Cholangiocarcinoma Clinical Trials - Evaluation of the Patient's Experience in Medical Studies for Cholangiocarcinoma

An informed consent form (ICF) for participants in Power Clinical Trial's observational study.

Date: January 12, 2023

Cholangiocarcinoma Observational Study Overview

This is an opportunity to take part in an observational study. The goal is to learn about how different factors during the clinical trial process can affect your willingness and ability to participate and complete the trial.

Your participation will be completely anonymous and the information we gather will be used to better understand why some people may have trouble completing or joining a clinical trial. It's important to note that this is an observational study, which means that your treatment plan would not be changed or influenced by your participation.

Another important thing to know is that being a participant in this study is different from being a patient, it's just an observation of your experience. We just want to document what happened during the clinical trial process, to help us learn more about how to make the process better. This form is a record of our chat and should be a helpful reference for you as you go through the trial.

Some Important Notes About This Cholangiocarcinoma Clinical Trial

Here are a few important things you should know about this clinical trial:

- First, it's completely up to you whether you want to take part. You can opt out at any point.
- As mentioned before, this is an observational study, which means that your participation would not affect your care or treatment plan in any way. The study staff would not be able to diagnose any illnesses, give you medication or manage your treatment.
- If at any point during the trial, you're unsure or don't understand something, please don't hesitate to ask and let us know.

Purpose of This Cholangiocarcinoma Clinical Trial

The main reason for conducting this research is to gain a better understanding of why some people with cholangiocarcinoma are not able to participate in or complete clinical trials. Historically, certain groups of people have been more likely to participate in clinical trials, but there hasn't been much research to understand why this is the case.

Our goal is to find out which aspects of a clinical trial may make it more difficult for patients to take part or see it through. We will look at this data through different demographic lenses and identify trends that could help improve the experience of future cholangiocarcinoma patients during clinical trials.

Comparison to Other Cholangiocarcinoma Clinical Trials

One way this trial is different from others for cholangiocarcinoma is that it is an observational study, which means that patients will not be required to follow any specific treatment plan. Unlike other interventional trials, you will not receive therapy as part of the study.

It's worth mentioning that this research team is not familiar with all the other clinical trials available for cholangiocarcinoma patients. However, you can easily find more information about cholangiocarcinoma studies by searching clinicaltrials.gov. You can also search Power's participant reference site for cholangiocarcinoma clinical trials that are currently recruiting participants. These platforms list various cholangiocarcinoma studies that you may be eligible for, or interested in.

Potential Risks You Should Be Aware Of

Before deciding to participate in this trial, there are a few things you should be aware of.

Firstly, you will be required to have frequent online check-ins and meetings with the study team throughout the project.

It's important to keep in mind that any changes to your treatment plan can be risky, so it is essential to think carefully before joining any clinical research.

However, unlike other interventional trials, this observational study will not affect your treatment plan in any way.

Another thing to consider is that there is a small risk of confidentiality being breached. This means that information about your participation in the study could be shared with someone else.

To minimize the risk of this happening, all data will be handled and stored securely with encryption and password protection. The likelihood of a confidentiality breach is low, and safety measures are in place to protect your personal information.

It is worth noting that for this study, we will need to collect and use data about you.

Benefits To Consider

By conducting this study, we hope to learn more about factors that may influence patient participation and completion in clinical trials for cholangiocarcinoma. This information could then be used to improve the design and recruitment strategies for future studies, potentially resulting in higher participation rates and a more diverse patient population.

Your Responsibility as a Participant

As a cholangiocarcinoma patient participating in this study, you can expect to fill out a questionnaire every two weeks. Each one should take around 30 minutes to complete. Additionally, every three months, you will receive check-in calls.

It's worth noting that this study is observational, and does not require you to change or affect any trial you are already participating in. If you have any questions about the interventional trial you are enrolled in, please don't hesitate to reach out to your care team.

More Reading Materials On Representation in Clinical Studies?

You can find more information on clinical trial participation rates by looking into the following studies:

Bakermans-Kranenburg, Marian J., and Marinus H. van IJzendoorn. "The first 10,000 Adult Attachment Interviews: Distributions of adult attachment representations in clinical and non-clinical groups." *Attachment & human development* 11, no. 3 (2009): 223-263.

Patry, Christian, Simon Kranig, Neysan Rafat, Thomas Schaible, Burkhard Toenshoff, Georg F. Hoffmann, and Markus Ries. "Cross-sectional analysis on publication status and age representation of clinical studies addressing mechanical ventilation and ventilator-induced lung injury in infants and children." *BMJ open* 8, no. 11 (2018): e023524.

Participant Statement

I have reviewed the information provided to me, both in writing and verbally, and my questions have been answered to my satisfaction.
I understand that my participation in this study is completely voluntary and that I can choose to withdraw at any time without penalty.

By signing this form, I am not giving up any of my legal rights. I will receive a copy of this consent form for my records.

By signing below, I am confirming my agreement to participate in this research study.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Statement of Person Doing the Informed Consent Discussion

I have reviewed the information in this document with the participant and I am satisfied that they understand the potential risks, benefits, alternatives, and procedures associated with this study.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date