

# CONSUMER GUIDE TO CLINICAL TRIALS

## WHAT IS A CLINICAL TRIAL?

Clinical trials are medical research studies that aim to find a better way to manage a particular disease. The purpose of a clinical trial is to evaluate new approaches to learn how people respond to them and what side effects might occur as a result. Clinical trials are considered to be part of best practice medicine and are one of many options for treatment of a disease or illness.

Different kinds of clinical trials are available to health consumers. Some of these include:

**Treatment trials:** These involve trials of experimental treatments, drugs or new approaches to surgery or radiation therapy.

**Prevention trials:** These consider new ways to prevent disease. They are usually less invasive and may include medicines, vaccines, vitamins or changes to lifestyle or behaviour.

**Diagnostic or screening trials:** These involve evaluating tests or procedures for diagnosing and detecting diseases or conditions.

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

Participating in research is voluntary. It is important that you never feel forced to take part in a trial.

Participating in a clinical trial could result in benefits for consumers.

- Clinical trials enable consumers to access the newest, most up-to-date research treatments, before they are available to the general public. Participating in a clinical trial may also allow consumers to gain advice and treatment from leading medical experts in cutting edge medical facilities and provide them with greater understanding of their condition or illness.
- Participating in a clinical trial also allows a consumer to play an active role in their healthcare and their treatment.
- Clinical trials may be important for people with rare or difficult to treat conditions for which there may be limited evidence about how the condition is best treated or managed.
- People participating in clinical trials may be monitored more closely and comprehensively compared with those receiving standard treatment.
- Other consumers may benefit in the future through the lessons learned, both good and bad, during the clinical trial



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## WHAT SHOULD YOU CONSIDER WHEN THINKING OF PARTICIPATING IN A CLINICAL TRIAL?

It is important that you have an in-depth discussion with your health provider (for example, GP or specialist) as well as the medical researchers undertaking the trial regarding the benefits and risks. There are some possible risks for consumers participating in clinical trials and it is very important that you seek advice and guidance to ensure that you understand these. You should also consider both immediate and long-term side effects.

### Some possible risks include:

- The treatment in the clinical trial may have different, unpleasant or more serious side effects than those known with the best current treatment.
- The consumer may be more inconvenienced and may have to undergo more treatment, tests, hospital visits or complicated medication requirements. For example, participants may need to keep a symptom diary, collect 24 hour urine specimens or wear a monitor overnight.
- The treatment in the clinical trial may not work.

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## WHO CAN PARTICIPATE IN A CLINICAL TRIAL?

A clinical trial is designed for a specific group of people and there are strict guidelines about who is eligible to participate. These guidelines normally outline **inclusion criteria** that allow an individual to participate in the trial. These could be factors such as age, gender, the type and stage of a disease, previous treatment history and other medical conditions. **Exclusion criteria** are also often identified in the guidelines. These are the factors that would prevent an individual from participating. The inclusion and exclusion criteria are to ensure all consumers in the clinical trial have the same characteristics so that the trial will generate reliable results for future medical practice or to have a new treatment approved by health authorities.

## INFORMED CONSENT

Before agreeing to participate in a clinical trial, it is important that you are informed of all the essential facts about the trial. The medical researchers undertaking the study must ensure that you are aware from the beginning and throughout the trial of all the details of the study. For example, you will want to know the study's purpose, duration, required procedures and key contacts. Potential risks, benefits to you and effects on your family or carers when participating in a clinical trial must also be clearly explained before you agree to participate. This is called **informed consent**. The information you need is usually given to you in a **Patient Information Statement** provided by the people conducting the trial. It should be written clearly in a way that you can understand. It is important to understand that only some consumers in a trial will receive the new treatment and others may receive either a placebo (a medical treatment that is inactive) or the standard medication for that disease. You should ask about anything that is not clear to you.

It is also important to know that you are able to leave a clinical trial at any time and are not obliged to remain in a trial if you no longer wish to participate.

If you choose to leave a clinical trial there will be no impact on your access to standard treatments for your condition.

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# QUESTIONS?

It would be helpful to write down questions you have before seeing your doctor. Some questions that could be useful include:

## **ABOUT THE TRIAL**

- What is the purpose of the trial?
- What is the goal of treatment? Does it aim to cure my condition or only to manage it?
- Has the clinical trial been approved by an appropriate body and does it have ethics approval?

## **TREATMENT**

- Has the treatment been tested before, and if so, was it successful?
- Will I receive the experimental treatment, or will I possibly receive the current standard treatment or a placebo (a medical treatment that is inactive)?
- What kinds of tests and experimental treatments are involved?
- Who will be in charge of my care? Who can I contact for support and information during the trial?

## **SIDE EFFECTS**

- How do the possible risks, side effects and benefits in the study compare with my current treatment?
- Could the treatment in the clinical trial have different, more unpleasant or more serious side effects compared with those associated with other existing treatment options?
- If people receiving one treatment in the trial respond much better than people receiving the other treatment, will all participants be able to access the more effective treatment?

## **DURING THE TRIAL**

- Could I experience inconvenience due to more treatment, tests, hospital visits or complicated medication requirements?
- How might this trial affect me and my family?
- What will my responsibilities be during the trial?
- How long will the trial last?
- Will I be required to spend time in hospital? Can I continue with my normal lifestyle?

## **COSTS**

- Where will the trial be conducted and will I have to travel for treatment?
- Will I have to pay for the treatment? How much will it cost?
- Will I be paid? Will my expenses be covered?
- If I live in a rural or remote area, will I be eligible for travel assistance?
- If there are complications that arise from the trial, who is responsible for paying for treating them?

## **AFTER THE TRIAL**

- What type of long-term follow up care is part of this study?
- Will the results of the trials be provided to me?
- Will I have access to the experimental treatment after the trial if I wish to continue with it?
- How will my privacy be protected?

## HOW TO FIND OUT ABOUT AVAILABLE CLINICAL TRIALS

In the first instance, it is best to talk to your medical practitioner to seek advice on clinical trials. Your medical practitioner should be able to provide advice on relevant clinical trials as well as provide you with general information about clinical trials.

- It is a good idea to seek out information about clinical trials in general and about a specific clinical trial from a number of sources. CHF encourages you to talk to any of the health professionals involved in your care – GP, specialist, nursing or allied health professionals.
- Contact health consumer organisations with an interest in your health condition and ask to speak to someone who can answer questions about clinical trials.
- Look at the information on the websites below.

**australianclinicaltrials.gov.au** is a website developed by the National Health and Medical Research Council (NHMRC) which provides general information about clinical trials for consumers, health care providers, researchers and industry.

You can also search online for clinical trials that may be suitable for you.

**anzctr.org.au** is the Australian New Zealand Clinical Trials Registry (ANZCTR) which has an online register of most clinical trials being conducted in Australia and New Zealand.

**clinicaltrials.gov** is a United States based website that lists international clinical trials. You can filter for trials that include Australia and then for the disease of interest by using the advanced search tab.

There are also disease-specific registries for clinical trials. For example, Australian Cancer Trials **australiancancertrials.gov.au** includes the latest information on clinical trials in cancer care and is designed for consumers.

Disease-specific support groups may also know about clinical trials for people with that disease or have clinical trials listed on their websites. For links to Consumers Health Forum members who may offer information on clinical trials visit **chf.org.au**. It is important that you seek independent information on clinical trials.

Clinical trial matching services aim to match consumers to clinical trials for which they are eligible and may be a useful source of information. Some organisations also have online clinical trial registries for volunteers or people from particular disease groups. For example, **register4.org.au** brings together breast cancer research participants.

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## MORE INFORMATION

Speak with your medical practitioner to find out further information on clinical trials, read the information provided on **australianclinicaltrials.gov.au** or contact the Consumers Health Forum on 02 6273 5444 or visit **chf.org.au**

**australianclinicaltrials.gov.au** is an Australian Government initiative



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