Exploring Patient Engagement Patterns and Participation Trends in Mantle Cell Lymphoma Clinical Trials

An Informed Consent Form For Mantle Cell Lymphoma Patients in <u>Power Clinical Trial's</u> Observational Study

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Understanding the Significance of This Informed Consent Form

If you find yourself completing this paper, it indicates that you may be eligible to participate in a unique observational clinical study for mantle cell lymphoma patients. This detailed guide reveals the study's main goals, elaborate implementation strategy, and different ramifications, both good and potentially negative. Prior to making a decision, it is critical to investigate the specifics of your possible participation, and receiving counsel from a reliable source can provide useful information. If any section of this text is confusing or if you have any queries, the researcher is willing to answer them.

The Significance of Mantle Cell Lymphoma Clinical Trials

Mantle cell lymphoma (MCL) is a type of non-Hodgkin lymphoma (NHL), which is a cancer that originates in the lymphatic system, a part of the body's immune system. MCL specifically arises from a type of white blood cell called B-lymphocytes, or B-cells. It is considered a relatively rare and aggressive form of lymphoma.

Clinical studies with a distinct emphasis on mantle cell lymphoma play a pivotal role in evaluating the safety and effectiveness of novel treatments for this disease. These trials

are instrumental in ascertaining whether new medications surpass conventional therapies, providing substantial evidence to endorse their broad utilization.

This particular study stands out as it centers on the firsthand experiences of individuals battling mantle cell lymphoma who are actively engaged in a clinical trial featuring medicinal interventions. The primary objective is to meticulously scrutinize trial completion rates and voluntary withdrawals within this patient group.

Uncovering the Essence of Observational Trials

Engaging in this medical trial means delving into an observational study, a distinctive aspect of clinical research crafted with precision to extract insights through unobtrusive observation of patients while preserving their treatment regimens.

Researchers will solely observe your journey, meticulously gauging the outcomes of your condition without any alterations. This particular trial design holds paramount importance in augmenting our comprehension of the inherent progression of a specific medical ailment and its ramifications for individuals afflicted by it. By actively participating in this observational study, you assume a pivotal role in expanding the frontiers of medical knowledge and propelling advancements in the care afforded to those enduring the same condition.

Setting Apart This Trial from Other Mantle Cell Lymphoma Clinical Investigations

Recognizing the unique attributes of this research study is of utmost importance. It operates exclusively on an observational basis, indicating that your participation will not involve any specific treatments or interventions. To arrive at an informed decision regarding potential involvement in a clinical trial, it is essential to comprehend the spectrum of mantle cell lymphoma clinical investigations, encompassing interventional studies where participants undergo diverse treatment regimens.

Formulating an educated choice concerning your potential participation in a clinical trial necessitates an active approach that includes research and comparison of various trials. Resources such as Clinicaltrials.gov and similar platforms provide a wealth of information on <u>research pertaining to mantle cell lymphoma</u>. Moreover, Power's specialized web platform furnishes a comprehensive list of ongoing <u>mantle cell</u>

<u>lymphoma clinical trials</u> actively soliciting volunteers. Arming yourself with diligent research and a thorough grasp of different clinical trial categories empowers you to decisively shape your participation decision.

Active Engagement in Clinical Trial Surveys

We extend a warm invitation to actively share your experiences within the framework of this observational clinical investigation. This endeavor entails the completion of questionnaires every two weeks, requiring approximately 20-30 minutes of your valuable time. Additionally, we are fully prepared to conduct check-in calls at quarterly intervals, a practice that will continue throughout your participation in the trial.

It is crucial to emphasize that your involvement in the survey phase of the trial is entirely optional. You retain the autonomy to choose whether to respond to specific questions or complete the full questionnaire. Furthermore, you have the freedom to discontinue your participation in the trial at any time, should you decide to do so. Understanding that the decision to enroll in a clinical study is highly personal, we are dedicated to providing the necessary support. Your privacy and comfort are of utmost importance to us, and we are committed to respecting and assisting your decision-making process throughout the trial.

Preserving the Confidentiality of Your Answers

Upholding the complete confidentiality of your information stands as a paramount concern throughout this research study. To maintain your anonymity, we respectfully request that you avoid including any personal or identifiable information in your questionnaire responses. The dedicated research team is steadfast in their determination to enhance the safeguarding of your privacy. Nonetheless, it is crucial to recognize that specific legal situations may arise that necessitate the sharing of personal data.

Understanding Potential Health Risks

While clinical trials have made substantial advancements, it is vital to acknowledge the potential health risks that participants might encounter, especially in studies assessing new medications.

However, our observational clinical research employs a distinctive approach, intentionally mitigating these risks by abstaining from the administration of experimental therapies to participants. Instead, our primary emphasis is on thorough monitoring and outcome assessment, ensuring the prevention of any undue health hazards.

Prospective Gains

Though immediate advantages may not be evident to participants in this observational clinical research, their engagement possesses the potential to influence others greatly. The information collected from participants will be utilized to advance future strategies for enlisting individuals with mantle cell lymphoma, potentially broadening the scope of medical investigation. Those who embark on this therapeutic odyssey have the capability to ignite profound change in the realm of medical research, potentially steering the path for future mantle cell lymphoma patients.

Enhance Diversity in Clinical Trials

A multitude of online resources eagerly await your active participation if you're driven by an unquenchable curiosity to delve into the intricate realm of diversity within clinical trials.

Whether your objective is to grasp the intricacies of the challenges and opportunities linked to clinical trial diversity or to expand your own horizons, the following resources could prove immensely valuable:

Joseph, Galen, and Daniel Dohan. "Diversity of participants in clinical trials in an academic medical center: the role of the 'Good Study Patient?'." *Cancer* 115, no. 3 (2009): 608-615.

Polo, Antonio J., Bridget A. Makol, Ashley S. Castro, Nicole Colón-Quintana, Amanda E. Wagstaff, and Sisi Guo. "Diversity in randomized clinical trials of depression: A <u>36-year review." *Clinical Psychology Review* 67 (2019): 22-35.</u>

Confirmation of Informed Consent

I hereby confirm that I have dedicated sufficient time to comprehending and assimilating the information provided in the informed consent form. This understanding has been achieved through either independent review or with the guidance of a trusted individual who has explained its contents to me. All of my inquiries and concerns have been addressed comprehensively to my complete satisfaction.

I am fully cognizant that my participation in this study stems from my own volition, and I retain the sole authority to withdraw my consent without any obligation to provide reasons or assume financial obligations. I have been assured that a copy of this informed consent form will be furnished to me for my personal records.

After careful deliberation and a thorough review of all the materials presented to me, I hereby grant my consent to participate in this study, signifying my informed and autonomous decision.

Participant Name

Participant Signature

Date

Confirmation from Informed Consent Facilitator

I confirm that I have engaged in a comprehensive discussion with the participant, meticulously unraveling the intricacies encompassed within this written document. My objective was to ensure that the participant possessed a complete understanding of the primary objectives of the research, the methodology employed, potential risks and benefits, and other essential components inherent to the mantle cell lymphoma clinical trial. The participant was afforded ample opportunity to raise questions and express concerns or clarifications. It is imperative to underscore that the participant's involvement in this study is entirely voluntary, and they retain the unimpeded right to withdraw at any time, for any reason, without incurring any financial obligations.

Following the participant's granting of consent, a diligently maintained duplicate of this written document was provided to them, serving as a repository for their specific information.

Printed Name of Assisting Researcher

Signature of Assisting Researcher

Date