A Detailed Exploration of The Perspectives and Experiences of Patients in Colorectal Cancer Clinical Trials

This is an informed consent form for colorectal cancer patients joining Power Clinical Trial's observational medical trial.

Date: May 26, 2023

Colorectal Cancer Clinical Trial Overview

Colorectal cancer, also known as colon cancer or rectal cancer, refers to the development of cancerous growths in the colon or rectum, which are parts of the large intestine. It is one of the most common types of cancer worldwide.

Your participation in this observational clinical research is extremely valuable since it allows people with colorectal cancer to contribute their own experiences and unique viewpoints. These vital contributions have the potential to affect the development of novel therapies and support services dramatically. This trial's findings will be critical in furthering our understanding of colorectal cancer, ultimately leading to better patient outcomes.

The major goal of this study is to provide significant insights into the factors that may lead to reduced participation or completion rates in clinical trials among patients with colorectal cancer. We gladly welcome you to participate in our observational clinical investigation, in which we hope to detect recurring trends in patient experience that may have an influence on these rates. We wish to guarantee you that any information you offer during the trial will be treated with strict secrecy and meticulously analyzed.

It is crucial to stress that this experiment is entirely observational, with no changes to your existing treatment course. Your participation in this research does not imply that you will get any therapy. This document will serve as a complete reference throughout

the trial process, offering specific information on the recruiting process and introducing you to the specialized trial team.

Informed Consent and Study Specifics: Your Voluntary Participation

Participating in this study is entirely voluntary, granting you the freedom to discontinue your involvement at any time you desire. It is essential to emphasize that your decision to participate or withdraw will have no impact on your treatment plan. This adherence to voluntary participation is a standard practice in medical research studies. Furthermore, it is crucial to note that this study is purely observational, meaning that your diagnosis, medications, and care will continue uninterrupted if you are currently undergoing treatment. The study team is explicitly prohibited from interfering with your treatment or monitoring your care status.

Seeking Clarity and Support: Clear Understanding of the Study

Ensuring that you have a confident and clear understanding of the study's details is vital to us. If you encounter any uncertainties or require additional explanations, please do not hesitate to seek clarification. The study team is readily available to address any questions or concerns you may have regarding instructions, explanations, or any aspect of the study. We highly value and prioritize your comprehension and peace of mind. Your comfort and confidence throughout the study are of utmost importance to the study team.

Exploring Factors Hindering Participation of Patients in Colorectal Cancer Clinical Trials

Over the years, clinical trials have primarily focused on specific demographic groups, resulting in a limited understanding of the barriers that prevent individuals with colorectal cancer from participating in these trials. The primary goal of this research study is to gather comprehensive information from participants in order to identify consistent factors that hinder the enrollment and completion of clinical trials by individuals with this condition. By meticulously analyzing the collected data from various demographic perspectives, this study aims to uncover patterns that impact the experiences of future colorectal cancer patients. Your active participation in this study

can provide invaluable insights that have the potential to improve the participation and completion rates of individuals with this condition in clinical trials.

Differentiating Interventional and Observational Studies: Ensuring Clarity for Participation

In order to take part in this study, it is essential to be enrolled in an interventional clinical trial. It is important to note that participating in this observational clinical study will not have any impact on your existing colorectal cancer care regimen if you are already involved in a different clinical trial. If you have any concerns or inquiries about your interventional clinical trial, we strongly encourage you to reach out to your care team for additional information and clarification. Understanding the distinction between interventional and observational studies is crucial to ensure informed participation in this research study.

Active Engagement: Study Requirements and Follow-up Calls

As a participant in this observational clinical study, your commitment will involve completing bi-weekly surveys, which are expected to take around 30 minutes of your time. Additionally, there will be quarterly check-up calls specifically scheduled for your interventional clinical trial, separate from this observational research. It is crucial to ensure that you schedule and attend these calls as required to actively participate in both components of the study and fulfill the study requirements.

Evaluating Potential Risks: Minimal Risks in the Observational Study

Engaging in a medical study requires careful consideration of potential risks. However, in this observational clinical trial, the risks are minimal. Given that this study is solely observational, there is no possibility of altering your care regimens, thus eliminating the potential for adverse effects on participants. Furthermore, we take the confidentiality of your information seriously. To safeguard your privacy, we employ encryption and password protection for all electronic data, minimizing the risk of any breach during regular video conferences and online reporting.

Assessing Potential Benefits: Contributing to Enhanced Clinical Trials

Participating in this study offers potential benefits that extend beyond individual involvement. The outcomes of this trial will provide valuable insights into the factors that can impact the participation and completion rates of diverse colorectal cancer patients in clinical studies. This knowledge will play a crucial role in improving future clinical trials that aim to include individuals with colorectal cancer. By actively participating in this study, you have the opportunity to make a significant contribution to a deeper understanding of the factors that may influence the participation of diverse patient populations in these trials, ultimately benefiting the community as a whole.

Setting this Study Apart from Other Colorectal Cancer Clinical Trials

In contrast to many other research on colorectal cancer, this study takes a distinctive approach by being purely observational. This means that participants are not required to follow any predetermined course of therapy. It is important to acknowledge that while the study team may not possess extensive expertise in previous colorectal cancer research, there are resources available to assist you. ClinicalTrials.gov provides a comprehensive list of colorectal cancer studies, and Power's reference page offers an up-to-date compilation of actively seeking colorectal cancer clinical trials where volunteers are needed.

Exploring Diversity in Clinical Trials: Recommended Readings for Insight

Although research on the representation of diverse populations in clinical trials remains limited, there are notable studies that offer valuable insights. We have curated a list of recommended readings to broaden your knowledge on this topic:

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.

Donofrio, Gabrielle, and Hao Feng. "Skin of Color Representation in Standardized Grading Scales and Clinical Studies in Cosmetic Dermatology." *Dermatologic Surgery* (2022): 10-1097.

These recommended readings shed light on the representation of diverse populations in clinical trials, providing valuable insights into the importance of inclusivity in research. By exploring these resources, you can deepen your understanding of the significance of diversity in clinical trial participation.

Robust Measures to Protect Your Privacy

Maintaining the privacy and confidentiality of your personal information is a top priority in this clinical study. We have implemented rigorous measures to ensure the utmost protection. Your records will be assigned a unique code or number, guaranteeing complete anonymity throughout the study. All identifying materials will be securely stored in a locked file cabinet under the close supervision of the researcher. We highly value your privacy and are committed to not disclosing any personal information without your explicit consent, except when required by law, such as in situations involving abuse or suicide risk.

Giving of Consent

By signing below, I acknowledge that I have been fully informed about the nature and purpose of this study. I understand that my participation is entirely voluntary, and I have the freedom to withdraw from the study at any point without experiencing any adverse consequences. I greatly appreciate the assurance that my decision to withdraw will not impact my current or future medical care. I kindly request a copy of this consent form for my personal records.

_____

Printed Name of Participant

_____

Signature

_____

Date

Confirmation of Participant's Comprehensive Understanding

As the clinical trial personnel responsible for discussing the consent form with the participant, I am pleased to confirm that the participant has demonstrated a thorough understanding of the risks, benefits, and procedures involved in this clinical research. Through open and informative discussions, all questions and concerns have been addressed, ensuring that the participant has a clear comprehension of the implications and protocols of the study.

_____

Printed Name of Person Getting Consent

_____

Signature of Person Getting Consent

_____

Date