



## Drug Development Stages: New Drug Approval to Market Authorization

Omar Javeed\*

Department of Pharmacology, Quaid-i-Azam University, Islamabad, Pakistan

### ARTICLE HISTORY

Received: 27-Nov-2023, Manuscript No. AJPBP-24-124124;  
Editor assigned: 30-Nov-2023, PreQC No. AJPBP-24-124124 (PQ);  
Reviewed: 14-Dec-2023, QC No. AJPBP-24-124124;  
Revised: 21-Dec-2023, Manuscript No. AJPBP-24-124124 (R);  
Published: 28-Dec-2023

### Description

The journey of a new drug from its inception in the laboratory to market approval is a complex and rigorous process that involves multiple stages. Each stage is meticulously designed to ensure the safety, efficacy, and quality of the drug before it reaches patients. This article discusses about the various stages involved in bringing a new drug from initial discovery through preclinical and clinical trials to market approval.

### Discovery and development

The pharmaceutical odyssey begins with the discovery of a potential new drug. This stage involves extensive research and experimentation to identify compounds that exhibit therapeutic potential. Scientists scrutinize various chemical structures and mechanisms to pinpoint a molecule with the desired pharmacological effect.

Once a promising compound is identified, the development phase kicks in. Researchers optimize the chemical structure, analyse potential risks, and assess the compound's potential for therapeutic use. This phase involves *in vitro* studies and animal testing to understand the drug's behaviour in biological systems.

### Preclinical testing

Before a new drug can be tested on humans, it must undergo rigorous preclinical testing. This stage involves comprehensive laboratory and animal studies to evaluate the drug's safety, toxicity, and efficacy. Researchers collect data on the compound's pharmacokinetics (absorption, distribution, metabolism, and excretion) and pharmacodynamics (the drug's effects on the body).

The findings from preclinical testing are crucial in determining whether the drug should proceed to the next phase: Clinical trials. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA), review the preclinical data before granting approval for human trials.

### Applications in healthcare

Clinical trials are a series of carefully controlled studies conducted in human volunteers to assess the safety and effectiveness of a new drug. The process is divided into three phases:

**Phase I:** This phase involves a small group of healthy volunteers and aims to evaluate the drug's safety, dosage, and side effects. Researchers closely monitor participants to understand how the drug is metabolized and excreted.

**Phase II:** In this phase, the drug is administered to a larger group of patients who have the target condition. The focus is on assessing the drug's efficacy, optimal dosage, and potential side effects. This phase provides critical insights into the drug's therapeutic benefits.

**Phase III:** The drug is tested on an even larger group of patients in this phase to confirm its effectiveness and monitor adverse reactions. This phase is crucial for gathering statistically significant data to support the drug's safety and efficacy claims.

### Regulatory review

After successful completion of clinical trials, the pharmaceutical company submits a New Drug Application (NDA) to regulatory agencies for review. The regulatory authorities meticulously examine the clinical trial data, preclinical findings, and manufacturing processes to ensure compliance

with safety and efficacy standards.

The regulatory review process is comprehensive and may involve multiple rounds of communication between the pharmaceutical company and regulatory agencies. The FDA, for instance, reviews the NDA and may convene an advisory committee to seek external expert opinions before making a final decision.

### **Approval and post-market surveillance**

If the regulatory authorities are satisfied with the submitted data, they grant market approval for the new drug. This milestone allows the pharmaceutical company to market and distribute the drug to healthcare providers and patients.

Post-market surveillance is a crucial aspect of drug

development. Even after approval, companies are required to monitor the drug's performance in real-world settings. Adverse events or unexpected side effects that may not have been apparent in clinical trials could surface during widespread use.

Bringing a new drug from initial discovery through preclinical and clinical trials to market approval is a meticulous and resource-intensive process. The pharmaceutical odyssey demands collaboration between scientists, researchers, regulatory agencies, and healthcare professionals to ensure that new drugs meet stringent safety and efficacy standards. The journey, while challenging, is ultimately aimed at delivering innovative and life-changing treatments to patients in need.