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What are clinical trials?

Clinical trials are a part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat disease. Treatments might be new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. The goal of clinical trials is to determine if a new test or treatment works and is safe. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses. Doctors and other health professionals conduct clinical trials according to strict rules that are set by the U.S. Food and Drug Administration (FDA). These rules make sure that people who agree to be in clinical trials are treated safely.

What are the different types of clinical trials?

There are several different types of clinical trials, some are listed below:

- Treatment trials test new possible treatments, new combinations of drugs, or 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. These approaches may include medicines, vitamins, vaccines, 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.

What is a protocol?

A protocol is a study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

What is an IRB?

Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB). An IRB is made up of doctors, researchers, and members of the community. Its role is to make sure that the study is ethical and that the rights and welfare of participants are protected, this includes making sure that research risks are minimized.

Where can I find information about current clinical trials?

Information about clinical trials conducted by federal and private organizations can be found at ClinicalTrials.gov[External Link Disclaimer](#). This site offers information about the location of clinical trials, their design and purpose, participation criteria, and additional information about the disease and treatment under study.

How can I find a study at Morehouse School of Medicine?

To find studies at Morehouse School of Medicine, log on to

<http://www.msm.edu> then go to the research tab, R-Center portal, research resources and clinical trials.

Who can participate in a clinical study?

Clinical studies have standards outlining who can participate. These standards are called eligibility criteria and are listed in the protocol. Some research studies seek participants who have the illnesses or conditions that will be studied, other studies are looking for healthy participants, and some studies are limited to a predetermined group of people who are asked by researchers to enroll. The factors that allow someone to participate in a clinical study are called inclusion criteria, and the factors that disqualify someone from participating are called exclusion criteria. They are based on characteristics such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

How can I participate in a clinical trial?

Find a clinical trial that's right for you by searching ClinicalTrials.gov[External Link Disclaimer](#). If you are a healthy volunteer, contact the study coordinator listed for the clinical trial. If you are a patient volunteer talk with your doctor. You may need a referral to participate in a study.

What should I consider before agreeing to participating?

Participating in a clinical study contributes to medical knowledge. The results of these studies can make a difference in the care of future patients by providing information about the benefits and risks of therapeutic, preventative, or diagnostic products or interventions. Clinical trials provide the basis for the development and marketing of new drugs, biological products, and medical devices. Sometimes, the safety and the effectiveness of the experimental approach or use may not be fully known at the time of the trial. Some questions to consider before making a decision:

- What is the purpose of the study?

- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the treatment?
- Will I be reimbursed for other expenses?
- Will results of the trials be provided to me?
- Who will be in charge of my care?
- What type of test are involved?
- Can my exam results be shared with my personal physician?

What will it cost me?

In most cases, taking part will not cost you or your insurance company anything. In some studies, the research team may bill your insurance company for drugs, devices, and services they provide. The study informed consent form will describe any costs to you in detail. If the information in the consent form is not clear, you should ask the research team to explain any costs before you sign the consent form.

Will I be paid to participate?

Some studies compensate participants for the time they spent participating in a trial; generally this amount is given to cover expenses for parking, transportation, meals, and possibly for lost work time; however, payment may not be substantial enough to constitute inducement to participate for monetary gain. The NIH compensates study participants for their time and, in some instances, for the inconvenience of a procedure. There are standard compensation rates for the participant's time; the study's principal investigator determines inconvenience rates.

What is an informed consent?

Informed consent is the process in which researchers communicate with potential and enrolled participants about a clinical study. It provides the potential benefits as well as the risks to the patient. It informs the patients that participation in the trial is voluntary, and they may discontinue participation at any time. The informed consent process is to protect participants. It begins when a potential participant first asks for information about a study and continues until the study ends. After learning about the study, you will be able to ask the researcher or his/her staff questions. You should only agree to take part after you clearly understand the study and feel comfortable. You should take time to talk over your decision with your doctors, family, and friends. If you agree to take part, you will be asked to sign an "informed consent form." The informed consent process goes on even after you are taking part in the study. If researchers learn new information after you begin the study, they must share this with you.

How am I protected from harm in a study?

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built-in safeguards to protect you. Each trial follows a carefully controlled protocol – a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain secret and will not be mentioned in these reports. The main duty of the IRB is to protect study participants. The IRB requires that every participant in a clinical trial be informed about the possible risks, benefits, and available alternatives. Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB).

Who sponsors and conducts clinical studies?

Clinical studies are sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations, and Federal agencies.

Every clinical study is led by a principal investigator, who is often a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals.

Will I still see my regular doctor?

Typically, participants continue to see their usual health care providers while enrolled in a clinical study. While most clinical studies provide participants with medical products or interventions related to the illness or condition being studied, they do not provide extended or complete health care. By having his or her usual health care provider work with the research team, a participant can make sure that the study protocol will not conflict with other medications or treatments that he or she receives.

What if I change my mind and withdraw from the study?

You can leave a clinical trial at any time. Clinical trial participants can withdraw from the study at any time without jeopardizing the rest of their standard medical care. You should inform the research team about your desire to withdraw and the reasons for leaving the study.

What happens at the end of the study?

At the end of a study, the researchers analyze the data that were collected from all participants throughout the study. Findings and data collected about you will be compared to other participants. In clinical trials, doctors and specialists in biostatistics would conduct the analysis and report the findings to scientific meetings and medical journals. Data will also be shared with experts and various government agencies responsible for the approval of new drugs, biologics and devices. Not all experimental treatments receive final FDA approval in the end.

What happens when the study is over also varies from study to study. Sometimes patients can remain on the study drug if they are responding to the new treatment; however, this is the

exception rather than the rule. Generally, participation ends when the study ends because it might not be safe or effective to continue treatment based on what is known at the time.