

# Clinical trials



**If you have been diagnosed with a blood cancer you may be asked to take part in a clinical trial. Clinical trials are research studies that help determine whether a new treatment is safe, effective and works better than the current treatment.**

**Each study is designed to answer specific questions and to find better ways to screen, diagnose, prevent, or treat a disease or condition.**

## **The need for clinical trials**

Trials provide the evidence that a treatment works. Some clinical trials help to determine if a new treatment is safe and can improve the health of patients. Other trials compare a new therapy to an existing one to find out which is better at treating or preventing a disease.

## **The benefits of participating in a clinical trial**

Participation in a clinical trial provides an opportunity to have access to the latest treatments, or latest developments in existing treatments for your condition.

What doctors learn in trials helps people who may get cancer in the future.

## **The risks**

There are both known and unknown risks with any clinical trial. Be sure you understand the known risks before you join any study. The risks depend on the type of treatment being studied and your health. Often these side effects are temporary and end when the treatment stops. However some side effects may continue for a long time and may be serious.

## **How do I find out if I'm eligible?**

Each trial has guidelines about who is eligible to join the clinical trial. The criteria vary by study and could include your age, gender, medical history, current health status, the particular type or stage of disease you may have and how many treatments you have already had. Before you join the trial, you will be asked to sign an informed consent form.



## Informed consent

Before participating in a clinical trial you must be provided with an 'informed consent' form. This document explains the design, the risks and potential benefits of the trial. You should be informed about what your involvement in the trial means, how many visits will be required, how the drug therapy is given and how many tests or procedures you will undergo.

Most trials require you to fill out questionnaires throughout the trial. These look at how the trial has affected your mood, daily living, and how the side effects are impacting on your life quality.

If there is something on the form you don't understand, ask questions. Study doctors and nurses are available to answer your questions and help you understand the risks and benefits of the trial.

## How clinical trials work

There are three phases of clinical trials. Each treatment being tested has to go through all three phases before its benefit can be assessed.

**Phase 1:** trials look at whether a trial treatment is safe or has harmful effects. This is the initial testing in humans and involves a small number of participants.

**Phase 2:** trials involve testing the drug or drug combination in people with the condition the drug is being tested for. This phase looks at how well a treatment works, whether it is effective and the best dose to give.

**Phase 3:** trials involve large scale testing in several hundred to several thousand people for a thorough understanding of a treatment's benefits and side effects.

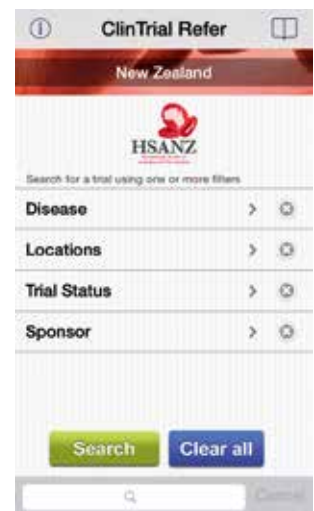
## The protection of rights

In New Zealand all trials must be approved by an ethics committee based within the Ministry of Health. Any new drug being tested has to pass approval after thorough inspection by Medsafe. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. Any information collected and recorded as part of the trial must have a code instead of your name.

## The completion of the trial

After you complete the trial you may or may not be able to continue receiving the drug. Once the trial ends, researchers analyse the data to understand the safety and effectiveness of the treatment. You can ask for the results of the trial, these however may not be finalised for a couple of years after the study ends.

You can download the app ClinTrialRefer (New Zealand edition) to find out which trial at which hospital is available for your condition.



For more information please contact Support Services on [supportservices@leukaemia.org.nz](mailto:supportservices@leukaemia.org.nz) or 0800 15 10 15

[leukaemia.org.nz](http://leukaemia.org.nz)