COMMUNITY LIVER ALLIANCE™

GLOBAL AWARENESS. LOCAL IMPACT.



An Introduction to Clinical Trials for Patients

Clinical Trial Guidelines for Health Care Patients

The CLA Clinical Trial Guidelines is a resource tool to help you learn more about clinical trials. Through our downloadable toolkit and informational video, you can educate yourself more thoroughly on the purpose and process of clinical trials. Deciding to participate in a trial is a team effort. Our tools will give you a head start in understanding what a clinical trial is, the benefits and risks, as well as how the process works - so you can feel confident in speaking with your doctors, family, and caregivers about your options. If you're considering a clinical trial, we want to help you prepare and ensure you understand as much as you can as a first step.

Goals

Our clinical trial guidelines, will:

- Help you make an informed decision about participating in a clinical trial.
- Provide you with credible and current clinical trial opportunities.
- Provide resources and access to clinical trial opportunities.

Table of Contents

What are clinical trials? 4

Who should consider clinical trials and why? 5

What questions should I ask if offered a clinical trial? 6

Where are clinical trials conducted? 7

Are clinical trials safe? 9

What should I think about before joining a clinical trial? 10

What is the FDA's role in approving new drugs and medical treatments? 11

What do the terms placebo, randomization, and blinded mean in clinical trials? 12

How do I find out what Phase a drug is in as part of the clinical trial? 13

What happens after a clinical trial is completed? 14

What happens to drugs that don't make it out of clinical trials? 15

How do I participate in a clinical trial? 16

Where can I find clinical trials? 17

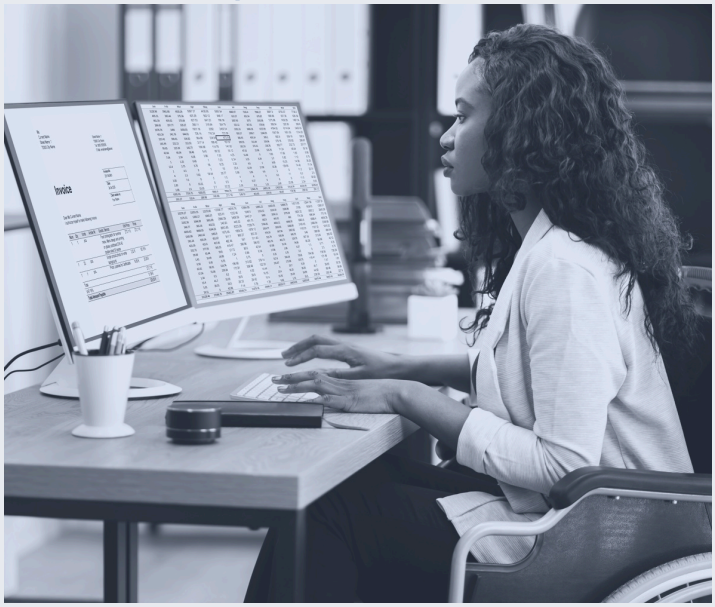
Questions to Ask Your Healthcare Provider 18

Questions to Ask the Clinical Trial Team 20

Glossary 22

What are clinical trials?

Clinical trials are research studies in which people volunteer to help find answers to specific health questions. When carefully conducted, they are the safest and fastest way to find new treatments and ways to improve health. Clinical trials are conducted according to a plan, called a protocol, which describes:



- the types of patients who may enter the study
- the schedules of tests and procedures
- the drugs involved
- the dosages, or amount of the drug
- the length of the study
- what the researchers hope to learn from the study

Volunteers who participate in the study must agree to the rules and terms outlined in the protocol. Similarly, researchers, doctors, and other health professionals who manage the clinical trials must follow strict rules set by the FDA. These rules make sure that those who agree to participate are treated as safely as possible.

Who should consider clinical trials and why?

Some people participate in clinical trials because none of the standard or approved treatment options have worked, or they are unable to tolerate certain side effects. Clinical trials provide another option when standard therapy has failed. Others participate in trials because they want to contribute to the advancement of medical knowledge.

All clinical trials have guidelines, called eligibility criteria, about who can participate. The criteria are based on such factors as age, sex, type and stage of disease, previous treatment history, and other medical conditions. This helps to ensure that the researchers will be able to answer the questions they plan to study. Therefore, not everyone who applies for a clinical trial will be accepted.

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. Learn more about FDA's efforts to increase diversity in clinical trials.

If you are thinking about taking part in a clinical trial, you should feel free to ask any questions or bring up any issues concerning the trial at any time.

What questions should I ask if offered a clinical trial?

The study

- What is the purpose of the study?
- Why do researchers think the approach may be effective?
- Who will fund the study?
- Who has reviewed and approved the study?
- How are study results and safety of participants being monitored?
- How long will the study last?
- What will my responsibilities be if I take part?
- Who will tell me about the results of the study and how will I be informed?

Risks and possible benefits

- What are my possible short-term benefits?
- What are my possible long-term benefits?
- What are my short-term risks, and side effects?
- What are my long-term risks?
- What other options are available?
- How do the risks and possible benefits of this trial compare with those options?

Participation and care

- What kinds of therapies, procedures and/or tests will I have during the trial?
- Will they hurt, and if so, for how long?
- How do the tests in the study compare with those I would have outside of the trial?
- Will I be able to take my regular medications while taking part in the clinical trial?
- Where will I have my medical care?
- Who will be in charge of my care?

What questions should I ask if offered a clinical trial?

Personal issues

- How could being in this study affect my daily life?
- Can I talk to other people in the study?

Cost issues

- Will I have to pay for any part of the trial such as tests or the study drug?
- If so, what will the charges likely be?
- What is my health insurance likely to cover?
- Who can help answer any questions from my insurance company or health plan?
- Will there be any travel or childcare costs that I need to consider while I am in the trial?

Tips for asking your doctor about trials

- Consider taking a family member or friend along for support and for help in asking questions or recording answers.
- Plan what to ask — but don't hesitate to ask any new questions.
- Write down questions in advance to remember them all.
- Write down the answers so that they’re available when needed.
- Ask about bringing a tape recorder to record of what's said (even if you write down answers).

WHERE ARE CLINICAL TRIALS CONDUCTED?

Clinical trials can be sponsored by organizations (such as a pharmaceutical company), federal offices and agencies (such as the National Institutes of Health or the U.S. Department of Veterans Affairs), or individuals (such as doctors or health care providers). The sponsor determines the location(s) of the trials, which are usually conducted at universities, medical centers, clinics, hospitals, and other federally or industry-funded research sites.

ARE CLINICAL TRIALS SAFE?

The FDA works to protect participants in clinical trials and to ensure that people have reliable information before deciding 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 participants, some may be unavoidable because they are still learning more about the medical treatments in the study.

The government requires researchers to give prospective participants complete and accurate information about what will happen during the trial. Before joining a particular study, you will be given an informed consent document that describes your rights as a participant, as well as details about the study, including potential risks. Signing it indicates that you understand that the trial is research and that you may leave at any time. The informed consent is part of the process that makes sure you understand the known risks associated with the study. Informed consent is the process of providing you with key information about a research study before you decide whether to accept the offer to take part. The process of informed consent continues throughout the study.

To help you decide whether to take part, members of the research team explain the details of the study. If you do not understand English, a translator or interpreter may be provided. The research team provides an informed consent document that includes details about the study, such as its purpose, how long it's expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits. You can then decide whether to sign the document. Taking part in a clinical trial is voluntary and you can leave the study at any time.

WHAT SHOULD I THINK ABOUT BEFORE JOINING A CLINICAL TRIAL?

Before joining a clinical trial, it is important to learn as much as possible. Discuss your questions and concerns with members of the health care team conducting the trial.

Also, discuss the trial with your health care provider to determine whether or not the trial is a good option based on your current treatment. Be sure you understand:

- what happens during the trial,
- the type of health care you will receive,
- any related costs once you are enrolled in the trial,
- the benefits and risks associated with participating.

WHAT IS FDA'S ROLE IN APPROVING NEW DRUGS AND MEDICAL TREATMENTS?

The FDA makes sure medical treatments are safe and effective for people to use. They do not develop new therapies or conduct clinical trials. Rather, they oversee the people who do. The FDA staff meet with researchers and perform inspections of clinical trial study sites to protect the rights of patients and to verify the quality and integrity of the data.

HOW DO I FIND OUT WHAT PHASE A DRUG IS IN AS PART OF THE CLINICAL TRIAL?

There are 4 phases of biomedical clinical trials:

- **Phase I** studies usually test new drugs for the first time in a small group of people to evaluate a safe dosage range and identify side effects.
- **Phase II** studies test treatments that have been found to be safe in phase I but now need a larger group of human subjects to monitor for any adverse effects.
- **Phase III** studies are conducted on larger populations and in different regions and countries and are often the step right before a new treatment is approved.
- **Phase IV** studies take place after country approval and there is a need for further testing in a wide population over a longer timeframe.

Talk to the clinical trial coordinator to find out which phase the clinical trial is in. Learn more about the different clinical trial phases and whether they are right for you.

WHAT HAPPENS AFTER A CLINICAL TRIAL IS COMPLETED?

After a clinical trial is completed, the researchers carefully examine information collected during the study before making decisions about the meaning of the findings and about the need for further testing. After a phase I or II trial, the researchers decide whether to move on to the next phase or to stop testing the treatment or procedure because it was unsafe or not effective. When a phase III trial is completed, the researchers examine the information and decide whether the results have medical importance.

Results from clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which experts review the report before it is published to ensure that the analysis and conclusions are sound. If the results are particularly important, they may be featured in the news, and discussed at scientific meetings and by patient advocacy groups before or after they are published in a scientific journal. Once a new approach has been proven safe and effective in a clinical trial, it may become a new standard of medical practice.

Ask the research team members if the study results have been or will be published. Published study results are also available by searching for the study's official name or Protocol ID number in the National Library of Medicine's PubMed® database.

WHAT HAPPENS TO DRUGS THAT DON'T MAKE IT OUT OF CLINICAL TRIALS?

Most drugs that undergo preclinical (animal) research never even make it to human testing and review by the FDA. The drug developers go back to begin the development process using what they learned during with their preclinical research.

HOW DO I PARTICIPATE IN A CLINICAL TRIAL?

The first step is to talk to your doctor to see if clinical trials are an option for you. If clinical trials are a good option for you, contact the clinical trial coordinator to see if you meet the requirements for the clinical trial. If you meet the initial requirements, you will be scheduled for a pre-trial screening where tests will be done to help researchers decide if you are a candidate for the trial. The pre-trial screening also will be an opportunity for you to learn more about the clinical trial including its benefits and risks.

WHERE CAN I FIND CLINICAL TRIALS?

One good way to find out if there are any clinical trials that might help you is to ask your doctor. Other sources of information include:

- **FDA Clinical Trials Search**. Search a database of Federally and privately supported studies available through clinicaltrials.gov. Learn about each trial's purpose, who can participate, locations, and who to contact for more information.
- **Clinicaltrials.gov**: Conduct more advanced searches
- **National Cancer Institute** or call 1–800–4–CANCER (1–800–422–6237): Learn about clinical trials for people with cancer.
- **AIDS Clinical Trials and Information Services (ACTIS)** or call 1–800–TRIALS–A (1–800–874–2572): Locate clinical trials for people with HIV.
- **AIDSinfo.** Search a database of HIV/AIDS trials, sponsored by the National Institutes of Health's National Library of Medicine.
- **NIH Clinical Research Trials and You**: Learn more about the basics of clinical trial participation, read firsthand experiences from actual clinical trial volunteers, and see explanations from researchers.
- Currently 30 states have laws or agreements requiring health insurance plans to cover at least the cost of routine care when participating in clinical trials. To find out more about the regulations in your state visit: **cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs**

QUESTIONS TO ASK YOUR HEALTHCARE PROVIDER

1. Are clinical trials an option for me? If so, what types of clinical trials am I eligible for?

2. Do you know of clinical trials that I can participate in that would be a good option for me?

3. What are the benefits of participating in a clinical trial?

4. What are the risks associated with participating in a clinical trial?

5. If I am assigned to a placebo group, will the treatment be available to me after the trial?

6. What symptoms or signs should I be looking for to know if I am having positive or negative side effects to the experimental treatment?

7. How will participating in a clinical trial affect my other health conditions?

8. Can I continue to take my current medications if I participate in the clinical trial?

9. Do I follow up with you during the trial or the clinical trial team?

QUESTIONS TO ASK THE CLINICAL TRIAL TEAM

1. What is the purpose of this clinical trial?

2. Why is this experimental treatment believed to be effective?

3. What are the benefits associated with this clinical trial?

4. What are the risks associated with this clinical trial?

5. How do the possible benefits and risks of this trial differ compare with my current treatment?

6. What short and long term impact will this trial have on my day to day activities?

7. What is expected of me if I participate in this clinical trial?

8. What kinds of tests are involved?

9. How long will the clinical trial last?

10. Is it possible that I may receive a placebo?

QUESTIONS TO ASK THE CLINICAL TRIAL TEAM

11. Will I need to pay for any part of this clinical trial?

12. How will I know that the experimental treatment is working?

13. What happens if my condition gets worse during the clinical trial?

14. If for some reason I need to stop my participation in this clinical trial, how do I communicate that and to whom?

15. Who will be responsible for my care?

16. Should I continue to see my own doctor during the clinical trial?

17. What type of long term follow up care is part of this study?

18. What happens at the end of the clinical trial?

19. Will I be told the results of the clinical trial? When?

GLOSSARY

Clinical trial: A clinical trial is a medical research study conducted to find answers to health questions. Clinical trials are often conducted to evaluate new medications, combination of medications, or new ways to use current treatments. Clinical trials are also conducted to evaluate new tests, equipment, and procedures for diagnosing and detecting health conditions and to find vaccines to prevent illnesses.

Control group: A control group consists of participants who receive either standard treatment or a placebo and serves as a comparison group to measure the effectiveness of the experimental treatment other participants are receiving.

Double blind study: A double blind study is a clinical trial in which both the participant and clinical trial team do not know which participants are receiving the experimental treatment and which are receiving a placebo or standard treatment.

U.S. Food and Drug Administration (FDA): The Food and Drug Administration (FDA) is a government agency responsible for ensuring the safety and effectiveness of all medications, vaccines, medical equipment used for prevention, diagnosis, and treatment.

Informed consent: Informed consent is the process of learning about the clinical trial before deciding whether or not to participate. There is an informed consent form that all participants are required to review and sign if they want to participate in the clinical trial. The informed consent form will include information on the clinical trial process, including tests that may be conducted, known risks and benefits of experimental treatment, length of clinical trial, and clinical trial contact information.

GLOSSARY

Institutional Review Board (IRB): An Institution Review Board is a committee of health care professionals and community members, who review, approve, and monitor clinical trials to make sure potential risks are as low as possible and that the clinical trial follows ethical and legal codes for medical practice.

Placebo: A placebo is an inactive pill, liquid or powder that looks like the experimental treatment but has no effect on the body. In some clinical trials, experimental treatments are compared with placebos to evaluate the effectiveness of the experimental treatment.

Protocol: A protocol is the clinical trial plan that explains the purpose and process of the trial. A protocol will include information such as who can participate, how many people will participate, what the treatment plan involves, type and frequency of tests, how the results will be measured, reasons why the clinical trial may be stopped, reasons why the researchers may stop giving the experimental treatment to a participant, known and likely side effects of the experimental treatment, and potential benefits of the experimental treatment.

Randomization: Randomization is a method used to randomly assign participants to treatment and/or control groups.

Single blind study: A single blind study is a clinical trial in which either the participant or the clinical trial team does not know if the participant is taking the experimental treatment.

RESOURCES

- FDA Clinical Trials Search
- Clinicaltrials.gov
- National Cancer Institute or call 1–800–4–CANCER (1–800–422–6237)
- AIDS Clinical Trials and Information Services (ACTIS)External Link Disclaimer or call 1–800–TRIALS–A (1–800–874–2572).
- AIDSinfo
- NIH Clinical Research Trials and You
- cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs

Get in touch

100 W. Station Square Drive, Suite 212

412-501-3CLA (3252)

Support@communityliveralliance.org

www.communityliveralliance.org

COMMUNITY LIVER ALLIANCE™

GLOBAL AWARENESS. LOCAL IMPACT.