Program Summary

CARE – Creating **A**ccess **R**eimbursing **E**xpenses **-** Daily direct patient advocacy, clinical trial navigation and out-of-pocket clinical trial expense reimbursement program.

IMPACT - **IM**proving **P**atient **A**ccess to **C**ancer **C**linical **T**rials – 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.

Community IMPACT - (pilot) Community outreach and engagement public health initiative in the poorest neighborhoods of Philadelphia aimed at building a replicable program to improve cancer and overall health outcomes.

PATH – Patient **A**ccess **T**ransforming **H**ealth – 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 created to bridge this gap and remove the barriers. Lazarex is a publicly funded 501(c)(3) charity and has served over 5,000 patients. We are focused on improving the outcome of cancer care for cancer patients and the medically underserved, by identifying FDA approved clinical trial options, providing assistance with ancillary costs for patient clinical trial participation and a travel companion, and facilitating community outreach and engagement.

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.

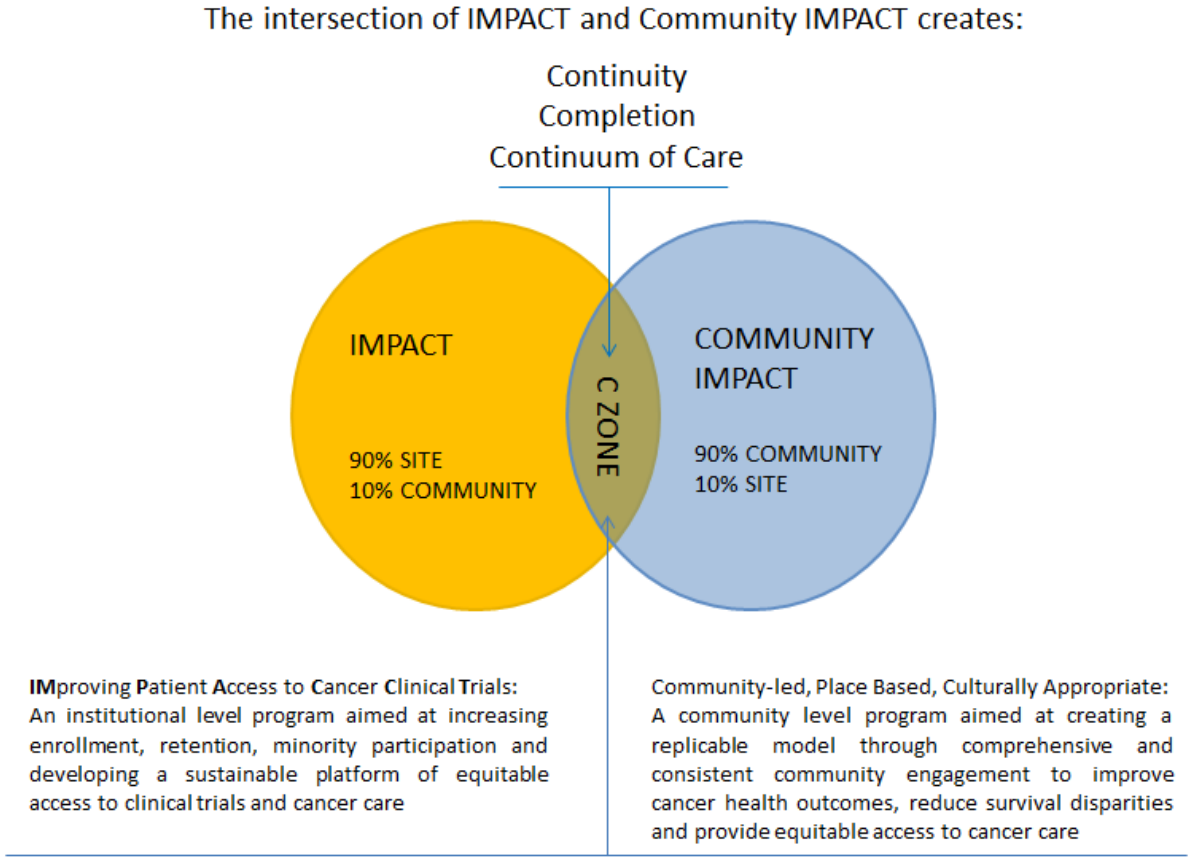
IMPACT – The Solution - (IMproving **P**atient **A**ccess to **C**ancer **C**linical **T**rials)

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. 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. IMPACT was launched in California at UCSF and USC Norris in January of 2018. It is currently being launched at Penn Med Abramson Cancer Center in Philadelphia, PA and MD Anderson Cancer Center in Houston, TX.

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.

Community IMPACT (pilot)

Working with Drexel University School of Public Health in Philadelphia, Lazarex Cancer Foundation is committed to building healthy communities through a novel pilot program, Community IMPACT. The overall goal of Community IMPACT is to improve the understanding and awareness of the burden of cancer on patients and their families, and the opportunities for the prevention and treatment of cancer for residents in minority and disadvantaged communities in Philadelphia, as well as health practitioners and policy makers, in order to inform the development and implementation of strategies to prevent cancer, treat it more effectively and create equitable access to cancer resources. Community IMPACT combines exemplary public health qualitative and quantitative assessment and research methods with a grassroots community engagement effort in communities that are often not invited to lead their own health futures. The impact of the initiative will be to transform both the way we think about cancer prevention and the actions we implement to reduce cancer burden and disparities.



In collaboration with our institutional **IMPACT** program (**IM**proving **P**atient **A**ccess to **C**ancer **C**linical **T**rials), **Community IMPACT** is being led by Drexel University, which brings its extraordinary resources in research and community engagement to this public health initiative. We have built the project around a place based, community-led model of engagement, developing an approach and team of community advocates at the Drexel Center for Neighborhood Partnerships in West Philadelphia, and then will extend this model out to other neighborhoods, medical, and academic centers in Philadelphia through peer-to-peer community leadership and direction. At the core of this collaboration is the **Cancer Wellness HUB**, a "safe space" for community members to talk about their health concerns in relation to cancer and explore their options from prevention through treatment and clinical trials. They will have the opportunity to develop personal relationships with Cancer Care Companions to overcome historical and cultural barriers for better health outcomes and help them feel welcome in an unfamiliar environment.

Site Selection Criteria
Diverse population
Disparities in health outcomes
Prevalence of cancer
Socioeconomic disproportion
Presence of major medical and academic center/s
Clinical trial portfolio / expansion capacity
Community resources

Program Infrastructure:
Site Survey – baseline for data analysis
IMPACT Study Protocol
REDCap data repository
Consent Language and Collateral
In-Service Training
IRB Approval Required

PATH – Patient **A**ccess **T**ransforming **H**ealth

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, cringe at the thought of 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 and manages all patient communication support regarding the reimbursement process. The In-take team provides monthly status reports back to the site for enrollment continuity and quarterly reports to the sponsor on patient

enrollment data demographics, travel expenses by category, and total reimbursement dollars expended. The typical results are increased patient participation and diversity, and improved sense of patient well-being. The vehicle we use to efficiently engage in reimbursement activity with a sponsor is a designated declining balance account. This allows for programmatic work to occur and coordinates financial outflow with actual expenses and services provided by Lazarex.

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 Published January 29, 2018

(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 Bill #: HD617	waiting for vote	Vote	2020
Florida	have sponsor	Vote	2021
New York	securing sponsor		2021
Ohio	have sponsor		2021
Maryland	securing sponsor		2021