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Commentary

Different Phases of Clinical Trails: Design and Classification

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DESCRIPTION

Clinical research is medical research which is involving human subjects. There are two types: observational studies and clinical studies. Clinical trials are research studies conducted in individuals and intended to evaluate medical, surgical, or behavioral interventions. These are the primary methods researchers use to find out whether new treatments such as new drugs, diets, and medical devices (such as pacemakers) are safe and effective. Clinical trials are often done to find out if new treatments are more effective than standard treatments and/or have harmful side effects. A clinical trial is a study to test a new drug, existing drug, device, or other treatment. Many clinical trials are investigating new ways of detecting, diagnosing, or measuring the extent of disease. Some are even looking for ways to prevent disease outbreaks. Researchers are still testing these methods using human volunteers, and the same rules apply. Doctors use clinical trials to see if a new drug, treatment, or combination works and is safe to use in humans.

Clinical trials are important for developing new treatments for serious diseases such as cancer. All new treatments must undergo clinical trials before being approved by the Food and Drug Administration (FDA). Cancer clinical trials can take years. It can take months or years, to find out if a cancer treatment is working or not. Goal in clinical research is to use appropriate statistical techniques to design studies that can draw valid and meaningful scientific conclusions that can be extrapolated to the 'real world'. Study Design have to make a choice before choosing. Establish research objectives and select an appropriate subject population that is most representative of the study population. This therefore requires well-designed clinical studies, guided by ethical principles, on a strong foundation of detailed methodology. Phase 1 trials are typically the earliest human drug trials. However, doctor may ask if would like to participate in a Phase 0 trial. These studies are aimed at finding out if the drugs are working as researchers would expect based on laboratory studies. Phase 0 trials typically involve only a small number of people and very small doses of the drug. Although the drug dose is too low to treat cancer, it also reduces the chance of side effects. The Phase 0 study is designed to find out: Whether the drug reaches cancer cells, what happens to the drug in the body, and how cancer cells in the body respond to the drug? They may perform additional scans and provide additional samples of blood and cancerous tissue (biopsies) to help researchers to understand what is going on. Phase 1 Study is sometimes called Phase I.

These are usually small studies with only a few patients. The study may be open to patients with advanced cancer of any kind, usually those who have already received all other available treatments. The purpose of the Phase 1 trial is to find out how much of the drug is safe to give, what side effects occur, what happens to the drug in the body, and whether the treatment helps shrink the cancer. In phase 1 trials, patient recruitment occurs very slowly. It doesn't employ a lot of people, but it can take a long time to complete. These are often dose escalation trials. This means that the first few patients to join are taking very small doses of the drug. If all goes well, the next few will have slightly higher doses. Until they find the optimal dosage, and so on. Researchers monitor the side effects people experience and how they feel. Many blood tests are sometimes done in phase 1 trials as researchers see how body copes with and gets rid of drugs. They will carefully record any side effects may have and when they occur. They should do this first before testing a potential new treatment to see if it works. Well, many are not. Phase 2 Studies Phase 2 is sometimes referred to as Phase II. Not all treatments tested in Phase 1 trials progress to Phase 2 trials.

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