

# Understanding clinical trials

Cancer research can lead to better treatment and improved outcomes for people with cancer. Past research has led to the health programs and treatments that we have today, as well as improvements to overall cancer survival rates.

Clinical trials are research studies that determine if a new approach (intervention) to prevention, screening, diagnosis or treatment works better than the methods currently being used. They also examine whether these new approaches are safe.

Clinical trials require people to volunteer as participants. If the clinical trial proves that the intervention being tested is more effective than existing options, it may become the new standard of care for patients. Clinical trials are also important to establish any potential risks or side effects for patients.

## Types of clinical trials

- **Treatment trials** – new medicines, combinations of medicines or other new treatment methods such as surgery, new approaches to surgery or the use of medical devices.
- **Prevention trials** – new ways to prevent cancer which may include medicines, vaccines, vitamins and changes to lifestyle or behaviour.
- **Screening trials** – new ways of detecting cancer before symptoms are apparent.
- **Diagnostic trials** – evaluating tests or procedures used to diagnose cancer.

- **Quality of life trials** – ways to improve comfort and quality of life for people with cancer.

## How are clinical trials conducted?

Most clinical trials have four phases with each phase designed to answer a separate research question. Early phases usually involve small numbers of people to assess the effectiveness and safety of the intervention. If there are promising results, the trial moves on to the next phase of testing which involves larger numbers of people.

Most clinical trials are delivered from metropolitan hospitals or cancer centres. Tele-oncology models of care for regional and rural patients now allow clinicians in metropolitan centres to work with smaller centres to enrol and treat patients in clinical trials. Some regional areas are also beginning to set up regional clinical trial units.

## Are clinical trials safe?

Clinical trials in Australia are regulated by an international standard of practice, called Good Clinical Practice. This ensures trials are conducted to a high scientific standard and that they are safe for patients who take part. Before a clinical trial commences, several committees examine and approve the trial and confirm that it is ethical and of scientific merit.

## What does it cost?

Participating in a clinical trial is free for Australian residents and citizens. You may also be reimbursed for out-of-pocket expenses, such as travel costs.

## Participating in clinical trials

Participation is voluntary and you can withdraw from a study at any time, without it affecting your care. To take part in a trial you will need to give informed consent. This means signing a form saying you understand what is involved and that you agree to take part.

It's always a good idea to ask your doctor if there is a trial suitable for your condition, but you should never feel pressured to join a clinical trial. Before making your decision, it's important that you take time to understand what's involved and how your participation may impact you:

- What is being tested in the trial and why?
- How will you benefit from the research?
- How long will the study last? Where will treatment take place?
- Will you be reimbursed for out-of-pocket expenses?
- Who will oversee your cancer care during the trial?
- What are the risks and who to contact if there is a problem?
- Potential side effects and their treatment?
- Will you miss out on other treatment opportunities later if you participate?
- Can you take other medication or complementary therapies during the trial?

- Who will have access to your personal information?
- Which Ethics Committee approved the study?
- Can you be involved in more than one study?

## Trial eligibility criteria

Before a clinical trial can take place, researchers develop a detailed plan for the study, which includes the rules around who can take part (eligibility criteria). To participate in a trial you must meet the eligibility criteria, which may include:

- age or gender
- type or stage of cancer
- symptoms or side effects caused by the cancer
- length of time since being diagnosed or treated
- previous treatments
- whether you have any other health conditions

Even if you are willing to participate in a trial, you may be ineligible if you don't meet the criteria. This can be very stressful, upsetting and frustrating.

## How to find a clinical trial

For more information about clinical trials speak to your healthcare team or contact our Specialist Nurse Support Team on **1300 881 698** or **support@pancare.org.au**.

You can also check the following online resources:

**anzctr.org.au**  
**australiancancertrials.gov.au**  
**vccalliance.org.au**  
**opin.ai**

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