Non-Small Cell Lung Cancer Clinical Trials: Examination of Trends in Non-Small Cell Lung Cancer Patients' Medical Study Experiences

Consent Form For Power Clinical Trial's Observational Research

Date: March 10, 2023

Important Notes

You must give us your consent in order to participate in our clinical trial project. You are fully free to discontinue participating in the study at any time. This is a quick summary of the study and further details may be found in the consent form.

- Our investigation's goal is to find patterns in the experiences of non-small cell lung cancer patients who sign up for interventional clinical trials.
- To learn why a patient enrolls in, stays in, or departs a clinical trial, the study's primary procedures include filling out questionnaires and making follow-up calls.
- Given that this is an observational clinical research, the risk to the participants is quite low. If you want to take part, there might not be a clear medical advantage.
- The findings of this study will contribute to our understanding of the factors influencing clinical study enrollment rates, which will be helpful for patients with small cell lung cancer.
- You won't be deprived of any of your standard benefits, privileges, or rights if you choose not to participate in this trial.

We strongly advise you to carefully read the consent form and to ask any questions you may have before making a decision. Before making a decision, it is also suggested that you speak with your family, close friends, trusted advisors, and/or medical specialists.

Why is this clinical trial being conducted?

The percentages of participants in clinical studies haven't always been perfectly representative of a particular group. This research examines the variables that affect a patient's choice to enroll in, discontinue participation in, or resume participation in a clinical trial for non-small cell lung cancer. Additionally, in order to evaluate whether any outcomes are statistically significant, we are seeking to recruit individuals from a range of demographic groups.

How will the clinical study proceed?

You have been asked to take part in this study because you have non-small cell lung cancer, are currently enrolled in an interventional trial, and are getting a certain treatment.

It is an observational clinical research. As a result, we wouldn't offer you any kind of treatment or medicine to test for anything. The following is an overview of our process in case you choose to participate in our study:

1. **Recruitment of Participants:** Non-small cell lung cancer patients who have taken part in, withdrew from, or finished a clinical study will be found using the electronic medical records systems of the clinical trial sites involved.

2. **Informed Consent:** The research team will get in touch with potential volunteers to explain the study's goals and to ask them to sign an informed consent form if they accept to participate. The study will make sure that the participants are aware of the purpose of the research and their participation rights.

3. **Data Collection:** Participants will be asked to complete a questionnaire every two weeks that asks about their demographics, medical histories, and the circumstances that caused them to sign up for, quit the clinical study early, or finish it. The research team will also communicate with participants through phone or video chat once every three months to learn more about their experiences during the clinical study.

4. **Data Analysis:** The research team will look through the collected data to find the factors that influence patient enrolment, withdrawal, and clinical trial completion. Statistical analysis will be used to determine the correlations between the variables.

5. **Dissemination of Results:** For the benefit of clinical trial stakeholders, the study's findings will be presented at conferences and published in scientific publications. The results will be used to enhance patient enrolment and retention in ongoing clinical trials for non-small cell lung cancer.

Can there be risks?

There may be risks associated with taking part in an observational clinical study for non-small cell lung cancer.

Even when observational studies do not incorporate experimental interventions like drug treatments or medical procedures, there are risks to be aware of. These risks may include the possibility of privacy violations, the possibility of psychological or emotional pain related to the subject of the research, and the possibility of poor results related to any procedures performed as part of the trial.

It is important to carefully read the informed consent form and discuss any questions or concerns with the research personnel before deciding whether to participate in a clinical trial.

Are there any advantages to participating in the study?

Participating in an observational clinical trial may help patients with non-small cell lung cancer since it advances medical knowledge and may improve treatment choices in the future.

Patients could also have access to specialized care and monitoring during the experiment. It's important to keep in mind that observational studies don't include experimental treatments like medications or surgery, so the individual patient might not get a direct medical benefit.

A person should ultimately base their decision to participate in a clinical study on their own situation and goals, and they should only do so after carefully assessing the pros and cons. Patients are recommended to discuss their alternatives with their doctor and the study team before making a decision.

Why would my involvement be halted?

The researcher or sponsor may stop your participation in the study at any time without your consent for a variety of reasons, including:

- if the investigation is suspended or stopped;
- if funding for the study is eliminated, suspended, or withdrawn;
- if it's considered to be in your best interests;
- If your health declines
- If you become pregnant;
- If, upon notification of modifications that might impact you, you decide not to proceed with the research; or,
- if you disregard the study's guidelines.

Non-Small Cell Lung Cancer Trial vs Others Trials

You are under no obligation to participate in this research project at any time, and there are no consequences if you choose not to do so.

If you're looking for additional non-small cell lung cancer studies, you may go to clinicaltrials.gov, a website sponsored by the National Institutes of Health (NIH) that includes a comprehensive database of clinical trials from all around the world. Trials may be filtered using a number of search criteria, including location and condition. As an alternative, you might search Power's reference page for a list of non-small cell lung cancer clinical trials that are now accepting new participants.

Is there other related research I can read on clinical trial diversity?

There are a few studies published online regarding clinical trial diversity that you can check. Here are some examples:

Loree, Jonathan M., Seerat Anand, Arvind Dasari, Joseph M. Unger, Anirudh Gothwal, Lee M. Ellis, Gauri Varadhachary, Scott Kopetz, Michael J. Overman, and Kanwal Raghav. "Disparity of race reporting and representation in clinical trials leading to cancer drug approvals from 2008 to 2018." *JAMA oncology* 5, no. 10 (2019): e191870-e191870.

National Academies of Sciences, Engineering, and Medicine. *Improving representation in clinical trials and research: building research equity for women and underrepresented groups*. 2022.

Is the data I provide safe?

The privacy of the personal information obtained for this project will be protected in every way.

It cannot be guaranteed that your personal information will remain completely private as it may be required to be disclosed by law. No publications or presentations of the research findings will include your name or any other information that may be used to identify you personally. Your medical information may be accessed for research, quality control, and data analysis by a number of entities, including accrediting bodies, government and regulatory authorities (including the FDA and OHRP), safety monitors, study sponsors, and authorized sponsor representatives.

You may occasionally be asked to complete an additional "Authorization Form" that details how and with whom your information may be used for research purposes. The data and/or study samples you submitted for this project may be shared with other Power researchers, researchers from other academic institutions, or researchers from outside commercial firms for future research without further informing you. Your confidential information will be removed and maintained in secrecy.

Giving of Consent

By signing below, you acknowledge that:

1. You affirm the following by ticking the box below:
2. You have read and fully comprehended the information in this informed consent form. You are recommended to discuss this information with others and seek additional viewpoints before making a decision.
3. Your concerns have all been adequately answered, and you have been given a thorough description of the study's procedures.
4. You have received all the information you require to take part in the research study.
5. You have considered the benefits, risks, and other options of participating in the study.

6. Participation in the research project is entirely up to you.
7. You are aware that participating in the research will not have any legal repercussions for your decision.
8. Any substantial new information about the research project that could influence your decision to continue participating will be communicated to you.
9. This permission form was given to you, and you have the chance to ask any questions you might have.

Signature by the Participant

_____	_____	_____
Name of Participant	Signature of Participant	Date

Signature by the Investigator

I personally gave the subject a non-technical explanation of the study, responded to any inquiries, and attested to the fact that the individual voluntarily agreed to participate.

Signature of the Investigator Who Obtained Consent Date of Signature

_____	_____	_____
Name of Investigator	Signature of Investigator	Date