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CRITICAL SUCCESS FACTORS OF EFFECTIVE DRUG DEVELOPMENT PROCESS: AN ANALYTICAL STUDY

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ABSTRACT

This article is aimed to describe factors which are effective towards the success of drug discovery and their development process. According to the research, there is no single explanation on behalf of this discussion as the content outlines crucial factors on its enhancement. Drug development is very critical process, because it helps to treat contemporary diseases and fight the new ones which are within the human populace. Before a drug can reach to an affected person, it should consider successful and rigorous factors that encourage the pharmaceutical developmental programs decide whether it's far safe, powerful towards treating the severe circumstances and also help them to, envision the correct dosage as well as the suitable administration path. The mentioned factors in the below section, are several outcome of this research therefore, such theories help pharmaceutical industry to study their capability techniques and encourage them to enhance medical development fulfilment prices and its productivity also. Advancement in sciences and technology is also helping this industry with many unique processes and level, from their ideation to development to its approval. There are many pharmaceutical drug development programs which are based on a global strategy that results to predictable expedited approval outcomes.

KEY WORDS: Pharmaceutical industry, Drug development, Contemporary diseases, Science and Technology, Administration.

INTRODUCTION

Drug development can be described as an entire process or a technique to bring a brand new drug or a tool in a market, which is an integrated, multidisciplinary therefore, undertaking several factors like medical trails, non-clinical safety checking out and regulatory permissions (Zurdo, 2013). The developers of medicine are on a venture for an efficient drug development procedure that can tend to isolate a drug molecule with an excessive opportunity of achievement which will help the researchers to bring it from "bench to beside" quicker (Petrova, 2014). It can basically be defined, as the process or method of drug improvement as

well as bringing a brand new pharmaceutical drug to the market as soon as a lead compound has been recognised through the method of their discovery. Procedure of drug discovery includes the identification of drug candidates, combination of compound and molecules, screening, characterisation as well as assays for therapeutic efficacy.

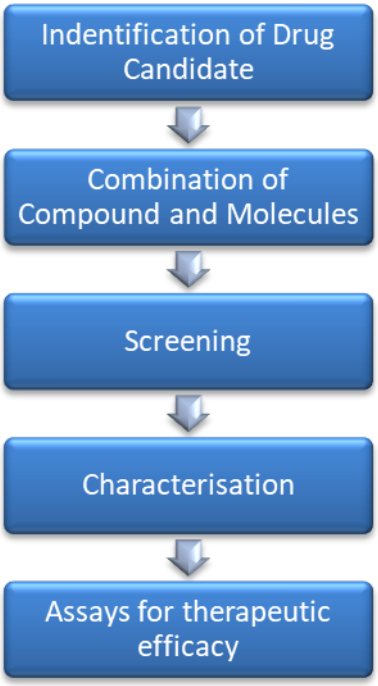

Figure 1 Typical Process of Drug Development

It is considered as an expensive process because of the high budgets by Research and development department as well as their clinical trials. During the process of effective drug development the average cost by R&D department for every efficacious is probably expected to be around $950 million to $2 billion. They take almost 13-15 years to come about and develop a new drug molecule from the time, as it has been brought properly then they are available in market for treating sufferers with several health issues. For its success, there are numerous factors which need to be required to keep fuelling new medicines that will help to cure and palliate many illnesses and few untreatable diseases that still afflict humanity. These compounds ensure to have a healing impact on the intended health issues, and then by identifying them it tends to check out for protection and its effectiveness begins. Therefore, generally most effective ones like 1 out of 6000 drugs or tablets make it towards the marketplace approval stage. Process of drug development requires a tremendous amount of time despite, they must follow some successful factors which will we explained briefly through this paper, so that its ingredient can go through many stages from their discovery to

their approval (Paul, et.al, 2010). Such drugs are stated to be a secure one only after it considers the described these successful factors and when an in-depth research is done. But, after inclusion of such factors the procedure of drug development and then bringing it to the marketplace is a very expensive process. Here, we are also able to delve into their different stages and ideas of drug improvement in various details that will ensure to assist the healthcare experts design and strategies a strong R&D that expedites its improvement and approval process. The mentioned trials offer them to examine and have a look at their specific goals that would eventually help them to identify and make sure with the safety of human individuals involved within the trails. Design and its development must go through certain implications to have an effect on an illness. While, designing a drug the R&D department must have an intensive expertise and knowledge of the medical scope and their target tends to play a precise part in that condition. Numerous screening methods are applied to find a structure based design and a hit compound which interacts with the desired target. Adoption of AI will also encourage developing and gathering huge amounts of treasured, chemical and structural data for faster H2L maximisation. The access to post market safety surveillance is also a critical factor on its evaluation as it aids to evaluate the drugs long term safety and its effectiveness after; it is approved and brought in the marketplace (Corsini & Ceska, 2011). These successful factors will help and provide us with some details which are related to the development process. It goes through intensive testing and clinical trials which are some of the essential factors needed to determine if the drug is safe or not (Hughes, et.al, 2011). Additionally, such factors are very beneficial and will be discussed further on how they are needed for drug optimisation for its efficacy and safety. Therefore, at the end the medicine gets approved and hence, the labelling process begins.

LITERATURE OF REVIEW

The drug development process is a complex intricacies which are sometimes seem to be impossible to determine the direction (Naylor & Chen, 2010). There are several guidelines, approaches, factors and standards that all people connected with the process are expected to follow and observe. It encourages numerous factors that help into getting a new medicinal drug to open marketplace which results after many phases of scientific research. Drugs are a substance other than food though, they are helpful and used to diagnose, treat and provide us relieve from symptoms related to a health issue, disease or from some peculiar condition. It is a chemical which alters processes inside the organism, and such chemicals are then utilised in

the medication for prevention, analysis and towards the treatment of a disease (Dias, et.al, 2012). But, before creating a new drug, the pharmaceutical organisation needs to consider several factors which are critical and required to prove that the proposed drug is very safe and effective. There are pivotal roles played by FDA, numerous researches and studies are conducted by R&D departments as well as pharmaceutical organisations within a huge time period to achieve an effective drug development procedure. It also includes regulatory bodies, principle investigators, laboratories, and surely the patients also. Drug development is a very long procedure which requires a lot of investments during its stages of evolution and they also help us to examine and monitor its effectiveness as well as side effects. The effectiveness of drug is only addressed by considering comprehensive factors on its development process (Robinson, et.al, 2015). Process of drug development is a lengthy process but rightly it should undergo certain factors like:

ASSESSMENT OF THE SAFETY PROFILE OF LEAD COMPOUNDS: This is one of the most critical factors while associating the laboratory based drug development with scientific and human trials. It helps them to identify the lead compound during the drug discovery by undertaking rigorous transition procedure and they are hired between the discovery and preclinical development step by several initial testing's related to pharmacology and toxicology (Alanine, et.al, 2003). Such factors are very crucial before the drug development procedure as it helps to assess the safety profile of the lead compounds using non-clinical animal studies. Safety profile of lead drug compound is very crucial because it will make us realise with the fact that it would not result in any kind of adverse effects.

PRE-CLINICAL PHASE: Then comes the pre-clinical phase where after assessing the lead compounds during the developmental process such compounds are afterwards refined, optimised and extensively tested in R&D department or laboratories of pharmaceutical organisations and they are examined in an animal or several alternative models (O'Brien, et.al, 2011). Before undertaking such trails, it must be ensured that the lead compounds are available in sufficient quantities during these studies. The major aim regarding this factor is to provide sufficient evidences of safety and efficacy and once such factors are assured it is useful in drug development process.

CLINICAL PHASES: The clinical phases are described under four stages for an effective procedure towards drug development. Phase 1 makes us realise that for an effective drug, the

active compound must be strictly controlled and manufactured under the guidelines of GMP conditions “Good Manufacturing Practise”. The above mentioned stage helped to realise its tolerance and effectiveness which were tested in a small group. After that, phase 2a and 2b were able to observe its effectiveness, tolerability and their dosage in a very larger group. These phases help to find right dosage. Therefore, the end phases 3 and 4 thus, the drug is tested among thousands of patients to check its effectiveness and safety in different patients. If these phases are successful then the manufacturer of pharmaceutical organisation can apply for its approval, which will eventually lead towards an effective drug in the market.

REGULATORY APPROVAL: These factors are undertaken during its development process, so that the drug is designed in such a way that we can assess a long term effect of the drug (Scannell, et.al, 2012). After the completion of clinical trials of the drug, the data collected during the process is analysed, examined and collected. Therefore, for its success and proper approval the collected data’s are then submitted to the appropriate authorities for a review. Before the drug or vaccine is brought in the marketplace it needs get an approval from a national regulatory authority. Ultimately at the end, only one compound makes it through and gets approved as a drug. Such factors during its process is very time taking because all results of drug discovery and testing needs to be presented to the competent authority with extensive documents.

POST MARKET MONITORING: After, receiving approval from National regulatory authority and marketing authorisation, the data is then collected regarding its effectiveness and safety. The collected data will help the drug developers of pharmaceutical industry realise the popularity of drug among patients taking the drug during health issues for medications ensure to compare with other treatments that are already available in the marketplace (Kesselheim & Darrow, 2015). Such monitoring will provide enough evidences to record and avoid numerous adverse events of the drugs during its development process.

TARGET IDENTIFICATION AND VALIDATION: It is one of the most successful factors in designing an effective drug thus; it will make researchers get a crystal clear understanding of the original and development of a disease. This helps them to understand the potential targets and identify them by the sources available. Therefore, after the validation and identification of targets the researchers or drug developers tend to validate their suitability towards the drug development before going through several screening test to identify their hits (Mohs & Greig, 2017).

HIT TO LEAD: Before moving further, the hit term can be referred to describe a chemical compound (lead compound) that has a desired healing impact to a recognised target molecule (Hoelder, et.al, 2012). The lead is manufactured compound from the screening process, thus it may be utilised in advanced stages. This factor is one of the most essential factors in the early stages of the drug discovery process. Therefore, the principle purpose of the H2L is to discover an appropriate leads to move alongside the pathway to a final clinically active drug.

LEAD GENERATION AND OPTIMISATION: The main motive towards drug development process by the mentioned factor is that, it helps to discover the proper and appropriate leads to move alongside the hit to lead process. It aims to enhance the most promising lead compound to encourage its effectiveness, lower the toxicity as well increase absorption. But, the lead properties must be adequate to examine its optimisation.

Even after such factors while outlining the process, the monitoring of drug in the area of application and risk-benefit ratio should be continuously monitored. For its more success, the globalisation is very crucial to provide the access to markets and new opportunities for drug discovery (Khanna, 2012). New sources of advanced technology and AI tools are being introduced in this sector for rapid testing of large number of compounds required in drug discovery process.

CONCLUSION

In simple words, through this above mentioned context help us conclude that, there are no simpler methods or process during the drug development process and one successful lead compound after its discover is no guarantee for a maintained pipeline. Therefore, it concludes that not a single pharmaceutical organisation is immune towards the direction of patent expires, bad price stress and failing of drugs. The productivity or drug development process will not be effective only because of some biological complexity and lack of expertise on such processes. Drug development needs to consider robust phenotyp-ic impact of the westernised way of life into the mind as sickness patterns unexpectedly changing. Pharmaceutical companies needs to better understand the needs of scientists and peoples working in R&D department as the lead drug compounds are finally developed and discovered by them, so they should also realise their terms of freedom to explore ideas and vital budget, in place of managerial attempt to control. If the above mentioned factors are encouraged in pharmaceutical industry then, the produced drugs to treat health issues will tend to enhance its reputation in the eyes of our society.

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