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fact sheet

CLINICAL TRIALS: WHAT YOU NEED TO KNOW

Cancer clinical trials are research studies that involve people with cancer. The goal of these studies is to find better ways to diagnose, treat, and prevent cancer. The results of the trials also provide information about how to reduce the risk of cancer in people who have not been diagnosed.

CLINICAL TRIALS

Clinical trials may provide an opportunity for patients to access the latest in cancer care and help identify new therapies for people with cancer. Patients are encouraged to discuss their treatment options, including whether a clinical trial is a viable option, with their health care team. Doctors across the country and around the world follow treatment guidelines developed from the results of clinical trials so they can deliver the best possible care to their patients. Today there are about 12 million cancer survivors in the United States, mainly because the new therapies developed in clinical trials are helping people with cancer live longer than ever before. That is why it is so important to continue this research.

HOW DO CLINICAL TRIALS WORK?

A clinical trial often starts with a scientific idea based on the results of laboratory research. Researchers who come up with these ideas usually work in cancer centers, universities, community clinics, pharmaceutical company labs, or hospitals.

Before any treatment is tested in a clinical trial, many scientists and physicians have studied it to learn how the drug is absorbed into the body, how long it lasts in the body, and whether it should be given by mouth or intravenously (through a needle into a vein).

Together, doctors and researchers design the studies and submit an investigational new drug application to the U.S. Food and Drug Administration (FDA). Scientists from the FDA review the procedure, technology, or drug and provide input. Additionally, experts review the trial at many different points during its development and make sure that the clinical trial is designed with the overall goal of improving cancer care for patients.

Clinical trials that test new drugs or other treatments are done in phases. Each phase has a different purpose and helps researchers answer different questions. If a new drug or treatment does not seem promising in the early phases, the research can be stopped.

RIGHTS AND PROTECTIONS

People who take part in clinical trials have both rights and protections to make sure their privacy and well-being are taken care of. One of the most important protections is called informed consent. This is a process to ensure that the participant understands all aspects of the study, including the risks and benefits. A written consent document is signed by a patient, stating that he or she has entered the trial of his or her own free will.

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As a patient in a clinical trial, you always have the right to leave a trial at any time for any reason. There will be no penalty and no harm done; all patients always have that legal and ethical right. Your doctor will also be in communication with the trial, and if it seems that the treatment is not working, the physician and patient together may decide to leave the trial.

Besides informed consent, you will be asked to sign another form called a HIPAA Authorization. Health Insurance Portability and Accountability Act (HIPAA), allows doctors to use your health information as part of the report on the study, without using your name or other personal details.

Each research institution, hospital, or cancer center that conducts clinical trials has a committee called an Institutional Review Board (IRB). An IRB includes doctors, nurses, lawyers, and people affected by cancer. The IRB reviews each clinical trial to make sure it is safe and ethical, in order to protect the people who take part. They review the study on a regular basis to be sure it is being carried out properly.

If you have concerns about any part of being in a clinical trial, speak with a patient representative at the institution where the trial is being conducted. The name and contact information for this person are usually included on the informed consent document. If a patient representative is not listed, ask if there is someone else you can speak with, such as a nurse or social worker.

QUESTIONS TO ASK

If you and your health care team have decided that a clinical trial is the right choice for you, there are a number of questions you should ask, including:

- What is the purpose of the study?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this study affect my daily life?
- How many visits per week or month will I need to make?
- How long will the study last?
- Is a hospital stay required?
- Who will pay for the treatment? Will the trial, or my insurance, cover all or part of it?
- What will I need to pay for myself?
- Will I be reimbursed for any expenses such as transportation?
- What type of long-term follow-up care is part of this study?
- How will I know that the treatment being studied is working? Will the results of the trial be given to me?
- Who will be in charge of my care?
- Are there other experts I can talk to about this study?
- Can I take the informed consent form home to talk it over with my family or partner?

CancerCare® Can Help

Founded in 1944, Cancer*Care* is the leading national organization providing free support services and information to help people manage the emotional, practical and financial challenges of cancer. Our comprehensive services include counseling and support groups over the phone, online and in-person, educational workshops, publications and financial and co-payment assistance. All Cancer*Care* services are provided by professional oncology social workers and world-leading cancer experts.

To learn more, visit **www.cancercare.org** or call **800-813-HOPE (4673)**.
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