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RESEARCH AND DEVELOPMENT ON DRUGS

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead substance has been identified through the process of drug discovery. Research in these areas generally comprises a combination of preclinical studies (in vitro studies, in vivo studies) and clinical trials. It takes about 12-15 years from the time of the detection of approved drugs and requires an investment of approximately $1 billion. [4]

An NCE is a molecule developed by the innovator company in the early drug discovery stage, which after undergoing clinical trials will turn into a drug that will a treatment for definite disease.

Nowadays drug development is dominated by small-molecule new chemical entities traditionally distinguished from macromolecular agents regarded as biologicals.

Synthesis of an NCE is the first step in the process of drug development. It is long important process. It can take decades to develop a new molecule. [3]

Next step is testing. Drug development is required to establish the physicochemical properties of the NCE. The process by which the chemical is made will be optimized so that from being made at the bench on a milligram scale by a synthetic chemist, it can be manufactured on the kilogram and then on the ton scale. It will be further examined for its suitability to be made into certain dosage form: aerosol, tablets, capsules, intravenous formulations. subcutaneous or intramuscular injectable. Most NCEs can will fail during drug development, either because they have some unacceptable toxicity.

Before starting any clinical trial, researchers must submit an application (IND) to investigate new drugs in the FDA. The application must contain the results of

preclinical studies, the chemical structure of the candidates for medicine, a description of their biological effects, a list of side effects, etc. In addition, the application includes a detailed plan of clinical trials, information about their venue and participants.

Clinical trials consist of three phases:

1. Initial clinical trials in a small group of healthy volunteers (from 20 to 100 people).

The main task of this test Phase is to find out how safe the preparation is for humans. Scientists study pharmacokinetics (chemical transformation of drugs in the body) and pharmacodynamics (mechanisms of action of drugs on the body) of the drug, find out whether the drug gives the desired effect, or there are no side effects. All studies are carefully scrutinized by scientists to determine the range of safe concentrations of the drug for humans and the transition to the next stage. [2]

2. Testing on a small group of patients (from 100 to 500 people).

During Phase 2 trials, scientists are studying short-term side effects and risks associated with drug use. They also try to answer the question "Does the drug work according to the expected mechanism?" and "Does it improve the condition of the patients?". Active doses and drug use patterns are being developed. If it shows itself well scientists are preparing for the next longer phase of clinical trials. [2]

3. Drug testing in a large group of patients to show the safety of drugs and their efficacy (about 1000-5000 people).

Researchers are studying the drug in a large group of patients in order to obtain complete statistics on the safety of the drug, its efficacy and the ratio of the resulting therapeutic effect and possible risks. This phase of the study is key to determining whether a drug is safe and effective. It also provides the basis for developing instructions for use of the drug. Phase 3 is the most expensive, and the longest of all studies. Tests are conducted simultaneously in different countries, in many groups of people. During this stage, full-scale production plans are being developed and a very complicated FDA application is being prepared for drug registration. [1]

The study of new drugs continues even after their approval. As far as more patients start using new medications, manufacturing companies are required to monitor the medication and periodically report to the FDA. Sometimes the FDA for the determination of long-term drug safety requires companies to conduct additional studies in the so-called Phase 4 trials.

Hence, the development of medicines is a long and complex process aimed at improving people's lives. Any new substance is subject to rigorous testing to reduce the risk to human health and achieve the maximum effectiveness of the new drug.

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