

What are clinical trials?

Clinical trials are research studies in which people help test treatments or approaches to prevention or diagnosis to see whether they are safe and effective. People who take part in trials are volunteers, usually patients.

Clinical trials are one stage of long and thorough health research. Trials are carried out in carefully planned steps, called phases, allowing researchers to ask and answer questions in a way that provides reliable information in the best interests of participants. Trials are an important part of the process the NHS goes through in making decisions about which approaches to prevention, diagnosis or treatment should be made available to the public.

Why do we need to do clinical trials?

Clinical trials are essential for developing better treatments and improving healthcare for both adults and children. It is important to remember that a potential new treatment may or may not be better than an existing one, and a trial is needed to find out.

As well as assessing whether a new treatment is safe and effective, trials can evaluate existing medicines or other approaches where this has not previously been done thoroughly.



What happens when a trial ends?

The people organising a trial should always ask everyone taking part if they want to know the results. Clear and comprehensive information must be provided to anyone who wants it. Sometimes, when a patient feels the treatment they have received during a trial has helped them, they may be able to continue with it after the trial ends. This can vary, so you should ask what will happen before you agree to take part.

Sometimes the NHS may decide that the costs of providing a treatment outweigh the benefits it gives to patients, so it is not made widely available. This can be distressing for patients, especially if they think the treatment could help them. Situations like this do occur, so organisations that represent patients, many of which are medical research or healthcare charities, work closely with those making decisions about treatment availability.

Find out more at:

Association of Medical Research Charities:
www.amrc.org.uk

Information from the NHS about trials:
www.library.nhs.uk/trials

National Institute for Health Research:
www.nihr.ac.uk

**NIHR Clinical Research Network
Coordinating Centre:**
www.crncc.nihr.ac.uk

Further copies can be requested from the NIHR Clinical Research Network Coordinating Centre website:
www.crncc.nihr.ac.uk/resources/order_form

Clinical Trials: What they are and what they're not Version 2
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NHS

**National Institute for
Health Research**

Clinical trials: What they are and what they're not



Are trials safe?

Large numbers of people take part in thousands of clinical trials in the UK every year. Rigorous processes, including review by an NHS Research Ethics Committee, are in place to protect the rights, dignity, safety and well-being of participants.

Each trial is designed to keep risk to a minimum. Doctors and researchers only ask people to take part who are suitable for the treatments being compared. Participants are monitored carefully throughout and their safety and well-being prioritised.

In March 2006 there was publicity and concern surrounding a trial in which six volunteers became seriously ill. This was an extremely rare event, which is one reason why it attracted such intense interest.

Aren't people who take part in the trials just "human guinea pigs"?

The "guinea pig" label is misleading, but it is easy to see why people might think this. In trials, some volunteers may get a new treatment while others are given a placebo or 'dummy' or what is currently thought to be the best available treatment. This is the only way to weigh up the risks and benefits of new and developing treatments to see if patients are helped and the treatment can be recommended for routine use.

The principle of 'informed consent' means that if you are thinking of joining a trial you must be given clear information about what the trial is for and what you are agreeing to take part in. You should remember that you can always pull out of a trial at any time and this will not affect your treatment in the NHS.

Aren't clinical trials all about drug companies making a profit?

The responsibility of companies to provide profits to their shareholders is a motive for developing new medicines. However, only drug companies have both the expertise and resources necessary for developing and manufacturing most new medicines, and having done so it is important that they do trials to test them.

When industry funds trials, there are often spin-off benefits for other organisations and individuals, including NHS patients and those who look after them, the government and medical research charities. These groups are increasingly working together to help patients.

However, not all trials involve drug companies and new medicines. The government and medical research charities often fund trials to study surgery, physical or psychological therapies, alternative or complementary treatments, or new uses for commonly used medicines.

Patients can be keen to know about nonmedical approaches, many of which are very beneficial, so it's important for patients and the NHS to gather reliable evidence about their effects. This means testing alternative treatments in trials to the same rigorous standards used for medicines.



Are volunteers paid to take part in clinical trials?

Patients often join trials to help improve medical knowledge about how to treat their own condition, or in the hope of gaining benefit from a new treatment or the support offered to people taking part. When volunteers receive money it is to cover expenses, loss of earnings or their time.

Doctors are occasionally paid to recruit people into trials. We hope they will tell you if this is the case, but do feel free to ask them.

Are trial results always made public?

Trial results should always be made public, whatever they show and whoever has funded them. Work is underway to help ensure that this happens. The government and charities usually publish the findings of trials they have funded and drug companies worldwide are also now committed to openly registering trials and making their results public.

