Transformation Requires Individual Advocates Leading in Science (TRIALS)

Creating a New Legacy - One Person at a Time

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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 Programming Feature

Tigerlily’s HEAL Policy CoE

Tigerlily Foundation has a 16-year history in the policy landscape. Our goal has always been to advocate for impact by driving policy making to create equity for patients. Patient advocacy leadership has always been key—here within Tigerlily and in guiding public policy. We water the seeds of inspiration and innovation, and working with advocates, advocacy organizations and stakeholders, have created policies and legislation that have changed the lives of millions of people. We are excited to culminate these years of momentum into our Health Equity Advocacy and Leadership (HEAL) Policy Center for Excellence (COE). Through the HEAL Policy COE, we seek to influence policy for these purposes through bi-directional learning, programs, and training to cultivate a center to exchange ideas, activate voices and create lasting change. Here are a few bills that Tigerlily’s HEAL Policy CoE has supported in order to effect change within the realm of clinical research and related healthcare policy:

- **Triple-Negative Breast Cancer (TNBC) Research & Education Act of 2023, H.R. 235**: This bill includes increased research funding to facilitate a better understanding of TNBC biology, risk factors, and potential therapeutic targets. This funding would enable researchers to develop innovative treatment strategies tailored specifically to TNBC and expedite the discovery of more effective therapies to save more lives.
- **Screening for Communities to Receive Early and Equitable Needed Services (SCREENS) for Cancer Act (H.R. 8185/S. 4440)**: This bill reauthorizes and updates the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), a critical safety-net program that provides breast and cervical cancer education, screening, and diagnostic services for underserved populations who are low-income, uninsured and underinsured who do not qualify for Medicaid. These screening and diagnostic services included here are often part of the eligibility requirements on clinical trials; having improved access to these tests can make clinical trial participation more easily achievable for this population.
• **Reducing Hereditary Cancer Act (H.R.4110 / S.3656):** Genetic testing for a hereditary predisposition to breast and other cancers is the standard-of-care and widely recognized as medically necessary for individuals with certain personal or family histories of the disease, yet if an individual who is eligible and recommended to have genetic testing has Medicare and has not already been diagnosed with cancer, they do not have access to this test. Knowledge of an inherited genetic mutation (i.e. BRCA1, BRCA2, ATM, CHK2, PTEN, etc.) can be life-saving for an individual and their family members; these tests are also very often required as part of the eligibility criteria for clinical trials. The Reducing Hereditary Cancer Act aims to modify the current Medicare statutes to close this gap in access by providing coverage for genetic testing for those with a known hereditary cancer mutation in their family and those with a personal or family history suspicious for hereditary cancer as well as provide access to increased cancer screening and risk-reducing surgeries as recommended for those with inherited genetic mutations. Like H.R. 8185/S. 4440, this bill improves access to the genetic tests that can bring clinical trial participation within reach for underserved populations.

**Real Stories: Insights from Clinical Trial Participants**

**Allanda Christenson**

**Allanda Christenson wants to share just how important the power of advocacy – especially self-advocacy – can be.**

Allanda starts off by sharing about her initial breast cancer experience. “I was diagnosed in August of 2021 with hormone-positive, HER2-negative breast cancer. I did all of the standard treatments but I was not informed about any clinical trials,” she says. “It was because of Tigerlily and other survivor groups that I even learned that clinical trials were an option for me…. I’m so grateful that I am a part of this community and that I got connected with these organizations to get this knowledge because I wouldn’t have otherwise.” While she had an excellent care team at Fred Hutchinson Cancer Center, she didn’t get any input when she had asked about clinical trial participation opportunities. Not one to wait for someone else to decide whether or not to share information, Allanda took charge. “I actually went searching for trials on my own,” she shares, “and I continue to.” Her search led her to the Eileen McGeever Breast Cancer Survivorship Program at University of Southern California’s Norris Comprehensive Cancer Center.

While we often think about clinical trials as a way to compare whether a potential new treatment is as good or better than other current treatments, there are a lot of other types of clinical trials available. The trial that Allanda is participating in is an observational study in which participants contribute to breast cancer research by sharing information about their experience as a cancer survivor and by providing occasional blood samples at a nearby laboratory location. The participant data that is gathered will help researchers understand the impact of stress, behavior, social factors, and diet on recurrence, and tracking and treating minimal residual disease. Participants can be located all over the U.S. and receive all of their materials by mail, which makes it an easy process. This study remains ongoing with a goal to enroll 1,000 women who have completed breast cancer treatment; for more information on participation, click [here](#).
Allanda highlights the importance of a strong and approachable study team, even in an observational trial like this one. “The study coordinators get you all set up with the paperwork…. The information was pretty clear about how you qualify, what you’re going to be doing, your rights, if they find something, everything you need to know. And if you have questions, there’s somebody that you can reach out to,” Allanda notes. As she shares, the study team is there to be a helpful resource throughout the whole study. Participants are encouraged to ask questions at any point, not just at the beginning when the study is being discussed for the first time. “The study coordinators, they’re there for you every step of the way for any questions or concerns. There’s a lot of educational material that you can talk about with the coordinator so you’ll understand your part.”

When asked about what kind of insights she would share with other advocates, Allanda encourages others to get engaged and be an active participant in their healthcare decisions and to consider clinical trial participation. “We cannot make progress in the breast cancer realm or any other disease without research, without science, without people willing to say, ‘you know what? I’m in this fight.’” As a strong proponent for making sure that future generations have the benefits of more precise treatment options, she further remarks, “I just want to encourage everyone out there to get involved for the sake of everyone coming after us…. Let’s move the needle, and we can’t do that without participating in science and research.”

Engagement and education to drive understanding of all of one’s healthcare options shouldn’t just be propelled on the patient side though; it should come from all areas of the healthcare team and healthcare system. Allanda highlights the importance of an established support network within the care team: “A patient should be assigned a patient navigator or a social worker, someone that the patient can build a relationship with. Someone that can help guide patients and their families from A to Z.” Putting the ‘care’ in the healthcare team is important, she observes. “I did most of my journey myself. My family works, my mom still works. I don’t have children or a spouse,” shares Allanda. Going through major health conditions and treatment decisions is always easier with a strong support network that can help act as a sounding board while thinking through the options and to provide any information that might be needed to fill in educational gaps.

“Allanda highlights the statistics around breast cancer as an impetus for change. “Black women are more likely to have aggressive and advanced stage breast cancer, and black women have the highest mortality rate of any U.S. racial or ethnic group. We have to improve these numbers, and the only way we can do that is to increase clinical trial participation and advocate for research funding.” She encourages everyone to put aside their perceptions and fears and to get involved in advocacy. “I was thinking well, I don’t have any special skills or training and my public speaking isn’t perfect. You know, those seeds of doubt that can be there? But just come as you are. Share your story. You can be your own advocate.”
Real Stories: Insights from Clinical Researchers

LaTisha Weaver

LaTisha Weaver is a Clinical Budget and Contract Negotiator with a game plan.

Looking forward in life, she’s started her own consulting business to support contract negotiation needs for clinical research with the goal to complete an ongoing nursing degree and become a clinical site owner in the near future. In her current role, she works with clinical trial sites such as hospitals and universities as a clinical trial is getting started to make sure that all parties agree on the details in the clinical trial agreements or “CTAs” that guide the trial site in their operation of the trial procedures. She also makes sure that all parties have the current protocol, the correct budget templates, and other key trial documents such as a letter of intent or a letter of indemnity.

Like many people in their current positions, LaTisha moved in to her analyst role after life threw her a 180. As a parent, she had been laid off from her previous role and was able to get a new position with a central laboratory organization that provides lab services for clinical trials. “I was really good with Excel and numbers so I dove in,” she says. “I was able to get an understanding of what a clinical trial is after being there for a little while.” Over time, LaTisha had the opportunity to work with more and more clinical trial documents and to continue expanding her understanding of all of the processes that happen behind-the-scenes to make a clinical trial work. “The work orders for budgeting, the CTA for the scope of work… it was very intriguing,” shares LaTisha. After gaining oncology experience at Wilmot Cancer Center and Tufts Medical Center, she decided to take a big leap into building herself a foundation for a new future role as a site owner by becoming a licensed practical nurse (LPN).

While juggling her new responsibilities, she’s found strength and support in clinical research advocacy and through her wonderful colleagues at Black Women In Clinical Research. “You suffer through imposter syndrome and you have to learn to stop fighting with yourself and actually trust yourself and your instinct,” says LaTisha. “I don’t need the nursing degree [to become a site owner], but I fight daily to be able to sit at tables with highly distinguished professionals, people having their PhDs and physicians. Whether it’s traditional or not traditional, I sit at the table with them.”

When asked about the drive to switch roles, LaTisha talks about wanting to make more of an impact and her passion for community engagement and education. “I want to first educate you on what’s going on. I want you to further understand the [condition] that you have and that you have options, options that other people haven’t already told you about… how a clinical trial may work for you,” she shares. She hones in on the importance of providing education to people in the communities – education about health conditions and about treatment options, not just about current trial opportunities. Empowering the community to feel confident in their understanding of their health condition and their options is important. Empowering someone to make informed decisions about their healthcare is what LaTisha aims for, and hopefully some of those decisions involve clinical trials. “People might have a feeling of not being heard,” she says, “I want to hear everything…. I want them to feel comfortable. I want them to know that we are here and that every voice will be heard.” Highlighting the need to get information into the community, “at the end of the day, it’s all about changing lives,” she says, “there are patients that can benefit from these studies.”
LaTisha brings her clinical trial knowledge and healthcare understanding with her and shares it wherever she goes. As an active advocate engaged in her church community, she talks about supporting her fellow parishioners through their healthcare needs: “being a member in the church who has gone to doctor visits with people or being that church sister that they call when they want to talk because a physician didn’t have proper bedside manner or because they’re not understanding what their drug or treatment is,” she shares. Advocating for clinical research is a balance of taking in the concerns of the community, empowering others through education, and amplifying this process wherever possible. Transitioning into a site owner role will be an effective way to continue bringing this brand of active, engaged support into the community on an even greater level.

I’m interested in participating... Now what?

You’ve been weighing your options and doing some research and you’re ready to consider joining a clinical trial. Now what happens? How do you know what questions to ask your physician or the study team at your local hospital or clinic? Where do you go to look for trials that you want to present to your doctor? There are so many questions that you know you want to ask to make sure you fully understand the pros and cons of a clinical trial, but maybe you’re just not sure where to start! Here are some great questions to ask your care providers and some tips that might help you feel more confident about asking these questions.

Questions to ask your care team

- Are you involved in any studies or do you know of any that are happening nearby?
- Is there a study that is right for me?
- What makes me a good candidate for this study?
- What is the purpose of the study?
- Who can join the study?
- Are there any tests that I need to do before I can join the study?
- Where will the study be located?
- How will I know that the treatment is working?
- What happens if the treatment does not work?
- Who will be in charge of my care?
- What is the plan to make sure there is good communication between my regular doctor and the study team?
- Who do I contact if I have questions about the study or my care? How do I contact them?
- Has the drug, device, or treatment been tested before?
- What kinds of tests and treatments are part of the study?
- What are the possible risks, side effects, and benefits that could happen if I joined the study?
- How do the possible risks, side effects, and benefits that could happen during the study compare with my current treatment?
- Are there any safety concerns so far in this trial?
- How might this clinical trial affect my daily life?
- Do I need to change my diet and exercise while I am participating in this trial?
- Will I need to find someone to care for my children, elders, pets, or self while I am participating in this study? Is this something that the hospital or clinic offers on-site?
- How long will the clinical trial last?
- What is the expected time commitment for me?
- What are the costs that I need to think about if I participate in this study?
- Who will pay for my treatment?
- Will I be reimbursed for other expenses outside of treatment and tests?
• What kind of financial or other support resources are available for me from the site? Are there support resources available for me from the Sponsor of this study? If yes, what are they and how do I access them?
• Is there a way for me to talk to other patients that are participating in this trial? If yes, how do I reach out to them?
• If I decide to stop participating in the study, how do I do that and what happens to my treatment plan?
• What are the reasons that I might be dismissed from the study after I join it and how will I be notified? What will happen to my treatment plan?
• Is there additional care included after the study ends?
• Will I have access to the clinical trial results? If yes, how will I receive them? If no, why not?

Where can I go to look for trials online?

There are a lot of different trial finding tools available online! A lot of them may be specific to trials that are located at one hospital or at one hospital system, or they might be specific to a health condition or a particular pharmaceutical company. Here, we’ll share with you some of our favorite tools and why we like to use them.

**BreastCancerTrials.org**
BreastCancerTrials.org (BCT) recently released a new trial finding tool on their website that allows individuals to search for trials focused on stage 0-III breast cancer. This trial searching tool can be found right on their homepage alongside their longstanding metastatic trial search application which focuses on stage IV breast cancer trials. Both of these tools are easy to use and allow patients or physicians to search and filter results not just by location, but also by the type of study, cancer biomarkers present, diagnostic timelines, and other key information. Patients can register for a free profile and send their trial matching results to their physician.

**Ancora.ai**
Ancora.ai is a unique trial matching tool that can search for trials beyond just breast cancer and uses the inclusion and exclusion criteria from trials to help match effectively where possible. With this tool you answer key questions about your condition – for breast cancer this might include staging, grading, biomarkers, and prior treatments – as well as about other concurrent health conditions; these health conditions may be either inclusionary or exclusionary criteria and are important to consider. Patients can register for a free profile and review their previously saved potential trials in a patient-centric dashboard.

**Centerwatch**
Like many other trial finding tools, Centerwatch uses information that is publicly available about current and future trials to populate a database that covers over 40,000 clinical trials across a wide variety of different medical conditions from Autoimmune Deficiency Syndrome (AIDS) to yeast infections (at the time of print, they didn’t have any for conditions that start with ‘Z’!). This tool allows for searching by any term, by global location, and by the phase of the trial. Users can also search by Sponsor, which may be a specific hospital, an academic institution, or a pharmaceutical company.

**ClinicalTrials.gov**
This site is the ‘classic’ trial searching tool that most patients are directed to use when considering clinical trials. There are many ways to search or narrow down results using this tool, such as trial phase, trial type, location, specific treatment, trial site or hospital location, and Sponsor name. However, this tool can be overwhelming and unintuitive to use since it is a very large listing and can often return large numbers of trials.
Tips at a glance

**Just Ask.** We can’t say it enough: Ask questions to both your doctor as well as the study team in charge of the clinical trial. Be empowered to take charge of your health condition, your treatment options, and your decision to volunteer for trial participation.

**Be Proactive.** Know and understand your health conditions and diagnoses. The more information that you know, the more empowered you will be to ask good questions and find a clinical trial that is right for you.

**Do your Research.** Use all of the resources you have available when looking up information on clinical trials near you: use the internet, advocacy groups, telehealth visits, or in-person doctor visits to learn more.

**Be Unstoppable.** Don’t let fear stop you! There are many practices and policies that have been enacted to ensure the safety and well-being of trial participants. Don’t let financial or logistical barriers stop you either – there are lots of supportive resources and advocacy groups like the ones noted below that can provide you a helping hand along the way.
Get Involved!

Sharing New Biomarker Testing Guidelines: Using Your Advocacy Voice

The American Society of Clinical Oncology (ASCO) and the Society of Surgical Oncology (SSO) published updated guidelines earlier this year for germline testing which broaden the population of breast cancer patients recommended to receive testing. Biomarker testing is incredibly important for physicians to determine treatment options and in determining if a person is potentially eligible for specific clinical trials. Below is a brief summary of the testing recommendations. Make sure to ask your physician if any of these recommendations apply to you and let your fellow community members know about these options. When it comes to biomarker testing, knowledge is power!

The testing recommendations include:

• BRCA1/2 mutation testing should be offered to all newly diagnosed patients with breast cancer who are at or under the age of 65 years and to select patients over the age of 65 years based on personal history, family history, ancestry, or eligibility for poly(ADP-ribose) polymerase (PARP) inhibitor therapy.

• All patients with recurrent breast cancer who are candidates for PARP inhibitor therapy should be offered BRCA1/2 testing regardless of family history.

• For patients with prior history of breast cancer and without active disease, testing should be offered to patients diagnosed over the age of 65 years and selectively in patients diagnosed after the age of 65 years, if it will inform personal and family history.

• Testing for high-penetrance cancer susceptibility genes beyond BRCA1/2 should be offered to those with supportive family histories; testing for moderate-penetrance genes may be offered if necessary to inform personal and family cancer risk.

• Patients should be provided enough pretest information for informed consent; those with pathogenic variants should receive individualized post-test counseling.

Updates From Industry

Breakthrough Therapy Designation for Genentech’s Inavolisib

Recently, the FDA granted breakthrough therapy designation to Genentech’s inavolisib for advanced hormone receptor-positive, HER2-negative breast cancer with PIK3CA mutation. This designation means that the development and review process for the drug can be quicker and allows the Sponsor access to more frequent and intensive FDA guidance in the submission process. Breakthrough therapy designations are generally limited to treatments that address unmet need for serious or life-threatening conditions. Receiving this designation means that inavolisib may be able to reach approval faster. This decision by the FDA was based on results from Genentech’s Phase III INAVO120 trial, which showed that inavolisib in combination with palbociclib and fulvestrant reduced risk of disease worsening or death by 57% compared to palbociclib and fulvestrant alone. This trial evaluated 325 patients to study the efficacy and safety of inavolisib in combination with palbociclib and fulvestrant versus placebo plus palbociclib and fulvestrant in people with PIK3CA-mutated, hormone receptor (HR)-positive, HER2-negative, locally advanced or metastatic breast cancer whose disease progressed during treatment or within 12 months of completing adjuvant endocrine therapy and who have not received prior systemic therapy for metastatic disease. Approximately 40% of people with HR-positive breast cancer have a PIK3CA mutation and often face poorer prognosis and experience resistance to endocrine treatments, thus there is a serious need for treatments specific to this mutation. Like with many other mutations, early testing for PIK3CA mutations can help identify appropriate treatments early on. For more information on this treatment and it’s designation, click here.
Biologics License Application Granted for Daiichi Sankyo and AstraZeneca’s Dato-DXd

The FDA has also recently accepted Daiichi Sankyo and AstraZeneca’s Biologics License Application (BLA) for datopotamab deruxtecan (Dato-DXd). Granting a BLA request allows an entity to manufacture a biologic product (like a new drug treatment) and deliver it across the U.S. This is an important preliminary step in the FDA’s approval process for new treatments. The FDA has noted that they expect to provide a regulatory decision (i.e., whether or not this new treatment will be officially ‘approved’) early in 2025. These decisions were based on positive data from the Phase III TROPION-Breast01 trial in which Dato-DXd showed improvement in progression-free survival rates for patients that received this treatment compared to those that received other treatments. This study focused on patients with unresectable or metastatic HR-positive, HER2-negative breast cancer previously treated with endocrine-based therapy and at least one systemic therapy. Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, notes “despite marked progress in the treatment of HR-positive, HER2-negative breast cancer, most patients with advanced disease develop endocrine resistance and face the prospect of one or several lines of chemotherapy. If approved, datopotamab deruxtecan has the potential to provide these patients an efficacious and better tolerated alternative to conventional chemotherapy.” For more information on this treatment and its BLA request, click here.

Early Results for AstraZeneca and Daiichi Sankyo’s DESTINY-Breast06 Trial with ENHERTU

AstraZeneca and Daiichi Sankyo have also recently shared results from their DESTINY-Breast06 trial in patients with HR-positive, HER2-low metastatic breast cancer. In this Phase III trial, ENHERTU® (fam-trastuzumab deruxtecan-nxki) shows improvement in progression-free survival rates in comparison to standard-of-care chemotherapy treatments such as capecitabine, paclitaxel, and Nab-paclitaxel in patients with HR-positive, HER2-low (IHC 1+ or 2+/ISH-) metastatic breast cancer following one or more lines of endocrine therapy. Up to 65% of HR-positive, HER2-negative breast cancers are HER2-low and an additional 25% may be HER2-ultralow. Currently endocrine therapies are widely used but result in limited efficacy over the long term. ENHERTU is a HER2-directed antibody and topoisomerase inhibitor, which means it prevents specific enzymes involved in cell growth (topoisomerases) from signaling to keep cells growing. This treatment is currently already FDA approved for individuals with unresectable or metastatic HER2-positive (IHC 3+ or ISH positive) breast cancer who have received a prior anti-HER2-based regimen, 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 6 months of completing adjuvant chemotherapy, and unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations and who have received a prior systemic therapy. For more information on this trial and ENHERTU, 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!

Related topics from Metastatic Trial Talk, our monthly newsletter for all topics related to metastatic breast cancer research and clinical trials:

- Understanding Informed Consent
- Are You Hesitant to Participate in Trials Because of Data Privacy?
- I Found a Trial I’m Interested In. What’s Next?
- Clinical Trial Participation: The Patient’s Journey
- How Does a Clinical Trial Benefit Me?

Clinical Trial Matching Tools

- Breast Cancer Trial Search: Clinical trial matching tool for people with DCIS and stage I-III breast cancer, post-treatment survivors, and people who are healthy/high-risk
- Metastatic Trial Search: Clinical trial matching tool for people with metastatic (stage IV) breast cancer