

What is a Clinical Study?

A clinical study is designed to assess the effects and/or safety of a potential new medicine or device on a group of volunteers.

During a clinical study, volunteers may have more tests and doctor's visits than they would usually have to treat their illness or health condition.



Volunteering for Clinical Research

Further information

Anyone interested in finding out more should first speak to their doctor or healthcare provider. More information can be found on the following website:

www.clinicaltrials.gov



Everyday, research uncovers new information about illnesses, health conditions and their treatments. By taking part in a clinical study, volunteers are an essential part of the research and testing of potential new medicines.

So let's find out more about clinical research...

What are the possible benefits of Clinical Research?

Each year, many thousands of people worldwide volunteer to take part in clinical studies. Volunteers may:

- Help to find new treatments for illnesses and health conditions
- Get medicines and health assessments as part of the study
- Help improve medical knowledge about the illness or health condition
- Play a more active part in their own healthcare



Who can be in a clinical study?

Each clinical study has different requirements for volunteers such as age, sex or medical conditions. People respond differently to medicines and other treatments so it is important to include both men and women from different ethnic groups.

The research team will look at the volunteer's medical history to find out if they can take part. The team will also tell the volunteer more about the study; this will help the volunteer to decide whether or not to take part.



Who sponsors a clinical study?

Charities, private organisations, governments and drug companies sponsor clinical studies to find better ways to treat illnesses and health conditions. These groups sometimes work together on studies.

Who conducts a clinical study?

The study may be conducted in a hospital, university, GP surgery or other healthcare setting (known as a site). A research team is led at each site by a doctor or other researcher (known as the Principal Investigator). The team may also include nurses and other healthcare workers.

Are there any costs to the volunteer?

No. Treatments and health assessments within the study are provided at no cost.

What is Informed Consent?

Informed consent is the process that takes place before volunteers join the study. A doctor on the team will explain what volunteers can expect, including the risks and benefits of taking part in the clinical study.

Volunteers will be given a consent form to read and any questions can be asked, such as:

- What other treatment choices are available?
- What happens after the study?
- What happens to the study information?

The consent form is approved by the ethics committee and describes the rights of volunteers in a clinical study. They will be told who will see their personal medical information, and how it will be kept private. A volunteer who decides to take part in a study will sign the consent form. Even if the form is signed the volunteer can still change their mind and stop at any time.

Any important personal health findings made during the study will be shared with the volunteer.

Who makes sure the rights of volunteers are protected?

Ethics committees must review clinical studies before they begin. The committee is a group of doctors, nurses and people from the community. Their job is to review all clinical studies to help protect the rights and safety of volunteers.

In addition, local Regulatory Health Authorities review the study and set requirements for drug testing. They also review the results from certain clinical studies to decide if a new medicine should be made available to the general public.

All clinical study volunteers are protected by an international code of conduct (The Declaration of Helsinki), which sets the standards for clinical research.