For more than 40 years, Breast Cancer Trials has conducted a breast cancer clinical trials research program for the treatment, prevention and cure of breast cancer.

There are almost 800 researchers, including oncologists, surgeons, study coordinators and nurses, who are involved in the conduct of the BCT research program.

The BCT’s research program brings together 102 institutions throughout Australia and New Zealand.

The BCT research program encompasses 83 clinical trials in various stages of recruitment, follow-up, analysis and publication.

We have contributed to more than 1,142 publications and our research has made a significant contribution to the advancement of medical knowledge, as well as improved treatments and prevention strategies.

We are very grateful to the many individuals, community groups, clubs and their members, businesses and corporate entities who make our research program possible with their generosity.

More than 15,700 women have participated in our breast cancer clinical trials since 1978.

We have contributed to more than 1,142 publications and our research has made a significant contribution to the advancement of medical knowledge, as well as improved treatments and prevention strategies.

We are very grateful to the many individuals, community groups, clubs and their members, businesses and corporate entities who make our research program possible with their generosity.
Our Research Saves Lives

Breast Cancer Trials is a group of world-leading breast cancer doctors and researchers based in Australia and New Zealand, with a commitment to exploring and finding better treatments and prevention strategies for people affected by breast cancer through clinical trials research.

For more than 40 years, we have conducted a breast cancer research program which has improved the treatment of this disease, led to changes in the way breast cancer is managed and has saved millions of lives through research collaboration.

Our research program involves multicentre national and international clinical trials, bringing together almost 800 researchers across 102 institutions throughout Australia and New Zealand. More than 15,700 women have participated in our research.

Clinical trials are an important 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.

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.

Our clinical trials involve a unique collaboration between our researchers, women who participate in our clinical trials and our supporters, who are all committed to exploring and finding better treatments for people affected by breast cancer, so that they can get on with living and loving their lives.

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.

Our Vision: Improving and saving the lives of people affected by breast cancer.

Our Mission: To conduct the highest quality clinical trials research that improves outcomes for people affected by breast cancer.

Case Study The HERA Clinical Trial

The HERA clinical trial was ground-breaking research for women with HER2 positive breast cancer, which showed that the drug trastuzumab (Herceptin) can significantly reduce the risk of breast cancer returning. The trial found that the administration of Herceptin following standard chemotherapy reduces the risk of the disease returning for women with early stage HER2 positive breast cancer by 46%.

The results of HERA provided new hope for women with HER2 positive breast cancer, which is a more aggressive form of the disease affecting approximately 20-30% of women with breast cancer. The study allowed for the use of a wide range of chemotherapy regimens before treatment with Herceptin, making the results relevant to many parts of the world. Following the results of the HERA clinical trial, Herceptin was listed on the PBS in Australia and Pharmac in New Zealand.

HERA was one of the largest adjuvant studies ever carried out among breast cancer patients and was conducted in Australia and New Zealand by Breast Cancer Trials, in collaboration with the International Breast Cancer Study Group and the Breast International Group. More than 5,000 women from 39 countries participated in the study worldwide, including 110 patients from Australia and New Zealand.

Dawn (left) was a participant in the HERA clinical trial, which has saved the lives of thousands of women in Australia and New Zealand like Nicole.
The Breast Cancer Trials Strategic Plan 2019–2023 builds on the successes of our past and current national and international collaborative trials activity, harnessing the expertise and passion of our multidisciplinary membership and collaborative partners. As we continue to lead a world-class breast cancer clinical trials agenda in Australia and New Zealand, we will expand the breadth of our research questions and our geographical footprint through a strategic approach to partnerships, resourcing and communication.

**Pillar 1: World-class Multidisciplinary Breast Cancer Clinical Trials**

Our diverse and innovative breast cancer clinical trials agenda is informed by clinical need and consumer priorities.

1.1 Leadership in breast cancer clinical trials

   Lead and proactively contribute to national and international breast cancer clinical trials relevant to the Australian and New Zealand population

1.2 Diverse clinical research focus

   Lead a diverse clinical research portfolio covering clinically relevant and consumer-centred research questions across the breast cancer continuum

1.3 Vibrant breast cancer clinical research community

   Foster a vibrant and engaged breast cancer research community with the capacity to conduct innovative breast cancer clinical trials

**Pillar 2: Sustainable Foundations for Research**

Our progressive breast cancer research agenda is underpinned by responsible management of financial and human resources, robust and transparent governance and use of technology for optimal benefit across the entire organisation.

2.1 Financial sustainability

   Enable achievement of our strategic goals through effective and responsible sourcing and transparent use of funds

2.2 Capacity and capability

   Create the optimal foundation for our research through the skills, capabilities and capacity of our governance and workforce

2.3 Harness technology

   Maximise the efficiency and effectiveness of clinical trial operations and organisational processes through effective use of technology

**Pillar 3: Driving Awareness and Influencing Change**

We are committed to driving awareness of our role and value, facilitating engagement and maximising the impact of our research through a strategic approach to communication, marketing and influencing.

3.1 Strategic communication and marketing

   Position BCT as the national and international leader in breast cancer research through strategic communication and marketing of our research agenda, activities, progress and outcomes

3.2 Key influencing

   Use our voice and influence to address barriers to clinical research and strengthen the translation of our research outcomes into practice

**Our Commitment**

Through our Strategic Plan we are committed to:

- Building and strengthening our strategic national and international partnerships to accelerate progress in/across breast cancer research
- Fostering and engaging our multidisciplinary membership to encourage active involvement in advancing our clinical trials agenda
- Ensuring the scientific rigour of our research activities
- Open and transparent communication about our goals, methods, progress and achievements
Breast Cancer Trials first began in 1978 and since then, we have grown to be the largest independent cancer clinical trials research group in Australia and New Zealand. Our clinical trials have led to improved treatments, have changed the way we manage breast cancer and have provided patients and their doctors with more treatment options.

We recently started two new world-first immunotherapy clinical trials that were developed by Breast Cancer Trials (BCT) researchers, called DIAmOND and CHARIOT. These trials aim to use the body’s own immune system to attack cancer cells and are investigating new immunotherapy treatments in two subtypes of breast cancer – HER2 positive and triple negative. Professor Sherene Loi is the Study Chair for these two exciting new areas of research.

With these new trials starting and several more scheduled to begin over the next 12 months, we are increasing our investment in our clinical trials research program and our investigation into new and improved treatments for different subtypes of breast cancer. Robust economic management of BCT’s assets and investment portfolio, together with the generosity of our corporate supporters and donors, means that BCT is in a strong position to not only manage our current clinical trials portfolio to completion but to also seek out new research opportunities.

Our 23-year corporate partnership with Avon, which has now ceased due to their closure in Australia, raised a staggering $11.7 million and helped BCT conduct life-saving research and improve treatments. We are also very grateful to the many thousands of individuals who generously donate to our research program, the corporate support from the Commonwealth Bank and The Australian Women’s Weekly, and the financial assistance we receive from Cancer Australia, the National Health and Medical Research Council and the Breast Cancer Research Foundation (USA). Our research would not be possible without this support.

The results of the TAILORx and SOFT/TEXT clinical trials were announced during the reporting period and are examples of how our research is improving treatments for people affected by breast cancer. The TAILORx clinical trial found that some women with the most common type of breast cancer may no longer need to have chemotherapy as part of their treatment when guided by a diagnostic test. And updated results from the SOFT and TEXT clinical trials found that adding ovarian suppression to tamoxifen reduces breast cancer recurrence and can improve survival in young breast cancer patients. BCT’s involvement in these international clinical trials demonstrates that we are providing opportunities for our members and clinical trial participants in Australia and New Zealand, to contribute to game-changing research that may benefit thousands of women with breast cancer in our region.

We celebrated our 40th anniversary as a research organisation last year and our 40th Annual Scientific Meeting (ASM) was held in July 2018 in Sydney, NSW, with a fantastic turnout. The ASM culminated with a special Conference Dinner, with a number of our founders, past Board Members, researchers and supporters in attendance. The success of BCT over our 40-year history has been largely due to collaboration and it was a wonderful event to bring everyone together in recognition of all that we have achieved as a research group.

BCT has a proud tradition of consumer involvement in the planning and conduct of clinical trials research and we established the Consumer Advisory Panel (CAP) in 1998. We would like to acknowledge the contributions made by Leonie Young, Cheryl Grant and Sheryl Fewster, who all completed their terms on CAP during the reporting period. Leonie was one of our original CAP members and was Chair of the committee from 2010 to 2018, Cheryl joined CAP in 2004, and Sheryl joined CAP in 2003 and is now the Chair of BCT’s Communications and Fundraising Committee. We sincerely thank them for their years of dedication and service.

Ms Leonie Young, Ms Sheryl Fewster and Ms Cheryl Grant completed their terms on the Consumer Advisory Panel.

It has been two years since BCT staff across our three departments of research, fundraising and business came together in one location at our headquarters in Newcastle, NSW. The move has been a great success, with greater interaction between departments and in the formation of one brand under one name. We recognise the hard work of our staff who manage a growing research portfolio, engage thousands of supporters and keep the business of BCT operating as an efficient and sustainable charity. Congratulations to Ingrid Laycock and Jane Murphy who celebrated 10-year and 5-year work anniversaries respectively.

This is an exciting time for our organisation, as we begin implementation of our Strategic Plan 2019-2023 which builds on our past successes over the last 40 years. The plan has three main pillars and goals: the conduct of world-class multidisciplinary breast cancer clinical trials; providing sustainable foundations for our research program which includes responsible financial management and transparent governance; and driving awareness of the BCT brand and positively influencing change. It’s an ambitious and exciting plan, that will help drive our activities over the next five years.

BCT has made a significant contribution to improved breast cancer survival rates and falling mortality rates over the last 40 years but we still have more work to do. This year, more than 19,500 people will be diagnosed with breast cancer in Australia and more than 3,500 in New Zealand. Our aim is to conduct the highest quality clinical trials research that will save lives, improve treatments and ultimately prevent breast cancer for every person who is diagnosed or at risk.
About Breast Cancer Trials

Breast Cancer Today

In 2019, approximately 19,371 + 164 PEOPLE will be diagnosed with breast cancer in Australia.

THAT'S 53 PEOPLE EVERYDAY

The risk of being diagnosed with breast cancer in Australia by the age 85 is 1 IN 7 FOR WOMEN

THAT'S 9 PEOPLE EVERYDAY

In New Zealand, the risk of being diagnosed with breast cancer by the age of 85 is 1 IN 675 FOR MEN

In Australia, it is estimated that 3,058 + 32 PEOPLE will die from breast cancer in 2019.

THAT’S 8 PEOPLE EVERYDAY

The number of people diagnosed with breast cancer is DECREASING

632 PEOPLE will die from breast cancer in New Zealand this year.

In New Zealand it is 88%

For New Zealand women, the risk of being diagnosed with breast cancer by the age of 85 is 1 IN 9

However the number of deaths from breast cancer is INCREASING

No. 1

In 2019, breast cancer is estimated to be the most commonly diagnosed cancer in Australia.

No. 2

Breast cancer is the 2nd most commonly diagnosed cancer in New Zealand.

Approximately 5–10%

Of breast cancers are due to a strong family history or genetic mutation, such as BRCA1 or BRCA2.
Our Research

The Year in Review

We experienced strong recruitment to the Breast Cancer Trials (BCT) research program during 2018–19, with the successful completion of accrual to three trials, and a positive start for newly opened trials during the period.

Our trials encompass a broad spectrum of breast cancer treatments, including surgery, radiotherapy and systemic therapy, in both early stage and metastatic settings in addition to breast cancer prevention.

Two BCT-initiated immunotherapy trials opened in the last year: CHARIOT and DIAmOND. Both trials are investigating a combination of two types of immunotherapy drugs for breast cancer.

The CHARIOT clinical trial is looking at treatment resistant-early stage triple negative breast cancer using nivolumab and ipilimumab. When the initial pre-operative chemotherapy has not effectively shrunk the cancer, the immunotherapy drugs are added to try to reduce the size of or eliminate the cancer entirely prior to surgery.

DIAmOND is for HER2 positive patients with metastatic breast cancer that is resistant to trastuzumab-based therapy, using durvalumab and tremelimumab with trastuzumab (and endocrine therapy if hormone receptor positive). Building on the results of the PANACEA trial, it is hoped that this combination will provide these patients with a higher chance of benefiting from immunotherapy. Both trials will provide early information about the effectiveness and safety of intensive immune modulation in breast cancer along with an extensive biological research program.

In a similar vein to DIAmOND, PATINA is for patients with metastatic HER2 positive breast cancer. However, PATINA also requires patients to be hormone receptor positive and in the first-line setting. Patients are randomised to receive endocrine therapy with or without palbociclib, with ongoing trastuzumab and pertuzumab, following completion of initial taxane chemotherapy. PATINA is based on the premise that palbociclib will augment the other three drugs to provide a longer duration of control over the breast cancer.

BCT local therapy trials POSNOC, PROSPECT and EXPERT are taking a de-escalation approach. The overarching aim is to find which patients might do well with less treatment, and thereby avoid some of the side effects and costs of those treatments that were not going to provide them with significant additional benefit. POSNOC is an international trial led by researchers in the United Kingdom, looking at whether patients who have cancer in one or two sentinel lymph nodes need further treatment or not. Patients on this trial are randomised to receive either: (1) further axillary treatment with surgery or radiotherapy, or (2) no further axillary treatment. PROSPECT, a BCT trial that has now reached its recruitment target, is using MRI to try to identify patients who may not need breast radiotherapy after breast conserving surgery for low risk early stage breast cancer.

EXPERT is another exciting BCT-led, de-escalation trial that has outpaced recruitment expectations, and will open internationally in the latter half of 2019. Like PROSPECT, it aims to assess if patients with low risk breast cancer can avoid radiotherapy after breast conserving surgery. It differs, however, in that it is a larger, randomised trial that uses the Prosigna® PAM50 genomic tumour test. The trial will determine the chance of breast cancer recurrence with and without radiotherapy, in women aged 50 and older, and may give some women the option of avoiding radiotherapy to the breast.

The neoadjuvant ELIMINATE trial completed recruitment with a total of 134 Australian patients of a total 5,795 worldwide - making us the third-highest recruiter globally. Patients with high risk early stage hormone receptor positive breast cancer were randomised to receive standard adjuvant endocrine therapy with or without palbociclib, a CDK4/6 cell cycle inhibitor. The results of the PARP inhibitor olaparib helps in preventing breast cancer recurrence. PARP inhibitors have shown promise in metastatic (advanced) breast cancer, and this trial looks at whether that translates into the early stage setting.

PALLAS is another large collaborative trial that completed recruitment during the reporting period with 434 Australian patients of a total 5,795 worldwide - making us the third-highest recruiter globally. Patients with high risk early stage breast cancer prevention whose BRCA gene mutation-related breast cancer. Patients without breast cancer prevention were randomised to receive standard adjuvant endocrine therapy with or without palbociclib, a CDK4/6 cell cycle inhibitor. The results of the PROSPECT trial that we previously participated in showed that palbociclib is effective in the metastatic breast cancer setting and (similar to OlympiA), the PALLAS trial hopes to show that palbociclib will help prevent breast cancer recurrence in early stages of the disease.

While the BCT trials described above focus on breast cancer outcomes such as breast cancer control, recurrence, or survival, many other relevant observations are recorded. These include patient-reported outcomes, looking at patients’ quality of life and symptoms; side effects and safety; and biological samples such as blood and tumour tissue. These additional outcomes ensure that even if the trial overall does not show an improvement in recurrence, progression or survival, we will still contribute to a better understanding of breast cancer, to inform future treatment and trials.
The Breast Cancer Trials research program involves almost 800 researchers in over 100 institutions throughout Australia and New Zealand. This partnership in multicentre national and international breast cancer clinical trials, together with collaborations with our international peers, has resulted in improved treatments for breast cancer, led to changes in the way we manage this disease and has saved millions of lives.

Validation of the significance and relevance of clinical trials research occurs through publication in peer-reviewed journals and by presentations at scientific meetings. During the 2018/19 reporting period, our research was presented in 50 publications or oral presentations, which included:

- 20 journals/e-publications
- 23 posters (12 x SABCS, 5 x ASCO, 3 x ESMO, 3 x MOGA)
- 1 oral presentation (ASCO)
- 4 editorials
- 1 commentary
- 1 letter

The following examples of our research were published in the reporting period.

**TAILORx: Finding the right patients for chemotherapy for early stage breast cancer**

Chemotherapy helps cure early stage breast cancer for selected women. However, a big question has been which women benefit most from receiving chemotherapy, and who would have been cured by surgery and hormone therapy alone. The TAILORx clinical trial used the Oncotype DX test, which examines 21 genes within the breast cancer to produce a Recurrence Score for patients with hormone receptor positive, lymph node negative breast cancer. The researchers showed that the 69% of women with an intermediate score could safely avoid having chemotherapy. These patients only needed hormone treatment. This study has changed practice around the world, allowing many patients to be spared the short and long-term side effects of chemotherapy.


**SOFT/TEXT: Ovarian suppression helps cure more young women**

Premenopausal women produce oestrogen from their ovaries, which can stimulate hormone (oestrogen) receptor positive breast cancer to grow. The SOFT and TEXT trials tested the use of a drug or surgery to stop the ovaries from making oestrogen, and thereby preventing breast cancer from returning. This report, after eight years of follow up showed that women who had ovarian suppression treatment in combination with either tamoxifen or exemestane were less likely to die or experience recurrence of breast cancer compared with those who received tamoxifen alone. This confirms an earlier report and provides greater confidence in the use of this strategy for premenopausal women. These trials have resulted in the cost of goserelin being subsidised for young women with hormone sensitive early stage breast cancer.


**IBCSG 23-01: Avoiding axillary clearance in early stage breast cancer**

Over the last few decades newer surgical and pathological techniques have made identification of axillary lymph nodes increasingly likely. However, it was not clear whether patients with only a very small amount of cancer in their sentinel node(s) should have all the other lymph nodes removed from under their arm. Long term follow up of this trial found that patients could safely avoid further surgery to remove lymph nodes despite having microscopic tumour deposits in their sentinel node. By avoiding further surgery, these patients are less likely to develop pain or swelling in their arm, without any increase in the chance of breast cancer recurrence.

SOLACE: New drug combinations show promise for patients with BRCA-positive and negative breast and ovarian cancer

The drug olaparib is effective against breast and ovarian cancer in patients with a BRCA gene mutation. Olaparib stops cancer DNA from repairing itself, leading to the death of cancer cells that also have other repair deficiencies, such as those with a BRCA gene mutation. The SOLACE trial, led by BCT, found that olaparib could be safely combined with a chemotherapy drug called cyclophosphamide, both given as tablets. Furthermore, patients with high grade serous ovarian cancer appeared to benefit from the combination, which will be tested in a larger trial. SOLACE was a new type of trial for BCT, which has previously focussed on conducting larger confirmatory breast cancer trials.


Breast cancer has a better prognosis if infiltrated by immune cells

Triple negative breast cancer has traditionally been difficult to treat and is generally associated with a poor prognosis. Chemotherapy can be very effective for some types of triple negative cancer, but outcomes vary among patients. This analysis, led by Professor Sherene Loi from the Peter MacCallum Cancer Centre in Melbourne, looked at 2148 breast cancer specimens from nine clinical trials including two trials BCT enrolled patients in (BIG 02-98 and IBCSG 22-00). These researchers found that patients with early stage breast cancer who had received chemotherapy had an excellent prognosis if their cancer had more tumour-infiltrating lymphocytes (TILs) within it. Large international collaborations like this are often needed to answer important questions about the behaviour of less common types of breast cancer. This study gives patients more information about their cancer and prognosis and in future might allow design of trials for patients according to the number of TILs. The research team was acknowledged at the recent St Gallen International Breast Cancer Conference and Professor Loi et al are working on the inclusion of information about this cell type in standard pathology reports.


Immunotherapy appears promising in HER2 positive advanced breast cancer

Immunotherapy has become an exciting new option for some cancer patients. However, until recently breast cancer has not seen the same successes as those seen in tumour types such as melanoma and lung cancer. In 2018, the Impassion 130 trial reported benefits with immunotherapy for triple negative breast cancer, setting the scene for expansion into other breast cancer subtypes. We conducted an early phase trial, called PANACEA, which showed that immunotherapy may be beneficial for some patients with advanced stage HER2 positive breast cancer that is resistant to currently available therapies. Patients in this trial whose tumour showed the PD-L1 biomarker were more likely to have tumour shrinkage with the study drugs (pembrolizumab in combination with trastuzumab). These results have led directly to the BCT-led DIAMOND trial, which is currently enrolling patients to test two immunotherapy drugs in combination with trastuzumab for advanced HER2 positive breast cancer.


A new resource to help patients make decisions about neoadjuvant therapy for breast cancer

Neoadjuvant (pre-operative) systemic therapy is recognised as an increasingly important treatment option for women with larger of more aggressive types of breast cancer. BCT-led research has shown that women who are offered neoadjuvant therapy would like to have a better understanding of their treatment options and be more involved in the decisions about their care. This trial involved the development and testing of a patient decision aid to give women access to that information. The trial showed that the decision aid was considered useful by both patients and their treatment team and was easily included in routine clinical care. Women who used the decision aid were more confident in their decision and were able to participate in decisions about their care. This resource is now available free of charge for use in routine clinical care.

The Breast Cancer Trials Annual Scientific Meeting (ASM) was held at The Westin, Sydney, from 25-27 July 2018, and this year’s event celebrated our 40th anniversary as a leading breast cancer research organisation.

The ASM is a well-known and established conference in the clinical trials calendar and includes two days of scientific sessions and a Trials Coordination Forum. It attracts leading international and local researchers to discuss the latest findings, developments in breast cancer research and new research ideas in breast cancer clinical trials. The ASM attracted more than 200 delegates including medical oncologists, surgeons, research nurses, study coordinators, radiation oncologists and clinical trials management personnel.

Our international guest speakers were:
• Associate Professor Peter Dubsky - Head of the Breast Cancer Centre at the Hirslanden Clinic St Anna in Lucerne, Switzerland;
• Professor Timothy Whelan - Associate Chair of Research in the Department of Oncology at McMaster University in Canada;
• Professor Carlos Arteaga - Director of the Harold C Simmons Cancer Centre and Associate Dean for Oncology Programs at UT Southwestern Medical Centre.

The 40th Annual Scientific Meeting in Sydney.

Breast Cancer Trials Awards

The BCT Board of Directors is pleased to provide the following awards and travel grants to recognise the valuable contribution of members to our clinical trials research program; provide professional development opportunities for members; recognise outstanding achievement by researchers, clinicians and scientists in their particular field; and help promote the research activities of BCT and encourage participation in them.

The following awards were presented at the 2018 ASM:

The Alan Coates Award for Excellence in Clinical Trials Research was presented to Professor Fran Boyle AM. This award recognises a member of BCT who has made an outstanding contribution to BCT’s clinical trials research program. It aims to assist the recipient in their professional development. Professor Boyle is a Professor of Medical Oncology, University of Sydney and the Director of the Patricia Ritchie Centre for Cancer Care and Research, Mater Hospital, Sydney.

Professor Boyle has been actively involved with Breast Cancer Trials for almost 20 years. Specifically, she was the Board Chair from 2012 to 2015, Chair, Scientific Advisory Committee from 2005 to 2010, Member of the Communications and Fundraising Committee, and Fran is the Deputy Chair of the CHARIOT trial. She has participated in many of the ground-breaking trials conducted by BCT, including HERA and POEMS.

The John Collins Medal and Travel Grant was awarded to Dr Synn Lynn Chin. This award was established to encourage potential academic Breast Cancer Surgeons and Registrars to become involved in clinical trials research. Dr Chin is a Breast Oncoplastic Surgery Fellow at the Sir Charles Gardiner Hospital.

The Study Coordinator Prize was presented to Ms Victoria Sproule. This prize acknowledges outstanding commitment to the BCT’s clinical trials research program by a Study Coordinator. Ms Sproule is the National Lead Clinical Research Coordinator at Genesis Cancer Care.

The Robert Sutherland Award for Excellence in Translational Research was presented to Professor Carlos Arteaga. This award recognises Translational Researchers and their achievements and contributions to improved patient outcomes. The award is open to Translational Researchers worldwide. Professor Arteaga is the Director of the Harold C Simmons Cancer Centre and Associate Dean for Oncology Programs at UT Southwestern Medical Center.

Avon Travel Grants were awarded to Sharon Clark, Jasmine Hee, Anita Krishnan, Lyndsey Grollman, Deepi Pandey, Angela Benson, Hollie Ritchie, Dr Sarah Khan and Dr Sara Wahlroos. These grants recognise Study Coordinators and junior clinicians who are unable to access institutional or other funding to attend the ASM.

The 40th Annual Scientific Meeting in Sydney.

Breast Cancer Trials Awards

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Dr Synn Lynn Chin receives the award from Professor John Collins.

The 40th Annual Scientific Meeting in Sydney.

Breast Cancer Trials Awards

The Robert Sutherland Award for Excellence in Translational Research was presented to Professor Carlos Arteaga. This award recognises Translational Researchers and their achievements and contributions to improved patient outcomes. The award is open to Translational Researchers worldwide. Professor Arteaga is the Director of the Harold C Simmons Cancer Centre and Associate Dean for Oncology Programs at UT Southwestern Medical Center.

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The 40th Annual Scientific Meeting in Sydney.
Discretionary Funding

Breast Cancer Trials (BCT) encourages development of investigator-initiated clinical trials. The BCT Scientific Advisory Committee (SAC) evaluates, selects and recommends new trial proposals based on scientific merit and the requirements of the broader BCT membership.

New Discretionary Funding projects awarded:

- Dr Richard Isaacs/Dr Navin Wewala: A phase II, randomised, double-blinded, placebo controlled, crossover trial to assess Pantoprazole’s effectiveness as prophylaxis against delayed chemotherapy-induced nausea and vomiting (CINV) in patients receiving adjuvant breast cancer chemotherapy (PantoCIN).

The status of previously awarded Discretionary Funding projects is:

**Ongoing:**

- Prof Tomas Kron: Deep Inhalation Breath Hold for reduction of cardiac toxicity in patients with left-sided breast cancer undergoing radiotherapy.
- Dr Yoland Antill: The timeline and quality of life implications of madarosis in patients undergoing cytotoxic chemotherapy for breast malignancy.
- Prof Phyllis Butow: The implementation of a Decision Aid for women with early-stage breast cancer considering contralateral prophylactic mastectomy (CPM): a pilot study. This follows on from the project completed during the previous reporting period: Development of a patient decision aid for women with early stage unilateral breast cancer considering contralateral prophylactic mastectomy (CPM).

**Projects in development:**

- Prof Bruce Mann: Economic evaluation of ANZ1002 PROSPECT.
- Dr Sheridan Wilson: Can anti-Mullerian Hormone (AMH) levels predict permanent loss of ovarian function and guide endocrine therapy (ET) choices in older pre/perimenopausal women undergoing chemotherapy for early breast cancer (EBC)?
- Dr Emma-Kate Carson: Phase II pilot study assessing melatonin as an intervention for sleep disturbance in early breast cancer.
- Dr Wanyuan (Wanda) Cui: Assessment of ovarian function as an endpoint in breast cancer clinical trials: a systematic review.
### Participating Institutions & Collaborators

#### International Collaborators

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<tr>
<th>Collaborator</th>
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<td>Alliance Foundation Trials, LLC (AFT)</td>
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<td>Translational Research in Oncology (TRIO)</td>
<td>France &amp; Canada</td>
<td>France &amp; Canada</td>
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#### Participating Institutions

The following institutions across Australia and New Zealand are involved in the conduct of the Breast Cancer Trials research program.

**ACT**
- Canberra Hospital, The Garran

**NSW**
- Calvary Mater Newcastle
  - Waratah
- Gosford Hospital
- Royal Prince Alfred Hospital
- Randwick
- Prince of Wales Hospital
- Randwick
- St Vincent’s Hospital, Sydney
- Darlinghurst
- Bankstown-Lidcombe Hospital
- Bankstown
- Royal North Shore Hospital
- St Leonards
- Border Medical Oncology
- Albury
- Lingard Private Hospital
- Merewether
- Port Macquarie Base Hospital
- Port Macquarie
- Nepean Cancer Centre
  - Kingswood
- Lismore Base Hospital
  - Lismore
- Tamworth Rural Referral Hospital
  - Tamworth
- Coffs Harbour Health Campus
  - Coffs Harbour
- Tweed Hospital
  - Tweed Heads
- Armidale Hospital
  - Armidale
- Breast & Endocrine Centre, Concord
  - Concord
- Concord Repatriation General Hospital
  - Concord
- Macarthur Cancer Therapy Centre
  - Campbelltown
- St George Hospital
  - Kogarah
- Royal Hospital For Women, Sydney
  - Randwick
- Riverina Cancer Care Centre
  - Wagga Wagga
- Liverpool Hospital
  - Liverpool
- Westmead Hospital
  - Westmead
- Manning Rural Referral Hospital
  - Taree
- Mater Hospital, Sydney
  - North Sydney
- San Clinical Trials Unit
  - Wahroonga
- Southern Highlands Cancer Centre
  - BOWRAL

**QLD**
- Icon Cancer Care Wesley
  - Auchenflower
- Royal Brisbane and Women’s Hospital
  - Herston
- Princess Alexandra Hospital
  - Woolloongabba
- Mater Adult Hospital, Brisbane
  - South Brisbane
- Nambour Hospital
  - Nambour
- Townsville Hospital, The
  - Douglas
- St Andrew’s Toowoomba Hospital
  - Toowoomba
- Cairns Hospital
  - Cairns
- Mater Cancer Care Centre
  - South Brisbane
- Sunshine Coast University Hospital
  - Birtinya
- Genesis Cancer Care Wesley
  - Auchenflower

**Our Research**

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### Participating Institutions & Collaborators (Continued)

#### Participating Institutions (Continued)

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13    | Annual Report 2019 |
Individual Givers

Individuals throughout Australia gave generously this year in response to our Appeals and as members of the Regular Giving Program. We are grateful to every supporter for their commitment to all those affected by breast cancer.

Our thanks also go to the many individuals and their families who shared their personal experience of breast cancer in our communications. Like Tanya Smith, the mother of three children, who was diagnosed with triple-negative breast cancer aged 41. Tanya featured in our 2018 Tax Appeal and prior to her diagnosis was not aware of the role breast cancer clinical trials research had in the treatments available to her.

After losing her mother to breast cancer, Dawn Cotterell was diagnosed in 2004 and participated in the HERA clinical trial. This research proved the treatment Herceptin for HER2 positive breast cancer which is today saving thousands of lives. Dawn featured in our Christmas Appeal and has been a long-term supporter.

Our sincere condolences go to the families of those supporters who sadly passed away during the year. We also acknowledge all donations given in memory of loved ones.

The following individuals generously remembered Breast Cancer Trials in their Will. Their legacy will help to advance research for the benefit of future generations and will never be forgotten.

Mrs Patricia E Brady
James O Fairfax AC
Mrs Helen Elizabeth Barron
Ms Noelena Tame
Dr Hugh James Falconer
Mr Peter Hoban
Ms Jennifer Lynne Hunt
Miss Doreen Letcher
Mrs Ethel May Murray
Mrs Miyoko Murray
Ms June Patricia Nagle
Mrs D Pickering
Ms Lola Maud Roach
Mr David Roderick Thomas
Miss Gwényth K Vitnell
Ms Patricia Worsley
Community Activists

Every year thousands of individuals, community groups and businesses donate their time, energy and money to support Breast Cancer Trials. We acknowledge and thank their tireless efforts, passion and support.

A sea of pink was seen on Australian golfing greens as 148 golf clubs held Tee Off for Breast Cancer Trials events throughout 2018. The commitment of the golfing community saw $165,000 raised to support all those affected by breast cancer. Many of the golf clubs and their members have held annual Tee Off events since it first began in 1997, and this event has become a much-loved day on the golfing calendar.

Congratulations to the following clubs who were our highest fundraisers in 2018:

- Kings Cove Golf Club, VIC $8,550
- The Sands Torquay Golf Club, VIC $8,320
- Eastlake Golf Club, NSW $8,200
- Tanunda Pines Golf Club, SA $7,612
- Pacific Harbour Golf & Country Club, QLD $6,012

The members of East Leisure and Golf Club in East Maitland NSW have been hosting Tee Off events since 1997. In 2018 they raised over $4,500 for Breast Cancer Trials.

Throughout 2018, many friends, family and work colleagues came together via raffles, cake stalls, morning and afternoon teas, patchwork quilting auctions, and other special functions to support Breast Cancer Trials.

Ben and Michael Kavich continued their wonderful initiative Race for a Cure for the second year, racing their pink liveried car in the 2018 Hi-Tec Oils Bathurst 6 Hour event. After Ben’s wife Toulia was diagnosed with breast cancer in 2016, the Kavich’s combine their love and talent for motorsports with raising funds for research. They finished second in their class and raised over $30,000.

The inspiration for each of our Pink Champions varied. Tina Grechko, a participant in the PALLAS clinical trial following her own diagnosis of breast cancer, took part in the HBF Run for a Reason and raised $1,800.

Michelle King from Gunnedah NSW organised another very successful event this year – a ball – which raised $8,850. The Southern Winterball Social Baseball Association raised close to $10,000 via their annual ‘Save the Boobies game’. Antonietta Vatta hosted an afternoon tea in honour of her mother, Libera Scotto who passed away from breast cancer. The afternoon tea raised $1,250 and Antonietta said “My mum would have been so happy to see all my friends gathered there to help support the all-important work of Breast Cancer Trials researchers and the women who participate in the trials.”

The 2019 edition of the Australian Women’s Health Diary was successful in raising net $950,000 bringing the total raised from the diary to $15.25 million since the first edition in 1999. Filled with important health information for women of all ages, this diary is also a practical every-day diary and has become a must-have for thousands of Australian women. Special thanks to The Australian Women’s Weekly and to Lisa Wilkinson our Diary Ambassador, and to newsagents nationally, Woolworths and Magshop for selling the diary. A big thank you to everyone who purchased the diary, and the dedicated team of people who produce this wonderful resource each year.
Corporate & Foundation Partners

Many well known corporate entities, medium and small businesses and trust and foundations have raised funds for BCT over the past year. We thank each one of them, their employees and customers for their generous support.

The 2018 Can4Cancer, a CommBank Foundation community initiative with Tour de Cure, raised $2 million to support cancer research. We received a grant of $200,000 towards two clinical trials – EXPERT and DIAmOND.

Funds were raised via walks held nationally and a 356 kilometre bike ride. Our thanks go to Commonwealth Bank employees for their participation and the Tour de Cure organisers and volunteers.

A final donation of $157,000 was received from Avon Australia before it closed operation in Australia and New Zealand in late 2018. This brings to the total raised by Avon, its Representatives and customers to $11.65 million since our partnership first began in 1996.

We continue to work with For Benefit Medicines, Australia’s first ‘for benefit’ pharmaceutical company. FBM was established under a social enterprise model and its sole purpose is to distribute 100% of profits to patient support and medical research in Australia.

The Australian Women’s Weekly has produced the Australian Women’s Health Diary on our behalf since the first edition in 1999 and our partnership is now in its 21st year. We are very fortunate to have a wonderful team at The Weekly who help to promote and produce the diary each year.
Breast Cancer Trials (BCT) is governed by a Board of Directors who drive the strategic direction of the group and work with the Chief Executive Officer and all staff, to implement the objectives of the organisation. BCT has a number of Board established committees to ensure the clinical trials research program and all associated activities, are undertaken to the highest standards.
Our People

Committees (Continued)

Scientific Advisory Committee

A/Prof Prue Francis
Medical Oncologist
Chair

A/Prof Nicholas Wilcken
Medical Oncologist
Deputy Chair

Prof Boon Chua
Radiation Oncologist
Craft Group Lead – Radiation Oncology

A/Prof Nicole McCarthy
Medical Oncologist
Craft Group Lead – Medical Oncology

Prof Andrew Spillane
Surgical Oncologist
Craft Group Lead – Surgical Oncology

Prof Frances Boyle AM
Medical Oncologist

Prof Phylis Butow
Psycho-Oncologist

Ms Raewyn Calvert
BCT Consumer Advisory Panel

A/Prof Ian Campbell ONZM
Surgical Oncologist

A/Prof Jacqui Chirgwin
Medical Oncologist

A/Prof Glenn Francis
Pathologist

Prof Val Gabbski
Statistician

Mrs Leslie Gilham
BCT Consumer Advisory Panel

Prof Belinda Kiely
Medical Oncologist

Prof Sunil Lakhanii
Pathologist

Ms Phillipa Lee
Chief Operating Officer-Research, BCT

A/Prof Elgene Lim
Medical Oncologist

Prof Geoffrey Lindeman
Medical Oncologist / Clinician-Scientist

Prof Sherene Loi
Medical Oncologist

Dr Janine Lombard
Medical Oncologist

Prof Bruce Mann
Surgical Oncologist

A/Prof Nick Murray
Medical Oncologist

A/Prof Peter O’Brien
Radiation Oncologist

Prof Kelly-Anne Phillips
Medical Oncologist

Dr David Porter
Medical Oncologist

A/Prof Andrew Redfern
Medical Oncologist

Mrs Leonie Young
BCT Consumer Advisory Panel

Dr Nicholas Zdenkowski
Medical Oncologist

*Stepped down May 2018
# Started May 2018
† Started July 2018
§ Started January 2019

Independent Data Monitoring Committee

Prof John Zalcberg
Acting Chair

Prof Gillian Duchesne

Prof Matthew Law

Prof Daniel Roos

Prof Mark Smithers

Prof Martin Tattersall

Prof Michael Quinn

* Stepped down June 2018
** Stepped down January 2019
*** Stepped down February 2019

Independent Data Monitoring Committee (EXPERT)

Dr Daniel Hayes
Chair

Dr Thomas Buchholz

A/Prof James Dignam

Dr Mary Gospodarowicz

Dr Alastair Thompson

Finance, Risk and Audit Committee

Ms Jennifer Horrigan
Chair

Mr Michael Hamar

Prof David Joseph

Mr David Pringle

Dr Soozy Smith

*Stepped down January 2019

Consumer Advisory Panel

Ms Leslie Gilham
VIC

Ms Karen Alexander
ACT

Ms Melissa Bell
NZ

Ms Raewyn Calvert
NZ

Ms Merryn Carter
VIC

Ms Tanya Hall
NSW

Ms Sheryl Fewster
WA

Ms Cheryl Grant
NSW

Ms Leonie Young
QLD

*Stepped down July 2018

Communications and Fundraising Committee

Ms Sheryl Fewster
Chair

Prof Fran Boyle AM

Ms Julie Callaghan

Ms Anna Fitzgerald

Mrs Jennifer Horrigan

Ms Marg O’Donnell AO

Prof Christobel Saunders AO

Dr Soozy Smith

Ms Fay Sowerby

*Stepped down November 2018
Breast Cancer Trials continues to be at the forefront of research in Australia and New Zealand with the role of the Consumer Advisory Panel evolving continuously. Over the past 12 months there has been a significant changing of the guard with the retirement of three highly esteemed members, Leonie Young (Former Chair), Cheryl Grant and Sheryl Fewster.

I would like to take the opportunity to personally thank them for their incredible contribution to not only the CAP but also their representation on behalf of Breast Cancer Trials (BCT) and consumers in breast cancer research over the past 20 years. While their experience and knowledge will be greatly missed, it has led to an exciting time for CAP, with new members who have the same committed focus on advocacy, participation and involvement in the development of clinical trials.

As BCT has grown, so has the role of the Consumer Advisory Panel. We are constantly exploring ways that we can better collaborate with clinicians and researchers while representing people who may be participants of clinical trials or who have been affected by breast cancer.

Our current members are:
• Raewyn Calvert
• Hamilton New Zealand
• Melissa Bell, Dunedin New Zealand
• Merryn Carter, Melbourne
• Karen Alexander, Canberra
• Tanya Hall, Newcastle
• Leslie Gilham, Melbourne

All members bring a different perspective to the CAP, which enables us to represent the broader community when performing our role as a CAP member.

CAP members are continually upskilling in order to undertake their roles and have also acted as spokespeople on behalf of the Group at media and promotional/fundraising activities. An example was a member recently awarded a scholarship to attend the Alamo Breast Cancer Foundation Patient Advocate Program at the 2018 San Antonio Breast Cancer Symposium. One thing we all have in common is our knowledge that BCT saves lives and supporting BCT in working towards this aim remains our main focus.

CAP is constantly aware of the changing landscape in breast cancer research and is continually looking to diversify while maintaining our knowledge base and our professional standing in the breast cancer community. Over the past 12 months, CAP has looked to establish new procedures aimed at maintaining continuity when there is a transitioning of new members with the establishment of position statements, terms of commitment and clarity around appointments. This development will allow us to advertise for new members in the near future and enable the CAP to have a strong cohort with diverse backgrounds and wide-ranging networks that will assist us to more broadly represent consumers and also enable us to be strong advocates on behalf of BCT. We will continue to advocate for people who may be participating or who have participated in clinical trials throughout representation on the BCT Scientific Advisory Committee, as Associate Investigators on BCT grant applications, as consumer representatives on Concept Working Development Committees and all relevant issues surrounding clinical trials including recruitment, protocols, patient informed consent and ethical issues.

Over the past 12 months there has been a strong commitment by both CAP members and IMPACT (Improving Participation and Advocacy for Clinical Trials) members in helping to raise community awareness of breast cancer clinical trials and research through various media platforms. This has enabled us to collaborate with BCT on various campaigns by participating in podcasts and videos which have been shared via the website, Facebook, Instagram and Twitter posts. One of the more rewarding campaigns was the “Trials Saves Lives” campaign where a number of videos were developed with the help of CAP & IMPACT members. Interviews were undertaken with trial participants and also with women who had benefited from the treatment once it had become standard of care. It gave a great insight into the importance of participation and the outcomes that can be achieved through clinical trials.

In July 2018 CAP members attended the BCT Annual Scientific Meeting in Sydney. It was a celebration of 40 years of BCT and 20 years of CAP. Also running concurrently with the ASM was the Annual IMPACT Advocate Program which since 2006, continues to educate breast cancer advocates about breast cancer scientific research and clinical trials not only in Australia and New Zealand but internationally. It is hoped that by attending, delegates can utilise the knowledge gained either throughout their consumer networks and the broader community or in their professional roles to inform and advocate for clinical trials.

The 2018 program was attended by five advocates from a wide range of backgrounds including consumers, nurses and representatives from breast cancer organisations. The program enabled participants to attend the BCT Annual Scientific Meeting, the Trials Co-ordinators Forum and daily Tutorial Sessions, which allowed attendees the opportunity to question and discuss relevant topics that had been addressed during the sessions. The tutorial sessions are invaluable and I would like to thank the 2018 tutors: Professor Cristin Print, Professor Fran Boyle and Associate Professor Nicholas Wilken. Throughout the program CAP members provided mentoring to attendees to ensure that they received the maximum benefit from the program.

With sadness one of our 2018 delegates succumbed to her disease not long after the July conference. It not only reminded us of the importance of clinical trials in improving outcomes and overall survival but it only strengthened both CAP and the IMPACT members’ focus on supporting clinical trials and research, and advocating on behalf of consumers such as our late friend and colleague. Vale Jeynelle Broatch.

Past and present members of the Consumer Advisory Panel at the 40th Anniversary Conference Dinner. L-R: Merryn Carter, Jennifer Bryce (retired), Raewyn Calvert, Melissa Bell, Leslie Gilham, Karen Alexander, Tanya Hall, Cheryl Grant (retired), Linda Reaby (retired), Leonie Young (retired), Carol Whiteside (retired), Sheryl Fewster (retired).

Leslie Gilham
Chair, Consumer Advisory Panel
Our Committed Staff

Breast Cancer Trials continues to be at the forefront of research in Australia and New Zealand with the role of the Consumer Advisory Panel evolving continuously. Over the past 12 months there has been a significant changing of the guard with the retirement of three highly esteemed members, Leonie Young (Former Chair), Cheryl Grant and Sheryl Fewster.

Why do you love working at Breast Cancer Trials?

I am proud to be a part of a team that shares the same vision and is dedicated to the mission of making a significant difference to the lives of all those affected by breast cancer.

Michelle Cairns – Business Department

Our clinical trials research has been informing and changing the way we treat and manage breast cancer for more than 40 years. It’s great to be part of this legacy for future generations.

Stuart Reeves – Research Department

The opportunity to contribute to positive social change and the privilege of sharing in our supporters unique journeys. Every day we connect people who have a passion about making a difference with a cause they care about, and together we are improving and saving the lives of people affected by breast cancer.

Belinda Carrall – Fundraising Department
Our Committed Staff (Continued)

Leadership Team

Dr Soozy Smith
Chief Executive Officer

Ms Julie Callaghan
Chief Operating Officer - Fundraising & Philanthropy

Ms Anna Fitzgerald
Communications Manager

Mr Joe Kelly
People, Performance & Culture Business Partner

Ms Phillipa Lee
Chief Operating Officer – Research

Mr David Pringle
Financial Controller

Staff

Heath Badger
Clinical Trials Program Manager

Corinna Beckmore
Protocol Development and Special Projects Officer

Elisa Bland
Supporter Engagement and Content Manager

Helen Braggett
Clinical Research Associate

Michelle Cairns
Accountant

Julie Callaghan
Chief Operating Officer - Fundraising and Philanthropy

Tamar Carpenter
Special Project Coordinator

Belinda Carrall
Community Fundraising Manager

Anna Cummins
Supporter Care Officer

Hannah Davis
Quality Assurance Officer

Annette Dempsey
Clinical Research Associate

Cheryl Dodds
Special Gifts Officer

Donna Douglass
Clinical Trial Administrator

Brooke Emmett
Clinical Research Associate

Anna Fitzgerald
Communications Manager

Akiko Fong
Clinical Research Associate

Nicole Francis
Clinical Trial Administrator

Juliette Gritten
Clinical Trial Administrator

Tracey Hay
Clinical Trials Program Manager

Tamicia Humby
Clinical Research Associate

Sandy Isles
Appeal Coordinator

Syed Jafari
Clinical Research Associate

Amy Jongerden
Clinical Research Associate

Joseph Kelly
People, Performance and Culture Business Partner

Ingrid Laycock
Clinical Trials Project Leader (Acting)

Phillipa Lee
Chief Operating Officer - Research

Eryn Leggatt
Community Fundraising Coordinator

Rose Lucas
Ethics and Regulatory Affairs Associate

Mai Ly
Clinical Research Associate

Kelly Martin
Individual Giving Manager

Carlie Mavin
Clinical Trials Project Leader

Stephanie McDonald
Clinical Research Associate

Lauren McNeil
Community Fundraising Coordinator

Belinda Mitchell
Clinical Research Associate

Caitlin Muller
Clinical Research Associate

Jane Murphy
Supporter Care Officer

Vicki Murray
Supporter Care Officer

Kristy Odelli
Clinical Research Associate

Lisa Paksec
Ethics and Regulatory Affairs Manager

David Pringle
Financial Controller

Flonda Probert
Clinical Research Associate

Stuart Reeves
Clinical Research Associate

Annabelle Regan
Digital Content Coordinator

Lauren Rennie
Clinical Trials Project Leader

Sarah Robson
Executive Assistant to the CEO

Yael Sagi
Ethics and Regulatory Affairs Associate

David Short
Fundraising Data Manager

Soozy Smith
Chief Executive Officer

Deborah Sutcliffe
Supporter Care Team Leader

Thao (Jenny) Vu
Clinical Research Associate

Angela West
Supporter Care Officer

Lindsey Wylde
Clinical Research Associate

Nicholas Zdenkowski
Medical Advisor
Breast Cancer Trials (BCT) achieved an operating surplus of $0.130m for the year ended 31 March 2019, a decrease of $0.078m from the prior year. There was operating income of $12.022m and operating expenses of $11.892m.

BCT is fortunate enough to derive income from a variety of sources including fundraising, grants, international clinical trial sponsors and investment income and as a result is not over-reliant on one source of income.

BCT generated gross fundraising income of $5.041m for the year, representing 42% of the total operating income. After inclusion of investment income there was a total surplus of $1.296m for the year, an increase of $0.183m from the prior year.

The planned research program has a forecast value of $25.884m, an increase of $11.116m (75%) over the planned program at the end of the prior year. This increase is due to the development of a number of new research projects during the last 12 months.
How You Can Help

Become A Member

**Researchers**

Membership of Breast Cancer Trials (BCT) is open to people who are actively involved in the conduct of the BCT research program.

There are two membership categories: Full Member and Affiliate Member. A Full Member is deemed by the Board to be or will be directly involved in the conduct of the BCT research program. An Affiliate Member is deemed by the Board to have an interest in, and awareness of, BCT and its research activities but who is not involved in the conduct of the BCT research program.

For more information or to complete a membership application form, visit [www.breastcancertrials.org.au/research-member-application](http://www.breastcancertrials.org.au/research-member-application).

**General Public**

Members of the general public who are interested in learning and receiving information about our research and fundraising activities, are encouraged to join IMPACT.

IMPACT – Improving Participation and Advocacy for Clinical Trials – is free and open to anyone interested in keeping up to date with the BCT research program. It aims to recognise the important contributions made by women to breast cancer clinical trials research, increase participation in clinical trials, provide members with reliable up to date information about our research, and educate members about the science of breast cancer and the conduct of our clinical trials so that they can become advocates in the broader community.

For more information about IMPACT, or to complete an online application form, please visit [www.breastcancertrials.org.au/impact](http://www.breastcancertrials.org.au/impact).
Participate In A Clinical Trial

People take part in clinical trials for many reasons including:

• 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;
• Many clinical trial participants are motivated to take part because 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.

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 participant entry, is available on the Breast Cancer Trials website at www.breastcancertrials.org.au.

Information about breast cancer clinical trials can also be found on the Australian New Zealand Clinical Trials Registry website at www.anzctr.org.au.

Leslie Gilham was a participant in the TEXT clinical trial and is pictured with her oncologist Dr Ross Jennens.
Support Life-Saving Clinical Trials Research

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.

There are many different ways you can connect with Breast Cancer Trials (BCT) and show your support. You might like to join our Regular Giving Program with automated, monthly donations, 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’ for BCT 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.

We are very fortunate that many individuals, community groups and well-known corporate identities partner with us to fund the important research BCT conducts.

To learn more about how you can become a supporter, please visit www.breastcancertrials.org.au.

The ladies of The Country Club Vincentia in NSW baked up a pink storm for their Tee Off event which raised $322 for Breast Cancer Trials.
Glossary

A

ACCRUAL TARGET: The targeted number of participants to be recruited to a clinical trial.

ADJUVANT THERAPY: Additional treatment used to improve the effects of surgical treatment. In cancer, adjuvant therapy may include chemotherapy, hormonal or radiation therapy after surgery, which is aimed at killing any remaining cancer cells.

ADJUVANT ONLINE: An internet-based computer program to assist health professionals and patients to discuss the risks and benefits of additional therapy options after breast cancer surgery.

ADVANCED BREAST CANCER: Metastatic cancer that has spread from the original site in the breast to other organs or tissues in the body. Also known as secondary breast cancer.

ADVERSE EVENT (AE): Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

ANTI-OESTROGENS: Anti-oestrogens work by stopping breast cancer cells from getting oestrogen. The most common anti-oestrogen is tamoxifen, and is an example of class of drugs referred to as a SERM (selective estrogen receptor modulator). Another anti-oestrogen that may be used in the treatment of metastatic breast cancer is fulvestrant. It may be recommended if other hormonal therapies have stopped working. Fulvestrant is known as a SERD (selective estrogen receptor downgrader).

AROMATASE INHIBITORS (AI): A class of drugs used in the treatment of breast cancer in postmenopausal women. Some cancers require oestrogen to grow. Aromatase is an enzyme that synthesises oestrogen. Aromatase inhibitors block the synthesis of oestrogen which lowers the oestrogen level and slows the growth of cancers. Examples include anastrozole, exemestane, letrozole.

AXILLA: The armpit.

AXILLARY DISSECTION: Surgery to remove lymph nodes from the armpit. The procedure can be performed either at the same time as breast surgery or as a separate operation.

AXILLARY LYMPH NODES: Lymph nodes in and near the armpit.

B

BIOMARKERS: Measurable biological characteristics associated with the presence or absence of disease. Biomarkers can help with the diagnosis, prognosis and treatment of diseases such as cancer.

BIOPSY: The removal of a small sample of tissue or cells from the body to help diagnose a disease.

BRCA1 AND BRCA2: Gene mutations that are connected to hereditary breast cancer. Women who carry these mutations are also at increased risk of developing ovarian cancer.

BREAST CONSERVING SURGERY: Surgery to remove part of the breast. Also called a lumpectomy or a wide local excision.

BREAST DENSITY: A measure used to describe the relative amounts of fat and tissue in the breasts as seen on a mammogram.

C

CHEMOTHERAPY: The use of medications that are toxic to cancer cells. These drugs kill the cells, or prevent or slow their growth. A standardised combination of such drugs in the treatment of cancer is referred to as a ‘treatment regimen’ e.g. cyclophosphamide, doxorubicin, docetaxel and capecitabine.

CLINICAL TRIAL: Research conducted with participants’ consent, which usually involves a comparison of two or more treatments or diagnostic methods. Clinical trials are conducted to gain a better understanding of the underlying disease process and/or methods to treat or prevent it. The clinical trial process includes Phase I, II, and III trials.

CONTRALATERAL PROPHYLACTIC MASTECTOMY: Removal of the healthy breast to reduce the risk of cancer recurrence.

CYCLIN-DEPENDENT KINASE 4/6 INHIBITOR (CDK): A drug that blocks the CDK4 and CDK6 proteins, which stops certain processes that cause cancer cells to grow and multiply. Examples include palbociclib, ribociclib, abemaciclib.

D

DOUBLE-BLIND TRIAL: A clinical trial in which neither the participating individual nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo or another therapy.

DUCTAL CARCINOMA IN SITU (DCIS): Abnormal cells in the breast ducts, which over time could develop into invasive breast cancer.
EARLY (Primary) BREAST CANCER: Breast cancer that has not spread beyond the breast or the axillary lymph nodes. This includes ductal carcinoma in situ and stage I, IIA, IIB, and IIIA breast cancers.

ELIGIBILITY CRITERIA: Participant eligibility criteria for clinical trials varies depending on the specific purpose of the trial. Typical criteria include age, stage of cancer type, prior treatment regimens and tumour characteristics.

ENDOCRINE-RESPONSIVE: Another name for hormone-responsive, or hormone receptor-positive breast cancer. Refer also to "hormone (endocrine) treatment".

ENDPOINT: Endpoints are used to measure the effect of a treatment being used in a clinical trial. Primary endpoints measure outcomes that will answer the primary (or most important) question being asked in a clinical trial, such as whether a new treatment is better at preventing disease-related death than the standard therapy. Secondary endpoints measure other relevant trial outcomes.

GONADOTROPIN-RELEASING HORMONE (GnRH) ANALOGUE/AGONIST: A medication such as goserelin or triptorelin that temporarily stops the ovaries from producing oestrogen. This treatment (e.g. zoladex) may be used for pre-menopausal women with hormone-receptor negative breast cancer in combination with chemotherapy, which may protect fertility. Using goserelin with chemotherapy may reduce the chance of cancer recurrence and may improve chance of survival.

GOOD CLINICAL PRACTICE (GCP): An international standard for the design, conduct, performance, recording and reporting of clinical trials; that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.

GRADE (TUMOUR GRADE): The degree of similarity of the cancer cells to normal cells. Grade is assessed by a pathologist. Grade 1 carcinoma is well differentiated and is associated with a better prognosis. Grade 2 carcinoma is moderately differentiated and is associated with an intermediate prognosis. Grade 3 carcinoma is poorly differentiated and is generally associated with a worse prognosis.

HER2 POSITIVE (HER2 amplified): HER2 stands for Human Epidermal Growth Factor Receptor 2. In HER2 positive breast cancer, the cancer cells have an abnormally high number of HER2 genes per cell. When this happens, too much HER2 protein appears on the surface of these cancer cells. This is called HER2 protein over expression or amplified. Too much HER2 protein is thought to cause cancer cells to grow and divide more quickly.

HER2 SIGNALLING PATHWAYS: One of the many complex processes associated with cell communication and action. The role of specific molecules in a cell which, via a cascade effect, inhibit or allow particular cell functions. Drugs being developed to inhibit these pathways might lead to new ways to block cancer cell growth and kill cancer cells.

HORMONE (ENDOCRINE) TREATMENT: Hormone (endocrine) treatment is used to treat breast cancers that are hormone receptor-positive, also known as hormone-responsive or endocrine-responsive. These cancers have receptors for the hormones oestrogen and/or progesterone; they are called ER and/or PR-positive cancers. There are several different types of hormone treatments. Some are taken as tablets (tamoxifen or aromatase inhibitors) and some are treatments to turn off or remove the ovaries (injections, surgery and sometimes radiotherapy).

HORMONE RECEPTORS: Proteins in a cell which bind to specific hormones. This stimulates the cell to act in a particular way.

HORMONE REPLACEMENT THERAPY (HRT): Drug therapy that supplies the body with hormones that it is no longer able to produce; usually to relieve menopausal symptoms.

HORMONE-RESPONSIVE: Also known as hormone receptor-positive or endocrine-responsive breast cancer.

HUMAN RESEARCH ETHICS COMMITTEE (HREC): The Human Research Ethics Committee's function is to review proposed research in order to ensure that the subject’s rights are protected and that risk of harm is minimised.

HYPOTHESIS: In research it relates to testing a concept or theory, or it can be developed as a result of research conducted.
IMMUNOHISTOCHEMISTRY (or IHC): Used to identify tissue components (e.g. abnormal cells in a cancerous tumour, different parts of biological tissue) by using a marker such as a fluorescent dye or an enzyme. The marker is attached to a type of protein (antigen) that finds another type of protein (antibody) and reacts to colour the target cells.

IMMUNOTHERAPY: a type of cancer treatment designed to boost the body’s natural defences to fight the cancer.

INDEPENDENT DATA MONITORING COMMITTEE (IDMC): An independent group of experts or adequately qualified individuals who monitor participant safety and treatment effectiveness data while a clinical trial is ongoing.

INFORMED CONSENT: Informed consent is a process whereby a person gives consent based on a clear understanding of the facts, any implications and possible future consequences. In the case of a clinical trial, these facts, implications and consequences are conveyed in the Participant Information Sheet and any associated materials.

INVESTIGATOR: A clinician who recruits clinical trial participants to trials at his/her hospital or treatment centre. Investigators take responsibility for protocol adherence at site and often collaborates with peers in a multidisciplinary team to ensure that patients are receiving the most suitable treatment options.

iPREVENT: A breast cancer risk assessment and risk management decision support tool designed to facilitate prevention and screening discussions between women and their doctors.

IPSILATERAL: On or affecting the same side of the body.


LOBULAR CARCINOMA IN SITU (LCIS): An area (or areas) of abnormal cell growth that increases a person's risk of developing invasive breast cancer later on in life. Lobular means that the abnormal cells start growing in the lobules, the milk-producing glands at the end of breast ducts.

LOCALLY ADVANCED BREAST CANCER: Cancer that has spread beyond the breast to the skin or chest wall, but not to distant organs such as the lungs or liver. It also refers to a tumour that is larger than 5 cms in size.

LUMPECTOMY: Also called “Breast Conserving Surgery”.

LYMPHOEDEMA: Swelling caused by a build-up of lymph fluid, as a result of lymph nodes being removed or not working properly.

MACROMETASTASES: Cancer cells that have spread (metastases) into the lymph nodes beyond the primary tumour and may be palpable or visible to the plain eye.

MADOROSIS: Loss of the eyelashes or of the hair of the eyebrows.

MAGNETIC RESONANCE IMAGING (MRI): A medical imaging device using a strong magnetic field and radio frequency to produce detailed images of internal body parts and structures. MRI is especially useful for imaging soft tissue like the brain, heart, muscles and tumours.

MAMMOGRAM: An x-ray of the breast.

MASTECTOMY: The surgical removal of the whole breast.

METASTATIC BREAST CANCER: Cancer that has spread from the original site in the breast to other organs or tissues in the body. Also known as secondary breast cancer or advanced breast cancer.

MICROMETASTASES: Small cancer cells that have spread (metastases) into the lymph nodes beyond the primary tumour and can only be detected by microscopic evaluation.

MONOCLONAL ANTIBODIES: A treatment designed to specifically target a cell within the body, particularly cancer cells. Different cancer types can be targeted with different monoclonal antibodies, examples include trastuzumab and bevacizumab.

MORBIDITY: The relative incidence of a particular disease within a defined population.

NEOADJUVANT THERAPY (Preoperative Therapy): Chemotherapy or hormone therapy used as a first treatment. Often used for large or locally-advanced cancers to shrink tumours before surgery.

NODAL STATUS: Whether a breast cancer has spread (node-positive) or has not spread (node-negative) to lymph nodes in the armpit (axillary nodes). The number and site of positive axillary nodes can help predict the risk of cancer recurrence.
OESTROGEN: The main female sex hormone produced mostly by the ovaries.

OESTROGEN RECEPTOR (ER): A protein that may be present on certain cells to which oestrogen molecules can attach. The term "ER-positive" refers to tumour cells that contain the oestrogen-receptor protein. These cells are generally sensitive to hormone therapy.

ONCOLOGIST: A doctor who specialises in treating cancer (oncology).

OOPHORECTOMY: The surgical removal of an ovary or ovaries.

OPEN-LABEL TRIAL: A clinical trial in which doctors and participants know which drug or treatment is being administered.

OSTEOPOROSIS: A disease characterised by low bone mass and deterioration of bone architecture, which increases the susceptibility to fractures.

OVERALL SURVIVAL (OS): The time from trial randomisation until death from any cause. Overall survival is regarded as the gold standard measure of benefit in clinical trials and requires a large number of patients and long term follow-up.

PAM50: The Prosigna Breast Cancer Prognostic Gene Signature Assay is a genomic test that analyses the activity of certain genes in early-stage, HR-positive breast cancer. The Assay may be used to make treatment decisions based on the risk of recurrence for postmenopausal women within 10 years of diagnosis after 5 years of hormonal treatment.

PARP (poly (ADP-ribose) polymerase) Inhibitors: A class of targeted therapy drugs (e.g. olaparib) that block an enzyme involved in DNA repair.

PARTICIPANT INFORMATION SHEET: A document that provides clinical trial participants with important information relating to a specific trial. The purpose is to assist the participant in the decision-making process regarding their potential participation in the trial.

PARTICIPATING INSTITUTION: Any public or private hospital or facility where clinical trials are conducted.

PHASE II CLINICAL TRIAL: The second stage of the evaluation of a new drug in humans; these trials evaluate drug safety and preliminary effectiveness in a large number of participants.

PHASE III CLINICAL TRIAL: Study the effectiveness of an intervention (e.g. study drug) in large groups of trial participants by comparing the intervention to other standard or experimental interventions (or to non-interventional standard care). Phase III studies are also used to monitor adverse effects and to collect information that will allow the intervention to be used safely.

PI3K (Phosphatidylinositol 3'-kinase): A protein produced by the body that can change the cell-to-cell communications which affect cell growth and survival.

PLACEBO: An inert tablet (such as a sugar pill), liquid or powder that has no active ingredient. In clinical trials, experimental treatments are often compared with a placebo to assess the treatment’s effectiveness.

PREDICTIVE FACTOR: A finding which assists a clinician to assess whether an individual’s cancer will respond either positively or negatively to a particular treatment. For example, the presence of oestrogen receptors predicts for response to hormone treatment. This term is often confused with “prognostic factor”.

PREVENTION TRIAL: Aims to find better ways to prevent breast cancer in healthy women.

PRINCIPAL INVESTIGATOR (PI): The person responsible for overseeing all aspects of a specific clinical trial at a BCT participating institution. Duties include recruiting participants, ensuring informed consent from participants, ensuring the trial protocol is adhered to, maintaining oversight of GCP at the site.

PROGESTERONE RECEPTOR (PR): A protein that may be present on certain cells to which progesterone molecules can attach. The term "PR-positive" refers to tumour cells that contain the progesterone-receptor protein. These cells are generally sensitive to hormone therapy.

PROGNOSTIC FACTORS: The combination of a number of aspects of a person’s general condition and disease diagnosis. General factors can include, but are not limited to, age, gender, lifestyle and medical history. Specific disease related factors can include disease diagnosis, stage, tumour size and location and treatment options. The combination of these factors can result in either a favourable or poor prognosis.

PROGRESSION-FREE SURVIVAL (PFS): The time from trial randomisation until cancer progression or death from any cause. PFS is considered a surrogate of overall survival, with the advantage that it can be measured in smaller clinical trials with shorter follow-up. Therefore it can be used to bring new therapies into clinical practice in a shorter timeframe.

PROPHYLACTIC MASTECTOMY: Surgery to remove one or both breasts to reduce the risk of developing breast cancer.

PROTOCOL: A written, detailed action plan for a clinical trial. The protocol provides the background, specifies the objectives, and describes the design and organisation of the trial.
Glossary

**QUALITY OF LIFE**: An individual’s overall appraisal of their situation and subjective sense of well-being.

**RADIOTHERAPY**: The use of radiation, usually x-rays or gamma rays, to kill cancer cells or damage them so they cannot grow and multiply.

**RANDOMISATION**: A method of preventing bias in research by ‘randomly’ assigning clinical trial participants to treatment groups. Randomisation ensures each treatment group has a similar range and number of participants, such that any differences between treatment groups at the end of the trial can be attributed to the trial treatments.

**RANDOMISED CLINICAL TRIAL**: A study in which participants are randomly assigned to one of two or more treatment arms of a clinical trial.

**RECURRENCE**: The return of breast cancer after a period of remission. During a recurrence, breast cancer cells which have evaded treatment may reappear at the original site or in another part of the body.

**RECURRENCE SCORE**: Obtained by the Oncotype DX® Assay, is a numerical value between 0-100 representing the likelihood of recurrence to distant parts of the body at 10 years post diagnosis.

**SENTINEL NODE**: The hypothetical first lymph node or group of nodes reached by metastasising cancer cells from a primary tumour.

**SENTINEL NODE BIOPSY**: Sampling of the sentinel lymph node into which the primary tumour is draining first to determine if a full lymph node exploration is needed.

**SEROUS ADVERSE EVENT (SAE)**: A serious adverse event (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; or requires intervention to prevent permanent impairment or damage.

**SIDE EFFECTS**: Unwanted effects of a drug or treatment (e.g. nausea, headache, hair loss side effects) may be short or long term, ranging from minor inconveniences to serious adverse events.

**STANDARD TREATMENT (THERAPY)**: The current best treatment known for a particular disease or condition.

**STUDY CHAIR**: An appropriately qualified clinician assigned by BCT to provide clinical advice and guidance for the development and ongoing conduct of a clinical trial.

**STUDY (or Trial) COORDINATOR**: A member of the research team at a BCT participating institution who works with site Investigators to ensure compliance with a clinical trial protocol. The role may include clinical and non-clinical tasks, such as data management.

**SUPRA-CLAVICULAR FOSSA**: An indentation (fossa) immediately above the clavicle, or collar bone.

**SYSTEMIC (ADJUVANT) THERAPY**: Treatment given in addition to surgery and radiation to treat breast cancer that may have spread to other parts of the body. It may include chemotherapy, targeted therapy and/or hormone therapy.

**TAMOXIFEN**: Used for the treatment of early and advanced breast cancers that are hormone-receptor positive. These breast cancers need estrogen to grow. Tamoxifen stops or slows the growth of these tumours by blocking estrogen from attaching to hormone receptors in the cancer cells. It is also used to prevent breast cancer in women with high risk of developing the disease. It is the most common hormone treatment for male breast cancer.

**TARGETED THERAPY**: Agents designed to attack specific molecular agents or pathways involved in the development of cancer. Trastuzumab (Herceptin) is an example of a targeted therapy used to treat breast cancer.

**TOXICITY**: Harmful side effects from an agent being tested.

**TREATMENT TRIALS**: Treatment trials are designed to test the safety and effectiveness of new drugs, biological agents, techniques, or other interventions in people who have been diagnosed with cancer. These trials evaluate the new treatment against standard treatment, if applicable.

**TRIPLE-NEGATIVE METASTATIC BREAST CANCER (TNBC)**: ‘Triple-negative’ is the term given to tumours which do not possess Oestrogen Receptor (ER) and Progesterone Receptor (PgR) proteins, and which do not over express the HER2 protein.

**TYROSINE KINASE INHIBITOR**: A drug that interferes with cell communication and growth and which may prevent tumour growth (e.g. lapatinib).