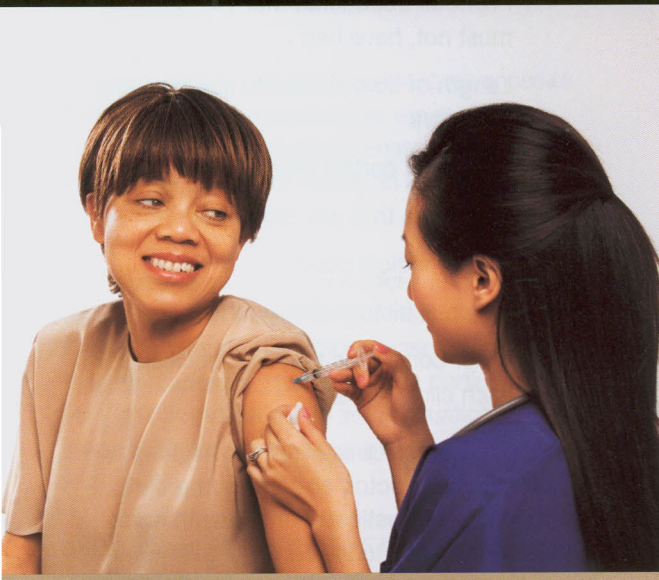
A Greater Understanding

A Practical Guide to Clinical Trials



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A Greater Understanding

Patient Advocate Foundation

MISSION STATEMENT

Patient Advocate Foundation is a national non-profit organization that serves as an active liaison between the patient and their insurer, employer and/or creditors to resolve insurance, job retention and/or debt crisis matters relative to their diagnosis through case managers, doctors and attorneys. Patient Advocate Foundation seeks to safeguard patients through effective mediation assuring access to care, maintenance of employment and preservation of their financial stability.

The purpose of this brochure is to address questions surrounding clinical trials. These new treatments need to be studied to make sure they are safe and as effective, or more effective, than current standard treatment options. We will discuss what clinical trials are and insurance issues related to reimbursement. For more in depth information please review, Patient Advocate Foundation's *Lighting the Way...Practical Guide to Clinical Trials.*

WHAT IS A CLINICAL TRIAL

A Clinical Trial is a study of new drugs, combinations of drugs (some already FDA approved for other purposes) and/or treatments to see how well they work – especially when compared with current standard of care treatment. Each study has rules about who can and cannot participate such as age, sex or stage of disease. "Clinical trials have protocols, or action plans, for conducting a trial. This helps the participant understand what will be done, how it will be done and why each part is needed. In the United States, an independent committee of physicians (Institutional Review Board), statisticians and members of the community must approve and monitor the protocol. They make sure that the risks are small and are worth the potential benefits." (http://www.nlm.nih.gov/medlineplus/clinicaltrials.html [1]

Each trial lists eligibility criteria for participation. For example, there are studies that need volunteers with a certain disease while others are looking for healthy people. Some trials want all female participants while others want all male participants. The sponsor of the study writes the protocol, which explains what the trial will do, how the trial will be conducted, location of the study, eligibility criteria, and how and when the participants will be evaluated. There are many sponsors of clinical trials. The National Cancer Institute has a webpage for locating clinical trials as well as a patient recruitment line to screen potential patients. Other sponsors include physicians, single institutions, the Department of Defense, the Department of Veterans Affairs, and/or biopharmaceutical manufacturers.

Clinical trials are done to gather information for many purposes. The purpose of the trial defines how it will be conducted. There are different types of trials:

- **Treatment Trials** test experimental treatments, new combinations of drugs, and new approaches to surgery or radiation therapy.
- **Prevention Trials** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. Approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
- **Diagnostic Trials** are conducted to find better tests or procedures for diagnosing a particular disease or condition.
- **Screening Trials** test the best way to detect certain diseases or health conditions.
- **Quality of Life Trials** (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.[1]

What are the phases of clinical trials?

Clinical trial phases are designed to test the new treatments being proposed. Phases of clinical trials go from phase 1 through phase 4. As results are obtained, the trial moves to the next phase. The 4 phases are as follows or defined as:

Phase 1: When a drug or treatment is in a Phase 1 trial, the researchers are studying to determine how the drug or treatment will be administered (by mouth, through the vein (IV), etc). The researchers are looking for the proper dose and monitoring for side effects. The study focuses on a small group of participants.

Phase 2: When a drug or treatment advances to a Phase 2 trial, the researchers are studying the results to determine the effectiveness of the drug or treatment. Phase 2 trials collect information on the safety and benefit of the treatment. The study expands to 100 or more participants.

Phase 3: When a drug or treatment advances to a Phase 3 trial, the researchers are studying to determine if one treatment is better than another. The trial agent is studied in comparison to current standard of care treatment. Phase 3 trials expand in size to several hundred to thousands of participants.

Phase 4: When a drug or treatment advances to a Phase 4 trial, the researchers are monitoring long-term safety and effectiveness of the treatment. These are also known as Post Marketing Surveillance Studies. [2]

As a drug or treatment advances in each phase of a clinical trial the number of institutions, or facilities, offering the trial increases. Major medical centers across the nation participate in Phase 2, 3 and 4 trials. In some situations, it may be possible for you to enroll in a clinical trial at a local facility.

In the United States, the FDA (Food and Drug Administration) requires all new drugs or treatments complete multiple years of testing before approving them for use as standard of care. All current drugs have been through Clinical Trial testing at some point to achieve the standard of care label from the FDA. Some consider clinical trials the most advanced cancer treatment therapy we have. Making the decision to enroll in a clinical trial is a personal one. Because of advances in medical science, clinical trials can offer you a chance to participate in cutting edge treatments, before they are available to the general public.

How will I know if I am eligible to participate in a clinical trial?

Each clinical trial has ***eligibility criteria***, which are requirements that patients must meet before they can participate. Eligibility criteria might include information about:

- Age and gender
- Type of cancer
- Stage (extent) of the cancer
- Previous treatments that you must, or must not, have had
- Length of time since you last received treatment
- Results of certain laboratory tests
- Medicines that you are taking
- Other medical conditions
- Previous history of any other cancer
- Other conditions that are specific to each clinical trial

If you have found a clinical trial you might qualify for, talk to your doctor, or contact the clinical trial's principal investigator or research nurse. A member of the study team will ask you questions about your medical history to see if you meet the study's eligibility criteria. These criteria are not used to reject potential participants, but rather to ensure safety. In addition, utilizing these criteria ensures the information obtained will answer the researcher's questions.

Insurance Issues related to clinical trials

Many times participation in a clinical trial requires learning more about your insurance policy. Many policies do not provide coverage for clinical trials that are considered Experimental and/or Investigational. This means the insurance company does not recognize the proposed treatment as a standard of care and will not pay for it. Some policies may cover trials in certain stages – for example, coverage for Phase 3 or Phase 4 trials. This information will be explained in your insurance policy language. Health plans may specify specific criteria a trial must meet to be covered. The trial might have to be sponsored by a specified organization, be judged "medically necessary" by the health plan, not be significantly more expensive than treatments the health plan considers standard, or focus on types of cancer for which no standard treatments are available. In addition, the facility and medical staff might have to meet the plan's qualifications for conducting certain procedures, such as bone marrow transplants.

Many states have passed laws or developed policies requiring health plans to cover the costs of certain clinical trials.
For more information, visit the NCI's Web site at http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs

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1 Medline Plus, Clinical Trials. Retrieved 2/25/2009 from http://www.nlm.nih.gov/medlineplus/clinicaltrials.html
2 Understanding Clinical Trials, retrieved 2/28/2009 from http://clinicaltrials.gov/ct2/info/understand

Patient Advocate Foundation is dedicated to ensuring that all Americans have access to healthcare. Case Managers are available to assist patients affected by debilitating or life threatening diseases by empowering them to be able to make informed decisions regarding their healthcare options. For further information, call the Patient Advocate Foundation at:

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