

(The following information was copied from www.clinicaltrials.gov)

1. What are clinical trials?

A clinical trial is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the safest and fastest way to find treatments that work in people, and new ways to improve health. All of Michigan Vascular Research Center's multi-centered trials are FDA (Food and Drug Administration) and IRB (Institutional Review Board) approved.

Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol.

2. Who are the FDA and the Institutional Review Board?

The Food and Drug Administration (FDA) administers the regulations governing the approval, conduct, review, and reporting of clinical research. In addition, to these regulations, the Institutional Review Board (IRB) must monitor the study. The primary role of the IRB is to safeguard the rights, safety, and well being of all trial participants, paying special attention to trials that may involve vulnerable populations. Because of patient safety the FDA and IRB play key roles in monitoring studies, and are both required in most instances, however, IRB approval is required when conducting any type of research.

3. Why are clinical trials done?

Many clinical trials are done to see if a new drug or device is safe and effective for people to use. Clinical trials are also done for other reasons. Some compare existing treatments to determine which is better. The current, approved treatments are called the "standard treatments." Sometimes clinical trials are used to study different ways to use the standard treatments so they will be more effective, easier to use, and/or decrease side effects. Sometimes, studies are done to learn how to best use the treatment in a different population, such as children, in whom the treatment was not previously tested.

For most trials, researchers, doctors, and other health professionals administer the clinical trials according to strict rules set by the Food and Drug Administration (FDA). FDA sets the rules to make sure that people who agree to be in studies are treated as safely as possible.

4. Where can people find out about clinical trials?

People can find information about clinical trials now being conducted now by searching clinicaltrials.gov. ClinicalTrials.gov is an interactive online database, managed by the National Library of Medicine. It provides information about both federally and privately supported clinical research in human volunteers. ClinicalTrials.gov is updated regularly and offers information on each trial's purpose, who is eligible to participate, locations, and phone numbers to call for more information.

Since ClinicalTrials.gov is only available online, individuals without Internet access can use the database at the public library or other publicly available internet portal.

5. Who should consider clinical trials and why?

It is important to test drugs and medical products in the people they are meant to help. It is also important to conduct research in a variety of people because different people may respond differently to treatments. FDA seeks to ensure that people of different ages, races, ethnic groups, and genders are included in clinical trials.

Some people participate in clinical trials because they have exhausted standard (approved) treatment options - which either did not work for them, or they were unable to tolerate certain side effects. Clinical trials may provide another option when standard therapy has failed.

Other people participate in trials because they want to contribute to the advancement of medical knowledge.

For each clinical trial, researchers develop eligibility criteria, such as the age, sex, type and stage of disease, previous treatment history, and other medical conditions. These criteria help to reduce the amount of variation in the study, without threatening the scientific integrity of the trial, by removing medical variations that might complicate analyzing the results.

Not everyone who applies for a clinical trial will be accepted. Volunteers may be excluded based on the eligibility criteria and/or the number of participants needed by the researchers to collect enough information to determine the safety and effectiveness of a therapeutic agent.

6. Are clinical trials safe?

The FDA works to protect participants in clinical trials and to ensure that people have reliable information as they decide whether to join a clinical trial. The federal government has [regulations and guidelines for clinical research](#) to protect participants from unreasonable risks.

Although efforts are made to control the risks to clinical trial participants, some risks may be unavoidable because of the uncertainty inherent in medical research studies involving new medical treatments.

The government requires researchers to give prospective participants complete and accurate information about what will happen during the trial. Participants must sign an "informed consent" document before joining the study indicating they understand that the trial is research, and that they can leave the clinical trial at any time. This informed consent is part of a process that ensures a prospective participant in a clinical trial understands what known risks might be associated with the study, and whether there are potential, but as yet unknown risks that may be associated with the product being studied. This information permits someone deciding whether or not to enter a clinical trial to make an informed decision about the level of risk they are willing to accept before they enter the trial.

7. What should people think about before joining a clinical trial?

People should learn as much as possible about the clinical trials that interest them. They should also feel comfortable discussing their questions and concerns with members of the health care team. Prospective participants should understand what happens during the trial, the type of health care they will receive, and any costs to them - which may or may not include the cost of the product, costs associated with administering the product, etc.

Anyone considering a clinical trial should also know that there are benefits and risks associated with participating.

Potential Benefits

Participating in well-designed and well-executed clinical trials is one approach for eligible patients/volunteers to:

- get actively involved in their health care.
- gain access to potentially new research treatments have access to expert medical care for the condition being studied, since investigators are often specialists in the disease area being studied.
- help others by contributing to medical research.

Possible Risks

There are generally known and unknown risks associated with clinical trials, such as:

- there may be unpleasant, serious, or even life-threatening side effects resulting from the treatment.
- the treatment may not be effective for the participant.
- the protocol may require more of the participant's time and attention than a standard treatment. (Participants may need to visit the study site on a regular basis, be subjected to additional tests, get more treatments than are normally necessary, stay in the hospital and/or follow complex dosage requirements.)

Payment/compensation:

Subjects are sometimes paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies is considered a recruitment incentive. Financial incentives are most often used when health benefits to subjects are remote or nonexistent. Volunteers may be offered compensation in certain trials for their time, and for discomfort that may be experienced during the trial. The amount of compensation is determined by the amount of time you will be required to dedicate to the trial, and to the level of discomfort that might be associated with medical or surgical procedures related directly to the study. Payment information, including the amount and schedule of payment(s), as well as any possible costs to volunteers who participate in a study, are discussed with potential participants during the informed consent process, and documented in the informed consent form.

8. What do the different “phases” of research mean?

- Phase I Initial humans studies are conducted with limited number of subjects (20-80) to assess safety.
- Phase II Studies are conducted with increased number of subjects (100-300) to assess effectiveness and further evaluate safety.
- Phase II Large scale human studies with (1,000-3,000) subjects are conducted over longer periods of time across multiple research sites continuing to assess effectiveness and safety.
- Phase IV Following FDA approval, expansive studies also known as post-marketing studies are conducted. They delineate additional information including the drug's risks, benefits and optimal use.