Investigating the Dynamics of Patient Engagement and Trends in Participation in Recurrent Prostate Cancer Clinical Trials

This is an Informed Consent Form For Recurrent Prostate Cancer Patients in Power Clinical Trial's Observational Study

Date: September 30, 2023

Grasping the Importance of This Informed Consent Form

If you find yourself in the process of completing this document, it indicates that you might qualify for participation in a distinctive observational clinical study tailored for individuals with recurrent prostate cancer. This comprehensive guide unveils the study's primary objectives, intricate implementation plan, and various implications, encompassing both positive and potentially negative outcomes. Before making a decision, it is essential to thoroughly investigate the particulars of your potential participation, and seeking guidance from a trustworthy source can offer valuable insights. Should any section of this text appear perplexing or if you have questions, the researcher is available to provide clarification.

The Significance of Recurrent Prostate Cancer Clinical Research

Recurrent prostate cancer refers to the return or reappearance of cancer cells in the prostate gland or surrounding areas after a period of initial treatment. Prostate cancer is typically treated with surgery, radiation therapy, hormone therapy, chemotherapy, or a combination of these treatments. After initial treatment, many patients achieve remission, where there are no detectable signs of cancer, and their prostate-specific antigen (PSA) levels become undetectable or remain at very low levels.

Clinical studies, with a dedicated focus on recurrent prostate cancer, play a pivotal role in evaluating the safety and effectiveness of novel treatments for this condition. These trials serve as essential tools to determine whether new medications outperform traditional therapies, providing substantial evidence to endorse their broader utilization.

What sets this study apart is its central emphasis on the firsthand experiences of individuals battling recurrent prostate cancer, actively participating in a clinical trial involving medicinal interventions. The primary objective is to meticulously examine trial completion rates and voluntary withdrawals within this specific patient group.

Unveiling the Essence of Observational Medical Studies

Becoming part of this medical trial involves immersing oneself in an observational study, a distinctive facet of clinical research meticulously crafted to uncover insights through unobtrusive observation of patients while maintaining their treatment regimens.

Researchers will purely observe your journey, systematically assessing the outcomes of your condition without any alterations. This particular trial design holds paramount importance in enhancing our understanding of the natural progression of a specific medical ailment and its consequences for individuals afflicted by it. By actively participating in this observational study, you play a pivotal role in expanding the horizons of medical knowledge and driving progress in the care provided to those enduring the same condition.

Distinguishing Features of This Trial Among Recurrent Prostate Cancer Clinical Investigations

Recognizing the unique attributes of this research study is crucial. It operates solely on an observational basis, indicating that your participation will not involve any specific treatments or interventions. To make an informed decision about potential involvement in a clinical trial, it is vital to understand the spectrum of recurrent prostate cancer clinical investigations, including interventional studies where participants undergo diverse treatment regimens.

Formulating an informed choice about your potential participation in a clinical trial necessitates an active approach that involves research and a comparison of various trials. Resources such as Clinicaltrials.gov and similar platforms provide a wealth of

information on research related to recurrent prostate cancer. Furthermore, Power's specialized web platform offers a comprehensive list of ongoing recurrent prostate cancer clinical trials actively seeking volunteers. Empowering yourself with diligent research and a thorough grasp of different clinical trial categories enables you to decisively shape your participation decision.

Actively Engaging in Clinical Trial Surveys: Your Choice Matters

We extend a warm invitation for you to actively share your experiences within the context of this observational clinical investigation. This endeavor involves 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 persist 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 have the autonomy to decide whether to respond to specific questions or complete the entire questionnaire. Moreover, you possess the freedom to discontinue your participation in the trial at any time, should you choose to do so. Recognizing that the decision to enroll in a clinical study is a highly personal one, we are dedicated to providing the necessary support. Your privacy and comfort are of the utmost importance to us, and we are committed to respecting and assisting your decision-making process throughout the trial.

Maintaining the Confidentiality of Your Answers

Upholding the complete confidentiality of your data is a fundamental commitment throughout this research study. To ensure your anonymity, we kindly ask that you refrain from including any personal or identifiable information in your questionnaire replies. The dedicated research team is determined to bolster the safeguarding of your privacy. Nevertheless, it's critical to acknowledge that specific legal circumstances may arise, mandating the disclosure of personal data.

Understanding Potential Health Consequences

While clinical trials have brought about significant advancements, it is vital to understand the potential health consequences that participants may face, particularly in studies evaluating new medications.
However, our approach in observational clinical research adopts a distinctive strategy, intentionally minimizing these consequences by abstaining from the administration of experimental therapies to participants. Instead, our primary focus lies in comprehensive monitoring and outcome assessment, ensuring the prevention of any unwarranted health risks.

Envisioning Prospective Benefits

While immediate benefits may not be immediately evident for participants in this observational clinical research, their engagement carries the potential to exert a considerable influence on others. The data gathered from participants will be utilized to refine future strategies for enlisting individuals with recurrent prostate cancer, potentially expanding the horizons of medical inquiry. Those who embark on this therapeutic voyage have the capacity to instigate profound shifts in the realm of medical research, potentially directing the path for future recurrent prostate cancer patients.

Advancing Diversity in Clinical Research

A plethora of internet resources eagerly awaits your active engagement if you are driven by an insatiable curiosity to explore the multifaceted aspect of diversity in clinical trials.

Whether your objective is to grasp the complexities of the challenges and opportunities associated with clinical trial diversity or to expand your own horizons, the following resources may provide invaluable insights:

Costa, David J., Michel Amouyal, Philippe Lambert, Dermot Ryan, Holger J. Schünemann, Jean Pierre Daures, Jean Bousquet, Philippe J. Bousquet, and Languedoc-Roussillon Teaching General Practitioners Group. "How representative are clinical study patients with allergic rhinitis in primary care?." *Journal of Allergy and Clinical Immunology* 127, no. 4 (2011): 920-926.

Varma, Tanvee, Joshua D. Wallach, Jennifer E. Miller, Dominic Schnabel, Joshua J. Skydel, Audrey D. Zhang, Michaela A. Dinan, Joseph S. Ross, and Cary P. Gross. "Reporting of study participant demographic characteristics and demographic

representation in Premarketing and postmarketing studies of novel cancer therapeutics." *JAMA Network Open* 4, no. 4 (2021): e217063-e217063.

Confirmation of Informed Agreement

I confirm that I have dedicated sufficient time to understand and assimilate the information contained in the informed consent form. This understanding has been achieved through either independent examination or with the guidance of a trusted individual who has explained its contents to me. All of my questions and concerns have been addressed thoroughly to my complete satisfaction.

I am fully cognizant that my participation in this study stems from my own volition, and I retain the exclusive right 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 provided to me for my personal records.

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

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Participant Name

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Participant Signature

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Date

Confirmation by Informed Consent Facilitator

I hereby confirm that I have engaged in a comprehensive discussion with the participant, meticulously elucidating the intricacies contained within this written document. My objective was to ensure that the participant possessed a comprehensive understanding of the primary research objectives, the methodology employed, potential risks and benefits, and other essential components inherent to the recurrent prostate cancer clinical trial.

The participant was afforded ample opportunity to pose questions and express concerns or seek clarifications. It is crucial to emphasize that the participant's involvement in this study is entirely voluntary, and they retain the unencumbered 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.

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Printed Name of Assisting Researcher

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Signature of Assisting Researcher

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Date