



# Understanding Clinical Trials

## WHAT ARE CLINICAL TRIALS?

A clinical trial is a research study conducted to answer specific questions about new treatments, technologies, tests or a new way of using an existing treatment. They are type of research project in which patients can volunteer to participate, sometimes to gain access to a new medicine as a means to treat and manage their lymphoma. These clinical trials are used to determine whether new therapies are both safe and effective. Clinical trials are critical for advancing therapies for lymphoma and are an important way for patients to access a certain medicine, test or technology not otherwise available for their type of lymphoma. They can test many aspects of treatment including:

- The safety and effectiveness of new medications
- The addition of new medications to standard treatments
- Looking at new ways to give standard treatments
- Compare a new treatment with old ones to see which produces better results with fewer side effects

Clinical trials are grouped into ‘phases’ depending on their design, and the information they are attempting to provide. Early phase trials focus on safety of very new treatments or new combinations of treatments, later phase trials build on information learned from the earlier phases. Each phase is designed to find out certain information. The phases build on the information learned from the previous phase. A significant amount of careful, detailed research is conducted on any new medication before it reaches the stage where it is tested on patients. Patients may be able to take part in different stages depending on their condition, their type and stage of cancer and the type of treatment, if any, they have already received. The protocol of a clinical trial is examined and approved by ethics committees and must meet rigorous government and medical standards. Doctors and nurses who conduct clinical trials have to undergo special training, and must follow certain rules relating to how they conduct the trials in their hospitals.

Trials which compare a new treatment with a standard treatment whose effects are already known are called randomised controlled trials. In these trials, a proportion of the patients receive the new treatment and the remainder receive the standard treatment. A computer determines which patient receives which treatment to ensure that the two groups are

well balanced and the comparison is truly objective and not biased. This is the process of randomisation and hence the term randomised trial.

Below is a table to explain the different phases and what they mean.

Clinical Trial	Description
Phase 1	New medicine or combination of medicines tested in a small group of patients to evaluate safety and determine safe dose of medicine and identify any side effects
Phase 2	The medicine is then tested in a larger group of patients to determine how effective the medicine is and further evaluate its safety
Phase 3	The medicine is then tested in a much larger group of patients by comparing the intervention to other standard or experimental interventions and is used to monitor adverse side effects and to collect information that will allow the medicine to be used safely
Phase 4	Once the medicine is approved for use these trials are designed to monitor the effectiveness of the approved medicine in the general population and to collect information about any adverse side effects associated with the new medicine over longer periods of time and may be used to investigate the use of the medicine in different indications

## SHOULD I PARTICIPATE IN A CLINICAL TRIAL?

Clinical trials may offer many benefits and risks. People in clinical trials are able to try new treatments that are not available to all patients and are monitored very closely. However, being part of the trial might mean that you receive the standard

treatment. If you receive the new treatment, it may or may not be more effective than the standard one. The healthcare team studying the new treatment will explain all of the possible risks and benefits of a specific clinical trial to you and provide written information about the trial.

## WHAT ARE THE BENEFITS OF PARTICIPATING IN A CLINICAL TRIAL?

The main benefit of participating in a clinical trial is that people can receive new treatments that are not yet available for clinical practice, or existing treatments that are not available for their circumstances. For example, if a person has received the standard treatment for their particular type of lymphoma and has not achieved the desired response, a clinical trial may be a good option.

Investigational treatments are not available to people outside of a clinical trial. For a treatment to be given to people in Australia, it must have been rigorously studied and tested, and must be approved by the Therapeutic Goods Administration (TGA). The TGA is the government body which assesses and monitors all therapeutic goods to ensure that they are of an acceptable standard before becoming available to the Australian community.

## WHAT ARE THE RISKS ASSOCIATED WITH PARTICIPATING IN A CLINICAL TRIAL?

You should be aware of the risks before participating in a clinical trial. They include:

- The treatment may be toxic such that you may experience severe or unknown side effects
- The treatment may prove less effective than standard therapies and offer little or no benefit
- You may be in the control group of the clinical trial and as such may receive a standard lymphoma therapy and not the experimental treatment

## WHAT IS INFORMED CONSENT?

People who choose to take part in a clinical trial must give informed consent. This means they acknowledge that they understand both the potential benefits and associated risks and that they are a willing participant. Participating is entirely voluntary. No person should be forced or pressured into participating in a clinical trial. Furthermore, once a person is in a trial they have the right to leave the trial at any time without explanation. Leaving a trial will in no way affect the attitude of your healthcare team, and you will still receive the best current standard treatments.

## CAN I LEAVE A CLINICAL TRIAL OR NOT TAKE PART AT ALL?

Yes you can leave a trial at any time, even if you have signed the paperwork. If you do decide to leave the trial or not take part, your doctor will discuss your treatment options with you. You have the right to change your mind at any time.

## WHAT DO I NEED TO DO TO PARTICIPATE IN A CLINICAL TRIAL?

A doctor will speak to you about the trial, the purpose of the study, any tests and procedures that will be done, what is involved and about informed consent. You will be given a Patient Information and Consent Form which explains all aspects of the trial and it is important to read this and ask any questions you have regarding the trial. If you then agree to take part in the trial you will be asked to sign the consent form. You will always have access to the trial doctors and nurses to ask questions and discuss any concerns you have.

## CLINICAL TRIALS

Clinical trials are essential in identifying effective medicines and determining optimal doses of these medicines for people diagnosed with lymphoma. People who are interested in participating in a clinical trial can find one using the following methods:

1. Speak to their specialist to see what options are available
2. The Australian Clinical Trial website: [www.australianclinicaltrials.gov.au](http://www.australianclinicaltrials.gov.au)
3. Go to the ClinTrial Refer website [www.clintrial.org.au](http://www.clintrial.org.au) to search available clinical trials.
4. Blood Cancer Research Western Australia: [www.bloodcancerswa.org.au/trials](http://www.bloodcancerswa.org.au/trials)
5. See 'Understanding Clinical Trials' fact sheet, [www.lymphoma.org.au/page/1218/fact-sheets](http://www.lymphoma.org.au/page/1218/fact-sheets)
6. "Understanding Clinical Trials in Lymphoma" videos by Prof Judith Trotman, Concord Hospital & Dr Michael Dickinson, Peter Mac: <http://bit.ly/2VBObIX>

## QUESTIONS TO ASK YOUR DOCTOR

- What is the purpose of this clinical trial?
- How long will the study last?
- Will I be better off in a study?
- How could the study affect my daily life?
- Will there be costs for me to be on the study?
- Is everyone with my disease eligible for this trial?
- If I take part in a trial, I won't get the best treatment available?

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