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# Review On: Drug Discovery and Clinical Evaluation of New Drug''

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**ABSTRACT:**
This survey of the problems and pitfalls involved in the evaluation of a new drug, from its initial study in animals, through clinical trials, until its introduction into general medical practice. The emphasis is on investigation in human patients. The wide range of topics covered
includes not only such technical subjects as experimental design and statistical analysis but also the delicate question of the ethics of experimentation on human beings. It is an excellent guidebook

**KEYWORDS :**
Drug discovery, pre-clinical evolution,In vitro, In vivo, Development And Approval process,Phase of clinical trial conclusion,etc

## I. INTRODUCTION :.

Drug discovery is a multifaceted process, which involves identification of a drug chemical therapeutically useful in treating and management of a disease condition. Typically, researchers find out new drugs through new visions into a disease process that permit investigator to design a medicine to stopover or contrary the effects of the disease.

**1.Drug Discovery *:***

Drug discovery is the process to which potential new medicines are identify. It was a wide range of scientific disciplines including biology , chemistry and pharmacology. In the past most drugs have been discovered at their identifying the active ingredient from tradition remedies for by the discovery. A new approach has been to a understand how disease and infections are control at the molecular and physiological level and target specific on this knowledge. The process of drug discovery in was the identification of candidate, synthesis, characterization and assay for therapeutic efficiency.

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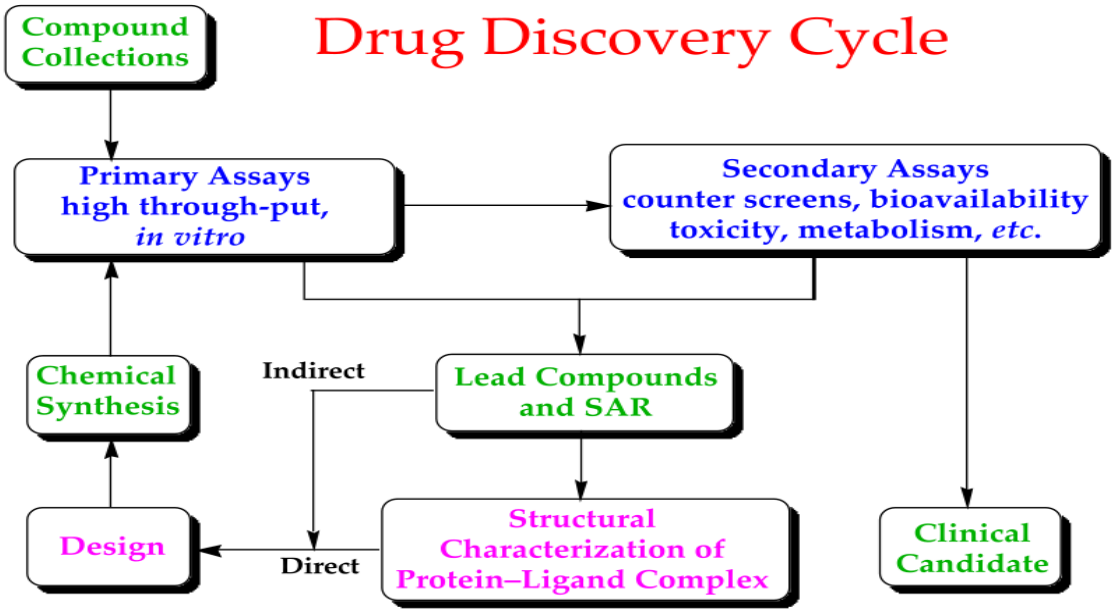


## II. DEVELOPEMENT AND APPROVAL PROCESS

***a). Devlopment :***

Firstly drug can be send to the company to test it .The company then sends CDER the evidence from these tests to prove the drug is safe and effective for its intended use. Before a drug can be tested in people, the drug company performs laboratory and animal tests to discover how the drug works and whether it's likely to be safe and work well in humans.

**b). FDA Approval :**

FDA approval of a drug means that data on the drug's effects have been reviewed by CDER, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population.

Clinical trials provide important information on a drug's efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of approval.

FDA reviews reports of problems with prescription and over-the-counter drugs, and can decide to add cautions to the dosage or usage information, as well as other measures for more serious issues.

**4. Pre -Clinical Evaluation *:***

Before testing a drug in human body or animal body research must find out whether it has side effects to harm human and animal body. The preclinical studies are conducted on animal models under laboratory conditions

There are two types of pharmaceutical testing

**1. In vitro:**

clinical trial outside the animal or human body

**2. In vivo:**

clinical trial conduct inside the body

The various experiment have been conducted during studies such as

1.Single dose toxicity studies
2. Repeated dose studies
3. Genotoxicity studies
4. Reproductive toxicity study

**5. Phase of clinical trial**

All new drugs are labelled as Investigational New D norugs (INDs) by UDFDA. All INDs undergo various stages of development. Clinical trials have been classically divided in to four phases as described below. In addition, phase 0 has been added in recent years.

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| Sr. no | Phase | Primary goal | Dose | Typical number of participants |
|---|---|---|---|---|
| 1 | **Pre-clinical** | Testing of drug in animals to gather efficacy, toxicity &pharmacokinetic | Unrestricted | Not applicable (in-vitro and in-vivoonly) |
| 2 | **Phase 0** | Pharmacokinetic,oral bioavailabili ty and half-life | Very small, sub therapeutic | 10 healthy volunteers |
| 3 | **Phase I** | Testing on healthy volunteers for dose ranging | Sub-therapeutic with ascend ing dose | 20-100 healthy volunteers (cancer pat ients for anti-cancer drugs) |
| 4 | **Phase II** | Testing of drug on patients to assess efficacy and side effects | Therapeutic dose | 100-300 patients wit h specific diseases |
| 5 | **Phase III** | Testing on patients to assess efficacy, effectiveness and safety | Therapeutic dose | 300-3000 patients of diverse sub-groups |
| 6 | **Phase IV** | Post-marketing surveillance-watching drug use in publi | Therapeutic dose | Anyone seeking treatment from physician |

## III. CONCLUSION:

The above review has given the information about discovery of drug & pre- clinical trials on the side effect animal or human body.Also Introduce the clinical phases.

## REFFERENCE:

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