

Clinical Trials in the Drug Discovery and Development Procedure

Emily Cooper*

Department of Pharmaceutics, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana, India

Perspective

Received: 01-Mar-2023, Manuscript No. DD- 23-94141; **Editor assigned:** 03-Mar-2023, Pre QC No. DD- 23-94141(PQ); **Reviewed:** 17-Mar-2023, QC No. DD- 23-94141; **Revised:** 24-Mar-2023, Manuscript No. DD- 23-94141(R); **Published:** 31-Mar-2023, DOI:10.4172/resrevdrugdeliv.7.1.009

***For Correspondence:**

Emily Cooper, Department of Pharmaceutics, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana, India

E-mail: cooperemily8778@gmail.com

Citation: Cooper E. Clinical Trials in the Drug Discovery and Development Procedure. RRJdrugdeliv.2023.7.009.

Copyright: © 2023 Cooper E. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

DESCRIPTION

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. Regulatory requirements for a new medication application are a major focus of many drug development processes. The majority of these studies are intended to identify a novel compound's key toxicities before it is used for the first time on humans. The evaluation of major organ toxicity, including effects on the brain, kidney, liver, digestive system, heart, and lungs, as well as impacts on other body systems that may be impacted by the drug (such as the skin, if the new medication is intended to be applied to or absorbed through the skin), must be done in accordance with the law.

Research & Reviews: Drug Delivery

Drug development procedure includes:

Discovery and development: A new drug's development starts in the lab. This can be accomplished using a variety of techniques, including target-based drug discovery, chemical library screening, and medication repurposing.

Preclinical research: To ensure that they are both effective and safe, medications are tested on humans.

Clinical research and FDA (Food and Drug Administration) review: Drugs are tested on people to make sure they are safe and effective. FDA review teams carefully look over all of the data submitted on the drug or device before deciding whether to approve it or not.

FDA post-market safety monitoring: FDA monitors all drug and device safety once products are available for use by the public.

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. 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 either 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. 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. 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.