



## **Program Summary**

**Lazarex CARE** - 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.

### **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 Patient Access to Cancer Clinical Trials)**

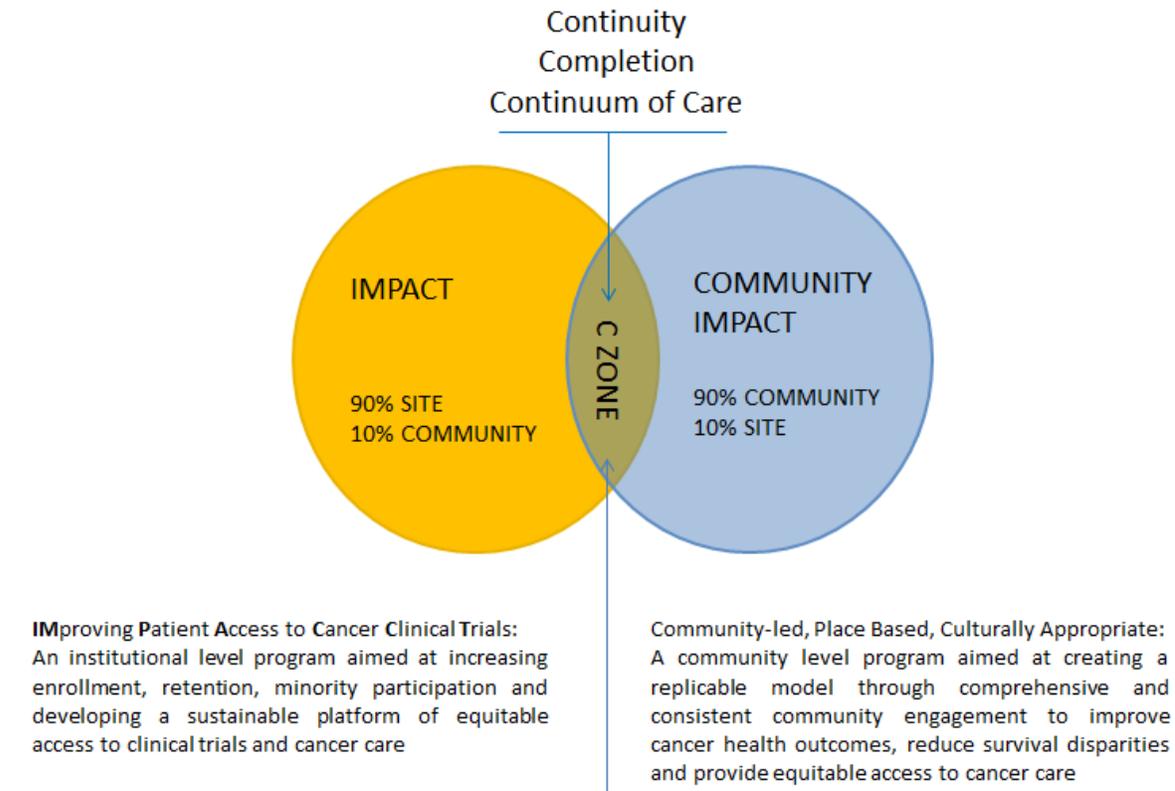
Lazarex is the only non-profit offering a complete solution to address and remove these barriers. While our Lazarex CARE program is noble – it is not sustainable. In 2013, Lazarex devised a plan to sustainably fix this intractable problem and actually fill this gap in cancer care. Lazarex partnered with 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.

The intersection of IMPACT and Community IMPACT creates:



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.

**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 – to establish baseline for data analysis  
IMPACT Study Protocol – Non-therapeutic interventional study  
Data Repository – REDCap database (Research Electronic Data Capture)  
Consent Language and Collateral – Provided in languages reflective of Catchment area  
In-Service Training – complete site and all indications for full site participation  
Financial Reimbursement Application- LCF  
Financial Reimbursement Process - LCF  
IRB Approval Required

**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 #: <a href="#">AB1823</a>  | passed unanimously | Effective | January 1, 2017   |
| Pennsylvania Bill #: <a href="#">HB126</a> | passed unanimously | Effective | October, 2018     |
| Texas Bill #: <a href="#">HB 3147</a>      | passed             | Effective | September 1, 2019 |
| Illinois #: <a href="#">HB 1711</a>        | passed unanimously | Effective | January 2, 2020   |
| Wisconsin #: <a href="#">SB 489</a>        | passed unanimously | Effective | February 2020     |
| Massachusetts Bill #: HD617                | waiting for vote   | Vote      | 2020              |
| Florida                                    | have sponsor       | Vote      | 2021              |
| New York                                   | securing sponsor   |           | 2020              |
| Ohio                                       | securing sponsor   |           | 2020              |
| Maryland                                   | securing sponsor   |           | 2020              |