Annual Report

2016/2017

Australia & New Zealand
Breast Cancer
Trials Group

Breast Cancer
Institute of Australia

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

Professor Kelly-Anne Phillips is the ANZBCTG Deputy Director of Research.

Associate Professor Sherene Loi is the ANZBCTG Study Chair of the PANACEA clinical trial and member of the ANZBCTG's Scientific Advisory Committee.

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About Us

The Australia and New Zealand Breast Cancer Trials Group is a group of world-leading breast cancer researchers who conduct clinical trials research for the treatment, prevention and cure of breast cancer.

We are the largest, independent, oncology clinical trials research group in Australia and New Zealand and our research program involves multicentre national and international clinical trials, bringing together more than 800 researchers in 90 institutions.

For almost 40 years, our research program has explored and tested new and better ways of treating and preventing breast cancer. Our work has improved the treatment of breast cancer, led to changes in the way breast cancer is managed and has saved millions of lives.

This research is supported by the generosity of thousands of people, through our fundraising department the Breast Cancer Institute of Australia, who share our mission for people affected by breast cancer, to live better, to live longer and to prevent breast cancer from ever occurring.

800
Members
There are approximately 800 members of the ANZBCTG, including surgeons, oncologists, study coordinators, nurses and breast physicians for example, who are involved in the conduct of the ANZBCTG's research program.

1,030
Publications
Number of publications the ANZBCTG has contributed to.

14,000
More than 14,000 women from Australia and New Zealand have participated in our breast cancer clinical trials research program.

90
Institutions
The ANZBCTG's research program brings together 90 institutions through Australia and New Zealand.

$80
Million
The Breast Cancer Institute of Australia has raised more than $80 million since 1995, so that ANZBCTG researchers can pursue the very best science.

Dr Ross Jennens
ANZBCTG Member

Ms Leslie Gilham
Clinical Trial Participant

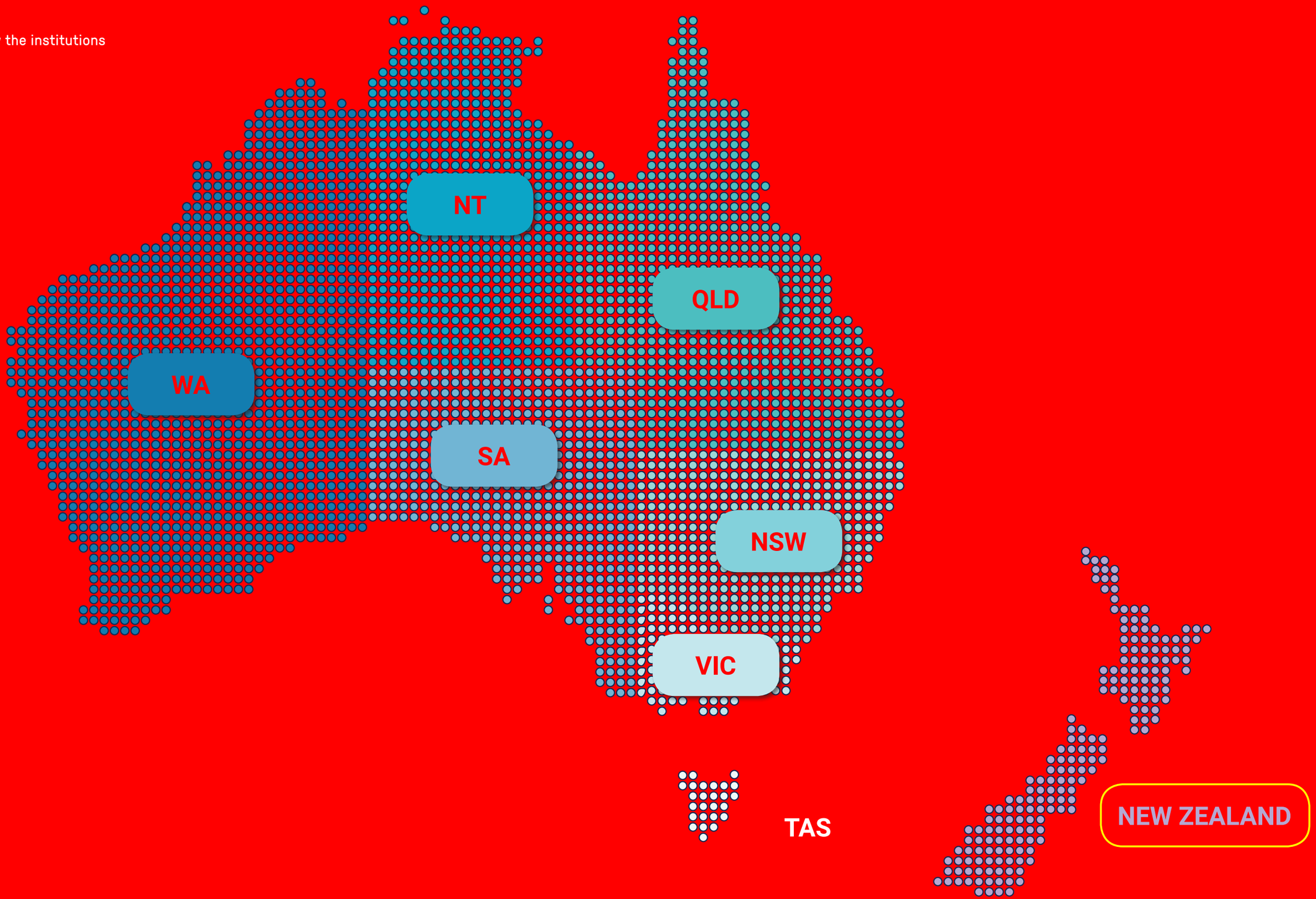
Ms Andrea Lewis
Supporter

Our research involves a unique collaboration between our members, women who participate in our clinical trials, and our donors and supporters.

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.

Participating Institutions

Click a state to view the institutions



Chair's Report

Professor Stephen Ackland

For almost 40 years, the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) has been committed to finding new and improved treatments and prevention strategies for every woman.

At the heart of this commitment is our world-class breast cancer clinical trials research program. This research is informing and changing the delivery of best-practice care, is addressing patient priorities and needs, and ensures that Australian and New Zealand researchers take part and also lead international clinical trials, contributing to our international competitiveness as a centre for high-quality research.

The clinical trials landscape has changed markedly since the ANZBCTG formed some four decades ago and we are operating in an increasingly competitive and disruptive research and not-for-profit environment. To ensure we maintain our research excellence and build on our past achievements, we must be responsive to change and maximise opportunities to raise funds to support our research. We also need to be far-reaching in the promotion of our research program and recognise the important role it has played in the improved survival rates and treatments available for women diagnosed or at risk of breast cancer today.

In the spirit of a lean and dynamic organisation continually striving for research excellence, over the last year we have embarked on an ambitious and dynamic program of change, which supports our 2014-2019 Strategic Plan. Over the coming months, one of the most significant changes will come to life with the merging of the ANZBCTG and our fundraising department, the Breast Cancer Institute of Australia (BCIA), to form one brand that represents one identity and one cause. The project will increase our brand awareness amongst members and in the community, maximise opportunities to fundraise to conduct the highest standard of clinical trials research, and highlight our unique point of difference in breast cancer.

In my final report as Chair of the ANZBCTG, I would like to acknowledge the work and involvement of all past and present Board members, as we implement the current Strategic Plan. The foundations for our current activities began some 10 years ago, as the Board of Directors sought to ensure a strong, vibrant and sustainable research organisation for the long-term.

In the reporting period, our Director of Research and one of the founding members of the Group, Professor John Forbes AM, announced his retirement. John has led an extraordinary research career and has been a mentor to many members of the ANZBCTG, including myself. He has made a significant contribution to the conduct of clinical trials research and helped pave the way for the involvement of Australia and New Zealand in high-quality collaborative international research programs. We sincerely thank John for his dedication and commitment and we wish him well in the future.

I wish to acknowledge Professor Fran Boyle AM, former Board Chair, and Professor Geoffrey Lindeman for their contributions to the ANZBCTG Board of Directors. Both Fran and Geoffrey completed their Board terms during the reporting period and we are indebted to their years of dedication and contributions. We welcomed Professor Christobel Saunders and Associate Professor Nicholas Wilcken to the Board, who have been long term members and supporters of our research program and we look forward to working with them in this new capacity.

I also acknowledge the retirement of Carol Whiteside, one of the original members of the ANZBCTG's Consumer Advisory Panel, who served on this committee for approximately 17 years. Carol brought a unique consumer insight to our research and fundraising activities, and I thank her for her involvement and dedication.

This is also my final year on the Board of Directors and I would like to thank all involved in the Group with whom I have had the pleasure to work with. I also welcome my successor Professor Bruce Mann to the position of Chair. I have no doubt that Bruce's passion and energy will serve the ANZBCTG well into the future, particularly as we approach our 40-year anniversary in 2018.

Professor Stephen Ackland
Chair, Board of Directors

Chief Executive Officer's Report

Soozy J Smith, PhD

The past year has been a time of significant progress across a range of ANZBCTG activities and has laid the foundations for a busy year ahead.

I am humbled by the dedication of our staff, members, clinical trial participants, donors and supporters, who are all committed to conducting the highest quality clinical trials research to improve outcomes for those affected and diagnosed with breast cancer.

I sincerely thank all of those involved in this unique collaboration, and the time and dedication they have pledged to our organisation – many in a voluntary capacity. Our shared achievements have changed practice in breast cancer treatment, management and prevention.

This year, more than 17,500 women in Australia and 3,000 women in New Zealand will be diagnosed with breast cancer. That's 56 women every day. It highlights the ongoing need for our clinical trials research program and why our activities remain just as important today, as when the Group formed almost 40 years ago.

We are determined as a research organisation to make a real difference for those affected by breast cancer, so that they can get on with living and loving their lives.

In the reporting period, the ANZBCTG continued to implement our ambitious strategic plan and we saw a number of important changes across the organisation. Our three departments of Research, Fundraising and Business were brought together into one location at our head office in Newcastle, NSW. Our research department was restructured to be more flexible and dynamic, and is able to respond to a changing clinical trial environment.

An exciting fundraising strategy has been developed which will ensure continued financial support for our clinical trials, so our researchers can answer important scientific questions. In addition, we are working on a more efficient Trials Management Database and trial payment system, which better supports the new clinical trial environment.

Our research and fundraising activities are supported by a team of devoted and enthusiastic staff, who play an important role in our success. I'm incredibly proud of our people, who conduct our research, fundraising and business activities on a day to day basis with passion, skill and determination. Without their hard work, our ongoing success would not be possible. We recognise and pay tribute to our staff length of service and in the last year this includes: Lisa Paksec (20 years); Heath Badger (10 years); and Corinna Beckmore and Cheryl Dodds (5 years).

It is important to acknowledge the financial support we receive from the Breast Cancer Research Foundation (USA), Cancer Australia, the National Breast Cancer Foundation, the National Health and Medical Research Council, and the University of Newcastle. This funding, together with support from our donors and corporate supporters through the Breast Cancer Institute of Australia, supports our research now and into the future. Thank you to Avon, the Commonwealth Bank of Australia and the Australian Women's Weekly, for their ongoing encouragement and commitment to improving the lives of women through breast cancer clinical trials research.

The next year will see the ANZBCTG open more clinical trials and invest more funding into our research program - a substantial 50% increase in research funding over the next year. Our strong financial position means that not only can we support our existing suite of trials but we can also invest in more investigator initiated research. Exciting times are ahead which will further enhance our reputation as one of the world's leading clinical trial research organisations. This investment in new and improved breast cancer treatments would not be possible without thousands of donors and supporters, who have been touched in some way by breast cancer. Your generosity is changing lives.

It is a privilege to lead the ANZBCTG and its wonderful people, as we continue on our vision to be a global and regional leader in research collaboration committed to a world without breast cancer.

Soozy J Smith, PhD
Chief Executive Officer

Breast Cancer Today

In Australia breast cancer is the leading cause of death from cancer in women aged

25-49

1 in 8 women will be diagnosed with breast cancer by the age of 85

In 2017, more than

17,500

women will be diagnosed with breast cancer in Australia

3,000

women will be diagnosed in New Zealand

That's

56 women everyday

There are **193,730**

people living in Australia who have been diagnosed with breast cancer in the past 31 years

Source: Australian Institute of Health and Welfare. Cancer In Australia 2017

Research Report

The ANZBCTG's research program involves multicentre national and international breast cancer clinical trials. This collaboration with researchers from approximately 90 Australian and New Zealand institutions and our global peers, means that we share knowledge and resources to achieve our ultimate goal of finding a cure for every person diagnosed with breast cancer.

We also aim to prevent breast cancer for all people at risk of developing it, and we strive to improve the quality of life for women and men diagnosed and treated for breast cancer.

Although great progress has been achieved to date, new treatments need to be trialled to ensure they are safe and effective. Current treatments must be used in the most effective manner, while researchers pursue strategies to minimise treatment side effects and support patients' quality of life.

Validation of the significance and relevance of the outcome of clinical trials research occurs through publication in peer-reviewed journals and by presentations at scientific meetings. During this reporting period, our research was presented in 47 abstracts/posters/oral presentations and publications, including:

- 18 posters: three presented at the American Society of Clinical Oncology conference, 14 presented at the San Antonio Breast Cancer Symposium and one at the St Gallen Breast Cancer Conference;
- Eight oral presentations: two at the 2016 San Antonio Breast Cancer Symposium, four at the Clinical Oncology Society of Australia's conference, one at the Annual Meeting on Supportive Care in Cancer, and one at the St Gallen Breast Cancer Conference;
- 19 journal/ e-publications.

Publications

Clinical trials intend to answer important questions to help improve breast cancer outcomes in a scientifically robust manner. This allows treating doctors to be confident that their recommendations for a patient's care are backed up by the best evidence possible. Breast cancer is not just a single disease, and best cancer care involves different modalities of specialist and supportive care. Hence there is a broad range of clinical trials running worldwide across all of these areas at any one time. The ANZBCTG spreads its resources across a number of these areas, changing to match local needs, skills and resources but allowing us to remain flexible enough to take advantage of opportunities as they arise.

This year's publications have offered new treatment strategies for the treatment of hormone receptor positive breast cancer, in both the adjuvant and metastatic setting. It is interesting that these outcomes have been achieved in differing ways. In the adjuvant setting two existing drugs, which had been used for many years, were combined. In the metastatic setting, the development of palbociclib, a new class of anti-cancer drug, was responsible. It is hoped that this new class of drugs may be further combined with existing therapies to offer further improvement in patient care.

Final Analysis of the HERceptin Adjuvant (HERA) Trial

The importance of treatment with trastuzumab (Herceptin) for women with early HER2-positive breast cancer is well known. This long term trial was designed to clarify for how long adjuvant trastuzumab should be continued for and the final results were published this year. Patients were randomly assigned equally to three groups. They received either standard chemotherapy alone (control group) or standard chemotherapy and either one or two years of trastuzumab. Worldwide 5,102 patients were randomised, including 110 from ANZBCTG centres. After 11 years of follow up those patients assigned to receive one year of trastuzumab had a significantly reduced risk of disease recurrence compared to those who received none. This is despite 'crossover' occurring in this trial. Crossover occurred when early results showed the advantage of trastuzumab treatment and it would have been unethical to deny this treatment to the control group patients who had not initially been allocated to receive it. This has the potential to make the use of trastuzumab seem less effective than it actually is. Two years of trastuzumab provided no additional benefit, so the standard of care remains one year of adjuvant trastuzumab.

This paper was published in The Lancet 2017; 389(10075):1195-1205, please refer to page 52.

ALTTO (ANZ 0702): No Advantage to Combine Lapatinib with Trastuzumab in Early Breast Cancer

The ALTTO clinical trial provided further support that one year of Herceptin (trastuzamab) remains the standard of care
in HER2-positive patients following surgery. The addition of a second agent targeted at the HER2 receptor, Lapatinib, in addition to trastuzumab had been shown to improve survival in advanced disease. This trial was designed to assess the role of combination treatment following surgery. 8,381 patients were randomised worldwide, including 223 from Australia and New Zealand. Patients were assigned to one of four groups: either drug on its own, or both drugs sequentially or concurrently. After 4.5 years of follow up, single agent Lapatinib was found to be less well tolerated and effective than single agent Trastuzumab. When used in combination, concurrent use suggested it was more effective than sequential use, however neither was a statistical improvement on trastuzumab alone. Hence, one year of trastuzumab treatment remains the standard of care.

This paper was published in the Journal of Clinical Oncology 2016; 34(10):1034-1042, please refer to page x.

High Risk Premenopausal Women May Benefit from the Addition of Ovarian Function Suppression to Endocrine Therapy

The SOFT and TEXT clinical trials were designed to see if the recognised benefit of endocrine therapy with aromatase inhibitors (AI) in post-menopausal women, could be translated to women who were premenopausal by using drugs, surgery or radiotherapy to suppress ovarian function. Previously, the standard of care for these women has been tamoxifen, as aromatase inhibitors in premenopausal women are ineffective if the ovaries continue to produce oestrogen. The trials were designed to be complementary and analysed together. Both trials randomly assigned premenopausal women with hormone sensitive breast cancer to receive either an AI, exemestane, plus ovarian function suppression or tamoxifen and ovarian function suppression over five years, or in the SOFT trial to tamoxifen alone.

This analysis combined the data from 4,891 premenopausal women with hormone receptor–positive, HER2-negative disease across both trials. It showed that a variety of individual factors can combine to increase the risk of breast cancer recurrence. The women with the highest risk of recurrence may experience a 10-15% reduction in rates of recurrence in the five years following diagnosis, with the use of exemestane plus ovarian function suppression instead of tamoxifen.

This paper was published in the Journal of Clinical Oncology 2016; 34(19):2221-2231, please refer to page x.

No Evidence to Suggest that the Addition of Ovarian Function Suppression to Standard Endocrine Therapy Affects Cognitive Function

In premenopausal women the use of tamoxifen following surgery, with or without chemotherapy in oestrogen receptor positive breast cancer, has been shown to reduce rates of breast cancer recurrence and death. The recently published TEXT and SOFT trials have shown that the addition of ovarian function suppression in combination with either the aromatase inhibitor exemestane or tamoxifen provides further benefit over tamoxifen alone, in some women. It is likely that this combination of treatment will be used increasingly in future. As hormonal treatment lasts at least five years, the side effect profile has to be a major consideration. A decline in cognitive function is a much feared side effect of breast cancer treatment and all components of cancer treatment may play a role. Oestrogen has an important role in cognitive functioning, and as ovarian function suppression results in very-low circulating oestrogen levels, its potential effect on cognition is an important consideration.

This sub-study from the SOFT trial, led by the ANZBCTG, involved 86 participants whose cognitive function was tested prior to and one year after commencing treatment with either tamoxifen and ovarian function suppression, exemestane and ovarian function suppression or tamoxifen alone. Although a small sample, no significant difference was found between the cognitive function of the groups. This suggests the addition of ovarian function suppression to the treatment of premenopausal women does not substantially affect cognitive function.

This paper was published in the British Journal of Cancer 2016; 114:956-954, please refer to page 54.

Addition of Ovarian Function Suppression to Tamoxifen Resulted in Worse Endocrine Symptoms and Sexual Functioning During the First Two Years of Treatment

This analysis of the patient reported data obtained from the SOFT trial was conducted in parallel to the efficacy analysis. Patients' experiences of individual symptoms and quality of life were investigated when adding ovarian function suppression to tamoxifen, also considering the influence of prior chemotherapy use. Trials investigating patient-reported outcomes provide information which is complementary to how effective a treatment may be, but this is extremely valuable in helping choose the most appropriate adjuvant endocrine therapy with an individual patient.

This analysis included 1,722 premenopausal patients with hormone receptor–positive breast cancer randomly assigned to receive adjuvant treatment with five years of tamoxifen plus ovarian function suppression (OFS) or tamoxifen alone, including 158 from Australia and New Zealand.

The addition of ovarian function suppression to tamoxifen resulted in worse endocrine symptoms and sexual function during the first two years of treatment. However, changes in global quality of life were small. This knowledge allows clinician to better inform patients about their treatment, balancing effectiveness and potential side effects. It also recognises areas of future interest to help develop and trial treatment strategies to address these side effects.

This paper was published in The Journal of Clinical Oncology; 34(14):1601-1610, please refer to page 54.

A New Treatment Option for Previously Untreated ER-Positive, HER2-Negative Advanced Breast Cancer

The majority of breast cancers are classed as hormone receptor positive. For over 50 years the main treatment strategy has been targeted at the oestrogen receptor. Unfortunately, the majority of these patients eventually become resistant to standard hormone treatments. Palbociclib is a new small molecule which inhibits CDK4 and CDK6, which are small proteins that play a key role in cell division. Previous research has shown that palbociclib in addition to standard hormone treatments could reverse this resistance. This trial followed encouraging results from previous trials and tested this new treatment in larger groups of women to test its efficacy and safety. A total of 666 women from 17 countries, including 20 from Australia and New Zealand, received either letrozole, a standard endocrine treatment, or a combination of letrozole and palbociclib. The combination was found to lead to a significant improvement in progression-free survival, with patients living 24.8 months before the need to change therapy compared to 14.5 months if they received letrozole only. However, the combination resulted in an increased side effect profile with 80% of patients experiencing a drop in their blood counts, albeit it did not cause an increase in hospital admissions. Overall, the combination therapy was well tolerated.

This paper was published in The New England Journal of Medicine 2016; 375(20):1925-1936, please refer to page 53.

Annual Scientific Meeting

Our 38th Annual Scientific Meeting (ASM) was a joint conference in November 2016 with the Clinical Oncology Society of Australia (COSA).

Located at the Gold Coast Convention and Exhibition Centre in Queensland, the ASM attracted approximately 800 delegates from Australia and New Zealand across a range of disciplines involved in oncology and breast cancer research.

The ANZBCTG last partnered with COSA for a joint conference in 2010 and it opens up the opportunity for members across both organisations to collaborate, network and share research news and information. The theme for the 2016 joint conference was Partners for Progress in Breast Cancer Research and Care.

Our international guest speakers were:

Dr Laura Esserman
University of California, USA;

Dr Deborah Fenlon
University of Southhampton, UK;

Dr Shom Goel
Dana-Farber Cancer Institute and Harvard Medical School, USA;

Dr Melinda Irwin
Yale University, USA;

Herbert P Wagner
A Man's Pink (Male Breast Cancer Advocacy Organisation), USA.

ANZBCTG Awards

Each year, the ANZBCTG recognises its' members and researchers, and the important role they play in the development of new breast cancer treatments and prevention strategies. The following awards were presented at the ASM:

- Adjunct Professor Linda Reaby AM was presented with The ANZBCTG Gold Medal, which recognises the contribution and achievements of a member of the ANZBCTG and their significant role in the development and conduct of breast cancer clinical trials in this region. This was the first time that a consumer was presented with the Gold Medal. For more than 20 years, Linda has been a tireless advocate in raising awareness of the importance of breast cancer research particularly clinical trials and for consumers to be involved in the scientific decision making process. Linda was the inaugural Chair of the ANZBCTG's Consumer Advisory Panel.
- Professor John Simes was presented with The Alan Coates Award for Excellence in Clinical Trials Research in recognition of a research career spanning nearly four decades. He has been a tireless advocate of the value of clinical trials and was an early advocate for making clinical trials research part of routine practice. John is the Director and one of the founders of the NHMRC Clinical Trials Centre in Sydney and was an ANZBCTG Board Director for approximately 13 years.
- Professor Sunil Lakhani was presented with The Robert Sutherland Award for Excellence in Translational Research. Sunil is the Head of Discipline of Molecular and Cellular Pathology at the University of Queensland's School of Medicine. He has made an outstanding contribution to all aspects of clinical academic work and a major international contribution to translational research. Sunil has made a significant contribution in the area of triple negative/basal like breast cancers and has received pilot funding from the ANZBCTG to develop a theranostic approach to the management of brain metastases.
- The 2016 recipient of The John Collins Fellow Medal was Dr Melissa Edwards, a trainee registrar in general surgery from New Zealand, who is mid-way through the first year of a PhD on the effects of comorbidity on breast cancer care and outcomes in New Zealand. This award was established to encourage potential academic breast cancer surgeons and registrars to become involved in the ANZBCTG's research program.
- The ANZBCTG Study Coordinator Prize acknowledges the significant contribution to breast cancer clinical trials research achieved by a Study Coordinator at one of our participating institutions. The 2016 recipient was Ms Amy Tang from Box Hill Hospital who has worked closely with our research department for a number of years across numerous trials such as SOFT and TEXT.
- Avon Travel Grants are generously supported by Avon and provide support for Study Coordinators to attend the ANZBCTG's ASM. The 2016 recipients were: Mrs Diane Canning, Ms Alison Coote, Ms Louise Francisco, Mrs Jenny Gilchrist, Mrs Lauren Keller and Mrs Mona Martyn-Smith.

Professor Stephen Ackland, Professor John Simes and Professor Alan Coates AM.

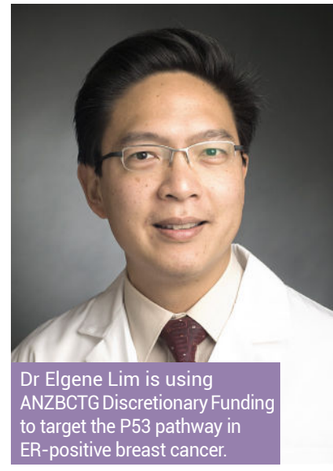
ANZBCTG Discretionary Funding

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

To date, the SAC Subcommittees - Local Therapy, Systemic Therapy and Supportive Care - assist the investigator in refining and developing concept stage proposals initiated by ANZBCTG members. Many of these are ultimately presented to SAC for consideration as future ANZBCTG supported clinical trials.

The ANZBCTG provides opportunities for its members to apply for Discretionary Funding for research projects that have been endorsed by SAC for progression.

Discretionary funding is provided by public donations made to our fundraising division Breast Cancer Institute of Australia. Guidelines for Discretionary Expenditure of Accumulated Funds are available on the Research Section of the ANZBCTG website (www.anzbctg.org).



Dr Elgene Lim is using ANZBCTG Discretionary Funding to target the P53 pathway in ER-positive breast cancer.

We are pleased to advise that in the reporting period, Dr Yoland Antill received seed funding (Category1a) for her project: Treatment of vaginal atrophy using fractional microablative CO2 laser in post-menopausal women with breast cancer on aromatase inhibitors: a pilot study.

The status of previously awarded Discretionary Funding projects is:

Completed

- Professor Phyllis Butow: Development of a patient decision aid for women with early stage unilateral breast cancer considering contralateral prophylactic mastectomy (CPM);

Ongoing

- Professor Tomas Kron: Deep Inhalation Breath Hold for reduction of cardiac toxicity in patients with left sided breast cancer undergoing radiotherapy;
- Dr Elgene Lim: Targeting the p53 pathway in ER-positive breast cancer;
- Dr Yoland Antill: The timeline and quality of life implications of madarosis in patients undergoing cytotoxic chemotherapy for breast malignancy.

The Year in Review

During the reporting period, the ANZBCTG had seven trials open to accrual, while the DOMINO and SOLACE clinical trials were closed to recruitment. An additional 11 trials were undergoing closure or were in long-term follow up.

In late 2016, the Trials Department was restructured to be more flexible and dynamic, to better respond to a changing clinical trial environment. We strive to be more efficient and will continually streamline our processes, as we concurrently maintain a strong pipeline of trial activity. We commend my colleagues in the Trials Department for their ongoing commitment and maintenance of high standards during the implementation of these changes and their ongoing support.

Also at the end of 2016, the international guidelines of good clinical practice (GCP) received the most significant amendment since their inception over 20 years ago. This is an acknowledgement that clinical trials have substantially evolved in complexity, technological capabilities and costs over time. The new GCP guideline encourages implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting, while continuing to ensure patient safety and reliability of trial results. The ANZBCTG's Trials Department supports the revised guidelines, whose central tenet is the optimal management of risks.

The Annual Report provides an opportunity to reflect on the achievements of the past year and to highlight future opportunities. The changes that we have made in our research department are reflected within the landscape of breast cancer clinical trials worldwide. For many years, improvements in breast cancer outcomes have focused on increasing available treatments including: new drugs, techniques and approaches. There is an increasing recognition that in some breast cancer patients with a good prognosis, some of these treatments are not essential to favourable outcomes and indeed the long-term side effects of certain treatments may prove detrimental to patients.

The March 2017 St Gallen Conference focussed on early breast cancer treatment standards, where the main theme was 'Escalating and De-escalating Treatment'. This important international event highlighted that it is essential for clinicians to know when to escalate treatment for the optimal results, as well as knowing when it is appropriate to de-escalate treatment that may be unnecessary. The consensus was that in certain scenarios, both surgery and radiotherapy can be minimised and that chemotherapy can be safely avoided in low risk patients.

It is in this spirit of de-escalation that the ANZBCTG will commence local recruitment to the ANZ 1601 EXPERT trial in the second half of 2017. The EXPERT study, chaired by Professor Boon Chua, hopes to recruit 1,170 patients locally and internationally. This long-term study aims to identify which breast cancer patients may be able to avoid radiotherapy after surgery and as a result, the side effects of this treatment. Significantly, this is the first time the ANZBCTG will lead and coordinate an international trial and we have worked intensively over the past year or so with our global collaborators, the Breast International Group (BIG) and the International Breast Cancer Study Group (IBCSG), to finalise the protocol and achieve local ethics approval. Local recruitment is imminent and we hope to recruit international patients in the first half of 2018.

As indicated above, escalation of treatment in some breast cancer sub-types remains important in order to achieve better outcomes. The ANZBCTG is the local sponsor of the global PALLAS trial, which is currently open to recruitment. Following the successes with palbociclib in the metastatic setting, this trial uses this new drug in combination with standard endocrine therapy in the adjuvant setting. It is hoped that patient outcomes will improve by reducing the likelihood that breast cancer will return after initial surgery.

Since initial success in the treatment of malignant melanoma, immunotherapy over the last five years has been the big news story within oncology. The number of tumour types in which trials have shown the potential benefit of this new class of treatment has grown. Some data show that certain breast cancer subtypes, in which there are currently limited treatment options, may benefit from these drugs too. The ANZBCTG hopes to be at the forefront of exciting developments in the trialling of immunotherapy in breast cancer treatment.

Collaboration has been the key to our significant research achievements over the past year. This involves our international research partners, the dedicated clinicians and their teams at ANZBCTG participating institutions, our scientific research and consumer committee members, and the committed staff in the Trials Department, who seamlessly draw together all research activities. We look forward to the next year, which will bring new opportunities and new trials, that we hope will lead to further improvements in the outcomes for women at risk or diagnosed with breast cancer.

Professor Kelly-Anne Phillips
Deputy Director of Research

Associate Professor Prue Francis
Chair, Scientific Advisory Committee

Associate Professor Nicholas Wilcken
ANZBCTG Board Director

Ms Phillipa Lee
Chief Operating Officer

Dr Rob Paterson
ANZBCTG Clinical Fellow

Open Clinical Trials

ELIMINATE: Improving Treatment Choices for Women with Oestrogen Receptor Positive Breast Cancer

Dr Nick Murray is the ANZBCTG Study Co-Chair of the ELIMINATE clinical trial.

Neoadjuvant therapy (treatment before surgery) aims to shrink the breast cancer in size to increase the chance of breast conserving surgery and to monitor the effect of treatment on the tumour. The ANZBCTG is the lead international group for the **ELIMINATE** clinical trial, which aims to ascertain whether combining two breast cancer treatments before surgery is more effective than one alone in women diagnosed with large oestrogen receptor-positive breast cancer. These two treatments, chemotherapy and hormone treatment, are usually given one after the other.

Oestrogen receptor-positive breast cancer grows in the presence of the hormone oestrogen. An enzyme called aromatase is responsible for the production of oestrogen in both pre and postmenopausal women, while the functioning ovaries in premenopausal women also produce oestrogen. Lowering or eliminating oestrogen using hormone treatments that block the aromatase enzyme and stop the ovaries from producing oestrogen is an effective way of treating breast cancer that is hormone-sensitive.

An aromatase inhibitor called letrozole blocks the aromatase enzyme from producing oestrogen making it an effective hormone therapy for postmenopausal women. Goserelin is a medication that causes a temporary menopause, preventing the ovaries from producing oestrogen which, when combined with an aromatase inhibitor like letrozole, is an effective hormone therapy for premenopausal women.

The ELIMINATE clinical trial, which commenced in Australia and New Zealand in May 2015, will investigate whether giving neoadjuvant hormone therapy and chemotherapy at the same time is more effective than neoadjuvant chemotherapy alone at shrinking the breast cancer before surgery. All participants in the ELIMINATE clinical trial will receive standard neoadjuvant chemotherapy for between 18 and 24 weeks before surgery. Two in every three participants will be randomly assigned to receive hormone therapy in addition to standard neoadjuvant chemotherapy.

Participants will be closely monitored by their doctor during neoadjuvant treatment and, after breast surgery, may be offered further treatment according to local standard of care. It is hoped that the results of this study will help determine the effectiveness of hormone therapy in combination with standard chemotherapy given before surgery and improve treatment choices and outcomes for women diagnosed with oestrogen receptor-positive breast cancer in the future.

ELIMINATE is open at 24 hospitals in Australia and New Zealand and has been extremely successful in recruiting participants at a much faster rate than anticipated. By the end of March 2017, 95 women were enrolled in the trial that aims to enrol 123 women in total. We anticipate reaching this target by the end of 2017, much sooner than the previously planned end date of December 2018. ELIMINATE is supported by an NHMRC Project Grant.

> “The first hospital to open for participant recruitment was activated in Melbourne in March 2015. We plan to recruit 123 women to the ELIMINATE trial over approximately 42 months at more than 20 hospitals across Australia and New Zealand. Recruitment has proceeded briskly and we are very hopeful that an answer to this important research question can be obtained sooner and provide more treatment options for women diagnosed with early breast cancer.”
>
> Dr Nick Murray and Associate Professor Prue Francis

Associate Professor Prue Francis is the ANZBCTG Study Co-Chair of the ELIMINATE clinical trial.

OlympiA: Improving Treatments for Patients with BRCA Mutations & High-Risk HER2-Negative Breast Cancer

OlympiA is an international clinical trial which will enrol 1,500 participants in approximately 500 centres worldwide. It is open to both women and men diagnosed with HER2-negative breast cancer provided they have an inherited BRCA1 or BRCA2 gene mutation.

Approximately 80% of all breast cancers are HER2-negative, and about 5% of these breast cancers also have inherited abnormalities in the breast cancer genes, BRCA1 or BRCA2. While many people diagnosed with HER2-negative breast cancer are successfully treated with currently available standard treatments (including breast surgery, chemotherapy and radiotherapy), some are not cured and so new treatments are needed.

The OlympiA clinical trial is investigating whether taking olaparib orally can reduce the risk of breast cancer coming back after all standard anticancer treatments have been completed. Participants will be randomly allocated (50:50) to either olaparib or a placebo. They will be reviewed regularly to ensure their safety. Follow-up of participants will continue for 10 years after the last person is enrolled.

It is hoped that the trial will show that olaparib improves the curability of patients with HER2-negative breast cancer and inherited BRCA1 or BRCA2 mutations, which may result in a new standard treatment for these breast cancer patients.

This trial is being conducted in partnership with the Breast International Group (BIG) and AstraZeneca. During the reporting period, the ANZBCTG enrolled 22 of the 862 women participating in this global trial.

Professor Kelly-Anne Phillips is the ANZBCTG Study Chair of the OlympiA clinical trial.

> “It is great news for Australian patients that 15 ANZBCTG member hospitals are participating in this innovative study. The first Australian patient joined the study in April 2015, and an ANZBCTG site recruited the first hormone receptor positive patient, globally, under an amendment to the protocol in late 2015.”

PALLAS: Reducing the Risk of Breast Cancer Coming Back for Patients with HR Positive, HER2-Negative, Early Stage Breast Cancer

The international **PALLAS** clinical trial is being conducted locally by the ANZBCTG, in collaboration with the Austrian Breast & Colorectal Cancer Group (ABCSG) and the Breast International Group (BIG).

PALLAS is open to both women and men diagnosed with Hormone Receptor (HR) positive, Human Epidermal Growth Factor Receptor 2 (HER2) negative, early stage breast cancer.

Although many patients with HR positive, HER2-negative breast cancer may be cured of their disease with optimal therapy, a significant number of patients with stage II and III disease will experience disease recurrence. Adjuvant endocrine therapy for breast cancer can be extremely effective, particularly with extension beyond five years, however disease recurrence can occur, with risk distributed over the decades following initial diagnosis. Methods to improve the efficacy of endocrine therapy, and delay the onset of resistance, are needed.

ER positive breast cancer biologically may demonstrate features suggestive of sensitivity to CDK4/6 inhibition with agents such as palbociclib. Given the demonstrated activity and safety of palbociclib in the first-line treatment of metastatic HR positive, HER2-negative breast cancer, supporting FDA approval, there is interest in whether the benefits of CDK4/6 inhibition may translate into the adjuvant setting. The purpose of the PALLAS study is to determine whether the addition of palbociclib to adjuvant endocrine therapy will improve outcomes over endocrine therapy alone for ER positive, HER2-negative early breast cancer.

The ANZBCTG has enrolled 50 of the 1,142 participants in the PALLAS clinical trial, as at the 31 March 2017. Up to 4,600 participants are expected to be enrolled in this trial internationally over a period of approximately three years.

> “It has been fantastic to see the level of enthusiasm from Australian patients and study sites for this important new international phase three study. ANZBCTG recruitment is proceeding well, and we expect to make a substantial Australian contribution. We have seen very promising results from palbociclib in the metastatic setting, and hope that this will translate into improved disease free survival in patients being treated with curative intent. We are fortunate to have this opportunity for a new collaboration on this study with the Austrian Group.”
>
> Dr Nicholas Zdenkowski

Dr Nicholas Zdenkowski is the ANZBCTG Study Chair of the PALLAS clinical trial.

PANACEA: Improving Treatment Options for Women with HER2-positive Metastatic Breast Cancer

In collaboration with the International Breast Cancer Study Group (IBCSG), the ANZBCTG is conducting the **PANACEA** clinical trial at selected Australian institutions. This clinical trial is suitable for women diagnosed with advanced HER2-positive breast cancer. The standard treatment for HER2-positive breast cancer that has progressed is to continue treatment with trastuzumab and to add another type of therapy or chemotherapy. The aim of this clinical trial is to find out the most suitable (maximum tolerated) dose of pembrolizomab and trastuzumab when these drugs are used together and to assess if their combined use is an effective treatment.

It is thought that cancer cells with increased levels of the protein called PD-1, avoid detection by the body's natural immune system. Trastuzumab and pembrolizumab are being given together to see if they can decrease the level of PD-1 in breast cancer and allow the body's immune system to identify and work against the cancer cells. To ensure that PANACEA is a suitable option for patients, the amount of PD-1 and HER2 receptors that are present in metastatic breast cancer tissue will be tested before entry to the trial.

Although trastuzumab and pembrolizumab have been given individually to cancer patients, this is the first trial that will test the combination of the two drugs. Initially, a small number of trial participants will receive both drugs at pre-specified doses and study doctors will assess any side effects until the maximum tolerated dose is determined. All participants will be regularly monitored throughout treatment to evaluate side effects, treatment tolerability and effectiveness of this combination therapy.

The ANZBCTG has enrolled 21 of the 57 women participating in PANACEA (31 March 2017) and is leading the international recruitment to this important trial. We anticipate that enrolment will end during 2017, with results likely to be presented at the end of the year. Preliminary findings may lead to expansion of the PANACEA study and we are hopeful that this trial will provide evidence of a new treatment option for women diagnosed with advanced HER2-positive breast cancer.

> "PANACEA is a very important, small, early phase clinical trial which will involve up to 10 institutions in Europe and Australia. Pembrolizumab is approved by the Pharmaceutical Benefits Advisory Committee for the treatment of advanced melanoma in adults and we hope that the PANACEA clinical trial will demonstrate a similar clinical benefit for women diagnosed with advanced HER2-positive breast cancer."
>
> Associate Professor Sherene Loi

Associate Professor Sherene Loi is the ANZBCTG Study Chair of the PANACEA clinical trial.

PENELOPE^{B}: Reducing the Risk of Breast Cancer Coming Back for Patients with HR Positive, HER2-Normal Primary Breast Cancer

The ANZBCTG is collaborating with multiple international groups in the German Breast Group (GBG) led **PENELOPE^{B}** clinical trial, which is suitable for women with hormone-receptor-positive, HER2-normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy.

Neoadjuvant (before surgery) chemotherapy can substantially reduce the size of a primary breast tumour to allow for breast conserving surgery and surgery for tumours that were inoperable before chemotherapy. Women who receive neoadjuvant chemotherapy followed by surgery and who have some cancer remaining in the surgically removed tissue have a higher than average risk of the cancer coming back (relapse). Standard treatment after surgery for hormone receptor (HR)-positive and HER2-normal (also known as HER2-negative) breast cancer usually includes at least five years of hormone (endocrine) therapy.

The PENELOPE^{B} clinical trial is designed to evaluate whether adding one year of treatment with a new medication called palbociclib (PD-0332991) to standard hormone therapy will improve outcomes for women with breast cancer that is HR-positive and HER2-normal. The trial drug, palbociclib belongs to a group of drugs called Cyclin Dependent Kinase (CDK) inhibitors. Palbociclib blocks CDK4 and CDK6, which stops certain processes that cause cancer cells to grow. It appears to be most effective against HR-positive, HER2-normal breast cancer.

The ANZBCTG commenced the PENELOPE^{B} clinical trial in Australia in January 2015. The trial participants will receive hormone treatment and will be randomly assigned to receive either palbociclib or placebo for 13 cycles. Half of the trial participants will be given palbociclib, and half will be given placebo. These women will be closely monitored by their doctor during and after trial treatment is completed. Blood and tumour tissue samples will be collected to help researchers understand why some trial participants may experience a greater benefit from the trial treatment compared with others. Planned analysis of these samples may also help explain why some trial participants experience more side effects.

At the end of the reporting period in March 2017, the ANZBCTG had enrolled 62 of the 908 women participating in this trial internationally. The current global recruitment target is 1,100 participants.

Associate Professor Nicole McCarthy is the ANZBCTG Study Chair of the PENELEOPE^{B} clinical trial.

> "Fifteen hospitals in Australia are currently open for participant entry to the PENELOPE^{B} trial. Investigators and their research teams are making an important contribution to this global clinical trial, with patients now recruited in eleven countries."
>
> Associate Professor Nicole McCarthy

POSNOC: Improving Treatment Options Where Breast Cancer Has Spread in the Armpit & Reducing Side Effects like Lymphoedema

The standard treatment for early breast cancer that has spread to one or two lymph nodes includes further treatment to the armpit (axilla). Prior research suggests that it may be possible to avoid removal of all axillary nodes or radiotherapy to the armpit and women may be spared the potential side effects of having extra treatment to the axilla including lymphoedema.

The UK led **POSNOC** clinical trial commenced in Australia and New Zealand in April 2016 and is designed for women with early breast cancer with macrometastases found in one or two sentinel lymph nodes. It may be that the long term prognosis for women when there are macrometastases in sentinel nodes is the same whether they have additional treatment to the armpit or not. All women taking part in this trial receive additional standard treatment following surgery to further reduce the growth of any remaining cancer cells. This trial studies factors such as the rate of breast cancer recurrence, both in the armpit, the breast and elsewhere around the body.

In the POSNOC clinical trial all participants will receive standard treatment, which may include chemotherapy and/or endocrine therapy and/or radiotherapy to the breast or chest wall, and will be randomly assigned to receive further axillary treatment (surgery to remove all the lymph nodes in the armpit, or radiotherapy to the armpit) or no further axillary treatment. All participants will be reviewed regularly to ensure their safety and tumour tissue samples will be collected for future research.

POSNOC is of considerable importance in terms of improving outcomes for women with breast cancer and also in understanding breast biology. By the end of March 2017, the ANZBCTG had enrolled 31 of the 656 women participating in this international trial.

Professor Bruce Mann is the ANZBCTG Study Chair of the POSNOC clinical trial.

> “Sixteen hospitals in Australia and New Zealand are currently open for participant entry to the POSNOC trial with a further four institutions preparing to activate this trial. Recruitment was initially slow but is gradually picking up. There is great interest amongst ANZ surgeons and other breast cancer specialists to rapidly complete this trial and generate important new information in this controversial area. We are hopeful that it will demonstrate that less intense treatment can be safely given to this group of breast cancer patients.”
>
> Professor Bruce Mann

PROSPECT: Identifying Women Who Can Safely Avoid Radiotherapy & the Side Effects of this Treatment

For women diagnosed with early invasive breast cancer, standard treatment often involves breast conserving surgery followed by radiotherapy to reduce the risk of breast cancer returning to that breast (local recurrence). The need for radiotherapy depends on the risk of local recurrence occurring after surgery alone. If the chance is known to be minimal, there may be no need for radiotherapy. At present however, no sizeable group of patients with minimal risk of local recurrence after surgery alone has been identified, so the vast majority of women are recommended to have radiation. The treatment is usually given as a daily dose over three to six weeks and receiving radiotherapy treatment can lead to some short and longer term side effects.

PROSPECT is a pilot clinical trial that we started in 2011. The study involves a relatively new technology, breast magnetic resonance imaging (MRI), in combination with a review of pathological features of the breast tumour, to prospectively identify women who may be able to safely avoid radiotherapy because their risk of local recurrence is very low. PROSPECT aims to examine whether the abnormalities that contribute to the likelihood of local recurrence (and hence the need for post-surgery radiotherapy treatment) can be detected by breast MRI. Samples of the tumour tissue removed during surgery will be collected to further our knowledge about breast cancer.

If it is found that radiotherapy can be omitted without a significant risk of local recurrence, it could alter the management of women with early breast cancer, as well as decrease costs to the health care system. This may be particularly significant for rural and remote women, who frequently choose total mastectomy (breast removal) to avoid the need to have radiotherapy treatment that requires them to be absent from home.

The ANZBCTG has registered 280 women who have undergone pre-operative breast MRI and of these, 127 were recruited to the study, as at the end of March 2017. We are aiming for 200 women in total to be enrolled in the PROSPECT clinical trial. PROSPECT is funded by ANZBCTG donor funds, with support from the National Breast Cancer Foundation and the Cancer Council of Victoria.

> “Nearly 300 women have agreed to participate in screening assessments for PROSPECT which is testament to the fact that personalised treatment and the avoidance of over treatment is an important consideration for women diagnosed with early invasive breast cancer. About 45% of those women screened have been eligible for the trial, and 127 are participating and have not had radiotherapy. With continued screening and recruitment activities we hope to reach the required target of 200 participants by the end of 2019. Plans are being made for how the outcome of PROSPECT will lead to future trials and may eventually offer a new treatment option to women diagnosed with very early breast cancer.
>
> Professor Bruce Mann

Professor Bruce Mann is the ANZBCTG Study Chair of the PROSPECT clinical trial.

Clinical Trials Accrual Completed

Participant follow-up continuing

The trials listed below have completed participant enrolment, which means the target sample size has been achieved and the trial has entered a 'follow-up phase'. During this period planned trial analyses will be completed and the results published in peer reviewed medical journals. Please refer to the Publications list on page 50.

	Opened by the ANZBCTG	Participant accrual completed
ANZ 1301 (DOMINO): A phase II study evaluating a decision aid for women considering neoadjuvant systemic therapy for operable invasive breast cancer.	November 2014	September 2016
ANZ 1103 (SOLACE): A phase 1 study of Olaparib, a poly ADP-ribose polymerase-1 (PARP) inhibitor, in combination with metronomic cyclophosphamide in patients with metastatic BRCA-associated cancer, triple negative breast cancer or serous ovarian cancer.	November 2012	September 2016
ANZ 1403/BIG 3-13/GO28888 (LORELEI): A phase II randomized, double-blind study of neoadjuvant letrozole plus GDC-0032 versus letrozole plus placebo in postmenopausal women with ER-positive/HER2-negative, early stage breast cancer.	October 2014	July 2016
ANZ 1202/TRIO-022/A5481008 (PALOMA-2): A randomised, multicentre, double blind phase 3 study of PD-0332991 (oral CDK 4/6 inhibitor) plus letrozole versus placebo plus letrozole for the treatment of postmenopausal women with ER (+), HER2 (-) breast cancer who have not received any prior systemic anti-cancer treatment for advanced disease.	May 2013	June 2014
ANZ 1102/BIG 4-11/BO25126/TOC4939G (APHINITY): A randomised multicentre, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer.	December 2011	July 2013
IBCSG 35-07/BIG 1-07 (SOLE): A phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following four to six years of prior adjuvant endocrine therapy for postmenopausal women with hormone receptor-positive, node-positive early stage breast cancer.	March 2008	August 2012
ANZ 02P2/IBIS-II (Prevention and DCIS): International multicentre trials of anastrozole versus placebo in postmenopausal women at increased risk of breast cancer and tamoxifen versus anastrozole in postmenopausal women with hormone-sensitive DCIS.	June 2005	February 2012

	Opened by the ANZBCTG	Participant accrual completed
IBCSG 34-05/SWOG S0230 (POEMS): A phase III trial of LHRH analogue administration during chemotherapy to reduce ovarian failure following standard adjuvant chemotherapy in early stage, hormone receptor-negative breast cancer.	April 2006	June 2011
IBCSG 25-02 / BIG 3-02 (TEXT): A phase III trial evaluating the role of exemestane plus GnRH analogue as adjuvant therapy for premenopausal women with endocrine-responsive breast cancer.	May 2004	March 2011
ANZ 0901 (TAILORx): A phase III, multicentre, multinational, randomised trial of adjuvant chemotherapy plus hormone treatment versus adjuvant hormone treatment alone for patients with previously resected, axillary node-negative, invasive breast cancer with various levels of risk for recurrence.	October 2009	October 2010
IBCSG 24-02/BIG 2-02 (SOFT): A phase III trial evaluating the role of ovarian function suppression and the role of exemestane as adjuvant therapies for premenopausal women with endocrine-responsive breast cancer.	May 2004	June 2010
IBCSG 23-01: A randomised trial of axillary dissection versus no axillary dissection for patients with clinically node-negative breast cancer and micrometastases in the sentinel node.	June 2005	February 2010
IBCSG 27-02/BIG 1-02/NSABP Trial B-37: A randomised clinical trial of adjuvant chemotherapy for radically resected loco-regional relapse of breast cancer.	July 2003	January 2010
ANZ 9602 (ATLAS): Adjuvant tamoxifen longer against shorter clinical trial in early breast cancer.	November 1995	March 2005
IBCSG 18-98/BIG 1-98: A phase III study to evaluate letrozole as adjuvant endocrine therapy for postmenopausal women with receptor (ER and/or PgR) positive tumours.	October 1999	May 2003
ANZ 92P1/IBIS-I: A study to determine whether tamoxifen is effective in reducing the incidence of breast cancer in women at high risk of developing breast cancer. This is a prospective double-blind placebo controlled trial.	April 1992	March 2001
ANZ 9801 (ATAC): A randomised double-blind trial comparing Arimidex® alone with Nolvadex® alone with Arimidex® and Nolvadex® in combination, as adjuvant treatment in postmenopausal women with breast cancer. (Follow-up of participants is by means of the LATTE protocol)	April 1998	June 1999

Consumer Advisory Panel Report

Ms Leonie Young

The ANZBCTG's Consumer Advisory Panel (CAP) has reached a major milestone – 18 years contributing to the Group's research program

The first consumer representative was invited to join the ANZBCTG in 1994 and CAP was officially formed in 1999. As Linda Reaby, the first consumer, aptly said on the occasion of her recent retirement - "We were the pioneers and had no model to follow."

CAP members are actively involved in all research undertaken by the ANZBCTG, from clinical trial concept and development through to implementation, recruitment, analysis and follow up.

Two CAP members are members of the ANZBCTG's Scientific Advisory Committee (SAC) and each CAP member is a member of one of the SAC Subcommittees, thus ensuring the perspective of women who have experienced breast cancer is represented. CAP members play a particularly important role in reviewing patient information and consent documentation which ensures patient materials for potential new clinical trial participants is clear and understandable. They are also actively involved in fundraising and community awareness initiatives of the Breast Cancer Institute of Australia (BCIA)

CAP has become a recognised model worldwide and over the years, 19 women have volunteered their time and expertise as members of the committee. It is also important to acknowledge three CAP members did not survive their breast cancer during their committee membership. Since the early 2000's CAP has always included a New Zealand member, and this year we have two members from New Zealand, thereby ensuring the issues for women in both countries are considered.

One of the longest serving members, Carol Whiteside, retired in November 2016. Carol resides in Newcastle NSW, and remains a staunch supporter of the ANZBCTG's research program. Her presence on the CAP will be greatly missed. Following Carol's retirement, we welcomed two new members: Melissa Bell from Dunedin, New Zealand, and Karen Alexander from Canberra. Current members also include –Raewyn Calvert, Hamilton New Zealand; Cheryl Grant, Sydney; Sheryl Fewster, Perth; Leslie Gilham, Melbourne; and myself as Chair.

CAP members are actively involved in the IMPACT Advocate Program and as the CAP Chair, I am also the IMPACT Consumer Coordinator. This Program offers a unique opportunity for a select group of women to enhance their knowledge and understanding of breast cancer research by attending the ANZBCTG's Annual Scientific Meeting (ASM). Participants attend daily tutorial sessions, which provide an invaluable opportunity to discuss the day's presentations with like-minded women and have their questions answered by researchers who are experts in their field. CAP members mentor the Program's participants and provide input and feedback into how to maintain the Program's relevance for breast cancer clinical trials advocates. The 2016 Program was held in conjunction with the joint ASM of the ANZBCTG and the Clinical Oncology Society of Australia (COSA) on the Gold Coast, Queensland. The Program was supported by daily tutors and we thank Associate Professor Nicole McCarthy, Associate Professor Nicholas Wilcken, and Dr Nicholas Zdenkowski.

The Cancer Trials Consumer Network (CTCN) is a network of representatives from each of the cancer clinical trials groups and it provides valuable learning and mentoring opportunities. I am the Chair of the CTCN, which meets three times annually and reports to the Executive Officer Network with facilitation assisted by COSA. The CTCN facilitated a breakfast session during the 2016 ANZBCTG and COSA ASM, addressing how researchers and consumers can enhance collaboration. The session was titled 'Not just a tick box: How engaging with consumers can add value to your research' and included presentations by Dr Debra Fenlon from the University of Southampton, Professor Bruce Mann from Melbourne, and myself, as well as a robust panel discussion with guest presenters and CAP members, Raewyn Calvert and Cheryl Grant.

CAP members have broad networks, collaborate with other cancer organisations and networks, and provide mentoring and training for consumers wishing to make a difference for people affected by cancer. They remain committed and feel privileged to be part of the ANZBCTG's research team and we look forward to continuing this successful partnership in working towards a world without breast cancer.

Leonie Young
Chair, Consumer Advisory Panel

CAP members L-R: Raewyn Calvert, Sheryl Fewster, Leonie Young, Melissa Bell, Karen Alexander, Leslie Gilham and Cheryl Grant.

Fundraising Report

Ms Julie Callaghan

Our researchers rely on the Australian community to support and help achieve positive outcomes for all those affected by breast cancer. Breast cancer clinical trials are costly and take time, and thus the need for sustainable, long term income is paramount to their success.

Thanks to the generosity of our supporters, $7.43 million was raised in 2016-2017 through initiatives and activities around the country, many of which are profiled on the following pages. The investment made to build our supporter base has helped to achieve a 33% increase in our net fundraising income over the past four years. This means we now have more funds available for our researchers to pursue opportunities and achieve the next breakthrough in breast cancer trials for the benefit of all women and their families.

BCIA has four main fundraising income streams and the results for 2016-2017 are shown below.

	2016/2017		2015/2016	
Donations	$2,634,105	36%	$2,867,002	46%
Corporate Support	$1,127,902	15%	$130,053	2%
Special Events and Projects	$1,939,630	26%	$1,833,493	30%
Bequests	$1,728,195	23%	$1,388,535	22%
Total Fundraising Income	**$7,429,832**	**100%**	**$6,219,083**	**100%**

BCIA's total operating cost this year, which includes direct fundraising and administration expenses, was $2,743,670 which is 37% of the total fundraising income. Our focus is to conduct best-practice fundraising initiatives which resonate with supporters and which generate sustainable income, whilst also being highly cost-effective so that this ratio is reduced and more funds are directed to the research program.

We also continue our work to ensure our fundraising activities and communications are timely, relevant, informative and inspiring. Our supporters help to shape the fundraising activities we conduct as we respond to their preferences about how they engage with us and show their support.

My sincere condolences go to the families of our supporters who sadly passed away during the past year. I also acknowledge those supporters who generously remembered the BCIA in their Will. Their legacy will help to advance research for the benefit of future generations and will never be forgotten.

This year we celebrated a wonderful milestone with our friends at Avon, recognising the 20th anniversary of our partnership and the $10.4 million donated through the Avon Breast Cancer Crusade. Avon is a truly philanthropic company, and it is our great privilege to work with them in our mutual goal to save lives from breast cancer.

I thank every individual, corporate partner, business and community group for their unwavering generosity and commitment this year. Our research program would not be possible without our supporters who, together with our researchers and the women who participate in our clinical trials, make up the unique collaboration needed to ensure advances are made so that every life is saved from breast cancer.

Julie Callaghan
General Manager, Breast Cancer Institute of Australia (BCIA)

Fundraising Snapshot 2016-2017

53,000 active supporters

$7.43 million raised in 2016–17

$1.75 million from 18 bequests

$80 million raised since 1995

1,800 regular givers
$550,000 income

6,000 new supporters acquired

$3 million value generated in media and CSA activity

500 community events
45,000 people

385 supporters give more than **$1000** annually

31,332 Facebook fans
250 posts with a reach of over 1 million

AVON donates **$1 million** bringing total to
$10.4 million

482 Commonwealth Bank morning teas raising
$100,00

Community Fundraising

500 community events involving over 45,000 people

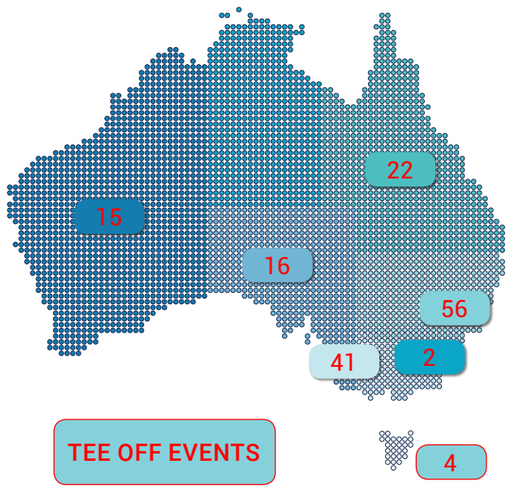
Many dedicated and energetic supporters throughout Australia got active in their communities helping to raise $418,000 this year. Individuals, community groups, golf clubs and businesses held special events and morning or afternoon teas, participated in sporting events, gave through workplace giving programs and played a round of golf to show their support for breast cancer trials research. We congratulate them for their passion and commitment to breast cancer trials research.

Tee Off for Breast Cancer Trials

Tee Off celebrated its 20th year this year and holds a special place in the hearts of golfers throughout Australia. This annual event unites golfers to play the sport they love, enjoy one another's company and raise funds to support their loved ones and friends affected by breast cancer. In 2016, Tee Off events were held in 156 golf clubs and a further 28 clubs made donations raising $175,000, bringing the total raised since 1997 to $1.9 million.

Congratulations to the following who were our highest fundraisers in 2016:

- Mornington Golf Club, VIC — $8,525.55
- Pacific Harbour Golf and Country Club, QLD — $8,030.05
- Macquarie Links International Golf Club, NSW — $7,855
- Woollahra Golf Club, NSW — $7,000
- Lakes View Country Club, VIC — $6,040



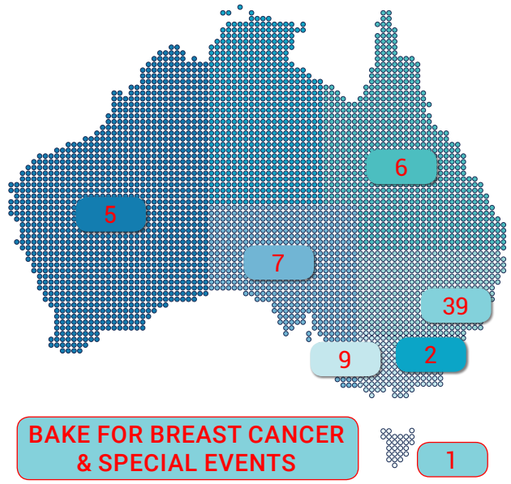
Bake for Breast Cancer

In its 2nd year, Bake for Breast Cancer is fast becoming a fun-filled way to get together with friends , family or work colleagues to raise funds for breast cancer trials research. It's easy to get involved with the registration system online through our website. The format is entirely up to the organiser, with many people choosing to hold morning or afternoon teas. This year 31 events were held, mostly as part of National Breast Cancer Awareness Month during October, raising $13,000.

For the last two years, Andrea Lewis, pictured at left wearing the pink scarf, has held a Bake for Breast Cancer fundraiser at her workplace. She invites her colleagues, family and friends along for morning tea with delicious cakes, raffles and even a masseuse who provided massages in return for a donation to BCIA! One of Andrea's close friends is a breast cancer survivor and she's very passionate about supporting breast cancer trials research to help every woman survive breast cancer.

Functions and Special Events

We're very grateful for the efforts of the 38 individuals, businesses and community organisations who held special events throughout the year and raised $72,000 for BCIA.

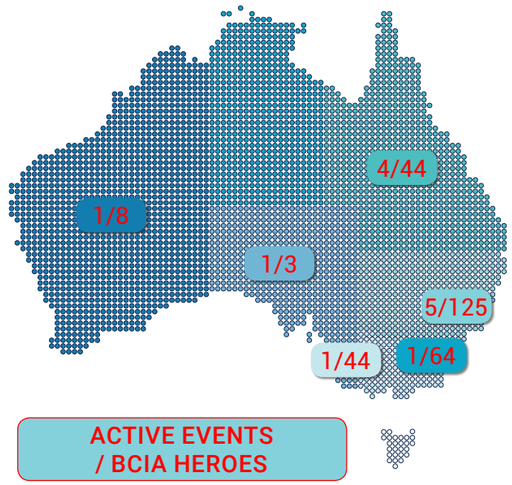


One of these events was held by the wonderful management and retailers at North Rocks Shopping Centre, which is located in north-western Sydney NSW. The Centre went pink in October 2016 as part of National Breast Cancer Awareness Month. A range of pink initiatives took place with special key tags sold and retailers decorating their shop windows pink, others created 'pink spot specials', and the butchers even turned their products pink! These efforts raised $7,951.78 for our research program.

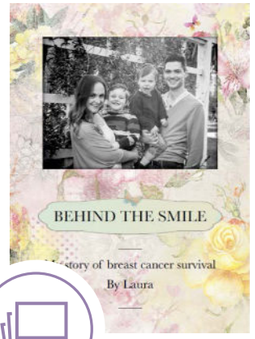
Team BCIA

Peer to Peer fundraising hit a record high in 2016, with $110,000 raised by a wonderful group of BCIA 'Heroes'. Each of these individuals raised funds through their participation in a wide variety of active events across Australia including the Sydney City2Surf, Run Melbourne and the Cole Classic and Sun Run.

We were fortunate to have 25 passionate and enthusiastic members join our Sydney City2Surf Gold Charity Team. Led by our CEO, Soozy Smith, each person on the team committed to raising a minimum of $1000 and were successful in raising $41,000! The team started at the front of the pack on race day, proudly wore our team singlets and hats, and many made new friendships on the day. Aged from 10 to 56, their motivations to join our team varied. Some ran in memory of a loved one who had sadly passed away, others in support of a loved one's recent diagnosis, and some in celebration of their own survival. Incredibly, two team members were undergoing treatment for breast cancer, one of whom is a participant on our Penelope B clinical trial.



Building a Community of Supporters



6,000 new supporters

In 2016-2017, BCIA continued initiatives to build our supporter base to help make more breast cancer trials research possible. Over 6,000 new supporters joined our mission to save more lives from breast cancer.

Many of them responded to the story of Laura, a young mother of two who was diagnosed with triple-negative breast cancer at age 32. Laura's personal feelings about her experience and how it affected her young family were shared in a special booklet called "Behind the Smile". Whilst the message about why we need more breast cancer clinical trials was explained in the brochure 'The Science of Saving Lives'.

New supporters also came via our annual Mother's Day Research Appeal when they made a donation in lieu of a Mother's Day gift for their mother or loved one. This year, we were able to achieve an extensive multi-channel media campaign, largely secured through free community service and pro-bono support, involving television, radio, newspapers, women's magazines and digital billboard advertising. Digital media promotions also played a big part in helping us to spread the word about this special activity with very positive feedback from supporters to the beautiful Mother's Day cards they gave their Mothers.

The Australian Women's Health Diary

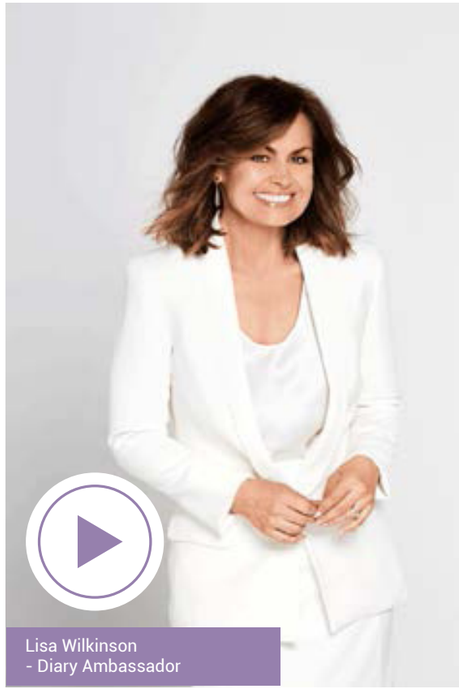
2017 edition raises a profit of $1.08 million

The Australian Women's Health Diary is a unique fundraising initiative established in 1999 with a dual purpose – to raise ongoing funding for breast cancer clinical trials research and to help improve the health and wellbeing of Australian women.

Now in its 19th year, the Australian Women's Health Diary continues to confirm its place as a must-have item for Australian women with sales increasing year on year. The 2017 edition raised a profit of $1 million bringing the total raised since the first edition in 1999 to $13.3 million.

With the help of our major sponsor The Australian Women's Weekly, each year the diary is filled with up to date and relevant health information for women of all ages to encourage and support a healthy lifestyle. It's also a practical and affordable diary and carries all the essential diary features to help keep track of busy lives.

An extensive marketing campaign, supported by our Diary Ambassador Lisa Wilkinson and the Nine Network, helped to spread the word and increase sales this year. This was assisted by our other major sponsors Avon and the Commonwealth Bank who also sold and promoted the diary to their customers. Magshop was secured as a new online stockist this year, which together with newsagents, Woolworths and Temple & Webster helped to ensure the diary's great success.


Lisa Wilkinson
- Diary Ambassador

Supporter Relationships

53,000 active supporters

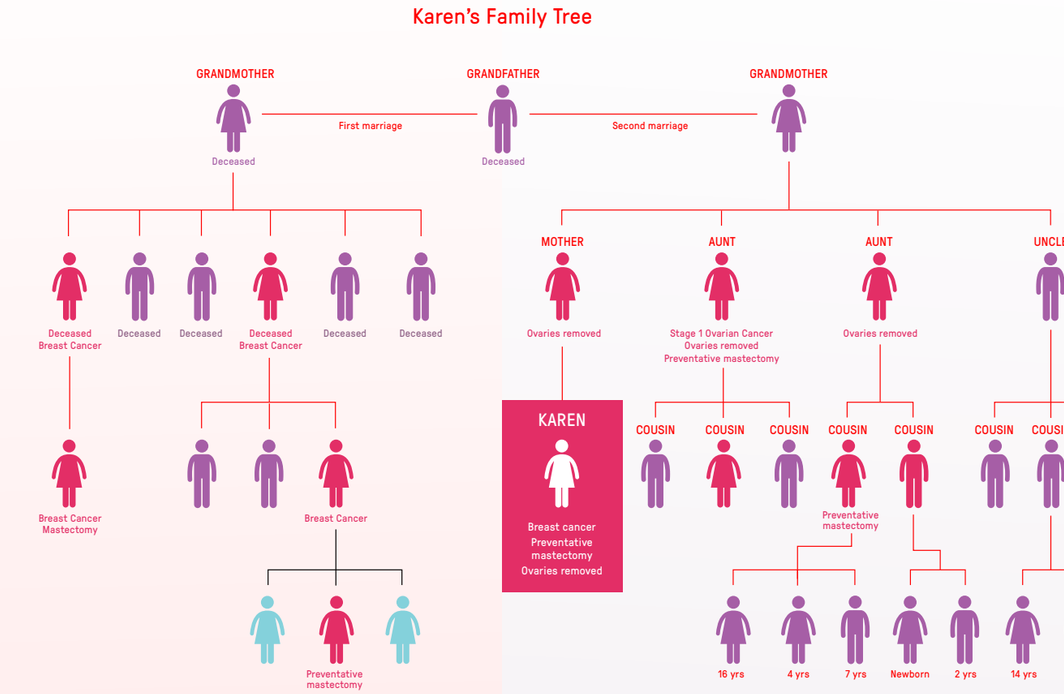
Individuals throughout Australia gave generously this year in response to our Appeals and as members of the Regular Giving Program. Through our communications we work to engage our supporters with the research they are helping to make possible, and the positive effect their support is having on the lives of all those affected by breast cancer. We are grateful to every supporter, and to the many individuals and their families who shared their personal experience of breast cancer throughout the year.

Christmas Appeal

Christmas is always a special time of the year and that's true for Emma and her daughter Amelia. They were looking forward to spending Christmas together in 2016 at home, as in 2015 Emma was hospitalised due to her breast cancer treatment and separated from her daughter who has Down syndrome and development issues. Their story was shared in our 2016 Christmas Appeal and many people were moved by Emma's crazy wigs, which she wore so that her daughter wouldn't be scared when she lost her hair due to chemotherapy. Supporters were asked to share their Christmas messages with us and we received so many inspiring and heartfelt messages which we displayed in our office, and our animated Christmas Tree kept on growing!

Tax Appeal

The 2016 Tax Appeal featured Karen who, when diagnosed with breast cancer at the age of 41, found out she had always been predisposed to getting breast cancer because she carries the faulty BRCA1 gene. The identification of this faulty gene had ramifications for her entire family as shown on her family tree. It's estimated in Australia that up to 50,000 people carry either the BRCA1 or BRCA2 gene mutation. Our OlympiA clinical trial is hoping to identify a new treatment option for those who are diagnosed with breast cancer and who carry the gene mutation.



Bequests

We gratefully acknowledge the following individuals, many of whom were long term supporters, for leaving a gift in their Will to BCIA.

Estate of the late Vincent John Adams
Estate of the late Gregory William McGrath
Estate of the late M K Balchin
Estate of the late Joan Evelyn Mills
Estate of the late Val Barton
Estate of the late Anne Murray
Estate of the late Beverley Brown
Estate of the late Carolyn Pearce
Estate of the late Ausilio Confalonieri
Estate of the late Elaine Sweetman
Estate of the late Loris Grote
Estate of the late David Roderick Thomas
Estate of the late Gladys Gulson
Estate of the late Veronica Tyson
Estate of the late Catherine H Guy
Estate of the late Trevor Bruce Ward
Estate of the late John Albert Mann
Estate of the late Mary Ellen Warwick

In Memoriam

We acknowledge the generosity of family and friends who have made gifts in memory of the following people.

Mrs Phylis Abela
Mrs Iris Abingdon
Mrs Doris Adams
Mrs Dorothy Aird
Mrs Helen Aitken
Mrs Rhoda Alcock
Mrs Faye Alsop
Mrs Kate Anderson
Mrs Margaret Armitage
Mrs Ann Ashby
Ms Annette Bailey
Ms Irma Balaban
Mrs Daisy Balagtas-Wilson
Mrs Daphne Ball
Ms Karen Barnett
Ms Luigina Basso
Mrs Joy Batchelor
Mrs Ruth Bayley
Mrs Elisabeth Bayliss
Mrs Heather Beacham
Mrs Wendy Beisley
Mrs Helen Bell
Mrs Queenie Bell
Mrs Paula Bennett
Mr Peter Bennett
Mrs Gabrielle Bertola
Mrs Donna Bertram
Ms Wendy Birch
Mrs Athol Bishop
Mrs Elizabeth Bishop
Mrs Joy Bishop
Mrs Lisa Blackshaw
Mrs Pauline Blackwell
Miss Jan Blakney
Ms Rosalyn Blunt
Mrs Roslyn Boersma
Mrs Kim Bouckley
Mrs Stella Bouffard
Mrs Robyn Boughton

Read full list

Corporate Partnerships

Partnerships spanning 20 years

This year saw another of BCIA's long term corporate partnerships celebrate a 20 year anniversary. Avon now joins Commonwealth Bank in reaching 20 years of actively supporting breast cancer clinical trials research, and thus the health and wellbeing of our community.

Many corporate supporters, large and small, contributed to the $1.1 million raised this year. The Australian Women's Weekly continues to produce and promote our Australian Women's Health Diary on our behalf. Since 2002, The Cartridge Recycler has been supporting BCIA, through the remanufacturing of toner cartridges, and this year reached the wonderful milestone of $200,000 raised. For Benefits Medicine, Australia's first not for profit pharmaceutical company, donated $20,000 from the sale of two generic breast cancer hormonal treatments. We're delighted to be working in partnership with For Benefits Medicine to spread the word and encourage support for this unique initiative.

Avon

A special Cocktail Function was hosted by Avon on Wednesday 31 August 2016 to celebrate the 20th anniversary of our partnership. Over 60 guests were in attendance to hear the latest updates in breast cancer trials research, and to see Ms Sharon Plant, Avon President and Managing Director, present a cheque for $500,000 raised from sales of Avon Breast Cancer Crusade Products during 2016. Ms Sally Obermeder was the MC and gave a heartfelt speech about her personal experience of breast cancer and her support for breast cancer trials research. Avon has now donated $10.4 million which has helped to identify new breast cancer treatments which are today saving many lives.

Commonwealth Bank

More than 480 morning teas were held by Commonwealth Bank Staff in branches throughout Australia during 2016 raising $100,000. The 2018 Australian Women's Health Diary was also sponsored by the Commonwealth Bank and sold in branches and through the Credit Card Rewards Program. Now in its 21st year, our partnership with the Bank has raised $4.3 million for breast cancer trials research. Our partnership continues to evolve and grow as we look to new workplace giving opportunities in 2017.

Our People

Board of Directors

Stephen Ackland

Fran Boyle

John Forbes

Michael Hamar

Jennifer Horrigan

Richard Isaacs

David Joseph

Geoffrey Lindeman

Bruce Mann

George Morstyn

Christobel Saunders

Nicholas Wilcken

Scientific Advisory Committee (SAC)
31 March 2017

Assoc Prof Prue Francis
Chair*
Medical Oncologist

Assoc Prof Nicholas Wilcken
Vice Chair*
Medical Oncologist

Prof Bruce Mann
Chair, SAC Local Therapy Subcommittee, Surgical Oncologist

Prof Kelly-Anne Phillips
Chair, SAC Supportive Care Subcommittee, Medical Oncologist

Assoc Prof Nicole McCarthy
Chair, SAC Systemic Therapy Subcommittee, Medical Oncologist

Prof Frances Boyle AM
Medical Oncologist

Prof Phyllis Butow
Psycho-Oncologist

Assoc Prof Ian Campbell ONZM
Surgical Oncologist

Assoc Prof Jacquie Chirgwin
Medical Oncologist

Assoc Prof Boon Chua
Radiation Oncologist

Prof Alan Coates AM #
Medical Oncologist

Prof Joanna Dewar
Medical Oncologist

Prof John Forbes AM
Surgical Oncologist

Assoc Prof Glenn Francis
Pathologist

Prof Val Gebski
ANZBCTG Group Statistician

Ms Cheryl Grant
ANZBCTG Consumer Advisory Panel

Prof Michael Green
Medical Oncologist

Prof David Joseph
Radiation Oncologist

Dr Belinda Kiely
Medical Oncologist

Dr Marion Kuper-Hommel
Medical Oncologist

Dr Chee Lee
Medical Oncologist

Ms Phillipa Lee
Chief Operating Officer, ANZBCTG

Prof Geoffrey Lindeman
Medical Oncologist / Clinician-Scientist

Assoc Prof Sherene Loi
Medical Oncologist

Dr Janine Lombard
Medical Oncologist

Dr Nick Murray
Medical Oncologist

Dr David Porter
Medical Oncologist

Assoc Prof Andrew Redfern
Medical Oncologist

Assoc Prof Clare Scott
Medical Oncologist / Clinician-Scientist

Prof R John Simes
Medical Oncologist / Statistician

Assoc Prof Raymond Snyder #
Medical Oncologist

Prof Andrew Spillane
Surgical Oncologist

Mrs Leonie Young
ANZBCTG Consumer Advisory Panel

Dr Nicholas Zdenkowski
Medical Oncologist

* From March 2017 # Stepped down March 2017

Independent Data Safety and Monitoring Committee
(31 March 2017)

Prof Martin Tattersall
Chair

Prof Gill Duchesne

Prof Matthew Law

Prof Michael Quinn

Prof John Zalcberg

Consumer Advisory Panel Members
(31 March 2016)

Leonie Young QLD, Chair
Consumer Coordinator, IMPACT Program

Karen Alexander * ACT

Melissa Bell * NZ

Raewyn Calvert NZ

Sheryl Fewster WA

Leslie Gilham VIC

Cheryl Grant NSW

Carol Whiteside ** NSW

* Commenced in March 2017
** Stepped down in November 2016

Staff Member Listing
1 April 2016 to 31 March 2017

Heath Badger
Clinical Trials Program Manager

Corinna Beckmore
Protocol Development and Special Projects Officer

Helen Braggett
Clinical Research Associate

Michelle Cairns
Accounts Administrator

Julie Callaghan
BCIA General Manager

Tanya Carlyle
BCIA Donor Engagement and Content Writer

Tamar Carpenter
BCIA Fundraising Data Manager

Anna Cummins
BCIA Donations Processing Coordinator

Haley Deacon
Clinical Research Associate

Annette Dempsey
Clinical Research Associate

Cheryl Dodds
BCIA Donations Processing Coordinator (Relief)/Special Gifts Officer

Donna Douglass
Clinical Trials Assistant

Breanna Edman
Supporter Care Officer

Brooke Emmett
Clinical Research Associate

Anna Fitzgerald
Communications Manager

Akiko Fong
Clinical Research Associate

Nicole Francis
Clinical Trials Assistant

Sharyn Frank
Information Support Officer

Juliette Gritten
Clinical Trials Assistant

Tracey Hay
Clinical Trial Program Manager

Ming Ho
Clinical Fellow

Tamica Humby
Clinical Research Associate

Connie Irvine
Trial Coordinator

Sandy Isles
BCIA Appeal Coordinator

Amy Jongerden
Clinical Research Associate

Ingrid Laycock
Clinical Research Associate

Phillipa Lee
Chief Operating Officer (Trials)

Rose Lucas
Ethics and Regulatory Affairs Associate

Mai Ly
Clinical Research Associate

Kirsten Lyndon
BCIA Community Fundraising Officer

Lauren Macnab
Clinical Research Associate

Kelly Martin
BCIA Donor Development Manager

Carlie Mavin
Clinical Trials Project Leader

Rechelle McMurtrie
BCIA Appeal Coordinator (Relief)

Belinda Mitchell
Clinical Research Associate

Jane Murphy
BCIA Supporter Care Officer

Vicki Murray
BCIA Supporter Care Officer

Rachael O'Donnell
Accounts Administrator

Lisa Paksec
Ethics and Regulatory Affairs Manager

Robin Paterson
Clinical Fellow

Kelly Phillips
Deputy Director of Research

Leonie Phillott
People Performance & Culture Manager

David Pringle
Financial Controller

Flonda Probert
Clinical Research Associate

Stuart Reeves
Clinical Research Associate

Lauren Rennie
Clinical Trials Project Leader

Hollie Ritchie
Ethics and Regulatory Affairs Associate

Lizzie Senior
BCIA Direct Marketing & Communications Manager

Alison Sheppard
Executive Assistant

David Short
BCIA Fundraising Data Manager

Soozy Smith
Chief Executive Officer

Renee Swanson
Project Officer

Kristy Taubman
Clinical Research Associate

Rochelle Thornton
Team Leader

Christine Wasik
Accounts Administrator

Contributors and Supporters

International Collaborators

Alliance Foundation Trials LLC (AFT)	USA
Austrian Breast & Colorectal Cancer Study Group (ABCSG)	Austria
Breast International Group (BIG)	Belgium
Breast European Adjuvant Studies Team (BrEAST)	Belgium
Cancer Trials Support Unit (CTSU)	USA
Clinical Trial Service Unit (CTSU)	UK
Cancer Research UK (CRUK)	UK
Derby Teaching Hospitals NHS Foundation Trust	UK
Eastern Cooperative Oncology Group (ECOG)	USA
German Breast Group (GBG)	Germany
International Breast Cancer Study Group (IBCSG)	Switzerland and USA
Canadian Cancer Trials Group	Canada
National Surgical Adjuvant Breast and Bowel Project (NSABP) / NRG Oncology	USA
Nottingham Clinical Trials Unit (NCTU)	UK
SouthWest Oncology Group (SWOG)	USA
Translational Research in Oncology (TRIO)	France and Canada

Funders and Supporters

Breast Cancer Research Foundation, USA
Cancer Australia
National Breast Cancer Foundation
National Health and Medical Research Council
University of Newcastle

Corporate Supporters

AVON the company for women

CommonwealthBank

The Australian Women's Weekly

For Benefits Medicine
The Cartridge Recycler

Supporters

We acknowledge the many thousands of individual supporters who gave generously during the past year, together with the following individuals, community groups and businesses who held activities throughout the year to raise funds.

Amy Hill	New South Wales
An Island Hideaway	Queensland
Annabelle Bull	New South Wales
Bayview Golf Club	New South Wales
Beverley Lapidge	South Australia
Blue Illusion Australia Pty Ltd	Victoria
Cam Foundation	South Australia
Camden Haven High School	New South Wales
Castle Hill Women's Bowling Club	New South Wales
Central Queensland University	Queensland
Cheryl Hastie	Tasmania
Church of the Good Sheperherd Handcraft Group	New South Wales

Read full list

Financial Report

The ANZBCTG is a not-for-profit, collaborative, national and international breast cancer clinical trials research group. It is an independent registered public company with academic affiliations.

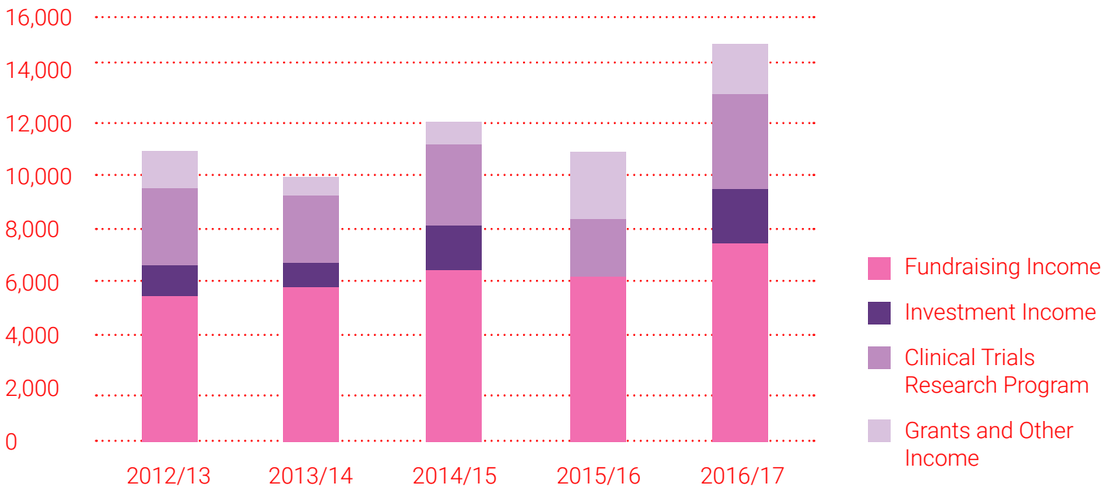
As a registered public company, the ANZBCTG undergoes an annual independent financial audit to ensure its compliance with all applicable company, taxation, charitable and financial legislation and regulation. Copies of the Group's full Financial Statements and Audit Report are available on the website.

The ANZBCTG receives income from a variety of sources and the most significant of which are:

- fundraising income (individual giving, special events, corporate support) and bequests;
- income on invested funds;
- external support for the clinical trials research program (pharmaceutical partnerships, international collaborative group partnerships, untied education grants);
- competitive grants awarded to the ANZBCTG (for example, Cancer Australia).

An analysis of the sources of the ANZBCTG's income over the last five years is:

Total Revenue ($000)					
	2012/13	**2013/14**	**2014/15**	**2015/16**	**2016/17**
Fundraising Income	5,571	5,839	6,436	6,219	7,430
Investment Income	1,057	935	1,661	0	2,037
Clinical Trials Research Program	2,869	2,446	3,000	2,187	3,495
Grants and Other Income	1,315	672	837	2,473	1,859
	10,812	**9,892**	**11,934**	**10,879**	**14,821**



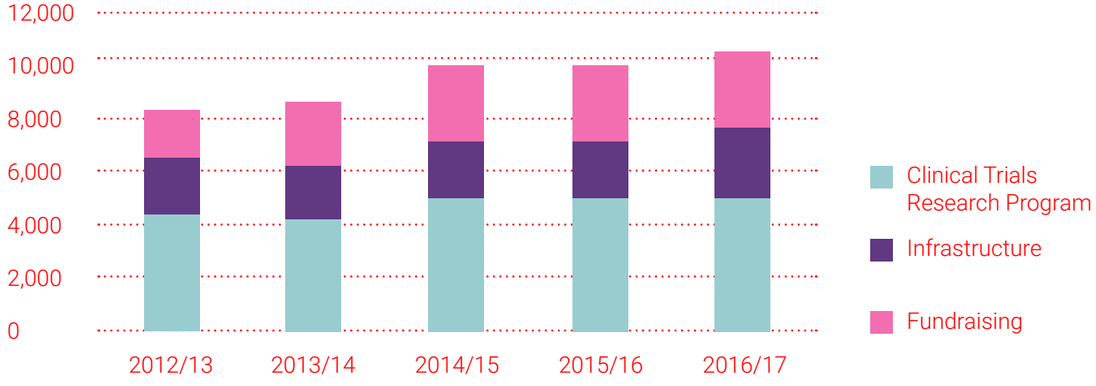
There has been a significant increase in revenue in 2016/17 largely due to a recovery in investment markets following a flat 2015/16, an increase in bequest income, the timing of corporate donations, and an increase in trials income, partly due to increased research activity.

Areas of ANZBCTG expenditure include:

- clinical trials research program (clinical trials development, activation, coordination and quality assurance activities, funding for participating institutions, randomisation and statistical analyses, research staff salaries, Annual Scientific Meeting and other meetings);
- other recurrent monthly infrastructure costs, administration staff salaries and core business expenses;
- direct fundraising and fundraising administration costs.

An analysis of the ANZBCTG's expenses over the last five years is:

Total Expenses					
	2012/13	**2013/14**	**2014/15**	**2015/16**	**2016/17**
Clinical Trials Research Program	4,496	4,260	5,057	5,099	5,123
Infrastructure	1,820	1,833	1,967	2,025	2,594
Fundraising	1,894	2,394	2,737	2,657	2,743
	8,210	**8,487**	**9,761**	**9,781**	**10,460**



Following the largely non-recurring increase in revenue in 2016/17 the ANZBCTG was able to report an unprecedented surplus for the year of $4.470 million. From a cash flow perspective, $3.536 million of this was utilised to acquire new premises that has allowed all the activities of the ANZBCTG and BCIA to be co-located and will result in significant operating efficiencies and cost savings into the future. This surplus has also enabled the ANZBCTG to increase trials research activity with a planned 50% increase in research expenditure in 2017/18.

With the acquisition of new premises, the ANZBCTG now has a total net asset base of $28.474 million. The ANZBCTG is therefore in a strong financial position to fund our current and planned clinical trials, which will take several years to complete.

David Pringle
Financial Controller and Company Secretary

Publications

In the reporting period from 1 April 2016 to 31 March 2017, the ANZBCTG contributed to 47 conference abstracts/posters/oral presentations and peer reviewed publications.

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Glossary

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 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, e.g. 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.

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: Women with a mutation in one of these genes have a higher than normal chance of developing breast or ovarian cancer.

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

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.

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, e.g. palbociclib.

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.

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.

HER 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: Also called biologic therapy, is a type of cancer treatment designed to boost the body's natural defenses to fight the cancer. It uses substances either made by the body or in a laboratory to improve or restore immune system function.

INDEPENDENT DATA SAFETY AND MONITORING COMMITTEE (IDSMC): 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.

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

LETROZOLE: An oral non-steroidal aromatase inhibitor for the treatment of hormonally-responsive breast cancer after surgery.

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: Breast cancer that has one or more of the following features: may be large (typically bigger than 5 cm); may have spread to several lymph nodes in the armpit (axilla) or other areas near the breast; and may have spread to other tissues around the breast such as the skin, muscle or ribs.

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.

MADAROSIS: 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: Treatment given prior to surgery or further treatment for cancer.

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: A branch of medicine that deals with cancer.

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 is 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.

PARTICIPANT INFORMATION SHEET: A document that provides clinical trial participants with important information relating to a specific trial. The purpose is to the 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 efficacy (effectiveness) in a large number of participants (up to several hundred).

PHASE III CLINICAL TRIAL: The most rigorous and extensive type of scientific clinical investigation of a new treatment. These trials are designed to determine the effectiveness of a treatment, often by comparing it to an existing standard therapy or a placebo, in a large number of participants (typically hundreds or thousands). A phase III trial is generally required before a drug would be approved by regulatory authorities for general use.

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 an ANZBCTG participating institution. Duties include recruiting participants, obtaining 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.

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 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 the ANZBCTG 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 an ANZBCTG participating institution who works with site Investigators to ensure a clinical trial protocol is adhered to. The role may include clinical and non-clinical tasks, e.g. data management.

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

SYSTEMIC THERAPY: The use of chemotherapy, hormone therapy and/or targeted therapy or a combination of these to target the entire body to destroy any cancer cells that may have spread to distant body parts but are below the level of clinical detection.

TAMOXIFEN: Used for the treatment of early and advanced ER-positive breast cancer in pre- and post-menopausal women. 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.

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.

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