CLINICAL TRIALS

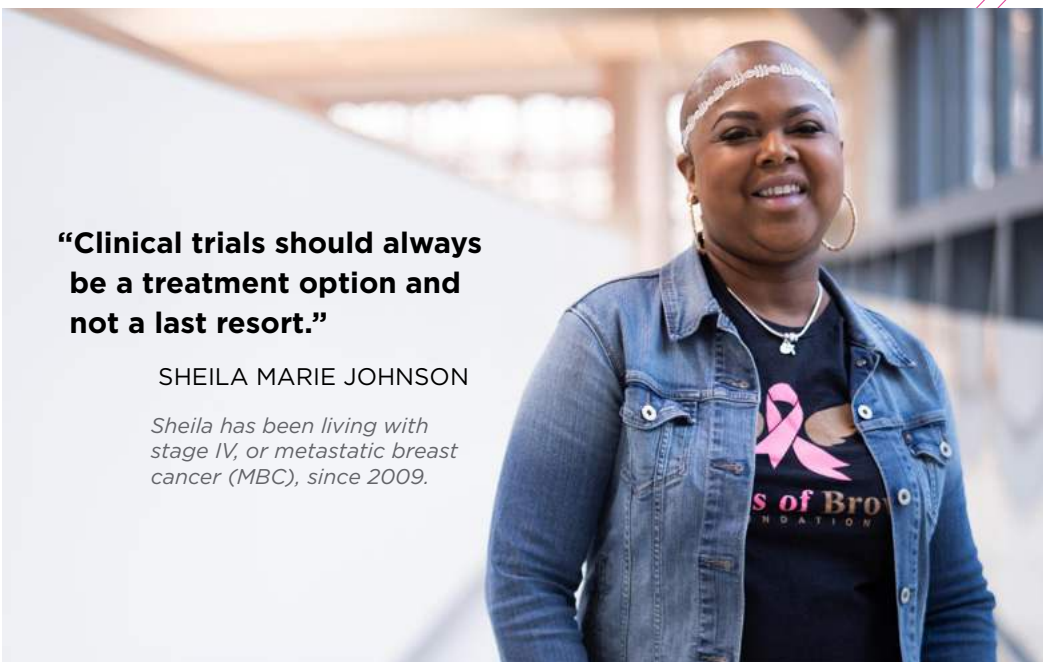
Did you know ...

Cancer clinical trial enrollment by adults in the U.S. is low, especially among members of racial or ethnic communities who often face higher breast cancer mortality (death) rates.

Watch Sheila Marie Johnson share her story about how she is benefitting from clinical trials. Also, hear from Dr. Barbara Segarra on how diversity improves clinical trials in this short video.

Susan G. Komen® Breast Care Helpline

If you or a loved one needs information or resources about clinical trials, call our Breast Care Helpline at 1-877 GO KOMEN (1877-465-6636) or email clinicaltrialinfo@komen.org.



What are clinical trials?

Clinical trials test the safety and benefits of new treatments as well as new combinations (or new doses) of standard treatments. They can also study other parts of care, including risk reduction, screening and diagnosis. People volunteer to take part in these research studies. Here we discuss breast cancer treatment clinical trials.

Breast cancer treatment clinical trials have led to many medical advances, such as the use of hormone therapy and chemotherapy.

Before a **treatment** is tested in a clinical trial, it's studied in a lab. Even though some treatments seem to work well in the lab, they don't always help people. That's why clinical trials are needed — to make sure the treatment is safe and effective for people.

The benefits of clinical trials

If you're thinking about joining a clinical trial, talk with your doctor. Some benefits are listed below:

- You have the chance to try a new treatment which may be better than the standard treatment.
- You're helping improve cancer treatment in the future by adding to research.

This fact sheet is intended to be a brief overview. For more information, visit komen.org or call Susan G. Komen's Breast Care Helpline at 1-877 GO KOMEN (1-877-465-6636) Monday through Friday, 9 a.m. to 10 p.m. ET or email at helpline@komen.org. Se habla español.

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Resources

BreastCancerTrials.org
in collaboration with Komen offers a custom matching service to help you find clinical trials that fit your needs. They also provide a Metastatic Trial Search Tool.

National Cancer Institute
cancer.gov/clinicaltrials

National Institutes of Health
cc.nih.gov

komen.org
Learn how Komen is helping people with any stage of breast cancer find and participate in clinical trials, including trials supported by Komen.

Related educational resources:

- Breast Cancer 101 – Clinical Trials video
- Five Truths About Breast Cancer Clinical Trials
- QTAD-Clinical Trials
- Metastatic Breast Cancer: Treatment Overview
- Treatment Overview for Breast Cancer
- Find the Right Clinical Trial. For You. For a Loved one.

There are 4 main phases of clinical trials:

Phase 1 (phase I)
Studies whether a new treatment is safe to use over a range of doses. The treatment may be given to people with different types of cancer.

Phase 2 (phase II)
Studies how well the treatment works for a certain cancer (such as breast cancer).

Phase 3 (phase III)
Studies how well the new treatment works compared to the standard treatment.

Phase 4 (phase IV)
Studies the long-term side effects of treatments or answers new questions about the treatment.

Placebos (or dummy pills)

Breast cancer clinical trials never use placebos instead of standard treatments. In some trials, everyone gets the new treatment. In other trials, you either get the new treatment or the standard treatment. So, even if you don't get the new treatment, your breast cancer will be treated the same as if you weren't in a trial. Sometimes you may get the standard treatment plus a placebo rather than the standard treatment plus the new treatment.

Enrolling in a treatment clinical trial

All clinical trials have **criteria** for joining the study. Criteria vary from study to study and may be based on:

- Type and stage of breast cancer
- Past treatments for breast cancer
- Other medical conditions

Informed consent

Informed consent is the process of reviewing the risks and benefits of the study. It's required for all clinical trials. Clinical trials must follow a strict plan called a protocol. The protocol follows medical, ethical and legal guidelines to keep you safe. Before joining a trial, a research coordinator, doctor or nurse will go over the study protocol with you. They'll answer any questions you have. If you decide to join the study, you'll be asked for your written permission. The document you sign is called a consent form. You will get a copy.

Being in a clinical trial is voluntary. You can leave the trial at any time, for any reason. Giving written permission to join the study doesn't force you to stay in the study.