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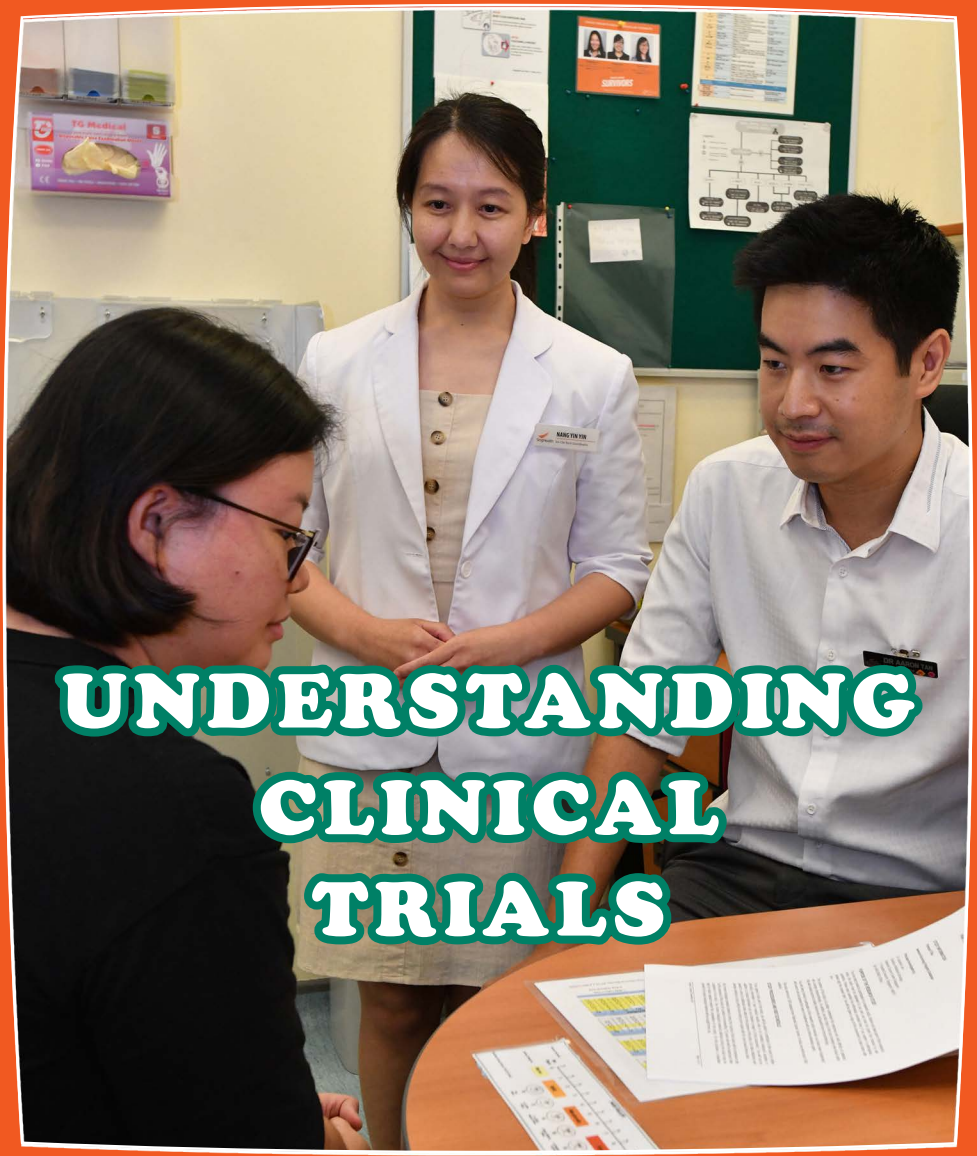

UNDERSTANDING CLINICAL TRIALS

An Educational Initiative by National Cancer Centre Singapore

Contents

Document No. CEIS-EDU-PEM-176/0823

First published: January 2014. Reprint: September 2015. Revised: August 2023.

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Acknowledgements:

We would like to thank Dr Matthew Ng Chau Hsien, Dr Darren Lim Wan Teck, Dr Yap Yoon Sim, Dr Tan Jing Ying Tira (Division of Medical Oncology, NCCS) and the clinical research coordinators (Division of Clinical Trials and Epidemiological Sciences, NCCS) for providing critical input and suggestions. We would also like to acknowledge the SingHealth Investigational Medicine Unit (IMU) and Clinical Pharmacology Laboratory for their collaboration and support in the conduct of clinical trials.

Preface

The National Cancer Centre Singapore (NCCS) is committed to provide the best care for our patients. To do so, we are continuously searching for improved treatment. Through clinical trials, we gain access to the latest and most up-to-date treatments.

The vanguard of cutting edge cancer treatment has been advancing at a furious pace, leading to the development of a myriad of novel approaches to treating cancer. Clinical trials provide a rational framework to evaluate them, and remain the primary strategy to forge ahead in our fight against cancer. We fervently hope that participation in clinical trials will ultimately translate to better patient outcomes.

This information booklet covers the relevant aspects of clinical trial participation, and serves to provide answers to common questions you may have. We aim to empower you and your family to make informed decisions as to whether to participate in the next generation of cancer care.

Professor William Hwang
Chief Executive Officer, National Cancer Centre Singapore

1. THE BASICS

HOW ARE NEW DRUGS DEVELOPED AND TESTED?

Before a new drug gets regulatory approval for clinical use in patients, it has to go through a very long process with many stages, as illustrated in the diagram below (Figure 1).

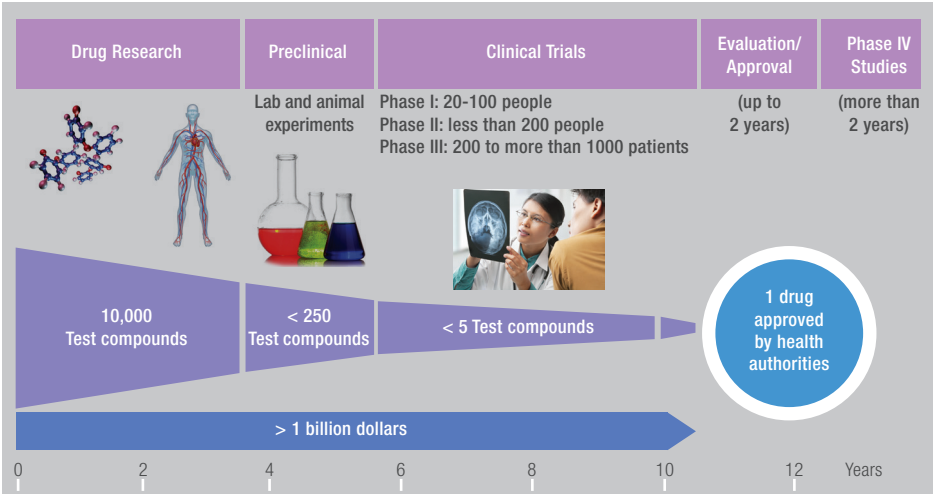


Figure 1. Drug development pipeline (Adapted from PhRMA Profile Pharmaceutical Industry 2010)

New drug discovery begins with laboratory research, after which they undergo further animal testing or 'pre-clinical studies'. During pre-clinical studies, a new drug candidate is tested for initial proof of its safety and effectiveness. Promising drug candidates will then be selected for testing in human clinical trials. The regulatory body (Health Science Authority, Singapore) will examine all the information obtained from the various stages of drug development and decide whether or not to approve the drug for treatment in patients. All drugs that are currently approved and routinely used in the treatment of cancer have undergone clinical trials.

WHY IS THERE A NEED FOR CANCER CLINICAL TRIALS?

Clinical trials for cancer treatments are approved research studies that are designed to test new drugs, drug combinations or approaches to treating cancer. Despite extensive efforts, we are still unable to cure most patients with recurrent or advanced cancer, which explains the critical need to search for new drugs and approaches. 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. 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.

WHAT ARE THE DIFFERENT PHASES OF CLINICAL TRIALS?

Before a new treatment is tested in patients, extensive laboratory and animal testing would have been done to identify the drug compounds that have promising anti-cancer activity and their potential side effect profile. Clinical trials in humans take place in different phases before the new treatment is approved by regulatory bodies, as shown in the following chart (Figure 2).

When you take part in a clinical trial, you will be invloved in one particular phase of the study. As a treatment moves through the different phases of clinical trial it has to meet the rigorous regulatory requirements for each phase. You remain in the phase of trial you are enrolled in.

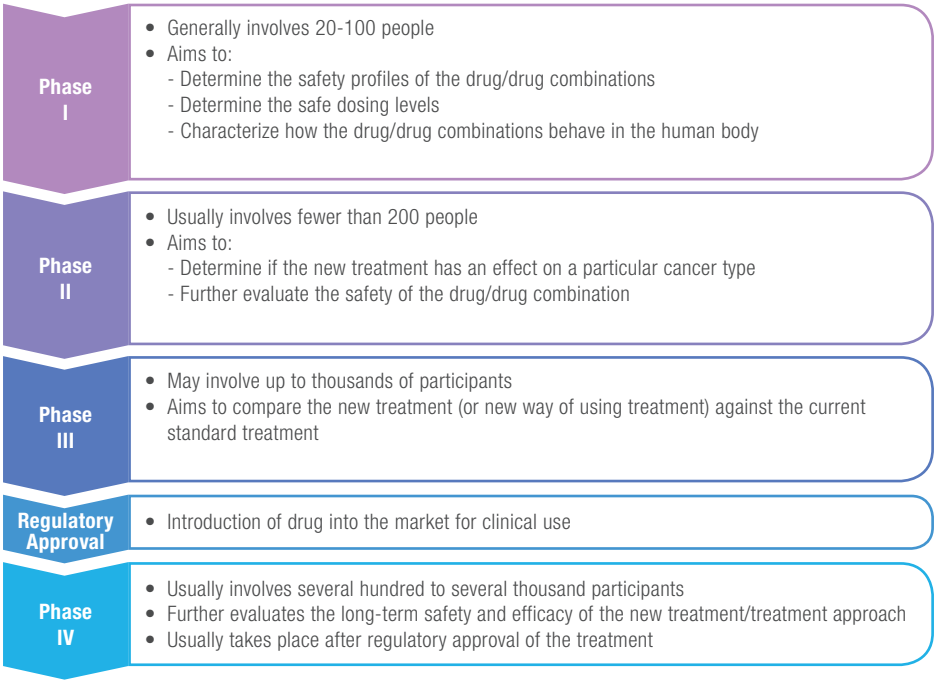


Figure 2. Phases of clinical trials

CLINICAL TRIALS IN NCCS

Today, NCCS is at the forefront of clinical cancer trials in Singapore that is aimed at developing novel and up-to-date treatments to improve the lives of patients with all different cancer types. We have over a decade of experience in conducting clinical trials and have completed a broad spectrum of more than 450 clinical trials to date. Our portfolio encompasses phases I to III trials, with most studies evaluating the effectiveness of novel molecular targeted agents, immunotherapies or combinations. Some of these trials are multi-centre trials that are conducted in many different medical centres and even different countries.

With collaborations both locally and internationally, our investigators have been actively designing the protocols for and conducting these clinical studies. We have a dedicated team of medical oncologists, radiation oncologists, surgeons, radiologists, scientists, clinical research coordinators (CRCs), nurses, pharmacists and administrators who work closely together in conducting these trials.

2. 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, who are also part of your clinical care team, will first assess your health, discuss your treatment options and explain to you the nature of clinical trials.

PRE-SCREENING MOLECULAR STUDIES

For some trials, the tumour may need to be tested further. This is to look for abnormalities in the tumour which may be targeted by specific drugs. Usually this laboratory testing may be performed on removed tumour tissue but sometimes patients may need to undergo a procedure to remove more tumour tissue for testing.

MAIN INFORMED CONSENT & SCREENING FOR ELIGIBILITY

You will then be taken through the informed consent process and be screened for eligibility for a particular trial. The informed consent and screening process will be explained in greater detail in this booklet.

TRIAL ENROLMENT

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

STUDY PROCEDURES AND FOLLOW-UP

- The trial procedures will be conducted in accordance with the study protocol. As a trial participant, you will have to undergo the study treatment and procedures as stipulated in the informed consent document.
- You may need to undergo more tests and come to NCCS for follow-up appointments more frequently as compared to those who are not taking part in clinical trials. This allow**s** us to monitor your condition closely and ensure your safety.
- 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 no longer benefit from the treatment or if you are unable to tolerate the treatment.

Figure 3. Steps and procedures involved in a clinical trial

AM I ELIGIBLE FOR CLINICAL TRIALS?

Clinical trials follow a strict protocol that outlines the criteria for eligibility. These criteria are specific to each trial and are commonly based on the following factors:

• Age

For cancer treatment trials in adults, the age range is usually quite wide. The majority of clinical trials in adults only enrol patients over the age of 21.

• Type of cancer

Many trials are only open to patients with a particular cancer type. This is because different types of cancers respond differently to different treatments and investigators may be trying to find out if a particular treatment works for a certain type of cancer. In addition, some trials may only be open to patients with tumours harbouring specific abnormalities because the treatment may have been specifically designed to target this abnormality.

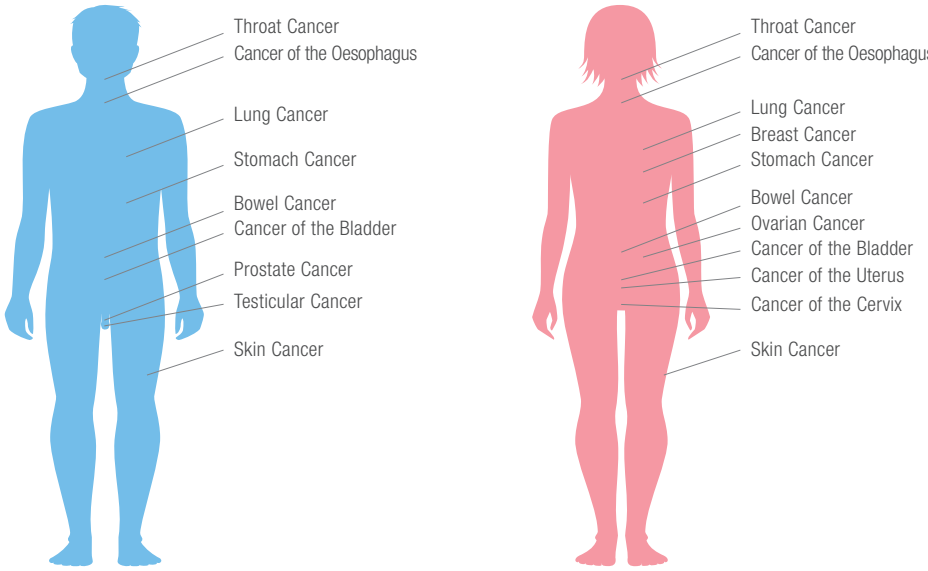


Figure 4. Different types of cancer by gender

Stage of cancer

Some trials, particularly Phase II and III trials, are only open to patients with a particular stage of cancer.

Previous treatment history & how long it has been since your last treatment

Some trials may exclude patients who have received a particular type of treatment, e.g. chemotherapy or radiotherapy. Phase III trials often exclude patients who have received multiple types of chemotherapy while Phase I trials are typically less strict. In contrast, some trials may also enrol only patients who have received a particular treatment prior to trial enrolment, e.g. only patients who have had radiotherapy or certain targeted therapies, are eligible.

Certain protocols may also specify the time interval from your last treatment to determine your eligibility for the trial. This is to ensure that the outcomes are the results of the study treatment alone, and not due to the prior treatments you have received.

General health

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

* As published in *Am J Clin Oncol*: Oken MM, Creech RH, and Tormey DC *et al. (1982)* Toxicity and response criteria of the eastern cooperative oncology group *Am J Clin Oncol* 5 *649-655*.

There are several scales that investigators commonly use to grade your general well-being and activities of daily living. Some examples of these scales include the Eastern Cooperative Oncology Group (ECOG) performance status, which ranges from 0 to 5, and Karnofsky performance status, which ranges from 0% to 100%.

Many trials select only patients with a particular performance status, e.g. ECOG status of 0-2. This is because patients with ECOG status of 0-2 are physically fitter and therefore more likely to be able to tolerate the rigour of a clinical trial and treatment with novel therapeutic agents.

Other medical conditions

Some trials may exclude patients with life threatening conditions or uncontrolled existing medical illnesses, e.g. severe heart problems, HIV/AIDS, diabetes, hepatitis B infections, etc.

Organ function

Even if your condition is not severe or life threatening, you may also not be able to take part in certain trials if your kidney, liver, heart and/or bone marrow functions are compromised.

These criteria are put in place to ensure, as far as possible, that the clinical outcomes are due to the effects of the study treatment(s) alone, and that you are not put at risk, especially in cases where the study treatment may have related side effects that may further aggravate your condition. You will be advised on the trials which may be suitable for you.

WHAT IS "INFORMED CONSENT"?

Informed consent is a process during which we 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. You will be provided with all the information relevant to the clinical trial. These include:

- What the clinical trial is trying to find out
- What treatment you will be receiving
- Alternative treatment options
- What is currently known about the type of treatment being studied
- What are the potential risks and benefits
- What tests and procedures you will be expected to undergo
- How often and for how long you will need to follow-up after an appointment
- How your blood or tissue samples will be used and kept for future research, if any
- Who pays for the costs of the trial
- How your privacy and confidentiality are protected
- Who to call if you have more questions

All this information will be included in the patient information and consent form (PICF), which you can take home, read and discuss with your family members, dependents and doctor. You must sign an informed consent form before enrolling onto a trial to demonstrate that you have been given such information and that you voluntarily agree to participate in the trial.

Signing this document, however, does not bind you to the trial and you may withdraw from the study at any point in time, even if the trial is not completed. Such decisions on your part will not compromise your relationship with your attending doctor, or affect your subsequent medical care.

HOW ELSE WILL I BE PROTECTED DURING A TRIAL?

Apart from the informed consent process, several important safeguard measures have also been put in place. For every clinical trial, there is a Principal Investigator (PI) who is responsible for the conduct of the trial. Before initiating a study, the PI has to obtain ethics and regulatory approval from the relevant authorities.

To obtain regulatory approval from the Health Sciences Authority in Singapore, investigators must provide relevant evidence that the treatment being investigated is acceptably safe and that the design of the trial has adequately taken into consideration the safety of participants. The trials also have to be conducted in accordance with the ICH Good Clinical Practice (ICH-GCP) principles, which will ensure that your rights, interests and safety are adequately protected, and that the data generated from the study is sound, valid and accurate.

In addition, for each clinical trial, ethics approval also has to be obtained from the SingHealth Institutional Review Board (IRB) before the trial can start. This review board is an independent ethics committee made up of professionals with knowledge of medicine, science and law. It is made up of both medical and non-medical personnel.

The IRB ensures that all clinical trials conducted are ethically sound and that the rights and welfare of the participants are adequately protected. They do so by inspecting the trial protocols and informed consent documents. They also ensure that any potential risks are minimized and that these risks are reasonable in relation to the potential benefits.

The study team will also ensure your safety through close follow-ups and careful on-going monitoring of the trials.

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

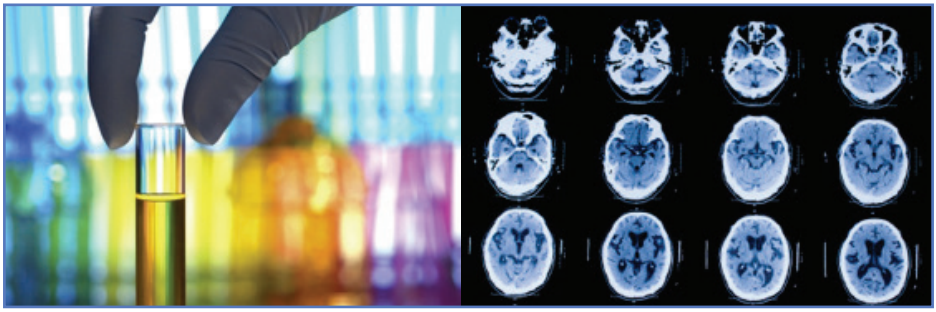
WHAT TREATMENT(S) WILL I RECEIVE DURING A TRIAL?

The treatment you receive depends on the trial that you are participating in. Based on the characteristics of your tumour, your treatment history and other clinical factors, the team will advise you on the trials that you are eligible for. Other than the trial drugs, you may also receive medications to prevent or treat the side-effects that you may experience.

WHAT ARE THE TESTS AND PROCEDURES INVOLVED?

The tests and procedures that you will have to undergo vary from trial to trial, but in general, these include blood tests (both for safety monitoring and trial purposes) and imaging scans to assess if the tumour is responding to the treatment, such as CT, MRI, PET, MUGA and other scans. Sometimes, biopsies of the tumour may be required as part of the trial, which your doctor will discuss with you.

Do note that you may have more frequent and longer check-ups during the trial. This allows us to monitor the effects of the study treatment on you more closely, and ensure that the study treatment is not doing you more harm than good.



WHAT ARE THE POTENTIAL RISKS AND BENEFITS OF PARTICIPATING IN A CLINICAL TRIAL?

Clinical trials are experimental in nature and we do not know how effective the study treatment will be compared to standard treatments. In addition, although these trials have been designed to minimise the risks for all participants, there may be unexpected side effects associated with new treatments or new approaches to treatment.

HOW LONG DO THESE TRIALS USUALLY LAST?

This really depends on several factors, including:

- How well you tolerate the study treatment
- How well your tumour responds to the study treatment
- How fast your disease progresses
- The type of treatment being given

In general, trial participants will continue receiving the study treatment until they no longer benefit from the treatment and the disease progresses, or if any undue side effects develop. However, do remember that you may withdraw from the trial at any point in time if you wish to.

WHO WILL PAY FOR MY PARTICIPATION?

Some clinical trials in NCCS are funded by the SingHealth and NCCS research funds, government organisations and other research funding bodies, such as the National Medical Research Council (NMRC). Some trials are also sponsored by pharmaceutical companies. The costs of the drugs may be partially or fully covered. In some trials, the costs of blood tests, scans, consultations, transport and hospitalisation may also be covered. But these costs may not be covered in other trials. This will be explained to you in greater detail during the informed consent process.

3. PHASE I CLINICAL TRIALS IN NCCS

WHAT IS MEANT BY 'DOSE ESCALATION'?

Since most of the drugs in Phase I trials are being tested for the first time in humans, there is a need to determine their safe dose levels and side effects. Phase I trials are usually designed as dose escalation studies. These trials typically enrol patients in small groups, with each successive group receiving progressively increasing dose(s) of the investigational treatment. The purpose of increasing the doses of the investigational drugs is to determine the safety and tolerability of the drugs at different dose levels in patients.

If you are one of the first patients to take part in a Phase I trial, you will be given a small amount of the drug(s). This amount is usually based on animal studies. If the first group of patients does not have any severe side effects, the next group of patients in the same trial will receive a higher dose of the same drug, and this goes on until the team finds the maximum tolerated dose (MTD). This will determine the recommended doses for further testing in Phase II and III trials.

Depending on how well you tolerate the drug or drug combination, Phase I trial protocols usually have guidelines on how to adjust doses in the event of side effects. Some Phase I trials may also permit an increase in the dose(s) of the drug or drug combination if you are benefiting from the treatment.

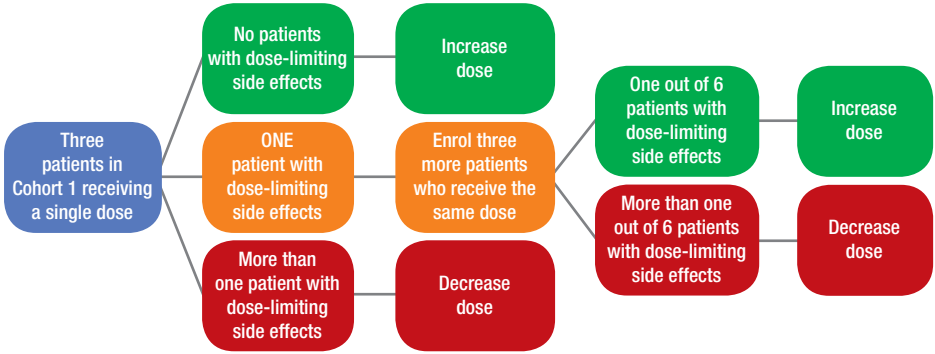


Figure 5. An example of dose escalation scheme in Phase I trials. This is an illustration of the "3+3 design", which is commonly used in Phase I cancer clinical trials.

Increasingly, Phase I trials may also include dose expansion cohorts after the MTD has been determined. This is to confirm the MTD and better characterise the safety profile of the study treatment before proceeding on with a Phase II study.

WHO CAN PARTICIPATE IN THESE TRIALS?

Phase I trials usually allow patients with different tumour types to take part. In some instances, where the study drug may have a very specific action, only patients with a selected type of tumour(s) may be allowed to participate. As drugs in Phase I trials are being tested for the first time in patients, there is a risk of unexpected side effects. Therefore, patients who participate in these trials have to be of good performance status and have good organ function.

WHAT SHOULD I EXPECT DURING A PHASE I TRIAL?

- Close monitoring & follow-up

  Participants of Phase I trials will be very closely monitored by the study team to ensure your safety. In general, you will need to come for weekly follow-up visits, especially in the initial stages of the trial. The frequency of clinical visits varies according to the nature of the trial. There may also be 1 or 2 overnight stays in hospital for safety monitoring during the early part of the treatment.

- Blood tests and scans

  For most Phase I trials, blood tests and scans are part of the procedures that you will have to undergo. These are essential for us to monitor how you are responding to the treatment and ensure your safety. In addition, blood samples may also be collected at specific time points for research purposes.

  In general, Phase I trials would often involve more frequent blood taking and scans compared to Phase II and III trials. These are essential for us to monitor how you are responding to the treatment and ensure your safety.

- Close communication with the study team

  There will be a research coordinator as well as the study doctor who will be looking after you, whom you can contact if you have any questions.

HOW LONG DOES A PHASE I TRIAL USUALLY LAST?

Phase I trials overall may take serveral years to complete. However, this may vary from one trial to another. Phase I trial participants generally continue receiving the study treatment until their disease progresses, if they cannot tolerate the treatment or if they choose to stop.

WHO WILL OVERSEE MY MEDICAL CARE IN NCCS WHILE I AM ON A TRIAL?

In NCCS, we have a dedicated Phase I clinical trial team that comprises medical oncologists, scientists, clinical pharmacologists, clinical research coordinators and nurses who will oversee your medical care throughout the trial. They will ensure that the study is conducted in accordance with the trial protocol, address the questions you may have and attend to any adverse events you may experience during the trial.

WHAT HAPPENS AFTER A TRIAL? WHAT WILL MY FOLLOW-UP CARE BE LIKE?

You will be referred back to your primary oncologist for treatment and follow-up care after the trial.

WHAT ARE THE RISKS AND BENEFITS OF PARTICIPATING IN A PHASE I TRIAL?

Phase I trials represent the earliest phase of clinical trial of a particular investigational treatment in cancer patients. If the treatment works, you may be one of the first to benefit. Some of your medical care and tests may also be paid for by the trial sponsor. In addition, you may be able to help future cancer patients by contributing to medical research.

However, we do not know for sure that the study treatment will be effective against your cancer. Also, there is a risk that you may experience side effects, some of which may be unexpected. This is especially true for Phase I trials, where we do not know much about the side effects of the treatment. Having said that, do note that these treatments have all been carefully researched in the laboratory before they are given to trial participants. We will monitor your condition closely, and will respond promptly to manage any adverse effects to minimise the risk to you. If you experience any side effects that you deem worrisome, please get in touch with the trial team as soon as possible.

4. LATE PHASE CLINICAL TRIALS

PHASE II TRIALS

If the investigational treatment successfully passes through a Phase I trial, it will then move on to a Phase II trial. In contrast to Phase I trials, the main aim of Phase II trials is to find out how well the investigational treatment works against a particular cancer type. In addition, doctors will also continue to monitor for side effects to provide additional data about the side effects of the study treatment and ensure participants' safety.

Although these treatments have been tested in Phase I trials prior to the conduct of Phase II trials, drugs in Phase II trials may not necessarily be safer or more effective against your cancer. While data from Phase I trials may allow us to understand the side effects of the investigational treatment better, you may still experience side effects that the trial doctors may not know about or expect.

PHASE III TRIALS

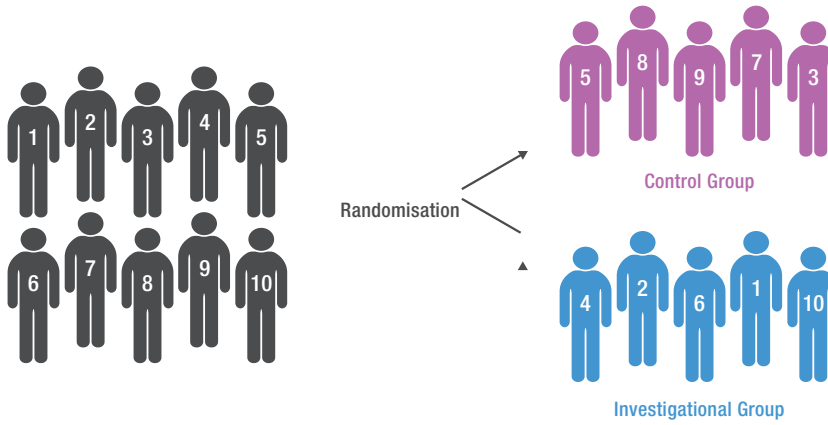
Phase III trials compare new treatments or approaches with the current standard of treatment. These trials provide the key evidence for safety and effectiveness of an investigational treatment that the regulatory agencies will consider in deciding whether or not to approve the drug or drug combination.

Phase III trials are usually large in scale, involving several hundred to several thousand patients and may take several years to complete as majority of trials of any phase are likely to be multi-centre.

5. FREQUENTLY ASKED QUESTIONS (FAQ)

HOW ARE CLINICAL TRIALS DESIGNED?

For Phase I and some Phase II trials, since the primary aim is to investigate the safety and effectiveness of the study treatment, all trial participants will be receiving the study treatment and they will be informed of the treatment they are receiving. For some Phase II and almost all Phase III trials, participants are randomly assigned to groups that receive different treatments.



For randomised cancer clinical trials, the treatment groups usually comprise the investigational group and the group receiving the current standard therapy. The process of randomisation is usually facilitated by a computer, which randomly allocates patients to the different treatment groups. The purpose of randomising the recipients of the different treatments is to ensure that each participant has a pre-defined chance of being treated with either the investigational treatment or the standard therapy, thus reducing bias.

For a clinical trial that includes randomisation, it is important that you understand that neither you nor the team doctors can choose the treatment which you will receive. Additionally, in cases where the trials are "double-blinded", neither you nor the doctor will know which treatment group you are in until the end of the clinical trial.

WHAT IS THE DIFFERENCE BETWEEN STANDARD TREATMENT AND EXPERIMENTAL TREATMENT?

Standard treatments are those that are widely accepted by medical experts as the "best proven" treatments for a specific cancer type. These treatments have been established to be useful in fighting the particular cancer type through previous clinical trials. On the other hand, experimental treatments are treatments that investigators believe have the potential to improve current standard treatments. If clinical trials demonstrate that an experimental treatment brings about improved outcomes compared to the current standard treatment, the experimental treatment will then become the new standard treatment or 'standard of care'.

WHY DO I NEED TO HAVE A BIOPSY DONE?

For some trials, we may have to obtain biopsy specimens from your tumour tissues to analyse for specific abnormalities (this is known as molecular screening) or to see if the trial drug is having an effect on the tumour. The testing of tumour samples will allow us to be more accurate in determining if there are any genetic changes or "mutations" in the tumour which may be treated with a particular drug.

Sometimes, the biopsy may be required to determine if you are eligible for a clinical trial because certain trials only enrol patients with certain tumour characteristics. The evaluation of tumour samples through biopsies will allow us to be more accurate in determining whether the tumour is sensitive to the drug being tested in a particular clinical trial. There may also be a need for you to undergo a repeat biopsy if we are unable to retrieve suitable samples from your previous biopsy or operation. This is because the cancer cells may have changed over time (evolved) and it is important to ensure that you are receiving the treatment that is most suitable for your present condition.

Biopsies do carry a risk of discomfort, bleeding, infection and can sometimes be serious. The risks will depend on which part of your body the biopsy is taken from. Your doctor will discuss with you if a biopsy is needed, where it will be taken from and the number of biopsies that will be done. Biopsies will not be taken if it is not safe to do so.

WHAT IS 'MOLECULAR SCREENING'?

In cancer, changes in the genes ("brains of the cell") may result in altered proteins that disrupt the way that cells normally communicate with each other. This may eventually lead to uncontrolled growth of the cancer cells. In the past, cancer cells were categorised based on the way they appear under the microscope. Today, we are able to identify changes in the genes and other signals in cancer cells and further capture this information as "molecular signatures". This has improved understanding of the processes that drive cancer growth which has led to the development of molecular-targeted drugs that specifically target these abnormal processes. For trials involving these targeted agents, molecular screening can help to detect the presence of these "targets" in your cancer cells.

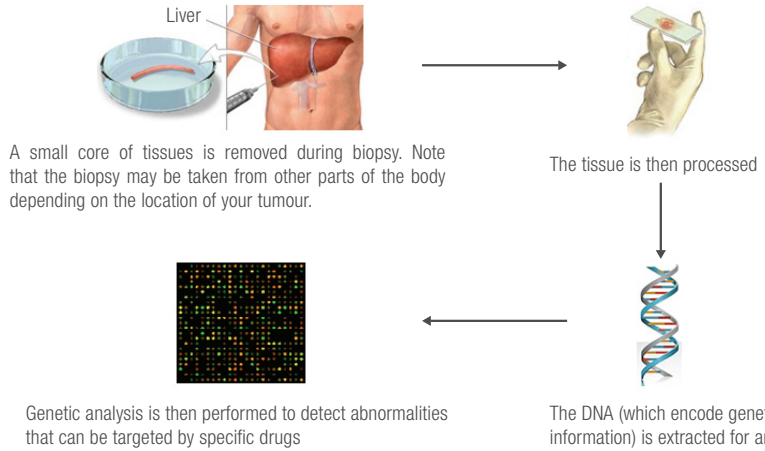


Figure 6. An illustration of molecular screening of tumour specimens. (Sources: 1) http://health.kernan.org/imagepages/9353.htm. 2) http://www.eugenegi.com/procedures/liver-biopsy. 3) http://commons.wikimedia.org/wiki/File:DNA_microarray.svg).

WHAT ARE THE CHANCES OF THE STUDY TREATMENT BEING EFFECTIVE?

Due to the limited number of patients that can be recruited in Phase I trials, the effectiveness of the trial drug is not known. There is no guarantee that you will have a positive response with the experimental treatment or that you will not experience any side effects. However, prior to clinical testing in patients, extensive testing would have been done in the laboratory and on animal models to show that the experimental drugs may be beneficial in humans.

WHO CAN I CONTACT FOR QUESTIONS RELATING TO A TRIAL?

You may discuss with your doctor and the clinical research coordinators if you have any further questions.

NOTES

For more information on cancer, please call the

Cancer Helpline at Tel: 6225 5655
or email cancerhelpline@nccs.com.sg

MONDAYS - FRIDAYS : 8.30am to 5.30pm

SATURDAYS, SUNDAYS & PUBLIC HOLIDAYS : CLOSED (Please leave a message. We will get back to you on the next working day. For urgent matters, please seek urgent medical attention.)

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