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Clinical Trials FAQs

This section lists some of the frequently asked questions that potential trial volunteers or clinical trial participants usually ask.

What are clinical trials?

Clinical trials are research studies done to find out if a treatment can improve people's health. A treatment can be a drug, medical device, medical procedure, or a change in a person's behavior such as diet or exercise. People who take part in clinical trials are volunteers. They may also be called "participants" or "subjects."

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Why should I participate?

The health of millions of people has been improved because of advances in medical care, made possible by clinical trial participants. People choose to participate in clinical trials for a variety of reasons, including the chance to play a more active role in their own health care, gain access to new medical treatments before they are available to the wider public, and help others by contributing to the future of medical science.

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What is a healthy volunteer?

A healthy volunteer is someone with no known or no significant health problems who participates in a clinical trial. Healthy volunteers are needed to participate in early phase studies to understand how a potential medicine works in the body. In addition, healthy volunteers are sometimes needed to help define the limits of "normal" and act as a "comparison" group to patients with the disease being studied.

What are the phases of clinical trials?

Clinical trials are conducted in phases. The trials in each phase have a different purpose and help researchers answer different questions:

- Phase I trials test an experimental drug, vaccine or device in a small group of participants (about 20-80 people) to evaluate safety, identify side effects, and determine how the drug should be used or delivered
- Phase II trials involve larger groups of participants than Phase I (about 100-300 people) and they are designed to assess whether an experimental treatment is safe and whether it works
- Phase III trials evaluate the safety and effectiveness in a greater group of participants (about 1000-3000 people), often in comparison to a placebo or standard treatment
- Phase IV trials are performed once a drug or vaccine has been approved for use and has reached the market, to seek more information about its risks, benefits, and optimal use

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What is a protocol?

A protocol is a study plan on which the clinical trial is based. The plan details what researchers will do in the study and is designed to safeguard the well-being of the participants and to help answer specific research

questions. A protocol will outline what types of people may or may not participate in the trial; the schedule of tests, procedures, medications, and dosages to be administered; the measurements to evaluate the effect of an intervention on participants; and the length of the study.

What are eligibility criteria?

All clinical trials have rules about who can and cannot participate. These rules are called “eligibility criteria” but may also be referred to as inclusion/exclusion criteria. The criteria are based on factors such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. The eligibility criteria define the patient population that is being studied and are designed to protect the safety of participants in the trial. Because of the criteria, not everyone will qualify to participate in the trial.

What is the placebo effect?

Placebos are inactive substances. In a clinical trial a placebo, made to look like the investigational treatment, is sometimes used as a comparator to the actual investigational treatment. The placebo effect is the real, or apparent, improvement in a patient's condition that results from the patient hoping to see a better outcome. To help eliminate this problem, participants are randomly assigned to receive the investigational treatment or placebo and blinding is used so that participants do not know which treatments have been assigned to them.

What is the difference between single-blind and double-blind studies?

Blinding is designed to prevent participants and the research team from influencing the trial results and to allow for the most scientifically accurate conclusions. In single-blind studies, the participant does not know what treatment they are given but the research team is informed. In a double-blind study, neither the participant nor the research staff know what treatment is given to each set of participants. The treatments are made to look the same as each other so that participants and research staff cannot tell the difference. If medically necessary, however, it is always possible to find out which treatment the patient in a clinical trial is taking.

Are there risks involved in participating in a clinical trial?

There are risks involved when participating in a clinical trial. When evaluating the risks of research, it is best to consider both the “type of harm” that might result from being a clinical trial participant and the “likelihood” of harm happening. Most clinical trials pose risks of minor discomfort, lasting only a short time, although some participants do experience more serious complications that require medical attention. The specific risks associated with any clinical trial will always be described in detail in the informed consent form, which a participant is asked to review before agreeing to take part in a clinical trial. The major risks will also be explained to a potential participant, by a member of the research team, who will answer any questions about the trial. Before making a decision about whether to participate in a clinical trial, a person should carefully evaluate these risks.

What safeguards are there to protect participants in clinical research?

Many measures are in place to protect the safety of clinical trial participants including careful protocol design, oversight of the trial by ethical review committees, and regular monitoring of the data collected. An ethical review committee is a group of doctors, scientists, advocates, researchers, and members of the community that has been formally designated to review and monitor all research involving humans. The role of the committee is to provide ethical oversight and to minimize risk to participants. During the study, the research team must inform participants of any new risks or side effects that are discovered during the course of the trial.

The following safeguards are also in place to protect the safety and rights of trial participants.

Protocol review. In almost every country, all new clinical trials are reviewed by a regulated independent review board or committee that is typically made up of medical specialists, statisticians, nurses, social workers, patient advocates, and medical ethicists. The purpose of these committees is to ensure that the trial is safe for participants before a clinical trial begins.

Informed consent. Participation in any clinical research trial is always voluntary. For every trial, a potential trial participant will receive a document called an informed consent form that outlines the protocol and explains the details of the trial in straightforward language. It will outline items such as the trial's purpose, risks and potential benefits, duration of the trial, required procedures, and key contacts. A member of the research team will also review the informed consent with each potential trial participant and answer any questions the potential trial participant may have. A potential trial participant may discuss the informed consent form with family and friends and will not be hurried into making a decision. The potential trial participant will be asked to sign the informed consent document only after they have a full understanding of the trial protocol and have decided to agree to participate. The informed consent is not a contract, and a participant may withdraw from the trial at any time and for any reason.

Can I stop participating at any time?

Yes. Clinical trial participants have the right to change their minds at any time even after they have started the clinical trial or at any time during the trial. It is important to contact the clinical trial site and inform the research team of a decision to stop participating to make sure steps are taken to safely transition a participant back to their previous care.

Will I be compensated for participating in a clinical trial?

Payment varies from trial to trial and country to country. In general, patients are not paid for participating, but expenses may be covered. However, there are times when payments may be made for participating, particularly for Phase I trials. The research team will clearly outline any compensation that will be provided during the informed consent process. It is also important for a potential trial participant to ask the research team about payment for expenses or indirect costs of participating in a trial, such as time away from work, travel to and from the research site, child care coverage during study appointments, etc.

Will my insurance need to cover any visits?

The role of personal insurance can vary by region and by trial and will be discussed with each participant before they enroll in a trial.

If I am interested in a specific clinical trial, how can I learn more?

To learn more about a specific trial, it is best to contact the research team assigned to the trial site. The research team will provide more details and answer any questions about the trial.

Is it possible to experience side effects during a clinical trial?

Participants in clinical trials are rigorously and closely monitored throughout the duration of the study, often seeing their doctor more regularly than if they were treated with the standard of care.[2] Although medicines have been thoroughly studied in a laboratory before patient volunteers are invited to participate in a clinical trial, as with all medicines, there is a possibility that side effects may be experienced.[3] Clinical trials can only proceed if the safety profile of the investigational treatment is accepted by health authorities and ethics committees.

The healthcare professionals (HCPs) within the research team ensure that patients are fully apprised of possible side effects before they agree to take part in any clinical trial.3 These could range from pre-empted, mild side effects that the research team may expect, or they could be more unexpected. Either-way, the treating HCP would keep a close eye on all trial patients and treat any emerging side effects promptly.[2]

Where do clinical trials take place?

Most clinical trials take place in either hospitals or health centers. To be part of a clinical trial, participants may be required to attend regular hospital or GP visits so that their progress on the study can be closely monitored.[2]

What are the advantages of being a participant in a clinical trial?

Patients taking part in clinical trials often benefit from a greater degree of clinical oversight and monitoring of their disease by their healthcare team – so more frequent visits and more thorough assessments of their disease status.[2]

For some patients who are perhaps unable to access alternative treatment options, or where existing medicines have failed to provide benefit, clinical trials can enable earlier access to new, innovative medicines.[2]

Additionally, supporting clinical trials helps progress scientific understanding of medicine and improves healthcare options for future generations.[1]

How long can a clinical trial last?

The length of a clinical trial varies depending on several factors, such as the type of illness and the type of medicine being researched.[4] For example, if the study is researching a treatment for a chronic condition, participants' progress on the trial may be tracked over a relatively long period of time. Studies of antibiotics on the other-hand conclude quickly as patients are typically treated on study for a few days only.

If the treatment appears to be helping a patient during a clinical study, can they continue taking the medicine after the trial has finished?

The treatment of patients coming off a clinical trial is at the discretion of their healthcare professional.

Once a clinical trial has finished, patients who have participated in the study may be able to continue taking the medicine for a period of time if it has provided a benefit. In these cases the patient would also continue to attend follow-up appointments with the healthcare professionals managing the study.

1. Sarah Cannon Research Institute. Clinical Trials FAQs. Available at: http://sarahcannonresearch.co.uk/for-patients/clinical-trials-faqs/. Last accessed May 2019.
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3. Cancer Research UK. Advantages and drawbacks of taking part in a clinical trial. Available at: http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-.... Last accessed May 2019.
4. Cancer Research UK. How long does it take for a new drug to go through clinical trials? Available at: http://www.cancerresearchuk.org/about-cancer/cancers-in-general/cancer-q.... Last accessed May 2019.

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