Abington Hematology Oncology Associates

Clinical Trials FAQ's

What are clinical trials?

Clinical trials are research studies that involve people who participate voluntarily. Each study that AHOH participates in tries to answer specific scientific questions and find better ways to prevent, diagnose, or treat cancer.

Why are cancer clinical trials important?

Cancer clinical trials contribute to medical knowledge and progress against cancer, thus improving patient care. Clinical trials are the only way new cancer treatments can be tested for success and safety before being made available to the public. The standard cancer treatments used today are based on previous clinical trial results.

What is the purpose of a cancer clinical trial?

Clinical trials are a critical component in expanding treatment options for people with all types of cancer. Because all new therapies must be evaluated through clinical trials, the greater the number of people who participate, the faster emerging anticancer therapies can be brought to patients. Clinical trials are also important because they offer hope to people with cancer by providing access to promising new therapies not yet available outside the study.

What are the types of cancer clinical trials?

There are four different types of cancer clinical trials, which include:

1. Treatment trials, which test new drugs, medical procedures, or combinations of treatments.

2. Prevention trials, which look for better ways to prevent diseases by either doing something (called action studies) like making lifestyle changes or taking something (called agent studies) such as medicines, vitamins, or minerals.

3. Screening trials, which look for new ways to test for the presence of a disease or health condition early, when it may be more easily treated.

4. Quality of life trials, which explore ways to improve comfort and quality of life for cancer patients.

What is a protocol?

A protocol is a study plan on which all clinical trials are based. The plan is carefully designed to protect the health of the participants as well as answer specific research questions. A protocol specifically outlines the purpose of the study as well as details such as who is eligible to participate, the study size, number of participants and describes the plan of care and collection of data. A study's protocol is carefully developed and reviewed by the Principal Investigator and the sponsoring organization. It is then reviewed and approved by an Institutional Review Board (IRB) to ensure trial procedures are consistently carried out. This protocol is used by every doctor taking part in the study.

How do clinical trials work?

Clinical trials are designed by cancer doctors and researchers, and they are conducted according to strict scientific and ethical principles. Before a cancer research study begins, a protocol is developed describing what will be done in the study, how it will be conducted and why each part of the study is necessary. This research protocol is reviewed by third-party experts to make sure that study is conducted fairly and that patients are well-informed of their rights. Each study has eligibility criteria regarding who can or cannot participate in the study, which may include the type of cancer, age, gender, medical history, and current health status.

Who participates in a clinical trial?

Patients considering participation in a clinical trial will receive important facts about the study's purpose and what is involved, such as the tests and other procedures used, and the possible risks and benefits of clinical trials. Should a patient decide to participate, he or she will be asked to sign a written consent form that outlines the details of the study prior to beginning the clinical trial. However, participation in the trial is completely voluntary and patients may stop at any time.

Why consider a clinical trial for your cancer treatment?

Those who do decide to participate can experience benefits, which may include:

- Access to a cancer treatment that isn't yet publicly available.
- Free or low-cost treatment for the duration of the study.
- Contributing to cancer research that may provide life-saving treatment to future cancer patients.

- A more active role in your own healthcare.
- Close monitoring from some of the best cancer doctors.

What are the benefits of participating in a cancer clinical trial?

- Patients receive quality care from [Practice Name] physicians and other health professionals who specialize in cancer care.
- Patients have access to promising new therapies that doctors hope will be more effective and less toxic than the standard treatment. These therapies are not yet available to patients outside the study.
- Patients can play an active role in your cancer care by expanding your treatment options.
- Patients who participate in clinical trials receive first-rate medical care during the trial and throughout treatment. Their overall health is closely monitored.
- By participating in clinical trials that can help bring a new cancer treatment to market, patients are contributing to the greater knowledge of cancer that may help other cancer patients in the future.

What are some of the possible risks of participating in clinical trials?

Some possible clinical trial risks that patients may face could include:

- Participants in randomized studies will not be able to choose the approach they receive.
- Some health insurances or managed care plans may not cover all patient care costs in a study, in which case the patient would be responsible for these costs.
- New treatment may have unknown side-effects or risks.
- The treatment being studied may be less effective than the standard treatment for that cancer.

Since risks vary in each individual situation, it's important to talk with your oncologist to understand the specific risks related to any clinical trial that you may be considering participation in.

How are my rights protected during a clinical trial?

Clinical trials are conducted according to strict scientific and ethical principles, and groups of experts at the national and local levels approve research studies before they begin. One important group who evaluates clinical trials is the Institutional Review Board (IRB) of the research organization implementing the trial. An IRB is made up of

doctors, researchers, community leaders and other members of the community. This board is focused on protecting the safety of participants by reviewing the protocol to make sure the study is conducted fairly, and participants are well-informed of their rights during the study.

Who pays for clinical trials?

There are two types of costs associated with a clinical trial: patient care costs and research costs.

1. **Patient care costs** are those costs related to treating your cancer, whether you are in a cancer research trial or receiving standard therapy. These costs are often covered by health insurance and usual copays and coinsurance would apply. Doctor visits, hospital stays, standard cancer treatment, lab tests, and imaging tests are considered patient care costs.

2. **Research costs** are those related to taking part in the trial. Often these costs are not covered by health insurance but are usually covered by the research trial's sponsor. Study drugs, as well as, additional lab and/or imaging tests performed solely for the trial are examples of research costs.

When you take part in a clinical trial, you may have extra doctor visits that you would not have with standard treatment. During these visits, your cancer care team carefully watches for side effects and your safety in the study.

Will I continue to work with my primary healthcare provider while in a cancer research trial?

Yes, most clinical trials do not provide complete primary health care.

Do I have to participate in a clinical trial?

No, your participation in a clinical trial is completely voluntary at all times. Cancer patients considering participation must first learn the key facts such as the purpose, risks, and benefits of the specific clinical trial. This process is called informed consent. It is important to ask lots of questions and consider all of your treatment options before you decide if taking part in a study is right for you.

How should I prepare for the meeting with the research coordinator or doctor?

There is a lot to learn regarding clinical trials. To ensure that you gather all the necessary information, come prepared with a list of possible questions to ask. You might also want to bring a device that can record the discussion. Additionally, consider asking a friend or relative to join you for support and to hear the responses to the questions.

Can I leave a clinical trial after it has begun?

Yes. Cancer research participation is strictly voluntary. Participants may withdraw their decision to participate at any time for any reason. When withdrawing from the clinical trial, you should let the research team know about it and the reasons for leaving the study.

What if the new treatment does not seem to be working for me?

With clinical trials, it is important to remember that the new cancer treatment may not be better than, or even as good as, the standard treatment. 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. If the cancer treatment you are receiving doesn't seem to be working, you should discuss with your oncologist to consider other cancer treatment options.

What do I do if I want to consider a clinical trial for my cancer treatment?

If you are interested in clinical trial participation, you should know as much as possible about the study. This means taking time to ask important questions regarding the study, including its purpose, the procedures involved, and expenses you'll be faced with. Other questions to ask about cancer research include:

- What is the purpose of this study?
- Has the new treatment been tested before? If so, what are the results?
- How can it help me? How will I know if the treatment is helping me?
- What other treatment options are available?
- How will participating in this study affect my daily life? What side effects might I experience?
- Are there possible long-term risks?
- Who is sponsoring this study?
- What kinds of treatment, medical tests or procedures will I have during the study? How often?
- Where will I receive my treatment?
- Who will be in charge of my care?
- How long will the study last?
- Will I have to pay for any treatments, tests or other charges?

•Will my health insurance cover treatments and tests I receive as part of this study?

•How am I protected? Will my medical records be kept confidential?

•What kind of follow-up care will I receive after the study?

•When do I have to make a decision about participating?

Do I have to go to a different oncologist if I participate in the trial?

No. Typically, patients who decide to participate in a clinical trial keep their current oncologist since clinical trials do not provide extended or complete healthcare. Maintaining a relationship with your doctor helps ensure that the study protocol will not conflict with other medications or treatments that you are receiving.