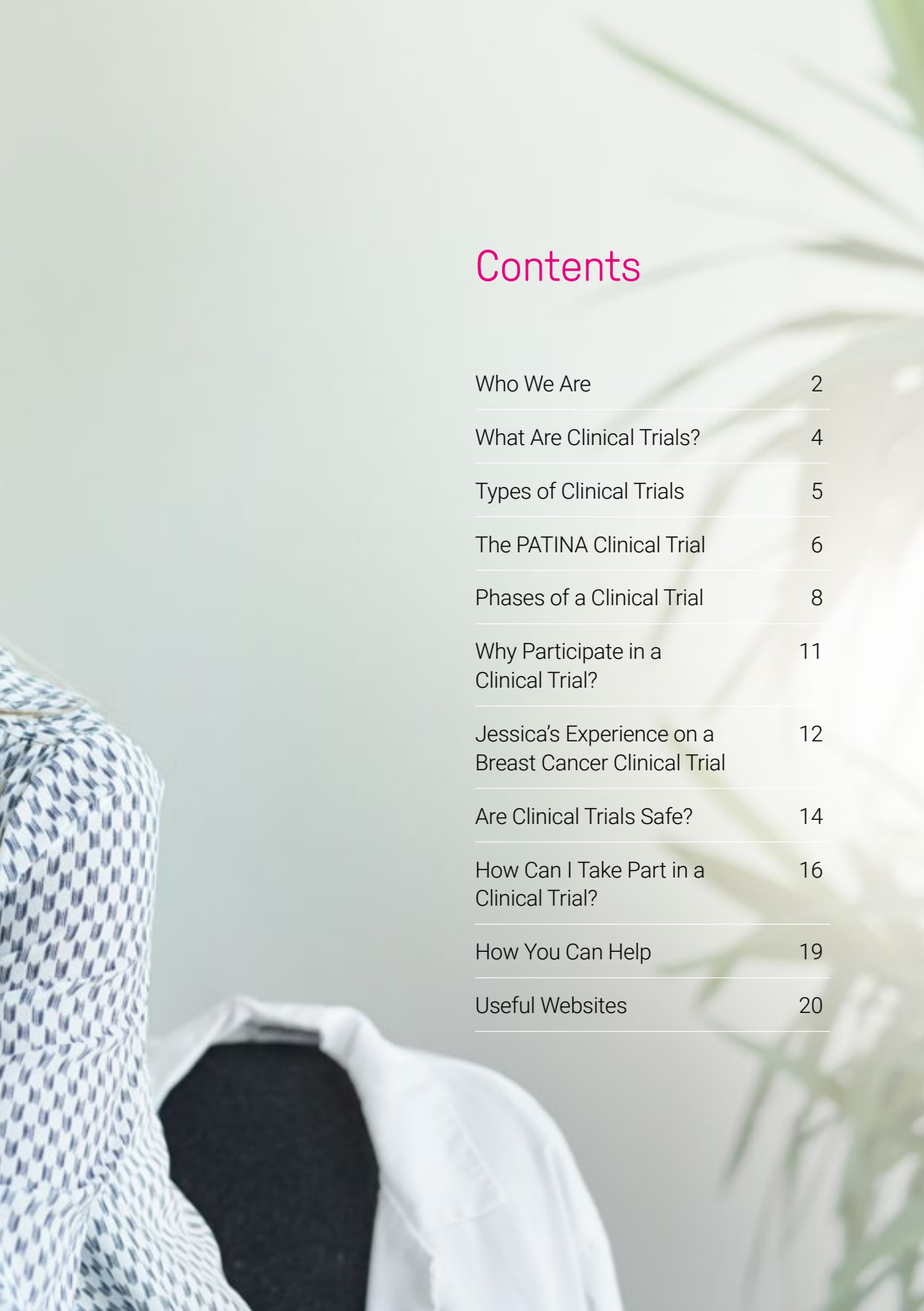
What are Breast Cancer Clinical Trials?

BREAST CANCER TRIALS

Contents

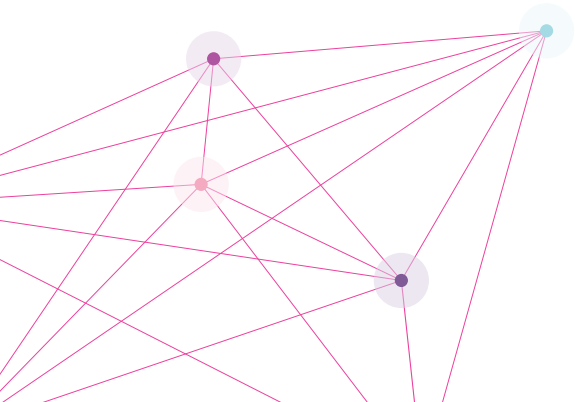


Who We Are

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 almost 800 researchers and more than 100 participating institutions, in Australia and New Zealand. More than 16,000 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.



800
Participating Institutions

100
Researchers

16,000
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.

Associate Professor Prue Francis is the Chair of BCT's Scientific Advisory Committee.

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 PATINA Clinical Trial

Despite significant improvements in the treatment of early stage breast cancer, approximately 30% of women experience metastatic disease relapse.

The PATINA clinical trial aims to find out if women and men with metastatic breast cancer could benefit from the addition of the drug palbociclib, when given in combination with anti-HER2 therapy (trastuzumab and pertuzumab) and endocrine therapy.

Brenda Theakstone (pictured) was diagnosed with metastatic breast cancer almost 20 years after her first breast cancer diagnosis. When she received her metastatic diagnosis, a surgeon advised her the only option would be palliative care and estimated she only had three months left to live. Devastated, Brenda and her husband Terry moved their 50th wedding anniversary forward, hoping to celebrate the occasion with family and friends in the time they had left together.

Around that time Brenda's oncologist recommended she participate in the PATINA clinical trial. Within a month of being on the trial, Brenda felt like she was getting her life back and three years later, she feels 'back to normal' and now describes herself as 'living with cancer'.

Although this outcome cannot be guaranteed for all trial participants, Brenda credits her participation on a clinical trial with giving her a future and giving hope to people with breast cancer.

To find out more about our open clinical trials, visit www.breastcancertrials.org.au/current-clinical-trials.

Brenda Theakstone is a participant in the PATINA clinical trial.

Phases of a Clinical Trial

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 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.

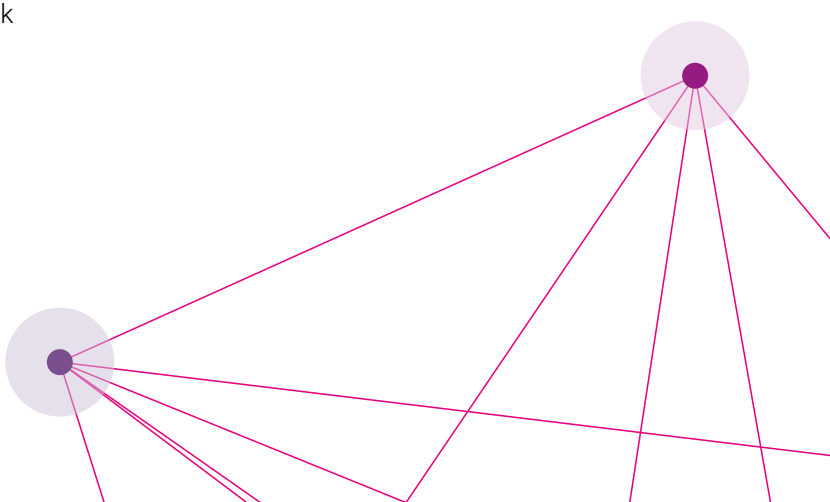
Professor Sarah-Jane Dawson is the
Study Chair of the CAPTURE clinical trial.

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.



Jessica's Experience on a Breast Cancer Clinical Trial

Jessica was only 33 years old and still breastfeeding her 10-month old son when she was diagnosed with breast cancer.

Jessica was vigilant about her breast health due to her strong family history. Her sister was diagnosed only eight weeks prior to Jessica, and her uncle and cousin have also received a breast cancer diagnosis. It was discovered she had the BRCA2 gene mutation and therefore had been at a higher risk of developing the disease.

Jessica's oncologist suggested she participate in the OlympiA clinical trial.

" After talking to my treatment team extensively, and reading the pamphlets and all the information, it became quite obvious that it was really important to do. "

OlympiA was open to patients with HER2 negative breast cancer who had an inherited BRCA1 or BRCA2 gene mutation. It tested if taking olaparib tablets twice a day for 12 months could reduce the risk of breast cancer coming back after all standard anticancer treatments have been completed.

Jessica's three children have a 50/50 chance of inheriting the BRCA2 gene mutation. She said this was a large part of why she decided to participate in a clinical trial.

" It didn't take me long to think, 'I've seen my cousin go through it, I've seen my sister go through it,' and when we were all diagnosed, we all had young kids. So you definitely think about the future of your kids and what you can do to make it easier or try to prevent this from happening to them. "

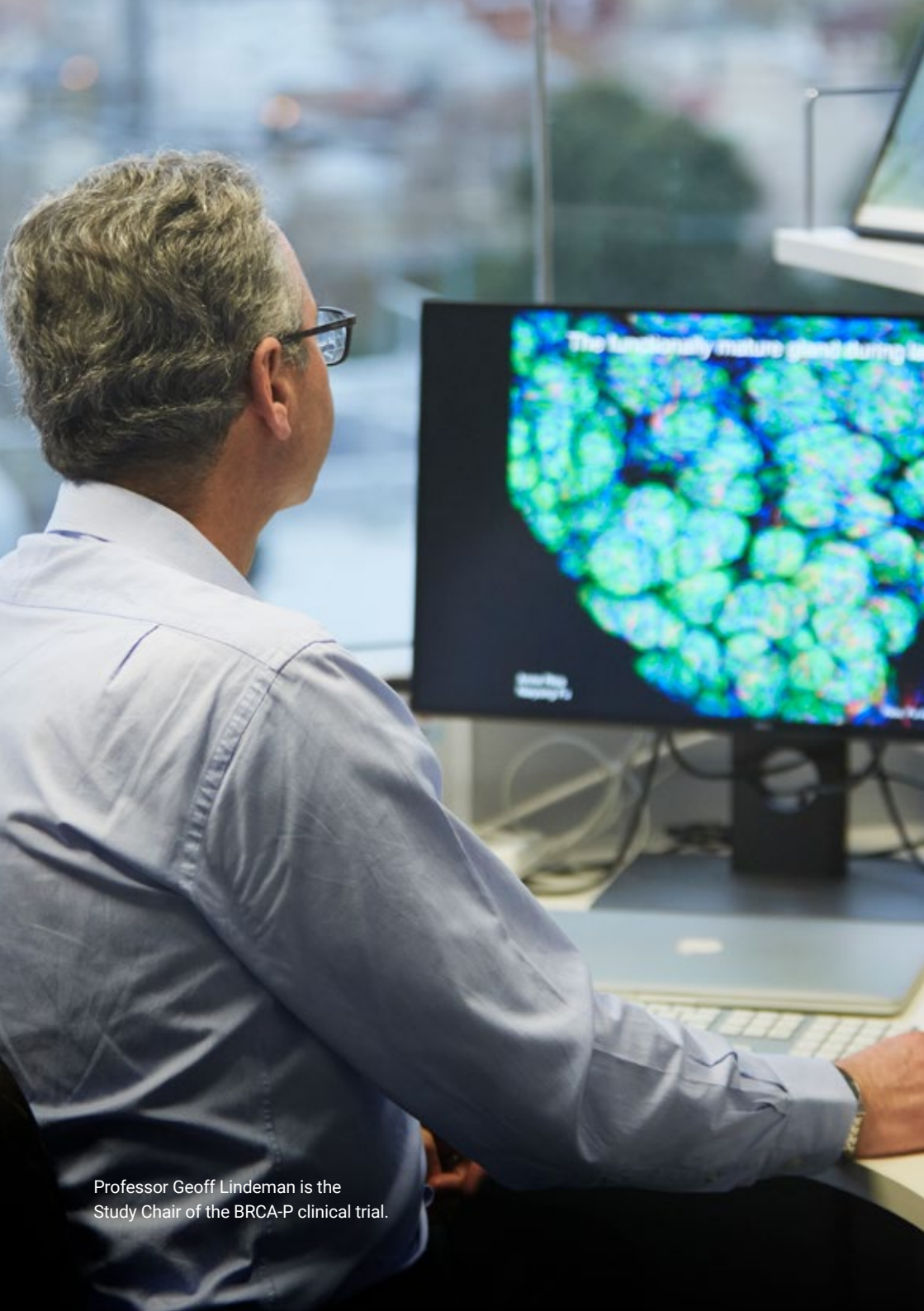
Jessica with her husband Tim and children Ashton, Harley and Kayla.

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”.



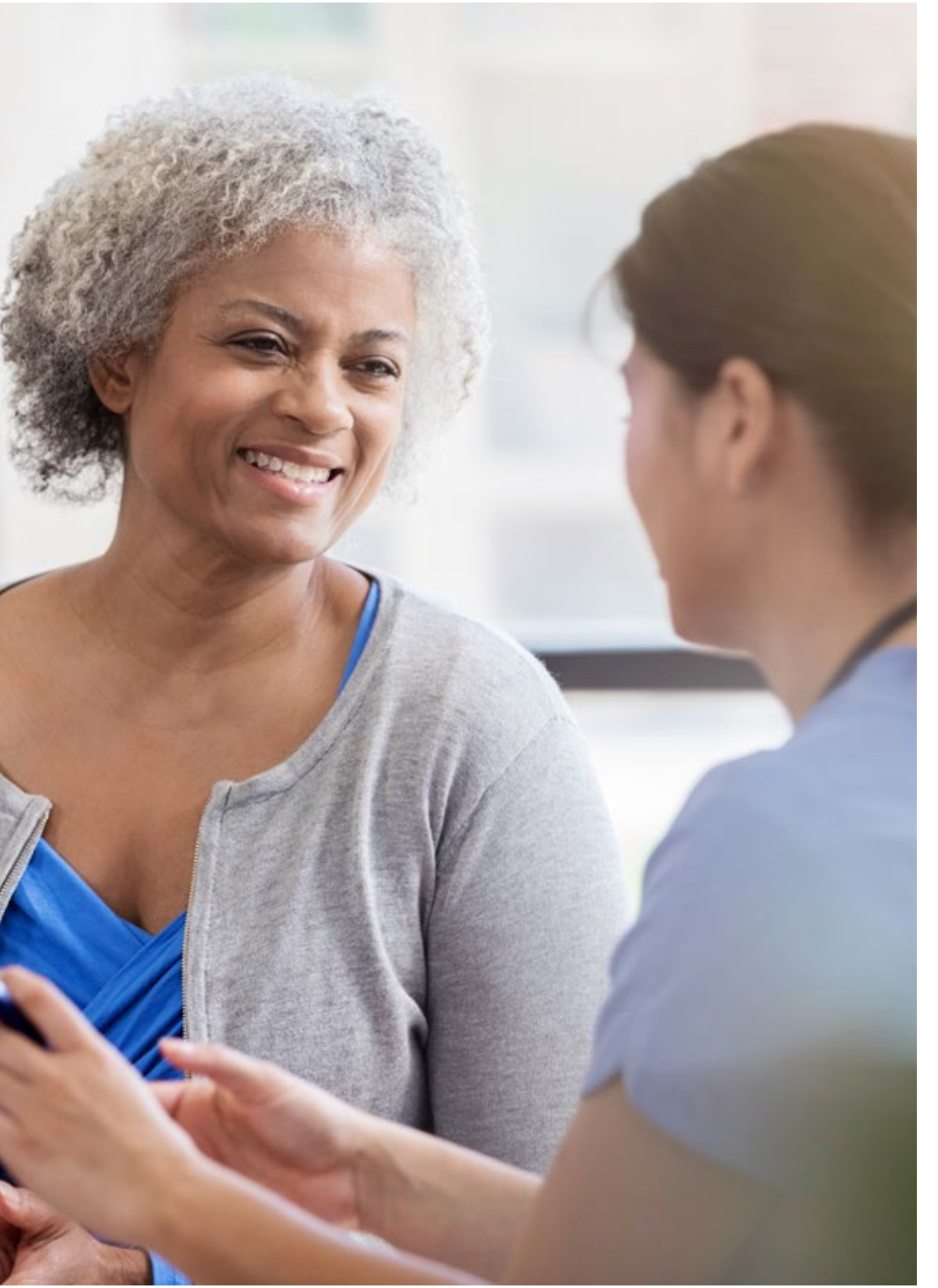
Professor Geoff Lindeman is the Study Chair of the BRCA-P clinical trial.

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.

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**.



The members and friends of Mona Vale Golf Club have been hosting Tee Off events since 2004, raising over $32,000 for our research.

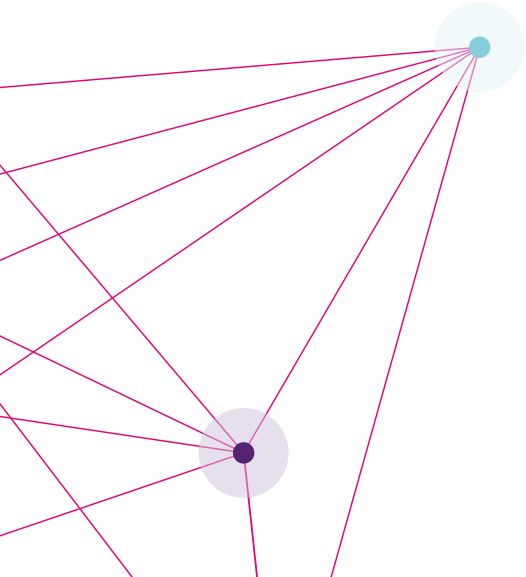
How You Can Help

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**.



Useful Websites

Australia:

Australian Clinical Trials
australianclinicaltrials.gov.au

Australian New Zealand Clinical Trials Registry
anzctr.org.au

Breast Cancer Trials
breastcancertrials.org.au

Breast Cancer Network Australia
bcna.org.au

BreastScreen Australia
cancerscreening.gov.au

Cancer Australia
canceraustralia.gov.au

Cancer Council Australia
cancer.org.au

Clinical Oncological Society of Australia (COSA)
cosa.org.au

National Health and Medical Research Council (NHMRC)
nhmrc.gov.au

Therapeutic Goods Administration
tga.gov.au

New Zealand:

Australian New Zealand Clinical Trials Registry
anzctr.org.au

Breast Cancer Aotearoa
timetoscreen.nz/breast-screening/

Breast Cancer Trials
Breastcancertrials.org.au

Cancer Society of New Zealand
Cancernz.org.nz

Cancer Trials New Zealand
cancertrialsnz.ac.nz

New Zealand Association of Clinical Research
nzacres.org.nz

New Zealand Ministry of Health
health.govt.nz

Waikato Breast Cancer Trust
brightasabutton.co.nz

International:

Clinicaltrials.gov
Clinicaltrials.gov

National Cancer Institute, United States
cancer.gov

EU Clinical Trials Register (EU-CTR)
Clinicaltrialsregister.eu

Trials Save Lives

BREAST CANCER TRIALS

PO Box 283
The Junction NSW 2291
Australia

P +61 2 4925 3022
F +61 2 4925 3068
E enquiries@bctrials.org.au

breastcancertrials.org.au

ABN 64 051 369 496

Follow Us

Follow Breast Cancer Trials on **Facebook**

Follow breastcancertrials on **Instagram**

Follow BCTrialsANZ on **Twitter**

Read the latest breast cancer news and stories on the **Breast Cancer Trials Research Blog** at breastcancertrials.org.au/research-blog

Listen and Subscribe to the **Breast Cancer Trials Podcast** on Apple Podcasts, Spotify, Google Podcasts or your favourite Podcast App. Just search for 'Breast Cancer Trials'.