MINISTRY OF HEALTH
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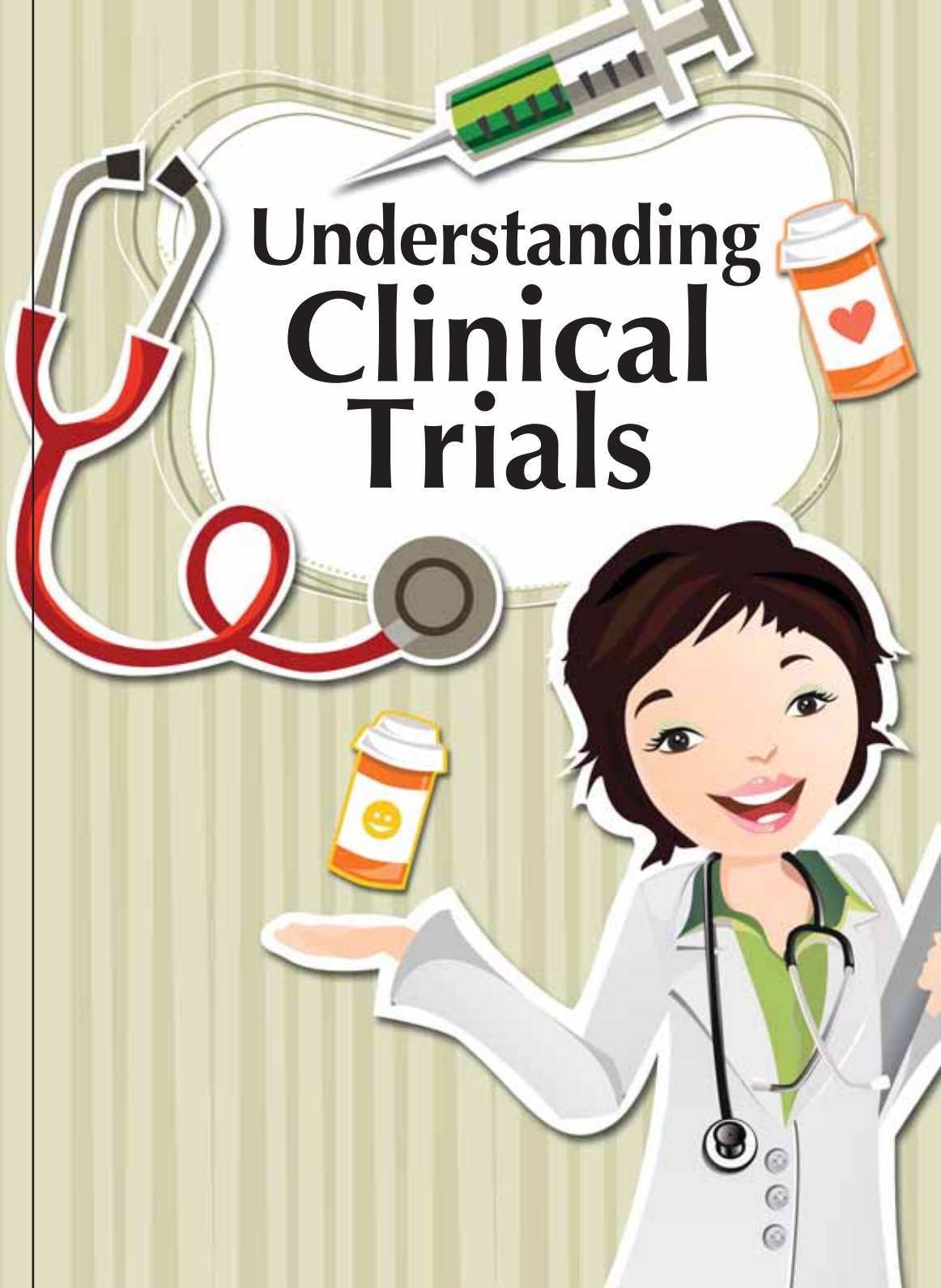
Understanding Clinical Trials



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Introduction

Your own well-being depends on staying healthy, but it also depends on what kind of drugs and treatments are currently available, in case you fall sick. Do you know that before any new drugs become available in the market, these drugs have to go through an elaborate process of trials to check their safety, dosage and efficacy? This process is known as “clinical trial”.

What are clinical trials?

Clinical trials are research studies that involve the public's participation to evaluate the safety and efficacy of either new or existing experimental drugs. During a clinical trial, the experimental drug is tested on a group of carefully selected people drawn from general public, and the test results are evaluated before the drug becomes available for use by patients.

Why are clinical trials important?

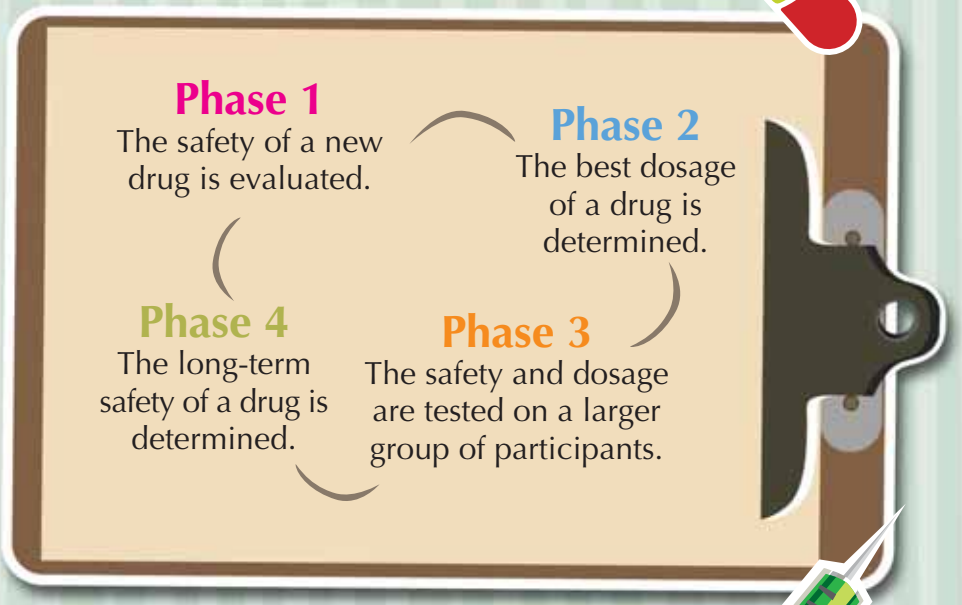
An important and necessary step in the process of developing new drugs and treatments, clinical trials help to:

1. treat illness
2. prevent illnesses
3. increase the number of patients cured
4. improve people's quality of life

Clinical trials ensure that experimental drugs or treatments are safe to use and are effective.

Let's understand the different phases of a clinical trial

Like climbing the steps of a ladder, researchers generally proceed with clinical trials one step at a time.



As you can see, each phase serves an important objective towards ensuring the safety and efficacy of new drugs.

You should not be surprised to find that clinical trials involve a lot of people from different backgrounds – and also an elaborate protocol.

Usually, a team of qualified doctors, nurses, medical investigators and statisticians lead clinical trials.

Before conducting a clinical trial, clinical trial investigators design a "Trial Protocol", which lays out clear guidelines and procedure on how to evaluate the treatment during the trials. To ensure the safety and well-being of the participants, the protocol needs to be approved by an independent review board and health authorities.

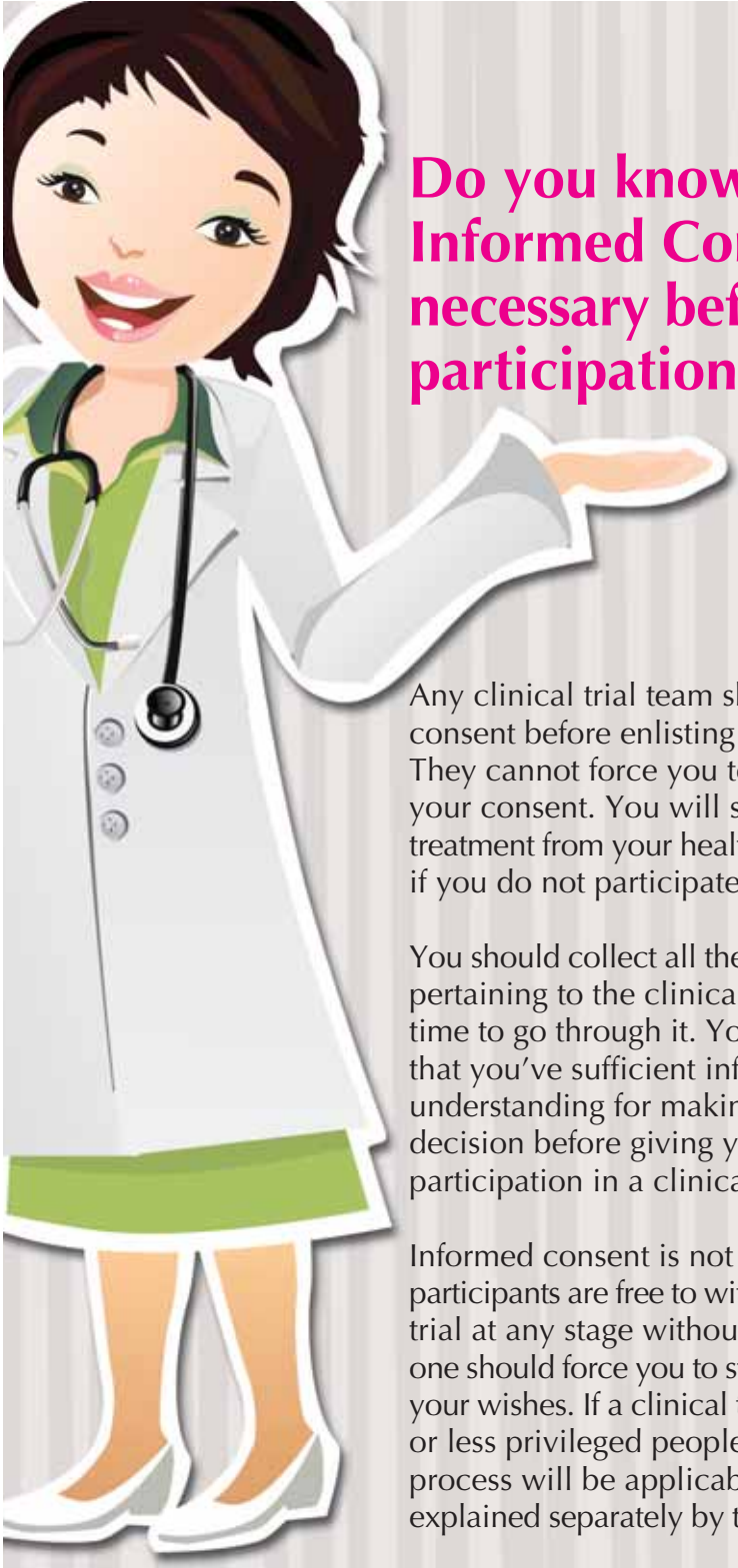
Any safeguards? Who regulates the clinical trials in Singapore?

All clinical trials must be designed and conducted according to strict guidelines to ensure the safety of participants, and are subject to review and approval by:

Institutional Review Board (IRB)/Ethics Committee (EC): All clinical trials must be approved by an institution's IRB / EC to ensure protection of participants' rights, confidentiality and well-being.

Health Science Authority (HSA): Clinical trials must also be approved by HSA, who issues a Clinical Trial Certificate before a trial goes live.

How can you contribute in clinical trial?



Do you know your Informed Consent is necessary before your participation?

Any clinical trial team should first seek your consent before enlisting you as a participant. They cannot force you to participate without your consent. You will still receive available treatment from your healthcare providers even if you do not participate in the clinical trial.

You should collect all the relevant information pertaining to the clinical trial and take your time to go through it. You should be satisfied that you've sufficient information and understanding for making an "informed" decision before giving your consent for participation in a clinical trial.

Informed consent is not a contract, and participants are free to withdraw from a clinical trial at any stage without any penalties. No one should force you to stay on the trial against your wishes. If a clinical trial involves children or less privileged people, a different consent process will be applicable, which will be explained separately by the clinical trial team.

You should also know about the risks associated with clinical trials and how these risks are minimised.

As a first step, clinical trial investigators inform all participants about the possible risks and side effects before a trial begins. Still, clinical trials may cause side effects that doctors cannot predict.

The following measures help to minimise the risks:

Prior testing

Before entering the clinical trial stage, new drugs undergo testing in a laboratory environment and also checked for safety on animals.

Close monitoring

During the trial, doctors closely monitor the participants, including conducting regular tests to ensure their safety and well-being. For this purpose, participants may need to visit their doctors on a scheduled basis.

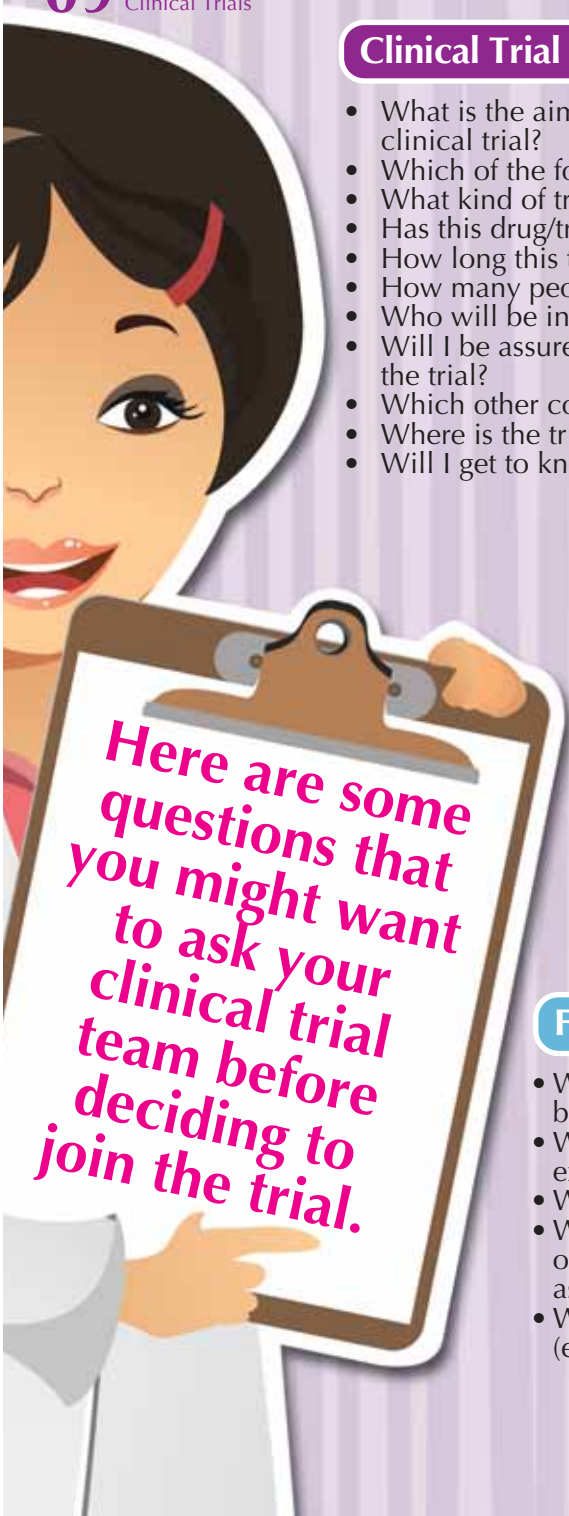
What if you develop unpleasant reactions during the trial?

Before the trial starts, your clinical trial team will inform you of the procedures in place for you to seek emergency help should you experience adverse reactions to the treatment. In such a situation, you should contact your doctor immediately.

It is rare for participants to be seriously harmed from the drugs received during clinical trials, although some may experience unpleasant side effects. You should consult your doctors in charge and clinical trial coordinators with regard to any side effects and they will advise you on the necessary follow-ups.

Where do you start if you wish to participate in a clinical trial?

Hospitals or pharmaceutical companies usually conduct the clinical trials, and they recruit participants through doctors. You may wish to speak to your doctor about the ongoing clinical trials in Singapore.



Clinical Trial Details

- What is the aim and purpose of a particular clinical trial?
- Which of the four phases the trial is in?
- What kind of treatment will be given during this trial?
- Has this drug/treatment been tested before?
- How long this trail would last?
- How many people are involved in this trial?
- Who will be in charge of my trial?
- Will I be assured of confidentiality during and after the trial?
- Which other countries this trial involves?
- Where is the trial site?
- Will I get to know the results or findings?

Health Issues

- Will the trial affect my daily life? If yes, how?
- How will the trial affect me physically and psychologically?
- What are the possible side effects and other risks?
- Will the treatment affect any of my pre-existing medical conditions?
- What are the procedures in place should I experience discomfort or side effects? And whom should I contact in such a situation?

Financial Issues

- Will the entire cost of the treatment be covered?
- Will I be reimbursed for my transport expenses?
- Will I get any inconvenience fee?
- Will I be covered/insured if I require outpatient treatment or hospitalisation as a result of participating in the trial?
- Will I be offered free or subsidised (experimental) treatment after the trial?

What happens when you join a clinical trial?

You will go through the following stages in the clinical trial process:

1. **Introduction:** You will be introduced to the clinical trial team, comprising of:
   Trial coordinators
   Doctors
   Nurses
   Researchers

2. **Verification:** Next, they will verify your suitability to take part in the trial.

3. **Group allocation:** Participants will be allocated to random groups to ensure each group has a mix of participants. A clinical trial usually has two groups:

   Trial group: This group will be given the new drug.

   Control group: The people in this group will either receive a currently available drug or a placebo*.

   *Placebo: An inactive drug with no effects on the participants.

4. **Drug/treatment:** The team will check your condition and administer the drug to you following a set of specific instructions and guidelines.

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5 **Monitoring:** During the trial, the trial team will schedule visits to see the doctor to review your condition and conduct tests. Regular communication between you and the trial team ensures your safety.

6 **Results:** At the conclusion of the trial, the results would be made known to everyone so that participants can make informed decision about their well-being.

What about the confidentiality of your personal information?

All the records of a clinical trial and your participation will be kept strictly confidential. Also, when the trial results are published or presented, no names or confidential information will be revealed.

Further information

Clinical Research in Singapore
www.clinicalresearch.org.sg

HSA Clinical Trial Website
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials.html