Clinical Trials: Frequently Asked Questions

What is a clinical trial?

Clinical trials are research studies that involve people. They are the final step in a long process that begins with research in a lab and animal testing. Many treatments used today are the result of past clinical trials. Clinical trials are designed to answer questions about new ways to:

- Treat conditions and diseases
- Find and diagnose disease
- Prevent disease
- Manage symptoms of a disease or its treatment

Why are clinical trials important?

Advances in medicine and science are the result of new ideas and approaches developed through research. New treatments must prove to be safe and effective in clinical trials with a certain number of patients before they can be made widely available.

Through clinical trials, researchers learn which approaches are more effective than others. This is the best way to test a new treatment. A number of standard treatments were first shown to be effective in clinical trials. These trials help us find new and better treatments.

What are the phases of clinical trials?

Most clinical research that involves the testing of a new drug progresses in an orderly series of steps, called "phases." This allows researchers to ask and answer questions in a way that results in reliable information about the drug and protects the patients. Most clinical trials are classified into one of three phases:

- Phase I trials: These first studies in people evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe. A phase I trial usually enrolls only a small number of patients, sometimes as few as a dozen.
- Phase II trials: A phase II trial continues to test the safety of the drug, and begins to evaluate how well the new drug works. Phase II studies usually focus on a particular type of cancer.
- Phase III trials: These studies test a new drug, a new combination of drugs, or a new surgical procedure in comparison to the current standard of care. A participant will usually be assigned to the standard group or the new group at random (called randomization). Phase III trials often enroll large numbers of people and may be conducted at many doctors' offices, clinics, and cancer centers nationwide.

In addition, after a treatment has been approved and is being commercially marketed, the drug's maker may study it further in a phase IV trial. The purpose of phase IV trials is to evaluate the side effects, risks, and benefits of a drug over a longer period of time and in a larger number of people than in phase III clinical trials. Thousands of people are involved in a phase IV trial.

What is randomization?

Randomization is a process used in some clinical trials to prevent bias. Bias occurs when a trial's results are affected by human choices or other factors not related to the treatments being tested. Randomization helps ensure that unknown factors do not affect trial results.

Randomization is used in some phase II and all phase III trials. These trials are called "randomized clinical trials." If you participate in such a trial, you will be assigned by chance to either an investigational group or a control group. Your assignment will be determined with a computer program or table of random numbers.

- If you are assigned to the control group, you will get the most widely accepted treatment (standard treatment or "standard of care").
- If you are assigned to the investigational group, you will get the new treatment being tested.

Comparing the control and investigational groups often clearly shows which treatment is more effective or has fewer side effects. If you are thinking about joining a randomized clinical trial, you need to understand that you have an equal chance to be assigned to either one of the groups. The doctor does not, and cannot, choose the group for you.

– Will I get a placebo?

A placebo is designed to look like the medicine being tested, but it is not active. **(Placebos are almost never used in cancer treatment trials.)** In some cases, a study may compare standard treatment plus a new treatment, to standard treatment plus a placebo. You will be told if the study uses a placebo.

– What is informed consent?

Before you agree to participate in any clinical trial, you will be educated about the study. You will receive information about the key aspects of the study, such as what types of treatment you may receive during the clinical trial. This is the beginning of a formal process called "informed consent." In addition to discussing the study with your doctors or study coordinators, a written consent form will be available for you to take home to read and discuss with your family and friends. The consent form will include:

- The study approach
- The intervention (such as a new drug or treatment) given in the trial
- The possible risks and benefits
- The tests you may have

If you decide to participate in a study, you will sign a consent form, but this is not the end of the informed consent process. Informed consent is designed to facilitate an ongoing conversation with your patient-care team so that you can make educated decisions about whether to participate - or to continue participating - in a clinical trial. Never hesitate to ask questions at any time about any aspect of the study or your care. **You can change your mind and leave the study whenever you want**, without prejudicing your treatment team or forfeiting access to other treatment.

Your research team has a duty to keep you informed, help you understand the information and answer your questions. We fully appreciate that clinical research and new, better treatments would not be possible without people like you!

– If I participate in a clinical trial, how will I be protected?

Informed consent is one of many safeguards in place to ensure patient protection. The federal government regulates most clinical research. All researchers prepare plans of action for their studies, called a "protocol." The protocol outlines how many people will

take part in the study, what medical tests they will receive and how often, as well as the treatment plan. The same protocol is used by every doctor who takes part in the study.

Before a study can proceed, its protocol must be reviewed and approved by the University of California, San Diego Institutional Review Board, which includes doctors, ethicists and members of the community. They ensure that the trial is safe and does not pose unethical risks to patients.

How do I know if I am eligible to participate in a clinical trial?

Each study has its own guidelines for who can participate, called "eligibility criteria." To ensure reliable results, researchers must study patients who are alike in key ways, such as having a particular type and stage of cancer or be a certain gender or age.

These guidelines help protect patients by ensuring that people who could be harmed by study drugs or other treatments are not enrolled. After the trial is completed, if it is proven to work, eligibility criteria helps doctors know which patient groups will benefit from the new treatment.

What is participating in a trial like?

Clinical trials take place in the same setting where standard patient care occurs. Your regular doctors, nurses, social workers and other health professionals are often part of the team that cares for you.

As a clinical trial participant, you may have more tests and office visits than patients following standard treatments. In addition to the treatment schedule prescribed by your physician, you may have other responsibilities, such as keeping a log or filling out forms about your health. Some studies continue to follow up with patients after treatment is over.

In addition to your doctor and nurse you will have a clinical research study coordinator to help you through the clinical trial. This individual will schedule appointments, make sure your labs are performed, ensure your visits go well, and will be on call for all questions relating to the trial.

What questions should I ask before participating in a clinical trial?

- About the trial
  - Why is this trial being done?
  - Why do the doctors who designed the trial believe that the treatment being studied may be better than the one being used now? Why may it not be better?
  - How long will I be in the trial?
  - What kinds of tests and treatments are involved?
  - What are the possible side effects or risks of the new treatment?
  - What are the possible benefits?
  - How will the doctor know if the treatment is working?
- Costs
  - Will I have to pay for any of the treatments or tests?
  - What costs will my health insurance cover?
- Daily life
  - How could the trial affect my daily life?
  - How often will I have to come to the hospital or clinic?

- Will I have to travel long distances?

- Comparing choices
  - What are my other treatment choices, including standard treatments?
  - How does the treatment I would receive in this trial compare with the other treatment choices?

How do I find out about available clinical trials?

Talk to your doctor or see Find a Clinical Trial.

For cancer clinical trials, use our search tool or see Cancer Clinical Trials.

How do I contact someone with additional questions?

Contact the Clinical and Translational Research Institute.

For cancer clinical trials, contact the Moores Cancer Center Clinical Trials Office.