

# The Drug Development Process: From Discovery to Market Approval

Stone Joseph\*

Department of Medicine and Department of Biochemistry and Biomedical Sciences, McMaster University, Hamilton, Ontario, Canada

## Correspondence to:

Stone Joseph

Department of Medicine and Department of Biochemistry and Biomedical Sciences,  
McMaster University, Hamilton, Ontario, Canada  
Email: [adammorgan@gmail.com](mailto:adammorgan@gmail.com)

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## 1. Introduction

The safety, effectiveness, and commercial acceptance of pharmacological goods are of utmost importance in the field of drug development. The regulatory system guiding drug development is examined in this article, with a focus on the crucial elements of safety, efficacy, and market acceptance. Any pharmaceutical item's creation is primarily focused on safety. Before a medicine is authorized for use in patients, its potential dangers must be carefully assessed and reduced. Strict regulations are set by regulatory organizations, including the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in Europe, and equivalent bodies in other nations [1].

### Preclinical Study

A preclinical study is the first step in the method, during which medications are examined in lab settings and on animal models. Determine the drug's pharmacokinetics (how it is taken, transported, metabolized, and eliminated in the body) during this stage in order to spot any potentially hazardous consequences. Preclinical testing data is then submitted to regulatory agencies as part of an Investigational New Drug (IND) application, which forms the basis for carrying out clinical trials on humans. To determine the drug's safety, effectiveness, and ideal dosage, clinical studies are carried out in stages. A small number of healthy volunteers participate in phase 1 examinations, which mainly aim to ascertain the drug's safety profile and dose range. In phase 2 studies, patients with the targeted disease or condition are added to the study group, and the drug's effectiveness and potential side effects are further examined. The purpose of phase 3 trials, which involve a greater number of patients, is to establish the drug's efficacy, keep track of its side effects, and evaluate it against other treatments or a placebo. Regulatory organizations keep a tight eye on the clinical trial's development throughout the process to guarantee patient safety and ethical behaviour [2].

### Clinical Trial Procedures

Clinical trial procedures must be reviewed and approved by

institutional review boards (IRBs) or ethical committees in order to safeguard the rights and welfare of research participants. To seek regulatory approval, a New Drug Application (NDA) or Marketing Authorization Application (MAA) is filed with the data collected from these studies, including adverse events, efficacy results, and other pertinent characteristics. It takes a careful and thorough process to evaluate safety and efficacy data. The clinical trial results, manufacturing procedures, and labeling data that have been submitted are all carefully examined by regulatory authorities in order to determine the drug's quality, safety, and efficacy. Prior to making a choice, they may also ask the medication sponsor for clarification or more details [3].

### Benefits of the Drug to Its Potential Risks

The drug's benefit-risk profile is a crucial factor to take into account during the review process. To determine if the benefits of the drug outweigh the dangers for the target patient population, regulatory bodies compare the possible benefits of the drug to its potential risks. Based on scientific evidence, this assessment will include the severity of the disease or condition, other treatments that may be available, as well as the overall safety and efficacy profile of the medication. A medicine can be marketed and sold to patients and healthcare providers if it successfully completes the regulatory evaluation procedure and is given marketing approval or market authorization. In order to monitor the drug's long-term safety and efficacy in real-world situations, regulatory authorities typically impose labeling requirements, post-marketing surveillance duties, and periodic safety reporting [4].

However, the precise conditions for market clearance vary depending on the regulatory authority. Even after a medicine has been given market approval, post-marketing surveillance, often known as pharmacovigilance, continues. Through the spontaneous reporting of adverse occurrences, post-approval clinical studies, and other surveillance mechanisms, pharmaceutical companies and regulatory organizations continuously monitor the safety profile of the drug. This continued observation assists in identifying and treating any uncommon or previously undetected adverse effects that may develop [5].

## 2. Conclusion

In conclusion, the process of developing a medicine is intricate and multifaceted, spanning a number of steps from original discovery to regulatory approval. To guarantee the security, effectiveness, and caliber of new pharmaceutical items, extensive scientific investigation, painstaking testing, and regulatory inspection are required. Through intensive investigation and target identification, a promising chemical is first found. An discovered candidate is put through preclinical testing in labs and on animals to gauge its safety and efficacy. Clinical studies in humans are then started by submitting an Investigational New Drug (IND) application to regulatory agencies. The pharmaceutical corporation submits a New Drug Application (NDA) to regulatory organizations for market authorization if the results are favorable. The full data package is examined by regulatory organizations to determine the drug's risk-benefit profile.. To develop safe and efficient pharmaceuticals that eventually improve outcomes for patients and advance healthcare globally, it need cooperation between researchers, academics, physicians, regulatory bodies, and industry players.

## 3. References

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