

# What are Breast Cancer Clinical Trials?





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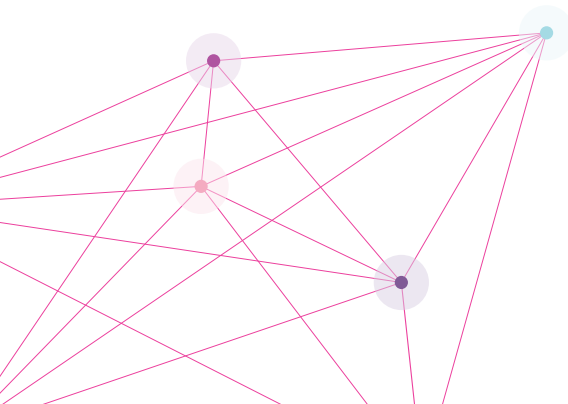
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## Who We Are

**Breast Cancer Trials (BCT) is a group of world-leading breast cancer doctors and researchers based in Australia and New Zealand, with a commitment to finding new and better treatments and prevention strategies for every person affected by breast cancer.**

Founded in 1978, BCT conducts a multicentre national and international clinical trials research program which involves more than 926 researchers in 116 institutions across Australia and New Zealand. More than 17,169 people have participated in our clinical trials.

Our research involves a unique collaboration between researchers, clinical trial participants and supporters, which has improved the treatment of breast cancer, led to changes in the way breast cancer is managed and has saved millions of lives through international research collaboration.





**926**

Researchers



**116**

Participating  
Institutions



**17,169**

Clinical Trial  
Participants

Professor Sherene Loi is the Study Chair of the Neo-N and DIAmOND clinical trials and is on the Breast Cancer Trials Board of Directors.



## What Are Clinical Trials?

**Clinical trials are an essential part of our health system and are necessary to find out if new treatments are more effective than those currently accepted as the best available standard of care. They are designed to answer a scientific question and compare whether a new treatment is better than the current treatment.**

All new breast cancer treatments or prevention strategies must be rigorously tested through the clinical trials process before they are made widely available to the community.

Professor Bruce Mann is the Director of Research at BCT.



## Types of Clinical Trials

There are many types of clinical trials for the prevention and treatment of breast cancer and studies which aim to improve a patient's quality of life.

The **BCT research** program encompasses more than 85 clinical trials in various stages of recruitment, follow-up, analysis and publication. The research program is coordinated at our headquarters in Newcastle, NSW.

**Prevention** clinical trials are designed to test new strategies to prevent breast cancer for people who have never had the disease but are at high risk. For example; those with a genetic mutation such as BRCA1 or BRCA2.

**Treatment** clinical trials are designed to find out which treatments are the most effective and to test new treatments to see if they are better at improving outcomes for patients compared to the current standard treatments available.

**Quality of life** assessments pay special attention to the breast cancer patient's feelings about the impact and side effects of treatment and aim to improve the overall experience of the patients who receive these treatments in the future.

## The Breast MRI Evaluation Study

**The Breast MRI Study aims to find out if having a breast MRI (Magnetic Resonance Imaging) after being diagnosed with breast cancer might change treatment plans and how this might affect patient outcomes.**

Laura McCambridge was just 31 years old when she was diagnosed with invasive breast carcinoma, after finding a lump in her breast. She underwent months of treatment, including a lumpectomy, four cycles of chemotherapy, a mastectomy and hormone therapy.

Laura works as a project manager coordinating clinical trials in stroke and dementia at the Florey Institute of Neuroscience and Mental Health in Melbourne, and knowing the importance of clinical trials research, she was eager to participate in one herself. She heard about the Breast MRI Evaluation Study from her surgeon.

“I have experienced quite a few benefits from being involved with the study. I had more one on one discussions with my surgeon, so I kind of felt like I had an extra layer of care, an extra layer of oversight by being involved with the study.”

“Research doesn’t always have direct benefits to the participant, but what you are almost always guaranteed is to have an involvement in contributing to the advancement of knowledge in the area and I think that’s really valuable and actually quite a cool thing to be able to say that you’ve been a part of.”





Laura McCambridge is a participant in the Breast MRI Evaluation Study.

## Phases of a Clinical Trial

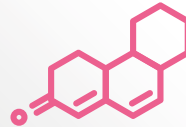
### PHASE 1



**Phase 1** clinical trials are conducted to test a new treatment for the first time in a small group of people (up to 50) to evaluate the safety and side effects of a new treatment or intervention. Phase 1 trials are not randomised.

If the treatment is proven successful in phase 1, it is moved to a **phase 2** study and tested in a larger group of people (several hundred) to determine how effective it is and to further evaluate its safety.

### PHASE 2



### PHASE 3



**Phase 3** clinical trials compare new treatments with the best currently available treatment (standard treatment) and study the efficacy of a treatment or intervention in large groups of people (several hundred to several thousand). It looks at which treatments work best for the disease, how the treatment affects quality of life and provides the opportunity to learn more about side effects. A phase 3 clinical trial could compare the standard treatment with a new treatment, a different dose of the same treatment or a different way of giving the same treatment.

A **phase 4** clinical trial is conducted after the new treatment or intervention has been approved and entered routine clinical practice. A phase 4 clinical trial aims to learn more about the side effects and safety of the new treatment, the long-term risks and benefits of the new treatment and how effective the treatment is when used in the general population over a longer period of time.

### PHASE 4





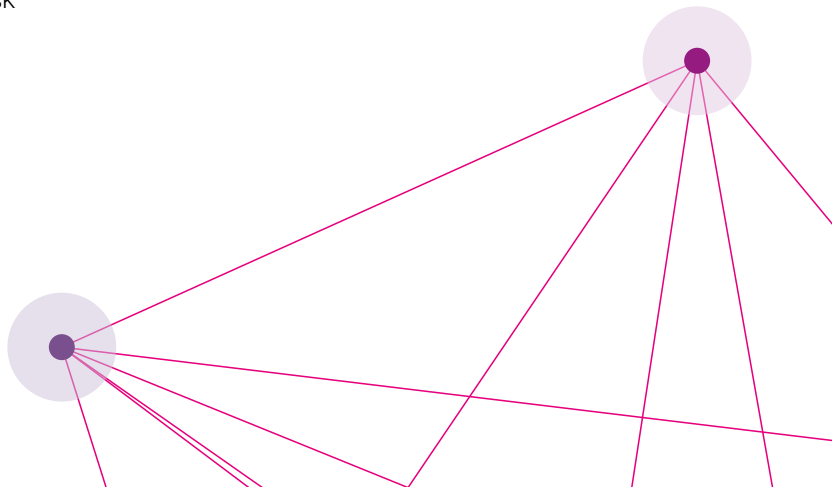
Professor Sarah-Jane Dawson is the Study Chair of the CAPTURE clinical trial.

## Why Participate in a Clinical Trial?

People take part in clinical trials for many reasons:

- They may be able to access a new treatment before it is routinely available as standard treatment for all breast cancer patients
- The treatments offered on a clinical trial include the best current standard treatment, compared with a new treatment which earlier research shows may be better
- Participating in a clinical trial helps to advance medical knowledge
- The results of current clinical trials may help improve treatments and outcomes for future women diagnosed with breast cancer or who are at risk

Clinical trial participants may be monitored more closely than patients who receive standard treatment and their treatment is rigorously documented. There are usually questionnaires to complete regarding the participant's feelings or reactions to the treatment. This careful follow up means that the outcomes of the clinical trial are the result of accurate and detailed information which is then published in peer reviewed scientific journals.



## Samantha's Experience on a Breast Cancer Clinical Trial

**At least one in 400 women in the developed world carries the hereditary BRCA1 gene mutation. This mutation is associated with approximately 70% risk of developing breast cancer and 40% risk of developing ovarian cancer over the course of a lifetime.**

Currently, many women with the BRCA1 gene mutation undertake life changing preventative measures for breast cancer, including the surgical removal of their breasts. The BRCA-P clinical trial hopes to offer these women a better prevention option.

Samantha was only 21 years old when she found out she carried the BRCA1 gene mutation, after inheriting the genetic mutation from her mother, who was diagnosed with breast cancer when Samantha was 12 years old.

The BRCA-P clinical trial is a randomised, double-blind, placebo-controlled study, which means participants and their study doctor, do not know if they are receiving the trial drug Denosumab or a placebo.

A placebo is a treatment that looks just like the active medication but has no effect.

Though Samantha had a 50/50 chance of receiving the placebo drug, she said the benefits of participating in the study far outweighed the possibility she may not receive the trial drug.

“You're getting the screening, you're getting the support, you're getting your questions answered, and that was something truly less invasive than a double mastectomy.”

Samantha hopes her participation in the BRCA-P clinical trial and her openness in discussing this participation, will benefit women now and in the future.





Samantha Weeks is a participant in the BRCA-P clinical trial.

## Are Clinical Trials Safe?

**The guiding document for the conduct of a clinical trial is called a protocol. Clinical trial protocols are written by experienced clinicians and a team of experts in breast cancer treatment, translational research and trials coordination. All clinical trials conducted by Breast Cancer Trials are monitored by our Scientific Advisory Committee.**

The clinical trial protocol outlines the reason for doing the study, who may participate, the treatments and tests involved, when these will be done and why. The protocol must be approved by an independent panel of scientists, medical professionals and consumers, called an ethics committee. The progress of the clinical trial and the safety of clinical trial participants is carefully reviewed and monitored by an Independent Data and Safety Monitoring Committee and by the ethics committee responsible for approving the clinical trial.

Before joining a clinical trial, potential participants must understand why the clinical trial is being conducted, the potential risks and benefits and what their involvement would include. The decision to participate is made on the basis of information provided to the patient by their treating doctor. Written information about the clinical trial will also be provided. Both the doctor and the potential participant must be satisfied that all information about the clinical trial is understood and a statement to this effect is signed by both parties. This process is called "obtaining informed consent to participate in a clinical trial".



Dr Nicholas Zdenkowski is  
the Chair of BCT's Scientific  
Advisory Committee.

## How Can I Take Part in a Clinical Trial?

**If you would like to participate in a breast cancer clinical trial, you should discuss this with your treating doctor.**

A list of our current clinical trials that are open for participation is available on our website at [breastcancertrials.org.au/current-clinical-trials](http://breastcancertrials.org.au/current-clinical-trials).

Information about all breast cancer clinical trials conducted in Australia and New Zealand can be found on the Australian New Zealand Clinical Trials Registry website at [www.anzctr.org.au](http://www.anzctr.org.au).









The members and friends of Maitland Ladies Golf have been supporting Breast Cancer Trials since 1997, raising over \$60,000 for our research.



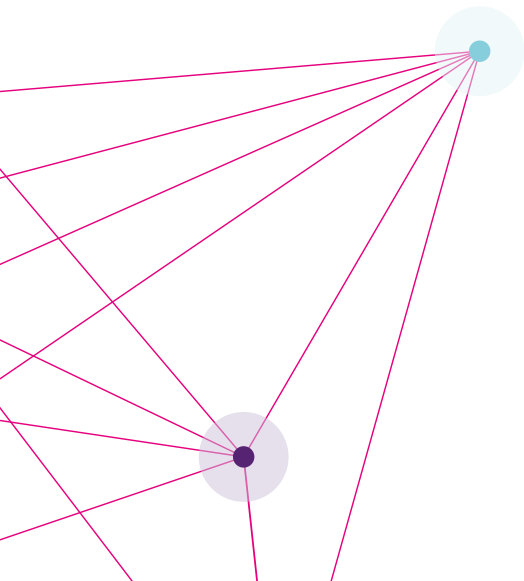
## How You Can Help

**Exciting medical discoveries need clinical trials if they are to change the lives of people diagnosed with breast cancer. Financial support for Breast Cancer Trials is critical to ensuring better treatments, prevention and a future filled with hope for all women.**

There are many ways you can connect with Breast Cancer Trials and show your support. You might like to make an automated, monthly donation; or make a gift for your mother in time for Mother's Day. Making a gift in memory of a loved one is a special way you can honour their memory.

Or what about 'getting active' by participating in a sporting event, or holding a function and seeking support from your family, friends and work colleagues? And if you love golf, our Tee Off for Breast Cancer Trials may be the event for you.

To learn more about how you can become a supporter, please visit [www.breastcancertrials.org.au](http://www.breastcancertrials.org.au).



## Useful Websites

### Australia:

**Australian Clinical Trials**

[australianclinicaltrials.gov.au](http://australianclinicaltrials.gov.au)

**Australian New Zealand Clinical Trials Registry**

[anzctr.org.au](http://anzctr.org.au)

**Breast Cancer Trials**

[breastcancertrials.org.au](http://breastcancertrials.org.au)

**Breast Cancer Network Australia**

[bcna.org.au](http://bcna.org.au)

**BreastScreen Australia**

[cancerscreening.gov.au](http://cancerscreening.gov.au)

**Cancer Australia**

[canceraustralia.gov.au](http://canceraustralia.gov.au)

**Cancer Council Australia**

[cancer.org.au](http://cancer.org.au)

**Clinical Oncological Society of Australia (COSA)**

[cosa.org.au](http://cosa.org.au)

**National Health and Medical Research Council (NHMRC)**

[nhmrc.gov.au](http://nhmrc.gov.au)

**Therapeutic Goods Administration**

[tga.gov.au](http://tga.gov.au)

### New Zealand:

**Australian New Zealand Clinical Trials Registry**

[anzctr.org.au](http://anzctr.org.au)

**Breast Cancer Aotearoa**

[timetoscreen.nz/breast-screening/](http://timetoscreen.nz/breast-screening/)

**Breast Cancer Trials**

[Breastcancertrials.org.au](http://Breastcancertrials.org.au)

**Cancer Society of New Zealand**

[Cancernz.org.nz](http://Cancernz.org.nz)

**Cancer Trials New Zealand**

[cancertrialsnz.ac.nz](http://cancertrialsnz.ac.nz)

**New Zealand Association of Clinical Research**

[nzacres.org.nz](http://nzacres.org.nz)

**New Zealand Ministry of Health**

[health.govt.nz](http://health.govt.nz)

### International:

**Clinicaltrials.gov**

[Clinicaltrials.gov](http://Clinicaltrials.gov)

**National Cancer Institute, United States**

[cancer.gov](http://cancer.gov)

**EU Clinical Trials Register (EU-CTR)**

[Clinicaltrialsregister.eu](http://Clinicaltrialsregister.eu)



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