1. What are clinical trials?

Clinical trials are a key research tool for advancing medical knowledge and patient care.

A clinical trial involves research using human volunteers (also called participants) that is intended to add to medical knowledge. In a clinical trial participants receive specific interventions or treatment according to the research plan or protocol. This sets out in detail the process and design of the study, the treatment(s) to be used and the measurements that will be required.

All parties (investigators, study co-ordinators and pharmaceutical company employees) involved with the development and testing of the study medicine must follow the study protocol.

The people who volunteer to be studied during these trials are advised beforehand of possible risks. Before a clinical trial can begin for a treatment, medication or device, it must show promising results in laboratory or animal tests.

2. What happens during a clinical trial?

At the beginning of a clinical trial, a team of doctors, nurses and other health professionals checks the health of the participant and gives specific instructions for using the treatment, medication or device throughout the trial. The team monitors the participant as the trial progresses and stays in touch after the trial is completed.

3. Are clinical trials safe?

For the most part, yes. However, sometimes clinical trials are for experimental medications intended for very sick people, so in those cases there are generally more risks involved. The patient will always be advised of the risks involved.

Clinical trials are governed by clearly defined international and local ethical and legal codes. In 1981 in the US, regulations of the US Food and Drug Administration made it a requirement that all regulated clinical trials be reviewed and approved by an Institutional Review Board (IRB) before and during the course of the trial. In New Zealand this is done by The New Zealand Health and Disability Ethics Committee, a committee of volunteers including experts and lay people such as doctors, scientists, clergy, and other community members. Their primary goals are to protect the public, to evaluate whether the potential benefits of study participation outweigh the risks, and to ensure that patients are not coerced into participating in a clinical trial.

If you would like advice as to your rights as a participant in a clinical trial you may approach a Health & Disability Consumer Advocate by contacting:

- Free Phone: 0800 555 050
- Free Fax: 0800 2 SUPPORT / 0800 2787 7678
- Email: advocacy@hdc.org.nz.

Clinical trials that are sponsored by manufacturers of drugs or medical devices are not covered by Accident Compensation Corporation (ACC). Therefore compensation is provided by the company sponsoring the clinical trial which is at least as comprehensive as that available under ACC. The investigator will provide further details during the consent process.

4. Who can participate in a clinical trial?

All clinical trials have guidelines about who can participate. Criteria may include age, gender, the type and stage of a disease, previous treatment history and other medical conditions.**hy participate in a clinical trial?**

You can access new research treatments before they are widely available, and your participation also may help others by contributing to medical research.

5. Do I have to stay in a hospital or leave my home for a clinical trial?

Participants are generally asked to come in for regular office visits at an accessible clinical trial site, which may be a doctor's office or dedicated clinical trial centre. Some trials require more doctor visits than would be normal for an illness or condition.

Many trials involve a physical examination or medical history review after enrolment. A description of what's expected of the participant should be made available before signing the informed consent document.

6. What kind of paperwork do I have to sign?

The Clinical Research Staff of a clinical trial explain the risks and potential benefits involved. This information is also provided in an informed consent document, which the participant (or legal guardian) is required to sign before taking part in the trial. The minimum required elements of an informed consent include the following:

- Purpose of research
- Foreseeable risks
- Potential benefits
- Disclosure of alternative procedures
- Confidentiality
- Course of action if more than minimal risk involved
- Who to contact
- Participation is voluntary

7. Can I quit after a clinical trial starts?

Yes. You can leave a clinical trial at any time without it affecting your future care with the primary health care provider.

8. How long do clinical trials typically last?

They vary greatly. Some last just a few days while others take years.

9. If I decide to take part in a clinical trial, what should I do to prepare?

You should learn as much about the trial as possible before signing the informed consent document. Helpful questions to ask the trial directors include:

- What is the purpose of the study?
- Who is going to be in the study?
- Why do researchers believe the experimental treatment being tested may be effective?
- Has it been tested before?
- What kinds of tests and experimental treatments are involved?
- How do the possible risks, side effects and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the experimental treatment?
- Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this study?
- How will I know that the experimental treatment is working?
- Will results of the trials be provided to me?
- Who will be in charge of my care?

10. Where can I find understandable definitions of some of the scientific terms used during a clinical trial?

The Clinical Trials website in New Zealand has a list of terms commonly used in clinical trials.

http://clinicaltrials.health.nz/resource-centre/glossary/

11. Where can I get more detailed information about clinical trials?

- http://clinicaltrials.health.nz/
- http://www.medicinesnz.co.nz/clinical-trials/
- http://clinicaltrials.gov
- http://www.centerwatch.com

12. How can I be sure a clinical trial is legitimate?

The Clinical Trial's Research Staff should be willing to answer all of your questions, such as who is sponsoring the trial, whether the trial protocol is compliant with local and international regulations, what is the purpose of the trial, what the possible risks are and how long the trial is expected to last.

A reliable starting point is the National Institutes of Health Clinical Trial Registry at http://clinicaltrials.gov. This site lists more than 103,000 trials in more than 170 countries. You can search for a trial using criteria such as condition or disease treated, medication or therapy used, or site country. Each entry includes a trial description, sponsors, purpose, estimated completion date, eligibility criteria and contact information.

13. What are the different types of clinical trials?

There are several kinds of trials, each with a different purpose:

- Treatment trials test experimental treatments, new combinations of drugs or new approaches to surgery or radiation therapy.
- Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning.
- Diagnostic trials evaluate tests or procedures for diagnosing a disease or condition.
- Screening trials evaluate methods of detecting a disease or health condition.
- Quality of Life trials (or Supportive Care trials) evaluate methods of improving the comfort and quality of life of patients with chronic illness.

14. Are there different phases of clinical trials?

To be approved by the U.S. Food and Drug Administration, an experimental drug or treatment has to pass through several phases of clinical trials.

- **Phase I Trials**

  Phase I trials test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety and identify side effects.

- **Phase II Trials**

  After safety has been confirmed, phase II trials test the experimental drug or treatment in a larger group of people (100-300).

- **Phase III Trials**

  Phase III trials test the experimental drug or treatment in a large group of people (1,000-3,000) to confirm its effectiveness. Usually, two successful trials are required before a drug or treatment is approved by the U.S. Food and Drug Administration.

- **Phase IV Trials**

  Phase IV trials acquire additional information about an experimental drug or treatment after it has been approved.

15. Who sponsors clinical trials?

Clinical trials can be sponsored by organisations or individuals such as physicians, medical institutions, foundations, voluntary groups and pharmaceutical companies.