

Clinical Trials and Research Studies

Patient information

Helping solve the skin cancer problem

After receiving a diagnosis of melanoma or non-melanoma skin cancer, you may be offered participation in a clinical trial. Clinical trials are conducted to help find better ways to prevent, screen, diagnose or treat a disease or to improve the quality of life of those who have this disease.

Clinical research at MIA

Clinical research started at Melanoma Institute Australia (MIA), formerly known as the Sydney Melanoma Unit, in the late 1960s. Since then, the large number of patients willing to participate in clinical trials has enabled MIA—and these patients—to make major contributions to many critically important clinical research findings. Several of these findings have resulted in the approval of medications to treat and prevent melanoma, as well as changing management of melanoma patients in Australia and throughout the world.

Unfortunately, many questions remain unanswered, and therefore clinical trials continue at MIA to help get to **our mission of zero deaths from melanoma**. Our current trials focus on determining the value of new immunotherapy and targeted therapy medications, surgery, radiotherapy and quality of life studies.

What are clinical trials?

Clinical trials are conducted worldwide by universities, hospitals, research institutions and drug companies. They vary in size from single centre studies to studies conducted at multiple centres in several countries. Teams of doctors, nurses, scientists, research assistants, data managers, pharmacists and other health professionals supervise participants throughout the trial process.

Trials are very strictly regulated and each one follows an approved, carefully controlled protocol. A protocol is a study plan that ensures the safety of participants in the trial and is designed to answer specific research questions.

Before the trial can begin, the protocol must be reviewed and approved by a Human Research Ethics Committee (HREC), made up of medical and scientific professionals and members of the public. It is the HREC's responsibility to ensure the protection of the rights, safety and well-being of people involved in a trial.

Translational research

You may also be asked to consider providing samples of your blood or tumour for translational research. Translational research aims to bring together scientific research in the laboratory with clinical research that has direct impact on the wellbeing of patients. Our translational research focuses on looking for markers in blood and melanoma tissue that may be used to predict response to drug treatments and determining why some patients respond well to treatment while other patients do not experience the same benefits.



Informed consent

Choosing to participate in a clinical trial is an important decision. Informed consent is the process of gathering and understanding the information about a trial to make an informed decision on whether you want to be a part of the trial.

You will always receive written information, including the 'Patient Information Sheet' and the 'Consent Form', for the specific trial you are being asked to consider. You will be given ample time to discuss the trial with your doctor and trial staff. The Patient Information Sheet includes details about the trial such as the aim, procedures involved, duration, alternative treatment options, risks, benefits, costs and key contact details.



When you feel that you are fully informed, you can decide whether to participate or not. If you choose to participate you will be required to sign the Consent Form. A signed copy of this form will be given to you to take home. Informed consent is also a continuing process throughout the trial providing participants with any new information that may affect their continuation in the trial.

During the trial you and/or your doctor may decide it no longer suits your needs. You can withdraw from trial participation at any time without concern that it will affect your future care.

Trial types and phases

There are different types of clinical trials.

- **Treatment trials** are the most common type of trial, testing experimental treatments, new drug combinations or new approaches to surgery or radiotherapy.
- **Prevention trials** test new ways to prevent disease in people who have never had the disease or to prevent the disease from returning in those previously treated.
- **Screening trials** test the best way to detect a disease.
- **Diagnostic trials** are conducted to find better tests or procedures for diagnosing a disease.
- **Quality of Life trials (or Supportive Care trials)** explore ways to improve the comfort and quality of life for people with a disease.

Phases

New treatments must go through three phases of testing before there is sufficient evidence the treatments are safe and effective, and can then be approved by the Therapeutic Goods Administration (TGA) for use by all patients.

- **A Phase I trial** is the first time a new treatment is tested on humans. Safety and dosage ranges are tested and side effects identified. Only a small number of people are involved.
- **A Phase II trial** involves a more detailed evaluation of effectiveness and safety. A larger number of people are required for a Phase II trial.
- **A Phase III trial** involves formal comparison of the experimental treatment with the current standard treatment to work out which is better. This requires a much larger group of participants to be involved.

People who consent to a Phase III trial are randomly selected to receive the experimental treatment or the current standard treatment. In a Phase III trial, random treatment allocation is necessary so that each group has a similar mix of people to ensure the treatments can be compared without bias. Neither you nor the trial staff can choose which treatment you will receive. If the trial involves a new drug, it is possible that you and the trial staff might not be told which treatment group you are in; this is known as blinding and is used to prevent bias.

In some trials experimental treatments are compared with a placebo, an inactive pill, liquid or powder that has no treatment value. You will be informed if the trial you are considering is blinded or placebo controlled. If it is required for your safety or future care, 'unblinding' can be done to allow you and your treatment team to know what treatment you were on. The decision to 'unblind' your treatment allocation will be made by your treating doctor if it is required for your safety or future care.



Why should I join a trial?

People choose to participate in trials for different reasons. There are benefits and risks involved in joining any trial.

Benefits:

- You have an active role in your own healthcare.
- You can access new research treatments.
- You may experience a treatment benefit.
- You will possibly help others, including your own children and grandchildren, by contributing to medical research.
- You will experience increased personalised care and attention.
- You will increase your knowledge about melanoma and its treatment.
- You may find some of your treatment costs are covered.

Risks:

- The experimental treatment may not be effective for you.
- You may experience side effects of the experimental treatment.
- The trial may require more of your time and attention, including more trips to the study site, more treatments and more investigations.

Please remember that clinical trial participation is voluntary. You may withdraw from a trial at any time without affecting your ongoing care at MIA. Speak with the clinical trial staff if you require further information.

Please note: The information in this brochure is of a general nature and should not replace the advice of healthcare professionals. All care has been taken to ensure the information presented here is accurate at the time of publishing (July 2021).