Review Article
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Target product profile: A planning tool for the drug development

Abstract

Drug development is a very expensive and time consuming process. Industries develop a tool known as Target Product Profile (TPP), which is simply a planning tool for the development of a drug candidate from discovery to clinical development programs. This establishes safety, efficacy, and marketing suitability of the drug. FDA issued guidance on TPP for better communication between the sponsor and regulatory agencies, with an emphasis of drug development towards intended labelling content and promotional claims. It lacks insight towards marketing viability of the development program. To get marketing success, Industries incorporated strategies within the framework of FDA guidance. Such strategies having three components:

a. Target market profile, the foundation of framework

b. Strategies target profile, the steps for reaching marketplace

c. Target product profile for market launching. This framework guides the clinical development decisions and builds the foundations for commercial success.

Keywords: drug development, clinical development, project plan, TPP, food and drug administration

Volume 3 Issue 4 - 2017

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Received: October 01, 2016 | **Published:** July 28, 2017

Abbreviations: TPP, target product profile; FDA, food and drug administration; GMP, pharmaceutical good manufacturing process; QBD, quality by design; PAT, process analytical technology; TMP, target market profile; STP, strategic target profile

Introduction

The aim of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product. Many new regulatory initiatives were introduced in the last decade e.g. Pharmaceutical Good Manufacturing Process (GMP) for 21st Century,[1] Quality by Design (QbD).[2] Process Analytical Technology (PAT)[3] and Quality System initiative.[4] All these approaches provide a better understanding of the products. Since pharmaceutical development takes approximately 10 years with a cost of close to a billion dollars, a tool is required that provides a structured plan. Such a tool is known as Target Product Profile (TPP).[5–7] It is simply a planning tool in the development stage of Pharmaceutical R&D process, in which a drug candidate from discovery is subjected to clinical development to determine safety, efficacy, and marketing suitability. This concept was originated in 1997 through discussions between FDA and a Clinical Development working group for improving sponsor and FDA interactions.[5,6] The working committee recommended the use of a "template" that summarizes a drug labeling concept to help focus discussions and aid in the understanding between sponsors and the FDA.[7] The outcome of the discussions resulted in minimization of the risk of late stage drug development process, increasing the probability of obtaining optional safety and efficacy data in a timely manner, improving labeling content and possible minimization of time involved in drug development.[7]

TPP key elements

TPP is an important part of the drug development project. If TPP is used properly it designs clinical research strategies', decision making within the organization and constructive communication with the regulatory authorities. The specific key elements of TPP[4,5] are:

a. Therapeutic moiety, Dosage form, strengths, route of administration, rate of administration and desired in vitro and in vivo release of the drug

b. Manufacturing information

c. Product packaging information including container/closure, quality of the product including stability, sterility, purity, and proposed expiration date

d. Target patient population (e.g. age, sex, general health, mental awareness and any cultural factors)

e. Clinical setting (acute vs chronic, severity of the condition and target duration of treatment)

f. Phase I study results on safety, tolerability, absorption, clearance

g. Bioavailability and other pharmacokinetic parameters

h. Phase 2 and 3 studies including minimum effective dose, patient/investigator feedback, safety, efficacy and adverse events

TPP is a starting point of the development project planning and the following areas are also within the framework of the project.[4]

a. Strategy

b. Clinical and marketing requirements and priorities

c. Patient requirements

d. Technical requirements (research and biological features development)

e. Comparison between desired vs minimally accepted features

To initiate above activities several project teams are required, each of which consists of the members from sponsors, scientists, and marketing group and higher management.

TPP strategy

As mentioned earlier, FDA issued guidance on TPP for better communication between sponsor and regulatory agencies with an emphasis on drug development towards intended labeling content and promotional claims.[7] It lacks insight towards marketing viability of the development program. In order to get marketing success, strategies are required to develop within the framework of the program8. Product go/no-go decision making or clear format for the progress discussions of intra-company project team or enhance development for better marketplace or better communication to investors, portfolio managers and senior management are all important strategies and are required to build within the framework of FDA's definition of the TPP. Such strategic framework is based on three components.[8]

a. Target market profile (TMP)

b. Strategic target profile (STP)

c. Target product profile (TPP)

TMP is the foundation for the framework and it provides marketing information e.g. how the potential product would fit into medical practice by computing the needs of the current and future stakeholders and understanding pharmacogenomics benefits. When there is a major market shift, YMP will change and it requires updating at that time.

STP provides the information on how to reach marketability. The STP describes the specific solution needed by the marketplace as described in TMP. The STP should be consistent with company core competency, mission and strategy. Furthermore, it (STP) is a valuable decision-making tool for determining the viability of the program from the onset and is the benchmark to assess continuing investment at each stage. The TPP is the product profile of the drug which needs to be launched. TPP is also a record for clinical development program to guide the number, design and timing of clinical findings and product attribute.

Advantages

Market approval

There are several advantages for TPP. It helps project teams, and various functional teams as well as higher management teams to project or review various aspects of drug development process.[7] This increases the probability of obtaining safety and efficacy data in time and can minimize the risk of late stage drug development failure. Moreover, it allows for improved label content as wells as a decrease in the total amount of time spent on the entire drug development process. Apart from this, TPP can streamline the interactions with FDA by focusing meetings on various changes and also can save FDA meeting times, for example, by allowing the sponsor to bypass discussion of the history of the drug development programs.[7]

Other sections

Other sections of TPP that may not be necessary for marketing approval documents but contain marketing information that the higher management teams would like to consider during drug development process. This includes Primary markets, Pharmacogenomics, various expenses, target Price, various standards, and possible product extensions.[7,8]

Conclusion

Thus it is concluded that TPP is a valuable tool for drug development when the marketing attributes are integrated within the framework of FDA's definition of the TPP. This framework not only guides the clinical development decision, but also the foundation for marketing success. It also contributes to the ultimate goal of driving greater efficiencies and shorter timelines to the approval of an optimally marketable and profitable product.

Acknowledgements

None.

Conflict of interest

The author declares no conflict of interest.

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