Investigating the Clinical Trial Journey and Engagement of Neuroendocrine Tumor Patients

This is an informed consent form for neuroendocrine tumor patients joining Power Clinical Trial's observational clinical study.

Date: July 21, 2023

A Call to Research

As a neuroendocrine tumor patient, extend a warm and exclusive invitation to you, encouraging you to embrace the role of a valuable participant in our research study. To ensure absolute clarity about the study's purpose and what it entails to be a participant, this consent form has been meticulously prepared. In the event that you come across unfamiliar terms or concepts while reviewing the document, our dedicated research staff is readily available to provide thorough explanations and guidance.

Your decision to participate holds immense significance, and we sincerely urge you to take the necessary time in contemplation. Should you have any questions or uncertainties, rest assured that we are here to address them with utmost attentiveness. Additionally, we encourage open dialogue with your family, friends, personal physician, trusted healthcare professionals, or members of your community to help you make an informed decision.

It is of utmost importance to reiterate that participation in this study is an entirely voluntary act, devoid of any obligation. Your involvement as a participant will not only enrich our understanding but also contribute to the advancement of vital medical research, thereby making a tangible impact on healthcare practices.

Introduction to This Neuroendocrine Tumor Clinical Trial

A neuroendocrine tumor (NET) is a rare type of tumor that arises from specialized cells known as neuroendocrine cells. These cells are found throughout the body, particularly in organs such as the lungs, gastrointestinal tract, pancreas, and adrenal glands. Neuroendocrine cells have characteristics of both nerve cells and hormone-producing endocrine cells, which makes NETs unique compared to other types of tumors.

Our study is committed to comprehensively monitoring and understanding the myriad elements that shape your journey through the neuroendocrine tumor clinical trial enrollment process.

All data collected during this study will be treated with the utmost confidentiality and stripped of personal identifiers, thereby enabling us to discern patterns in neuroendocrine tumor patient experiences. This invaluable analysis delves into the factors often contributing to lackluster enrollment rates and incomplete trials.

Crucially, it is crucial to reiterate that this research is purely observational, ensuring that your current treatment regimen remains unaffected should you choose to participate.

In addition to serving as written confirmation of your interactions with our site personnel and recruiting coordinators, this document may serve as a helpful reference point throughout your involvement in this clinical investigation. Your participation stands to contribute significantly to our understanding and pursuit of advancements in the management of neuroendocrine tumors.

Exploring Neuroendocrine Tumor Patient Experiences

Overcoming the inherent bias towards specific demographic groups in clinical trials is crucial for comprehensive medical research. In this pursuit, our study takes on the task of extensively collecting data on the experiences of neuroendocrine tumor patients enrolled in clinical trials. By doing so, we seek to identify the pivotal factors that hinder patient participation and successful trial completion.

To gain a deeper understanding, our research team will conduct a comprehensive analysis of the amassed data from diverse demographic standpoints. This analytical endeavor aims to uncover recurrent patterns that could offer invaluable insights into the future well-being of neuroendocrine tumor patients. Armed with this knowledge, we can actively reshape the landscape of clinical trial design and implementation, fostering a more inclusive environment that benefits a broader spectrum of patients and improves overall research outcomes.

The Benefits of Joining an Observational Clinical Trial

Your decision to participate in this observational clinical trial plays a vital role in advancing our understanding of neuroendocrine tumors and the ways we can better support future patients. Your valuable contribution will help uncover critical insights that can lead to improved participation rates and foster greater inclusivity in future studies.

Through the meticulous collection and analysis of data derived from your participation, our objective is to identify key factors that can significantly enhance the overall experience for neuroendocrine tumor patients. The results obtained from this study hold the potential to shape the landscape of future research and clinical practices, ultimately benefiting individuals affected by this challenging condition.

Addressing Risks in this Observational Clinical Study

Prioritizing the safety and well-being of participants is paramount when considering clinical trial involvement. It is crucial to underscore that this observational clinical study will not entail any changes to your current treatment plan, thereby eliminating potential risks linked to treatment modifications.

Throughout the study, interactive online reporting and video calls serve as essential means of connecting with neuroendocrine tumor patients. However, it is essential to be aware of the potential risk of data breaches during these virtual interactions. At Power's clinical trials, we have taken robust measures to safeguard your personal information. By implementing secure and encrypted communication channels, we ensure that all data transmitted during these calls remains confidential and protected. Moreover, all call logs and electronic consent forms are meticulously stored anonymously within a highly-secure environment to maintain the privacy of your data throughout the study.

Finding More Neuroendocrine Tumor Clinical Trials

This study stands apart from conventional neuroendocrine tumor trials due to its distinctive observational approach. Unlike interventional clinical trials, which focus on specific treatment interventions, this study revolves around meticulous observation and comprehensive data collection.

As a participant in this observational clinical trial, you can take comfort in the knowledge that there will be no treatment recommendations or alterations to your current treatment plan. The primary objective is to gather a wealth of data and insights pertaining to the neuroendocrine tumor and the profound impact it has on the lives of patients. By joining this study, you hold the opportunity to make a substantial contribution to the existing pool of knowledge and potentially influence future advancements in neuroendocrine tumor care.

For those seeking to explore alternative research options, clinicaltrials.gov serves as a valuable resource to discover other ongoing neuroendocrine tumor studies. Additionally, Power's online page provides a dedicated section devoted to neuroendocrine tumor clinical trials, offering a wellspring of information for those interested in delving deeper into available opportunities.

Exploring Diverse Perspectives on Participation in Clinical Studies

For those eager to delve deeper into the dynamics of participation rates in clinical trials, an enriching experience awaits through the following recommended sources. These references encompass a wealth of information and comprehensive studies solely dedicated to the exploration and understanding of the factors that significantly influence individuals' decisions to engage in clinical research.

By immersing yourself in this diverse literature, you gain access to valuable insights that shed light on the complexities affecting participation rates. Your engagement in these resources actively contributes to the broader comprehension of clinical trial recruitment, potentially fostering the development of innovative strategies that enhance engagement and inclusivity in future research endeavors.

Resources to explore:

Loree, Jonathan M., Seerat Anand, Arvind Dasari, Joseph M. Unger, Anirudh Gothwal, Lee M. Ellis, Gauri Varadhachary, Scott Kopetz, Michael J. Overman, and Kanwal Raghav. "Disparity of race reporting and representation in clinical trials leading to cancer drug approvals from 2008 to 2018." *JAMA oncology* 5, no. 10 (2019): e191870-e191870.

Borno, Hala T., Sylvia Zhang, and Scarlett Gomez. "COVID-19 disparities: an urgent call for race reporting and representation in clinical research." *Contemporary Clinical Trials Communications* 19 (2020): 100630.

Guidelines for Neuroendocrine Tumor Patients Participating in the Study

Active participation in this study necessitates your involvement in bi-weekly surveys, with each session thoughtfully designed to last approximately 30 minutes. Additionally, to gather critical data and insights relating to your journey as a neuroendocrine tumor patient, quarterly check-in calls will be an integral part of the clinical trial process.

Vitally, it is crucial to recognize that this observational study exclusively caters to individuals who are presently enrolled in an interventional clinical trial. Rest assured, your primary care doctor's prescribed treatment and methodology will remain entirely unaffected, ensuring that your participation in this observational study does not influence your ongoing treatment plan.

Throughout the course of the trial, our dedicated staff will be your unwavering support system, available at your beck and call to address any concerns or questions that may arise. We wholeheartedly encourage you to reach out to our compassionate team at any given moment, as we remain steadfast in providing personalized assistance and guidance throughout your participation.

Enrolling in this clinical study necessitates seeking permission and counsel from your existing care team. Their invaluable expertise will guide you in determining whether this study aligns harmoniously with your unique circumstances and priorities.

Embracing Informed Consent

I wholeheartedly confirm that I have dedicated ample time and effort to thoroughly read and grasp every nuance of the informed consent form, either independently or with the unwavering support of a trusted individual who graciously read it aloud. Each of my inquiries and uncertainties has been addressed with the utmost diligence, leaving me entirely content with the clarity provided.

Without a shadow of a doubt, I am acutely aware that my involvement in this study stems from a voluntary decision, granting me the autonomy to withdraw my consent at any given point, sans the imposition of any obligation or financial burden. Additionally, I

gratefully acknowledge that I will be furnished with a personal copy of this informed consent form for my records.

After a period of introspection and profound consideration of all disseminated information, I take immense pleasure in bestowing my consent to participate in this study, driven solely by my unwavering volition.

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Printed Name of Participant

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Participant Signature

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Date

Affirmation of Informed Consent Discussion: Statement by the Facilitator

In full confidence, I attest that I have embarked on an extensive and enlightening discussion with the participant, leaving no stone unturned in ensuring their profound understanding of the contents outlined in this form.

I can unequivocally confirm that the participant has not only grasped the implications but has also demonstrated unwavering comprehension of the potential benefits, risks, and procedures entailed in their meaningful participation in this neuroendocrine tumor clinical trial. Without a shadow of a doubt, every crucial aspect pertaining to the study has been thoughtfully elucidated, and all queries or uncertainties voiced by the participant have been addressed with the utmost attentiveness and skillful resolution.

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Printed Name of Person Taking Consent

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Signature of Person Taking Consent

_____

Date