

~~CLINICAL~~

Transformation Requires Individual  
Advocates Leading in Science  
(TRIALS)

*Creating a New Legacy -  
One Person at a Time*

DECEMBER 2023



**Tigerlily  
Foundation**  
*Beauty. Strength. Transformation.*

## Looking Back at 2023

*Tigerlily Foundation's Clinical Trials Program delivers transformational programs that accelerate the delivery of innovative treatments to our patients with a strategic focus on populations that are facing the highest disparities. Our goal is to support transparency in the clinical trial space to foster trust, increase access to clinical trials for those most in need, and dismantle the barriers that exist for participation of individuals from underrepresented populations.*

### What Tigerlily and our advocates accomplished in 2023

- Launched patient-driven RAISE (Resources and Assistance for Support and Empowerment)— an innovative and patient-curated platform to capture and meet financial and non-financial patient needs, offer solutions to eradicate clinical trial barriers, and improve adherence, trust and patient experience
- Launched national clinical trials educational campaign, *My Living Legacy*, across both traditional and social media outlets sharing informational messaging with several million listeners and readers over audio, digital and traditional news outlets, and multiple social media platforms and at community based events
- Spoke at 25 Clinical Trials Events as the Patient Voice
- Presented scientific posters or shared print information on RAISE at *AACR Cancer Health Disparities in Racial and Ethnic Minorities and the Medically Underserved* and *San Antonio Breast Cancer Symposium*
- Integrated ANGEL Patient Advocate in the advisory review of patient-facing clinical trial recruitment materials and clinical trial documents across several projects with sponsors to support the development and design of inclusive trials and culturally appropriate messaging
- Launched Tigerlily Foundation's Clinical Trials Newsletter, which provides educational information about clinical research to establish and build trust around clinical trials
- Launched updated Tigerlily Foundation [Clinical Trials webpage](#), which includes resources and tools to support education and empowerment around clinical trials, stories of trial researchers and participants, and other beneficial information
- Revised informational resources such as the Clinical Trials Barrier Toolkit and Understanding Clinical Trials guide which are being used by patients, providers, and sponsors
- Launched national tour highlighting the power of patient advocacy in communities that have the highest disparities sharing information about clinical trials, community engagement, and developing trusted partnerships
- Co-creation of a patient-driven, site-directed guidance framework called "I Am Included", with the intent to increase clinical trial diversity and accelerate delivery of innovative cancer treatments
- Invited to join the White House Cancer Moonshot committee to develop solutions for community engagement and clinical trials, and to develop holistic solutions to equity in healthcare
- Media features on the importance of clinical trial participation in outlets like ESSENCE, Today.com, BlackDoctor.org, Urban Health Today, NPR, and FOX local news affiliates in Atlanta, Detroit, and Houston
- Highlighted clinical trial experiences in two episodes of Season 3 of BREATHE Tv, Episode 5: The Importance of Research, Science, & Clinical Trials and Episode 9: MBC & Clinical Trials

- Incorporated empowering educational messaging on clinical research in all issues of MY LIFE Magazine in 2023, including an entire issue focused on clinical trials
- Partnerships with more than 30 industry and advocacy partners to support integration of diversity and inclusivity principles in clinical trials

## Tigerlily Patient Support Programs

### BREATHE Tv

[BREATHE Tv](#) is a sacred space, an educational and inspirational breast cancer lifestyle web series that brings together patients, providers, and loved ones in a space of purpose while engaging in authentic and meaningful conversations about cancer, women's health, and lifestyle.

The topic of clinical trials is frequently discussed in many of our episodes in addition to being the main topic of conversation of two specific episodes in Season 3, "***The Importance of Research, Science & Clinical Trials***," and "***Metastatic Breast Cancer and Clinical Trials***." Season 4 of BREATHE Tv will feature episodes every other week starting this month!



## Real Stories: Insights from Clinical Trial Participants

Tigerlily Foundation has partnered with GSK on the My Living Legacy campaign. This campaign drives awareness and education on clinical trials for communities across the U.S. and aims to normalize conversations about clinical trial participation for communities that are often under-represented in clinical trials. Through this campaign, we've highlighted the clinical trial participation stories of three of Tigerlily's ANGEL advocates: Christina Mackey, Keisha Stephney, and Faridah Thomas. Read through the links below to learn more about each of their stories!



### **Christina Mackey**

Christina Mackey, a Houston, TX mother of two, was diagnosed with Stage 3 triple-negative breast cancer at 33 years old after finding a lump in her breast and undergoing her very first mammogram. After many rounds of chemotherapy, her doctors at MD Anderson suggested that she participate in a clinical trial. After signing up and receiving treatment on the study, Christina's cancer shrank by 97%. Christina notes that the clinical trial she participated in "saved her life" and finds sharing her experience and reaching others about clinical trials is "life-preserving work." Learn more about Christina's story in the article below:

[\*Black mom, 33, was diagnosed with aggressive breast cancer. A clinical trial 'saved her life'\*](#)



### **Keisha Stephney**

At age 51, Bay Area resident Keisha Stephney was diagnosed with triple-negative breast cancer after her mammogram was delayed due to COVID-19. More than two years and 41 rounds of chemotherapy later, Keisha is still battling against breast cancer. She joined a clinical trial to find answers and wants to encourage more Black women to get involved in clinical research in order to make a difference in future treatments and patient outcomes. To read more about Keisha's experience, read the story below:

[\*My Living Legacy: Bridging the Gap in Clinical Trial Representation\*](#)



### **Faridah Thomas**

Just after her 40th birthday, Atlanta local Faridah Thomas learned she had triple-negative breast cancer. But instead of starting immediate treatment, it took her months to find a doctor she felt took her experience as a Black woman into account when developing a treatment plan. Even after finding the right doctor, clinical trials for breast cancer were never offered as an option. Faridah later participated in a clinical trial for a different condition and now spend time actively sharing about her experiences as a trial participant to encourage others to take charge of their health and consider joining a clinical trial. You can learn more about Faridah's experiences as a clinical trial participant below:

[\*Conyers breast cancer survivor encourages Black women to ask about cancer research studies\*](#)

## Real Stories: Insights from Clinical Researchers



*Beatrice Doe, Clinical ResearchER and Project Specialist*

Beatrice Doe is currently a Project Specialist who supports clinical trials for a Contract Research Organization (CRO). CROs are often the partners to pharma companies when it comes to running the clinical trials – team members on the CRO side like Beatrice make sure all of the data is accurate and complete, they make sure the site team members like the nurses and doctors are following all of the right steps, and they tackle a lot of the administrative and process work that keeps a clinical trial up and running smoothly.

Prior to her role as a project specialist, she worked as a clinical research coordinator (CRC) at a pediatric institute. While a CRC, Beatrice was able to support a variety of different clinical trials, including cardiology studies and COVID-19 studies. As part of her duties, she spent a lot of time reviewing patient charts to identify potential patients who would be eligible to benefit from joining a clinical trial based on their medical conditions. Working on patient recruitment, Beatrice had the chance to reach out to families and introduce them to clinical research, sharing information about clinical trials and specific studies that she felt that someone would be able to participate in. As a CRC, Beatrice notes that her favorite aspect of the role was to “make sure that our patients were receiving the best care,” whether this was through face-to-face contact, phone calls, or even check-in text messages. Highlighting how important the personal touch was, she mentioned how much patients “appreciated that our site was really focused on them.”

When asked about what she finds the most fulfilling about her current and previous roles in clinical research, Beatrice highlights her time working on patient recruitment efforts. “I enjoy watching the families light up at the fact that maybe what you (the research team) are doing could help their child or even the general public. They like feeling like they’re making a difference.” In particular, she calls out how important it is to get families comfortable with clinical trial participation – and then how it’s doubly rewarding to be able to help break down their fears and see them excited to participate in a trial. One approach to drive and support trial participation by marginalized populations is to ensure that the patients and the local community are able to connect with and see themselves within the study team. “I enjoy the aspect of seeing people who initially did not want to join a study but then were more open to joining after seeing the study team and realizing there were people that looked like them leading the study,” she mentions.

Beatrice also provides a shout out to patient advocates. “I think the most important thing [in encouraging trial participation from populations that are not well represented in clinical research] is patient advocacy. Patient advocates are very important in the community, they provide information to people about all of

their different options they might not have known about. Patient advocates can align with community leaders, churches, and others to really connect and support the communities; they do so much for accessibility to care too.” As a former site study team member, she continues to highlight the importance of study teams getting out there and engaging with the communities they serve. “Being out there, showing our faces, explaining about the services they’re able to provide, explaining clinical trials to everyone” is key in building that connection between communities and clinical research, Beatrice notes. Study team members have the responsibility to “provide the knowledge for people in communities to make their own decisions.” “It’s not about telling them what to do,” she says, “it’s about providing the information and the support and the care.”

Beatrice highlights how important it is to consider participation: “Every person that joins can change the future; maybe it isn’t always your particular situation, but you’re able to help the future population... and that’s a beautiful thing.”



## Decoding Clinical Trials: What does it all mean?

Randomized-Crossover-Double blind-Phase what? Clinical trials can seem mysterious enough as it is, but when it comes to the names of the studies, there are a lot of terms that might not be very familiar. Tigerlily Foundation is here to help you learn the language in order to understand trials better. We want you to feel empowered and confident when it comes to thinking about clinical trials! Read more below to learn the ins and outs of clinical trial terminology.

### Phase 1:

Phase 1 trials are the first time a treatment is used by people. A small group of healthy people are given a drug or medical device to learn about side effects and dosing (how much of the treatment a person should take for it to work).

### Phase 2:

Phase 2 trials start after Phase 1 trials. The people that take part in these studies have the disease or condition that is being studied. These studies see if the new treatment is safe and effective.

**Phase 3:**

Phase 3 trials start after Phase 2 trials. These are often the last studies before the FDA decides whether a treatment is safe enough and works well enough to be available for everyone. In these trials, the drug or medical device is given to a larger group of patients with the disease or condition being studied.

**Phase 4:**

Phase 4 trials are sometimes called 'post-market' studies and are performed after the treatment has been made available to everyone. This type of trial provides more information about the treatment's safety and how well it works.

**Randomized:**

In a randomized study, participants are assigned to receive different treatments through a random or chance-based process. This helps prevent bias.

**Single-blind:**

In a single-blinded study, participants do not know which treatment they have received but their doctors do. Participants will often find out after the study has finished.

**Double-blind:**

In a double-blinded study, neither participants nor their doctors know which treatment the participant has received until the study has finished. Once the study has finished, participants and doctors will learn which treatment was provided. Double-blinding is used to prevent bias and to limit the "placebo effect" where some people may have a positive reaction to their treatment even if it was not a treatment that was anticipated to have a positive reaction.

**Open-label:**

In an open-label study, both the participant and the doctor know which treatment the participant has received. Open-label studies often include treatments that have already been FDA-approved for one condition but are being studied for another condition.

**Crossover:**

In crossover studies, participants often switch treatments halfway through the study. For example, participants receiving treatment A first might receive treatment B halfway through the study, and those who received treatment B first may then switch to treatment A.

**Placebo:**

Placebo is a term that generally refers to either an inactive treatment or a treatment that is considered standard of care or the “default” treatment. In most studies, the placebo will be the standard of care treatment, as study participants generally do not withgo treatment if it is needed. For example, a new cancer treatment might be studied against the most commonly prescribed available treatment. An inactive placebo may be used in very early studies where a new treatment is being compared against an inactive placebo in healthy people to see if there are any side effects of the new treatment.

**Interventional:**

Interventional studies are clinical trials where the doctor assigns a treatment to the participant, whether it is a drug, a medical device, behavioral therapy, or other procedures. This is the largest category of studies.

**Observational:**

Observational studies are clinical trials where the doctor does not assign a treatment to the participant. Typically, these studies include large populations who are assessed for general health outcomes based on their condition, environment, or other factors.

**Non-inferiority:**

Non-inferiority is a term that means “not worse than.” These studies are designed to show that one treatment is not worse than another treatment.

**Dose-escalation:**

A dose-escalation study is a clinical trial that is designed to find the optimal dose of a new drug. In these studies, participants are assigned to different groups, starting with a very low dose and gradually increasing until the highest dose that does not cause side effects is determined. These studies may also be referred to as “dose-finding” studies.



## Get Involved

### WISDOM Trial

Most physicians still use a one-size-fits-all approach to breast screening in which all women, regardless of their personal history, family history or genetics (except BRCA carriers) are recommended to have annual mammograms starting at age 40. Mammograms benefit women by detecting cancers early when they are easier to treat, but they are not perfect. With the current screening approach, half of the women who undergo annual screening for ten years will have at least one false positive biopsy. This study compares annual screening with a risk-based breast cancer screening schedule, based upon each woman's personal risk of breast cancer. The investigators have designed the study to be inclusive of all, so that even women who might be nervous about being randomly assigned to receive a particular type of care (a procedure that is typical in clinical studies) will still be able to participate by choosing the type of care they receive. Women who have the highest personal risk of developing breast cancer will receive more frequent screening, while women with a lower personal risk would receive less frequent screening. WISDOM is also making a focused effort to enroll Black women in the trial. Past studies tended to contain a majority of White women and therefore, there is less data on how screening can benefit Black women. Researchers are taking a number of steps to include as many Black women as possible in the study while also increasing the diversity of all women enrolled.

## Updates From Industry

- In November, the FDA approved the combination of capivasertib (Truqap, AstraZeneca Pharmaceuticals) and fulvestrant for patients with metastatic or locally advanced HR+, HER2- breast cancer that is positive for PIK3CA/AKT1/PTEN biomarker alterations. At the same time, the FDA also approved a new test designed to identify these specific biomarker alterations in order to assess whether patients should consider this new treatment combination. In the clinical trial that compared this combination versus fulvestrant without capivasertib, progression-free survival rates doubled in the group of patients that received both treatments together. Read more about this new approval [here](#).
- The American Cancer Society's Blue-button Project team, supported by Amgen, has recently published several articles discussing ways to better match patients to clinical trials. One article demonstrates use of an automated screening tool that reviews electronic health records and compares with eligibility criteria for regionally-located clinical trials, finding trials for 91% more patients than traditional approaches. Another article recommends changes in policy, staffing, and procedures that could better support the opportunity to match eligible patients with trials. Lastly, the third article reviews existing methods for trial matching and identifies both challenges and solutions within through direct interviews with healthcare providers involved in clinical research. Read more about the ACS and the Blue-button Project [here](#).

- The White House Office of Science and Technology Policy is leading a new project to improve the way clinical trials are designed and managed. The Clinical Trials Readiness Initiative will support more inclusive clinical trials and will make them simpler and more accessible to all. Roundtables and listening sessions were held to capture unmet needs that this initiative is designed to address. The top-listed action for this initiative is to enable more diverse participation in clinical trials; to achieve this, more diverse workforces will be needed at hospitals and clinics and increased community outreach and education opportunities will come into play. Many other groups are partnering together on this project to ensure it's plans can be met. In the long run, this initiative aims to increase distribution of trial sites to areas with minimal existing opportunities, to increase diverse participation in clinical research, to simplify study design for care providers and trial participants, and to better engage with communities in order to establish the trust necessary to support clinical research. Read more about The White House's plans to support clinical research [here](#).

## Featured Partners

### BreastCancerTrials.org

BreastCancerTrials.org (BCT) is a non-profit service that encourages individuals affected by breast cancer to consider clinical trials as a routine option for care. To make this possible, BCT:

- Helps individuals who are interested in clinical trials find studies that are right for them.
- Lists all of the U.S.-based trials on ClinicalTrials.gov and Cancer.gov that are currently looking for participants with trial information written in patient-friendly language (or "lay language").
- Provides accurate information about why clinical trials are important and how they are structured.
- Helps care providers and patient navigators find trials for patients

BCT provides lots of resources and guidance to breast cancer patients considering clinical trials as a treatment option. If you are considering participation in a clinical trial, you might be wondering about how your personal data will be used. Click [here](#) for some helpful resources on this topic through BCT!

For more information on clinical trials and trial terminology, please visit BCT's Metastatic Trial Talk content below:

- Clinical Trial Phases
  - [All About Phase IV Clinical Trials](#)
  - [All About Phase III Clinical Trials](#)
  - [All About Phase II Clinical Trials](#)
  - [All About Phase I Clinical Trials](#)
- Clinical Trial Design
  - [What Are Crossover Trials and How Do They Work?](#)
  - [All about Basket and Umbrella Trials](#)
  - [How Participants are Divided into Treatment Groups in Clinical Trials](#)
  - [What are Placebos and How Are They Used in MBC Clinical Trials?](#)
  - [What is a Washout Period?](#)

- Other Helpful Information
  - [What Do Drug Names Mean?](#)
  - [Expanded Access](#)
  - [Clinical Trial Outcomes: What is Being Studied and How is it Measured?](#)
  - [Commonly Used Terms in Clinical Trials](#)

## Patient Access Network (PAN) Foundation

The [PAN Foundation](#) is a national patient advocacy and charitable organization that helps underinsured patients with life-threatening, chronic, and rare diseases—including [breast cancer](#)--get the medications and treatments they need by assisting with their out-of-pocket costs and advocating for healthcare access, equity, and affordability.

### Financial assistance for out-of-pocket treatment costs

Feeling overwhelmed by out-of-pocket medication costs? Apply for one of the PAN Foundation's more than 70 disease-specific assistance funds. If you're a patient or caregiver looking for financial assistance to help with your out-of-pocket treatment costs, we encourage you to learn more. [Find a fund and review the eligibility requirements today.](#)

### Transportation assistance

The PAN Foundation offers financial assistance for qualified patients who need help traveling to the care they need. Learn more about the [eligibility requirements for PAN's transportation assistance program.](#)

### Track the status of over 200 charitable patient assistance funds, all in one place

The PAN Foundation offers [FundFinder](#), a free web tool, to help you and your loved ones quickly find financial assistance across nine charitable organizations. With FundFinder, you can easily track the status of more than 200 funds and sign up to receive text message or email alerts when funding for a specific disease becomes available. [Sign up for your free account today.](#)

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