



# Clinical Trials

**The following information will provide an overview of clinical research trials. If you should be invited to participate in a study either in these rooms or elsewhere, you will be provided with more specific information.**

## **What is a clinical trial?**

Clinical trials are research studies in which people help doctors and researchers find ways to improve health care. Each study tries to answer scientific questions and to find better ways to prevent, diagnose, or treat disease.

The purpose of a clinical trial is to find out whether a medicine or treatment regimen is safe and effective for the treatment of a specific condition or disease. Clinical trials compare the effectiveness of the study medicine or treatment against standard, accepted treatment, or against a placebo if no standard treatment exists.

## **Why are clinical trials important?**

Clinical trials are important because they compare new treatments with accepted treatments. They allow researchers to find out whether a new treatment works better than accepted treatments. The new treatment might work as well as or better than standard therapies. And the new treatment might have fewer or better-tolerated side effects. On the other hand, the new treatment might not work as well or might cause more side effects than standard treatments.

Clinical trials help pharmaceutical or biotechnology companies develop medicines and treatments that are safer and more effective with fewer side effects. Clinical trials also help these companies decide whether it is worthwhile to seek approval from the Australia therapeutic goods administration (TGA) for a certain medicine or medical device. If a treatment does not work as well as standard therapy, then the TGA is not likely to approve it. Clinical trials are also important in finding treatments if no standard treatment exists. Clinical trials help show how well the new treatment works and what side effects it may cause.

## **How do clinical trials work?**

Your doctor will help you find out whether you are eligible to take part in a clinical trial. The trial will have a very strict set of criteria that all participants must meet. If you meet the criteria, you may be "randomised" to either the new medicine, a medicine that is considered standard therapy, or a placebo.

Every clinical trial in the Australia must be approved and monitored by a Human Research Ethics Committee (HREC) to make sure the risks are as low as possible and worth any potential benefits.

After you are accepted by the clinical trial and you give your consent to take part, you will be given a structured program to follow. You will have a schedule of tests, doctor appointments, and treatments. You may also be asked to keep a diary of your experience during this time.

Clinical trials usually require you to have more medical tests than you would have if you were not in the trial. The cost for any additional medical tests will be covered by the doctor or company running the trial. Therefore being involved in a clinical trial will not cost you anything nor will you be paid.

### **What are the phases of a clinical trial?**

A medicine or treatment regimen must go through three phases before it is approved for use by the **Therapeutic Goods Administration (TGA) in Australia**.

**Phase I:** A new medicine is tested for the first time on a small group of healthy people or people with specific conditions or diseases. Researchers evaluate the safety of the medicine or treatment, the best dose or schedule to use, and what types of side effects occur.

**Phase II:** The medicine or treatment is tested on a larger group of people with specific conditions or diseases. This phase helps researchers find out how well a medicine or treatment regime will work to treat a particular problem.

**Phase III:** The medicine or treatment regimen is tested on even larger groups. The medicine is studied to find out how well it works compared with standard treatment or placebo and whether it improves specific areas in your life, such as how well you are able to keep up with your usual routine.

**Phase IV:** Medicines or treatment are also studied after they are approved to find new uses for the medicine, different ways to administer it, additional safety information or compared to standard therapy.

### **What are the risks?**

You should be fully informed about the possible risks and benefits of the trial before you consent to participate.

What are the risks of clinical trials:

- The new treatment may not work as well as standard treatments.
- You may experience unpleasant, serious, or even life-threatening side effects from the treatment.
- The treatment may not work for you.

The trial may require more of your time than standard treatment. You may have to:

- Make more trips to the study site.
- Have more treatments.
- Receive your treatment in a hospital.
- Take more medicine more frequently or at rigidly prescribed times.
- Keep a written diary of your experience.

### **How is my safety protected?**

Every clinical trial in Australia must be approved and monitored by a Human Research Ethics Committee (HREC) to make sure the risks are as low as possible and are worth any potential benefits.

The ethical and legal codes that apply to medical practice also apply to clinical trials. Most clinical research is regulated by the government, with specific rules to protect the participants. Clinical trials follow a carefully controlled study plan (protocol) that explains what everyone will do in the study. During the clinical trial, researchers report the results of the trial at scientific meetings, to medical journals, and to government agencies. Your name will remain secret and will not be mentioned in these reports.

### **What to think about?**

Participation in a clinical trial is voluntary. No one can force you to participate. You should be fully informed about the possible risks and benefits of the trial before you consent to participate. If you choose not to take part, you will be offered the standard therapy for your disease.

Your taking part in a clinical trial may not benefit you directly. But in the future it may help other people who have the same disease.