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Commentary

Drug Discovery and Development Process

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Abstract

Only a tiny percentage of compounds that are discovered as candidate pharmaceuticals are authorized as new drugs each year; by drug discovery and development process, we refer to the pipeline of pharmaceutical research and development from concept to after the patient. Despite advancing technology and more knowledge and understanding, the amount of innovative medications produced and FDA-approved has not grown. In addition, the price of research and development is rising.Work being done to help allay these worries is interesting given the lengthy timescales, rising costs, and complexity of the drug discovery process. Having said that, novel pharmacological modalities have been investigated that go beyond small molecules and may lead to new therapy approaches; patient stratification may expedite discovery and lead to more targeted development.

INTRODUCTION

The process of finding prospective new drugs is known as drug discovery. It crosses several different scientific fields, including as biology, chemistry, and pharmacology.

DESCRIPTION

There are several stages and steps involved in the drug discovery process. It may often be broken down into four major stages:

- Early Drug Discovery
- Pre-Clinical Phase
- Clinical Phases
- Regulatory Approval.

Let's examine the key actions that each of these stages of developing a new medicine takes.

1. Early drug discovery: There are several actions and tests involved in the early drug discovery process. In order to find and improve prospective leads to a certain objective, researchers work together. In order to potentially treat a disease, the leads essentially need to have a desired impact on a particular biological target. Currently, in silico platforms, biochemical tests, cell cultures, and numerous animal models are used in the laboratory to conduct research. Target Identification and Validation, High Throughput Screening or High Content Screening, Hit Identification, Assay Development and Screening, Hit-To-Lead (H2L), Lead Generation and Optimization, and In Vivo and In Vitro Assays are the sub-processes that are involved in this step (Lee D, 2013).

2. Pre-clinical phase: The second step is the Pre-Clinical Phase, one of the four main stages of the drug discovery process. The compounds discovered during Early Drug Discovery are thoroughly investigated in a lab setting as well as using animal or alternative models throughout the Pre-Clinical Phase. Prior to Human Clinical Trials starting, there must be adequate proof of safety and efficacy. Once this is established, it is also helpful to determine the right dosages to test in humans. It must be guaranteed that the new chemical will be accessible in appropriate amounts during the clinical investigations before the Clinical Trials begin. Previously, only tiny quantities were needed, thus manufacturing now needs to be adjusted to the vastly increased demand in the Clinical phase (Steuer AE et al., 2019).

3. Clinical phases: Phase I, Phase II, Phase III, and Phase IV make up clinical trials. Each of these stages will be covered in more detail in the following sections. However, in the first stage, a relatively small number of healthy subjects—typically 20 to 80—will be used to examine the drug

candidate's tolerance and safety.

Phase I: Phases II(a) and II(b) are initiated to assess the efficacy, tolerability, and dose in a larger group once tolerance and effectiveness have been examined in a small group. The dosage form is initially created for this.

Phase II: The goal of phase II(b) studies is to determine the proper dose, while phase II(a) studies focus primarily on the therapy concept (proof of concept). 100 to 500 adult study participants are typically enrolled in phase II studies.

Phase III: In the final stage prior to a potential drug approval, doctors test the medication on thousands of patients to check if the efficacy and safety can be verified in a wide range of individuals. Additionally, medication interactions are examined (Pascal Kintz, 2006).

Phase IV (Post-Market Monitoring): Studies commonly referred to as post-marketing surveillance trials, are conducted following receipt of regulatory approval for marketing. On the efficacy and safety of the new medicine, more thorough data may be acquired. More people using the medication allows for more data collection and allows for comparison to other existing therapies. These studies are intended to evaluate a drug's long-term effects. Adverse occurrences can be noted and prevented in this way (Crown D et al., 1988).

4. Regulatory approval: Data is then gathered and evaluated when a clinical trial for an active drug is complete. The necessary authorities can then evaluate it after it has been filed. A national regulatory body or centralized mechanism must get approval before a medication or vaccination may be commercialized. In the end, only one of the many chemicals studied successfully passes the regulatory testing and clinical trial phases. Due of this, only one chemical may be used to make a medication or vaccine (Pesce A et al., 2012).

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CONFLICT OF INTEREST

Author declares no conflict of interest.

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