CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

Breast Cancer Research Program

Strategic Plan

INTRODUCTION

The Congressionally Directed Medical Research Programs represents a unique partnership among the U.S. Congress, the military and the public to fund innovative and impactful medical research in targeted program areas. The CDMRP manages programs with formalized strategic plans that identify program-specific research priorities; how to best address these urgencies; short- and long-term goals; investment strategies; and ways to identify and evaluate program successes with respect to the priorities.

The Breast Cancer Research Program Strategic Plan identifies the high-impact research goals most important to its stakeholders while providing an adaptable framework to meet the changes in the medical research environment that addresses those goals. This plan aims to provide greater clarity of the program's goals over time. Congress appropriates funding for the BCRP on an annual basis; therefore, there is no guarantee of future funding. The BCRP will review the Strategic Plan during the program's annual Vision Setting meeting and update goals as necessary.

BCRP BACKGROUND AND OVERVIEW

Based on recommendations from the BCRP Programmatic Panel members, the BCRP developed the following vision and mission in response to congressional intent:

VISION: A world without breast cancer

MISSION: To end breast cancer for Service Members and their Families, Veterans, and the general public by funding innovative, high-impact research through a partnership of scientists and consumers

Background:

When the BCRP received its first congressional appropriation in 1993, the Institute of Medicine, now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine, was commissioned to make recommendations to the Department of Defense on: (1) the peer review procedures to employ and (2) the preferred programmatic investment strategy for the funds.[1]

The BCRP continues to follow IOM recommendations as the guiding principles of the program:

1. Conduct a two-tier peer review system.

The IOM recommended "a peer review system that reflects many of the traditional strengths of existing review systems but is tailor-made to accommodate the goals and the novel and complex program the committee has proposed."

To ensure both scientific excellence and programmatic relevance, the BCRP administers a two-tier review process consisting of peer and programmatic review.

In addition, the IOM recommended including consumers such as breast cancer survivors on the panels that conduct programmatic reviews. The BCRP adhered to the IOM guidance when initiating the program in 1993. In 1995, the BCRP expanded implementation of the IOM guidance further by integrating consumers as peer review panel members.

2. Enable scientists to propose their best ideas, unrestricted by the program.

The IOM recommended that "the best way to ensure that only first-rate research is funded is not to target specific disciplinary areas but, rather, to create a structure that allows the best ideas to emerge from all disciplines." The IOM further recommended to "encourage innovative ideas and cross-cutting proposals that can shed light on the fundamental questions in the causation, prevention, detection, diagnosis, and optimal treatment of and recovery from breast cancer."

The BCRP invests across the full spectrum of basic, translational and clinical research. Consistent with IOM's recommendations, the BCRP designed award mechanisms that meet the following objectives:

- Accelerate high-impact research
- Encourage innovation and stimulate creativity
- Bring new investigators into the breast cancer field
- Facilitate meaningful collaborations

Congress appropriated $4.241 billion to the BCRP in fiscal years 1992–2023 (FY92–FY23), and $150 million in FY24. Through FY23, the BCRP supported 7,365 awards and anticipates 70 awards for FY24, depending on the quality and budgets of the recommended applications. The BCRP funds research at for-profit, nonprofit, public and private organizations such as universities, colleges, hospitals, laboratories and companies. The CDMRP posts award data and abstracts of funded research on the website https://cdmrp.health.mil.

MAJOR ACCOMPLISHMENTS

To date, BCRP-funded projects have resulted in over 19,400 scientific publications and over 1,300 patents, patent applications and invention reports. In addition, BCRP-funded projects contributed to the following breakthroughs in treatments, diagnostics and prognostics, risk assessment and resources:

Treatments

- Trastuzumab (Herceptin®): Monoclonal antibody to treat human epidermal growth factor receptor 2 positive (HER2+) breast cancer
- ATLAS Clinical Trial: Demonstrated reduced risk of recurrence or death from breast cancer in women who took tamoxifen for 10 years versus 5 years, changing clinical practice for individuals with estrogen receptor positive breast cancer
- Palbociclib (Ibrance®), Abemaciclib (Verzenio®), Ribociclib (Kisqali®): Small molecule cyclin-dependent kinase inhibitors to treat hormone receptor positive, HER2- breast cancer
- Prone Radiotherapy: Radiation treatment in the prone position to reduce unnecessary radiation exposure of the heart and lungs

Diagnostics and Prognostics

- Sentinel Lymph Node Biopsy: A standard of care technique to determine tumor staging and the need for more extensive lymph node surgery
- Molecular Breast Imaging: A nuclear medicine technique to produce high-resolution functional images of the breast
- Digital Mammography and Breast Tomosynthesis: A three-dimensional digital mammography tool for advanced breast imaging
- Breast Cancer Index®: A test to evaluate the likelihood of recurrence and benefit from extended endocrine therapy
- MetaSite Breast™: A test to predict the metastatic potential of a primary breast cancer
- MenaCalc™: A prognostic test to predict recurrence and metastasis

Risk Assessment

- Identification of Breast Cancer Risk-Associated Mutations: BRCA2 617delT, PTEN and PALB2
- OncoVue® and BROCA Cancer Risk Panel: Genetic-based tests to assess risk of breast cancer

Resources

- BreastCancerTrials.org: A resource to inform patients of ongoing breast cancer clinical trials
- Dyson Family Risk Assessment Program: Provides risk assessment, screening and preventive services to individuals with a family history of breast or ovarian cancer
- Patient-Derived Xenograft Models: Publicly available models to study tumor growth, metastasis, drug efficacy and prognosis
- nCounter® Myeloid Innate Immunity Panel: Commercialized tool for basic and translational immuno-oncology research

RESEARCH AND FUNDING ENVIRONMENT

As part of strategic planning each year, the BCRP considers the research portfolio and dollar investments of other funding organizations.

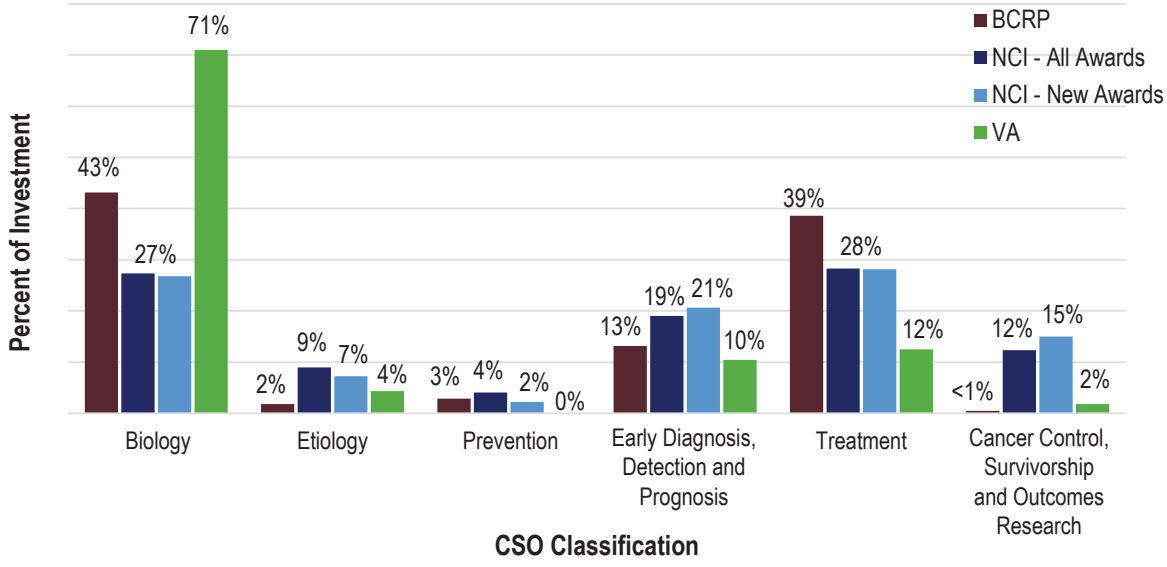
The figure and table below represent an analysis of breast cancer research investments between 2018 and 2022 for the BCRP, the National Cancer Institute, and the U.S. Department of Veteran Affairs. Research dollars were attributed to projects in proportions equal to the percentage of the relevance of the project to breast cancer, ranging from 1% to 100%. Each project was coded using the International Cancer Research Partnership Common Scientific Outline classification system organized by broad areas of scientific interest in cancer research. For projects with more than one CSO code, the budget was split evenly between the assigned codes.

Breast Cancer Research Funding by Organization (2018-2022)

Funding Agency	Dollars Invested
BCRP	$637.5M
NCI (All Awards)	$3.0B*
NCI (New Awards)	$505.5M
U.S. Department of Veteran Affairs	$14.3M

*Billion

Breast Cancer Research Classification Funding by Organization, 2018 -2022



*Funding data for the NCI was obtained from the ICRP database and includes intramural and extramural research. Funding data for the VA was obtained directly from organization and manually coded by BCRP program staff. VA awards are exclusively for intramural PIs.

- Between 2018 and 2022, the BCRP invested the second-highest amount of funds in breast cancer research after the NCI. However, while the BCRP invested in only new awards, the NCI invested about 17% of its funds in new awards and allocated remaining funds to support the out-years of existing continuing awards.
- The two research areas in which the BCRP invested the most funds are Biology and Treatment. The program invested minimally, less than 1%, in Cancer Control, Survivorship and Outcomes research, which is consistent with the BCRP's focus on research aimed at eradicating breast cancer.
- The NCI's new awards were invested in all research areas, with Biology and Treatment as the highest funded categories.

BCRP STRATEGIC DIRECTION

Considering the major accomplishments resulting from BCRP-funded projects and the research and funding environment, the BCRP remains focused on addressing the knowledge, research, and clinical gaps that continue to make breast cancer a global health issue.

The overall goal of the BCRP Strategic Plan is to establish a strategy to achieve breakthroughs toward ending breast cancer. The BCRP expects that those affected by and/or at risk for breast cancer including Service Members and their Families, Veterans, and the general public will benefit.

The BCRP's Breast Cancer Landscape that is available on the BCRP website provides the program's strategic direction and a broad overview of what is currently known, as well as the gaps and needs, regarding the topics that are most pertinent to the BCRP mission of ending breast cancer. The intent of the Breast Cancer Landscape is to provide the breast cancer community with concise information about the "state of breast cancer." Applicants to the BCRP award mechanisms are strongly encouraged to read the Breast Cancer Landscape before preparing their applications.

The BCRP strategic goals are the program priorities to address its strategic direction and its mission to end breast cancer. The program will assess progress toward meeting the strategic goals in the near-term, or 3-5 years; and medium- to long-term, or 6 plus years.

To address its strategic direction, the BCRP seeks to invest in the following strategic goals, representing the most important Overarching Challenges within the BCRP mission. Consistent with its historical strategic approach to enable investigators to propose their best ideas, the BCRP does not define what types of research projects or products the program will fund. Strategic goals may span from basic research studies to translational research projects and clinical trials.

STRATEGIC GOALS

- Prevent breast cancer (primary prevention)
- Identify determinants of breast cancer initiation, risk, or susceptibility
- Distinguish deadly from non-deadly breast cancers
- Conquer the problems of overdiagnosis and overtreatment
- Identify what drives breast cancer growth; determine how to stop it
- Identify why some breast cancers become metastatic
- Determine why/how breast cancer cells lie dormant for years and then re-emerge; determine how to prevent lethal recurrence
- Revolutionize treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival
- Eliminate the mortality associated with metastatic breast cancer

The BCRP intends to make all information, data and research resources generated under the awards funded by the program available to the scientific research and consumer advocacy communities and to the public.

INVESTMENT STRATEGY

The BCRP five-year investment strategy outlines the program's approach to soliciting the type of research that will facilitate accomplishment of its strategic goals. Each year during the program's Vision Setting meeting, the BCRP reviews the investment strategy and revises it as needed. BCRP award mechanisms support innovative, high-impact research in multiple categories and are summarized below.

Innovative Early Ideas	Mature Ideas	Translational	Clinical	Investigator-Focused and Team Science*
• Breakthrough Award Level 1	• Breakthrough Award Level 2	• Breakthrough Award Level 3 • Clinical Research Extension Award	• Breakthrough Award Level 4	• Era of Hope Scholar Award • Transformative Breast Cancer Consortium Award • Transformative Breast Cancer Consortium Development Award

**May span basic, translational, clinical*

MEASURING PROGRESS

NEAR-TERM OUTCOMES, THREE TO FIVE YEARS

The BCRP will measure near-term outcomes by tracking the amount of funding invested in each strategic goal or Overarching Challenge. The program will identify understudied overarching challenges and encourage more research in those areas. In addition, the BCRP will track publications, patents and clinical trials of funded research and expects these outcomes to vary based on the stage of the research projects.

MEDIUM- TO LONG-TERM OUTCOMES, SIX OR MORE YEARS

The BCRP will measure medium- to long-term outcomes for each strategic goal or Overarching Challenge, to include publications, patents, clinical trials, commercialization of products, and changes in the standard of care for patients. The program expects this will vary based on the stage of the research projects. The BCRP may also perform analyses of these outcome measurements within each major breast cancer subtype.

REFERENCES

1. Institute of Medicine. 1993. "Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command." *The National Academies Press*.