IMPACT – Improving Patient Access to Cancer Clinical Trials

A 3-year nationwide program to increase cancer clinical trial enrollment, retention, minority participation and equitable access - getting cancer drugs to market faster and finishing oncology clinical trials on time and on budget.

Lazarex Cancer Foundation

We improve the outcome of cancer care for advanced stage cancer patients and the medically underserved, by providing assistance with costs for FDA clinical trial participation, identification of clinical trial options, community outreach and education. For over a decade, Lazarex Cancer Foundation has uniquely provided these services as a public charity.

We remove the primary barriers to trial participation; we increase awareness and trust, empower and sustain access, reduce health disparities, and optimize the diversity of the patient pool for evaluating the safety and efficacy of new therapies. Though this undertaking is noble it is not sustainable. Along with several Comprehensive Cancer Centers nationwide, Lazarex is now spearheading a program to sustainably address this gap in cancer care; **IMPACT** - **Im**proving **P**atient **A**ccess to **C**ancer **C**linical **T**rials.

Lazarex Cancer Foundation/IMPACT Program Founding Sponsor: AMGEN

Lazarex Cancer Foundation is currently rolling out the IMPACT Program in CA at:

USC Norris Comprehensive Cancer Center
Keck Medicine of USC

UCSF Helen Diller Family Comprehensive Cancer Center

Future IMPACT Program locations under consideration:

Philadelphia: U of Penn / Abramson, Thomas Jefferson / Sydney Kimmel, Temple / Fox Chase, Drexel University / Hahnemann

Bench to Bedside Challenges: Inadequate Clinical Trial Fulfillment and Diversity, Incomplete Assessment, Abandonment of Translational Medicine and the Perception of Inducement

Clinical trials are the capstone of the drug development process. Patient participation is crucial to the successful completion of a trial**. Obstacles to trial participation – primarily ancillary costs – lie squarely on the shoulders of patients**, adding to their financial toxicity when they can least afford it, creating a barrier to clinical trial participation.

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, which may be their only survival option.

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.

New targeted drug development efforts are shrinking the prospective patient population, making it necessary to recruit patients from a wider geographic area, intensifying recruitment challenges and increasing patient ancillary costs.

Lengthened time to completion often leads to industry abandonment of therapeutic agents due to impending patent expiration. Finally, in the recent past, industry stakeholders had been handcuffed by the perception of inducement, preventing the shift of the financial burden from the patient back into industry.

Making the Case

Billions are spent annually on cancer drug R & D. New drugs must successfully complete the FDA clinical trial process to get to market yet very few do. Why? The primary reason is lack of patient enrollment. How do we remove barriers and increase patient enrollment? We relieve patients of the financial burden of participation and engage with industry stakeholders to cover the ancillary costs.

In January of 2018 the FDA released guidance language at the urging of our founder, Dana Dornsife, which carves out patient reimbursement for travel expenses to clinical trials from inducement. By working with policymakers to remove the stigma of inducement and encourage industry support we increase trial participation, diversity and completion rates, finish trials on time and on budget, and preserve patent years before a drug goes generic. This collectively provides compelling and permissible motivation for industry support of ancillary costs for patients. The result is getting more drugs to market, reducing failure rates and creating timely and equitable access to the new treatments patients need to stay engaged in their fight with cancer.

The Solution: IMPACT

In 2013, LCF and #1 ranked Massachusetts General Hospital formed the Lazarex MGH Cancer Care Equity Program (now re-branded as IMPACT) and achieved a 29% increase in overall participation and doubled minority participation in cancer clinical trials in a 3-year experimental study.

Parlaying this success, Lazarex has developed the **IMPACT** program to coordinate efforts amongst all stakeholders; academia, medicine, policy makers, industry, public health and community organizations. These institutions are representative of the best in cancer care and public health programs. **IMPACT** leverages their academic, medical, research, socioeconomic, ethnic, racial, policy, and geographic assets, incorporating a range of cancer clinical indications and therapeutic interventions.

The key to achieving sustainable change is creating a convergent effort amongst all stakeholders. Our 3-year **IMPACT** program facilitates this convergence, generating a revolutionary powerhouse to create a replicable, "boots on the ground" action plan, bringing significant and sustainable change to the status quo of clinical trial recruitment, retention, minority participation, completion, and translational science - providing equitable and timely patient access to cancer discovery.

This is a 3-year study with a comprehensive approach in the following areas:

- Improving patient enrollment, retention, minority participation and equitable access in oncology trials
- Focusing on patient navigation at the community level, including the most at risk patients
- Increasing education and community outreach efforts about clinical trials and early detection at the patient, social service and medical professional levels, with specific concentration on minority and medically underserved communities and patients who are socioeconomically challenged
- Providing data management, bio statistical and epidemiologic analysis to rigorously evaluate the outcomes of the program
- Accomplishing the necessary changes in policy to successfully engage with industry at the State and Federal levels
- Monitoring the big picture: big data, population science, industry trends, best practices, policy, etc.

The Proposal - a detailed budget and deliverables can be provided upon request