Clinical trials are an important step in discovering new ways to treat breast cancer. Whether a new therapy, procedure or test becomes part of standard treatment for breast cancer depends largely on clinical trial results.

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 test 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 some trials, such as observational trials, the product of the trial is knowledge, or an approach, that may contribute to improvements in breast cancer care such as information about risk or survivorship support.

How do clinical trials work? Clinical trials are part of the enormous effort needed to bring various products or knowledge about breast cancer care to patients. The long journey—which can take up to 15 years and cost more than $2.5 billion—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 their ideas down to just a few. Next, resources and funding must be secured to test the most promising ideas in clinical trials.

Clinical trials are then conducted through an orderly series of steps or phases that build on one another. Each phase is designed to answer certain questions. Many volunteers are needed to take part in clinical trials. Those who participate help further the knowledge base that helps improve breast cancer care. At the end of this long journey, just one product or idea, out of 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.

<table>
<thead>
<tr>
<th>3 to 6 years</th>
<th>6 to 7 years</th>
<th>.5 to 2 years</th>
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<tbody>
<tr>
<td><strong>Basic Research/Drug Discovery</strong></td>
<td><strong>Pre-Clinical Research</strong></td>
<td><strong>Clinical Trials</strong></td>
</tr>
<tr>
<td>5,000-10,000 potential products</td>
<td>250 potential products</td>
<td>5 potential products</td>
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**Phase 1**
Tests how a new product should be used and whether it’s safe.

**Phase 2**
Tests whether the new product works and is beneficial.

**Phase 3**
Compares the effectiveness of the new product against the current standard treatment.

**FDA Review**
1 approved product

"Funding Valley of Death"

20-100 volunteers

100-500 volunteers

500-5,000 volunteers

For more information, call the Komen 1-877 GO KOMEN (1-877-465-6636)

Clinical Trial Information Helpline

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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 changes.
- **Screening** trials test new ways to better detect abnormalities in the breast, when they may be more easily treated. 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 more than 520 clinical trials.

**What We’re Investigating**
- Testing several new drugs and combinations of existing drugs — such as immunotherapies—to better treat triple negative breast cancer (TNBC) and metastatic breast cancer.
- Testing innovative health care delivery methods to optimize treatment, improve care and reduce breast cancer disparities in people of color and underserved populations.
- Testing whether doctors can use an imaging method to monitor how effectively breast cancer bone metastases are responding to hormone (endocrine) therapy.

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

- **19 Clinical sites** working together to conduct innovative, biologically-driven clinical research
- **57 approved clinical trials.** Over half the trials include patients with metastatic disease
- **More than 5,500 clinical trial participants**

**WHAT WE’VE LEARNED from Komen-funded clinical trials**

- Ultrasound tomography (uses sound waves to create 3-D images) or Molecular Breast Imaging (MBI) may be more effective at detecting breast cancer than mammography, especially for women with dense breasts.
- Lymphoseek® is more effective at identifying which lymph nodes contain cancer and results in fewer side effects than the traditional diagnostic test, which uses blue dye and a radioactive tracer.
- Findings from the TAILORx clinical trial used the Oncotype Dx biomarker test and big data to show that 70 percent of women with hormone receptor-positive breast cancer may not need chemotherapy.