Clinical trials are an important step in discovering new ways to treat breast cancer, and often determine whether a new therapy, procedure or test will become part of the standard of care.

What is a clinical trial? Clinical trials are studies involving people who volunteer to take part in research studies. There are two types of clinical trials: interventional and observational. In an interventional study, the participant is assigned to a group that receives one or more interventions such as a new drug, device, procedure or diagnostic test to assess its safety and efficacy. In an observational study, participants are not assigned to an intervention – they are only observed and the outcomes measured by researchers. These types of clinical studies are often used to identify cancer risk factors or behaviors among different populations, or identify survivorship issues.

Clinical trials investigate more than just new treatments. They may also test other products such as new tools, devices or methods to assess risk, prevent or diagnose breast cancer. In observational trials, the product of the trial is knowledge, or an approach that may contribute to improvements in breast cancer care.

How do clinical trials work? Clinical trials can take up to 15 years and cost more than $2.5 billion. This process begins in the lab, where thousands of scientists spend years testing tens of thousands of ideas. Through a long and difficult process of elimination, researchers narrow down these ideas to just a few. Next, resources and funding must be secured for the most promising ideas that will be tested in clinical trials.

There are multiple phases in a clinical trial, and each phase is designed to answer certain questions. At the end of this long journey, just one product or idea out of the initial thousands is brought to patients.

Clinical trials are at the heart of all medical advances. Conducting trials is a long, expensive process filled with stops and starts, but today’s clinical trials will lead to new and improved standards of care for breast cancer in the future.

Learn more about breast cancer clinical trials. breastcancertrials.org

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WHAT WE’VE LEARNED from Komen-funded clinical trials

Ultrasound tomography or Molecular Breast Imaging may be more effective at detecting breast cancer than mammography, especially for women with dense breasts.

Lymphoseek® more effectively identifies cancer-containing lymph nodes and results in fewer side effects than the traditional diagnostic test, which uses blue dye and a radioactive tracer.

The TAILORx clinical trial used the Oncotype Dx biomarker test and big data to show that 70% of women with hormone receptor-positive (HR+) breast cancer may not need chemotherapy.

The RxPONDER clinical trial results support the safety of forgoing chemotherapy for some post-menopausal women with lymph node positive, HR+, HER2- breast cancer.

There are many types of cancer clinical trials, each designed to answer different research questions.

**Risk Assessment** trials explore how a person’s genes make them more or less likely to develop breast cancer. They may also identify the causes, patterns or incidence of breast cancer.

**Prevention** trials look for better ways to reduce risk and prevent breast cancer from developing. They may study medicines, vitamins, vaccines, minerals or lifestyle.

**Screening** trials test new ways to better detect abnormalities in the breast, leading to earlier diagnosis and treatment of breast cancer. Screening trials may test new technologies, blood tests (biomarkers) or methods to improve screening rates.

**Diagnostic** trials test better ways to identify or diagnose breast cancer. They may identify or test methods such as biomarker tests to help predict response to therapy or whether cancer will return or progress.

**Treatment** trials test new treatments or new ways of using existing treatments, such as new drugs, improved approaches to surgery or radiation, vaccines and combinations of treatments.

**Supportive Care** trials explore ways to improve comfort and quality of life for people living with cancer, their loved ones and caregivers during and after treatment.

OUR RESEARCH INVESTMENT: Since 1982, Komen research grants have supported more than 530 clinical trials

What We’re Investigating

- Using circulating tumor DNA (ctDNA) collected from people with breast cancer to identify biomarkers that will help develop more effective treatments.
- Detecting and analyzing dormant disseminated tumor cells (DTCs) and tailoring treatments to kill them, which may prevent metastatic recurrence in some patients.
- Using a gene panel test on tumor samples from patients with specific types of metastatic breast cancer (MBC) to develop more effective, personalized treatments for an ethnically diverse population.

$15.5 million to the Translational Breast Cancer Research Consortium (TBCRC)

19 clinical sites working together to conduct innovative, biologically-driven clinical research

61 approved clinical trials. Over half the trials include patients with metastatic disease

More than 6,200 clinical trial participants

Supported by Komen Grants (1982-2022)

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