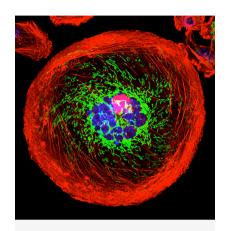
Advances in Breast Cancer Research

NCI-supported researchers are working to advance our understanding of how to prevent, detect, and treat breast cancer. They are also looking at how to address disparities and improve quality of life for survivors of the disease.

This page highlights some of what's new in the latest research for breast cancer, including new clinical advances that may soon translate into improved care, NCI-supported programs that are fueling progress, and research findings from recent studies.



A polyploid giant cancer cell (PGCC) from triple-negative breast cancer.
Credit: National Cancer Institute

Research in Breast Cancer Screening

Breast cancer is one of a few cancers for which an effective screening test, mammography, is available. MRI (magnetic resonance imaging) and ultrasound are also used to detect breast cancer, but not as routine screening tools for people with average risk.

Ongoing studies are looking at ways to enhance current breast cancer screening: options:

- The NCI-supported Tomosynthesis Mammographic Imaging Screening Trial (TMIST) is evaluating whether 3-D mammography is better than standard 2-D mammography at detecting breast cancers early enough that they can be treated successfully.
- Several NCI-supported studies are investigating the use of mammography with a contrast dye to improve screening among women with a history of breast cancer and women with dense breasts.
- Some NCI-supported researchers are exploring the use of markers such as breast stiffness to identify cancer in women with dense breasts.
- Researchers are looking for ways to use artificial intelligence (AI) to improve early detection of breast cancer. For example, one NCI-supported study looked at how using artificial intelligence algorithms can improve mammogram interpretation.

Two concerns in breast cancer screening, as in all cancer screening, are:

- the potential for diagnosing tumors that would not have become life-threatening (overdiagnosis)
- the possibility of receiving false-positive test results, and the anxiety that comes with follow-up tests or procedures

To limit the potential for overdiagnosis and overtreatment, researchers are studying screening methods that are appropriate for each woman's level of risk.

The Women Informed to Screen Depending on Measures of Risk (WISDOM) study is comparing risk-based screening—that is, screening at intervals based on an individual's risk—to the standard annual screening mammography.

Researchers are also studying which populations are at highest risk of overdiagnosis. A 2023 study found that older women have a substantial risk of overdiagnosis, highlighting the need for conversations with their health care providers about the potential benefits and harms of continuing

Ductal Carcinoma In Situ

Ductal carcinoma in situ (DCIS) is a precancerous condition in which abnormal cells are found in the lining of a breast duct. Women diagnosed with DCIS have a substantial risk of overdiagnosis and overtreatment because there is currently no way to tell which lesions found on screening mammograms will progress to invasive disease.

Depending on their level of risk, women diagnosed with DCIS almost always have surgery and possibly other treatments. A 2024 trial showed that women with low-risk DCIS who undergo active monitoring were no more likely to be diagnosed with invasive breast cancer after two years than those who undergo surgery with or without radiation therapy. However, longer follow-up is needed to assess the long-term safety of forgoing surgery.

Other trials are ongoing to study whether managing patients diagnosed with DCIS with active surveillance and hormonal therapy can help prevent overtreatment. One NCI-supported study is using artificial intelligence to identify patients with DCIS who are at higher risk of disease progression and may need more aggressive treatment.

Research in Breast Cancer Treatment

The mainstays of breast cancer treatment are surgery, radiation, chemotherapy, hormone therapy, targeted therapy, and immunotherapy. While many drugs have been approved to prevent and treat breast cancer, scientists are continuing to develop new treatments and combinations of treatments to fight the disease.

Hormone Therapy for Breast Cancer

Some breast cancers have receptors for the hormones estrogen and/or progesterone. Therapies that block the growth-promoting effects of estrogen on tumors with

hormone receptors can be used to treat such cancers, called hormone receptor (HR), or sometimes estrogen receptor (ER)– positive cancers. Hormone therapy, also referred to as endocrine therapy, can be used to treat both early-stage HRpositive breast cancers and advanced or metastatic disease.

Many hormone therapies exist for treating breast cancer, and these drugs work in several different ways, including suppressing ovarian function, blocking estrogen production, and blocking estrogen's effects.

- A selective estrogen receptor degrader (SERD) is a drug that binds to and breaks down ERs. An oral SERD, called elacestrant dihydrochloride (Orserdu), has recently been approved by the Food and Drug Administration (FDA). It is more effective than other hormone therapies, like fulvestrant (Faslodex), an injectable SERD, for postmenopausal women and men with advanced estrogen receptor (ER)–positive, HER2-negative breast cancer who have mutations in the *ESR1* gene. *ESR1* mutations can make the cancer resistant to other hormone therapies.
- Imlunestrant is also an oral SERD that has been shown to be more effective in slowing the growth of ESR1-mutant tumors in women with advanced, ER-positive, HER2-negative breast cancer than standard hormone therapy. The combination of imlumestrant with abemaciclib (Verzenio), a drug that blocks cell growth, was better than standard hormone therapy in both those with ESR1 mutations and those with unmutated ESR1.
- In postmenopausal women with hormone receptorpositive early-stage breast cancer, the use of a test that
 looks at the expression of certain genes can be used to
 determine whether or not chemotherapy will be beneficial.
 Ongoing research is looking at whether adding
 chemotherapy to treatment with ovarian suppression and
 hormone therapy for premenopausal women with ERpositive/HER2-negative breast cancer reduces the risk of
 recurrence in women who are at high risk of their cancer
 returning.
- Researchers are also studying whether the combination of

hormone therapy and radiation therapy is more effective than hormone therapy alone in treating women with lowrisk early stage breast cancer.

 Tamoxifen, an established hormone therapy for breast cancer, has been shown to reduce the rate of recurrence over 15 years in people with DCIS who were treated without radiation therapy.

Targeted Therapy for Breast Cancer

Many targeted therapies have been approved to treat breast cancer. These targeted therapies, which include monoclonal antibodies and small-molecule drugs, target proteins that control how cancer cells grow, divide, and spread.

Monoclonal antibodies

Monoclonal antibodies are proteins designed to attach to specific targets on cancer cells. One type of monoclonal antibody, called an antibody-drug conjugate, helps carry chemotherapy drugs directly to cancer cells without harming other cells.

Datopotamab deruxtecan (Datroway) is an antibody-drug conjugate under investigation for some metastatic breast cancers, including metastatic triple-negative breast cancers. In a large clinical trial, women treated with datopotamab deruxtecan lived longer without their disease getting worse than women treated with chemotherapy. The drug received FDA approval in 2025 for ER-positive metastatic breast cancer.

- The antibody-drug conjugate trastuzumab deruxtecan (Enhertu) was initially approved for the treatment of HER2positive breast cancers. The monoclonal antibody trastuzumab (Herceptin) delivers the chemotherapy drug deruxtecan directly to tumor cells that have HER2 on their surface.
- A 2024 study also showed improved outcomes with trastuzumab deruxecan compared to chemotherapy. This led to extend the approval for use in some people with metastatic breast cancer that has low or very low levels of

Small molecule drugs

Small molecule drugs are a type of targeted therapy that can enter cancer cells and block critical functions.

- In 2024, the FDA approved a triplet therapy that combines the small molecule drug inavolisib (Itovebi) with fulvestrant (Faslodex), a hormone therapy, and palbociclib (Ibrance), another small molecule drug, for certain patients with advanced or metastatic HR-positive breast cancer who have genetic mutations for a protein called PI3K. Inavolisib blocks the resulting overly active forms of PI3K, while palbociclib blocks the activity of the CDK4 and CDK6 proteins, which control cell growth.
- CDK4/6 inhibitors (palbociclib, ribociclib [Kisqali], or abemaciclib [Verzenio]) added to endocrine therapy improve progression-free survival (PFS) in women with metastatic breast cancer. Ribociclib has been shown to improve overall survival (OS).
- For women with early-stage, hormone receptor positive breast cancer, ribociclib given for three years in combination with an aromatase inhibitor has also been shown to reduce risk of recurrence.
- Capivasertib (Trugap), approved by the FDA in 2023, blocks the Akt pathway, which promotes tumor growth. A phase 3 trial showed that capivasertib plus fulvestrant increased how long people with advanced HR-positive breast cancer lived without the disease getting worse.
- For younger women with metastatic ER-positive, HER2negative breast cancer, results from a large trial showed that the combination of the small molecule targeted drug ribociclib and hormone therapy was much better than chemotherapy at slowing tumor growth.
- In women with high-risk, node positive ER-positive breast cancer, abemaciclib given for two years in combination with endocrine therapy has also been shown to decrease the risk of recurrence.

Immunotherapy for Breast Cancer

Immunotherapy is a type of treatment that helps the body's immune system to fight cancer more effectively. Previous studies have shown that some immunotherapy drugs, known as immune checkpoint inhibitors, improve how long some people with advanced breast cancer can live, particularly those with triple-negative breast cancer. Recent studies provide some evidence that immune checkpoint inhibitors may improve outcomes in some people with HR-positive, HER2-negative breast cancer.

Pembrolizumab (Keytruda) in combination with chemotherapy is approved for treatment of women with metastatic triple negative breast cancer that has high expression of PD-L1. A study in patients with early-stage triple negative breast cancer showed that giving pembrolizumab before surgery, followed by one year of pembrolizumab after surgery, led to better response than chemotherapy alone. This led to FDA approval of pembrolizumab in the early-stage setting.

A current NCI-supported study is looking at patients with early-stage triple-negative breast cancer who had a complete response to treatment before surgery still need more treatment afterward. The standard treatment is to give pembrolizumab 27 weeks after surgery. The goal is to find out if observation alone works just as well as continuing pembrolizumab in preventing the cancer from coming back.

NCI researchers are trying to find ways to use cellular therapies, including CAR T-cell therapy and T-cell transfer therapy, to treat solid tumors, such as breast cancer.

- An ongoing clinical trial is using tumor-infiltrating lymphocytes (TILs) to shrink tumors in women with metastatic breast cancer.
- In another trial, NCI researchers are researching a type of T-cell therapy where a person's T cells are engineered in a laboratory to attack cancer cells and then given back to the patient. The study is recruiting patients with solid cancers, including breast cancer.

For a complete list of drugs for breast cancer, see Drugs Approved for Breast Cancer.

NCI-Supported Breast Cancer Research Programs

Many NCI-supported researchers working at the NIH campus, as well as across the United States and world, are seeking ways to address breast cancer more effectively. Some research is basic, exploring questions as diverse as the biological underpinnings of cancer and the social factors that affect cancer risk. And some are more clinical, seeking to translate this basic information into improving patient outcomes. The programs listed below are a small sampling of NCI's research efforts in breast cancer.

TMIST is a randomized breast screening trial that compares two Food and Drug Administration (FDA)-approved types of digital mammography, standard digital mammography (2-D) with a newer technology called tomosynthesis mammography (3-D).

The Breast Specialized Programs of Research Excellence (Breast SPOREs) are designed to quickly move basic scientific findings into clinical settings. The Breast SPOREs support the development of new therapies and technologies, and studies to better understand tumor resistance, diagnosis, prognosis, screening, prevention, and treatment of breast cancer.

The NCI Cancer Intervention and Surveillance Modeling Network (CISNET) focuses on using modeling to improve our understanding of how prevention, early detection, screening, and treatment affect breast cancer outcomes.

The Confluence Project, from NCI's Division of Cancer Epidemiology and Genetics (DCEG), is developing a research resource that includes data from thousands of breast cancer patients and controls of different races and ethnicities. This resource will be used to identify genes that are associated with breast cancer risk, prognosis, subtypes, response to

treatment, and second breast cancers. (DCEG conducts other breast cancer research as well.)

The goal of the Breast Cancer Surveillance Consortium (BCSC), an NCI-supported program launched in 1994, is to enhance the understanding of breast cancer screening practices in the United States and their impact on the breast cancer's stage at diagnosis, survival rates, and mortality.

There are ongoing programs at NCI that support prevention and early detection research in different cancers, including breast cancer. Examples include:

- The Cancer Biomarkers Research Group, which promotes research in cancer biomarkers and manages the Early Detection Research Network (EDRN). EDRN is a network of NCI-supported institutions that are collaborating to discover and validate early detection biomarkers. Within the EDRN, the Breast and Gynecologic Cancers Collaborative Group conducts research on breast and ovarian cancers.
- NCI's Division of Cancer Prevention houses the Breast and Gynecologic Cancer Research Group which conducts and fosters the development of research on the prevention and early detection of breast and gynecologic cancers.

Breast Cancer Survivorship Research

NCI's Office of Cancer Survivorship, part of the Division of Cancer Control and Population Sciences (DCCPS), supports research projects throughout the country that study many issues related to breast cancer survivorship. Examples of studies funded include the impact of cancer and its treatment on physical functioning, emotional well-being, cognitive impairment, sleep disturbances, and cardiovascular health. Other studies focus on financial impacts, the effects on caregivers, models of care for survivors, and issues such as racial disparities and communication.

Breast Cancer Clinical Trials

NCI funds and oversees both early- and late-phase clinical

trials to develop new treatments and improve patient care. Trials are available for breast cancer prevention, screening, and treatment.

Breast Cancer Research Results

The following are some of our latest news articles on breast cancer research and study updates:

- Some Women Avoid Breast Cancer Screening After False-Positive Mammogram Results
- Breast Cancer May Spread by Recruiting Nearby Sensory Nerves
- How Breast Cancer Risk Assessment Tools Work
- Can Some People with Breast Cancer Safely Skip Lymph Node Radiation?
- Study Adds to Debate about Mammography in Older Women
- Pausing Long-Term Breast Cancer Therapy to Become Pregnant Appears to Be Safe

View the full list of Breast Cancer Research Results and Study Updates.

Reviewed: April 8, 2025

If you would like to reproduce some or all of this content, see Reuse of NCI Information for guidance about copyright and permissions. In the case of permitted digital reproduction, please credit the National Cancer Institute as the source and link to the original NCI product using the original product's title; e.g., "Advances in Breast Cancer Research was originally published by the National Cancer Institute."