

~~CLINICAL~~

Transformation Requires Individual  
Advocates Leading in Science  
(TRIALS)

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

FEBRUARY 2024



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



Dear Friends,

*We are excited to share the tremendous progress and impact of Tigerlily Foundation's efforts in our ongoing mission to achieve equity in healthcare with a heightened focus on diversity, equity and inclusion in clinical trials. As an organization deeply committed to listening to, learning from, and co-creating with patients, we have made significant strides in addressing the multi-faceted challenges that patients face when it comes to knowing about clinical trials early, being at the forefront of the development of solutions in collaboration with stakeholders, to include the community, biotechnology companies, CROs, and more.*

*At the core of our approach is to build solutions advised by patients, with patients and delivered in ways that are easily understood by anyone. We are proud to work alongside patients, other advocacy groups, physicians, policymakers and others to creating a living legacy of hope and transformation. Clinical trials are about people, about heart beats, and about developing and delivering the right treatments to people in a way that makes them feel safe.*

*Our unique approach is rooted in meeting individuals where they are, acknowledging their lived experiences, and empowering them to be active participants in their healthcare journey. This is embodied in our ANGEL program, which is embedded in the community. Through our partners such as BMS, Exact Sciences, GSK, Labcorp, Pfizer, and Seagen, our ANGEL Advocates work to forge meaningful partnerships and best practices to provide patient education, resources, and support. These collaborations are critical to building authentic, sustained relationships in the community – ones forged naturally and that are consistently engaged with. These efforts have not only increased clinical trial awareness but have also fostered a culture of inclusivity, belonging and trust.*

*Looking ahead, Tigerlily is excited to highlight the work of our patients, the community, and our partners. Thank you for all you do to ensure that all individuals have access to the care and resources they need to thrive and live their best life in their best health.*

Sincerely,

**Maimah Karmo**



## How Tigerlily is Leading Best Practices Toward Equity in Clinical Trials

*Tigerlily Foundation and our ANGEL Advocates are at the forefront of clinical research, guiding industry leaders at pharmaceutical companies to build trust at a community level and to ensure clinical trials and trial materials are designed in an inclusive, culturally appropriate way. Read below to learn about some of Tigerlily's recent and ongoing projects in which Tigerlily is leading the field for patients and advocates:*

### Successful Clinical Trial Partnerships

- Partnering with [Seagen](#) to develop and expand Tigerlily's library of disease-agnostic barrier toolkits and to create a framework to guide patients and clinical trial sites by supporting educational efforts, empowerment to overcome barriers, and to drive trust between community members and clinical researchers
- ANGEL Advocate guidance on study design, recruitment material review, and digital outreach in support of clinical trials for [Exact Sciences](#)
- With key site leaders and patient experts, Tigerlily is working with [Labcorp](#) to establish a framework for sites and site staff to drive inclusivity in clinical research at the site level
- Designing advocate-led educational digital educational outreach in collaboration with [Menarini Stemline](#)
- With [GSK](#), Tigerlily created an advocate-driven educational campaign to build trust around clinical trials in underserved communities. The campaign was a great success, reaching 171 million+ listeners through a radio PSA, 33 million+ readers through interviews for online news outlets, 5 million+ viewers through television news outlets, 1,600 unique visitors on the campaign website, 286,000+ viewers through patient advocate influencers on social media platforms, and 400+ individuals through direct, active conversations at in-person community events.
- Through work with [BMS](#), the BMS Foundation and the ANGEL Leads have reached out to clinical stakeholders in the target areas to establish relationships and collaborate on health equity work in the community, sharing educational resources and support, collaborating on community outreach events and screening events, providing physician-facing educational resources to address and eliminate barriers for patients
- Through our partnership with Community Advisory Boards (CABS), we attended CAB meetings... and more.
- Through our Healthcare Center and Community Oncology Partnerships, we work with more than 3,500 healthcare centers distribute Tigerlily's MY LIFE Matters Magazine featuring patients and other stakeholders.



## Tigerlily's MY LIFE Matters Magazine

MY LIFE Matters Magazine is a digital and print magazine collaboration with Tigerlily Foundation & Elephants and Tea. Each magazine takes a heart-centered look at important topics that impact the cancer community, with a focus on individuals living with metastatic cancer. The magazine is educational, supportive, and intentional. Articles are written by Survivors, Thrivers, medical experts, patient advocates, and caregivers. Sharables, tips, infographics, and educational tools are also provided in the magazine. In 2023, MY LIFE Matters came out with a special double issue focused on clinical trials, in which the stories and experiences of patients who have been a part of clinical trials were featured. [Click here](#) to read this issue!

## Real Stories: Insights from Clinical Trial Participants



### **Syreeta Coleman**

Syreeta Coleman, Tigerlily Foundation ANGEL advocate and clinical trial participant, has a message for our newsletter readers: *“If you want to be part of the solution, get out there!”*

Syreeta, who has worked in the healthcare industry for over 20 years supporting insurance processing and data analytics, has participated in several clinical trials. While she’s participated in women’s health studies in the past, Syreeta is currently enrolled in a breast cancer clinical trial. She notes that as part of the study, she gets to continue being on the same treatment that she was on prior to enrolling in the trial, so there aren’t any major changes to her life as a result of new treatment side effects. Syreeta also highlights that receiving extra care and additional testing or imaging opportunities is her favorite perk of trial participation – she’s been able to have more scans done as part of the trial assessments than she would have had without participation. Having a strong understanding of insurance processing, co-pays, and hospital processes, Syreeta shares how important the access to high-touch care can be for trial participants: *“I was glad to be able to get a more thorough workup. Insurance doesn’t want to cover our PET scans – most survivors that I know have not had a PET scan because they can’t afford it. But this trial allowed me to get a PET scan. And I get assessment on all of my biomarkers every other month. That’s a big plus for me.”*

Syreeta’s physician reached out to her about the trial, knowing that she had an interest in participating in a study if the right one was available. While she acknowledges that not all people are asked and might need to do the asking themselves, she points out that physicians might not ask about trial participation because there simply aren’t any trials nearby that are currently enrolling or that their patient might qualify for. However, it’s up to the patient themselves to make sure that their physician knows they’re interested, even if there aren’t any ongoing trials at the moment. And if the patient doesn’t feel like the physician is listening, *“you can always leave. If your doctor isn’t working for you, find a new doctor. That’s okay,”* says Syreeta. And she highlights this in regards to trial participation as well. *“If you’re in a clinical trial, you don’t have to stay there if it’s not beneficial for you and your life. Life happens, things change. But you won’t know until you take the chance. And that’s what we need to do, is to take the chance,”* she says.

She highlights being surrounded by healthcare colleagues as a big driver in making her feel comfortable and empowered in talking about and participating in clinical research. *“Clinical trials might sound intimidating, but it’s just another way of saying *research*,”* she says. *“Everyone knows what research is, it’s just finding the answer to a question or finding the solution to a problem. You go on Google and look things up, that’s doing research.”* Acknowledging the lack of representation in trials, Syreeta shares that she *“wants to be the face of clinical research, the face that isn’t currently represented... there’s just not enough African American women or men that sign up for clinical trials because they’re afraid of the ‘what ifs’, but we won’t know if we don’t try it.”* The fear of the unknown or lack of awareness on how clinical trials work is a big barrier to participation, Syreeta highlights, especially when patients don’t feel like anyone in clinical research looks like them -- that’s what she wants to change. She highlights this as a driving factor for her in the way she advocates for others to think about clinical trial participation. *“If you see a familiar face, you might think ‘oh, well she did it so I could do it too.’ We’re never going to be able to conquer anything if we just sit here. We have to get up, we have to do it.”*

*“If you’re led to it, then follow through. You had the idea of it (participating), so do it. The *idea* of it can turn into you *doing* it, and that can help the next person and those that come after you.”*

## Real Stories: Insights from Clinical Researchers



*Dr. Lovie Negrin, APRN,  
FNP-C, AG ACNP  
Director of Research at  
Randomize Now*

In her daily efforts, Dr. Negrin is a double board-certified clinical research nurse practitioner working in both acute care and family medicine. Having seen low participation from racial and ethnic minority communities compiled with a lack of diverse representation in medical staff overseeing clinical research efforts, she switched gears from an academic/institutional environment to open a community-focused clinical research site called Randomize Now. [Randomize Now](#) is a medical research center near Atlanta, GA that specializes in hosting clinical trials that target racial and ethnic groups that are typically underrepresented in research participant populations. At Randomize Now, Dr. Negrin highlights that education, accessibility, and cultural competency are key drivers of their work in increasing clinical trial participation by underrepresented populations. As a site director, she oversees the clinical research staff at the site and supports trials as a sub-investigator or nurse practitioner.

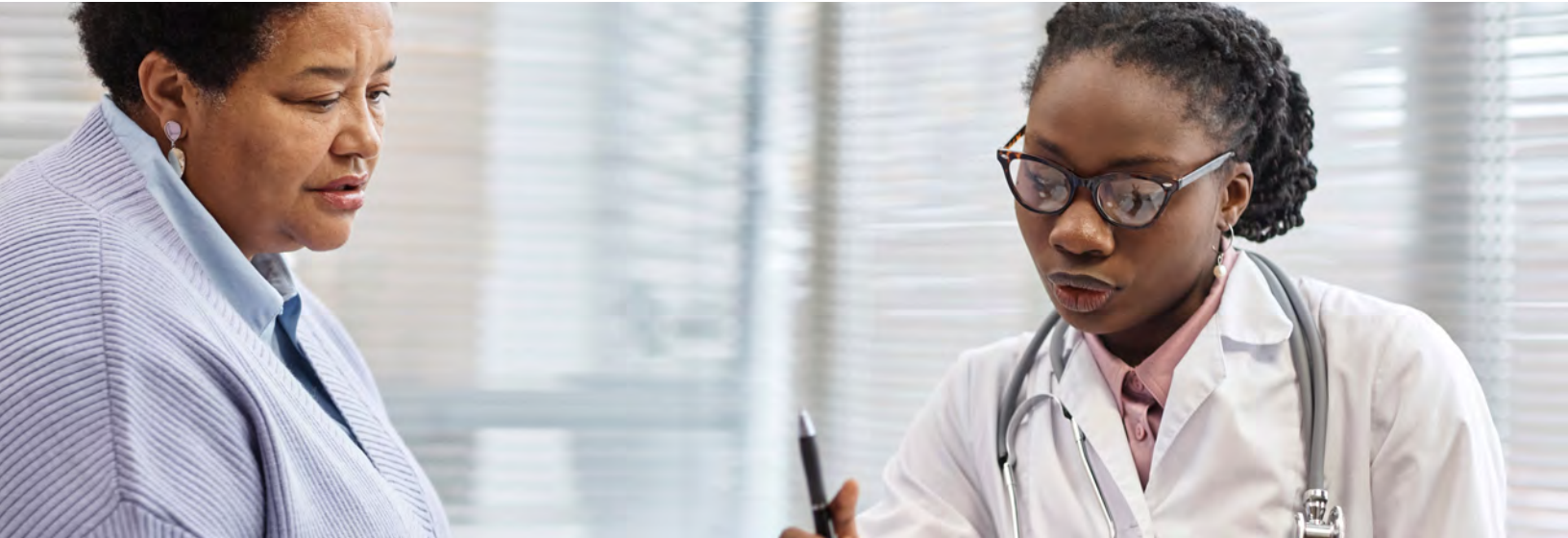
Sharing her thoughts on representation in clinical research, she notes how important it is for patients to “see someone who looks like them at the bedside.” “There is a lot of fear in the Black community when it comes to clinical research,” she says, “so for them to see someone who looks and sounds like them, who is going to advocate for them, who is going to say ‘these are the things we’ve done to make sure Tuskegee doesn’t happen again’ ...that’s what gives me the passion behind what I’m doing.” Acknowledging previous wrongs in scientific research is important, but focusing on how the medical field has corrected the way it operates is most beneficial in helping patients break that barrier of fear. “I try to always take things from the angle of the patient,” she shares.

Through her experience in clinical research, Dr. Negrin calls out that it’s overwhelming to try to solve every barrier for every underserved population and that it often isn’t effective to engage in sweeping attempts that might not be relevant or beneficial for everyone equally. “We’re not the only minority or underserved population,” she notes, “but the Black community is my niche... it’s my area of expertise... we all have to take a small part of this ocean.” Working together with other physicians who are actively engaged with other populations, she underlines the importance of working together to solve these broad challenges bit-by-bit.

Dr. Negrin highlights the importance of outreach initiatives and community engagement in increasing trial participation by underserved or historically excluded populations. She shares that it’s particularly helpful to have a presence at events where other organizations that provide housing support, financial assistance, insurance services and similar aid mechanisms since these events often bring in a lot of attendees who fall into the category of underserved and underrepresented. Events like these also end up being a great way

for her research site to meet and engage with other community organizations, often resulting in additional outreach partnerships and engagement opportunities.

When asked what she finds most fulfilling about her role, Dr. Negrin highlights how rewarding it is for her to see older adult populations (i.e., over the age of 60 years), especially those in the Black community, ask about participating in clinical research. She also underscores the importance of intersectionality in underrepresented populations and how challenging it often can be to engage these individuals in clinical research. “To see an (older) Black man or woman contact me and say ‘I want to know about your initiatives,’ it is just the most satisfying thing... they want to participate, they’re educating their families... it’s so important,” she says.



## The Importance of Participation

You hear it all of the time – Participating in a clinical trial is so important! – but you don’t always hear about why participation is important. As a patient, it is important to know that clinical trials can be a potential treatment option. Clinical trials might provide you with a treatment that can result in a longer life, relief from your conditions, or a better quality of life for you as the recipient of that treatment. But clinical trial participation is bigger than just the potential benefits to you – it’s about helping develop treatments for future generations, for people with similar conditions, for those that need it the most now and in the years to come. Not only are clinical trials necessary to develop new treatments, but participation from people of all backgrounds helps researchers, patients, and advocates learn more about diseases and ensure that new treatments work safely and effectively in all people. The best way for researchers to understand all of the nuances of how different bodies work is to ensure that all of those different bodies are represented in clinical trials.

Right now, we don’t see appropriate representation in clinical trials. For example, one study reviewed breast cancer rates in 2010 and 2011 across all racial and ethnic subtypes and identified that 12.2% of HER2+ breast cancer cases studied were in Black or African American women<sup>1</sup>. Yet, in the clinical trial data documented in the submission and approval of Margenza® (margetuximab-cmkb, MacroGenics) in 2020, only 5% of clinical trial participants were Black or African American<sup>2</sup>. In order to ensure that medicines being developed are truly going to be effective for all of the individuals who have the condition being treated and will be taking the medicine, clinical trials need to include appropriate representation of the populations that have the condition. Bridging gaps like this one is one of many reasons that clinical trial participation is important. Read on below for more insight:

- Cutting edge treatments: Participants have the opportunity to receive the latest therapies and interventions that may not yet be widely available.
- High-quality care: Trial participants are very closely monitored by a team of healthcare professionals and specialized support personnel throughout the entire study.
- Developing the future: Participating in a clinical trial allows someone to be part of a process that can prolong their life while developing better medicines for the future.
- Building health equity: Representation from all communities in clinical trials allows for equitable access to the innovative treatments and advances in healthcare that are developed through clinical research.
- Empowerment: By actively encouraging BIPOC (Black, Indigenous, and People of Color) participation in clinical research, clinical trials can help break down barriers that limit current access to healthcare advancements.
- Addressing health disparities: Gaps in health outcomes can be highlighted and solutions can be identified by ensuring that clinical research includes individuals from all communities.
- Building trust: Increased representation fosters trust between research institutions, clinical trial sponsors, and underrepresented or historically excluded communities. In turn, this trust can encourage future trial participation and the development of better, more effective medicines for all.

*References:*

1. Chen, L., & Li, C. I. (2015). *Racial disparities in breast cancer diagnosis and treatment by hormone receptor and HER2 status. Cancer Epidemiology, Biomarkers & Prevention, 24(11), 1666–1672.* <https://doi.org/10.1158/1055-9965.epi-15-0293>
2. Cavazzoni, P., Anagnostiadis, E., & Lolic, M. (2021, February). *2020 Drug Trials Snapshots Summary Report. Drug Trials Snapshots.* <https://www.fda.gov/media/145718/download>







## Get Involved!

### I-SPY 2 Trial:

The I-SPY-2 trial examines outcomes of neoadjuvant therapy for locally advanced breast cancer. This study has been ongoing since 2010, pioneering a long-term, multi-arm study design. The I-SPY2 Trial's groundbreaking adaptive, multi-agent design allows up to five agents (or combinations of agents) to be evaluated in parallel. It uses one master protocol across all study arms and timelines with a common control group that all therapies are measured against. At time of consent, a new participant's breast cancer is classified into one of 10 molecular subtypes. Then, for each participant in the trial, I-SPY 2's adaptive randomization process assigns a participant to a treatment focusing on treatments that have been successful in the participant's specific tumor subtype. Based on the participant's tumor subtype, diagnostic data from assessments like MRIs and biomarker tests, and treatment received, the predicted probabilities of the treatment being studied in the various subtypes are updated in real time. This helps to refine the way that trial participants are assigned treatments. If these probabilities for an experimental agent reach a pre-determined level of efficacy in one or more molecular subtypes, it is declared a success (i.e., the treatment "graduates"). Alternatively, it may be stopped for futility after reaching a maximum number of participants. At any point new treatments can be studied on the trial through a protocol amendment. Currently, this trial is actively enrolling for several different treatments.

Whereas many trials are sponsored by one pharmaceutical company, this trial is led by a non-profit healthcare organization called Quantum Leap Healthcare Collaborative that receives support from the National Cancer Institute and many different nonprofits, advocacy organizations, and industry entities.

## Updates From Industry

- Chimeric antigen receptor (CAR) T cell therapies are a big topic lately, especially in oncology fields where precision approaches in treatment are necessary. With CAR-T cell treatments, T cells are taken from the patient and modified to be able to recognize and attack specific patterns found only in the cells being targeted, like cancer cells. These modified T cells are then given back to the patient where they can attack only the targeted cancer cells. Currently, CAR-T cell therapy has shown success with this approach and one treatment developed by Novartis and the University of Pennsylvania has been [FDA-approved](#) to treat blood cancers like acute lymphoblastic leukemia (ALL); this approach is currently in development for the treatment of solid tumors like breast cancer. This type of treatment is currently being studied at research institutions like City of Hope in Duarte, California, where an [ongoing study](#) examines how these genetically engineered T cells can be designed to target and destroy HER2+ cancer cells. [Additional ongoing studies](#) examine potential targets for CAR-T cells in the treatment of triple negative breast cancer (TNBC), a breast cancer subtype that is notoriously difficult to target due to the lack of typical receptor targets such as HER2, ER, and PR. After positive results in [early studies](#), a research team at Penn is [planning a clinical trial](#) that will study use of CAR-T cells in clearing residual tumor cells that may remain after surgical resection.
- Genomic diagnostic tests that can help physicians decide on the most effective therapies for specific breast cancer subtypes are becoming more specialized as new testing approaches are developed and paired together. The [Breast Cancer Index](#)<sup>®</sup> is a test that provides an individual assessment for those with hormone receptor-positive subtypes that can determine whether or not extended anti-estrogen therapy will be beneficial. Similarly, the [HER2DX](#)<sup>®</sup> test looks at biomarkers for several different genes and biological processes in individuals with early stage HER2+ breast cancer and can provide insight on the probability of response for several therapies. This type of diagnostic test can also be used to identify early cases of breast cancer as an addition to existing screening procedures, as highlighted in the coming [INTERCEPT clinical trial](#) which examines cancer biomarkers using a less-invasive liquid biopsy procedure rather than a typical tumor biopsy.



## 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!

### Topics on BCT’s Metastatic Trial Talk

- CAR-T Cell Immunotherapy:  
[Adoptive Cell Therapies: A Type of Immunotherapy for MBC](#)
- Biomarkers and Treatment Decisions:  
[Non-Treatment Trials: Predicting Response to Treatment and Decision Support](#)  
[Biomarkers to Guide MBC Treatment Decisions: PIK3CA, BRCA1/BRCA2, and PD-L1/PD-1](#)  
[Biomarkers to Guide MBC Treatment Decisions: dMMR/MSI-H, TMB, and NTRK Fusion](#)  
[Biomarkers to Guide MBC Treatment Decisions: ESR1, PALB2, TROP2, HRD, ctDNA, and CTCs](#)
- Diversity in Clinical Trials:  
[Steps Toward Expanding Eligibility Criteria to Increase Diversity in Clinical Trials](#)  
[Why Are MBC Outcomes Worse for Black Women Than White Women?](#)

### Trials of Interest on BreastCancerTrials.org

- [CAR-T cell therapy](#)
- Treatment planning/decision making
- Genetic testing

### Facing Our Risk of Cancer Empowered (FORCE)

FORCE is a national non-profit organization focused on people and families affected by hereditary cancers. Our community includes people with inherited mutations in ATM, BRCA1, BRCA2, CHEK2 and other genes. facing hereditary breast, ovarian, pancreatic, prostate, colorectal and endometrial cancers.

FORCE’s Research Search and Enroll Tool connects people with inherited mutations to research studies enrolling people like them. We prioritize studies that are focused on advancing treatment, prevention and quality of life for people and families with hereditary cancer. Our Featured Research Studies are written in plain language, have clear guidance on who is eligible to participate, includes the study locations and contact information of the coordinator. Here are the quick links to get started:

- [Find research studies](#)
- [View a list of surveys, interviews and registries](#)
- [Search for prevention, detection, quality of life or treatment studies by cancer type](#)

Navigating the landscape of clinical trials can be overwhelming, but we are here to assist. Through our website, we offer [tips and resources](#) to help individuals locate clinical trials and studies that align with their unique situations. We also offer [Peer Navigation](#) to match people with a trained FORCE Peer Navigator to answer questions and provide resources over the phone or via email.

Does cancer run in your family or have you tested positive for an inherited mutation and you want to make a difference and help shape research? FORCE offers free training to people with no science background to use their personal experiences to help guide hereditary cancer research. [Learn more and enroll in our FRAT program.](#)

