

TO YOUR HEALTH—*James Burke, MD*

Questions and Answers about Cancer Clinical Trials

Clinical research is essential to the treatment of cancer. Since many cancers are still incurable, clinical trials provide the only means of testing new drugs aimed at improving or curing different cancers. The following information about clinical research trials may be helpful to cancer patients or their loved ones who are considering a clinical trial for their cancer care.

Why should an individual participate in a clinical trial?

Clinical trials allow patients access to potentially beneficial drugs before approval by the Food and Drug Administration (FDA). In addition, individuals can contribute to medical progress and the greater good of society. The average new cancer drug takes 10 years to attain FDA approval. After FDA approval the drug is available to oncologists for patient treatment. Before FDA approval, new drugs are only available as part of a clinical trial.

Most patients in this situation do not have 10 years to wait for FDA approval.

The majority of new drugs entering clinical trials will not be approved by the FDA (due to toxicity or lack of efficacy) but as we learn more about cancer biology the number of effective drugs in testing is increasing.

In cancer care, most trials study the best chemotherapy plus a new drug being developed versus the best chemotherapy plus placebo. In this scenario, all patients receive the best treatment approved with only half receiving the drug being studied as well. Therefore, even if randomly assigned to the placebo plus chemotherapy group, patients receive the best treatment available just as if they were not participating in a clinical trial.

What costs are patients responsible for on clinical trials?

Clinical trials are covered by Medicare and most insurance policies. Therefore, no additional treatment costs are incurred by patients participating in clinical trials. Drugs not yet approved by the FDA are provided free by the entity sponsoring the trial (drug companies or the National Cancer Institute). Before agreeing to participate in a clinical trial, patients should ask the treating physician to verify insurance coverage.

How do I find out more about clinical trials to see if I am eligible?

Ask your physician if there are any trials available for which you might qualify. Not all clinical trials are offered at every hospital or clinic. Unfortunately, only three percent of patients treated for cancer in the U.S. are being treated on a clinical trial. This has been identified by the National Cancer Institute (NCI) as a major shortcoming of community cancer care. You may need to research clinical trials at different cancer centers in your area. All clinical trials are also published online at www.clinicaltrials.gov. This website allows patients and physicians to search for trials based on disease, stage, and location.

How do patients know whether a clinical trial is right for them?

Your physician can help to answer your questions. All patients will read and sign an informed consent document describing the objective of the study, potential risks and benefits, treatment schedule and patient's right to not participate or drop out at any time. The FDA reviews and approves all clinical trials of new drugs as well as a local institutional review board

(IRB) to provide additional oversight that is site-specific.

In summary, clinical trials are the only way we can improve the treatment of cancer as a society. For an individual patient, clinical trials allow access to the latest new drugs being developed. Over the past decade the number of new cancer drugs has increased substantially with a related improvement in safety and patient outcomes. I advise all of my patients to take advantage of clinical trials if available to increase their treatment options, particularly for currently incurable diseases which have limited treatments available. Today's clinical trial may hold tomorrow's cure. **AM**



James Burke, MD, is Director of Cancer Research at Billings Clinic Cancer Center, in Billings, MT. He completed medical school at Georgetown University in Washington, D.C., and his internship and residency were at University of California, San Diego. Dr. Burke's fellowship in oncology and hematology was completed at University of California, San Francisco. He is board certified in internal medicine, medical oncology and hematology.


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