

Program Summary

CARE - Creating Access Reimbursing Expenses - Daily direct patient advocacy, clinical trial navigation and out-of-pocket clinical trial expense reimbursement program.

IMPACT - IMproving Patient Access to Cancer Clinical Trials – Institutional Comprehensive Cancer Center program to increase clinical trial enrollment, retention, and minority participation in cancer clinical trials and create a sustainable platform for equitable access.

Cancer Wellness HUBs – (pilot) a place based and culturally appropriate safe space for community residents to talk about and address their health concerns across the continuum of cancer care. It is our goal to make the HUB a replicable model to improve cancer and overall health outcomes.

PATH – Patient Access Transforming Health – a transactional service designed to improve enrollment and diversity in sponsor specific cancer clinical trials through patient reimbursement of out-of-pocket costs, community outreach, and engagement.

About Lazarex Cancer Foundation and Lazarex CARE

Sometimes, in a patient's battle with cancer, they are exposed to a gap in cancer care when they progress to advanced stage and all available treatment options fail them. Most often, despite their desire to continue fighting their disease, hospice is the recommended course of action. For these patients, medical breakthroughs offered through clinical trial participation are an alternative to hospice; however, there are many barriers to participation that seem insurmountable for patients who are emotionally, physically, and financially spent. In 2006 Lazarex Cancer Foundation was founded and the CARE program was created to bridge this gap and remove the barriers. Lazarex is a publicly funded 501(c)(3) charity and has served almost 7,000 patients in cancer clinical trials. We strive to improve cancer health outcomes, FDA cancer clinical trial diversity and enrollment, and patient access to care by providing assistance with clinical trial navigation, reimbursing trial related travel costs, and partnering with at-risk communities to mobilize resources.

Clinical trials are the capstone of the drug development process. Patient participation is crucial to the successful completion of a trial. Patient recruitment to clinical trials has historically plagued the research industry; 11% of trials never enroll a single patient, 37% are grossly under enrolled; delaying the approval of drugs, increasing development costs, and most egregiously preventing patients from taking advantage of medical breakthroughs in technology. Only 6% of eligible patients participate in trials and only 5% are racial or ethnic minorities. This negatively affects statistically valid assessment of the safety, efficacy, and value of new therapeutic agents for multiple segments of our population. Through our CARE Program we improve the diversity of clinical trial participation.

IMPACT – The Solution

Lazarex is the only non-profit offering a complete solution to address and remove these barriers. While our Lazarex CARE program is noble – it is not sustainable. In 2013, Lazarex devised a plan to sustainably



fix this intractable problem and actually fill this gap in cancer care. In 2013, Lazarex partnered with Massachusetts General Hospital and formed the [Lazarex MGH Cancer Care Equity Program](#). We achieved a 29% increase in overall participation and doubled minority participation in cancer clinical trials. Parlaying this success, Lazarex has expanded and rebranded the initiative into **IMPACT**, a 3-year pilot study at Comprehensive / Cancer Centers. The goal of IMPACT is to permanently fix this problem and generate a sustainable proof of concept action

plan that will be universally adopted to transform the status quo of clinical trial recruitment, enrollment, retention, minority participation, completion, and translational science - providing equitable and timely access to cancer discovery for ALL patients.

IMPACT was launched in California at UCSF and USC Norris in January of 2018. Upon conclusion in December of 2020, IMPACT achieved an astounding 63% minority participation with 52% of its participants coming from households earning \$25,000 or less. Clearly, IMPACT is reaching the most vulnerable as these are patients who could never consider participating in clinical trials without travel reimbursement. IMPACT is currently underway at Penn Med Abramson Cancer Center in Philadelphia, PA, MD Anderson in Houston, TX, and at several USOR Community locations.

Cancer Wellness HUBs

Our learnings from both the CARE and IMPACT programs have revealed the need to create a fully immersive community cancer program that is replicable, sustainable, and affordable – yielding the **Lazarex Cancer Wellness HUB** concept - what we consider to be the “heartbeat” of our work in this arena. The Cancer Wellness HUBs are a safe space for community members to talk about their health concerns across the continuum of cancer care. Residents will have the opportunity to develop personal relationships with HUB Cancer Care Companions to overcome historical and cultural barriers for better health outcomes and help them feel welcome in an unfamiliar environment.

The Lazarex Cancer Wellness HUB is a place based, community led, and culturally appropriate model of community engagement. We combine exemplary public health best practices, localized mixed method assessment and community investment. This creates a platform where individuals and communities are given a voice, access to resources, and support to better navigate their health and health outcomes throughout their cancer journey. We incorporate input from residents, community organizations, health practitioners, policy makers, and other stakeholders to inform the development and implementation of HUB strategies. The HUB is changing both the way we think about cancer prevention and the actions we take to reduce cancer burden and disparities in underserved communities.

The HUB is not just an information source – it functions as an actual hub within the community, bringing together the many resources and services required to manage the cancer journey and provide the greatest opportunity for a successful result. The original Philadelphia HUB is a bricks and mortar facility providing a local and culturally appropriate resource to answer questions, navigate historical fears, misperceptions, and cultural barriers, understand the implications of family cancer history and the importance of screenings (hereditary predisposition to cancer), explore options for prevention through lifestyle choices, and support patients from treatment to clinical trials.

The Philadelphia Cancer Wellness HUB will continue to be the incubator of new ideas and strategies to keep the program relevant and it provides a great opportunity to explore various aspects of the concept to see what works best. However, this approach is cost prohibitive and limits our opportunities for expansion. Therefore, we are developing a more cost effective “pop-up” version of the Cancer Wellness HUB in the greater Los Angeles and San Francisco Bay areas through a continued affiliation with Drexel University, USC Norris Comprehensive Cancer Center, UCSF Helen Diller Family Comprehensive Cancer Center, and their associated community organizations. Rather than having a physical facility that requires significant financial resources to operate and maintain, the pop-up concept allows us to utilize existing facilities (churches, schools, YMCA, community centers, health clinics, etc.) within the community and still have continuous, place-based, and culturally appropriate community engagement on a consistent basis. We will offer the same programming and engage across the continuum of cancer care to improve cancer health outcomes and address health disparities.

PATH – Patient Access Transforming Health

PATH is transactional service designed to improve enrollment and diversity in sponsor specific cancer clinical trials through patient reimbursement of out-of-pocket costs, community outreach, and engagement. One of

the primary barriers to clinical trial participation is financial toxicity, making the out-of-pocket travel expense associated with participating in a trial unbearable for most patients. Historically, the perception of inducement has hindered industry participation to fully cover these costs. Our recent success in the policy and legislative arena has established a permissible environment for biopharma support of these expenses.

A key component of PATH is relieving the institution of any involvement in the patient reimbursement process. Institutions are focused on administering patient care and by their own admission, they just simply do not have the bandwidth to sufficiently engage in reimbursement activity. The net result is that most often, funding provided to a site by a sponsor for patient out-of-pocket expense is not making its way to the patient in a timely manner – if at all. Clinical Research Coordinators and Social Workers who are already overburdened, shy away from performing reimbursement tasks and are thrilled to designate these responsibilities to Lazarex, allowing them to do what they do best – take care of patients. The basic premise of PATH is to offer patient expense reimbursement either prior to or at the time of clinical trial consent – addressing financial concerns at the beginning of the decision process allowing the patient to decide what is best for them medically as opposed to what they can afford to do.

If a patient is interested in the Lazarex Financial Reimbursement Program (FRP) the site refers them to Lazarex. The Lazarex Patient In-take team assumes the process from there; determines patients eligibility through the application process, informs the patient of acceptance into the program within 3 days of receiving a completed application, generates a patient agreement outlining specific approved reimbursements, provides a travel log, and begins the reimbursement process. Patients are reimbursed for approved and documented travel expense every month (more often if needed) via EBT or check.

Policy and Legislation Summary

Historically, the biopharma industry has been handcuffed by the perceptions of inducement and coercion in relation to their ability to reimburse patient expense per FDA Guidelines. By working with policymakers to remove the stigma of inducement, create a permissible environment, and encourage industry support, we increase trial participation and improve diversity. The collective result is getting more drugs to market, reducing trial failure rates, and creating timely and equitable access to the novel therapeutics in clinical trials that patients need to stay engaged in their fight with cancer. Given our policy and legislative success at the FDA, Federal and State levels, we have removed many of the barriers for stakeholder participation. We believe that this new permissive environment, coupled with an attractive ROI will create momentum and generate enough interest for key stakeholders to adopt patient expense reimbursement as a matter of “best practice” to permanently and sustainably fix the current access and equity issues as a matter of course.

Federal:

[FDA Guidance Language](#)

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(Excerpt)

Paying research subjects in exchange for their participation is a common and, in general, acceptable practice. Payment to research subjects for participation in studies is not considered a benefit that would be part of the weighing of benefits or risks; it is a recruitment incentive...

In contrast to payment for participation, FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence....

State:

California Bill #: AB1823	passed unanimously	Effective	January 1, 2017
Pennsylvania Bill #: HB126	passed unanimously	Effective	October 2018
Texas Bill #: HB 3147	passed	Effective	September 1, 2019
Illinois #: HB 1711	passed unanimously	Effective	January 2, 2020
Wisconsin #: SB 489	passed unanimously	Effective	February 2020
Massachusetts #S2984	passed	Effective	January 1, 2021
Florida	securing sponsor	Vote	2021 / 2022
New York	have sponsor	Vote	2022
Ohio	have sponsor	Vote	2021 / 2022
Maryland	securing sponsor	Vote	2022
Montana	have sponsor	Vote	2023
New Mexico	have sponsor		