CLINICAL TRIALS FAQ

ANSWERS TO FREQUENTLY ASKED QUESTIONS

What is clinical research?

Clinical research is medical research involving people. There are two types: observational studies and clinical trials.

Observational studies observe people in normal settings. Researchers gather information, group volunteers according to broad characteristics, and compare changes over time. For example, researchers may collect data through medical exams, tests, and/or questionnaires about a group of older adults over time to learn more about the effects of different lifestyles on cognitive health. These studies may help identify new possibilities for clinical trials, which test and evaluate an intervention in a controlled manner.

Source: NIH

What are clinical trials?

Clinical trials are human research studies aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment – such as a new drug, diet, or medical device (a pacemaker, for example) – is safe and effective in people. Clinical trials are required by the FDA to demonstrate the safety and effectiveness of new interventions.

Source: NIH

What kind of interventions do clinical trials evaluate?

In general, clinical studies (including clinical trials) are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions. Some common reasons for conducting clinical studies include:

- Evaluating one or more interventions (for example, drugs, medical devices, or approaches to surgery or radiation therapy) for treating a disease, syndrome, or condition
- Finding ways to prevent the initial development or recurrence of a disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches.
- Evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition
- Examining methods for identifying a condition or the risk factors for that condition
- Exploring and measuring ways to improve the comfort and quality of life through supportive care for people with a chronic illness

Source: clinicaltrials.gov

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How safe are clinical trials?

Before the FDA approves a clinical trial to begin, scientists perform laboratory tests and studies in animals to test a potential therapy's safety and effectiveness. If these studies show favorable results, the FDA gives approval for the intervention to be tested in humans.

There is risk to any intervention, and every drug has side effects. An institutional review board (IRB) is responsible for making sure that the risks are reasonable when compared to the demonstrated benefits for participants in each phase of a clinical trial.

Researchers are required by the FDA to educate those interested in participating about the risks of the clinical trial, a process called informed consent. Informed consent allows you to make an educated decision about whether to participate in a clinical trial based on factors such as duration of the study, risk, and potential side effects.

Participants in a clinical trial are never deprived the standard of care treatment (or approved treatments they are already receiving) for a health condition being studied.
You can remove yourself from a clinical trial at any time, for any reason.

Sources: NIH and *FDA*

Why would I want to participate in a clinical trial?

Major medical breakthroughs can only happen with the help of clinical trial participants. There are many reasons why people choose to join a clinical trial. Some join because the treatments they have tried for their health problem did not work; others participate because there is no standard treatment for their health problem; and some healthy participants are interested in finding ways to prevent certain diseases – especially those that may be common in their own families. Clinical trials allow you to gain access to the newest medical advancements and help make them available to the world.

Source: NIH

How do I find a clinical trial and become a participant?

If you are receiving treatment at UAB Medicine, your doctor likely is aware of clinical trials that might benefit you, and he or she often serves on research teams. Your doctor will often notify you if there is a clinical trial specific to your condition. Whether you have a medical condition or are healthy, you may still be interested in searching for clinical trials in which to take part. You can search for clinical trials underway at UAB by clicking here.

All current clinical trials in the United States are searchable at clinicaltrials.gov, a website managed by the National Institutes of Health (NIH).

Once you read an entry for a clinical trial, you then can determine if you may be eligible by reaching out to the research team, which can decide if you meet the inclusion/exclusion criteria.

Sources: NIH and clinicaltrials.gov

What will happen after I express an interest in participating in a clinical trial?

Here's what happens in a trial:

1. Study staff explain the trial in detail and gather more information about you.
2. Once your questions are answered and you agree to participate, you sign an informed consent form.
3. You are screened to make sure you qualify for the trial.
4. If accepted into the trial, you schedule a first visit (called the baseline visit). The researchers conduct cognitive and/or physical tests during this visit.
5. You are randomly assigned to a treatment or control group.
6. You and your family members follow the trial procedures and report any issues or concerns to researchers.
7. You may visit the research site at regularly scheduled times for new cognitive, physical, or other evaluations and discussions with staff. At these visits, the research team collects information about the effects of the intervention and your safety and well-being.
8. You continue to see your regular physician for usual health care throughout the study.

Source: NIH

What should I ask the research team about a clinical trial?

Anyone interested in participating in a clinical study should know as much as possible about the study and feel free to ask the research team questions about the study, the related procedures, and any expenses. The following questions may be helpful during such a discussion. Answers to some of these questions are provided in the informed consent document. Many of the questions are specific to clinical trials, but some also apply to observational studies:

- What is being studied?
- Why do researchers believe the intervention being tested might be effective? Why might it not be effective? Has it been tested before?
- What are the possible interventions that I might receive during the trial?
- How will it be determined which interventions I receive (for example, by chance)?
- Who will know which intervention I receive during the trial? Will I know? Will members of the research team know?
- How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?
- What will I have to do?
- What tests and procedures are involved?
- How often will I have to visit the hospital or clinic?
- Will hospitalization be required?
- How long will the study last?
- Who will pay for my participation?

- Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this trial?
- If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- Will results of the study be provided to me?
- Who will oversee my medical care while I am participating in the trial?
- What are my options if I am injured during the study?

Source: clinicaltrials.gov

What if my clinical trial is stopped early?

If a trial is stopped early, all enrolled participants must be notified for practical and ethical reasons. You will have a chance to ask questions and hear from the research team about next steps.
Some reasons why a trial might be stopped early include:

- The treatment or intervention being studied is clearly more effective or beneficial than existing ones.
- Participants are experiencing unexpected and severe side effects.
- The harm from the treatment or intervention is clearly greater than the benefits.
- The treatment or intervention is unlikely to have a meaningful effect, even if the study continues.
- Not enough participants could be recruited.
- The results of other trials are published that answer the research question or make it irrelevant.

Source: NIH

What happens after a clinical trial?

The length of a clinical trial or study varies, and this information will be shared with participants. After a clinical trial is completed, the researchers make decisions about the meaning of the findings and whether further testing is needed. After a phase I or phase II trial, the researchers conduct statistical analyses to evaluate the likelihood of success and decide whether to move on to the next phase or stop testing the treatment or procedure. When a phase III trial is completed, the researchers examine the information and decide whether the results indicate that the treatment or procedure was safe and effective.

Source:NIH

Will I have continued access to the intervention?

Clinical trials do not provide extended or complete health care. Usually when a study ends, the drug or product that is being tested will not be available to participants until it has gone through additional testing and approval.

In some cases, study participants can stay on the study drug through what is called an open label extension. In this type of study, participants who were part of a randomized controlled trial are invited to continue taking the drug after the initial study ends.

After the clinical trial, there may be a waiting period before you can participate in another trial. One reason for this waiting period is to be sure that the original experimental drug is out of your system and would not influence the results of the next study.

Source: NIH

Can I continue to see my doctor and receive care?

Participants should continue to see their usual health care providers while enrolled in a clinical study. Most clinical studies provide participants with medical products or interventions related to the illness or condition being studied, but they do not provide extended or complete health care. By having their usual health care provider work with the research team, participants can make sure that the study guidelines will not conflict with other medications or treatments they receive.

Source: clinicaltrials.gov

What happens to my personal information?

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge. HIPAA applies to all phases of clinical trials and continues to apply when the results of clinical trials (known as case studies) are published or presented to an audience. Physicians must obtain written HIPAA authorization before publishing papers or making presentations containing your personal health information, except when they are conducting certain medical education activities.