



~~CLINICAL~~

Transformation Requires Individual
Advocates Leading in Science
(TRIALS)

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

OCTOBER 2023



Tigerlily
Foundation
Beauty. Strength. Transformation.

Tigerlily Foundation (Tigerlily) strongly believes in ensuring that all communities, particularly BIPOC communities have equal access to clinical trial opportunities. We want you as patients, caregivers, and advocates - especially those of you from BIPOC communities - to have the understanding and resources to feel empowered to consider clinical trials as a treatment option for your medical care. Through this new newsletter from Tigerlily, we hope to provide you with information that you'll find helpful in getting a better understanding of how clinical trials work and how patients and trial participants are supported, especially through programming from Tigerlily and our partners.

Tigerlily Patient Support Programs

Tigerlily's RAISE Platform: Getting Patients the Support They Need

Tigerlily understands that it is often challenging for patients to ask for help especially when they are dealing with cancer. We also know that there are people in every patient's community that would like to provide support but don't know what patients need. In partnership with The WiTT Group, Tigerlily has launched a patient support platform called RAISE (Resources and Assistance for Support and Empowerment). The RAISE platform breaks down this barrier by enabling patients living with breast cancer to leverage their network of friends, family, and others to get the non-clinical support they need without the stigma and emotional labor involved with asking for help.

The platform is free to patients and donors! Patients can start getting the help they need by registering at <http://tigerlily.wittforever.com>, creating a "support registry" type list of needs (both financial and non-financial), and inviting their network and community to join their care circle in order to help them. In addition, Tigerlily can make a patient's support registry visible to other donors so patients can get additional support from those that want to help. Additional features and resources will be added to the RAISE platform in the near future as well!

Donors can support patients through the platform either by giving directly to patients themselves or by donating to the Tigerlily fund; through either method, all donated funds go directly to patients. Even the smallest donations can bear a meaningful change in someone's life! Please consider donating to patients on the RAISE platform through this link: <http://tigerlily.wittforever.com>.



Real Stories: Insights from Clinical Trial Participants



Camille Lewis, Tigerlily ANGEL and Patient Advocate

From Reluctant Participant to Clinical Trial Advocate: Camille Lewis had every reason not to join a clinical trial

Author: Anita Brazill

Four years ago, Camille Lewis received her breast cancer diagnosis by phone during work. The diagnosis – a malignant and aggressive tumor – was a shock and changed Camille’s life. After discussing treatment options, she was invited to consider participation in a clinical trial. “The complicated packet of information I was given, which described the trial, looked like a lot of work to go through. I was already overwhelmed and apprehensive,” she said. Camille was hesitant to consider trial participation as she didn’t have any personal connections that could share their previous experience with her. In addition, the trial obligations felt like a tall hill to climb. After reviewing the information and discussing trial participation with friends, her care team, and other resources, she decided to move forward and conquer her concerns. She began to understand that joining a clinical trial meant she would get not only the current and best “standard of care” treatment, but that she would be provided extra clinical attention, including more diagnostics and imaging. “I decided I had to take every opportunity to save my own life,” she said. Now, after joining a trial, Camille educates other women and encourages them to consider clinical trial participation.

To learn more about Camille’s story and how she shares her story through her activities as a Tigerlily Foundation ANGEL, follow the link below: <https://www.tigerlilyfoundation.org/programs/clinical-trials/>

Real Stories: Insights from Clinical Researchers

Jazmin Barnes, CRA

Jazmin Barnes is a Clinical Research Associate (CRA) that helps support clinical trials in North Carolina and its surrounding regions. As a CRA, she reviews documentation for clinical trials at many different trial sites, which are typically hospitals and academic universities. Jazmin is responsible for making sure that sites and site staff are fully trained and conducting the clinical trial according to the processes and procedures in the study protocol to ensure patient safety at every step. One of the highlights of clinical trial participation, she notes, is that patients receive especially good care from their physicians. Currently, she is supporting pediatric trials which she notes can be both heartbreaking and incredibly rewarding at the same time.



Jazmin Barnes, CRA

When discussing how clinical researchers can help encourage the communities they serve to raise their hand for participation, Jazmin notes the importance of having site staff and study teams engage directly in the community to build that foundational relationship of trust. She cautions against transactional relationships and suggests that sites should focus on continuing to establish and maintain long-term partnerships. “All it takes is one person to have a good experience, to say ‘I participated in a clinical trial and I loved it,’ and someone will ask and then more will ask and eventually people will start signing up,” she says. “Speaking with a leader in the community to identify the best way to foster that community relationship” is a key starting point, Jazmin shares. “Finding the right thing to work with the community to make the partnership fun and educational is just the beginning,” she says.

As a CRA, Jazmin shares that the most fulfilling aspect of her role in clinical research is the opportunity to be part of the process in which a new treatment comes to life, saving those that receive it in the future. “Hopefully one day, the drug we’re currently studying will be on the market for someone to get. There are so many diagnoses that we haven’t found a treatment for, so hopefully one of these treatments will be the one that save’s someone’s life,” she says. Jazmin also highlights that “it’s important to have everyone participate because we can’t expect to have a new drug come out that’s going to benefit us if they don’t have our information. Also, the representation – it’s always good to know that your population is included, that Sponsors are looking at everyone as a whole to see how new medicine affects us all, not just one population. We’re all going to need something sometime.”

When thinking about key information to share with potential clinical trial participants, Jazmin wants readers to know that “you’re not a guinea pig, there are thousands of people involved in monitoring trials to make sure they’re safe. And there are so many people in the clinical research community beyond your doctor or care team who are happy to answer any of your questions. If you do decide to participate, know that you’re saving someone else’s life in addition to saving your own. That drug could save your life, your spouse’s life, your grandparent’s life, your child’s life; that’s why it’s important for all of us to show up.”



How Clinical Trials Have Been Made Safer

Empty promises and false pretenses have been a consistent feature throughout early medicine, especially in clinical trials. The historical events that occurred during the Tuskegee Syphilis Study, the Stanford Prison Experiment, the Havasupai Diabetes Project, and many others have led directly to the development of many laws and oversight groups that focus specifically on the safety of human beings as clinical research participants. Over the last 50 years, these protective measures have continued to expand to ensure that clinical trial participation is voluntary, well-informed, respectful, and beneficial for the participant. Read about some of the key developments that have occurred below to learn more about how clinical trials have been made safer.

National Research Act (1974)

What is it?

This law created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, required *voluntary informed consent* by participants, and required *institutional review boards* to oversee studies that include human participants.

What does it do?

The National Research Act ensures that all clinical trials are reviewed by a group of medical and ethical experts to confirm that the study is appropriately safe and ethical. This act also requires medical experts to review all of the details of the study with each participant before the participant can voluntarily decide to join the study.

Belmont Report (1979)**What is it?**

This document established ethical principles to guide biomedical research, ensuring that the following are the underlying principles in every clinical trial: *respect* for persons, *beneficence* (prioritization of the participant's wellbeing), and *justice*.

What does it do?

The Belmont Report requires informed consent of the participant in a way that is fully truthful and built on integrity; this report dictates that participants must be treated with courtesy and respect. The Belmont Report also confirms that all studies maximize benefit and minimize risk to the participants and that all procedures are reasonable, non-exploitive, and just.

Federal Policy for the Protection of Human Subjects ("Common Rule", 1991)**What is it?**

This policy unified regulations across federal departments and agencies and also conferred additional protections for vulnerable populations, including pregnant women, fetal and neonatal persons, children, and prisoners.

What does it do?

Key features of this policy support the understanding of and compliance with human study participant protections by creating common principles around compliance, informed consent practices, and institutional review boards. This policy also increased protective guidelines for vulnerable populations.

National Bioethics Advisory Commission (1995), President's Council on Bioethics (2001), Presidential Commission for the Study of Bioethical Issues (2009)

What is it?

These three groups established expert-led councils to continually review regulations, policies, and procedures to ensure protection of volunteer clinical trial participants.

What does it do?

These advisory panels identify and promote socially and ethically responsible policies and practices in clinical research and other scientific fields. The continued growth and expansion of these groups shows a continual effort to ensure that clinical trials are safe and ethical for human participants.

FDA Guidance on Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry (2022) and Consolidated Appropriations Act (2022)

What is it?

This FDA guidance and government law require clinical trial sponsors (most often pharmaceutical or medical device companies) to submit diversity action plans before their drug or device can be approved for the general public to receive.

What does it do?

The diversity action plans that are required are documents that explain how sponsors will ensure the demographic makeup of the trial participants is appropriate for the demographics that bear the burden of disease; this means the new treatment will be studied in the people that need the treatment most. These documents specifically highlight the ways in which sponsors will include participants from historically excluded and underrepresented populations. The expected outcome is that medical experts will have a better understanding of how a new treatment works across all types of people, making it safer for all.

Acknowledging and understanding the previous failures and ethical errors in medicine allows us to identify ways to ensure that the historical atrocities like the ones noted above are not repeated. With the help of these expert-led groups, guidances, and laws, a framework has been established to ensure that clinical trials are ethical and just and that clinical trial participants are voluntary and well-informed. Safety and justice, especially for historically underrepresented and vulnerable populations, will continue to be a key underlying feature of all clinical trials.



Updates from Industry

AstraZeneca announced the US Food and Drug Administration (FDA) has granted Priority Review for their investigational combination therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer following recurrence or progression on or after an endocrine-based regimen. The new drug application is based on data from the CAPItello-291 Phase III trial presented at the 2022 San Antonio Breast Cancer Symposium and recently published online in *The New England Journal of Medicine*. For more information regarding this announcement, please see AstraZeneca's [press release](#).

Daiichi-Sankyo announced that the U.S. Food and Drug Administration (FDA) has approved ENHERTU® (fam-trastuzumab deruxtecan-nxki) for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy. This approval makes ENHERTU the first approved HER2-directed therapy for patients with low levels of HER2 expression. The approval by the FDA is based on the results of the historic DESTINY-Breast04 clinical trial presented at ASCO. Targeting this lower range of expression in the HER2 spectrum offers another approach to delay disease progression and extend survival in patients with metastatic breast cancer. For more information, please review Daiichi-Sankyo's press release [here](#).

Novartis recently shared data from their NATALEE trial, examining Kisqali in HR-positive, HER2-negative early breast cancer. Kisqali is the first and only CDK4/6 inhibitor to demonstrate a consistent, clinically meaningful benefit across a broad population of patients with HR+/HER2- early breast cancer, regardless of disease stage, menopausal or nodal status. Results were also consistent across all secondary endpoints, including distant disease-free survival and recurrence-free survival, with a trend for improved overall survival. The safety profile of Kisqali was favorable at 400 mg with low rates of symptomatic adverse events and limited treatment modifications when administered up to three years. Collectively, NATALEE results have the potential to more-than-double the number of patients who could benefit from treatment with a CDK4/6 inhibitor in the adjuvant setting. Novartis plans to submit these Phase III data to regulatory authorities in the US and Europe before end of year. For more information from Novartis, please click [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!

Ongoing trials through BCT’s Trial Finder:

- [Triple negative trials](#)
For more information, review BCT’s Metastatic Trial Talk article on TNBC: [Triple Negative Metastatic Breast Cancer: Beyond ER, PR, and HER2](#)
- [ER low trials](#)
For more information, review BCT’s Metastatic Trial Talk articles on ER low breast cancer: [What is ER Low Breast Cancer?, How is ER Low Used in Clinical Trials?](#)
- [CAR-T immunotherapy trials](#)
For more information, review BCT’s Metastatic Trial Talk article on CAR-T immunotherapy: [What is CAR-T Immunotherapy?](#)

Triage Cancer

Triage Cancer is a national, nonprofit organization that provides free education on the legal and practical issues that may impact individuals diagnosed with cancer and their caregivers, through events, materials, and resources. We also offer a Legal & Financial Navigation Program where people can get free, one-on-one assistance.

We dream of a world where everyone has access to information and resources needed to find their best path forward.

Life never feels more valuable and finite than after diagnosis. In an instant, plans change, and questions, needs, and challenges arise. Without the right answers and support, that diagnosis is daunting, frustrating, and overwhelming.

We believe that those diagnosed with cancer should spend their time and energy how they choose, secure in the knowledge that they have objective, accurate information, and necessary resources to make the right decisions.

