

# The Process of Drug Development from Discovery to Market

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## Perspective

### INTRODUCTION

The development of new drugs is a complex and expensive process. It takes years of research, testing, and regulatory approvals before a drug can be launched in the market. In this article, we will go through the different stages involved in drug development and the challenges faced by researchers and pharmaceutical companies. Once a lead molecule has been found through the process of drug discovery, the process of drug development is used to bring a new pharmaceutical medicine to market. Preclinical research on microbes and animals is part of this process, as is requesting regulatory status, such as through the US food and drug administration, to begin human clinical trials for an investigational new drug. It may also include the step of securing regulatory approval with a new drug application to market the drug. It normally takes more than ten years for a vaccine or medication to be approved, from concept to preclinical testing in the lab to clinical trial development, including phase I-III trials.

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### DESCRIPTION

#### **Stage 1:** Discovery and pre-clinical testing

The first stage of drug development involves the identification of a potential drug candidate. This can be done through various approaches, such as screening of chemical libraries, target based drug discovery, or repurposing of existing drugs.

Once a drug candidate is identified, it undergoes pre-clinical testing to evaluate its safety and efficacy. This stage involves testing the drug in cells and animal models to ensure that it does not cause any harm and has the desired therapeutic effect.

#### **Stage 2:** Clinical trials

If a drug candidate passes the pre-clinical testing, it can proceed to clinical trials. Clinical trials are conducted in human subjects to evaluate the safety, efficacy, and pharmacokinetics of the drug.

#### **Clinical trials are conducted in three phases:**

Phase 1 trials involve a small group of healthy volunteers to evaluate the safety and pharmacokinetics of the drug.

Phase 2 trials involve a larger group of patients with the target disease to evaluate the efficacy and optimal dosage of the drug.

Phase 3 trials involve an even larger group of patients with the target disease to confirm the safety and efficacy of the drug in a real world setting.

The results of clinical trials are submitted to regulatory agencies, such as the FDA in the US, for approval.

#### **Stage 3:** Regulatory approval

Regulatory approval is the most challenging and time consuming stage of drug development. The regulatory agencies evaluate the safety, efficacy, and quality of the drug and decide whether it can be launched in the market.

The regulatory approval process involves the submission of a New Drug Application (NDA) or a Biologics License Application (BLA) to the regulatory agency. The application includes all the data generated during pre-clinical and clinical testing, as well as information on the manufacturing process, labeling, and packaging of the drug.

The regulatory agency can approve the drug for marketing, request more data or reject the application. The approval process can take several years and involve multiple rounds of review and communication between the pharmaceutical company and the regulatory agency.

#### **Stage 4:** Post-marketing surveillance

Once a drug is launched in the market, it is monitored for its safety and efficacy through post marketing surveillance. This stage involves collecting data on the drug's use in real world settings and evaluating any adverse events or side effects that may arise.

Pharmaceutical companies are required to report any adverse events or side effects to the regulatory agency and take appropriate action, such as issuing warnings or recalls if necessary.

### CONCLUSION

The process of drug development is a long and complex journey that involves multiple stages of testing, evaluation, and regulatory approval. The high cost and risk associated with drug development are major challenges faced by researchers and pharmaceutical companies. However, the development of new drugs is crucial to improving patient outcomes and addressing unmet medical needs. The success of drug development depends on the collaboration between researchers, pharmaceutical companies, regulatory agencies, and patients.