

Cancer clinical trials

What are cancer clinical trials?

A cancer clinical trial is a research study with participants which provides essential information about important issues in the management of patients with cancer, most commonly the effects of different treatments. Clinical trials may not only improve the health outcomes for the volunteers who participate, but may also improve treatment for people who develop cancer in the future.

In cancer research, clinical trials can answer questions about how to:

- prevent cancer, e.g. using diet, exercise or drugs
- determine any genetic predisposition to cancer
- detect cancer earlier, e.g. screening methods
- diagnose cancer, e.g. new technologies
- treat cancer using different protocols, or combinations of new drugs
- control symptoms or side effects e.g. complementary therapies or conventional medications
- enhance quality of life, e.g. evaluate ways to improve this during and after treatment

Why do we need clinical trials?

Results produced in trials can help people with cancer in the future and participating in a trial may also provide a direct benefit to the participants in that trial. Clinical trials are often used to prove the effectiveness of new treatments.

Advancements in treatments are the result of clinical research which is the basis on which a new medication or protocol is developed.

Clinical trials can tell us if the new treatment is more effective than the current standard treatment, and determine any risks and side effects of that treatment.

How do cancer clinical trials help people with cancer?

Cancer clinical trials may help in the following ways:

- The treatment you receive on a clinical trial will be the best available treatment, or treatment that may prove to be even better than the current standard treatment for the disease (the researchers will not know this for sure, which is why the trial is being done).
- You will receive extra personalised care and monitoring from the research nurses and treating doctors because their treatments, tests and follow-up procedures must abide by strict protocols and guidelines.
- You may gain extra information about your cancer and treatment.
- Your health may be improved after receiving treatment.

How does a cancer clinical trial work?

Clinical trials are designed after lengthy research in the laboratory where researchers investigate the effect of treatments on cancer cells in humans and in animals.



Different studies are designed to test a range of different treatments including:

- drugs or vaccines
- combinations of treatments
- new methods of delivering radiation or performing surgery

A study protocol plan is prepared which includes key information about the reason for the study, specific eligibility requirements and further information about the treatment(s) involved in the study. There are very strict ethical requirements that need to be adhered to before a trial protocol will be approved by an independent ethics committee.

What are the phases of cancer clinical trials?

Clinical trials involve a series of testing of new treatments and are split into various phases. These phases are designed to ensure the treatment is safe, effective and also to determine whether it works better than the standard treatment. Each phase is represented below.

PHASE 1	Shows that a new treatment is safe amongst a small group of people approximately 15-30 people.
PHASE 2	Provides more information on how the treatment works and its safety rating. This data is collected on a larger group of people.
PHASE 3	The aim is to compare the new treatment with the standard treatment.
PHASE 4	For the purposes of monitoring progress for a longer term, once the intervention has been marketed.

Who can participate in a cancer clinical trial?

Cancer clinical trials have strict guidelines or criteria that determine a patient's eligibility. The aim of inclusion and exclusion criteria is to ensure that participants have as many of the same characteristics as possible, thereby producing more reliable and comparable results.

Examples of important characteristics include type and stage of the cancer, previous treatments and other medical issues.

Are there risks?

Like all medical interventions, clinical trials do have some risks such as:

- **Side effects** - a person may experience none, some or all of the side effects, which may be mild, moderate or severe.
- **No guarantee** - it is unknown if taking part in the study will result in an improvement in your condition and it cannot be guaranteed whether you will receive any benefits. You may have a positive response, may remain the same or even get worse.
- **Added commitment** - a trial may require extra time and attention compared to the standard treatment, including extra visits to the hospital. Participating also requires taking in a lot of information and paperwork.

Talk to your doctor about the risks and side effects of being on a cancer clinical trial.

What cancer clinical trials are available in WA?

Cancer research and clinical trials are quickly evolving and the list of cancer clinical trials available in WA can change frequently.

You can find out information about current trials that may be suitable for you in several ways:

- **Speaking to your consultant or medical team** - your doctor may be able to advise you of any trials for which you are eligible.
- **ClinTrial Refer** - available in both website and App versions this includes trials from a wide range of cancer treatment areas including: chemotherapy, radiotherapy, surgical procedures and preventive measures.
- **Australian Cancer Trials** - housed on the Cancer Australia website, this page provides information on the latest clinical trials in cancer care, including trials that are currently recruiting new participants.
- **Cancer Trials WA** - designed to connect patients and healthcare providers to clinical trials that are currently open for recruitment in Western Australia.

Not all trials are run in every centre or hospital. You may have to travel to a different location to participate.

Frequently Asked Questions

Do all trials find better treatments?

No, not in all cases. The trial may conclude that the treatment being tested is not better than the current standard treatment, or they may result in side effects which will be worse than the standard treatment.

How long will a study last?

This depends on the study. Firstly, the recruitment phase can take months or years to establish the right number of participants. The length of each study will vary, but often it takes years or even decades. However, as a participant you may only be involved for a short period of this time, e.g. you may be required a few times a week or possibly for a once off visit for only a couple of hours.

Sometimes studies will require participants to be surveyed for some time.

Are clinical trials only appropriate for people who have already tried all of their other standard treatment options?

No. You are able to consider looking into clinical trials at various stages during your care, from diagnosis and beyond.

Are clinical trials safe?

Participants are protected in many ways when they take part in a clinical trial and the treatments are tested in a laboratory before they are given to people. They usually commence testing on humans (who undergo monitored surveillance) first in phase 1 trials.

In all cases the trial plan is reviewed by both a scientific panel as well as an ethics committee before its final approval.

How much does it cost to participate?

Participation in a trial is free for Australian residents and citizens. Some associated costs such as travel might be encountered, especially for regional participants.

For regional participants, it may be worth discussing financial support with a social worker.

Can I leave a clinical trial?

Yes. If you decide that you no longer want to participate you can stop (withdraw) at any time, for any reason.

Withdrawal will not affect your future care, and you will be returned to receiving the standard treatment for your type of cancer.

Further information

For further information contact Cancer Council's information and support line on **13 11 20** or speak with your doctor or medical team.

Further resources can be found at cancerwa.asn.au/research/clinical-trials