

ABOUT

CLINICAL

TRIALS



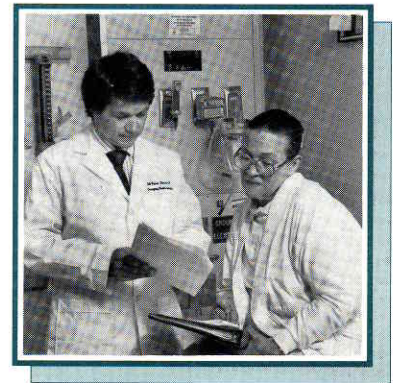
MARION MERRELL DOW INC.

About Clinical Trials

A **clinical trial** is a scientific study that tests the effectiveness of a new medical treatment, drug, or device with patients. While years are spent in laboratory and animal research to determine the general use and safety of a new treatment, a clinical trial studies the exact effects of it on people.

A clinical trial may show that the **investigational treatment** is better than, as good as, or no better than the **standard treatment** for the same condition. Or it may confirm the discovery of a successful treatment of a disease for which there never had been a treatment at all.

A clinical trial is a partnership and a commitment between doctors and volunteer patients. It is the final test in a series of many carefully controlled scientific studies that are done to improve the quality of life.



Contents

If you are eligible and interested in taking part in a clinical trial, this brochure can help answer some basic questions you may have. You can find the highlighted words defined for you in the glossary at the back of this brochure. Ask your doctor any questions not answered here or for more information about a specific clinical trial.

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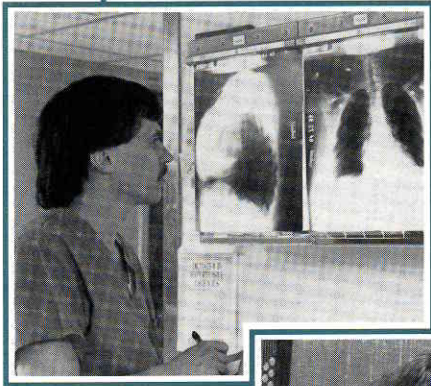
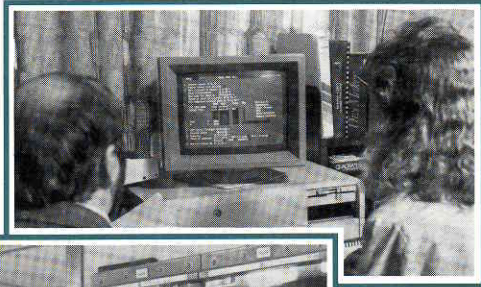
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Questions & Answers



Why are clinical trials needed?

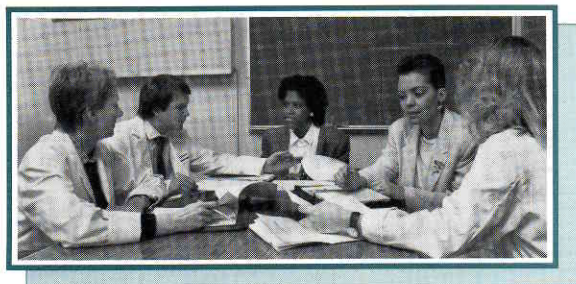
The medical world cares about the human condition. That's why researchers constantly look for better or new ways of treating illness and disease. But their discoveries can not be put into general use until controlled testing has been done on actual patients.

Clinical trials are the only way that testing can be done. The **Food and Drug Administration (FDA)** requires clinical trials before it can approve a new treatment as safe and effective for public use. Clinical trials are the link between research and the relief of human suffering.

Who conducts clinical trials?

Pharmaceutical companies, research institutions, or other health organizations may be the **sponsor** of a clinical trial. They are responsible for funding and for designing its **protocol**. A protocol is a set of detailed guidelines that **clinical investigators** follow in order to conduct the same clinical trial at several different locations.

Although pharmaceutical companies sponsor a clinical trial, only trained doctors, nurses, and medical researchers actually conduct the trial itself.



Why should I participate in a clinical trial?

Two reasons: to help yourself and to help others.

It's possible the treatment being tested will improve your health. A new drug or new procedures may reduce pain or perhaps even cure your illness. All clinical trial patients receive a great deal of personal medical attention.

You may also decide to participate in a clinical trial for the satisfaction that comes from being a part of scientific research. Every day, there are people hoping for a breakthrough treatment that will make coping with an illness easier or eliminate it altogether. Clinical trial volunteers help make those discoveries available to people all across the country and around the world.

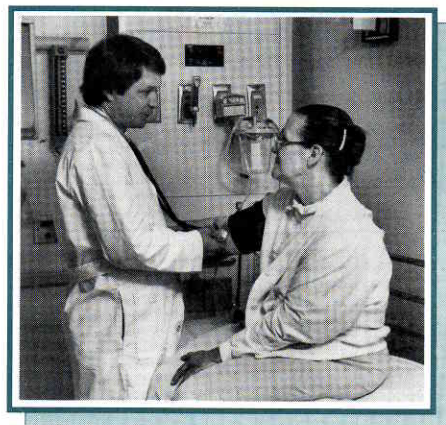
Remember: Deciding whether or not to participate, or to continue to participate, in a trial is entirely up to you.

Who is eligible to be in a clinical trial?

Every clinical trial attempts to answer some very specific research questions. To do this, each trial has certain requirements about your health, medication, age, and other things. You must meet the requirements of a particular trial to be an eligible volunteer. Ask your doctor or nurse about the eligibility requirements for a particular trial.

What is a clinical trial like?

Participating in a clinical trial is much like a regular visit to a hospital, medical clinic, or doctor's office, but with even greater personal attention. The success of any trial depends on its volunteers. Patients are treated professionally and with care.



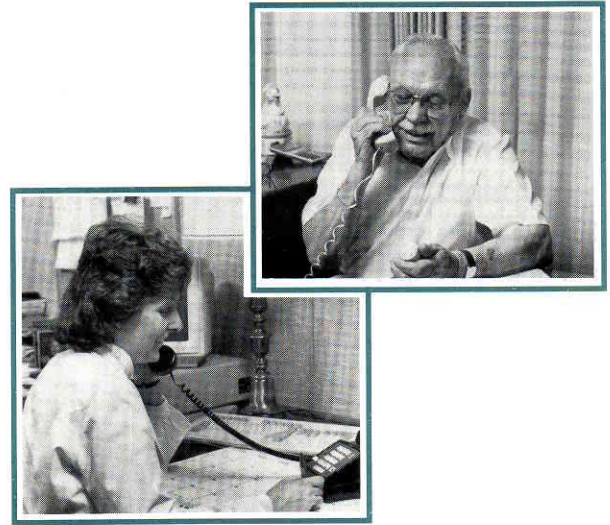
What are the risks?

Risks vary from trial to trial. Unfortunately, no one can say with certainty what the risks of a particular trial might be. Although researchers expect certain results from each trial, the fact that a treatment is still being studied makes it impossible to rule out side effects or adverse reactions.

While it is possible that some side effects could be permanent or even life-threatening, most are temporary and will go away as soon as the treatment is stopped.

What is needed of me?

Your first responsibility is to fully understand your commitment to the trial. The trial investigators and sponsor need you to be at appointments on time, to follow their instructions carefully, and especially to take any medication exactly as told. They need you to take the trial seriously. Your full cooperation and participation is needed if the investigators are to collect the information they must have for a successful study.



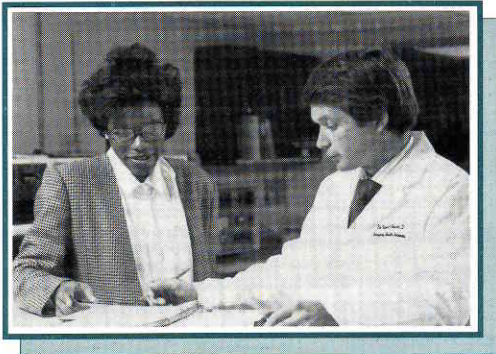
What can I expect from the clinical trial team?

More than anything else, you have the right to expect complete information about the trial. Don't participate in any clinical trial unless your questions have been reasonably answered.

You will be given an **informed consent** form to read and sign. This is required by law to make sure you understand what is involved in a trial. It should include an honest discussion of potential risks and benefits. You should also expect complete information about the schedule and duration of the trial, directions to the trial location, and the name of someone you can contact with questions or problems.

How am I protected as a clinical trial patient?

As a patient under a doctor's supervision, you are protected by the same laws and ethics that normally regulate the medical profession. Informed consent helps protect you by making sure you have been given all the necessary information about a trial. The FDA regulates clinical trial advertisements to reduce misleading claims. It also requires an **institutional review board** to review the general progress of the trial.



More Questions

What to ask your doctor before participating in a clinical trial:

- What is the purpose of the trial?
- What treatments will be done and how?
- How is patient safety going to be checked?
- What are the possible side effects and risks of this treatment?
- How could this treatment benefit me?
- Other than the one being tested, what treatments are available for the same condition?
- How will the trial affect my daily life?
- How long will the trial last?
- Where is the trial being done?
- Who is sponsoring the trial?
- Will I have to pay for anything?
- What happens if I am harmed by the trial?
- Will I be able to stay on this treatment when the trial is over?

Questions you've thought of for your doctor:

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Summary...

Think it over carefully

Deciding to participate in a clinical trial means weighing possible benefits against possible risks. You will always be free to change your mind and stop participating in a trial at any time. However, you are urged not to join a clinical trial out of curiosity. When even a few patients quit out of disinterest or for other reasons stop participating mid-trial, there may not be enough patients left to achieve reliable results. It's a commitment that should only be made after carefully discussing all the facts with your doctor or nurse and thinking about your own reasons for participating.

Glossary

Clinical trial terms

Clinical trial: A scientific study that tests the effectiveness of a new medical treatment, drug, or device with patients.

Clinical investigator: A medical researcher in charge of carrying out a clinical trial's protocol. This could be a doctor, nurse, pharmacist, or other health care professional.

Food and Drug Administration: The government agency that sets guidelines on the manufacture, testing, and use of drugs and medical devices. All drugs and medical devices must be approved by the FDA before they can be used by the general public.

Informed consent: The complete and open discussion of all procedures, benefits, risks, and expectations of a clinical trial between clinical investigators and potential patients. The FDA requires all patients to sign an informed consent form before participating in a trial.

Institutional review board: A group of health care professionals from the institution where the clinical trial takes place, as well as members of the local community. The board makes sure all FDA and protocol regulations are followed and reviews all trial activities including recruitment and advertising, and potential risks.

Investigational treatment: The drug or device being tested during a clinical trial.

Pharmaceutical company: A business that researches, develops, tests, manufactures, and/or sells medical drugs and devices.

Protocol: A detailed plan carefully designed by a clinical trial sponsor. It sets guidelines for a trial and usually involves several different trial locations.

Sponsor: The pharmaceutical company, research institution, or other health organization that funds a clinical trial and designs its protocol.

Standard treatment: A treatment currently in wide use and approved by the FDA for a particular disease or illness. In some trials involving new investigational treatments, there may be no pre-existing treatment at all. In these cases, the lack of any treatment is itself considered the standard treatment. Generally, the investigational treatment is hoped to be safer or more effective than the standard treatment.

Notes

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