Clinical Trials

What is a Clinical Trial?

"Clinical trial" is the scientific term for a test or study of a drug or medical device in people. These tests are done to see if the drug or device is safe and effective for people to use. Doctors, health professionals, and other researchers run the tests according to strict rules set by the OHRP [1] and the FDA [2].

What are the Phases of a Clinical Trial?

Clinical trials are conducted in a series of steps, called phases. Each phase is designed to answer a separate research question.

- **Phase I**: Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II**: The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III**: The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Phase IV**: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Additional information on clinical trials can be found at clinicaltrials.gov [3] and on the FDA website [4].

How Research Participants Are Protected

- **Institutional Review Boards (IRBs)**: Scientists, doctors and other people from the local community serve on Stanford’s IRBs to review and monitor the research involving people. They review studies to help make sure that potential subjects can understand the study, that there is the least possible risk to research participants, and that the risks are reasonable in relation to the expected benefits. IRBs ensure research participant selection is fair and that informed consent is done correctly.
- **Data Monitoring Committees**: These committees are used mainly when one treatment is being compared with another and in studies where treatments are selected for patients at random. These committees are particularly important in tests of treatments for serious or life-threatening disease. These experts review information from studies to make sure they are being done in a way that is safest for the research participants. During a study, if the committee finds that the treatment is harmful or of no benefit, it will stop the study. If there is evidence that one treatment gives a greater benefit than another, the committee stops the study and all research participants are offered the better treatment.
- **FDA Inspections**: FDA inspects records, clinics, and other research sites involved in a study to make sure research participants are being protected and studies are being done correctly.
What Are the Risks?

Many studies require that neither the participant nor the doctor knows whether the participant is receiving the experimental treatment, the standard treatment or a placebo (an inactive substance that looks like the drug being tested). In other words, some research participants may be getting no treatment at all.

Some treatments that are being tested have side effects that can be unpleasant, serious or even life-threatening. Because the treatments being studied are new, doctors don't always know what the side effects will be. Some side effects are temporary and go away when the treatment is stopped, while others can be permanent. Some side effects appear during treatment, while others may not show up until after the treatment is over.

The risks depend on the treatment being studied and should be fully explained to you in the informed consent form.

What else is part of informed consent (relating to clinical trials)?

Additional provisions outlined by the FDA or OHRP include:

- that the study involves research of an unproven drug or device
- other procedures or treatments that you might want to consider instead of the treatment being studied
- that FDA may inspect study records, but the records will be kept confidential
- whether any medical treatments are available if you are hurt, what those treatments are, where they can be found, and who will pay for the treatment

Additional Questions to Consider

- What are my other treatment choices? How do they compare with the treatment being studied?
- What side effects can I expect from the treatment being tested? How do they compare with side effects of standard treatment?

Source URL: https://researchcompliance.stanford.edu/panels/hs/forms/for-participants/clinical_trials

Links