



**BREAST CANCER TRIALS
RESEARCH STRATEGY
2022 - 2026**

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SUMMARY

Breast Cancer Trials (BCT) is a collaborative research organisation with a mission to conduct the highest quality clinical trials research that improves outcomes for people affected by breast cancer. The organisational Strategic Plan 2019 – 2023 sets out three pillars, the first of which is to conduct world class multidisciplinary breast cancer clinical trials.

This strategy is based on stakeholder consultation, aiming to create a roadmap to enable BCT to achieve its mission. It details key themes and sub-themes, along with goals, outcomes and measures of success. The strategy intends to facilitate opportunities for BCT to pursue research based on clinical need and consumer expectation, in line with its strengths in clinical trials research. An adaptable proactive approach to research will co-exist with an ongoing opportunistic approach, guided by strategic themes.

The four themes are:

1. Conducting trials in the areas of greatest patient need and potential impact as identified in the consultation process;
2. Broad collaboration with the right people and organisations, nationally and internationally;
3. Remove barriers and enhance clinical trials participation;
4. Learning the most from every trial.

Table 1. BCT Research Strategy Framework

The BCT Research Strategy will provide a roadmap for:				
Optimising existing research	Progressing new research priorities		Extending the reach and relevance of BCT research	
<i>Define what we do well Look for opportunities to strengthen / continue to make progress in core areas</i>	<i>Identify and progress new areas of focus: clinical areas / research types for BCT to contribute to and which are feasible in Australia and New Zealand</i>		<i>Expand engagement with existing and new members and partners Extend access to relevant BCT trials through innovative trial processes Expand the diversity of BCT trial participants</i>	
New research opportunities will be generated through a combination of opportunistic and proactive approaches				
Encourage and respond to ideas from the active BCT community and from local and international partners			Proactively drive ideas and activity in key areas of unmet need	
<i>Both opportunistic and proactive approaches will be valued and encouraged There are likely to be interactions and intersections between the two</i>				
Research opportunities exist across the breast cancer continuum and spectrum of disease types It is important to formalise the parameters used to prioritise BCT investment				
Impact <i>Potential to inform or change clinical practice, potential to improve breast cancer outcomes and likely timeframe for this</i>	Urgency <i>Critical timeframe for acting on the opportunity (e.g. funding / partnership opportunity or window of influence)</i>	Relevance <i>Relevance for the Australian and New Zealand population Alignment with consumer, beneficiary and donor priorities</i>	Alignment <i>Alignment with BCT vision and approach (e.g. multidisciplinary, multicentre clinical trials) Includes consideration of likelihood of research area already being progressed by others</i>	Practicality <i>Feasibility of doing the research in ANZ Identified leader(s) Likelihood of funding</i>
<i>Examples of clinical priorities include early diagnosis, precision approaches to management of early disease, metastatic disease, and quality of life/supportive care/survivorship Examples of new types of research include earlier consideration of translational research and innovative trial designs suitable for the Australian/New Zealand contexts</i>				
Having a formal Research Strategy will underpin proactive communication, engagement and fundraising opportunities				
<i>Increased understanding of purpose, focus and impact of BCT across the breast cancer community</i>	<i>Engagement of existing members to encourage ideas and concepts</i>	<i>Engagement of new members with expertise in priority areas</i>	<i>Engagement of potential partners</i>	<i>Enable impact and needs-based messaging to engage, retain and acquire supporters</i>

ABOUT BCT

Breast Cancer Trials (BCT) is a collaborative clinical trials group across Australia and New Zealand, with the mission of conducting high quality clinical trials research that improves the outcomes of people affected by breast cancer. To fulfil this mission, BCT is developing a Research Strategy that leverages existing strengths while focusing on future needs and opportunities.

Historically, BCT has coordinated phase 2 and 3 clinical trials with a focus on efficacy endpoints. Translational and patient-reported outcome endpoints are often incorporated in trials as secondary endpoints. Trial selection has typically been opportunistic and depends on approaches from the membership, international partners or industry. Ideas may be submitted as concepts for development or as a developed protocol for implementation at BCT sites. Trials may be initiated and led by BCT or undertaken through international collaborative group partnerships or industry-sponsored partnerships.

To conduct its research, BCT works with a network of 109 institutions, 830 members, a Scientific Advisory Committee, a Consumer Advisory Panel, and operations staff. Funding is from BCT fundraising activities, competitive grants and collaboration with industry. Over the last 40 years, BCT has made major contributions to improved patient outcomes and to the advancement of the Australian and New Zealand breast cancer workforce.

BCT ORGANISATIONAL STRATEGIC PLAN

The Breast Cancer Trials Strategic Plan 2019–2023 builds on the successes of our past and current national and international collaborative trials activity, harnessing the expertise and passion of our multidisciplinary membership and collaborative partners. As we continue to lead a world-class breast cancer clinical trials agenda in Australia and New Zealand, we will expand the breadth of our research questions and our geographical footprint through a strategic approach to partnerships, resourcing and communication.

Strategic Pillars

Pillar One: World-Class Multidisciplinary Breast Cancer Clinical Trials

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

Pillar Two: Sustainable Foundations for Research

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

Pillar Three: Driving Awareness and Influencing Change

Commitment to driving awareness of BCTs role and value, facilitating engagement and maximising the impact of BCTs research through a strategic approach to communication, marketing and influencing.

The Research Strategy will underpin all three pillars of the BCT Strategic Plan.

BACKGROUND TO THE BCT RESEARCH STRATEGY

As part of the organisational strategic plan, BCT is developing a Research Strategy that will:

- provide a strategic framework for BCT research over the next 5 years, identifying research topics and methods that are likely to make the greatest contribution to improvements in outcomes for people affected by breast cancer;
- ensure that BCT resources and the expertise of the BCT community are used optimally;
- ensure that BCT can proactively respond and adapt to future research opportunities and needs.

To inform the Research Strategy, BCT has undertaken background scoping work, including a review of past BCT member feedback, consumer priorities, and priorities agreed by international cancer and breast cancer trial groups. A series of small stakeholder focus groups were held in early August 2020 to reflect on the scoping activity and identify future opportunities and areas of unmet need in diagnosis and management of breast cancer and patient outcomes that could be considered within the BCT Research Strategy.

HOW THE STRATEGY WAS DEVELOPED

1. Scoping Exercise

A literature review was undertaken to identify current and future priorities for breast cancer research. A summary was drawn from publications and papers written by international and national oncology groups, and by consumer organisations. This scoping paper was presented to the stakeholders to stimulate discussion.

2. Focus Groups

Facilitated focus groups/interviews were held with 21 stakeholders from a range of disciplines. Participants were purposefully selected with a view to capturing insights from individuals who are not members of the BCT Board, Scientific Advisory Committee (SAC) or other committees.

Stakeholders consulted were supportive of BCT adopting a proactive Research Strategy, while remaining open to opportunistic identification of trial concepts and research ideas. Feedback highlighted the need to be strategic (in identifying priorities) and brave (in exploring new areas and being selective about areas to pursue). It was suggested that priorities should consider types of research and clinical areas in which Australia and New Zealand can make a strong contribution.

Stakeholders identified a range of potential priority areas for BCT research. Stakeholder focus group discussions were iterative, with content from each group informing the content of subsequent discussions. Stakeholder feedback was synthesised and presented to the Research Strategy workshop participants as a basis for their discussions.

3. Strategy Workshop

Senior BCT members participated in a half day facilitated workshop to discuss the outcomes of the focus groups and refine the priority topics that form the basis of the strategy. These members represented the BCT scientific leadership.

4. Research Strategy

Outputs from the focus groups and workshop were summarised. This strategy document was then developed in consultation with BCT leadership (CEO, COO, Medical Advisor), Scientific Advisory Committee and the BCT Board.

WHAT IS THE STRATEGY?

This strategy sets out a plan for Breast Cancer Trials' research program to align with themes that have been identified as key priorities. There are multiple sub-themes that will contribute towards the achievement of the goals, and in turn the organisational strategic plan. This strategy will be implemented between 2021 and 2025.

In the focus groups and workshop, stakeholders emphasised the importance of maintaining a multidisciplinary approach, promoting an inclusive culture, and clearly communicating plans, activities and opportunities. In the workshops the value of consumer involvement in BCT research to date, the importance of maintaining a consumer-centered approach and understanding how research will address unmet needs and improve outcomes for people affected by breast cancer were key messages. The importance of consumers, particularly those with a connection to breast cancer, to advocate, donate and fundraise for BCT clinical trials was also noted.

Themes are listed along with sub-themes that contain specific goals, how those goals will be achieved, and measures of success. These themes are guiding principles but are not exhaustive. Future research directions are impossible to predict accurately and comprehensively. Opportunities may arise that are not included in the strategy, and these should be given due consideration as to whether they will contribute to the overall BCT mission.

Points of agreement:

1. BCT should facilitate both opportunistic and provocative strategies for generating trial ideas;
2. Both approaches should be valued and encouraged and there are likely to be interactions and intersections between the two;
 - Opportunistic approaches can continue to make optimal use of insights and expertise from within the current active BCT community
 - A proactive strategy can be used to drive activity in priority areas of need and are feasible for Australia and New Zealand to undertake
3. Regardless of how trial ideas and concepts are generated, consideration should be given to strengthening outcomes and potential for changing practice;
4. A consumer-centered approach is critical with emphasis given to consumer insights about what is important, what we are asking out trial participants to do, and the value of consumer advocacy.

Feedback from stakeholder focus groups and the Research Strategy workshop suggests the following high-level framework for the BCT research Strategy (Table 2).

Table 2. Proposed framework for the BCT Research Strategy based on stakeholder, Board and SAC feedback.

1. Lead and participate in high-quality collaborative clinical trials to improve breast cancer outcomes in Australia and New Zealand		
Continue to encourage trial ideas and concepts from BCT members and partners	Continue to engage with international clinical trial partners about opportunities	Actively promote and resource planning in priority areas (new)
<p>This will require:</p> <ul style="list-style-type: none"> • agreement and communication about the main types / phases or research with greatest impact for breast cancer patients (e.g. multidisciplinary, multicenter clinical trials with the potential to change practice, core focus on phase 2/3 trials) • agreement on core areas of strength and priority areas in which targeted activity is needed to drive progress (clinical areas of unmet need and/or types of research) 		
2. Strengthen the reach and relevance of BCT trials		
<ul style="list-style-type: none"> • Use engagement to promote available trials and expand the range of sites participating in BCT trials (within feasible trial designs) • Extend access to BCT trials through initiatives such as telehealth / tele-trials / e-consent • Consider how to strengthen the diversity of population groups within BCT trials and overcome barriers such as geographic location, language, ethnicity, culture and age 		
3. Enhance governance, engagement and communication to support the research strategy		
<ul style="list-style-type: none"> • Review governance and establish new working groups where required to drive activity in priority areas • Develop / strengthen partnerships with relevant Australian / New Zealand / international organisations with relevant interests and expertise • Continue to identify and pursue funding opportunities for trials and / or associated infrastructure • Actively and consistently promote BCT services and resources • Communicate widely about past, current and planned activity 		

THEMES

Conducting trials in the areas of greatest need and potential impact as identified in the consultation process

This theme considers the key areas central to BCT being best placed to successfully conduct patient centered clinical research designed addressing the priority areas of unmet need for patients and the health care system.

Rationale:

BCT aims to coordinate a diverse portfolio of multidisciplinary trials with the potential to benefit patients throughout their diagnosis, treatment and follow-up. Specific areas of need include prevention of breast cancer/DCIS, screening, curative intent early stage, metastatic disease, supportive care, psycho-oncology and survivorship. BCT, as a multidisciplinary group, is ideally positioned to develop and conduct trials that represent an integrated approach to patient care.

Goals:

- BCT aim to maintain a diverse clinical trial portfolio with the intention of making significant impact on the prevention and cure of breast cancer;
- BCT to take a proactive approach to the defining research questions in priority areas of clinical unmet need and conducting best practice clinical trials to address those questions;
- Trials should have representatives from multiple craft groups in protocol development, trial conduct, analysis and interpretation. Craft groups include surgery, medical oncology, radiation, psycho-oncology, medical imaging and pathology.

Activities:

- SAC review of trial types to identify those suitable for progression towards activation at BCT sites;
- Development of a prioritisation system for assessment of trials according to and within priority areas;
- Undertake targeted calls for research concepts in priority areas and/or conduct facilitated concept development activities to define research questions in priority areas;
- Needs based fundraising to raise funds for identified key priority research areas;
- Communication with membership as well as relevant internal and external stakeholders about priority areas;
- Promotion of discretionary funding to develop trial ideas and engaging with priority groups where growth in representation in the membership is needed.

Metrics:

- Measure of new concepts and trials with two or more craft groups involved;
- SAC consideration towards a balanced multidisciplinary portfolio to progress towards activated trials;
- Diverse range of trials progressing towards activation each year.

Clinical trial priority areas:

- Prevention/Screening trials;
- Early-stage curative intent trials;
- Metastatic disease;
- Supportive care, psycho-oncology and survivorship;
- Multidisciplinary.

Trial types:

Clinical trials (phase 2 and 3) have been the primary focus for BCT coordinated trials and remain the gold standard for trials assessing new treatments, and interventions. Many legitimate research questions are not well suited to RCTs for a variety of reasons, and therefore other trial types will be considered so long as they align with BCT research strategy.

These trial types may include:

- Pre-operative (neoadjuvant, window of opportunity) studies that are not randomised;
- Innovative trial designs (platform studies, umbrella trials, registry trials) that may not include randomisation;
- Single arm de-escalation studies if the event rate is expected to be very low.

Preclinical research is important in the BCT pipeline, but BCT does not intend to conduct this type of research directly. It can be supported by BCT if there is potential for this research to lead to a clinical trial.

Collaboration with the right people and organisations

This theme acknowledges the need for engaging with individuals and groups to ensure BCT is successful in conducting trials significant to patient outcomes, driving change practice in the clinical management of breast cancer and improving health care systems.

Rationale:

Building and maintaining a network of breast cancer researchers is a key factor in successful research. Part of the strategy is to identify priority areas of unmet need, to know about developments in breast cancer, and be agile and responsive to those developments. This will put BCT in a position to foster the development of scientifically competitive and important trials of the latest interventions or methods.

Goals:

- For BCT to have and maintain a broad diverse membership of individual clinicians and researchers representing all areas of the breast cancer management continuum;
- To engage with new members with expertise in priority areas;
- For BCT to be known and recognised by our peers, as the primary breast cancer clinical trials organisation in Australia and New Zealand, and by other specific target audiences for the impact we make to the treatment, prevention and cure of breast cancer.

Activities:

- Utilise the research strategy to drive the communication and fundraising strategy;
- Grow the academic and operational links to clinical organisations such as BreastSurgANZ, MOGA, RACP, RCPA and COSA with the intention of increasing BCT clinical membership and engagement of existing and emerging researchers;
- Use the Annual Members Survey to engage the membership with the intention of understanding clinical priority areas and new research opportunities;
- Development of mutually beneficial partnerships with relevant organisations with a focus on creating new networks;
- Leverage the data transparency platform to convey the abundance of BCT data resources and demonstrate the benefits of BCT membership;
- Review SAC structure and functions to ensure it provides optimal assistance to the Board and the Trial Department to realise the research strategy and program.

Metrics:

- Meaningful membership growth in priority areas;
- Measures of clinician and researcher engagement;
- Measures of collaborative and cross-disciplinary activity and impact with respect to the overall research strategic direction and individual research projects and trials;
- Measure of BCTs engagement in research across the translational spectrum, from the development of new interventions through to clinical trials and implementation into clinical guidelines and practice.

Remove barriers and enhance clinical trials participation

This theme considers how to increase diversity within BCT trials by acknowledging and addressing traditional barriers to participation which may include geographic location, language, ethnicity, culture and age.

Rationale:

Australia and New Zealand have excellent track records of recruitment to clinical trials, however this recruitment is often limited to major centres, and patient demographics may not be completely representative of the broader patient population. Equity in the recruitment of a geographically, ethnically and socio-economically diverse and representative population is warranted. Overcoming barriers and being able to recruit trial participants from a wider range of centres may allow faster recruitment, better access to new treatments, improved outcomes, and faster translation of knowledge.

Goals:

- Address or minimise the impact of barriers to clinical trial access and participation through the implementation of novel strategies;
- Increase representation of first nations people and minorities in BCT clinical trials including where possible BCT committees;
- Continuing to increase awareness of BCT and the clinical trials that BCT conducts in specific target audiences.

Activities:

- Consider and implement strategies addressing barriers associated with trial access such as physical access, geographical location and trial associated visit burden;
- Adopting and embedding technological systems and innovative trial procedures designed to broaden clinical trial access and streamline participation for all stakeholders;
- Provide opportunity and actively seek participation of first nations, minority and CALD representatives in BCT clinical trials and committees.

Metrics:

- Number of participants recruited using decentralised models for participation (tele-trials/telehealth);
- Number of institutions engaging with tele-trials and telehealth system to facilitate recruitment;
- Number of institutions and participants using electronic platforms over traditional manual systems;
- Number of participants recruited where English is a second language.

Subthemes:

- Telehealth and distributed pre-screening;
- Broadening trial inclusion criteria;
- E-consent;
- Rural/regional engagement;
- First nations people, minority and CALD participation in clinical trials.

Learning the most from every trial

This theme considers how to leverage the most from each trial that BCT undertakes with a view to maximising the return on commitments made by donors, funders and participants

Rationale:

Each trial is a significant investment in financial and human terms. The knowledge gained from trials should be maximised through excellence in the scientific rationale, methodology and conduct. Where possible tissue collection and translational research should be incorporated in each trial with tissue banking for future research a standard. With the rapid pace of biotechnology advancements even if the primary outcome of a trial is negative, there is a wealth of potential within the data and tissue samples collected.

Goals:

- Ensure each project is assessed for feasibility of PROMS, health economics, translational research opportunities;
- Maximise the utilisation of data and tissue samples collected through implementation of mechanisms that allow researchers to be granted access to data and tissue collected for each trial;
- Provide the opportunity for BCT trial data to be used in data driven research that goes beyond the scope of the initial trial purpose.

Activities:

- Development of a data transparency platform accessible by BCT members and researchers to know the following about each trial conducted by BCT;
 - Parameters of what data (types and frequency) were collected, including patient reported outcomes
 - Tissue sample collected, including the number and volume of samples that remain available for access
- Link the data transparency platform to processes for applying for access to trial data and tissue samples;
- Proactively seek expression of interest for translational research projects of banked tissue specimens;
- Develop policies to incorporate processes allowing secondary use and data driven research for all BCT clinical trials.

Metrics:

- Establishment of a data transparency platform;
- Numbers of research proposal applications received for access to datasets and/or tissue samples;
- Number of additional publications/presentations attributed to BCT trials.

Subthemes:

- Translational research;
- Patient reported outcomes;
- Biobanking of specimens;
- Engagement in research across the translational spectrum, from the development of new interventions through to clinical trials.