

# HELPFUL FACTS

## Clinical Trials

### What is a Clinical Trial?

Clinical trials are studies to find new ways to prevent, detect and treat cancer. The purpose of each clinical trial is to answer a specific question. Our physicians carefully design these studies to find new ways to improve care and quality of life.

There are different types of clinical trials. The type of trial depends on what is being studied. Each study tries to answer a different scientific question. The development of the clinical trial is the result of a carefully thought out research process.

### Types of clinical trials include:

- **Cancer treatment trials** test new treatments. Examples of cancer treatment trials include the testing of new:
  - Cancer drugs
  - Approaches to surgery or radiation therapy
  - Combinations of treatments
  - Methods, such as gene therapy
- **Cancer prevention trials** test new ways to reduce the risk of developing certain types of cancer. Prevention trials are carried out with healthy people who have not been diagnosed with cancer. They may also be carried out with people who have had cancer and are trying to prevent cancer from coming back (recurrence). There are two kinds of cancer prevention trials:
  - Action studies (doing something) find out whether actions people take can prevent cancer. Examples would be, exercising or quitting smoking.
  - Agent studies (taking something) are to find out whether taking certain medicines, vitamins, minerals, or food supplements (or a combination of them) can prevent cancer.
- **Cancer screening trials** test the best way to find cancer. Especially in its early stages. Screening trials test new ways of finding cancer in people before they have any cancer symptoms. These methods of detecting cancer, often called screening tests, can include:
  - Imaging tests - tests that take pictures of areas inside the body
  - Laboratory tests - tests that check blood, urine, and other body fluids and tissues
  - Genetic tests - tests that look for inherited genetic markers linked to some types of cancer
- **Cancer genetics trials** seek to determine how a person's genes can influence detection, diagnosis, prognosis and treatment. These trials help increase our understanding of the causes of cancer. They also help in developing targeted treatments based on tumor genetics.



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- **Quality of life trials** study ways to improve comfort and quality of life for cancer patients. Examples of these types of trial include the study of:
  - Drugs to reduce the side effects of cancer treatment
  - Problems encountered by cancer patients, such as fatigue, nausea, pain, weight loss, a risk for second cancers, and depression
  - The benefit of nutrition, group therapy, and other approaches

## ***Why Consider a Clinical Trial?***

People take part in cancer clinical trials for many reasons. Certainly, they hope to benefit personally from the new approach under study, since clinical trials also give patients access to the latest advances available in the nation. Others participate as a way to prevent or treat cancer that may arise in their family or community at large.

## ***How are clinical trials carried out?***

Research with people is carried out according to strict scientific and ethical principles. These include:

- Each clinical trial has a protocol (action plan) that explains how the study will be carried out.
- The person in charge of the study is called the investigator. This is usually a doctor. The investigator prepares the protocol for the study. This protocol explains what will be done and why. It outlines:
  - how many people will take part in the study
  - what medical tests they will receive and how often
  - the treatment plan

The same protocol is used by each doctor that takes part in the study.

- For patient safety, each protocol is approved by:
  - The organization that sponsors the study (such as the National Cancer Institute or American Cancer Society).
  - Penn's Institutional Review Board, (IRB). This board, which includes consumers, clergy, and health professionals, reviews the protocol to ensure that the research will not expose patients to extreme or unethical risks.
  - The Cancer Center's Clinical Trials and Scientific Review and Monitoring Committee, which is approved by the National Cancer Institute and reviews the scientific merit of a clinical trial before it begins.
- Each study enrolls people who are alike in key ways. Each study's protocol describes the characteristics that all patients in the study must have. These key characteristics are called eligibility criteria. Eligibility criteria differ from study to study, depending on the research purpose. They may include such factors as age, gender, the type and stage of cancer.

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[Cancer.PennMedicine.org](http://Cancer.PennMedicine.org) and [OncoLink.org](http://OncoLink.org)



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- Cancer clinical trials are carried out in three different phases. Each phase answers different questions about the new treatment.
  - **Phase I trials** are the first step in testing a new treatment in humans. In these studies, researchers look for the best way to give a new treatment. Such as, by mouth, IV drip, or injection and how frequently it should be given. They also try to find out if and how the treatment can be given safely (e.g., best dose). They also watch for any harmful side effects. Because less is known about the possible risks and benefits in Phase I, these studies usually include only a small number of patients who would not be helped by other known treatments.
  - **Phase II trials** focus on learning whether the new treatment has an anticancer effect. Such as: does it shrink a tumor or improve blood test results? As in Phase I, only a small number of people take part because of the risks and unknowns involved.
  - **Phase III trials** compare the results of people taking the new treatment with results of people taking standard treatment. In most cases, studies move into Phase III testing only after a treatment shows promise in Phases I and II. Phase III trials may include hundreds of people around the country.

## ***Special Considerations for Women and Minority Populations***

The trials conducted at our Cancer Center include all populations except in those instances when it is clinically indicated for a certain group. For example, prostate cancer trials only accept male patients for their studies.

Cancer Center investigators pay particular attention to actively including women and minority populations in their research efforts. The unique strength of a well-designed and conducted clinical trial that involves women and minorities is its ability to provide information of direct benefit to these groups. Research that represents our community at large, in turn, enables health professionals to make better judgments about treatment and caring for all types of patients. We are also sensitive to the fact that certain groups may have particular issues about participating in trials and our physicians and staff are prepared to discuss any questions that you may have.

## ***Questions to Ask Your Doctor or Nurse***

### **Is there a study that might be right for me?**

- Why is the study being done?
- How might it help me?
- What will happen to my cancer if I take part in the study? What will happen to my cancer without this study?
- What were the results of any prior studies of this treatment?

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- What other treatments could I get if I don't take part in the study? What are the risks and side effects of that treatment?

## **If I join the study:**

- How am I protected?
- What tests and treatments are in the study?
- Will I continue to see my current doctor, or will I be seeing a different one (or both)?
- What effect will the study have on my daily activities? Will I still be able to work or go to school?
- Will I have to be in the hospital?
- What are the possible risks or side effects for me?
- How do the risks and side effects of other treatment options compare with the study?
- Will my insurance cover being in the study?
- Will there be extra costs because of the study?
- How will I be checked after the study?

**Talk to your Doctor or Nurse about a Clinical Trial that might be right for you.**

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