A Quick Guide to Clinical Trials (Part 1: An Overview)

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Clinical trials are the core of medical research. Investigations are performed to determine how new treatments will work in human patients and valuable data concerning the benefits and risks of new drugs, medical approaches, and procedures are collected. Clinical trials are conducted to find effective ways to understand, prevent, diagnose, and treat diseases. However, clinical studies are also conducted to improve the quality of life of patients with chronic illnesses.

Trial Protocol

Each clinical trial is designed very carefully to provide the greatest amount of information at the lowest possible risk, and to achieve this, a protocol, or an action plan, is prepared. This plan describes what is to be done in the study, how it will be done, which information would be gathered, and why the different parts of the investigation are necessary.

The eligibility criteria for participating in a clinical trial are also listed in the protocol. Some studies require participants with a particular illness. Whereas some studies seek healthy volunteers or people with specific characteristics regarding gender, age, weight, lifestyle/habits, or others.

Interventional and Observational Studies

Clinical trials are of two types: Interventional and Observational studies. In case of interventional studies, the participants are treated in accordance with a research plan created by study investigators and the results are usually compared with the data obtained for subjects who receive either no treatment or a treatment that is already available. The “intervention” may include new drugs or devices, novel medical procedures, or changes in the participants’ behavior (diet, sport activities, etc.)

In an observational study, the participants are monitored to assess health outcomes under particular conditions. However, in this case the investigator has no direct control over the experiment and makes no attempt to affect the outcome of the study.
Observational studies are advantageous as they involve patient populations that are closer to clinical practice, they are cheaper than interventional studies, and are used to investigate rare outcomes, detecting unusual side effects. Another advantage is that some studies are performed quickly and easily.

Before a new drug or an innovative medical approach can be tested on humans, extensive laboratory research is required, sometimes spanning over several years. In most cases, this research involves conducting experiments on animals and/or human tissues. In case the studies prove to be successful, the investigators may send the data to an independent committee (usually comprises physicians and scientists) who would then approve and monitor any further tests involving human participants.

Phases of Clinical Trials

Clinical trials are conducted in several phases, and each one of them has a different purpose and is designed to answer a particular set of questions.

Phase I studies usually involve a small number of healthy volunteers (20–100) and are designed to assess the safety of a drug, device, or procedure; determine the appropriate dosage range; and identify any potential side effects. If a treatment is found to be safe enough, it can be tested in phase II.

Phase II studies are conducted to determine whether a treatment is effective or not and to further evaluate its safety. These trials normally involve a few hundred participants (100–300).

Phase III studies are carried out on large groups (i.e. several hundreds to several thousands) of participants to confirm the effectiveness of a new medical approach and to monitor its benefits along with any adverse effects. Most phase III studies are randomized trials, which means that one group of patients receives the new treatment while a “control” group is treated by following the standard procedure or by using a placebo. Phase III trials may also study different populations and dosages or assess the effect of combining a new procedure with other treatments. Once Phase III is complete, a new medical approach or drug may be approved by a regulatory agency such as the US Food and Drug Administration.

Phase IV studies are performed after a new drug, device, or procedure has been marketed. These studies are designed to collect additional data regarding the effect of the approved drug (device or procedure) in various populations and determine any long-term side effects it may have.

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