

# Clinical trials

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This factsheet provides a brief introduction to the types of clinical trial that people with HIV might be asked to join. There is also information on how a trial is organised and what your rights and responsibilities are if you join a trial. You can find out more about some of the major HIV-related clinical trials and the important advances that have been made in HIV treatment as a result in our factsheet, *HIV and clinical trials*. This factsheet also gives some information on how to find out about, and join, a trial.

A clinical trial is a research study, where a new drug or treatment is tested to assess its benefits and risks. A trial will try to find out:

- if the treatment is safe
- if the treatment has any side-effects
- if the new treatment is better than any existing treatments.

People may choose to take part in clinical trials because this research helps doctors understand more about a condition or treatment, which may benefit them or others in the future.

## Who runs clinical trials?

In the UK, research and clinical trials are often part of the NHS's work, involving doctors and other health professionals who treat people. This research will often take place in hospitals or clinics.

Research also takes place in universities and research institutes, in social care services, and in the private sector (e.g. trials run by a pharmaceutical company).

## How are trials regulated?

There are legal requirements on how a trial should be run. The Medicines and Healthcare products Regulatory Agency (MHRA) reviews every trial before it starts.

The detailed plan for a trial (the 'protocol') lays down procedures for how treatment will be given, who is eligible, the length of the study, how results will be assessed, and so on.

An ethics committee must approve the protocol. These committees are responsible for protecting the rights and interests of people in the trial. Until approval, researchers cannot recruit any participants.

## How are trials organised?

A new treatment is first tested in the laboratory. If the results from these tests are promising, clinical trials are started in people. There are a number of stages, or phases.

- Phase I: This stage is to see if a drug is safe to be tested in humans and what the right dose might be.
- Phase II: This stage looks at the effectiveness of a drug in the short term, normally about six months.
- Phase III: This stage normally lasts at least a year and compares the new drug to an existing treatment or a dummy treatment called a placebo.

## Types of trials

**Comparison studies:** In these studies, one group of people will receive a new treatment, the other group will be given the treatment that is in current use.

**Randomised trials:** If a trial is comparing two treatments it is normally randomised. This means that people are selected at random, usually by a computer, to ensure that treatments are being tested in people who have similar characteristics.

**Placebo-controlled trials:** If there is no current treatment, the study will be a placebo-controlled trial. This compares the safety and effectiveness of the new treatment to a dummy treatment called a placebo. You won't know if you are taking the active treatment or the placebo.

**Blinded trials:** Many trials are 'blinded'. This is to make sure that your or your doctor's expectations don't influence the results of a study. If a study is 'double blinded' it means that neither you nor your doctor knows which treatment you are taking. If it is 'single blinded' it means that you do not know which treatment you are taking, but your doctor does. In an 'open label' study, both you and your doctor know what treatment is being given.

**Dose studies:** Some trials compare different doses of drugs. Sometimes these studies are 'blinded'.

**Non-treatment studies:** A lot of research is conducted in HIV clinics that doesn't provide access to any new treatment. This research is often called 'observational'. A sample of clinic patients is recruited, aiming to make this group representative of clinic users. These studies help doctors gain a better understanding of important issues related to HIV treatment and care, or life with HIV. The study may simply involve looking at your medical records, but it could involve other elements, such as some tests. Participation is always voluntary.

## Information about a trial

All trials have a protocol, which sets out the trial's aims and objectives. Trials also have rules about who can and cannot join. These are called inclusion and exclusion criteria.

You should always be given written information about a trial. You should read it carefully and ask questions if there is anything you don't understand.

Before you join a trial you have to give your written consent. You should only give this after the trial has been explained, including the possible risks and benefits of taking part. You should not have pressure put on you to join a trial. Saying no to joining a trial should not affect the standard of care you receive.

## Rights and responsibilities

You have both rights and responsibilities if you join a trial.

If you are considering joining a trial, there are a number of issues you may want to consider. You can find a list of questions you may want to ask in our factsheet *Thinking of joining a clinical trial?*

If you do join a trial, you can withdraw at any time without having to give a reason.

You should be given details of how to contact somebody if there is an emergency.

You also have responsibilities if you join a trial. For example, you will need to take your treatment as instructed and to keep any appointments.

It's also important to tell your doctor if you experience any changes in your health or develop any symptoms.

You can find more information on clinical trials, and on making the decision whether or not to join one, on the NHS Choices website at [www.nhs.uk/Conditions/Clinical-trials](http://www.nhs.uk/Conditions/Clinical-trials) and in the booklet *Understanding Clinical Trials*, from the UK Clinical Research Collaboration, available online at [www.ukcrc.org](http://www.ukcrc.org).