Exploring Patient Experiences of Individuals Joining Chronic Lymphocytic Leukemia Clinical Trials

This is an informed consent form for chronic lymphocytic leukemia patients joining Power Clinical Trial's observational medical trial.

Date: June 2, 2023

Overview

Chronic lymphocytic leukemia (CLL), an intricate hematological malignancy, arises from the abnormal proliferation of lymphocytes within the blood and bone marrow. Typically observed in older adults, CLL is characterized by its slow-progressing nature and poses significant challenges in terms of diagnosis and treatment.

The exact cause of CLL is still unknown, although certain genetic and environmental factors have been implicated in its development. Chronic lymphocytic leukemia clinical trials are therefore essential in finding cures or treatments for the condition.

This clinical trial is an observational study. We will not require you to change your treatment. We will also not recommend new treatment options.

You are under no obligation to continue your participation if you do not want to. Your engagement in this trial is entirely voluntary. This adherence to voluntary participation is consistent with accepted practices in clinical research investigations. It is important to stress that your decision to participate will have no bearing on your current treatment strategy. Your diagnosis, treatments, and care will not be impacted if you are currently receiving treatment because this study is solely observational. It is expressly forbidden for the study team to get involved with your care or keep track of how it is going.

We place great importance on ensuring that you have a clear understanding of the study's details and feel confident throughout the research process. If you have any doubts or need further explanations, we strongly encourage you to seek clarification without hesitation.

Our dedicated study team is readily available to address any questions or concerns regarding instructions, explanations, or any aspect of the study. Your comprehension and peace of mind are of utmost value and priority to us.

Why This Study is Being Conducted

This research study aims to address the limited understanding of the challenges faced by specific demographic groups of chronic lymphocytic leukemia patients in their participation in clinical trials.

By examining past clinical trials, the objective is to gather comprehensive information from participants and identify consistent factors that hinder their enrollment or completion. Through a thorough analysis of diverse demographic perspectives, this study seeks to uncover patterns that influence the experiences of future CLL patients. Your active involvement in this valuable research holds the potential to provide unique insights, ultimately enhancing the participation and completion rates of chronic lymphocytic leukemia patients in clinical trials.

Enrollment in an interventional clinical trial is required to participate in this study. If you are currently undergoing treatment for chronic lymphocytic leukemia (CLL) as part of another clinical trial, it is important to understand that your involvement in this observational clinical study will not impact your current treatment plan.

We encourage you to reach out to your healthcare team if you have any questions or concerns regarding your participation in the interventional clinical trial, as they can provide you with more information and clarification. It is essential to be aware of the distinctions between different types of studies in order to engage in research in an informed manner.

Patient Responsibility

It is important to complete the study requirements, which include completing twice-weekly surveys taking about 30 minutes, in order to participate in this observational clinical trial. Additionally, the interventional clinical trial you're taking part in will have its own set of quarterly check-up calls. It is essential to plan and join these calls on time if you want to participate fully in both elements of the study.

Risks

Prior to deciding on study participation, it is crucial to evaluate the potential risks involved. In this particular observational clinical trial, the risks are minimal. As it is solely an observational study, there is no possibility of altering care regimens, ensuring that participants will not experience any adverse effects. Moreover, to address concerns regarding confidentiality, we employ encryption and password protection measures to secure all electronic data, minimizing the risk of breaches during regular video conferences and online reporting.

Benefits

Your participation in this study holds the potential for numerous benefits. The outcomes derived from this trial will yield invaluable insights into the factors that influence the participation and completion rates of a diverse range of chronic lymphocytic leukemia patients in clinical studies. This newfound knowledge will play a pivotal role in improving future clinical trials aimed at incorporating individuals with chronic lymphocytic leukemia. By actively engaging in this study, you can make a significant contribution toward advancing our understanding of the factors that shape the involvement of diverse patient populations in these trials.

Distinguishing This Study from Other Chronic Lymphocytic Leukemia Clinical Trials

This study employs a purely observational approach, with no predetermined treatment course that participants must follow. It is essential to acknowledge that while the study team may not possess extensive expertise in previous chronic lymphocytic leukemia research, there are accessible resources to provide assistance. ClinicalTrials.gov offers a comprehensive listing of chronic lymphocytic leukemia studies, enabling individuals to explore additional options. Power's reference page, on the other hand, provides an up-to-date compilation of actively seeking chronic lymphocytic leukemia clinical trials — presenting potential volunteers with further opportunities for participation.

Investigating Diversity in Clinical Trials: Suggested Resources

While research on the representation of diverse populations in clinical trials is limited, there are several studies that offer valuable insights. We have curated a list of recommended readings that you may find engaging and informative:

Oh, Sam S., Joshua Galanter, Neeta Thakur, Maria Pino-Yanes, Nicolas E. Barcelo, Marquitta J. White, Danielle M. de Bruin et al. "Diversity in clinical and biomedical research: a promise yet to be fulfilled." *PLoS medicine* 12, no. 12 (2015): e1001918.

Taran, F. Andrei, Haywood L. Brown, and Elizabeth A. Stewart. "Racial diversity in uterine leiomyoma clinical studies." *Fertility and sterility* 94, no. 4 (2010): 1500-1503.

These recommended readings provide valuable insights into the representation of diverse populations in clinical trials, offering a broader understanding of the importance of inclusivity in research.

Strong Confidentiality Protocols for Your Protection

The preservation of your personal information's privacy and confidentiality is a chief interest in this clinical study. To verify the highest level of defense, we have instituted rigorous measures. Your records will be assigned a discrete code or number to conserve total anonymity throughout the study. All identifying materials will be securely kept in a locked file cabinet under close scrutiny of the researcher. We honor your privacy greatly and are dedicated to not divulging any personal information without your express consent, except in instances where the law demands disclosure, such as circumstances involving abuse or suicide risk.

Participant's Acknowledgement of Voluntary Participation and Consent

By affixing my signature below, I confirm that I have received comprehensive information about the nature and purpose of this study. I comprehend that my participation is wholly voluntary, and I have the liberty to withdraw from the study at any time without encountering any negative consequences. I greatly value the assurance that my decision to withdraw will not affect my current or future medical care. I politely request a copy of this consent form for my personal records.

_____
Printed Name of Participant

_____
Signature

_____
Date

Verification of Participant's Complete Understanding

As the clinical trial personnel responsible for elucidating the consent form to the participant, I am pleased to verify that the participant has demonstrated a comprehensive understanding of the risks, benefits, and procedures associated with this clinical research. Through candid and informative discussions, all questions and concerns have been fully addressed, ensuring that the participant has a sound understanding of the implications and protocols of the study.

_____
Printed Name of Person Getting Consent

_____
Signature of Person Getting Consent

_____
Date