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Editorial

The Process of Drug Development

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Drug development is the process of bringing a new pharmaceutical drug from the point of its discovery (i.e., identification of a lead compound or molecule – either a small synthetic molecule or a biological molecule with pharmacological property) to the market.

New Drug Development involves the following steps including four Phases of Clinical Trials

- Preclinical studies on microorganisms (*in vitro*) and animals (*in vivo*) to gather efficacy, toxicity and pharmacokinetic data. The preclinical studies assist pharmaceutical companies to choose a molecule to move forward to the next step.
- Filing an Investigational New Drug (IND) application to initiate clinical trials on humans which include Phase I, Phase II, Phase III clinical studies,
- New Drug application (NDA) to market the drug,
- Phase IV Clinical Studies.

The Drug Development process begins with the research in the laboratory and animal testing to answer basic questions on safety.

Drugs are then tested on humans to make sure they are safe and efficacious.

In US the Food and Drug Administration (FDA) monitors and regulates the new drug development process. Other countries have their respective drug regulatory agencies. The FDA plays a minimal role in the preclinical research phase. Once a pharmaceutical company finds sufficient evidence of a drug efficacy in animals, an IND application is submitted to FDA for approval after which human trials begin.

The process of new drug development is complex, costly, laborious and time consuming, often times with failures referred to as 'attrition rate".

Ultimately, the process of drug discovery and drug development bring hope and relief to millions of patients.

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