UT Southwestern
Medical Center

Clinical Studies Quick Reference Guide

What Are Clinical Studies?

A clinical study (or clinical research) is medical research involving people. The purpose is to uncover better ways to diagnose, treat, prevent, and understand human disease. People volunteer to participate in clinical studies.

What Are the Types and Phases of a Clinical Study?

There are two types of clinical studies:

1. **Interventional Clinical Trials:** In these studies, researchers test new ways to prevent, detect, or treat disease. Treatments might be new or combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. Clinical trials can also test other aspects of care, such as improving the quality of life for people with chronic illnesses.[1]
2. **Observational Studies:** Observational studies help researchers understand a situation and develop hypotheses that can be tested in clinical trials. Observational studies can find associations between things but can't prove that one thing causes another.[1]

Study Phases

Clinical trials have four phases, or steps, in the clinical research process. When you see a clinical trial name, you may notice that it includes Phase I, II, III, or IV, or it may be written as Phase 1, 2, 3, or 4. Here's what those phases mean:

20-100 Participants

Phase 1

Researchers test a drug or treatment in a small group of people (20-100) for the first time. The purpose is to study the drug or treatment to learn about its safety and identify side effects.

100-300 Participants

Phase 2

The new drug or treatment is given to a larger group of people (100-300) to determine its effectiveness and to further study its safety.

1,000-3,000 Participants

Phase 3

The new drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.

Several Thousand Participants

Phase 4

After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment's benefits and optimal use.

What Does It Mean to Participate?

By participating in a clinical trial, participants are helping the medical community collect information on future treatments and services. This involvement may mean extra care and close follow-up for the participant, access to new treatments, or sharing participants' disease experiences. It could also involve additional visits and travel. Research requires a lot of thought before deciding whether to participate, as it may not improve the participant's condition. Therefore, participants need to consider the potential benefits and risks of their participation in a clinical study, such as encouraging them to ask questions if they are unsure of what they have read or been told. Participation in a clinical study is always voluntary, which means that participants can leave a study at any time.

[1] nih.gov/sites/default/files/about-nih/public-trust/clinical-trials-infographic.pdf

Why Should a Patient Participate?

At UT Southwestern, we need participants for various types of studies. Different people have different reasons for becoming research participants. Here are common reasons why people choose to take part in research studies:

- To help improve treatment for others in the future suffering from the same condition
- To make a difference in society
- To improve their own health
- To gain access to cutting-edge treatment options that might not be available outside the research setting

What Can Participants Expect?

Here's what happens before and after participants are enrolled in a clinical study or clinical trial:

1. **Prescreening:** For trials enrolling participants with a particular medical condition, some prescreening may occur behind the scenes before we meet with the participant. Staff members will explain the trial in detail for studies enrolling healthy volunteers and gather more information about the potential participant during the prescreening process.
2. **Informed Consent:** Informed consent is an essential part of participating in a clinical study. It is the process of learning the key facts about a clinical study before deciding whether to participate. Once a participant has all their questions answered, they will be asked to sign an informed consent form if they agree to participate. Participants should take the time to review the informed consent document carefully and decide if they feel comfortable participating in the study.

   The participant will receive a copy of the document, which they can refer to in the future. Also, note that informed consent is a continuous process that does not end with a signed document. Therefore, participants should always feel free to ask questions about their involvement in a study at any time during or after their participation ends. Researchers will also provide participants with any new information during the study if it could affect their willingness to participate.
3. **Screening Visit:** Once the participant has consented to take part in a study, they may be asked to undergo other procedures and tests, such as filling out questionnaires or having blood work, to confirm that they qualify for the study. The participant may be asked to make a special visit for screening.
4. **Enrollment and Participation:** Once the participant has been enrolled, the study team will review with them the study procedures and schedule tests and other appointments. The participant will follow the trial procedures and report any issues or concerns to the study team. Remember, participating in a clinical study is totally voluntary, and the participant can decide to stop at any time. Study participants continue to see their regular physician for usual health care throughout the study.
5. **End of Study:** Patient participation in the study is complete. Researchers may provide participants with information about finding results once the study data is analyzed.

For more information about clinical trials, please visit:

- utswmed.org/patient-resources/clinical-trials
- utswmed.org/cancer/clinical-trials
- parklandhealth.org/clinical-trials