Exploring the Manufacturing and Testing Processes of Pharmaceuticals

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When a doctor prescribes you a medicine, how does she know it could be helpful? Your doctor relies on experience, medical knowledge and training, but also on information and conclusions drawn from clinical trials.

Clinical trials are research studies that test a medical intervention aimed at treating, diagnosing, or preventing a disease or health condition in human volunteers. The intervention could be a drug, a medical procedure or device, or a behavioral therapy, such as diet or exercise.

Some clinical trials are done to test whether a drug or treatment is safe and effective for people to use. Others test two or more treatments to see which is more effective than the other(s). Clinical trials can also be done to investigate a drug or treatment in different groups of people, such as children, the elderly, or those with certain medical conditions.

How Do Clinical Trials Work?

Drugs are first subjected to non-human tests in a laboratory. These lab tests are done to determine a level of safety. Results of these tests are then sent to the U.S. Food and Drug Administration (FDA), and the FDA determines if the treatment is safe enough to be studied in human volunteers.

A committee, known as an Institutional Review Board (IRB), must approve all proposed clinical trials. The members of the IRB review the design of the proposed study, the credentials of the investigators and evaluate the proposed trial to provide their opinion that it is ethical and that proper safety precautions are being taken. Only after the trial is approved by the IRB may participants be recruited. Once the trial has been approved, it must then be monitored by the IRB to ensure that the study is being conducted ethically and safely.

Clinical trials are conducted in phases. Each phase is designed to answer different questions that researchers may have about a drug or treatment.

How Can You Participate in a Clinical Trial?

In order to participate in a clinical trial you must meet the specific criteria defined for that clinical trial. These criteria can include things such as age, race, gender, past medical history, and your current health status. Healthy volunteers are needed for some studies, while for others, only those with certain conditions or diseases are eligible.

To help protect your safety and to help you understand your role in the study, you'll first be informed of the details of the trial and given information about its protocol. A trial's protocol is the detailed plan that includes information on the reason for conducting the trial, eligibility guidelines, planned treatments and tests, potential side effects, and the length of the trial.

If you're interested in enrolling in a trial, you will be given the opportunity to ask questions and obtain even more information. In order to enroll, you'll also need to read and sign an informed consent form. This form describes the protocol to study volunteers and signing it indicates that you have been informed about the trial and its procedures.

Signing this form also indicates that you have had and will continue to have the opportunity to ask questions about the purpose of the study and any potential risks. While signing this form also means that you agree to participate in the trial, you can still choose to withdraw at any time.

How Can You Find a Trial That's Right for You?

The National Institutes of Health (NIH) maintains a database of clinical trials where potential participants can find information about trials that are recruiting as well as learn about completed trials. This database allows you to sort trials by disease, location and other considerations. It also includes trials that are recruiting participants in the United States as well as internationally.

Contributor: Josefin Dolsten

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References

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, Discover the fascinating journey of how drugs are made and tested at Pfizer. Explore the meticulous process of drug development, ensuring safety and efficacy.

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