Thank-you for your support

White Coats Foundation

White Coats Foundation is a NFP Australian based Registered Charity. The foundation was established in recognition of the need to raise awareness about the role of clinical trials in advancing medical science and healthcare.

What is a Clinical Trial?

A clinical trial is a research study that tests whether a new treatment option such as a medicine, device, surgical procedure or preventative therapy is better than the standard treatment for a specific medical condition/disease.

Clinical trials may also be used to determine whether existing treatments can be safely and effectively used for other diseases/conditions.

Clinical trials involve patients or healthy human volunteers (participants) who are carefully monitored to verify whether the treatment under investigation is safe and effective.

The outcome of clinical trials informs the label on your prescription medicine that tells you how much and how often to take your treatment. Without clinical trials there would be no treatments on the pharmacy shelf. Without consenting participants there would be no clinical trials.

Why Participate in a Clinical Trial?

There are a number of possible advantages to participating in clinical trials Participating in a clinical trial is voluntary. Participants should never feel forced or coerced to participate. Some of the possible benefits to participating in a clinical trial include:

- Access to potential new treatments in circumstances where current approved options are limited or there are none
- Obtaining the clinical trial medicine at no cost during the trial;
- Receiving extensive medical care associated with the clinical trial;
- Contributing to the development of future lifesaving or life-enhancing treatments.

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How are research participants protected?

Clinical trials are highly regulated to ensure that the interests of participants are protected. There are measures in place to ensure trials are conducted to the highest standard and in the safest manner possible.

- Potential participants are provided with information about the trial before deciding if they want to participate. During the trial process, they also receive ongoing information as it comes to light. Participants are never locked-in and may withdraw from the trial at any time.

- All human research must be approved by a human research ethics committee (HREC) or through another appropriate ethics review process in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007. The HREC reviews the validity of the clinical trial, weighs up potential risks verses potential harms, and the ethical acceptability of the trial method, ensuring participant protection is their priority.

- All Australian research involving the administration of drugs, vaccines, other chemical agents, or devices needs to be notified to the Therapeutic Goods Administration (TGA), a branch of the Australian Government.

How are Clinical Trial medications approved?

Clinical trials collect data and evidence to demonstrate the safety and effectiveness of new treatment options. They are evaluated and approved by the TGA before the new treatment can be made available to Australians more broadly.

Other Australian Government committees such as the Pharmaceutical Benefits Advisory Committee (PBAC) or Medical Services Advisory Committee (MSAC) are involved in assessing and approving the cost of the new treatment option for listing on the Pharmaceutical Benefits Scheme (PBS) or Medicare Benefits Schedule (MBS) respectively. Once the cost has been negotiated, the new medication can be made available in the pharmacy for your doctor to prescribe it for you.

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What are Trial Phases ?

Clinical trials are usually described based on their phase. The Health Authorities such as the TGA in Australia, typically require Phase I, II, and III trials to be conducted to determine if the treatment option can be approved for use.

In **Phase I** clinical trials new intervetions are tested on a small number of people (20-80) to assess safety. The intervention can be a new medicine, vaccine, or type of medical test. If the therapy is not safe, it will not progress to Phase II.

In **Phase II** clinical trials, new interventions are tested on a larger group of people (can be several hundred) to determine if the new intervention works as intended and to further evaluate safety.

In **Phase III** clinical trials, interventions are tested on very large numbers of people (hundreds to thousands) to expand on understanding of safety & effectiveness, & to compare interventions to existing treatment options. Overall risks and benefits are also monitored further.

Phase IV trials are conducted after approval to continue monitoring the effects of the new treatment within the general community

The phases of clinical trials test treatments under investigation to find the right dose and to ensure the right health outcomes are achieved whilst monitoring for side effects.

How can I access Clinical Trials?

The most common way to access a clinical trial is by asking your doctor, specialist or nurse. They will be able to help you find a potential clinical trial, if available, and check if you may be eligible to participate. Another option is to access clinical trial registries online, which list active clinical trials. There are many clinical trial registries in existence internationally and in Australia there is the Australian New Zealand Clinical Trial Registry (ANZCTR). You can find some further information https://whitecoatsfoundation.org/clinical-trials/resources/

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Our References

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Therapeutic Goods Administration [TGA]. (2020). Australian clinical trial handbook: guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods (V2.2). Commonwealth of Australia, Canberra. https://www.tga.gov.au/node/5263

Australian Clinical Trials https://www.australianclinicaltrials.gov.au/consumers