ABOUT CLINICAL TRIALS

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 are measured by researchers. These types of clinical studies are often used to identify cancer risk factors or behaviors among different populations or to identify quality of life topics that are important to survivors or those living with breast cancer.

CLINICAL TRIALS INVESTIGATE MORE THAN JUST TREATMENT, 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.

CLINICAL TRIALS CAN TAKE UP TO 15 YEARS AND COST UPWARDS OF $2 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.

<table>
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<tr>
<th>BASIC RESEARCH/DRUG DISCOVERY</th>
<th>PRE-CLINICAL RESEARCH</th>
<th>CLINICAL TRIAL</th>
<th>FDA REVIEW</th>
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<tbody>
<tr>
<td>5,000-10,000 potential products</td>
<td>250 potential products</td>
<td>5 potential products</td>
<td>1 approved product</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.

For more information, call the Komen Breast Care Hotline 1-877 GO KOMEN (1-877-465-6636) or the Clinical Trial Information Hotline.

Read more about the importance and benefits of clinical trials and how to take part in a clinical trial.
WHAT WE’RE INVESTIGATING

- A Phase II clinical trial testing a new drug called GDC-0084 in combination with trastuzumab (Herceptin) for the treatment of people with HER2-positive (HER2+) breast cancer brain metastases.

- A blood test for early detection of rapidly growing breast cancers that can be used to determine risk of recurrence and better tailor treatment plans in order to decrease overtreatment and to improve survival.

- Determining how differences in genes for people with metastatic breast cancers affect survival and outcome disparities among racially diverse populations with the goal of developing more personalized therapies.

$17.25 Million to the Translational Breast Cancer Research Consortium (TBCRC)

- 64 approved clinical trials, over half including patients with metastatic disease.

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

- More than 6,600 clinical trial participants.

SPOTLIGHT

Listen to Komen Scholar Dr. Antionio Wolff talk about a Komen-supported clinical trial designed to improve communication between people with breast cancer and health care providers.

WHAT WE’VE LEARNED FROM KOMEN-FUNDED RESEARCH

- Tilmanocept (Lymphoseek®) more effectively identifies cancer-containing lymph nodes and results in fewer side effects than the traditional diagnostic test, which uses blue dye and/or a radioactive tracer to guide sentinel lymph node biopsy.

- The RxPONDER trial has shown that many postmenopausal women with lymph node-positive, hormone receptor positive (HR+) HER2-negative (HER2-) breast cancer can safely skip chemotherapy.

- 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.