~~CLINICAL~~

Transformation Requires Individual Advocates Leading in Science (TRIALS)

Creating a New Legacy - One Person at a Time

APRIL 2024

Tigerlily Foundation

Beauty. Strength. Transformation.

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. 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. This newsletter is co-designed with the support of our ANGEL advocates to highlight Tigerlily's efforts in the clinical research space, to provide educational information in an accessible and culturally appropriate manner, and to share industry-wide developments with our audience. The Tigerlily Team wants all of our readers to have the knowledge and resources that they need to feel empowered, supported, and educated when it comes to taking charge of their healthcare and knowing that clinical trials can be a treatment option.

Tigerlily's #MyLifeIsMyLegacy

#MyLifeIsMyLegacy series by Tigerlily Foundation is a collection of intimate vignettes showing the lives and living legacies of remarkable individuals. Personal stories of people living with Stage IV cancer, early-stage cancer in addition to medical experts, industry trailblazers, and caregivers who have not been diagnosed with cancer. These stories build a bridge of knowledge, love, faith, hope and transformation that help us understand the impacts of cancer and provide guidance that will help generations to come. Some of these individuals share their experiences with and thoughts on clinical research, knowing that trials are necessary to develop each and every new treatment that is needed. Check out our most recent stories on Tigerlily's website *here*!

Real Stories: Insights from Clinical Trial Participants

Shakisha Davis, M.Ed

Shakisha Davis is an active Tigerlily Foundation ANGEL Advocate that wants to highlight her experiences with the power of advocacy – *especially* when it comes to advocating for one's own health. As a clinical trial participant in multiple studies, she's had a variety of different experiences. Shakisha credits Tigerlily's clinical trial education during the ANGEL Advocate training with making her feel confident about her understanding of clinical trials and her comfort level around trial participation.

The first trial Shakisha participated in started off smoothly – she highlights her study healthcare team members as being knowledgeable and helpful in getting her set up as a study participant. "I had a really good nurse navigator, I had a really good team," she notes. The trial option was initially presented to her by her doctor as a different approach to radiation treatment, one that was more precise and more targeted, which sounded like a great opportunity that wouldn't require much burden beyond her standard treatment plan. "It wasn't going to be anything extra," she says, "I didn't have to do much, it was just about the way the radiation was administered, that was the only difference. I thought, 'yeah, I could do this.'"

"It was going fine, it was all good. And then it wasn't."

With only three of the 36 radiation treatments in the study remaining, Shakisha began experiencing some discomfort. Throughout a day, it started off as an itching sensation, but by the end, grew into a seriously uncomfortable situation. She was losing her skin in the areas that were irradiated, right around the band of her bra, all of the way around the front and back. "My skin came off. It was burning. I could barely put on a shirt," she says. She relayed her concerns about these serious side effects to her study team, but they continued to ask her to complete her series of treatments. "It was one of the only times I felt like a number," she relayed, "they seemed more focused on getting me through the treatments than how I was actually doing… it was like they forgot about me as the patient." With only three treatments remaining and the study team being so persistent, she thought "maybe I can do it, I can just finish the study, it's only three more treatments." But after seeing the burning and skin loss worsen after another treatment, Shakisha needed to advocate for herself and her own well-being. "I stopped just before the end. That was the best decision I could have made for myself, that was me advocating for myself." As a trial participant, it's important to remember that participation is entirely voluntary. And as a patient, there's nobody that knows your experiences better than yourself, so it's up to you – as a patient and as a participant – to make the choices that are the best for you.

After learning more about clinical trials through Tigerlily, Shakisha is an active supporter of clinical trial participation even in spite of her initial experience. "I know I made the right decision, but now I fully grasp how important it is to finish a trial. I do wish I could have finished those last two radiation treatments because my information could have been used for a greater cause," she shares. While Shakisha still prioritizes self-advocacy, she has a better understanding of the needs of clinical research. Highlighting how learning more has helped her to move forward, she says "now I've begun to understand what the study team was doing, they knew that my information could help a lot of people. I think they just lost sight of things in the moment, but I understand why they wanted me to still finish the treatments." "If I were offered a trial today, I would definitely consider it," she says.

"I'm big on helping the next person. If it can help my family, my friends, or even people I don't know, I'm all for it," Shakisha says. She understands how important it is to participate in clinical research in order to design better treatments, understand medical conditions more deeply, and to help build a better future of healthcare for coming generations. She considers trial participation as "doing her part" for the future. Sharing her story "gives me purpose, it gives me a purpose to that pain, even those unpleasant parts," she says. Shakisha encourages others to learn more and think about trial participation too.

"Do your research, learn about it. Clinical trials are not just a way to do tests on someone, it's how they learn more about medicine. Know that it serves a greater purpose and that you're a part of that impact, you helped bring forth new discoveries."

Real Stories: Insights from Clinical Researchers

Finding My Purpose

By: Dr. Lisa Treviño, PhD

Dr. Lisa Treviño, PhD

Dr. Lisa Treviño is an avid advocate who has dedicated much of her life to bringing clinical research to those who need it most. Driven to learn more after her young niece battled Acute Lymphocytic Leukemia (ALL), a common form of childhood cancer, she focused her post-graduate efforts at St. Jude Children's Research Center in Memphis, TN. Dr. Treviño highlights this drive and the momentum it carries as "the constant desire to learn more and more so that I may be that conduit of information to educate and inform the patients and families in my community." This drive, this purpose to lend a hand and an ear to those who need it most has been a powerful force guiding her career. "I had the opportunity to translate study material and study information and informed consent forms to Spanish-speaking families with children with cancer at Texas Children's Hospital. There is no better feeling in the world than when you are able to fully explain something to someone, with an accompanying understanding, such that you are potentially changing, even saving a life," she shares. Later, she started a clinical research program at a health care organization in her home town located along the Texas-Mexico border with a Hispanic patient population of over 90%. "Being the voice for patients in most need is a responsibility I hold dear, and it drives me to go above and beyond in advocating for their well-being. The act of empowering someone with education and information so they make an informed decision is so rewarding on so many levels," she writes.

Read more about Dr. Treviño's story on Tigerlily Foundation's Clinical Trials webpage featuring interviews with individuals involved in clinical research *here*. Dr. Treviño's article was also a feature in MY LIFE Matters Magazine and can be found *here*.

Different Types of Trials

All clinical trials are not alike! You might be familiar with the different phases of clinical trials, but did you know that there are different types of trials too? Not all trials are designed to study a specific treatment – there are trials out there that look at all kinds of different information, including cause-effect relationships, prevention approaches, diagnostic methods, and genetic patterns. Read more below to learn about the differences in all of these different types of studies and think about whether they'd be something that you might have an interest in participating in!

Observational

Observational studies focus on observing changes (or the lack of changes) in a group of participants without specifically intervening or treating a health condition. These studies provide doctors with detailed information about how different bodies work depending on different characteristics or personal backgrounds. Studies in this category might also examine new methods or approaches for detecting certain health conditions. There are a lot of different types of observational studies:

Diagnostic and Screening

Studies that fall in this category are those that compare new and currently used tools or methods for diagnosis or screening of health conditions. An example of these kinds of studies might be comparing a new liquid tumor biopsy method (i.e., blood sampling) with the "gold standard" or most commonly used approach for tumor confirmation, which would be a standard tumor biopsy.

Genetic

Genetic studies often look at biomarkers or specific genes to determine if there is a correlation (i.e., a cause-and-effect relationship) between the presence of these biomarkers or genes and a specific health condition. Studies like these can help doctors and scientists develop very tailored treatments that are specific to a person's genetics. An example of a genetic study would be a study that looks at specific BRCA gene subtypes and identifies if specific mutations are correlated with the development of specific cancers.

Epidemiological

These studies look at certain characteristics of study participants, like race, ethnicity, age, diet, and other identifiers to see if they correlate with certain health conditions. An example of this might be a study that compares participants who have and have not been exposed to secondhand smoke to see if that exposure correlates with the development of lung cancer or other health conditions that are related to smoking.

Interventional

Interventional studies are those that include an intervention led by a doctor and the study team. This intervention might be a medication, a device, a new surgery, or lifestyle change. These studies examine how a specific intervention affects an existing or potential health condition.

Treatment

Treatment-based studies are the ones we're most familiar with when we think about clinical trials. In these studies, trial participants often receive some sort of treatment for a health condition that they currently have. The effects of this treatment on their health condition are compared against the effects of another treatment. Most often, the comparison treatment will be the "gold standard", a term for the treatment that is most effective and most commonly used. An example of this would be a study that compares a new HER2-targeting breast cancer drug against a treatment like Enhertu® that has been commonly used to treat HER2-positive breast cancers. In cases in which the health condition is minor, a new treatment may be compared against no treatment. An example of this kind of treatment study would be examining a new type of bandage on a small cut or scrape to see if it helps the wound heal faster than if no bandage were applied.

Prevention

Prevention studies are those that examine use of a treatment with the goal of preventing a specific health condition from developing. Here, doctors are looking to see if using one treatment versus another can either completely prevent or at least delay the onset of specific conditions. An example of a prevention study might be a vaccine study in which some participants receive a new vaccine and some participants receive the currently used vaccine against an infectious disease like the flu and over time, the number of people who received each vaccine and did or did not get the flu are compared.

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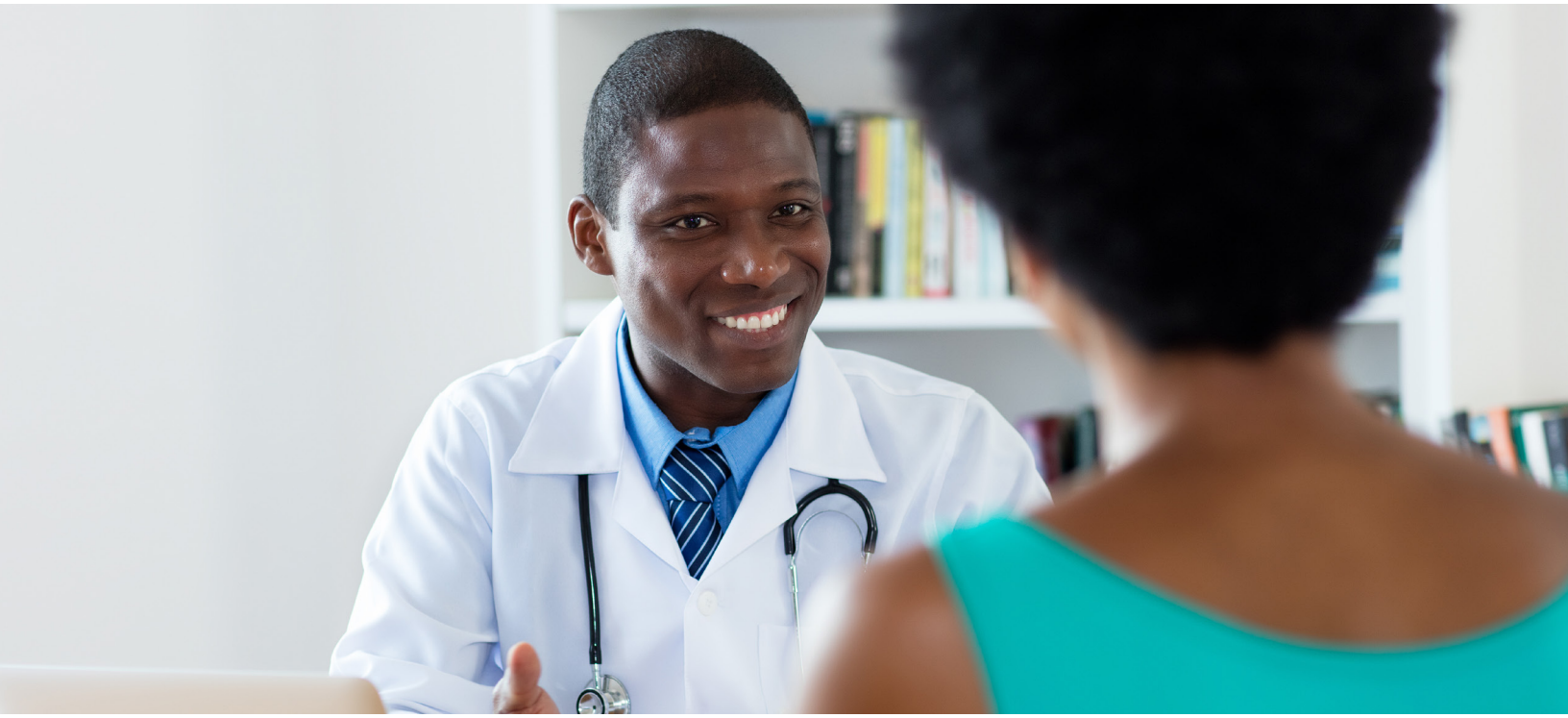

Get Involved!

All of Us Research Program:

All of Us is a broad research program designed to create a large database of health information across diverse individuals from all races, ethnicities, ages, and backgrounds. The information collected from participants in this program will be used to inform thousands of different clinical studies across a variety of health conditions. This information will help doctors understand risk factors for diseases, study treatments in people with different characteristics, connect individuals to clinical trials that might be right for them, and understand how technology can be used to support healthcare in a patient-centric manner. This research program is supported and led by the National Institutes of Health (NIH). The team overseeing this program believes that participants are partners – all research volunteers have access to their information and have a say in how the program is run. All eligible people, living anywhere in the United States, can join the All of Us Research Program. All of Us is free to join, and participation will always be free. People who take part in the program will answer surveys on different topics. They will be asked to share their electronic health record. They may give samples of blood, urine, and/or saliva for lab and DNA tests. The health information that participants share with All of Us will go into a secure database. To learn more about this program, visit their webpage *here*.

Updates From Industry

- **New indication for Daiichi Sankyo, Inc.'s Enhertu®**

On April 5, 2024, the FDA granted accelerated approval to fam-trastuzumab deruxtecan-nxki (Enhertu®, Daiichi Sankyo, Inc.) for adults with unresectable or metastatic HER2+ solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options. Enhertu is an antibody-drug conjugate treatment that targets HER2 specifically. For this new tumor-agnostic indication, efficacy was evaluated in 192 adults with previously treated unresectable or metastatic HER2+ solid tumors who were enrolled in one of three key trials in the DESTINY trial series. Although Enhertu is most often thought of as a treatment for HER2+ breast cancer, this indication allows it to be used for other HER2+ cancers such as lung cancer, colorectal cancer, and others. The major efficacy outcome measure in all three trials was confirmed objective response rate (ORR), and an additional efficacy outcome was duration of response (DOR). Read more about this new expanded indication *here* and *here*!

- **Using circulating tumor DNA to identify biomarkers**

Tissue taken from breast cancer tumors is often tested for biomarkers like ER, PR, and HER2. This information can help doctors guide specific treatments or other interventions. A new option that is becoming more prevalent is using circulating tumor DNA (ctDNA) to look for biomarkers. This type of DNA is released into the bloodstream when cancer cells die and break down. Because it contains the same biomarker components, it can be used to more easily identify their presence. Studying ctNDA requires a blood test whereas standard biopsies require a tissue sample. This approach can be used for many different things, including determining if a drug will work before prescribing it, predicting recurrence, identifying high-risk status, and looking for treatment resistance markers. Learn more about ctDNA on webpages *here* and *here* or in *this journal article*.

- **Early results from I-SPY2 trial**

Agendia® has recently shared initial information from the I-SPY2 clinical trial showing the predictive ability of their Signature ImPrintTN test in assessing immunotherapy response for patients with Triple Negative Breast Cancer (TNBC). A recent presentation given at the 14th European Breast Cancer Conference in Milan, Italy, shows that the test was able to accurately predict both response and non-response in early-stage TNBC patients. Moving forward, this test may be able to be used to inform whether or not to use immunotherapy as a treatment approach for TNBC patients when physicians are assessing likely treatment strategies. The I-SPY2 trial was designed to assess patient tumor biomarkers and identify different treatment classes most likely to be effective based on the tumor biomarker profile. For more information on the I-SPY2 trial, visit the study website *here*. For more information on the results of the Signature ImPrintTN test in the I-SPY2 trial, read a recent press release shared *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!

Trials of Interest on BreastCancerTrials.org

Observational Trials
Screening/Detection
Genetic Testing
Surveys/Interviews/Registries
Making Treatment Decisions
Imaging

Interventional Trials
Chemotherapy
Hormone Therapy
Radiation
Surgery
Targeted Therapy
Vaccines and Immunotherapy

Supportive Care Trials
Managing Side Effects
Complementary and Integrative Medicine
Physical Activities/Exercise
Support/Education

Prevention Trials
Preventing Breast Cancer
Preventing Recurrence

Family Reach

Family Reach is the **only national nonprofit** focused exclusively on helping people with **cancer** access **food, housing, transportation, and utilities during treatment.** Surviving cancer requires more than medicine — patients also need a roof over their heads and food on their tables.

For those enrolled in or looking to enroll in a clinical trial, the high costs associated with travel, lodging, and meals can be especially challenging. Our *Financial Resource Center* helps remove these barriers for clinical trial participants and beyond. The Financial Resource Center contains:

- Personalized, up-to-date resources for housing, food, transportation, and utilities
- Guidebooks and tip sheets for managing household bills, talking about finances during treatment, and saving money on everyday essentials
- Funds, when available, for housing, food, transportation, and utilities

Visit our *Financial Resource Center* and learn more about our *Clinical Trial Access Program* and partnerships.

TIGERLILY ANGEL ADVOCACY PROGRAM

ANGEL Advocate Approved