# A Patient-Centered Analysis - Finding Patterns in Experiences of Patients in Esophageal Cancer Clinical Trials

## Informed Consent Form (ICF) For Power Clinical Trial's Esophageal Cancer Clinical Trial

Date: April 13, 2023

### Understanding the Significance of the Informed Consent Form in Clinical Research

The informed consent form plays a crucial role in clinical research, providing potential participants with comprehensive information about the study and ensuring they are aware of the potential risks and benefits before consenting to participate. The form consists of two parts - the Patient Information Sheet and the Certificate of Consent - both of which serve unique purposes. While the Certificate of Consent indicates the participant's voluntary agreement to take part, it does not waive their legal rights or oblige them to continue involvement. Participants should keep a copy of the form for their records.

### Enhancing Esophageal Cancer Cancer Treatment through Clinical Trials

Esophageal cancer is a type of cancer that occurs in the esophagus, which is the muscular tube that connects the throat to the stomach. Esophageal cancer can develop in the cells lining the inner surface of the esophagus and can spread to nearby lymph nodes and other parts of the body.

Esophageal cancer is often diagnosed at an advanced stage, when the cancer has already spread, making treatment difficult. Common symptoms of esophageal cancer include difficulty swallowing, chest pain, weight loss, and persistent coughing.

Clinical trials for esophageal cancer play a crucial role in advancing medical knowledge and improving patient care. These studies provide researchers with opportunities to explore new treatment options and gain insights into the underlying causes of the disease. For patients, clinical trials offer access to top medical specialists and cutting-edge medications that may not be available through traditional treatment options.

Unfortunately, underrepresented groups may have lower participation rates in clinical trials due to various factors, such as limited access to information, mistrust of the healthcare system, and communication difficulties. This clinical study aims to understand these factors and develop strategies for increasing participation rates in underrepresented groups.

By identifying the reasons for low participation rates in underrepresented groups, we can create more effective plans for increasing participation rates in upcoming clinical trials. It is important to note that participation in this clinical trial is entirely voluntary, and participants can withdraw at any time without facing any negative consequences.

Participants face minimal risk during the study's primary procedures, which involve completing surveys and follow-up calls. Prospective participants should carefully review the consent form and consult with their loved ones, trusted advisers, and medical professionals before making a decision.

## The Clinical Trial Process

In this clinical trial, we aim to gain insights into the disease by conducting observational studies without any intervention in your current treatment plan. If you choose to participate, the researcher will interview you to collect data and understand the disease's impact on your life. However, they cannot diagnose or recommend any treatment. This research aims to improve the understanding of the disease and develop better treatments for it in the future. Your participation in this study is voluntary, and you can withdraw at any time without any repercussions.

## Exploring Patient Decision-Making in Esophageal Cancer Clinical Trials

Our clinical study is focused on understanding the factors that affect patients' decision-making when it comes to participating in clinical trials for esophageal cancer.

We are particularly interested in learning about the reasons that led you to enroll in a clinical trial and what influences your decision to continue or discontinue.

Your participation in this study is voluntary, and it will not have any impact on your current treatment plan. We will conduct interviews to collect data, which will help us identify the barriers and motivators that impact patient participation in clinical trials.

By participating in this study, you can help us develop more effective strategies for improving patient recruitment and retention in clinical trials for esophageal cancer. If you decide to participate, you can withdraw from the study at any time without any negative consequences. Your contribution will be greatly appreciated and valued.

## Esophageal Cancer Clinical Trials: Comparing Observational and Interventional Studies

Numerous interventional clinical trials are available for esophageal cancer patients, but this particular trial differs in that it is purely observational, with no required participation in any specific treatment plan.

It should be noted that a variety of other research opportunities are available, and while we cannot list them all, interested individuals can check clinicaltrials.gov for a comprehensive list of esophageal cancer studies or visit Power's website to discover available options for esophageal cancer clinical trials.

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## Resources for Learning More about Diversity in Clinical Trials

For those interested in the importance of diversity and inclusivity in clinical trials, we recommend exploring published studies for insights and strategies:

Unger, Joseph M., Dawn L. Hershman, Kathy S. Albain, Carol M. Moinpour, Judith A. Petersen, Kenda Burg, and John J. Crowley. "Patient income level and cancer clinical trial participation." *Journal of Clinical Oncology* 31, no. 5 (2013): 536.

Nipp, Ryan D., Kessely Hong, and Electra D. Paskett. "Overcoming barriers to clinical trial enrollment." *American Society of Clinical Oncology Educational Book* 39 (2019): 105-114.

## Statement of the Patient

As a participant in an interventional clinical trial for esophageal cancer, I acknowledge that I have been selected to take part in the study voluntarily. I have thoroughly reviewed and understood the consent document, and any questions or concerns I may have had have been addressed. I hereby give my full consent to participate in the research and acknowledge that I may withdraw from the study at any time without any negative consequences. I also understand that my personal information will remain confidential, and all data collected will be kept secure.

## Participant's Signature

| _____ | _____ | _____ |
|---|---|---|
| Name of Participant | Signature of Participant | Date |

## Confirmation of Obtaining Consent for Research Study

As the designated individual responsible for obtaining the participant's consent to participate in the research study, I made certain that all aspects of the study were thoroughly explained to the participant. This included providing a comprehensive overview of the consent form and answering any questions that arose. I can confirm that

the participant gave their consent to participate in the study voluntarily, without any undue influence or pressure. Lastly, I provided the participant with a copy of the consent form for their own records.

## Signature of the Person Obtaining Consent

| _____ | _____ | _____ |
| --- | --- | --- |
| Name | Signature | Date |