

## Questions and Answers about Clinical Studies

### What Is a Clinical Study?

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies that researchers might ask people to join: clinical trials (also called interventional studies) and observational studies.

#### Clinical Trials

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet. Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention). The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants. For example, investigators may give a standard blood pressure drug to half the participants and a new drug to the other half, and then compare the blood pressures of the participants in the two groups.

#### Observational Studies

In an observational study, investigators assess health outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial). For example, investigators may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health.

### Who Conducts Clinical Studies?

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.

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Clinical studies often are sponsored, or funded, by an organization such as a pharmaceutical company, an academic medical center, a foundation, or a Federal agency such as the National Institutes of Health.

### Why are Clinical Studies Conducted?

In general, clinical studies are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions. Some common reasons for conducting clinical studies include:

- Evaluating one or more interventions (for example, drugs, medical devices, approaches to surgery or radiation therapy) for treating a disease, syndrome, or condition
- Finding ways to prevent the initial development or recurrence of a disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches.
- Evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition
- Examining methods for identifying a condition or the risk factors for that condition
- Exploring and measuring ways to improve the comfort and quality of life through supportive care for people with a chronic illness

### What Happens During a Clinical Study?

A clinical study is conducted according to a research plan known as the protocol. The protocol is designed to answer specific research questions and to safeguard the health of participants. It contains the following information:

- The reason for conducting the study
- Who may participate in the study (the eligibility criteria)
- The number of participants needed
- The schedule of tests, procedures, or drugs and their dosages
- The length of the study
- What information will be gathered about the participants

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### Who Can Participate in a Clinical Study?

#### Eligibility

Clinical studies have standards outlining who can participate, called eligibility criteria, which 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. Other factors may be based on things such as age, the type and stage of a disease, previous treatment history, and other medical conditions.

#### Consent

Informed consent is a process in which researchers provide potential and enrolled participants with information about a clinical study, and the people decide whether they want to enroll or continue to participate in the study. The informed consent process should provide enough information for a person to understand the risks of, potential benefits of, and alternatives to the study. Information will be given in a consent document, the process may involve recruitment materials, verbal instructions, question-and-answer sessions, and activities to measure participant understanding. In general, a person must sign a consent before joining a study to show that he or she was given information on risks, potential benefits, and alternatives and understands it. Signing the document and providing consent is not a contract. Participants may withdraw from a study at any time, even if the study is not over.

### Why Do People Participate in Clinical Studies?

Some people may be interested in the possible benefit they might receive by taking part in a clinical study. Some studies may provide participants the chance to directly benefit from the testing of a new way to treat, diagnosis, or prevent disease; others do not. Studies also may involve some risk of harm or injury to the participant. The possible benefits and risks of a particular study will be described in the consent form for that study.

Many people take part in clinical studies because they want to contribute to medical knowledge. Clinical studies provide the basis for advancement in medical care, including the development of new drugs, medical devices, and biological products. The results of these studies can make a difference in the care of future patients.

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### Questions to Ask

Anyone interested in participating in a clinical study should know as much as possible about the study and feel comfortable asking the research team questions about the study, the related procedures, and any expenses. The following questions might be helpful during such a discussion. Answers to some of these questions are provided in the consent form. Many of these questions are specific to clinical trials, but some also apply to observational studies.

- What is being studied?
- Why do researchers believe the intervention being tested might be effective? Why might it not be effective? Has it been tested before?
- What are the possible interventions that I might receive during the trial?
- How will it be determined which interventions I receive (for example, by chance)?
- Who will know which intervention I receive during the trial? Will I know? Will members of the research team know?
- How do the possible benefits and risks of the study intervention compare with those of my current treatment?
- What will I have to do?
- How often will I have to visit the hospital or clinic?
- What tests and procedures are involved?
- What costs are involved, and who will pay for them?
- Will I receive any compensation?
- How long will the study last?
- What type of long-term follow-up care is part of this trial?
- Who will oversee my medical care while I am participating in the trial?
- If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- Will results of the study be provided to me?
- What are my options if I am injured during the study?