FACTS FOR LIFE

Clinical Trials

What is a clinical trial?

Clinical trials are carefully controlled research studies. People volunteer to take part in them. They are done to test the safety and benefits of new ways to prevent, diagnose or treat disease. They also identify risks that may not yet be known. Clinical trials have led to many medical advances, such as screening mammography, lumpectomy and the use of tamoxifen.

There are three main types of clinical trials:

Phase 1 (phase I) tests to see if a new treatment is safe to use over a range of doses. This phase also looks for early signs of effectiveness.

Phase 2 (phase II) tests to see if the treatment works for a specific disease.

Phase 3 (phase III) compares the effectiveness of the new treatment against a standard treatment.

Not all clinical trials fall neatly into one category. Some trials may be a combination of two categories, such as a phase I/II or phase II/III trial.

Before a treatment is tested in a clinical trial, it has been studied in a laboratory (lab). Lab research helps find treatments that could benefit breast cancer patients.

But, treatments that seem to work well on breast cancer cells or on animals in the lab do not always work as well for people. That is why clinical trials are needed — to make sure the treatment will be safe and effective for people.

Enrolling in a treatment clinical trial

After a breast cancer diagnosis, you are faced with many choices. One of the most important choices is about treatment. Clinical trials are a great way to receive treatment, but may not be an option for everyone. With the help of your doctor, you can make an informed choice if one is right for you. On the back of this fact sheet is a list of the pros and cons of joining a clinical trial. There is also a list of resources where you can get more information. Review this list and write down your questions. Then talk to your doctor. Your questions are important, and your doctor should take the time to go over them with you. Also, ask for input from co-survivors (family and friends) who matter to you.

To protect people and to provide consistent testing, clinical trials must follow a strict plan called a protocol. The protocol follows medical, ethical and legal guidelines to ensure patient safety. As part of the protocol, you may be randomly assigned to 1 of 2 study groups. One group gets the treatment being studied and the other group gets the standard treatment. Many clinical trials, especially those for metastatic breast cancer, are not randomized and all participants get the same treatment.

Many people are concerned about getting a placebo, or sugar pill, instead of life-saving treatment. Most often in a breast cancer treatment clinical trial, you will get either the new treatment or the standard treatment. Even if you do not get the new drug (or other new therapy), your breast cancer will be treated just as it would if you were not in the trial. Sometimes, you may get standard treatment plus a placebo rather than standard treatment plus a new treatment.

Informed consent

Informed consent is the process of reviewing the risks, benefits and options for the study. It is required for all clinical trials. Before joining a trial, a research coordinator or nurse will go over the study protocol with you. He/she will answer any questions you have. Once you decide to join the study, you will be asked for your written permission. The document you sign is called a consent form. You will get a copy.

Remember that being in a clinical trial is your choice. You may leave the trial at any time, for any reason. Consenting and giving written permission to join the study does not force you to stay in the study.

Resources

For more information about clinical trials or specific studies currently recruiting participants, contact one of the resources listed below.

BreastCancerTrials.org in collaboration with Susan G. Komen® offers a custom matching service that can help you find a clinical trial that fits your health needs.

National Cancer Institute
1-800-4-CANCER
www.cancer.gov/clinicaltrials

National Institutes of Health
www.cc.nih.gov/
www.clinicaltrials.gov/

CenterWatch Clinical Trials Listing Service™
www.centerwatch.com

Coalition of Cancer Cooperative Groups
www.cancertrialshelp.org/

ECancerTrials.com
www.ecancertrials.com/

The pros and cons of clinical trials

People with breast cancer who are thinking about joining a clinical trial should discuss the risks and benefits with their doctor. For some, it may be best to use standard treatment. Others may be good candidates for clinical trials. Some of the pros and cons of joining are listed below.

Pros

- You could have the chance to get a new treatment that may be more effective than the standard therapy.
- You are helping to add to new research that could improve cancer treatment in the future.
- Even if you are not assigned to receive the new treatment, you will still get the best standard treatment available.

Cons

- The new treatment may not work as well as the standard treatment.
- If the study is a randomized trial, you cannot choose which treatment you get (you will be assigned to one treatment or another).
- The new treatment being tested may have unexpected side effects.
- In some cases, your insurance company may not cover all the costs of being in a clinical trial. Usually, extra costs are paid for by the research program, but you should ask about this.

Related fact sheets in this series:
- Making Treatment Decisions
- Research on Breast Cancer Treatment
- Treatment Choices for Early Breast Cancer — An Overview