

# What are Breast Cancer Clinical Trials?









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## Who We Are

**Breast Cancer Trials (BCT) is one of the world's leading breast cancer research organisations, dedicated to finding new and better treatments and prevention strategies for people affected by this disease.**

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, patient advocates, clinical trial participants and supporters, which has improved the treatment of breast cancer, led to changes in the way breast cancer is managed and have saved millions of lives through research collaboration.

Together we are grounded and defined by one simple belief: We can and we will find new and better treatments and prevention strategies for every person affected by breast cancer that saves lives today, tomorrow and forever.





**116**

Participating  
Institutions



**926**

Researchers



**17,169**

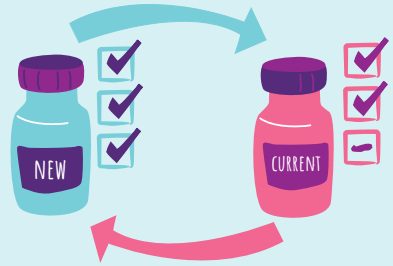
Clinical Trial  
Participants



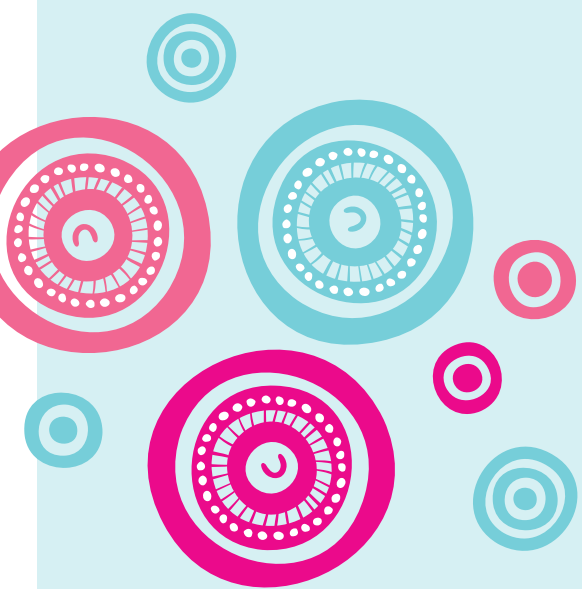
Professor Sherene Loi is the Study Chair of the Neo-N and DIAmOND clinical trials and is on the Breast Cancer Trials Board of Directors.

# What Are Clinical Trials?

Clinical trials compare whether new treatments work better and/or have less side-effects than current treatments.



All new treatments, prevention strategies and health plans are tested through the clinical trials process before they are given to people in the community.



## Types of Clinical Trials

**Prevention** clinical trials test new strategies to prevent breast cancer. They benefit people who have never had breast cancer but who are at high risk.



**Treatment** clinical trials find out which treatments are the most effective. New treatments are tested to see if they improve outcomes for patients compared to current treatments.



**Quality of life** assessments are also conducted to understand patients' feelings about the impact and side effects of treatment. They aim to improve the overall experience of patients who receive treatments in the future.





## Joy's Story

### **Proud Wailwen woman Joy Reid, known as Aunty Joy, describes herself as a breast cancer survivor.**

"I am one of the First People of this land and I am a sufferer and a survivor," she says.

Aunty Joy was diagnosed with stage four breast cancer in 2004. The treatment she received allowed her to continue living a full life, which includes advocating for those in her community to take early action in relation to their health.

"Women are the keepers of knowledge and the ones that keep the family together. Aboriginal and Torres Strait Islander society is matriarchal, but yet, we still don't give ourselves enough credit.

"We are strong black sisters, and we need to care for ourselves," she says.

Aunty Joy is passionate about educating those in her community to get screened regularly and participate in breast cancer clinical trials. She says by participating in research, we can help to protect future generations.

"It's not just about your own health. Participating in breast cancer clinical trials helps our daughters, granddaughters and other women.

"Breast cancer clinical trials are the reason my treatment worked and I am still here. If my cancer were to return, or get worse, I know there are more options for me now than when I was first diagnosed, thanks to clinical trials research," said Aunty Joy.







# Phases of a Clinical Trial

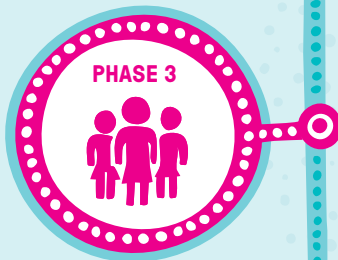


**Phase 1** Clinical trials are conducted with a small group of up to 50 people to test the safety and side-effects of a new treatment.

**Phase 2** If the treatment is successful in phase 1, a phase 2 study is conducted with a group of several hundred people to determine how effective it is and to further evaluate its safety.



**Phase 3** Clinical trials compare new treatments with the best currently available treatment in large groups of several hundred to several thousand people. It looks at which treatments work best, how they affect quality of life and what the side effects are. A phase 3 clinical trial may compare the standard treatment with a new treatment, a different dose of the same treatment or a different way of giving the same treatment.



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



## Why Participate in a Clinical Trial?

People participate in clinical trials for many reasons:

- To access a new treatment before it is available as a standard treatment;
- To compare the best current standard treatment with a new treatment;
- To advance medical knowledge;
- To play a more active role in their own health care;
- To help improve treatments and outcomes for those who are diagnosed with breast cancer in the future or who are at risk.

People who take part in a clinical trial are usually monitored more closely than others. It is important for any side-effects to be recorded including those relating to emotions and feelings. People have an opportunity to ask questions about their treatment and this extra attention often helps them feel well cared for and supported.



## Andrea's Story

### **Andrea Casey, a proud Aboriginal woman from Victoria, was diagnosed with breast cancer in 2012.**

Andrea was always aware of her risk, as her grandmother and two aunts also had breast cancer, and her grandmother's sister tragically passed away from the disease.

A year after her diagnosis, Andrea graduated with a Bachelor of Education. Instead of entering into teaching, she used her skills and experience to help her community understand the importance of cancer screening, encourage participation in breast cancer clinical trials and help empower Aboriginal women and men through education about their healthcare options.

Andrea says, "I am passionate about ensuring our people know about the screening programs and that we work to find culturally safe and appropriate ways for us to screen, as well as to educate Aboriginal people about the best treatments."

"Our outcomes are worse for many reasons, but one reason is that cancers are found later and are more advanced, so these cancers cannot be treated as easily or successfully unlike cancers that are found earlier."

Andrea is a proud advocate for BCT research and works to educate Aboriginal women and men about the importance of participating in clinical trials.

"I would like to say to our people, that taking part in a clinical trial is an important way for us to look after ourselves and for the generations coming after us."

"We can change the future for our women yet to be diagnosed."

"Early detection saves lives. Be screened and look after yourself. And get involved with clinical trials research, so that we can find the best treatments for our future generations," she says.







## Are Clinical Trials Safe?

**Clinical trials are guided by a document called the “protocol” setting out the rules, guidelines, and what the trial is about. It is written by a team of experts in cancer treatment, research, and trials coordination. All Breast Cancer Trials research is monitored by a Scientific Advisory Committee.**

The protocol outlines the reason for doing the study, who may participate, the treatments and tests, and when these will be done and why. It must be approved by an ethics committee which includes scientists, medical professionals and members of the community. The progress of the trial and the safety of participants is carefully reviewed and monitored by an Independent Data and Safety Monitoring Committee and the ethics committee.

Before joining a clinical trial, potential participants must understand why it is being conducted, the potential risks and benefits, and what their involvement will include. This information is provided to the patient by their treating doctor. Both the doctor and the potential participant must sign a statement declaring that all information is understood. This process is called ‘obtaining informed consent to participate in a clinical trial’.





## How Can I Participate 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 open clinical trials with BCT is available at [breastcancertrials.org.au/current-clinical-trials](https://breastcancertrials.org.au/current-clinical-trials).

Information about all breast cancer clinical trials in Australia and New Zealand is on the Australian New Zealand Clinical Trials Registry website at [anzctr.org.au](https://anzctr.org.au).

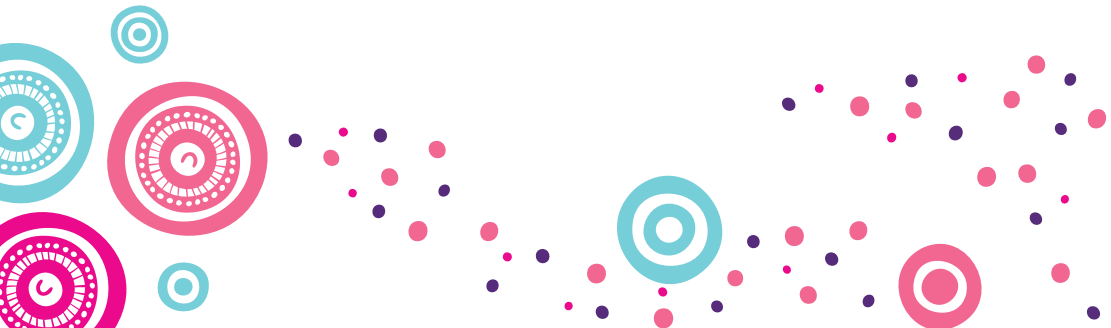
## Emma's Story

**Kamilaroi woman Emma McInnes was diagnosed with breast cancer in 2019 after finding a lump while getting ready for work. Instead of going to her shift, she went straight to her GP. She was only 29 years old.**

Throughout her treatment, Emma discovered she carried the BRCA2 gene mutation, which meant she was at a higher risk of developing breast cancer over her lifetime. The BRCA1 and BRCA2 gene mutations are passed down from your mother or father. If your parent has the mutation, there is a 50/50 chance it will be passed down to you.

As the mother of a teenage son, Emma says she supports BCT research to ensure the future health of her son, family and community is protected.

As someone who has benefited from clinical trials research, she encourages anyone who is offered a place on a trial to talk it through with family, friends, their GP, or community, and consider participating.







## Further Information

For more information about clinical trials, see the following 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 Coalition**

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

**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)

**Breast Cancer Research Trust**

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



The Artwork by Ngarrindjeri artist Jordan Lovegrove of Dreamtime Creative represents Breast Cancer Trials (BCT) working together to ensure every person affected by breast cancer has access to the best treatment and prevention strategies available. The three large meeting places in the centre represent trial participants, supporters, and researchers. The smaller meeting places throughout the artwork represent different people and communities affected by breast cancer. The patterns radiating from the centrepiece represent BCT working with these communities to improve and save the lives of people affected by breast cancer.





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