The Problem:

Despite a cancer patient’s desire to fight their disease, all too often, available treatments don’t work. For these patients, medical breakthroughs offered in clinical trials can be an alternative to hospice. However, there are too many obstacles preventing the majority of patients from accessing those breakthroughs… especially when they are emotionally, physically and financially exhausted.

More often than not, cancer clinical trials require patients to travel frequently to receive treatment, lab testing and other trial protocol. On average, patients must travel 544 miles RT to the trial site and the financial burden is on the patient to get there. Travel costs add up quickly for frequent airfare, hotel stays, parking, gas and/or tolls, and many patients can’t afford the compounding expenses. As a result, they are forced to choose between daily living expenses and pursuing hope in a clinical trial.

Why are clinical trials so important?

Clinical trials are essential to the development of new treatments and patient participation is crucial to the successful completion of a trial. However, dismally low participation has historically plagued the research industry; 11% of trials never enroll a single patient and 37% are grossly under enrolled. This not only delays the approval of new drugs; it increases development costs and, most egregiously, prevents patients from taking advantage of medical breakthroughs. Only 6% of eligible patients participate in clinical trials and only 5% of those patients are racial or ethnic minorities. This prevents researchers from proving the safety, efficacy and value of new treatments for ALL cancer patients.

What is Lazarex Cancer Foundation and Lazarex CARE?

In 2006 Lazarex Cancer Foundation was created to remove key barriers keeping 94% of cancer patients from participating in clinical trials. A publicly funded 501(c)(3), Lazarex has served more than 4,000 patients over the past 13 years. Lazarex is focused on improving the outcome of cancer care for cancer patients and the medically underserved by finding FDA approved clinical trial options for which they may be eligible and providing financial help with travel costs for them and a companion so they can get to the clinical trial. Lazarex also facilitates community outreach and engagement.
What is IMPACT?

IMPACT (IMproving Patient Access to Cancer Clinical Trials) is an unprecedented reimbursement, outreach, and education program helping cancer patients learn about and access advanced treatment in clinical trials. It involves a revolutionary collaboration between Lazarex Cancer Foundation, industry (various biopharmaceutical companies), and the designated institutions where IMPACT is implemented.

When IMPACT offers reimbursements, studies show patients are able to choose to participate in clinical trials. Consequently, clinical trials see increased patient enrollment, more minority participation, and improved retention rates. In addition to the benefits for individual patients, there is also a greater chance the trial will be successfully completed and, ultimately, treatments will be FDA approved more quickly. All this stands to benefit many more patients down the road.

IMPACT allows patients the freedom to choose hope over hospice.

How was IMPACT Developed?

While the Lazarex CARE program is noble, it is not sustainable. In 2013, Lazarex devised a plan to fix this problem permanently. Lazarex partnered with Massachusetts General Hospital and formed the Lazarex MGH Cancer Care Equity Program. The program improved patient participation by 29% and doubled minority participation in cancer clinical trials. With that success, Lazarex expanded and rebranded the initiative into IMPACT, a 3-year pilot program that will ultimately be rolled out to other Comprehensive/Cancer Centers nationwide. IMPACT launched in California in June 2018.

What is the goal of IMPACT?

The goal of IMPACT is to permanently fix the clinical trial recruitment system by shifting the financial burden of participation from the patient to the appropriate industry stakeholders who need patients to participate in order to get new drugs to market. This shift will allow ALL patients to have more access to cancer clinical trials when they need and want to participate, thus paving a path to more innovation in cancer therapies.
How exactly will the IMPACT program work?

The Lazarex IMPACT program is laser focused on educating cancer patients about clinical trials as a treatment option and presenting the possibility for financial reimbursement. Cancer patients whose conditions have not improved via standard treatment will be counseled about clinical trial options. If they are eligible for a clinical trial happening at an IMPACT-designated institution, the patient can be reimbursed for their travel so they can participate in the clinical trial. IMPACT member community partners and oncology clinics will also be prompted to refer patients to the IMPACT program. If they are eligible for a clinical trial outside of an IMPACT-designated facility, LCF will provide the reimbursement through the Lazarex CARE program.

In addition, IMPACT coordinates a community outreach effort called NeighborGood with other community organizations, advisors, health clinics and health fairs to raise awareness about topics across the cancer care continuum such as prevention, early diagnosis through screenings, clinical trial education, etc. all with the goal of improving patient health outcomes.

How is IMPACT different from the services currently being provided by LCF to clinical trial prospects and participants?

On a daily basis, LCF supports patients who come to them by helping the patients find a clinical trial, and then providing reimbursement for travel costs associated with trial participation costs, no matter where those trials are happening in the United States.

IMPACT is a 3-year institutionally based, proof of concept program collecting data to make the case to industry (biopharmaceutical companies) that covering these out of pocket costs for trial participants will result in increased enrollment, retention, minority participation and more equitable access.

IMPACT expands upon the work of LCF through the addition of this hospital/institution-based program by proactively reaching out to patients who are currently engaged with the hospital/institution.

Why is IMPACT necessary in addition to the services currently provided by LCF?

Patients discover LCF’s navigation and reimbursement opportunities through a variety of ways: word of mouth, social media, or a medical counselor. For the past 13 years LCF has bridged this gap in cancer care and helped over 4,000 patients get to their clinical trial treatments. However, this noble undertaking does not solve the problem at
its source. We need a sustainable solution at the industry level. IMPACT represents an innovative, proactive, patient-centered approach involving a collaboration between LCF, the institutions that treat patients, and the biopharmaceutical industry that conducts the clinical trials that produce life-saving new drugs.

**How is IMPACT Funded?**

IMPACT has been launched with the financial backing of the biopharmaceutical industry. Biopharmaceutical companies benefit when they have higher enrollment and greater patient diversity in their clinical trials, as do current and future patients, who benefit from groundbreaking, life-saving advances forged through clinical trials. New FDA guidance allowing for patient reimbursement in cancer clinical trials means industry can now help with those reimbursements. Industry realizes reimbursement creates equitable access for all patients, improves chances of the clinical trial’s successful completion, and ultimately improves health outcomes. Currently, IMPACT is funded through various grants. The IMPACT Founding Sponsor is Amgen. A grant from Gilead is helping fund IMPACT’s outreach and education program called NeighborGood.

**Who is eligible for reimbursement through IMPACT?**

Patients whose income is up to seven times the federal poverty level qualify for reimbursement through IMPACT on a sliding scale.

**Where does IMPACT exist?**

IMPACT is currently launching at the University of California, San Francisco (UCSF) Helen Diller Comprehensive Cancer Center and the University of Southern California (USC) Norris Comprehensive Cancer Center. Other university medical centers and other hospitals across the country are hoping to implement IMPACT. Lazarex Cancer Foundation is currently working to secure industry sponsors to enable the program to expand to those institutions and beyond.
Who administers IMPACT at the various locations/hospitals?
Each institution has a clinical trial coordinator who will serve as the liaison between the patient and Lazarex Cancer Foundation.

What is the plan and timeline for rolling out IMPACT across the country?
As soon as funding is secured, the program will expand. We have additional sites in mind, based on areas that have the greatest need. We are currently focused on institutions in PA and are in preliminary conversations with several others.

As IMPACT grows, will LCF cut back on its ongoing support and services to clinical trial prospects and participants?
No. LCF will continue the work of finding clinical trials for patients and reimbursing them for travel costs associated with cancer clinical trials as long as patients come to them seeking help.

Could the monetary resources being used in this outreach effort be better utilized by financing direct, patient-by-patient medical treatments??
No. The issue that IMPACT is designed to address is how to more effectively identify more patients who could benefit from clinical trials and thus expand the clinical trial pipeline. This approach addresses a critical need: how to deliver the patients clinical trials need to have a better chance of succeeding. That helps more patients who otherwise have run out of medical options, it helps the entire clinical trial system, and will result in more life-saving drugs being developed. We must make investments in new programs to change the system, take the financial burden off today’s patients who no longer benefit from standard treatments, and ultimately produce new drugs that will improve all patient outcomes.