

## Clinical Trials - my health, my decision

Choosing to participate in a clinical trial is an important personal decision. The information in this brochure may help in making that decision.

### What is a clinical trial?

A clinical trial is a scientific study of a new medicine involving patient and non-patient human volunteers. Clinical trials confirm whether medicines are safe and effective to introduce as new treatments for a particular disease or condition. Clinical trials are also used to find better ways to use existing medicines.

### Why are clinical trials needed?

Clinical trials are necessary to show that the medicine is safe and effective for use in humans. Clinical trials help establish if the medicine being studied will work, what, if any, are the side effects and what the correct dose should be. This helps doctors to decide if the medicine is more effective and/or safer than existing medicines or treatments. They may also provide information about whether the medicine could be effective in treating other illnesses.

Without clinical trials, medicines cannot be approved for use in Australia.

### How are clinical trials approved?

Before clinical trials can go ahead they need to be approved by independent ethics committees. These ethics committees operate in accordance with the guidelines issued by the National Health and Medical Research Council and ensure that clinical trials conform to the Declaration of Helsinki<sup>1</sup> and to international Good Clinical Practice guidelines<sup>2</sup>.

### Who runs a clinical trial?

Each clinical trial is led by a doctor. The clinical trial team includes doctors and nurses as well as pharmacists and other health care professionals. The clinical trial team is responsible for checking the health of the participants at the beginning of the trial, monitoring them during the trial, and staying in touch with them for a period of time after the clinical trial has been completed.

### What are the benefits from participation in a clinical trial?

There are a number of possible advantages of participating in clinical trials. These can include:

- Gaining early access to new medicines not otherwise available;
- Obtaining the clinical trial medicine at no cost, at least during the trial;
- Receiving extensive medical care associated with the clinical trial; and
- Contributing to the development of future life-saving or life-enhancing treatments.

Participation in clinical trials is not, however, without its downsides.

- You may experience some side effects from the trial medicine
- The trial medicine may not work for you
- You may be placed in the control or reference group and may not receive the trial medicine.
- You may need to visit the hospital or doctors' room more frequently and/or stay there longer

### How can a person participate in a clinical trial?

Before making this important decision a person must be given a full written plain-language explanation of the clinical trial by a doctor. Only after carefully considering this document should a person provide their written consent to participate.

The explanation of the study will include things such as the:

- Eligibility criteria;
- Possible risks and benefits of the new medicine;
- The risks of any side-effects;
- The type, frequency and risks of any medical tests or procedures that may be undertaken as part of the trial; and
- The participant's rights and responsibilities.

Potential participants will be made aware that they can withdraw from a study at any time, without any effect on ongoing medical care and that their involvement is entirely voluntary.

The clinical trial will commence when a sufficient number of people have been enrolled to participate in the clinical trial. This may take some time.

### What happens if side effects occur from taking a medicine in a clinical trial?

By the time a medicine reaches the clinical trial stage it has already been extensively tested for likely side effects. However, especially with new medicines, there might be additional side effects. It is not possible to predict in advance if any side effects will occur but, if they do, appropriate care will be provided to participants.

### What happens with the results from clinical trials?

The results of clinical trials are made available to doctors so that they can make scientifically valid assessments of the benefits and risks of a new medicine for their patients. The results may also be published in medical journals and other relevant publications.

In addition, study doctors will be notified of the results of the study as they are made available and so it is recommended that participants keep in touch with their doctor so that they too can be advised of the results.

All details of a participant's treatment are kept confidential even when the results of the study are published. Results of the treatment will be analysed, but confidentiality is assured.

### What else do I need to know about clinical trials?

If you decide you would like to participate in a clinical trial, you should discuss it with your doctor in order to make an informed decision.

Questions you can ask include:

- What is the purpose of the study?
- What pre-existing conditions must participants have?
- Are there any particular conditions that would exclude me?
- Why is this treatment expected to be effective? Has it been tested before?
- What kind of tests and procedures are involved?
- How do the possible risks, side effects and benefits of the study compare with my current treatment?
- How might the trial affect my daily life?
- How long will the trial last?
- Will I need to be hospitalised?
- Are there any risks involved?
- Will participating in a trial affect my life insurance and medical insurance status?
- What will happen if I suffer a serious side effect as a result of the trial?
- Will I have access to the medicine after the trial is over?

Further information on clinical trials can be obtained from:

Therapeutic Goods Administration  
[www.health.gov.au/tga](http://www.health.gov.au/tga)

National Health & Medical Research Council  
[www.health.gov.au/nhmrc](http://www.health.gov.au/nhmrc)

Medicines Australia  
[www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

Research Australia  
[www.researchaustralia.com.au](http://www.researchaustralia.com.au)

The Cancer Council of NSW  
[www.cancercouncil.com.au](http://www.cancercouncil.com.au)

1. <http://www.health.gov.au/nhmrc/issues/helsinki.htm>
2. <http://www.ich.org/pdf/ICH/e6.pdf>

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[www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

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