Learn about **clinical studies**

from people who have been there

This brochure aims to help you learn about clinical studies through the experiences of study participants – and experts too.

It isn't everything you need to know about clinical studies, but we hope it inspires you to find out more.

Why be part of a clinical study?

Improvements in health care do not just happen. Quality clinical research is essential to ensure improvements in preventing and treating disease are based on high-quality evidence.

This research would not be possible without the people who take part in clinical studies.

NSW GOVERNMENT

Meet our panel:

Carol Vleeskens
Consumer advocate and study participant

"My involvement in clinical studies allows me to give back to researchers and clinicians who have helped me with my musculoskeletal conditions."

Dr Emily Saurman
Senior Research Fellow and ethics committee member

"Clinical studies are an opportunity to have a voice in health care and change things for the better. There are excellent processes to ensure that studies are safe and ethical."

David Napier
Study participant

"If you're prepared to commit time and energy to being involved in clinical studies, you can achieve the great satisfaction of contributing to health research."

Cindy Kok
Study participant

"Taking part in a research study gave me the personal satisfaction of knowing the information would help other mothers."

Dr Abhijit Pal
Medical oncologist and cancer researcher

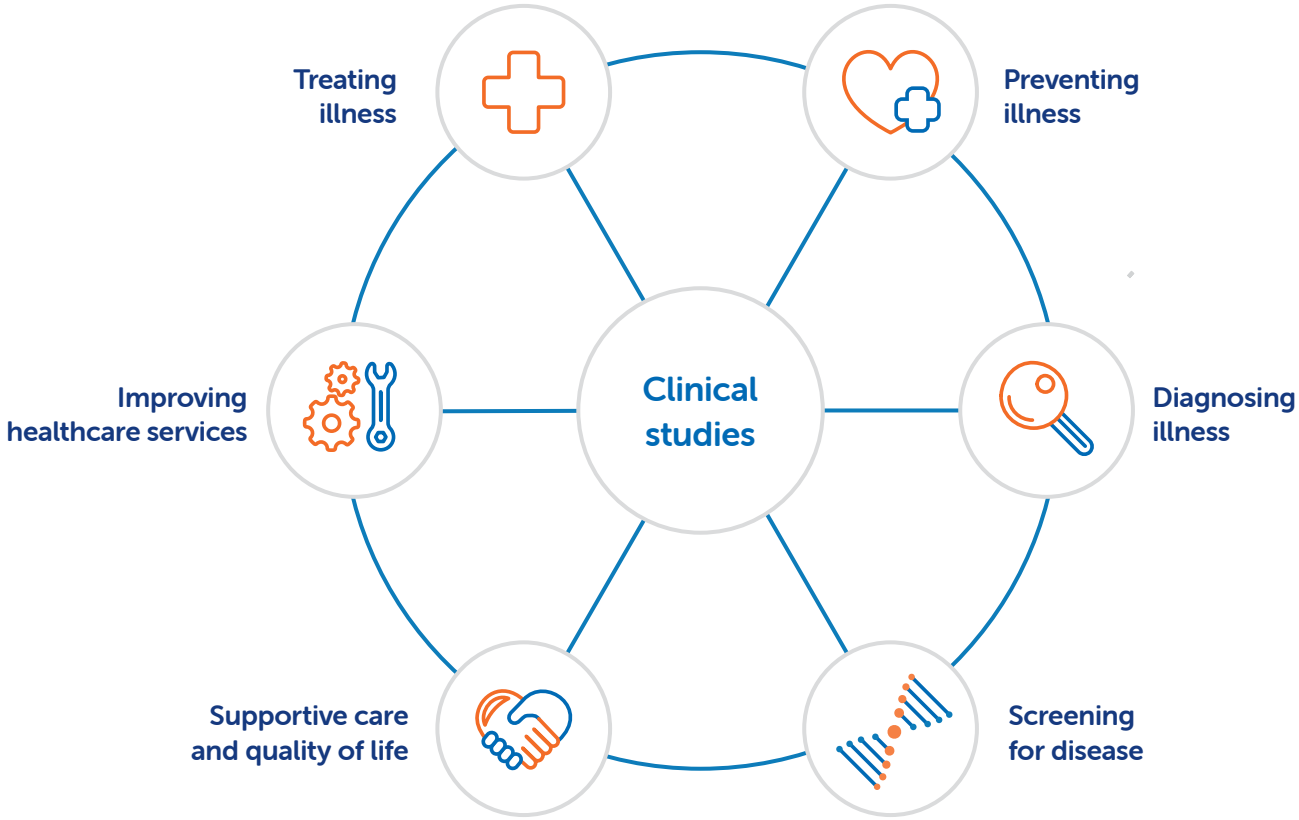
"Clinical studies offer the cutting edge in medicine – the treatments of tomorrow delivered today. Some of the best outcomes I've seen have been in patients who participated in clinical studies."

What are clinical studies?

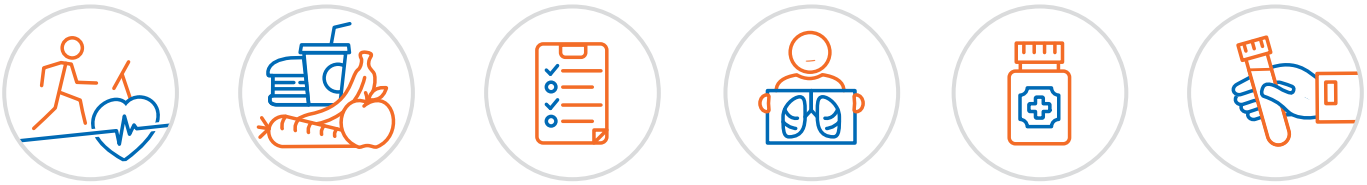
Clinical studies are research investigations that test new ways to prevent, diagnose and treat health and medical conditions.

Some people think that clinical studies only test new drugs – but they are much more than that.

Types of clinical studies



What are some of the different ways to take part in a clinical study?



Having physical tests

Making lifestyle changes

Completing questionnaires

Having scans

Taking medication

Donating samples

Weighing it up

All clinical studies have benefits and risks.

If you're thinking about participating in a clinical study, here are some of the benefits and risks to consider.

Benefits

The clinical study may improve how you and your healthcare team manage your condition.

"In a mental health study, I learnt to use techniques, like relaxation, to manage stress and emotions. I was able to open up about my feelings in ways I had never done before."

– David Napier

There will likely be closer monitoring of your condition, care and treatment.

"Health care is excellent in Australia. However, in a clinical study, there are even more resources, staffing and capacity. The care received in a clinical study is usually greater than in an ordinary setting."

– Dr Abhijit Pal

You may learn more about your health condition.

"In the dementia study, I learnt a lot about my eating habits and my memory. I am now more aware of the ageing process and of the possibility of dementia. It's improved my physical health as well."

– Carol Vleeskens

Risks

You may experience side effects or be impacted by taking part in the study.

"One of the tests showed my daughter was at higher risk of developing autism. I wasn't prepared for that but, by taking part in the study, I was able to learn more and discuss the findings with my GP. It highlighted how studies can impact you and the importance of asking questions."

– Cindy Kok

You may need extra treatments, tests and hospital visits than with standard treatments.

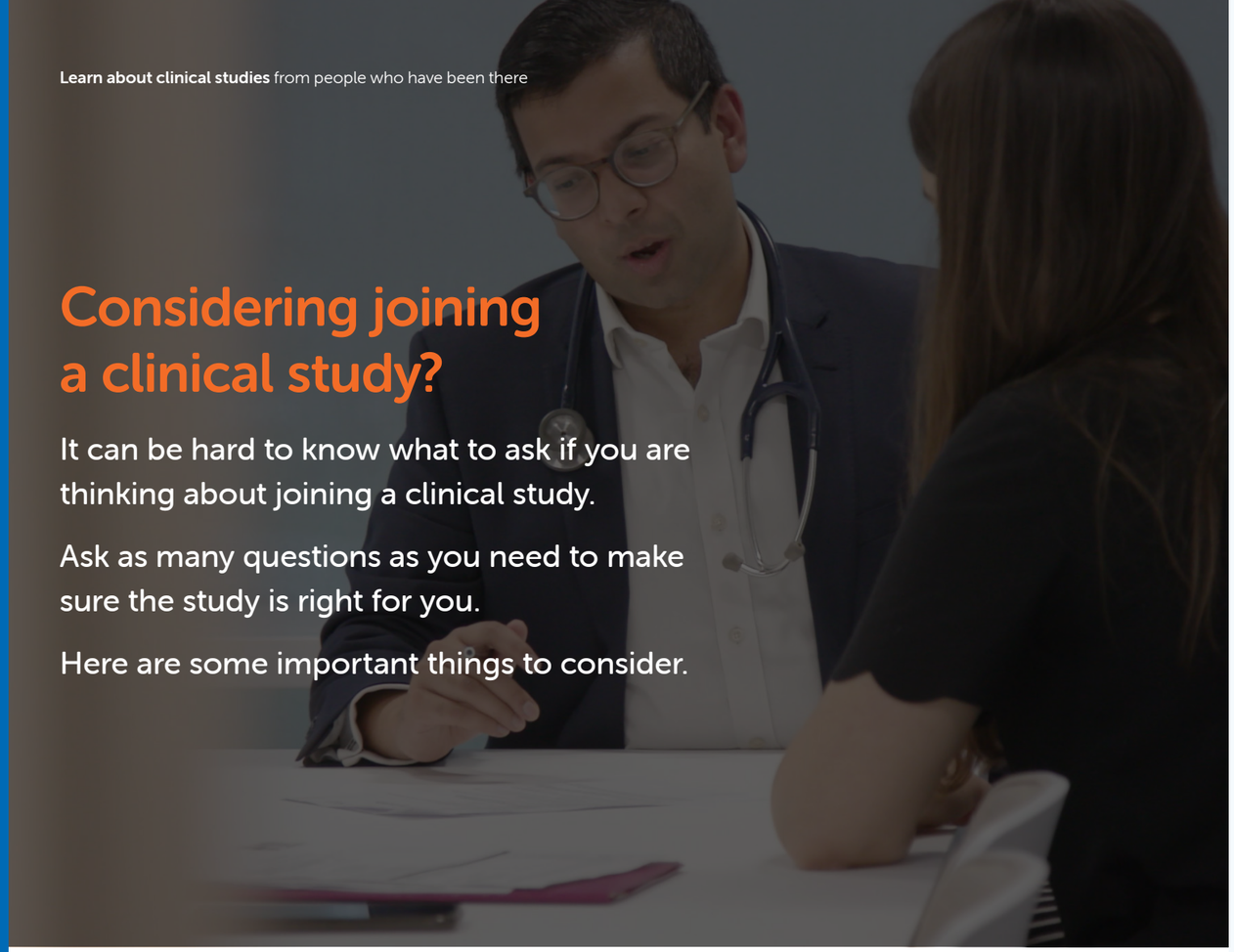
"I made ten trips to Sydney University over three months to visit the professor involved in the study. I also did daily practice and reporting. It was a big commitment, but it was worth it as I learnt so much about how to manage stress and anxiety."

– David Napier

There are different levels of risk depending on the type of clinical study.

"Risk is part of life and risk is definitely part of research. Some clinical studies, such as those involving your data, are low risk, but some are higher risk, where you may take a drug that is not used in routine practice. Researchers will talk with you about the risks of participating in a study. Ultimately, the decision is yours."

– Dr Abhijit Pal



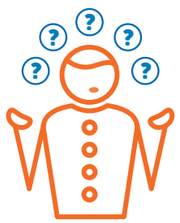
Considering joining a clinical study?

It can be hard to know what to ask if you are thinking about joining a clinical study.

Ask as many questions as you need to make sure the study is right for you.

Here are some important things to consider.

Daily life



How might this study affect my daily life?

"Clinical studies take more time than usual care because it's not just about providing care, it's about learning more. This means researchers and doctors need to do more tests or see you more often."

– Dr Abhijit Pal

What do people do on a study?

"People can be involved in clinical studies in many ways. It may be filling out a form, completing a questionnaire, being involved in a group discussion, doing an interview, or giving blood."

– Carol Vleeskens

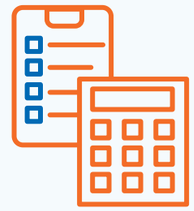
What happens if I experience side effects from the study?

"The biggest fear of patients can be developing serious side effects while on the study. As a clinician, I will do everything to minimise and manage side effects. The patient comes first."

– Dr Abhijit Pal

Learn about clinical studies from people who have been there

Approvals and finances



Who has approved the clinical study and how do I know that it is safe?

"All clinical studies need to be reviewed and approved by ethics committees to ensure they are safe and well run. Ethics committees are made up of people from diverse backgrounds who provide in-depth perspectives and challenge researchers to think about how they can best conduct clinical studies."

– Dr Emily Saurman

Do I have to pay to take part in the study?

"If you are interested in being involved in a study, it's important to ask if you will be reimbursed for your costs, such as transport and childcare. You might be offered reimbursement for your time."

– Carol Vleeskens

Who is conducting and paying for this study?

"You'll receive a participant information sheet, which will tell you who is running the study and paying for it."

– Carol Vleeskens

After the study

How will I find out about study results?

"If you decide to be involved in a study, ask the researchers how long it's going to take and how you will hear about the results."

– Carol Vleeskens

What happens after the study?

"After taking part in a clinical study, your health care will continue as normal. The study team will discuss with you any relevant findings from the study, and if needed speak with your regular clinicians about any treatment you received during the study or any changes to your healthcare management."

– Dr Abhijit Pal

What is informed consent?

- Informed consent is a process that tells you what the study involves and what is expected of you.
- It is a conversation that aims to empower you to consider taking part in a clinical study.
- Consumers often work with researchers to design participant information sheets and consent forms.

Questions about informed consent

Why do I have to provide informed consent to take part in a clinical study?

"The informed consent process is important because it ensures you understand what is happening in the study and why, and what is being asked of you. You can use this information to decide if you want to take part in the study."

– Carol Vleeskens

What happens to information about me once I have given informed consent?

"All clinical studies need to follow privacy laws. Your information must be kept secure and confidential. When the study results are shared in reports or publications, your identity will be protected."

– Dr Emily Saurman

Can I withdraw consent?

"If you consent to be part of a study, you can withdraw at any time. Informed consent is an ongoing conversation and it's part of Good Clinical Practice, which is the code that governs all research."

– Dr Abhijit Pal

Find out more

Ask your doctor, nurse or a healthcare professional about clinical studies that might be available for you to participate in. Scan the QR code for more resources.

Australian Clinical Trials Alliance

CT:IQ Clinical Trials: Thinking Smarter

To learn more please visit www.medicalresearch.nsw.gov.au/clinical-trials