What is a clinical trial?
A clinical trial is a research study that involves volunteers. Many clinical trials study new treatments. They may also study new ways of preventing cancer, diagnosing cancer, managing side effects, or improving a patient’s quality of life. Clinical trials may offer a patient treatment options not otherwise available, access to high-quality care, and the chance to help other patients with cancer. Almost all medical advances related to the prevention and treatment of cancer are a result of clinical trials.

What are the phases of a clinical trial?
Research is completed in three phases. Phase I aims to show that the new treatment can be given safely to people. Phase II provides more information about the safety of the treatment and how well it works. Phase III tests the treatment in a large group of people to determine how it will be used, often comparing it with a standard treatment.

How is a patient safely monitored?
Patient safety is the highest priority in clinical trials. Before a clinical trial begins, it must be approved by an institutional review board (IRB) that ensures the clinical trial’s protocol is ethical and that participant rights are protected. During the study, a data safety monitoring board (DSMB) protects patient safety by regularly reviewing the research data and making recommendations to stop, change, or continue the study. Several federal regulations also help ensure safety, requiring that participants be given written information on every aspect of the clinical trial. Participants are seen regularly by the research team—doctors, nurses, and other health care professionals—to monitor their health and determine the safety and effectiveness of the treatment being tested. It is also important to know that a participant can leave a study at any time for any personal or medical reason.

Is a clinical trial right for me?
It is important for a person with cancer to consider all treatment options, including clinical trials. Talk with your doctor to learn about current clinical trials and whether they may be appropriate for you. As with any treatment, you need to weigh the benefits of participating in a clinical trial against the potential risks. For some, a clinical trial may be the best treatment option available. For example, most children with cancer participate in clinical trials, and these studies have improved survival for children with cancer. Talking with people who have participated in a clinical trial may be helpful.

Several websites listed at www.cancer.net/clinicaltrials allow you to search for current clinical trials. All clinical trials have specific participation requirements that help keep patients safe and ensure researchers get the information needed to answer the study’s questions.
Questions to ask the doctor
Your doctor can help you understand more about clinical trials. Consider asking:

• What clinical trials are open to me?
• What happens during a clinical trial?
• What are the benefits and risks of participating in a clinical trial?
• Will you continue to be a part of my care during the clinical trial?
• Where can I learn more about clinical trials?

Questions to ask a clinical trial’s research team
Before participating in a clinical trial, ask the research team for as much information as possible. Consider asking:

• What is the purpose of this clinical trial?
• What is the specific approach being studied?
• What other treatment options are available to me?
• Who or what organization is sponsoring the clinical trial?
• Who has reviewed and approved this clinical trial?
• What are my responsibilities during the clinical trial?
• What are the possible risks and benefits of participating in this clinical trial? How do they compare with the risks and benefits of the standard treatment?
• Where will the clinical trial take place? Will I need to stay in the hospital?
• Are there costs associated with my participation in this clinical trial?

Find additional questions at www.cancer.net/clinicaltrials.

The ideas and opinions expressed here do not necessarily reflect the opinions of the American Society of Clinical Oncology (ASCO) or The Conquer Cancer Foundation. The information in this fact sheet is not intended as medical or legal advice, or as a substitute for consultation with a physician or other licensed health care provider. Patients with health care-related questions should call or see their physician or other health care provider promptly and should not disregard professional medical advice, or delay seeking it, because of information encountered here. The mention of any product, service, or treatment in this fact sheet should not be construed as an ASCO endorsement. ASCO is not responsible for any injury or damage to persons or property arising out of or related to any use of ASCO's patient education materials, or to any errors or omissions.

To order more printed copies, please call 888-273-3508 or visit www.cancer.net/estore.