

Understanding Clinical Trials

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Introduction

Clinical trials help researchers find answers to questions about health, diseases, medications or devices. They can also help find ways to improve your health or experience.

Joining a clinical trial is completely voluntary and comes with benefits and risks. If you join a trial, you may get to try new medicines or treatments that you would not otherwise be able to access. If you choose not to join a trial, you will get standard care and treatment.

The goals of clinical trials are to:

- Check the safety, effectiveness or different doses of new medicines.
- See if adding another medicine to a standard protocol may have better results.
- Find new ways to give treatment. For example; can a medicine, normally given into your vein, be just as safe and effective as a tablet or injection into your tummy?
- Compare a new treatment to current treatments to see which one is better.
- See if results are similar with different groups. For example, children and adults, normal weight and overweight or people with different diseases.

Phases of clinical trials

There are several phases to a clinical trial and you might only join one phase. They start off with less people, to check for safety. If it is thought to be safe, the next phase will include more people. Each phase builds on the information from the previous phases.

Phase 1 – A new medicine or combination of medicines is tested with a very small group of people. The aim is to test the safety of the medication (or combination). Phase 1 studies also aim to find the safest dose of medicine, and identify any side effects.

Phase 2 – The medicine is tested in a larger group of people to see if it is effective and safe in a larger group.

Phase 3 – The medicine is tested in a much larger group of patients. Phase 3 trials compare results with people having experimental and standard treatment. The aim is to see if the new medicine or treatment is more effective than the others. In a larger group, more side-effects may be found so can add to the safety warnings. This information helps researchers and doctors to know how to use the medicine safely.

Phase 4 – Once the medicine is approved for use, data is still collected. This is often called post-market data. These trials are designed to monitor the effectiveness of approved medicines in the general population. It is also a time where new information is collected to see if the safety and effectiveness is the same in the general population as it is in the trials. Sometimes new side-effects can occur in the general population that were not reported in earlier trial phases.

Benefits of joining a clinical trial

Advances in medical treatment would not be possible without clinical trials. Trials allow researchers to test new medicines, combinations of medicines, or new ways of providing treatment to improve outcomes and experiences for patients. Some clinical trials look at how to:

- improve medicines to make side effects more manageable
- diagnose illnesses earlier
- best treat different people with different illnesses.

Clinical trials give you a chance to try new treatments that would not otherwise be available to you. If you have a cancer that has not responded to other treatments, a clinical trial can give you another option to try.

Risks of joining a clinical trial

There are risks to joining any phase of a clinical trial. You need to consider these along with the benefits. Some risks to consider include:

- The treatment is new, so not all side-effects are yet known.
- The treatment in a clinical trial may be less effective than standard treatments.
- Some clinical trials include a group receiving the standard treatment and others receiving the experimental treatment. You do not get to choose which group you are in. Often neither you or your doctor will know which group you are in. This is done because if you or your doctor know which group you are in, it may change the way side-effects and symptoms are reported.

How to join a clinical trial

You can ask your doctor about joining a clinical trial at any time. Although it is best to ask before you start treatment. This is because clinical trials have strict rules for joining, and the treatment you have may impact your eligibility to join the trial. Your doctor may also offer to enroll you in a trial. It is ok to say yes or no if this is offered. You will still be treated with the same respect either way.

You can also look online for clinical trials that may be suitable for you. Some websites include:

The Australian Clinical trial website
www.australianclinicaltrials.gov.au

ClinTrial Refer www.clintrial.org.au

Australian New Zealand Clinical Trials
Registry www.anzctr.org.au

Paediatric (childhood) Trials Network
Australia (PTNA) www.ptna.com.au

Blood Cancer Research Western Australia
www.bloodcancerwa.org.au

Informed and voluntary consent

To join a clinical trial you will need to sign a form to say you give voluntary and informed consent. Informed consent means the researchers or doctor have explained the trial to you. This should include all possible risks and benefits, explained in a way that you understand. It also means that you have been given time to consider the information, and ask any questions you may have.

Voluntary consent means that you were not forced, bribed, threatened or coerced into giving consent. You should be told that you do not have to take part in the clinical trial and you would still be treated fairly with respect. Treatment options if you do not join the clinical trial should also be explained to you.

By signing the consent form, you acknowledge that you understand the information given to you. It is a way of saying you understand there are potential

risks and benefits, and you are willing to take part in the clinical trial.

Withdrawing consent

You can withdraw consent and leave the trial at any time without penalty. Even if you signed the consent form, or had treatment, you can change your mind. If you do, or if you're concerned about any part of the clinical trial, please talk to your doctor. They will be able to talk to you about your treatment options if you leave the clinical trial.

Ask your doctors these questions before you start treatment.

To help you get the best information you need to make an informed decision about joining a clinical trial. We have thought of some questions you might like to ask your doctor before joining a trial.

- What is the purpose of the clinical trial?
- How long will the clinical trial last?
- Will I be better off if I join the trial?
- How will the clinical trial affect my everyday life?
- Will I have to pay anything for any part of the clinical trial?
- If I take part in the clinical trial, will I be getting the best treatment for my condition?
- Can I take part in the trial if I live in the country? Will I need to be away from home?

- What are the risks and benefits if I join the clinical trial?
- If I choose to leave the clinical trial, can I still get the standard treatment?
- If I live away from the clinical trial centre, is there financial support for transport, accommodation and travel so I can participate?

Summary

- Clinical trials are an important way to find new medications, treatments or combinations of treatment to improve outcomes for lymphoma and CLL patients in the future.
- Clinical trials may provide you with access to medications you would not otherwise be able to access.
- Joining a clinical trial is completely and totally voluntary.
- You have the right to ask your doctor about any clinical trials you may be eligible for, or you can look for clinical trials with the links above.
- You can withdraw your consent to a clinical trial at any time.
- There is no guarantee that a clinical trial will give you a better outcome than standard treatment.

Resources and support

Lymphoma Australia offers a wide range of resources and support for people living with lymphoma or CLL, and their carers. How to access our resources:

- **Visit** our website www.lymphoma.org.au for more information.
- **Phone** our Lymphoma Care Nurse Hotline on 1800 953 081.
- **Email** our Lymphoma Care Nurses nurse@lymphoma.org.au
- **Booklet:** Understanding Non-Hodgkin Lymphoma (NHL)
- **Downloadable information:** Visit our [website](#), or give us a call if you would like some more information on a variety of topics related to lymphoma
- **Join** our Facebook page [Lymphoma Down Under](#) (make sure you complete all the membership questions when you join).

Cancer Council offers a range of services, including free counselling, to support people affected by cancer, including patients, families and friends. Services may be different depending on where you live. You can contact them at www.cancer.org.au or by phone on 13 11 20.

Medicare Australia: Check with your GP if you are eligible for a Mental Health Treatment Plan (MHTP). This plan is funded by Medicare and can provide you with up to 10 sessions with a registered psychologist. More information can be found [here](#).

WeCan is an Australian supportive care website to help find the information, resources and support services you may need following a diagnosis of cancer. You can visit their website at www.wecan.org.au.

Canteen provides support for young people aged 12-25 years who have cancer, or, who have a parent with cancer. Find out more at their website here www.canteen.org.au.

Health Translations: A collection of health related information collected by the Victorian Government with resources in different languages. You can visit their website at www.healthtranslations.vic.gov.au.

Disclaimer: Lymphoma Australia has taken every precaution to make sure the information in this document is accurate and up-to-date. However, this information is intended for educational purposes only and does not substitute for medical advice. If you have any concerns about your health or wellbeing, please contact your treating team.

