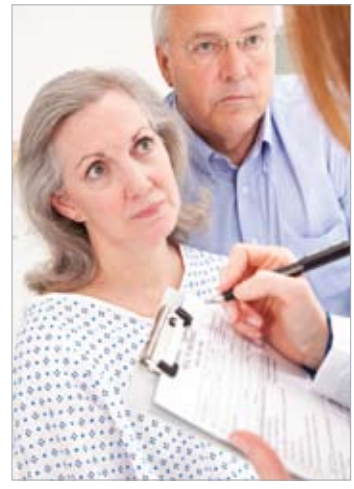
Clinical trials: A treatment option to think about

Would you consider participating in a clinical trial? You may not appreciate being asked this question when you have so many questions of your own about your cancer diagnosis and treatment. But this is a very important question. Participation in a clinical trial is more than being a part of discovering a new treatment or finding new uses, called *indications*, for an existing drug. It may be a treatment option for you to consider when discussing treatment plans with your oncologist.



Clinical trials are used to gather information: on the safety and effectiveness of new treatments, or new indications for existing treatments. Some clinical trials are designed to confirm the results of previous studies or to continue monitoring a treatment. Clinical trials are defined by type (treatment, prevention, diagnostic, or screening) and by phase (I, II, III, IV). The type defines what clinicians will ultimately do with the information: treat, prevent, diagnose, or screen for cancer. The phase identifies what information researchers are focusing on: safety and most effective dose, the effect of treatment on the tumor, how well the treatment works, or gather additional information after the Food and Drug Administration has approved the treatment for use in the general population. Clinical trials are described at the top left, and phases are described on the next page of this section.

Clinical trials may be sponsored by government agencies such as the National Institutes of Health (NIH) or the National Cancer Institute (NCI). Other sponsors of clinical trials are research organizations that conduct clinical trials, and drug and biotechnology companies that are developing new treatments or conducting further tests on existing ones.

You will undoubtedly have many questions when considering this option. In addition to NCI, organizations such as the American Cancer Society (ACS), Cancer*Care*, and many individual cancer organizations offer information about clinical trials. The information ranges from general information about clinical trials to contact information for potential participants.

This section is a general overview of clinical trials. It is designed to help you find answers to some of your questions and show you where additional information is available. Participation in a clinical trial is a very personal decision between you, your family, and your doctor. The editors of *Oncology Nurse Advisor* hope this information helps you make the best decision for you.

Types of clinical trials

Not all clinical trials are to determine the safety and effectiveness of a drug or treatment. Some clinical trials are to find tests or methods of predicting who may develop cancer, how to prevent it, or how to improve the lives of those who have cancer. The purpose of each type of clinical trial is described here.

- **Treatment** Used to test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy
- **Prevention** Used to find better ways to prevent cancer in people who have never had it or to prevent cancer from recurring
- **Diagnostic** Used to find better tests or procedures for diagnosing cancer
- **Screening** Used to improve methods of detecting cancer
- **Quality of life** Used to explore ways to improve the quality of life for persons with cancer

Source: Understanding clinical trials. ClinicalTrials.gov Web site. http://clinicaltrials.gov/ct2/info/understand#Q18. Accessed February 3, 2012.

Words to know

Clinical trial (also called *clinical study*) A type of research study that tests the effectiveness of new medical approaches in people. These studies test new methods of screening, prevention, diagnosis, or treatment.

Double-blinded A clinical trial in which the medical staff, the patient, and the people who analyze the results do not know the specific treatment the patient received until after the clinical trial is ended.

Continued on page 44

Words to Know

Continued from page 43

Eligibility criteria Requirements designed to make sure participants in a trial are similar (such as age, type and stage of cancer, general health, and previous treatment). This ensures that study results are caused by the therapy being tested and not by other factors.

Expanded access (also called *compassionate use*) A way for a patient with cancer to receive a promising but not yet fully studied or approved therapy when no other treatment option exists.

Informed consent (also called *consent process*) The process in which patients are given important information about the clinical trial to help them decide if they wish to participate. New information that may affect a patient's decision to continue in the trial may also be provided.

Placebo An inactive substance or treatment that looks the same as, and is administered in the same way as, an active drug or treatment being tested. The effects of the active drug or treatment are compared to the effects of the placebo.

Protocol A detailed plan that explains what a study is for, how it will be conducted, and why it is being conducted. The plan also includes information on the number of participants, who can participate, the type of treatments, how the participants will be monitored, and the information to be collected.

Randomization The process by which participants are assigned to separate groups for comparison of different treatments or interventions. Each participant has an equal chance of being assigned to any of the groups.

Tissue A group or layer of cells that work together to perform a specific function.

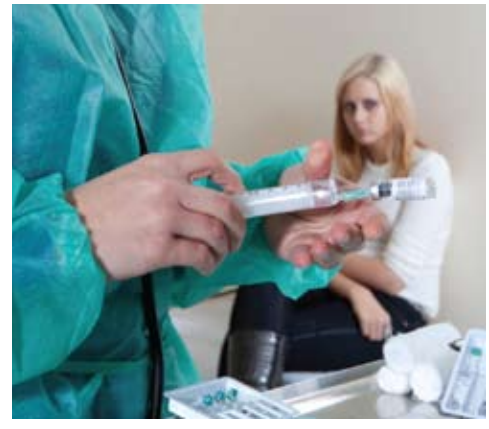
Source: Dictionary of cancer terms. National Cancer Institute Web site. http://www.cancer.gov/dictionary. Accessed February 6, 2012.

Clinical trial phases

Clinical trials are conducted in phases. Each phase focuses on answering particular questions about the drug or treatment being studied. In the early phases, the focus is on determining if the treatment is safe. Later phases are used to determine if the treatment is more effective than the standard treatment.

Phase I This phase is usually the first clinical trial that involves humans. The purposes of phase I clinical trials are to determine that the treatment is safe and at what dosage the treatment is most effective treatment with the lowest risk of adverse effects. Phase I clinical trials usually involve 15 to 30 participants who are watched very closely at administration and during the time periods between doses.

Phase II After a treatment is shown to be safe, phase II clinical trials are used to determine if the treatment works. Doctors observe the effects of the treatment on the cancer. Does it shrink the tumor? Does it slow or stop disease progression? Does it improve the patient's quality of life? Does the treatment help the patient live longer than expected with the standard treatment? Phase II clinical trials generally include less than 100 participants.



Phase III The goals for phase III clinical trials include confirm how well the treatment works, compare the new treatment with standard treatments, and collect information on side effects and how to use the treatment safely. A large number of participants (several hundred to several thousand) from all over the country or throughout the world are included in this phase. A process called randomization is used to determine which patients receive the new treatment. A placebo may be used if doctors want to determine if the new treatment will improve the effectiveness of an existing treatment; however, a placebo is not used by itself in cancer clinical trials if a standard therapy is available.

Phase IV This phase is used to gather additional information on the effectiveness of a treatment after it has received approval for use by the US Food and Drug Administration (FDA). Phase IV clinical trials are used to determine the long-term effects of using a treatment.

Sources: American Cancer Society. *Clinical Trials: What You Need to Know.* Atlanta, GA: American Cancer Society; last medical review/last revised September 2010. McCabe M, Messner C. *Clinical Trials: Improving the Care of People Living With Cancer.* New York, NY: Cancer*Care*; 2009. National Cancer Institute. *Taking Part in Cancer Treatment Research Studies.* Rockville, MD: US Department of Health and Human Services; revised September 2011. NIH Publication No. 12-6249.

Resources

American Cancer Society Clinical Trials Matching Service
www.cancer.org/Treatment/TreatmentsandSideEffects/ClinicalTrials/app/clinical-trials-matching-service
A free, confidential program that helps patients, their families and health care workers find cancer clinical trials most appropriate to a patient's medical and personal situation

CenterWatch
www.centerwatch.com/
A global source for information on clinical trials, including open and ongoing clinical trials, e-mail notification of new trials, drug information search capabilities, clinical research education, and patient resources

ClinicalTrials.gov
www.clinicaltrials.gov/
A listing of currently ongoing and open clinical trials provided by the National Library of Medicine

Coalition of Cancer Cooperative Groups
www.cancertrialshelp.org/
Education, outreach, advocacy, and research for cancer clinical trials related information for physicians and patients

Information booklets for participants

The National Cancer Institute (NCI)

www.cancer.gov

The following booklets are available through the National Cancer Institute. The booklets are free and can be printed from the Web site or ordered from the NCI.

- *Taking Part in Cancer Treatment Research Studies:* This booklet explains what clinical trials are, what you might expect if you decide to participate in a trial, and things you should think about when making a decision about participating in a clinical trial.
- *If You Have Cancer and Have Medicare … You Should Know About Clinical Trials:* This booklet is a resource for Medicare recipients who have cancer. It provides general information about cancer clinical trials, what Medicare will cover, and questions you should ask before you agree to participate.
- *Providing Your Tissue for Research: What You Need to Know:* This booklet explains the role of tissue research. It answers questions you may have such as what is tissue, how is it collected, what will be done with the tissue, and what if I change my mind after the tissue is collected.

Cancer*Care*

www.cancercare.org

The following booklet is available through Cancer*Care*. The booklet is free, and it can be read on the Web site or ordered from Cancer*Care*.

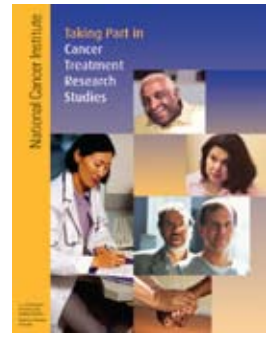
- *Clinical Trials: Improving the Care of People Living With Cancer:* This booklet provides general information about clinical trials, including the benefits of participating in clinical trials, the rights of and protections for clinical trial participants, and frequently asked questions.

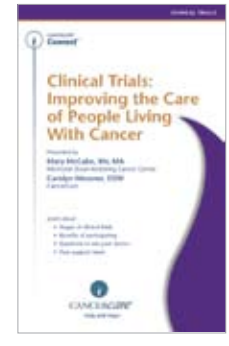
American Cancer Society (ACS)

www.cancer.org

The following booklet is available through the American Cancer Society. It is a free and can be downloaded and printed from the ACS Web site.

- *Clinical Trials: What You Need to Know:* This booklet discusses all facets of clinical trial participation, including why clinical trials are needed; what happens before, during, and after the trial; phases; types of clinical trials; costs and insurance coverage; and questions you should ask your health care providers and the research team.





Ten steps for selecting a clinical trial

1. **Understand clinical trials** Many Web sites are available with information on clinical trials. The American Cancer Society (ACS) and most cancer organizations offer information for patients who are considering participating in a clinical trial.
2. **Talk to your oncology care team** Ask your oncology care team about any clinical trials for which you may be eligible. They may know of a trial or be able to help you find one that is suitable for your cancer.
3. **Gather information on your cancer diagnosis** The Cancer Details Checklist, a form available on the National Cancer Institute (NCI) Web site, can help you gather information about your diagnosis and overall health. A member of your oncology care team can help you complete it.
4. **Search for a trial** The NCI and the National Library of Medicine (NLM) offer lists of clinical trials that are accepting participants. A clinical trial may be listed on both Web sites. The difference is how the information is presented. Use the list that you can understand the best.
5. **Search other sources for a trial** Other sources for lists of clinical trials include research organizations that conduct clinical trials, drug and biotechnology companies, clinical trial listing services, and cancer advocacy groups. These listings may include other trials not included in the NCI and NLM lists (see a partial list of resources on these pages).
6. **Make a list of potential clinical trials** Save or print the summary of the trials in which you are interested in participating. Review the summaries and ask yourself what is the purpose of the trial, do your details match those of the entry criteria, where do you need to go to receive treatment and how often, and for how long will the trial be conducted. The answers to these questions can help you determine if the trial will work for you and your family.
7. **Contact the clinical trial team** You can contact the team directly, have a member of your oncology care team contact them, or the clinical trial team may contact you if you provided your contact information through a Web site. You should ask to speak to the "trial coordinator," the "referral coordinator," or the "protocol assistant." Have your Cancer Details Checklist handy because the clinical trial team will ask for that information.
8. **Ask questions about the trial** Write down any questions you may have about the trial, especially those that may affect your decision on whether to participate. Ask the clinical trial team those questions and any others you may have.
9. **Discuss your options with your doctor** Your research will have provided the information about the treatments in the clinical trials; next, you should speak to your doctor about the risks and benefits of standard treatments. You should compare the risks and benefits of all your treatment options.
10. **Schedule an appointment** If you want to participate in a clinical trial, schedule an appointment with the clinical trial team. You will likely meet with the person you spoke with when you first contacted them.

Source: How to find a cancer treatment trial: A 10-step guide. National Cancer Institute Web site. http://www.cancer.gov/clinicaltrials/learningabout/treatment-trial-guide. Accessed February 6, 2012

EmergingMed
www.emergingmed.com/
An online resource for clinical trial information and assistance with matching patients to a suitable clinical trial

FAQ: ClinicalTrials.gov Clinical Questions
www.nlm.nih.gov/services/faqctgov.html
Frequently asked questions about clinical trials and the trials listed on NCI and NLM Web sites

National Cancer Institute
www.cancer.gov/clinicaltrials/search
Listing of currently ongoing and open clinical trials sponsored by the NCI

TrialCheck
www.trialcheck.org/Services/
Clinical trials search engine for health care professionals, includes a link for patient searches

More information about clinical trials specific to cancer types is available in the Clinical Trials and For Your Patient tabs on our Web site.