

What are Breast Cancer Clinical Trials?





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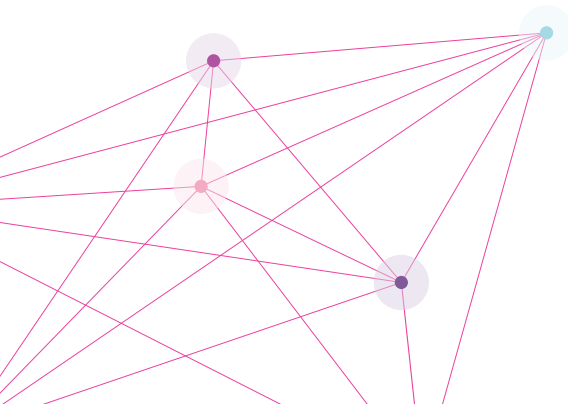
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Who We Are

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 1,000 researchers in 118 institutions across Australia and New Zealand. More than 17,900 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.





1,014

Researchers



118

Participating
Institutions



17,910

Clinical Trial
Participants

Dr Stephen Luen is the Study Chair
of the OLIO clinical trial.

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 95 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 OLIO Clinical Trial

Researchers are investigating a new treatment option for young women with the most common type of breast cancer.

The OLIO trial is investigating if the addition of either olaparib, or olaparib plus durvalumab, to neoadjuvant chemotherapy in young, pre-menopausal women with hormone receptor positive, HER2 negative early breast cancer that is homologous recombination deficient (HRD), improves breast cancer outcomes.

Prior to her breast cancer diagnosis, Rebecca Pickering had finally found a sense of calm after years of IVF treatment. Raising her two young daughters, Dottie and Daphne, and back at work full-time, life felt settled and “medical free” at last.

Following the birth of Dottie, Rebecca noticed some physical changes but initially attributed them to the hormone treatment she had received. When she raised her concerns with her doctor, tests confirmed her fears and she was diagnosed with breast cancer in 2024.

The weeks that followed were filled with scans and uncertainty as doctors worked to determine the stage of her cancer. Like many mothers, Rebecca’s greatest concern was for her children, particularly given her strong family history of breast cancer and the presence of the BRCA gene mutation.

Motivated by the potential benefits for her family and future generations, Rebecca chose to participate in the OLIO clinical trial. While treatment has been challenging, she believes clinical trials play a vital role in improving outcomes and quality of life for people affected by breast cancer.

“Anything that helps improve treatment plans, reduce side effects, or offer alternatives to chemotherapy is so important,” Rebecca says. “Research has already come so far, and I truly believe trials like OLIO will change the future for women.”



Rebecca Pickering, pictured with her family, is a participant in the OLIO clinical trial.

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

Phases of a Clinical Trial

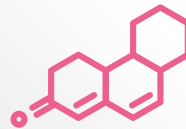
PHASE 1



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





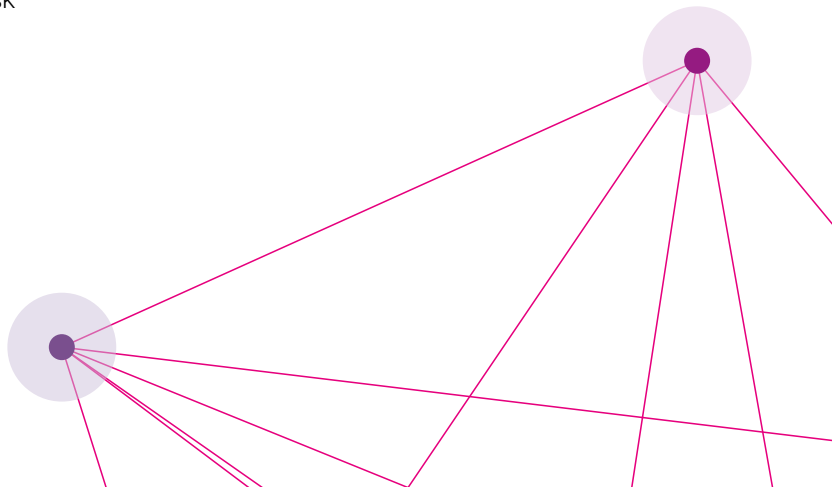
Professor Sarah-Jane Dawson is the Study Chair of the CAPTURE clinical trial.

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.



The CAMBRIA-2 Clinical Trial

The CAMBRIA-2 clinical trial aims to find out if giving a new endocrine therapy treatment known as a ‘selective oestrogen receptor degrader’ (SERD) is better at stopping cancer from coming back compared with the usual endocrine (hormone) treatments such as letrozole, anastrozole, exemestane or tamoxifen.

Wendy Rolls is a wife and mum of three daughters who enjoys golf, quilting, scrapbooking and spending time with her family.

In October 2023, Wendy found a small lump in her breast, and trusting her instincts, she decided to follow up with her doctor.

After several tests, a biopsy confirmed it was breast cancer, and Wendy’s world changed in an instant. She underwent a double mastectomy and focused on her recovery, all while continuing to manage the everyday responsibilities of family life and her busy schedule.

It was during this time that Wendy learned about the CAMBRIA-2 clinical trial, which is testing a new endocrine therapy treatment known as a ‘selective oestrogen receptor degrader’ (SERD) as a possible alternative to standard hormone therapy.

Like many women, Wendy was concerned about the long-term side effects of traditional treatments, including hot flushes, joint pain and fatigue, which can significantly impact quality of life.

Wendy decided to participate in the trial, not only for the possibility of a more tolerable treatment option, but also to contribute to research that could benefit future generations, including her daughters.

“This trial is looking at the current standard treatment drug that they have used on metastasised cancers, and assessing the benefit it has with early detection cancers, to see if it would keep the cancer from recurring. So, I think that’s a bonus.”

“And being on the trial, they monitor you more, you have more tests done, and they make sure that everything’s going along the way that they want it to.”



Wendy Rolls is a participant in the CAMBRIA-2 clinical trial.

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

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.

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 Maitland Ladies Golf have been supporting Breast Cancer Trials since 1997, raising **over \$75,000** for our research.

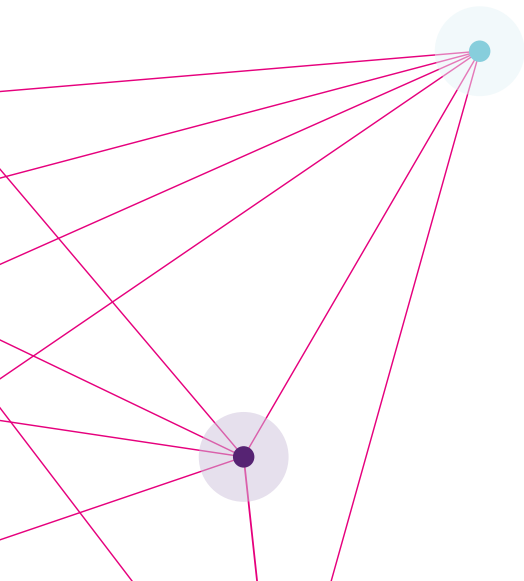
How You Can Help

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

Metastatic Breast Cancer Action Group

mbcc.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

International:

Clinicaltrials.gov

Clinicaltrials.gov

National Cancer Institute, United States

cancer.gov

EU Clinical Trials Register (EU-CTR)

Clinicaltrialsregister.eu



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