

Pharmacy, Drug Development and Technology: from the Laboratory to Pharmacy

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The discovery and development of a novel therapeutic agent to sell in the Pharmacy require a huge investment of time, money and the process is very risky [1-3]. The cost of drug development includes the discovery, the clinical trials and the failed drug fees [4].

Generally, the discovery time is situated between 3-20 years and is very essential because researchers spend all their time to investigate the property and the structure of the molecule that can fight the illness [2,5].

After this step, researchers start the preclinical trial which consists in working on animals. This phase gives immense details about the pharmacology, the pharmacokinetics and the toxicity of the testing drugs. The next step is the clinical trial from phase I to IV focuses on human subjects [6].

Note that, we have now in the literature the phase 0 trial which is a platform for drug development [7]. Phase 0 trial is a recent designation for optional exploratory trials conducted. Phase 0 trial means the administration of single subtherapeutic doses of the study drug to a small number of subjects around 10 to 15 [7,8]. By addition there, no data concerning the safety and the efficacy of the drug is obtained. This step is simply made to investigate the best pharmacokinetic parameters in humans [8]. It just prepares the phase I trial.

In the phase I trial, a small healthy volunteers is recruited between 2 to 200 participants. Researchers test the safety, the side effects, the best dose, and the formulation method for the drug [9]. The study is conducted generally in a clinical trial clinic, where the subject can be observed by full-time staff and Physicians [9]. The volunteers are also paid a variable inconvenience fee for their time spent by the sponsor. A phase II trial is made to check the biological effect of the drug [10]. For the phase II trial, 100 to 300 participants are recruited to follow how well the drug works.

Phase III trial is aimed to investigate how well the drug is by comparison to a "gold standard" treatment. Around 300 to 3000 participants are recruited. Researcher said that, this step is the most expensive for them because it is long and time consuming [2]. The phase III is also called the "premarketing phase" because it measures the consumer response to the drug.

When the drug has proved satisfactory after Phase III trials, sponsors combine all the information about the methods, the results of human and animal studies, manufacturing procedures, formulation details and shelf life in a documents.

The phase IV is the postmarketing surveillance trial. Sponsoring Company checked a new market for their drug. The phase IV trial involves pharmacovigilance in which the safety surveillance of the drug is made to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I-III clinical trials. For the phase IV clinical trial the minimum time period mandatory is 2 years.

In the world, approximatively 7 935 new drugs are in development in 2017. It is true, failed drug exists because industry estimates that on 10 000 molecules screened in the discovery process, only one will make it to the market as approved drug. Industry will never recuperate the cost of failed drugs [2].

An marketing authorization is issued to maintain the pharmaceutical product on the market. One of the reason why marketing authorization may be withdrawn, suspended, revoked is that, under normal condition of use the benefit over risk ratio is no more favorable or the drug is lack of therapeutic efficacy. This is why some drugs are retracted in the pharmacy after marketing authorization issued.

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