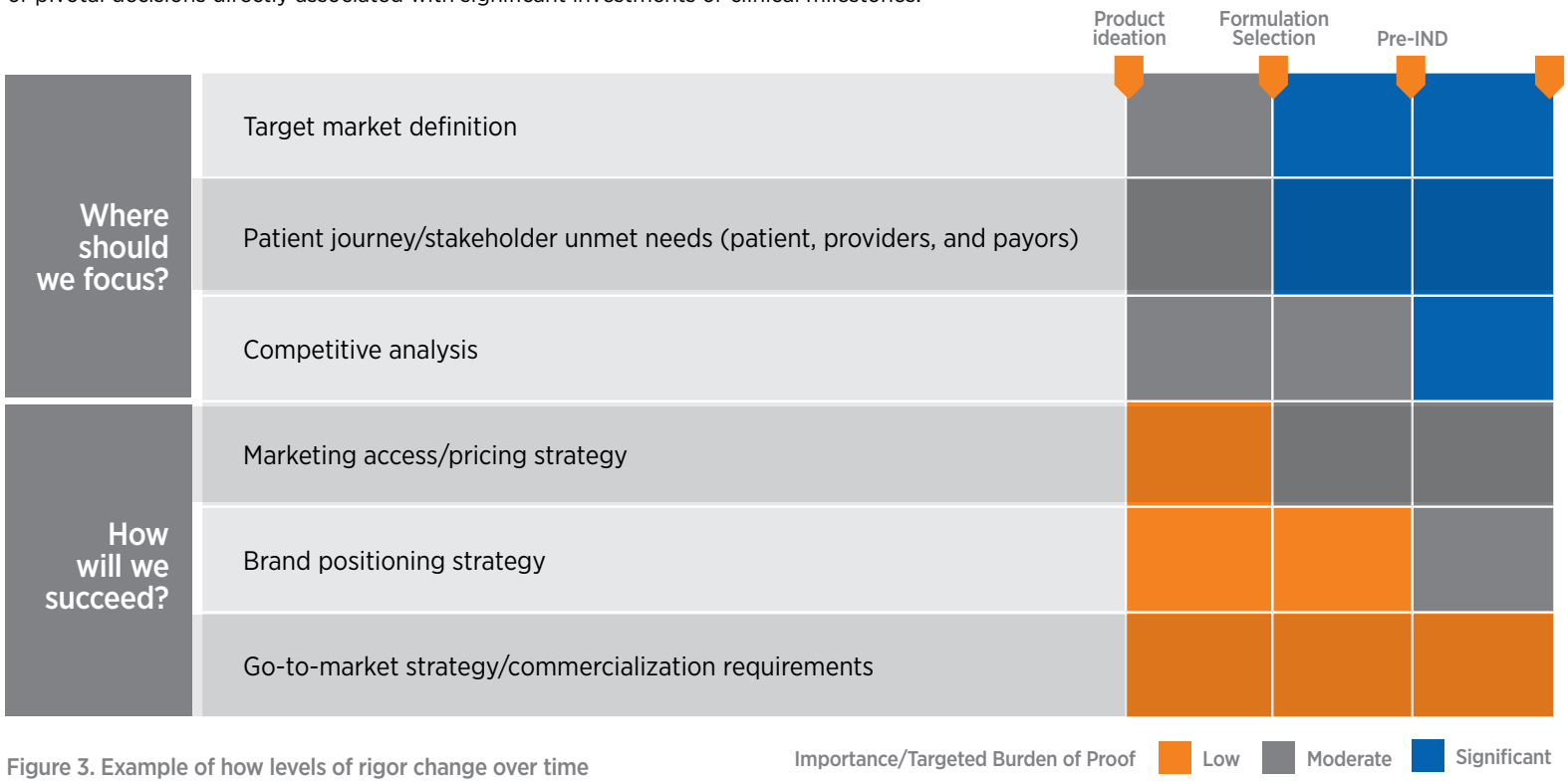

Figure 3. Example of how levels of rigor change over time

3. Be vigilant about refreshing or updating the TPP

Certain trigger events require an update or refresh of the TPP, including:

- Before any potential go/no-go decisions or incremental internal investment decisions
- Before discussions with potential external investors or commercial partners
- After new data is generated from the development program
- After new data is published by potential competitive programs
- After becoming aware of any other changes or shifts in the market that could impact access or uptake

Getting support for TPP development

A well-written, well-maintained TPP enables sponsors to document their development objectives and communicate them in a compelling fashion. At Premier Consulting, we understand that putting together a TPP requires commitment, persistence, and discipline. We also know it may be daunting. As a strategic product development and global regulatory consulting company, we are dedicated to helping biotech innovators transform their life-changing ideas and breakthrough science into new medical treatments. Our end-to-end solutions in strategy, regulatory, nonclinical, CMC, quality, and commercial help sponsors build and execute development plans that meet regulatory requirements and deliver results for themselves and the patients they serve.

Contact us to learn more about how Premier Consulting can help align development programs with regulatory and commercial objectives, or watch our free, on-demand webinar titled Leveraging the Target Product Profile (TPP) to Maximize Breakthrough Potential.

References

1. Breder CD, Du W, Tyndall A. What's the Regulatory Value of a Target Product Profile? Trends Biotechnol. 2017 Jul;35(7):576-579.

2. US Food and Drug Administration. Guidance for Industry and Review Staff: Target Product Profile – A Strategic Development Process Tool, Draft Guidance, March 2007. Available at http://www.ncai-cc.ccf.org/skills/documents/U.S.%20FDA%20Target%20Product%20Profile%20Guidance%20Document%20(2007).pdf

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About Premier Consulting

Premier Consulting is a strategic product development and global regulatory consulting company dedicated to helping biotech innovators transform their life-changing ideas and breakthrough science into new medical treatments.

Our end-to-end solutions in strategy, regulatory, nonclinical, clinical, CMC, quality, and commercial help sponsors build and execute development plans that meet regulatory requirements and deliver results for sponsors and the patients they serve.

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