Phase 1

Sickle Cell Foundation of Georgia, Inc. (SCFG) is one of the nation's oldest and most revered sickle cell advocacy organizations.

The primary objective of this campaign is to provide the funds needed to support research & protocol development of treatments via oils and any other approved delivery systems derived from Medical Marijuana (MMJ) to Sickle Cell Disease Patients.

The purpose of the human clinical trial is to research and develop protocols for the usage of medical cannabis and its derivatives to alleviate the severe pains associated with Sickle Cell Disease.

The study will determine the specific dosage needed of cannabinoids that will stay within the range of an ideal therapeutic window.

Staying within this specific range will ensure that patients will receive the correct amount of cannabinoids that will reduce overall pain and affliction associated with this disease while keeping the patient coherent and from experiencing psychoactive affects as well as possible addiction.

The same cannabinoids that can also be used to ease the pains associated with chemotherapy and other diseases that have painful side effects.

Clinical Trials Research & Protocol Development Overview

- the objective of trial
- primary and secondary end-point
- method of collecting data
- sample to be included
- sample size with scientific justification
- method of handling data
- statistical methods and assumptions

Statistical Sample Size Determination

Phase 1 (Local)
- Clinical Trials on Cannabinoids Delivery System
- 20 PATIENTS (10 MALES, 10 FEMALES ; AGES 18-40)
- Timeline 6-months

Phase 1 will demonstrate that there is a viable platform for the performance of trials that will support our thesis regarding pain management for sickle cell patients through the use of medical marijuana.

Phase 2 (Nationwide)
- 500 PATIENTS (250 MALES, 250 FEMALES ; AGES 18-40)

FDA Investigational New Drug Application (IND) Research (Non-commercial)

- Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Initial Goal: Start-up Budget & Use

Phase 1	Clinical Trials Research & Protocol Development, Testing & Management by Biotech Research Laboratories, Inc.
$25,000	for set-up, intake and screening (Marketing, Education & Outreach)
$100,000	for Research & Development
$28,000	for Biostatistician, IRB FDA Protocol Writer & Approval fees
$35,000	for Director of Medical Research
$37,000	for Indirect Cost
$25,000	for Fees & Commissions (Cost associated with campaign)
$250,000	**Total**

Action Plan & Schedule/Timeline

✔	Description of activities/tasks	Start Date	End Date	Team/Committee
	Develop Project Plan & Budget Lab & Team Research & Development Complete all contracts & agreements Finalize & Budget Approval	Oct 30, 2017	Nov 17, 2017	SCFG|Biotech
	Create Go Fund Webpage Develop & Implement Strategies Identify Donors & Major Contributors	Nov 13, 2017	Nov 24 2017	SCFG|Biotech|Oblander| IVA|Phoenix Tears
	Start Fundraising Campaign	Nov 27, 2017	Jan 31, 2018	SCFG|Biotech|Oblander| IVA|Phoenix Tears
	Start Clinical Trials Intake & Screening Research & Testing Protocols; FDA review	Jan 2, 2018	Jan 31, 2018	SCFG|Biotech| Phoenix Tears
	Phase 1 Clinical Human Trials Abstract Documentation	Feb 1, 2018	Aug 1, 2018	SCFG|Biotech| Phoenix Tears|ACMR