

## Clinical Trials

Created 1 Jul 2004 - 12:00am

This fact sheet provides you with information and some questions to ask if you are considering participating in a [clinical trial](#) [1] A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed. .

### **What is an HIV/AIDS [clinical](#) [2] Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science. trial?**

Clinical trials are experiments in which new therapies for HIV or new approaches to treatment are tested in people. There are many different types of trials and not all trials are designed to find out the same kinds of information. Whether you're considering entering a trial or trying to make sense of the results of a trial, it's important to understand the way that trials operate.

### **Who conducts clinical trials?**

Clinical trials are conducted, or 'sponsored', by a wide range of organisations. They include:

- Pharmaceutical companies, either solely or jointly with other research institutions;
  - Private research organisations under a grant from the government's National Health and Medical Research Council or from public donations; and
  - Publicly funded research organisations.
- Regardless of the type of organisation sponsoring the trial, it must be approved and monitored under the ethical and good clinical practice guidelines set down by the Australian Government (1)

### **What is a [protocol](#) [3] A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment ?**

All trials are based on a set of rules called a protocol. A protocol describes who may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a trial, participants are seen regularly by the research staff to monitor their health and to determine the safety and [effectiveness](#) [4] (Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the standard procedure, Phase II clinical trials gauge efficacy, and Phase III trials confirm it. of their treatment.

### **What are trial phases? (2)**

Clinical trials are conducted in a series of steps, called phases. There are four different types of trials, each one associated with a different phase in the development of a new treatment. It would be uncommon to find a trial that satisfied specific categories.

It is nonetheless a helpful guide.

**Phase I** trials are designed to determine whether a treatment is safe for people to take. Researchers test a new treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. **Phase 2** [5] **A smaller clinical trial designed to establish whether a drug is effective. Phase II studies are conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks. If there is evidence that the drug is effective, a Phase III study is undertaken, with a larger number of participants, to confirm this.** trials are usually the first time the treatment is given to people experiencing the condition (e.g. HIV, cancer) for which it is intended. The treatment is given to a larger group of people to see if it is effective and to further evaluate its safety. **Phase 3** [6] **A large clinical trial designed to establish whether a drug is effective and safe enough for widespread use. Phase III studies include expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.** trials aim to double check the effectiveness of the treatment demonstrated in Phase 2 trials. Phase 3 trials monitor side effects, compare it to commonly used treatments and collect information that will allow the treatment to be used safely. The end result is getting the treatment approved by the government. **Phase 4** [7] **Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.** trials are done after the treatment has been marketed to gather information on its effect in various populations and any side effects associated with long-term use. Phase 4 trials also study the use of the treatment in a clinical setting, as this may differ from the conditions under which the other trials were run.

## Who can participate?

All trials have **inclusion criteria** [8] The medical or social standards determining whether a person may be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe. and **exclusion criteria** [9] The medical or social standards determining whether a person may be disqualified from entering a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe., based on such factors as age, type of disease, medical history and current medical condition. These criteria are not used to reject people personally. Instead, they are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

## What happens during a trial?

The trial process depends on the kind of trial you participate in. Each trial team is led by a doctor and includes nurses as well as pharmacists and other healthcare professionals who are 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 trial has been completed. Some trials involve more tests and doctor visits than you would normally have. Your participation will be most successful if you follow the protocol carefully and stay in contact with the trial team.

Your experience of taking trial medications may be very different to that of your friends. Some people experience treatment side-effects and others do not. Trials, by definition, set out to show that something is different from something else (ie. compare things). In order to compare things fairly and rigorously scientists use **randomisation** [10] A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant , **blinding** [11] A randomized trial is "Blind" if the participant is not told which arm of the trial he is on. A clinical trial is "Blind" if participants are unaware on whether they are in the experimental or control arm of the study; also called masked. and controls (sometimes placebos).

## What is a [randomised trial](#) [12]A clinical trial in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial.?

In a randomised trial, people who join are randomly assigned to one of these. However, the process is not as random as you may think. Most trials adjust the randomisation so that the participants in each arm have more or less the same characteristics (ie. a similar range of ages). Participants in each arm receive a different treatment regimen. In some cases, people in one arm may receive a placebo.

## What is a placebo or control?

A placebo is an inactive pill, liquid, or powder that has no treatment value. In trials, [experimental](#) [13](Of a drug) Not licensed for use in humans, or as a treatment for a particular condition. Experimental drugs are studied in clinical trials to determine their safety and efficacy, and are sometimes made available via Special Access Schemes prior to their approval. treatments are often compared with placebos to assess the treatment's effectiveness. In some studies, the participants in the [control group](#) [14]A group of patients in a clinical trial who do not receive the drug or treatment being investigated, for the purpose of comparison with those who do. Participants in the control group of a clinical trial are either given standard treatment (excluding the drug being studied) or a placebo. will receive a placebo instead of an active drug or treatment.

The control group is there to answer an important scientific question: "If the people we gave this treatment to respond in this way, how does that compare with people we did not give this treatment to?" (3)

Because of the [placebo effect](#) [15]A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance., some people experience real physical changes when they take a placebo. People on the placebo arms of trials occasionally have CD4 increases, [viral load](#) [16]A measurement of the quantity of HIV RNA in the blood. Viral load blood test results are expressed as the number of copies (of HIV) per milliliter of blood plasma. reductions, and side-effects just like the people taking the real drug. Some trials do not have a placebo arm. These trials are designed to compare one treatment with another treatment (rather than one treatment with no treatment) and so these trials may have all active treatment arms. (4)

## What is a blinded study?

A blinded study is one in which participants do not know whether they are in the experimental or control group in a research study. Those in the experimental group get the medications or treatments being tested, while those in the control group get a standard treatment or a placebo.

## What is a [double-blind](#) [17]A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome; also called **double-masked study.** study?

A double-blind study is one in which neither the participants nor the study staff know which participants are receiving the experimental treatment and which ones are getting either a standard treatment or a placebo. These studies are performed so neither the patients' nor the doctors' expectations about the experimental drug can influence the outcome.

## What happens if there are side-effects?

By the time a treatment reaches the trial stage it has been extensively tested for likely side-effects. However, part

of the purpose of the trials is to see what unexpected side-effects emerge, and how severe or common they are. So as well as experiencing the benefits of new treatment, there may also be side-effects for some people. Problems or side-effects will be carefully recorded and relayed to the principal researcher to ensure that you are kept as safe as possible. Compensation is available for participants who suffer personal injury as a result of their participation in all trials.

## What are the benefits and risks?

There are benefits and risks associated with trials. By participating you can:

- Take an active role in your health care.
- Gain access to new treatments.
- Obtain expert medical care.
- Help others by contributing to research.

## Clinical trials have risks:

- There may be side-effects or adverse reactions to medications or treatments.
- The treatment may not be effective for you.
- You may be placed in the control group and may not receive the trial treatment until after the trial has finished; and
- The protocol may require a lot of your time for trips to the study site, treatments, hospital stays, or complex dosage requirements.

## How am I protected?

The government has strict guidelines and safeguards to protect people who choose to participate in trials. In Australia, trials must conform to the Ethical Principles of the Declaration of Helsinki and to International Good Clinical Practice guidelines. Before a trial can go ahead, it needs to be approved by independent [ethics](#) [18](In clinical trials) The process of determining that a proposed clinical trial conforms to a wide range of moral, scientific and ethical standards, to ensure that participants in the trial are not abused, mistreated or unfairly taken advantage of. Before a clinical trial can go ahead, it must be given approval via an independent ethics process. committees that operate according to the guidelines issued by the National Health & Medical Research Council (NHMRC Guidelines).

**What is [informed consent](#) [19]The process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study.**

Informed consent is the process of learning the risks and benefits of a trial before you decide whether to participate. These include:

- Why the research is being done and what the researchers want to accomplish.
- What will be done during the trial and for how long.
- What benefits can be expected and what other treatments are available.
- You have the right to leave the trial at any time.

If you are considering joining a trial, the research staff will give you a patient information statement that includes details about the study and a consent form.

Joining a trial is an important decision. You should ask the research team any questions you have about the study and the consent forms before you make a decision. It is also a good idea to take the consent documents home and discuss them with your partner, friends or family members.

Informed consent is more than signing a form. It is a process that continues through the study. You should feel free to ask the research team questions at any time.

## What happens with the results?

As well as being reviewed by the government authorities such as the Therapeutic Goods Administration, the results of the trials may be reported in the medical press and are made available to doctors. The publication of results is done so that doctors can make scientifically valid assessments of the benefits and risks of a new medicine for their patients.

Although the results of the study may be published, nothing that identifies individual patients will be released. All details of a clinical trial participant's treatment are kept confidential and patient anonymity is assured. In addition, your doctor will be notified of the results of the study.

## What should I know before I join? (5)

You should know as much as possible about the research study. It is important for you to feel comfortable asking questions and the clinical staff should answer them in a way you can understand. Some questions you might ask about the clinical trial include:

### 1. What is the trial about?

- Have you or others done this type of trial before? If so, what did you learn?

### 2. Who put this trial together?

- Who are the researchers? Who do they work for?
- Have they done a trial like this before?
- Is the government part of this trial? Who else is part of this trial?
- Who is paying for the trial?
- Is my doctor accepting a fee for [recruiting](#) [20]The act of signing up participants into a study. Generally this process involves evaluating a participant with respect to the eligibility criteria of the study and going through the informed consent process. me into this trial?
- Who will make money from the results?
- Who can I go to with questions or complaints?

### 3. Who is going to be in this trial?

- What kinds of people are you looking for? Why?
- How are you finding people for this trial?
- Can I quit the study after signing a consent form?
- Is there a support group for trial participants that I can join?

### 4. What will I get out of the trial?

- What are the benefits? The risks?
- Will I get treated the same as everyone else?
- What kinds of different treatments are offered in this trial?
- Is there a trial and a control treatment?
- Will I continue to get the clinical trial medicine after the study is complete?
- Is payment involved?
- Do I get reimbursed for my fares to and from the clinical trial centre?

## 5. What do I have to do?

- How much of my time will be needed?
- Will I need to take extra time off work?
- What extra tests or procedures will I be subjected to?

## 6. How will I be protected?

- Do I stand a chance of being harmed in the trial? In the future?
- Does the trial protect me from all types of harm? If I get harmed in any way, will I get all needed treatment and compensation?
- Who pays for the treatment or tests?

## 7. How will my privacy be protected?

- Who is going to see the information?
- Will my name be used?
- What are you going to do with the results of the trial?
- What happens to the information I give if I quit the trial?
- Is there a written guarantee of privacy?

## 8. What progress has been made?

- When did you start this clinical trial? How long will it last?
- How much of the clinical trial have you already done?
- Have there been any problems so far?

You can leave a trial at any time. If you plan to stop participating, let the research team know why. If you decide not to participate in the trial it will not affect the services provided to you by any health services.

## Getting information and support:

- Talk to your doctor.
- Albion Street Centre T (02) 9332 9600. HIV/AIDS, [Hep](#) [21]Any inflammation of the liver. It is usually caused by viral infection, toxic agents or drugs but may be an autoimmune response. It is characterised by jaundice, abdominal pain, liver enlargement and sometimes fever. The different types of viral hepatitis include hepatitis A (formerly called infectious hepatitis), hep B (serum hepatitis), hep C (formerly called non-A, non-B hepatitis), and hepatitis D, E, F and G. C clinical treatment and research centre. Trials, nutrition, counselling, antibody and viral load testing. NSP and pharmacy. Counsellor and doctor on call 24hrs (hours vary).
- ACON's Treatment Information Officers T (02) 9206 2013 or 9206 2036 or outside Sydney Freecall 1800 816 518. Call for up-to-date information about treatments for HIV.
- ACON's Women's HIV Support T (02) 9206 2012. Information, education, support and referral services to women living with HIV/AIDS.
- Positive Life NSW T (02) 9361 6011; Freecall 1800 245 667. A non-profit community organisation representing the interests of people with HIV in New South Wales.
- Multicultural HIV/AIDS Service T (02) 9515 3098 or outside Sydney Freecall 1800 108 098. Mon–Fri 9am–5pm. Bilingual/bicultural co-workers providing emotional support, advocacy and information to people living with HIV/AIDS from non-English speaking backgrounds.
- Heterosexual HIV/AIDS Service (Pozhet) T (02) 9361 6011 Freecall 1800 812 404 (national) or visit [www.pozhet.org.au](http://www.pozhet.org.au) [22] Men and women living heterosexually with HIV/AIDS.
- Consumers' Health Forum of Australia T (02) 6273 5444 or visit [www.chf.org.au](http://www.chf.org.au) [23]
- Medicines Australia T (02) 6622 4453 or visit [www.medicineau.net.au](http://www.medicineau.net.au) [24]
- Health Care Complaints Commission (HCCC) T (02) 9219 7444 or outside Sydney Freecall 1800 043 159 or

visit [www.hccc.nsw.gov.au](http://www.hccc.nsw.gov.au) [25] Monitors, resolves and investigates complaints about health care providers and health care services in NSW

**For regional NSW HIV/AIDS and related services:**

- Contacts A directory of services for people with HIV. Available from Positive Life NSW. T (02) 9361 6011; Freecall 1800 245 667 or visit [www.positivelife.org.au](http://www.positivelife.org.au) [26]

**References**

1. These are: Access to Unapproved Therapeutic Goods – Clinical Trials in Australia, Therapeutic Goods Administration, 2000; The National Statement on Ethical Conduct in Research Involving Humans, National Health and Medical Research Council, 1999; Guidelines for the Ethical Review of Research Proposals for Human Somatic Cell [Gene](#) [27] The most basic unit of genetic information. Therapy and Related Therapies, National Health and Medical Research Council, 1999.
2. See: Access To Unapproved Therapeutic Goods – Clinical Trials In Australia, Therapeutic Goods Administration May 2001 at: <http://www.health.gov.au/tga/docs/pdf/unapproved/clintrials.pdf> [28] & Medicines Australia [www.medicineau.net.au](http://www.medicineau.net.au) [24]
3. Medicines Australia [www.medicineau.net.au](http://www.medicineau.net.au) [24]
4. See: Access To Unapproved Therapeutic Goods – Clinical Trials In Australia, Therapeutic Goods Administration May 2001 at: <http://www.health.gov.au/tga/docs/pdf/unapproved/clintrials.pdf> [28] and Medicines Australia [www.medicineau.net.au](http://www.medicineau.net.au) [24]
5. See Medicines Australia [www.medicineau.net.au](http://www.medicineau.net.au) [24]

Produced by the Health Promotion Unit of Positive Life NSW.

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Funded by NSW Health.

This fact sheet was produced with the assistance of an unconditional grant from Gilead Sciences Pty Ltd.

Attachment	Size	Type
<a href="#">PDF version of this fact sheet</a> [29]	120.75 KB	 PDF

- [clinical trials](#)
- [Clinical trials database background information](#)
- [NAPWA member organisations' fact sheets](#)

**Links:**

- [1] <http://www.napwa.org.au/glossary/term/89>
- [2] <http://www.napwa.org.au/glossary/term/475>
- [3] <http://www.napwa.org.au/glossary/term/511>
- [4] <http://www.napwa.org.au/glossary/term/486>
- [5] <http://www.napwa.org.au/glossary/term/91>
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- [11] <http://www.napwa.org.au/glossary/term/474>
- [12] <http://www.napwa.org.au/glossary/term/514>

[13] <http://www.napwa.org.au/glossary/term/491>

[14] <http://www.napwa.org.au/glossary/term/93>

[15] <http://www.napwa.org.au/glossary/term/508>

[16] <http://www.napwa.org.au/glossary/term/416>

[17] <http://www.napwa.org.au/glossary/term/484>

[18] <http://www.napwa.org.au/glossary/term/498>

[19] <http://www.napwa.org.au/glossary/term/496>

[20] <http://www.napwa.org.au/glossary/term/489>

[21] <http://www.napwa.org.au/glossary/term/97>

[22] <http://www.pozhet.org.au/>

[23] <http://www.chf.org.au/>

[24] <http://www.medicineau.net.au/>

[25] <http://www.hccc.nsw.gov.au/>

[26] <http://www.positivelife.org.au/>

[27] <http://www.napwa.org.au/glossary/term/126>

[28] <http://www.health.gov.au/tga/docs/pdf/unapproved/clintrials.pdf>

[29] [http://www.napwa.org.au/files/7\\_ClinicalTrials\\_0.pdf](http://www.napwa.org.au/files/7_ClinicalTrials_0.pdf)