

## What Is 'Informed Consent'?

Informed consent is a process during which we will provide potential trial participants like yourself with information about the clinical trial(s) for which you are eligible. This process is intended to protect you as you will be provided with all the information relevant to the clinical trial.

## What Are My Rights As A Trial Participant?

As a trial participant, you will have the following rights:

- To be informed about the aims and procedures of the trial, the risks and benefits of the study treatment, and the alternative options to trial participation
- To ask questions, and get answers to them, if there is anything you do not understand
- To make an informed decision regarding your participation
- To withdraw from the trial at any point in time, without compromising your subsequent care.
- To receive the medical care that is best for you
- To privacy and confidentiality

*All clinical studies that are conducted have been approved by the Institutional Review Board (IRB) or Ethics Committee at each medical institution to ensure that the studies are ethical and appropriate, so that patients' interests are not at stake.*

For more information on cancer, please call the  
**Cancer Helpline at Tel: 6225 5655**  
or email [cancerhelpline@nccs.com.sg](mailto:cancerhelpline@nccs.com.sg)

MONDAYS - FRIDAYS : 8.30am to 5.30pm

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Scan here for more information on NCCS clinical trials

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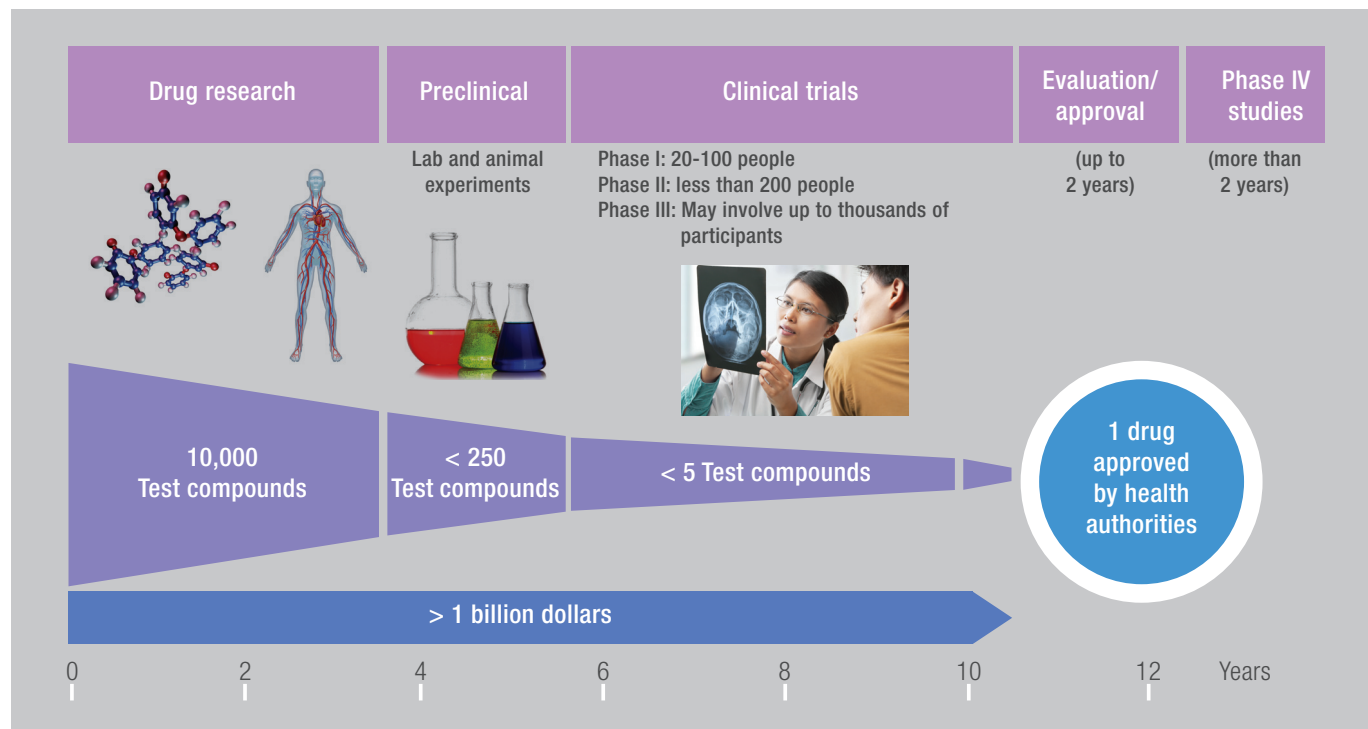
An Educational Initiative by National Cancer Centre Singapore

# What Are Clinical Trials?

Clinical trials offer alternative treatment options for many people with cancer. It is a research study that involves people. Before a new drug gets regulatory approval for clinical use on patient, it has to go through a very long and strict process with many stages as illustrated in the table below. All drugs that are currently approved and routinely used in the treatment of cancer have undergone clinical trials.

All clinical studies that are conducted have been approved by the Institutional Review Board (IRB) or Ethics Committee at each medical institution. This is to ensure that the studies are ethical and appropriate, so that patients' interests are not at stake.

**Drug development pipeline**  
(Source: PhRMA Profile Pharmaceutical Industry 2010)



## Why Is There A Need For Cancer Clinical Trials?

Cancer treatment clinical trials are approved research studies that are designed to test new drugs, drug combinations or approaches of treating cancer.

Clinical trials are integral to cancer drug development and the establishment of new treatment standards. It is through cancer clinical trials that researchers are able to determine whether new treatments are safe, effective and result in better outcomes than current treatments.

## How Does My Participation Help?

When you take part in a clinical trial, you contribute to the overall knowledge about cancer and help in the development of improved cancer treatments.

## Participating In A Clinical Trial

### What happens during a clinical trial?

The following flow-chart shows the different steps and procedures involved in a clinical trial.

#### PRE-SCREENING

The clinical trial team doctors will first assess your health, and explain to you the nature of clinical trials.

#### PRE-SCREENING MOLECULAR STUDIES

For some trials, the tumours may need to be tested. This is to look for abnormalities in the tumour which may be targeted by specific drugs.

#### MAIN INFORMED CONSENT & SCREENING FOR ELIGIBILITY

You will then be taken through the informed consent process and be screened for eligibility into a particular trial.

#### TRIAL ENROLLMENT

If you meet the eligibility criteria and agree to participate, you will then be enrolled into the clinical trial.

#### STUDY PROCEDURES AND FOLLOW-UP

- The trial procedures will be conducted in accordance with the study protocol.
- You will also have to follow closely the advice given by the study team, which may include: (1) taking part in all scheduled appointments and tests, (2) taking the medications as directed and (3) informing the clinical trial team regarding your symptoms and any adverse effects you may be experiencing.

#### END OF TRIAL

- Your participation in a clinical trial is completely voluntary and you may withdraw from the study at any point in time.
- In some cases, your doctor may have to stop the study treatment if you are unable to tolerate the treatment.