Developmental Pathway of an Investigational Product

Client's Name

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Introduction

In every industrial product, the developmental pathway is considered the most prominent step, which includes developing the product to its testing on a clinical level, so that it can be available commercially. The initial step in the developmental pathway consists of product manufacturing, after which the applications of the product are correctly analyzed. This phase in the developmental path is referred to as the non-clinical phase. If the product's benefits are more than its limitation during this phase, it is further processed into the clinical stage [1]. During the clinical phase, different experiments are performed on the product and determine whether the product has enough benefits or applications to be marketed commercially. For instance, in developing a new pharmaceutical drug, the first step is determining its applicability to the human body. If the clinical researchers find out that a particular product is beneficial in treating serious illnesses, then its detrimental impacts on the human body are determined. After determining the side effects of the human body during the clinical trials, the results are estimated [1]. If the specific drug has greater applications with its side effects nearly negligible, the researchers considered it suitable for usage on a commercial scale.

Milestones in a Developmental Pathway of an Investigational Product

Before the marketing of the investigational product, the product has to go through several processes during which the effect is investigated, and these investigational processes are referred to as the milestones of the developmental pathway. The most dominant milestones of the developmental path include product manufacturing, pre-clinical research, clinical trials, and approval from authorized bodies [2].

Product Manufacturing

Product manufacturing is the first step in the developmental pathway during which the researchers investigate the needs for the development of the product. For example, with the sudden outbreak of the Coronavirus-19, the researchers think that it is the need of the hour to synthesize a product, i.e., vaccine, that helps minimize the increasing trend of the illness throughout the globe [3]. As a result of this need, the researchers investigate different processes and discover a new product that solves the pandemic's concern.

Pre-clinical Research

Prior to the clinical research, pre-clinical research is performed during which laboratory animals are employed, and the impacts of the product are determined in such animals. If the product causes side effects in laboratory animals, then such product is not further processed into the clinical phase and is thus eliminated from the developmental pathway [2].

Clinical Research

After passing the pre-clinical research, the product is tested clinically on human participants as the metabolic system of the laboratory animals is closely related to that of humans [5]. Therefore, the safety is ensured that the investigational product would not have any side effects on the humans, which may be harmful.

Approval

The last phase of the developmental pathway is approval; in which it is determined whether the product is meeting the specific standards or requirements of the governing authorities. For example, in the case of drugs, approval from the Food and Drug Administration

is essential [5]. Once the FDA approves the product, it is marketed commercially to benefit from it significantly.

Components of IND

Investigation New Drug (IND) comprises several components that help the FDA determine the initiation of the clinical trials. The two most important element of IND includes the reasoning for the product and its safety in humans. The FDA only allows and supports the clinical studies and investigation of those products whose primary purpose is to serve humanity. For instance, to eradicate COVID-19 from the globe, the FDA emphasizes the researchers to bring forth products or drugs that help kill such a deadly viral strain. Thus, if the intention and purpose of marketing the product are valid in front of the FDA, it would allow its clinical studies [2]. Secondly, safety is an essential aspect that the researchers must keep while taking the product to the FDA for review. The FDA only allows the clinical trials of those products that have succeeded in pre-clinical research and have not shown any significant side effects [5]. If any drug successfully treats the particular illness but shows substantial detrimental impacts on the laboratory animals, the FDA would never support clinical studies.

The Difference in Applications of Drugs, Biologics, and Devices

Drugs, Biologics, and Devices have several applications and help make humans' lives easier and more comfortable. Concerning medicines, their most important application is the treatment of serious illnesses such as cancer, viral, or bacterial diseases. On the other hand, different devices such as ventilators commonly used within hospital facilities serve as the savior of human lives. During the developmental pathway of the drugs and devices, review and approval from the FDA are mandatory [4]. On the contrary, biologics are also essential, and extra

preventive measures are taken during their development, as they are derived from the organisms; therefore, they can have more side effects during clinical studies. During their development, the approval of the Provincial Health Services Authority is essential.

Conclusion

Thus, it is concluded that for the successful marketing of the investigational products, different clinical and non-clinical phases are essential during which the applications, side effects, and safety of the product are ensured. The investigational products must have a practical purpose behind their discovery and should be tested on laboratory animals in pre-clinical research. If their safety meets the specific requirements, it enters the clinical phase. Lastly, after completing the clinical stage, the investigational product is ready to be marketed commercially once it receives approval from the authorized and regulatory bodies.

References

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