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Overview to Drug Development Process

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ABSTRACT

Drug development processes as a overview, a basic idea regarding a process Many tests of molecular compounds to find possible beneficial effects against any of a large number of diseases. Existing treatments that have unanticipated effects. New technologies, such as those that provide new ways to target medical products to specific sites within the body or to manipulate genetic material, Steps in Drug Discovery process.

Keywords : Drug Development, Research, Preclinical Research, Clinical Research

I. INTRODUCTION

In the fields of medicine, and pharmacology, drug discovery is the process by which new candidate medications are discovered. Once a compound that fulfills all of these requirements has been identified, the process of drug development can continue, and, if successful, clinical trials.

- New insights into a disease process that allow researchers to design a product to stop or reverse the effects of the disease.
- Many tests of molecular compounds to find possible beneficial effects against any of a large number of diseases.
- Existing treatments that have unanticipated effects.
- New technologies, such as those that provide new ways to target medical products to specific sites within the body or to manipulate genetic material.

At this stage in the process, thousands of compounds may be

Potential candidates for development as a medical treatment. After early testing, however, only a small number of compounds look promising and call for further study.

Discovery

Discovery often begins with target identification – choosing a biochemical mechanism involved in a disease condition. Drug candidates, discovered in academic and pharmaceutical/biotech research labs, are tested for their interaction with the drug target. Up to 5,000 to 10,000 molecules for each potential drug candidate are subjected to a rigorous screening process which can include functional genomics and/or proteomics as well as other screening methods. Once scientists confirm interaction with the drug

target, they typically validate that target by checking for activity versus the disease condition for which the drug is being developed. After careful review, one or more lead compounds are chosen.

Product Characterization

When the candidate molecule shows promise as a therapeutic, it must be characterized—the molecule's size, shape, strengths and weaknesses, preferred conditions for maintaining function, toxicity, bioactivity, and bioavailability must be determined. Characterization studies will undergo analytical method development and validation. Early stage pharmacology studies help to characterize the underlying mechanism of action of the compound.

Formulation, Delivery, Packaging Development

Drug developers must devise a formulation that ensures the proper drug delivery parameters. It is critical to begin looking ahead to clinical trials at this phase of the drug development process. Drug formulation and delivery may be refined continuously until, and even after, the drug's final approval. Scientists determine the drug's stability—in the formulation itself, and for all the parameters involved with storage and shipment, such as heat, light, and time. The formulation must remain potent and sterile; and it must also remain safe (nontoxic). It may also be necessary to perform leachable on containers or packaging.

Pharmacokinetics and Drug Disposition

Pharmacokinetic (PK) and ADME (Absorption/Distribution/Metabolism/Excretion) studies provide useful feedback for formulation scientists. PK studies yield parameters such as AUC (area under the curve), Cmax (maximum concentration of the drug in blood), and Tmax (time at which Cmax is reached). Later on, this data from animal PK studies is compared to data from early stage clinical trials to check the predictive power of animal models.

Preclinical Toxicology Testing and IND Application

Preclinical testing analyzes the bioactivity, safety, and efficacy of the formulated drug product. This testing is critical to a drug's eventual success and, as such, is scrutinized by many regulatory entities. During the preclinical stage of the development process, plans for clinical trials and an Investigative New Drug (IND)

Phase 1 clinical studies

The first phase of human clinical testing involves a relatively small group of healthy people, usually a dozen to a few dozen, and it'll focus entirely on safety. This stage of study involves looking at how a drug is absorbed and eliminated from the body, as well as what side effects it may cause and whether or not it's producing the desired effect. Phase 1 clinical studies are also where maximum tolerated doses are established. It really is all about safety, although it's not uncommon for drug developers to tout early signs of efficacy in phase 1. If everything looks promising the study moves to phase 2, or midstage trials.

Phase 2 clinical studies

The two big changes between early stage and mid-stage trials are that the patient pool widens from a few dozen to perhaps 100 or more patients, and the patients being treated are no longer healthy volunteers but people being afflicted by the disease in question. Safety remains a big focus of phase 2 studies, with short-term side effects being closely monitored, although an increasing emphasis will begin to be placed on whether or not a drug is working as expected and if it's improving the condition or not. Phase 2 studies also establish which dose (if multiple doses were tested, as is often the case) performed most

optimally. If the experimental drug continues to look promising it'll move onto late-stage studies.

Phase 3 clinical studies

In phase 3 studies, safety remains a priority, but this is where efficacy also plays a big role. Phase 3 studies are designed by drug developers but approved by the FDA with guidelines for a clearly defined primary endpoint to determine the success or failure of a tested drug. Phase 3 trials involve even more patients, perhaps a few hundred to maybe thousands, and they are by far the longest and costliest of all components of the drug development process. This is also the stage where drug developers will begin to think about how they're going to ramp up production if the phase 3 results are promising. Assuming an experimental drug meets its primary endpoint and is demonstrated to be safe, the next step is to file for its approval.

New Drug Application filing

the seventh step in the drug development process is simple: filing a New Drug Application with the FDA. Unfortunately this isn't just a single page that says "please look at our drug!" An NDA can be tens of thousands or perhaps 100,000 or more pages long, and it contains all research and safety data examined during each of the six prior steps. Still, this stage isn't the point where the FDA has to make a decision to approve or deny the drug; it's merely a stepping stone that says it promises to review the application over the next 10 months. If the NDA is accepted a PDUFA, or Prescription Drug User Fee Act, date is set 10 months down the road (for a standard application) whereby the FDA is expected to make its decision. Keep in mind the FDA

PDUFA date and decision

More often than not, the FDA will wait until the PDUFA date to release its decision. Essentially the FDA has three choices: it can approve a drug; it can outright deny a drug (which is pretty rare from what I've witnessed in 15 years), or it can request additional information by sending a complete response letter, or CRL. A CRL simply states what was lacking that prevented the drug from being approved and offers suggestions as to how to remedy the situation. Often times it requires drug developers to run additional studies or perhaps alter their manufacturing process to appease the FDA. If approved by the FDA, the drug becomes immediately available for commercial production.

Phase 4 clinical studies

"Technically" an approved drug can make it to your medicine cabinet after step eight, but that doesn't mean the drug developer is off the hook yet. Even after approval, it's not uncommon for the FDA to request long-term safety studies be undertaken whereby drug developers are required to submit regular reports detailing any adverse events with the drug to the FDA. Even following approval, safety remains the top priority of the FDA.

From start to finish, the entire drug development process (steps 1 through 8) usually spans about 10 to 15 years, leaving drug developers with around a decade or less of patent exclusivity on branded drugs once they make it to market. This should help provide some insight into why prescription drug prices are so high, why drug companies may seem like they're taking "forever" in developing the next cure for a terrible disease, and why so few drugs actually earn a spot in your medicine cabinet.

Activity carried out during Drug Development:

- Research
- Safety
- Clinical
- Regulatory
- Manufacturing
- Marketing

Research:

- Compound Should be Novel and Patentable
- Fulfills All medical needs
- Compound should be Potent and selective

Safety:

- Nontoxic
- High margin of Safety
- Should not produce any Harmful effect

Clinical:

- Efficacious
- Tolerable

Regulatory:

- Quality Data
- Quality Documentation

- **Manufacturing:**
- Manufacturable
- Stable drug product
- Can scale up

Marketing:

- Pivotal studies
- Patient needs
- Competitive
- Return should be high on investment

Steps in Drug Discovery process:

Discovery and Development

Research for a new drug begins in the laboratory

Preclinical Research

Drugs undergo laboratory and animal testing to answer basic questions about safety.

Clinical Research

Drugs are tested on people to make sure they are safe and effective

FDA Review

FDA review teams thoroughly examine all of the submitted data related to the drug or device and make a decision to approve or not to approve it.

FDA Post-Market Safety Monitoring

FDA monitors all drug and device safety once products are available for use by the public.

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