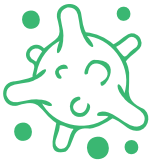
What is a clinical research study?

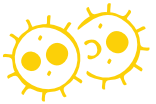
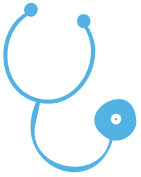


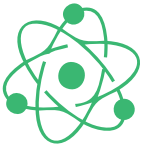










Doctors and researchers are always trying to find new medicines to help people with health conditions.

Clinical research studies are an important step in getting new medicines to people who need them all over the world.

This brochure explains what a clinical research study is and what is involved.

Keep reading if you would like to find out more!

Making medicines

Doctors and researchers are working all the time to discover new ways to prevent, detect, and treat health conditions. However, the discovery of a new medicine is just the beginning!

When new medicines are discovered, they are first tested in labs. Experiments are done in test tubes and in animals to see if the medicines work and if they are safe.

The most promising medicines are then tested in clinical research studies to see if they work to treat health conditions in people.

What is a clinical research study?

Clinical research studies answer important questions about a new medicine like...

- Is it safe?
- Does it work?
- Does it have side effects?
- How does it compare to other medicines?

If the results of clinical research studies show that an investigational medicine works safely in people, then it may be approved for doctors to give to patients.

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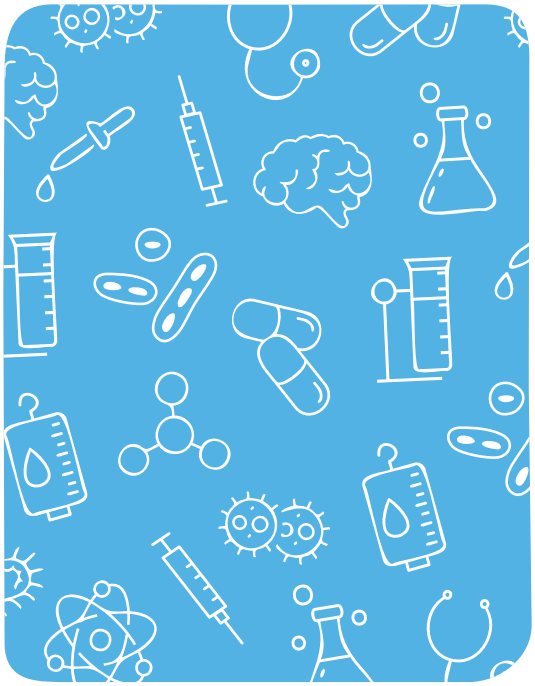
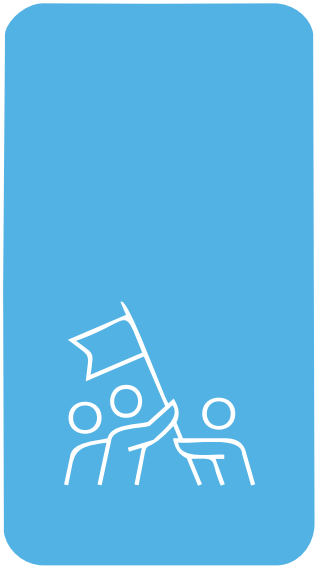


Why do clinical research studies include children and young people?



Children's and young people's bodies are different from adults' bodies. Their bodies are still growing and changing so sometimes health conditions and medicines affect them differently. Because of these differences, it is important to include children and young people as well as adults in clinical research studies.

Children and young people who take part in clinical research studies help researchers make sure that new medicines work and are safe for people their age.

Where do clinical research studies take place?

Clinical research studies often take place in hospitals and doctors' clinics. Sometimes the study team meets the people taking part in their communities or even over the phone or by video call.

Clinical research studies can be carried out in just one place, in many places in the same country, or even in different countries all over the world.

Each clinical research study has a study team. The study team is made up of healthcare professionals and researchers.

Who can take part?

Each clinical research study has its own eligibility criteria.

Eligibility criteria are the requirements that must be met for a person to take part in a clinical research study.

These criteria ensure that the people taking part are similar in terms of specific factors such as age and health condition.

When the people taking part in a clinical research study are similar, it is more likely that the results of the study are caused by the investigational medicine and not by anything else or by chance.

Eligibility criteria also keep people safe. They ensure that only people who are suitable for the clinical research study can take part.

Eligibility criteria include:

- inclusion criteria which are required for a person to take part.
- exclusion criteria which prevent a person from taking part.

What is a study medicine?

Study medicines are the medicines given to people taking part in clinical research studies. The different types of study medicine that you could get include:

Investigational medicine
This is the medicine being studied.

Placebo

This is made to look the same as an investigational medicine but does not have any real medicine in it.

Active comparator
A medicine that is already used by doctors to treat the health condition being studied.

In some clinical research studies, the investigational medicine is compared to a placebo or an active comparator to see how well it works to treat a health condition.

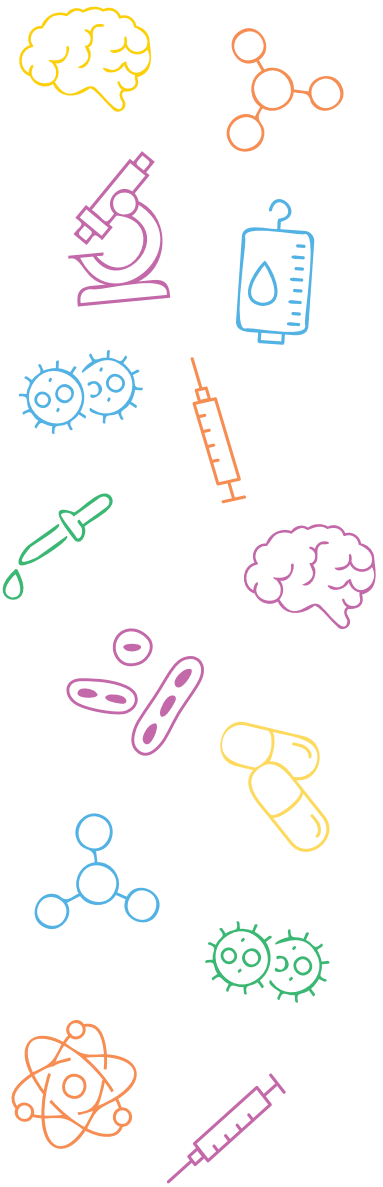
In some cases, everyone taking part gets the investigational medicine. This can happen when there is no other medicine available for people with a health condition.

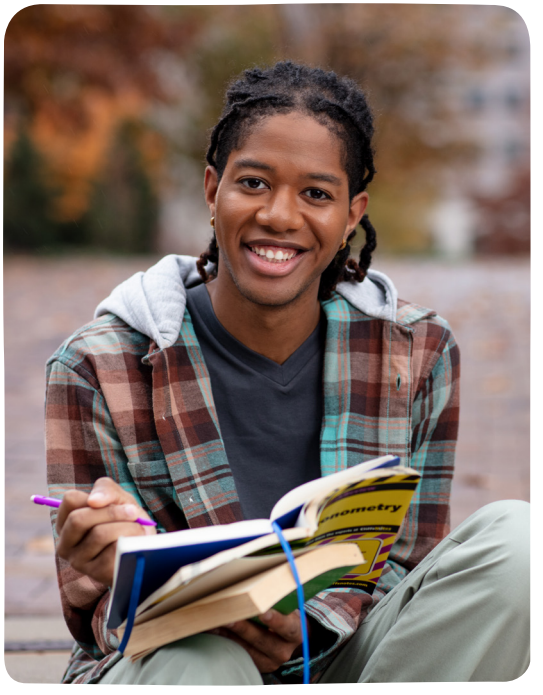
Who decides which study medicine people get?

Each person's study medicine is picked at random, like flipping a coin. A computer decides which study medicine each person will get. This is to make sure that the research study is fair.

In some studies, the study team and the person taking part will know which study medicine the person is getting.

In other studies, the person taking part and the study team won't know which study medicine the person is getting. This helps make sure that changes to people's health are caused by the investigational medicine, and not by what people expect will happen when they take it.





What would I have to do if I took part?

Before starting a clinical research study, you will meet the study team. They will ask you questions and carry out health checks to make sure that the clinical research study is a good fit for you.

If you meet the eligibility criteria, you will go to visits with the study team. These might be in-person at a study clinic, by phone, or online. The activities on each visit may vary, but the study team will tell you what to expect.

Activities may include:

- answering questions about your health
- filling out questionnaires
- health checks like blood tests or scans.

You may be asked to keep a diary to record when you take your study medicine and how you feel.

What are the risks and benefits of taking part?

Each clinical research study has its own risks and benefits. The children and young people taking part in clinical research studies are different from each other. They may experience risks and benefits in different ways.

Potential benefits

Children and young people who take part in clinical research studies help researchers find out if new medicines work and are safe for people their age. By taking part, you can help make progress in healthcare research possible.

Potential risks

Your safety and wellbeing are the most important part of any clinical research study but there are some risks. If you are thinking about taking part in a clinical research study, your study team will talk to you about what to expect.

Taking part in a clinical research study is a big commitment. You may have to take time away from your interests or hobbies to attend your study visits.

You may experience side effects from your study medicine. These are unwanted symptoms that can happen after taking medicine. Side effects can happen with all medicines even those that have already been approved for doctors to give to patients.

Your health and safety are very important to your study team. They will keep a close eye on you and answer any questions you may have.

How do I sign up?

If you find a clinical research study that you are interested in, talk to your doctor. They will give you all the information you need.

If you decide to take part, the study team will talk to you about:

- the clinical research study
- the study medicine
- what you would have to do, and
- how your personal and health data will be used, stored, and protected.

You will then need to give your permission to take part, this is called **assent.**

Your parent/caregiver will also need to give their permission for you to take part, for adults this is called **informed consent**.

It is up to you to decide if you would like to take part.

Your study team can answer any questions you may have and will explain the next steps.