



## Clinical Trials Factsheet

Clinical trials help to find better treatments for many diseases, including cancer. This fact sheet is for people with cancer or those close to them.

It explains:

- what clinical trials are
- the aim of clinical trials
- the different phases of clinical trials
- where to find out about clinical trials for your type of cancer

Your doctor may suggest you join a clinical trial. Or, you may like to ask your doctor about clinical trials for your type of cancer. If there is a suitable new treatment being studied, you may be able to join the trial.

We hope this fact sheet will help you make an informed decision about joining a clinical trial.

### What are clinical trials?

Clinical trials are medical research studies involving people. People who join trials are always volunteers.

Many people with cancer are now living longer, with a better quality of life, due to treatments developed using clinical trials.

There are many good ideas about how to improve cancer treatments. Clinical trials are the best way of testing promising new treatments to see if they are better than existing standard treatments.

They are the final step in a long process to prove the effectiveness and safety of a treatment.

Trials study radiotherapy, chemotherapy, surgery, biological therapies and complementary therapies.

Clinical trials may look at:

- risks and causes: how lifestyle, genetics/family

history and other factors can increase the risk of cancer

- cancer prevention: using drugs, exercise, vitamins/herbs or diet to prevent or reduce cancer risk
- screening methods to help find cancers early: for people at higher than average risk, or for the general public
- diagnosing cancer: using new scans or tests to help diagnose cancers earlier
- promising new treatments: new drugs or combinations of known and new drugs, new ways of giving treatment, and new types of treatment
- controlling symptoms or side effects: using new or existing drugs or complementary therapies to improve quality of life. These trials are called 'supportive care trials'. Examples include seeing whether acupuncture helps with pain and nausea or whether relaxation techniques reduce anxiety.

### What are clinical trials for?

By choosing to join a clinical trial, patients can help cancer research. Hundreds of thousands of people all over the world have taken part in clinical trials. These trials have found safer and more effective treatments for many cancers.

The main aims of clinical trials are to find out if a new treatment or procedure:

- is safe
- has side effects
- helps you feel better
- works better than the currently used treatment or procedure for your cancer type.

**Not all cancer patients can join clinical trials. Each study has criteria for who can join. There are not clinical trials for all types of cancer. Your doctor can tell you if there is a study that may be suitable for you.**

### **Why join a clinical trial?**

You may decide to join a clinical trial because:

- the treatment you receive will be at least the best available for your type of cancer
- your health may improve because of the treatment you receive
- you may receive a treatment you would not otherwise have access to
- your health will be carefully checked and you will feel supported by the treatment team running the trial
- you are hopeful that research will lead to a new treatment that will benefit people affected by cancer.

Cancer Council supports clinical trials of promising new cancer treatments. We know that patients who are treated in clinical trials usually fare better than patients who do not join a clinical trial. We also believe that cancer is claiming fewer lives because of treatments tested in clinical trials.

Clinical trials have found the most effective form of treatment for most cancers. For example, many clinical trials involving thousands of women have proven chemotherapy reduces recurrence and improves survival rates in women with early breast cancer.

**'I felt even if the treatment proved unsuccessful in my case, the information gathered could possibly save the lives of other women.'**

*Barbara, 62*

### **Are there risks?**

Like many established treatments, clinical trials of treatments carry some risks, such as:

- there may be unpleasant, serious or even life-threatening side effects
- the experimental treatment may not be effective.

Also, a trial may require more time and attention than the standard treatment would (e.g. more trips to the hospital).

Your medical team will discuss with you all the pros and cons of a trial.

### **Who is involved in clinical trials?**

Many people are involved in cancer research. A clinical trial may involve:

- a specialist doctor such as an oncologist, haematologist or surgeon, who prescribes and helps administer the trial treatment
- the researcher/investigator, who develops the trial and recruits patients
- the lead investigator, who looks after all aspects of the trial including letting people know about the results
- the research nurse or study coordinator, who explains the trial to you and liaises with your specialist and other members of the trial team; the nurse is often the main contact and support for patients during the trial
- pharmacists and scientists, who often play an important part in developing a trial, collecting and analysing information from the trial and giving advice about drugs, side effects and toxicity.

You may also get support or advice from people who specialise in diet, physiotherapy, psychology, social work or complementary therapy (e.g. acupuncturist or massage therapist).

After the clinical trial finishes, the trial team will continue to watch your health. Depending on the trial, this may be for days or weeks, or months or years.

## Phases of clinical trials

A new drug treatment is first tested in laboratories. If it looks promising it is then carefully tested in people during four phases of clinical trials.

**Phase 1** trials involve small numbers of patients. The treatment is first given at a low dose. Then the dose is increased while the patients are carefully checked and questioned about how it affects them. The aim is to find the safest dose level and the risks and side effects of the treatment.

**Phase 2** trials test how well the treatment works with specific cancers. These trials also involve small numbers of patients. They help find the best way to destroy the cancer with the least possible side effects.

Only treatments that have got through these two phases and have proven to be safe and effective will go into phase 3 trials.

**Phase 3** trials compare the new treatment with the best standard treatment or treatments. If it gives better results, it may become the new standard treatment. Phase 3 trials can involve hundreds or thousands of people from across one country or the world. Phase 3 trials are usually randomised controlled trials (see next column ►).

The three phases can take many years. A good result from a phase 3 trial might be:

- reduced size or disappearance of the cancer
- no further growth or spread of the cancer
- more months or years of life
- a longer time free of problems caused by the cancer
- fewer side effects from treatment.

When the new treatment has been through these three phases and is known to be better than existing treatments, it becomes the new 'gold standard' treatment.

**Phase 4** trials are carried out after a treatment has been licensed. They provide important information about safety, side effects and the long-term risks and benefits of a drug or other treatment.

## Quality of life studies

During a trial the researchers may also want to find out how the treatment and any side effects are affecting you day to day, for example:

- how well you are sleeping
- how often you have to travel to the hospital for tests and treatment
- whether your appetite or mood has changed.

This is known as a 'quality of life' study. Most well-planned trials (especially phase 3 trials) include a quality of life study.

## Do all trials find better treatments?

No. Some trials find that the treatment being tested does not work. Or it may have side effects that are worse than existing standard treatments. This information is also helpful to doctors, researchers and patients.

## Randomised controlled trials

Most phase 3 trials are randomised controlled trials. These are thought to be the best way to test new treatments. They compare a group that receives the promising new treatment with a group that receives the best current standard treatment (this is known as the control group).

In a randomised controlled trial, patients are randomly assigned to a group. They cannot choose which treatment they will receive.

You wouldn't randomise patients if you knew that one treatment was more effective than the other. Randomisation is approved by medical ethics committees only when it is clear a trial is needed to show which of two treatments is better:

- In an **open randomised controlled trial** researchers and patients know which treatment is given to each patient.
- In a **randomised controlled single-blind trial** patients do not know which treatment they are getting but researchers do.
- In a **randomised controlled double-blind trial**, even the researchers don't know which patients receive which treatment.

Without 'blinding', patients who know they are taking the new treatment might expect it to work better. If they expect it to work well, they might report hopeful signs but not bad signs. This would bias the trial by making the results appear better.

Your doctor will explain how randomisation is done.

### **Things to consider when joining a trial**

In a clinical trial, you will receive extra personal care and attention from the research nurse, doctors and other medical staff.

Everything about the trial will be explained to you before you consent to join the trial.

Before agreeing to join a trial it is important to understand:

- if the treatment does not act on your cancer or you have unacceptable side effects, it will be stopped and your doctor will discuss other treatments
- the possible risks and side effects of the treatment and whether you will need to have extra tests or hospital visits
- the trial treatment may work for most patients, but may not work for every patient in the trial
- you have a right to withdraw from the trial at any time.

### **Ethical issues and patients' rights**

In Australia, clinical trials have to be approved by a human research ethics committee before they can begin. This assures participants that their rights and any research benefits and risks have been carefully considered.

Every trial is bound by law to follow a set of strict rules or guidelines. This is called the 'trial protocol'.

### **Making an informed decision**

To help you make an informed decision about joining a clinical trial, your doctor will discuss the trial and how it may affect you.

After talking to your doctor, you will want to weigh up all the information. You may find it helpful to discuss it with your family and friends or seek an opinion from another doctor. Or talk with an

experienced cancer nurse on **13 11 20**.

Take your time to make the right decision for you. You may decide that joining the trial is your best option. Or you may decide not to join the trial. It is your choice.

If you decide to take part in a clinical trial, you will receive written information about the trial and be asked to sign an informed consent form. This tells you about treatments you may receive and possible benefits, risks and side effects. It also explains your rights and responsibilities as a trial participant.

If you join a clinical trial, you have the right to withdraw at any time. Doing so will not affect your relationship with your doctor or the continued treatment of your cancer. Whatever you decide, your doctor will not neglect your treatment.

If you decide not to join the trial you will receive the current best standard treatment.

**'I knew I could pull out of the trial at any stage and at no time did I feel I couldn't cope. All the potential side effects had been discussed before they occurred.'**

*Jim, 56*

### **Questions to ask your doctor**

Before agreeing to take part in a trial, you may like to ask your doctor:

- Which treatment/s are being tested in this trial and why?
- What are the benefits and risks of participating in this trial?
- What tests are involved with this trial?
- How will this trial impact me personally in terms of my time and daily life?
- Are there costs involved with this trial?
- What happens if I do not take part in this trial?

To download a list of other questions to ask your doctor about trials, visit [www.cancervic.org.au/trials](http://www.cancervic.org.au/trials)

### Where are clinical trials conducted?

Cancer specialists have a very good record in contributing to state, national and international clinical trials.

All the main hospitals/institutions and some community and private hospitals are involved in clinical trials. Many specialists in private practice are involved in national and international clinical trials.

Being involved in clinical trials shows a doctor is up to date with new treatments.

### How do I find cancer clinical trials in Victoria?

Search the Victorian Cancer Trials Link ([www.cancervic.org.au/trials](http://www.cancervic.org.au/trials)). This database will allow you to identify suitable clinical trials.

If you need assistance with using this database, call **13 11 20**, Monday to Friday, 9 am – 5 pm.

### More information

Thinking about joining a clinical trial can be overwhelming. There is a lot to take in. It can help to discuss your decision with someone. You may like to speak with:

- an experienced cancer nurse on **13 11 20**
- your trial nurse.
- your treating doctor

Or see our website [www.cancervic.org.au/trials](http://www.cancervic.org.au/trials)

### Useful links

#### Australia

Victorian Cancer Trials Link  
[www.cancervic.org.au/trials](http://www.cancervic.org.au/trials)

Australian Cancer Trials Online  
[www.australiancancertrials.gov.au](http://www.australiancancertrials.gov.au)

Cancer Trials Australia  
[www.cancertrialsaustralia.com](http://www.cancertrialsaustralia.com)

Australian and New Zealand Clinical Trials Registry  
[www.anzctr.org.au](http://www.anzctr.org.au)

#### International

ClinicalTrials.gov [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Cancer Research UK  
<http://cancerhelp.cancerresearchuk.org/trials/>

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