



# Understanding Clinical Trials

Josephine Silvestre, RN, MSN  
The University of Chicago Medical Center

October 13, 2007

# What is a Clinical Trial?

A study in which people participate as volunteers. A clinical trial is conducted to develop potential new treatments and medications and/or gain a better understanding of a disease or medical condition.

# Types of Clinical Trials

Treatment – test experimental treatments, new combinations of drugs, new approaches to surgery or radiation therapy

Prevention – look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning

Diagnostic – find better tests or procedures for diagnosing a particular disease or condition

Screening – test the best way to detect a disease/condition

Quality of life – explore ways to improve comfort and quality of life for individuals with a chronic illness

# Who Sponsors Clinical Trials?

Clinical trials are sponsored or funded by a variety of organizations or individuals such as:

- physicians
- medical institutions
- foundations
- pharmaceutical companies
- federal agencies (National Institutes of Health, National Cancer Institute, the Department of Defense, the Department of Veteran's Affairs)

# Phases of Clinical Trials

Phase I – test a potential new drug with a small number of people (20-80) for the first time to determine safe dosage and potential side effects

Phase II – test a drug with known dose and side effects with a larger number of people (100-300) to see if it is effective and to learn more about side effects

Phase III – compare the new drug with a commonly used drug; involves an even larger group of people (1000-3000)

Phase IV - conducted after the drug is approved and on the market to find out more about the treatment's long-term risks, benefits and optimal use; to test the treatment in different populations of people

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

[www.fda.gov](http://www.fda.gov)

# Phase II and Phase III Trials

- These phases usually involve the use of a control group, the standard by which experimental observations are compared.
- In trials that utilize a control group:
  - one group of patients is given an experimental drug/treatment while the control group is given either the standard treatment or a placebo (an inactive pill, liquid or powder that has no treatment value).
  - treatment that a patient receives is decided by “randomization” (coin toss done by computer)
  - usually involves “blinding”

# Barriers to Participation

Patient-related barriers include:

- Treatment received in a clinical trial may be less effective than standard care
- Receiving a placebo
- Being treated like a "guinea pig"
- Insurance company may not cover costs of study services

# Why Participate in a Clinical Trial?

- play an active role in your own health care
- gain access to new treatments before they are widely available
- assist in contributing to the body of knowledge that may assist others in the future

# Informed Consent

A process that ensures that a patient has reviewed the written details of a clinical trial, has had an opportunity to ask questions and have these questions answered and has made an informed choice to participate

# Informed Consent Form

- Purpose - why is the study being done
- What is involved? – description of the procedures involved in the study
- Study duration – length of time you will be participating in the study
- Potential risks/benefits – any risks or benefits (direct or indirect)
- Alternate treatments – any other treatment options (if applicable)
- Costs/compensation – costs to you/your insurance, costs covered by the sponsor; payment for participation
- Patients' rights/confidentiality – right to participate/withdraw; right to new information; right to confidentiality

# What Happens During a Trial?

- The research team strictly follows a protocol, which is a study plan that is carefully designed to safeguard the health of study participants.
- A protocol describes who can participate in a trial, the tests to be obtained, medications/treatments and their dosages, and the length of the study.
- Participants are closely monitored while on a clinical trial and are required to come in regularly to see the research team to determine the safety/effectiveness of the treatment.

# Safety of Study Participants

- All cancer clinical trials at the University of Chicago undergo a thorough review by our regulatory/ethical committee, Institutional Review Board (IRB) before they are approved and patients are enrolled.
- The IRB periodically (at least annually) reviews the research for continued safety.
- The IRB ensures the risks are as low as possible and are worth any potential benefits.
- Patients are closely monitored for adverse events (undesired actions or effects that may or may not be related to the study treatment).

# Costs

- Clinical services provided during a clinical trial are either research-related or related to usual medical care.
- Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance. The sponsor typically pays for these services.
- Usual medical care costs include any and all services that are considered medically necessary for your disease. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance.
- The types of charges are delineated prior to the start of the study to ensure against fraudulent billing practices.

# Review of Barriers to Participation

Patient-related barriers include:

- Treatment received in a clinical trial may be less effective than standard care
- Receiving a placebo
- Being treated like a "guinea pig"
- Insurance company may not cover costs of study services