KPMG

Target Product Profiles in Pharmaceutical Development

Introduction

Challenges with Drug Development

Fifteen (15) years and $2.8 billion, this is the estimated cost of successfully bringing one drug to market in an industry where over 1 in 10 drug candidates never progress to approval. Causes of failures range from lack of clinical efficacy, unmanageable toxicity or side effects and poor pharmacokinetic (PK) profile.

The cost of these failures push up the costs for approved drugs as developers require a return on investment (ROI) to support future innovation. However, payers have increasingly mature policies and frameworks in place to determine the maximum price they are willing to pay often at a steep discount.

It is notable that in one review 10 % of failures were attributed to lack of commercial interest and poor strategic planning. In our own experience companies have experienced significant delays and unexpected costs at all stages of clinical development where changes were required either following internal review or following engagement with regulators. The cost of poor planning can require late stage Chemistry Manufacturing Controls (CMC) changes and costly comparability studies, restrictions to label and requirement to perform costly Phase IV studies and restrictions on reimbursement and therefore access.

Regulatory bodies such as Federal Drug Association (FDA), European Medicines Agency (EMA) and the UK's Medicines and Healthcare products Regulatory Agency have recognised these challenges and offer a wide range of programs designed to support and where possible expedite clinical development. However, to truly maximise these interactions the company needs to present a clear development plan with the end user, the patient and Healthcare professional (HCP), at the centre. One of the key tools to communicate this plan is the Target Product Profile (TPP).

What is a Target Product Profile?

Per the WHO definition, 'A Target Product Profile (TPP) outlines the desired 'profile' or characteristic of a target product that is aimed at a particular disease or diseases TPPs state intended use, target populations and other desired attributes of products including safety and efficacy-related characteristics. Such profiles can guide product research and development'[1].

Key questions that can be answered in a TPP are critically important to the decisions taken by the internal development teams eg.

- **Indications:** What is the expected commercial label?
- **Population:** Which markets will the product be launched and which patients have the highest unmet need?
- **Clinical Efficacy:** What are the recognised endpoints for the indication, and what would constitute a significant benefit over existing treatments?
- **Safety and Tolerability:** Consideration to setting in which the drug will be taken and quality of life improvements with improved safety profile
- **Stability:** Any special storage requirements, and in use stability?
- **Route of Administration:** Benefit to the patient in terms of use, requirement for a delivery device, when will that be developed?
- **Dosing Frequency:** What is the current Standard of Care, benefit of reduced frequency of dosing?
- **Cost:** Cost per dose target, commercial team modelling and timing for Health technology assessment (HTA) engagement?
- **Time to Availability:** Competitive landscape analysis.

When should I have a TPP in place?

A TPP is a valuable document to guide all of the disciplines involved in progressing a candidate from discovery to First-In-Human (FiH), through pivotal trials to commercial. Therefore, the earlier in development it can be implemented the bigger the benefits to teams determining candidate selection, non-clinical models, manufacturing process and clinical development leads.

The concept of the TPP was originally developed by the Food and Drug Administration (FDA) to facilitate communication between the organization and industry[3]. One of the most valuable meetings in early development is the FDA Type B Pre-IND meeting. Having a version of the TPP presented at this meeting allows for more fruitful conversation with the multidisciplinary teams at the FDA allowing for greater understanding of target indication, patient population and feedback on trial design but also on requirements to accessing expedited pathways.

The document can also serve as an excellent resource when engaging with investors and during due diligence activities add significant clarity.

Benefits of a TPP

- **Serves as a multiple function such as strategic tool for the manufacturers, technical dossier.**
- **Communication tool between the R&D and commercial functions.**
- **Helps in evaluating the progress of the drug development process**
- **Helps in preventing failures at a later stage of development**
- **Improved regulatory outcomes[2],**

KPMG clinical, regulatory experts are ready to provide support to evaluate the competitive landscape, unmet medical need, attributes of existing, approved products, regulatory guidelines and other relevant details and support to draft a high quality TPP.

We will help you to create a streamlined TPP for therapeutic products which will serve as a strategic map for your asset, either small molecule drugs or therapeutic proteins, used to treat or cure disease. We can assist in TPP generation for assets at all stages of development, whether early in development, innovative product or re-purposed asset in life cycle management.

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[1] https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/who-target-product-profiles

[2] Bandyopadhyay A. Target product profile: A planning tool for the drug development. MOJ Bioequiv Availab. 2017;3(4):111-112

[3] Adria Tyndall, Wenny Du & Christopher D. Breder The target product profile as a tool for regulatory communication: advantageous but underused, Nature Reviews Drug Discovery 2017

Our Expertise

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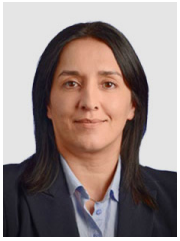

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