BEGINNING WITH THE END IN MIND:
Using a Target Product Profile (TPP) to Guide Strategic Medical Device and Diagnostic Development

Introduction
Medical device and diagnostic makers face myriad challenges when developing a new product, including working within resource and financial constraints, deciding which opportunities have the highest return on investment (ROI), determining differentiating claims and positioning within the market and, in some cases, aspiring to the possibility of attaining multiple indications across multiple therapeutic areas. Developing a multidisciplinary framework to address these challenges and inform the decision-making process can provide medical device and diagnostic organizations with a significant advantage in early product development, resulting in a higher probability of approval and successful product launch.
The Target Product Profile (TPP), a concept originally aimed at pharmaceutical drug development, is a multidisciplinary strategic development process tool that can be adapted by medical device and diagnostic programs for product development. Implementing a robust and disciplined TPP process can help to drive alignment in cross-functional strategies, leading to more effective and cohesive product development.

**What is a Target Product Profile (TPP)?**

In 2007, the U.S. Food and Drug Administration (FDA) released draft guidance regarding the Target Product Profile (TPP) as a "strategic development process tool" that summarized a drug development program in terms of labeling concepts and facilitated discussion between the FDA and industry.1 In essence, the TPP is a living document that defines the value proposition and key differentiators of an intended commercial product and assists in the product development strategy.

A well-structured TPP includes a detailed analysis of the following aspects of a potential new product in comparison to a competitor product or standard of care (SOC):

- Desired indications
- Safety and efficacy or effectiveness claims
- Pricing and reimbursement
- Product valuation for each indication and, if possible, leading claims
- Differentiating product features
- Exclusivity measures to improve potential market share

Although the FDA Guidance document is aimed primarily at drug development, relevant principles of the TPP can be adapted to medical device and diagnostic programs, and the value of a well-planned TPP goes far beyond regulatory strategies to impact nearly every aspect of successful product development. In fact, many large Fortune 500 companies have adopted the TPP process to guide product development in their medical device portfolios.

The TPP is a common template that can be used for all products across a company portfolio to guide and align regulatory, preclinical, clinical, marketing, health economic outcomes and reimbursement (HEOR) strategies for a product from very early development to market entry. It assists companies in:

- Systematically comparing their product to SOC and/or a competitor’s product
- Developing and prioritizing indications and claims to pursue for their product(s)
- Identifying leading differentiating claims and, perhaps, product features that will be needed to sell their product(s) successfully

When executed correctly, the TPP process leverages multidisciplinary stakeholder input to define desired product labeling, which will drive cross-functional strategies (preclinical, clinical, regulatory, HEOR and market). Without the TPP process, companies often find each function writing their functional strategies in a vacuum without the input of the other functions. To make matters worse, Clinical Organizations may be asked to write clinical study protocols without ever discussing the key aspects of the TPP, which can lead to a wrong study design or even an expensive, and potentially unsuccessful, clinical trial. Thus, the TPP provides a clear advantage in ensuring cross-functional strategic alignment throughout product development and enabling identification of top opportunities with the highest return on investment.
Who is Involved in Developing the TPP?

The TPP development process involves extensive research and cross-functional discussions among stakeholders from the research and development (R&D), regulatory, preclinical, clinical, marketing, operations, and HEOR groups within a company’s product development program. These discussions usually occur over multiple face-to-meetings, with detailed reviews of each version of the TPP as it progresses.

While the TPP development process is typically owned by Project Management or the Project Leader, it requires parallel – rather than sequential – stakeholder input to ensure alignment at every step of product development, from early development to market entry. Parallel stakeholder input is vital for obtaining and ensuring ongoing multidisciplinary buy-in as the TPP document evolves, as the TPP will serve as the cornerstone for the individual departmental strategy development that will occur later on in the product development process.

What is the TPP Process?

The TPP process is an iterative one that should ideally begin after feasibility and it involves a thorough evaluation that includes:

- Due diligence/research, market data analysis and multidisciplinary brainstorming
- Target indications and claims
- Potential economic value of indications and claims
- The product’s best differentiating feature or outcome
- Strategy for positioning the product for exclusivity in the market

The TPP is a dynamic, living document that should be revisited and revised, as needed, throughout the course of product development. The more fully developed TPP then serves as a foundation for each function to begin to build and implement their strategies. As such, it can also be a useful tool for assessing, tracking and communicating any changes during the lifecycle of the development program, keeping in mind that, as a TPP changes, the functional strategies may need to be re-evaluated.

Performing Due Diligence, Market Data Analysis and Multidisciplinary Brainstorming

The first, and most time-intensive, step of the TPP process involves due diligence, market data analysis and multidisciplinary brainstorming on all possible indications and claims for the product, as well as the associated market potential for each indication and claim. The TPP stakeholders should:

1. Evaluate how the product performs and review existing literature on the product, competitive products and any treatment trends; and
2. Identify unmet needs and utilize thorough Voice of Customer (VOC) research to inform their brainstorming.

This process may take a while, but it is critical to take the time needed in order to obtain the most comprehensive and relevant supporting information on which the TPP will be based. Obtaining objective information also mitigates the risk of “group think,” that is, a situation where no one questions and everyone just goes along with the thoughts of other group members, even if there is evidence to the contrary. When brainstorming, it is important to not ignore the available evidence and to consider all possibilities, no matter how out of the box they may be. Some of the most innovative products have been developed based on thoughts or concepts that some would have considered crazy at first.
For each potential indication and claim, the team should determine the best comparator or SOC and gain an understanding of the regulatory and reimbursement environment. For example, based on the right safety, effectiveness and health economic outcome claims, could the potential product be reimbursed directly or would it just add cost to an otherwise maxed out Current Procedural Terminology (CPT) code?

Identifying Target Indications and Claims

Early identification of target indications and claims is an integral component of the TPP process, as it enables the company to select those indications and claims which have the highest potential reward and lowest risk in terms of probability of success. It also assists regulatory, preclinical and clinical teams in determining what data will be needed to support the selected indications and claims. Armed with knowledge about the supporting data required, sponsors are better able to design preclinical and clinical protocols that meet regulatory requirements.

Criteria to consider when selecting target indications and claims include:
- Will the indication validate the product’s clinical benefits?
- Will the indication demonstrate a competitive advantage?
- Is there a defined and efficient pathway to regulatory approval for the indication?
- Will the indication provide a foundation for expanded usages of the product in the future?
- What are the competitor products, treatment options or processes targeted at the same indication?
- What is the positioning of competitor products?
- Are there technical features of the product that might restrict its use to certain environments or anatomical sites?
- How do the potential contraindications of the product compare with current devices, treatment options or processes for the target indication?

Understanding Potential Economic Value

Calculating the potential economic value of a medical device for a specific indication and/or claim involves characterizing and validating current treatment patterns, as well as anticipating how the healthcare delivery system might evolve in the future. Factors to consider in the ever-changing healthcare landscape include market size, competitor pricing, target cost of goods sold (COGS), target pricing and the reimbursement environment. For example, if the proposed device is intended for use in single-stage breast reconstruction surgery, will it be reimbursed in countries that favor a two-stage reconstruction approach? Understanding the current SOC and how it differs from country to country and anticipating possible shifts in SOC for target indications may help sponsors to position their product for long-term success. A useful question to ask might be will the target indication and claim still be relevant to the market in five years, when clinical study data is available?

During this step of the TPP process, it is also important to identify whether potential claims could be related to time and cost savings or a reduction in adverse effects or complications when compared to current SOC or existing processes. These claims can support premium pricing strategies and contribute to the overall potential economic value of a product and, therefore, would need to be accounted for in protocol writing and study planning.
Determining the Product’s Best Differentiating Feature or Outcome

In order to achieve the highest ROI, it is critical to identify the product’s best differentiating feature or outcome, which may be related to either product design or product performance. This differentiating feature may help to support premium pricing for the product. For example, some transcutaneous aortic valves are difficult to reposition after they are deployed. If a company has developed a valve that is easily repositioned, this is a potential differentiator within the market, which could also have a major impact on patient outcomes. Once a differentiating feature or outcome has been identified, the TPP team should determine what data exist to support this differentiator and what data will need to be collected during development to support competitive positioning and marketing strategy for the product.

Gaining Insight into How to Best Position the Product for Exclusivity

The final step of the TPP process involves a multidisciplinary discussion on the best approach to positioning the product for exclusivity and market share, considering factors such as product availability, reimbursement data, regulatory classification, trademarking, branding strategy and intellectual property. As an example, if early product availability is a priority, the sponsor may choose to pursue clearance for a Class II device using the FDA 510(k) pathway with a general indication with a plan to expand to other more specific indications, rather than immediately pursuing specific claims requiring premarket application (PMA) approval. On the other hand, in order to gain exclusivity, a sponsor may elect to target a very precise and more rigorous product indication and claim, such as a reduction in a common widespread complication in a specified type of surgery which requires a more demanding and lengthy regulatory and clinical pathway to be able to develop the supporting evidence. In this case, high risk - high reward projects are not always popular, but should be considered along with the lower risk projects. The best positioning may depend on the organization’s tolerance for regulatory risk, as well as the organization’s resources.

A Sample TPP

- **Standard of Care or Key Comparator Device/Product**
  - Key Indications
  - Claims
  - Data support (none, on file, published)
  - Pricing
  - Reimbursement
  - Economic claims
  - Data support (none, on file, published)
  - Speed
  - Ease of use
  - Product availability date
  - Regulatory classification
  - Trademark/branding
  - IP

- **Your Device/Product**
  - Key Indications
  - Target Claims
  - Animal data support needed
  - Clinical data support needed
  - Pricing (select premium, parity, value)
  - COGS
  - Reimbursement
  - Economic data
  - Compared to current gold standard
  - Product availability date
  - Regulatory classification
  - Trademark/branding
  - IP
How is the TPP Used to Guide Strategy Development and Decision-Making?

A structured TPP ensures that a product development program is efficient and accounts for all of the relevant medical, technical, scientific and financial information needed to achieve a successful commercial outcome. If designed well and used properly, a TPP identifies issues early in the product development process and limits the likelihood of costly, late-stage development failures.

The TPP is invaluable for guiding strategy development across virtually every function of an organization, including R&D, regulatory, preclinical, clinical, operations, marketing and HEOR. Understanding treatment patterns and market trends, as well as the potential indications, claims and economic value associated with a product, aids in focusing R&D efforts. Early identification of target indications and claims helps to define study endpoints and labeling requirements that must be met, which is relevant for regulatory, preclinical, clinical and marketing teams. Careful study planning based on the TPP can potentially prevent trial delays and increase the probability of success. Target COGS and pricing can be used for developing a manufacturing strategy, while thorough evaluation of differentiating features and the current and future reimbursement environment is critical for HEOR strategy development.

The TPP process also streamlines the research involved in validating a product for development by leveraging multidisciplinary expertise and facilitating cross-functional communication. Applying the same disciplined and rigorous TPP to all products and indications in the organization’s portfolio provides Net Present Value (NPV) and ROI comparisons which enable informed portfolio decisions that prioritize products, indications and claims based on financial forecasts and provide a strong foundation for productive discussions with regulatory authorities, as well as investors and partners.

TPP Checklist for Success

Questions that Should Be Asked and Answered During the TPP Process:

- What is the product description?
- What data or literature is available for review for the various indications and claims?
- What is the unmet need, clinical benefit or value to others?
- Will the product be used for a new or existing procedure?
- What is the standard of care (SOC) for this indication?
- What is the future direction of SOC?
- What is the market potential for each indication and claim?
- What is the probability of success for each indication and claim?
- What are the product’s possible differentiating features and will they be obsolete in 5 years?
- What are all of the possible indications for this product (neurovascular, pulmonary, peripheral vascular, gastrointestinal, etc.)?
- What are all of the possible differentiating claims?
- Can premium pricing be justified?
- If so, will payors directly reimburse?
- How is the competitor successful?
- Where does the competition fall short?
- Does IP exist or can it be created?
- Can exclusivity be achieved with a more complex regulatory or clinical strategy?
- If so, what is the company’s tolerance or resource availability for such complexity?
- What are the COGS?
- How do development costs compare against five-year return on investment (ROI)?
- How does the net present value (NPV) or ROI compare against other projects?
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An essential multidisciplinary tool for Medical Device & Diagnostic companies, the Target Product Profile links regulatory, preclinical, clinical, marketing, health economic outcomes and reimbursement strategies and encourages active cross-functional communication from early product development through product launch. A disciplined TPP approach enables companies to “begin with the end in mind,” identifying and developing key strategic product attributes (indications, claims, differentiating features, etc.) required to meet unmet needs of patients and doctors. Using the same systematic TPP approach for all products and indications in their portfolios, medical device and diagnostic organizations can more easily make strategic portfolio decisions that prioritize products or investments; optimize the possibility of successful product approval and launch and maximize ROI; all while hopefully improving the lives of patients by placing the right focus on the right products at the right time for the right patients.

About Premier Research

Premier Research is a leading global contract research organization serving biotech, pharmaceutical and medical technology companies. The company has a wealth of experience in rare disease and pediatric research having managed about 100 projects in each area in the last five years alone. Its services include clinical research and regulatory outsourcing in the areas of analgesia; neurology; infectious, cardiovascular, and respiratory disease; dermatology; oncology; and medical devices.

Premier Research operates in 50 countries. It employs 1,000+ clinical professionals dedicated first and foremost to fulfilling each customer’s requirements in a timely, accurate, and cost-effective manner. This includes a strong international network of monitors and project management professionals combined with regulatory, data management, statistical, scientific, and medical experts, and staff at its well-established network of dedicated clinical sites.

Kimberly Hunsicker, MSN, CRNP, MBA
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Ms. Hunsicker comes to Premier Research with extensive leadership experience in global clinical research and product development. Most recently she was Senior Director, Global Clinical Operations at LifeCell Corporation, Bridgewater, NJ, where she was responsible for executive oversight of all global clinical research and development activities, the execution of complex strategic clinical plans and compliance with regulatory requirements worldwide. Perhaps even more important, she demonstrated a consummate ability to foster cross-functional relationships, communication and cooperation. Prior to LifeCell, Ms. Hunsicker was Vice President, Global Clinical Operations at Allergan Medical, Vice President, MD&D Project Management at Novella, and Director of Clinical Programs at J&J’sClosure Medical. She received an MBA from Moravian College, Bethlehem, PA and Master of Science in Nursing degree as a Certified Registered Nurse Practitioner from Villanova University, Villanova, PA.

“Medical device clinical research requires a special understanding of all types of unique medical devices and diagnostics, with a host of different patient populations. That’s what makes it so interesting and so exciting!” – Kimberly Hunsicker

References