Ulcerative Colitis Clinical Trials: Analyzing the Factors in Ulcerative Colitis Patients' Clinical Trial Experiences

An Informed Consent Form (ICF) For Power Clinical Trial's Ulcerative Colitis Observational Clinical Study

Date: February 3, 2023

About This ICF

This document is separated into two crucial parts that aim to provide you with complete information about the clinical study you are about to participate in. The first part is the Patient Information Sheet, which outlines the purpose of the study and explains your role as a participant. This section will give you a better understanding of what is expected of you and what benefits you may gain from participating.

The second part of the document is the Certificate of Consent, where you will be asked to sign and acknowledge your voluntary participation in the study. By signing, you are confirming that you have fully comprehended the information provided in the Patient Information Sheet and agree to participate in the study. Upon completion, you will be given a copy of the document for your records, so that you have a permanent record of your consent.

Ulcerative Colitis Observational Study Summary

The primary objective of this study is to examine the various factors that impact your ability to enroll and successfully complete a clinical trial for ulcerative colitis. We aim to gain a deeper understanding of the challenges and experiences of patients like you during the enrollment process, with the goal of improving it for future participants.

The study will gather non-identifiable data and analyze trends to identify any obstacles or inefficiencies that may lead to low enrolment and completion rates among ulcerative colitis patients. Rest assured that participation in this study will not affect your current treatment plan.

This document serves as written evidence of your discussions with our clinical study staff or recruitment coordinators. It is also a valuable reference for you as a participant in this observational study. By keeping a copy of this document, you can easily access and review the information you discussed with the staff at any time.

Why This Ulcerative Colitis Research Is Being Done

Clinical trials often seem to have a preference for a certain demographic, yet there is limited research to understand why some trial attributes hinder patient participation. This study aims to gather a comprehensive range of data on the clinical trial experiences of ulcerative colitis patients to identify the prevailing factors that may impact a patient's ability to enroll and complete the trial.

By analyzing the data from different demographic perspectives, we hope to uncover any recurring trends and provide valuable insights for the benefit of future ulcerative colitis patients. This study is an important step towards improving the clinical trial process and ensuring that it is accessible and inclusive for all patients, regardless of their demographic background.

Benefits of Joining This Observational Study

Your participation in this observational clinical trial has the potential to make a significant impact on the future of ulcerative colitis patients. By being a part of this study, you will play an essential role in uncovering ways to improve participation rates and broaden the reach of future studies. The results of this study will provide valuable insights into the experiences and challenges faced by ulcerative colitis patients during the clinical trial enrollment process.

This information will be used to develop strategies and make necessary changes to ensure that future clinical trials are more accessible and inclusive for patients with ulcerative colitis. By taking part in this study, you will be making a meaningful contribution to the advancement of medical research and the improvement of patient outcomes.

Risks of Joining This Observational Study

Participation in clinical trials often involves changes to your treatment regimen, which can come with certain risks. However, as this is an observational study, you will not be required to make any changes to your current treatment plan, meaning that you will not be exposed to any risks related to treatment modifications.

The study will utilize online reporting and video calls with participating ulcerative colitis patients over the course of the trial. While these methods of data collection offer convenience and ease of access, there is a potential risk of a data breach.

At Power's clinical trials, we take the security and privacy of our patients very seriously. We employ robust measures to minimize the risk of a data breach and ensure the safety of your information. During video calls, all data is encrypted and stored securely to prevent unauthorized access. Call logs and electronic copies of consent forms are also kept anonymously in a highly-secure environment to protect your personal information.

Other Trials For Ulcerative Colitis

Other studies in the field of ulcerative colitis are interventional clinical trials, where patients are required to undergo a different course of treatment than what they are currently receiving. This can pose some challenges and uncertainties for patients.

However, this observational clinical trial is different in that it will not require any changes to your current treatment plan. There will be no treatment recommendations or modifications to your current regimen.

If you would like to learn more about other studies in the field, you can explore the ulcerative colitis studies available on clinicaltrials.gov or visit Power's online page to view the available ulcerative colitis clinical trials you can apply to.

Additionally, you can gain further insight into the participation rates of clinical trials by reading up on the subject. Browse relevant academic journals, articles, and other resources that focus on the topic of clinical trial participation:

Shaya, Fadia T., Confidence M. Gbarayor, Huiwen Keri Yang, Marriette Agyeman-Duah, and Elijah Saunders. "A perspective on African American participation in clinical trials." *Contemporary clinical trials* 28, no. 2 (2007): 213-217.

Schmotzer, Geri L. "Barriers and facilitators to participation of minorities in clinical trials." *Ethnicity & disease* 22, no. 2 (2012): 226-230.

What Ulcerative Colitis Patients Have To Do As Participants

In this clinical trial, you will be expected to participate in bi-weekly surveys that will take approximately 30 minutes each. In addition, there will be quarterly check-in calls throughout the duration of the trial.

To be eligible to participate in this study, you must already be enrolled in an interventional clinical trial. Joining Power's trial will not affect the treatment and methodology prescribed to you by your primary care doctor.

If you have any concerns or questions during the course of the trial, you are encouraged to reach out to the study staff for clarification.

Before enrolling in this study, it is recommended that you speak with your healthcare team to ensure that it is appropriate for you to participate.

Participant Statement

I have thoroughly reviewed and comprehended the information provided above, which was also explained to me verbally. All of my questions were answered in a manner that satisfied my understanding.

I acknowledge that my participation in this observational study is completely voluntary and that I have the option to withdraw at any time without any consequences. By signing this form, I am not giving up any of my legal rights.

I understand that I will be given a copy of this consent form for my records.

By signing below, I am willingly and knowingly expressing my intention to participate in the clinical study described above.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Statement of Person Conducting Informed Consent Discussion

I have engaged in a comprehensive discussion with the participant regarding the information outlined in this form, and I am confident that the participant has a clear understanding of the benefits, risks, and procedures involved with this clinical trial for ulcerative colitis.

As a result of this discussion, I can assure that the participant has been provided with the necessary information to make an informed decision about their participation in this trial. Additionally, I am satisfied that the participant has a comprehensive understanding of the nature of the study and the procedures involved, including any potential benefits and risks.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date