

# Frequently asked Questions...

## ABOUT THE SELENIUM STUDY (E5597)

*The Eastern Cooperative Oncology Group (ECOG) prepared this fact sheet to help you understand cancer clinical trials and the prevention trial for non-small cell lung cancer using selenium.*

### *What is a clinical trial?*

A clinical trial is a study designed to find better ways to prevent or treat diseases such as cancer. There are several types of trials – prevention, treatment, diagnostic, screening, and trials that evaluate the quality of life for cancer patients in certain situations.

Clinical trials answer important scientific questions which can lead to advances in care. Trials are conducted in cancer centers, hospitals, clinics, and doctors' offices and may take five or more years to complete.

### *What is selenium?*

Selenium is an "essential trace element," meaning that it is a naturally-occurring substance required for normal, healthy functioning. Selenium reduces certain kinds of tumors in animals and enhances immune properties in humans. Recent nutrition intervention trials support the idea that selenium may reduce the risk of cancer in some instances. This is why this study has been developed.

### *What is the purpose of this study?*

This study has three purposes:

- To evaluate the effectiveness of selenium in reducing the incidence of new lung tumors in people who have been treated for Stage I (early stage) non-small cell lung cancer;

- To evaluate the occurrence of toxic side effects when taken over a period of years; and
- To compare the frequency of the development of specific cancers, mortality, and overall survival of people who are treated with selenium yeast with people who are treated with placebo.

### *What is a placebo?*

A placebo is a tablet that looks exactly like the medication being studied. However, it has no active ingredients. The selenium study is a double-blind, placebo-controlled study. This means that participants, medical staff, and other health care providers do not know who is taking selenium and who is taking placebo. This is to be sure that objective observations are made about any changes in your health status during the course of the study. Researchers use placebos in studies when there is no "standard" treatment, or when the standard treatment is observation.

### *What does participation in the selenium study involve?*

Because participants take a daily pill for four years, it is necessary to see if they will remember to take a daily medication. To do that, candidates participate in a "run in" or trial period for four weeks before becoming eligible for the trial.

If you are considered eligible, the next step is randomization. "Randomization" is like the "flip of a coin." It is a computer selection process that determines whether you will take selenium or placebo. In this trial, for every two people taking selenium, one will take placebo. The pills will be provided to you, at no cost, at your office visits every six months.

### *In this study, participants are required to:*

- Take a daily pill for four years and record it in a calendar diary;
- Complete a Baseline Questionnaire (about five minutes to complete);
- Complete brief follow-up questionnaires at each visit (about five minutes to complete); and
- If you are taking other supplements, agree to continue them as discussed with your doctor.
- If you smoke, the doctor will encourage you to enroll in a smoking cessation program and help you find a local one.

At the end of the four years, a member of your physician's staff will contact you periodically to monitor your health.



### *What are the benefits of participating?*

Whether or not selenium proves to be effective in preventing the development of new lung tumors, you will have the benefit of knowing that you are contributing to the improvement of care and treatment of other people with lung cancer.

### *What are the risks?*

Until the results of the study are analyzed, it is not known if taking selenium is an effective method of preventing lung cancer. There may be side effects from taking high doses of selenium, some of which may be severe or long lasting. However, most people do not experience side effects when taking the low dose of selenium offered in this trial.

Your doctor will tell you what to do if you experience any of these side effects: nausea, diarrhea, constipation, belching, red itchy skin, garlic breath or sweat, dry nails, hair loss, irritability, metallic taste, vomiting, tiredness, liver damage, or a general ill feeling. Complete details regarding risks will be provided to you before you start treatment on a clinical trial through a document called an "informed consent form."

### *Will insurance cover the cost?*

Unfortunately, the answer to this question is unclear. Medicare covers the routine costs of care required to participate in clinical treatment trials. Our research shows that many other insurers cover these costs as well, however, coverage may not be consistent from plan to plan. The pills for this study will be provided at no cost to participants. But the cost of the doctor's visits themselves may or may not be covered. Discuss this issue with your health care provider.

### *Who can participate?*

Each trial has specific requirements for participation in order to be able to evaluate the effect of the medication as accurately as possible. The selenium study is open to both men and women in all ethnic groups. Other requirements include:

- People who had surgery for stage I non-small cell lung cancer in the past three years; and
- People who have not had chemotherapy or radiation therapy.
- Your doctor will review other specific requirements with you.

### *What if I change my mind after enrolling in the study?*

Some people have a change of heart and want to stop participating in a study which you can do at any time. Hopefully, after completing the "informed consent process" which should answer all your questions about the study, you will feel confident about participating. However, if you think you want to stop, please discuss this with your doctor first.

### *Would my doctor stop my participation for any reason?*

Your doctor may decide to take you off the study if:

- You develop a new lung cancer;
- Your cancer comes back;
- You have serious side effects;
- Your health gets worse; or
- New information on preventing second lung cancers becomes available.
- Also, if early evaluation of the study shows that selenium works and prevents new lung cancers in people who have had lung cancer surgery, everyone involved in the study will be prescribed selenium as soon as possible.

### *Where can I get more information before deciding?*

Talk to your doctor about the study and ask any specific questions you may have. If you still have unanswered questions after reading this question and answer sheet and speaking to your doctor, call the ECOG Selenium Study Information Line, 215-789-3640, from 9 am to 4 pm Eastern Time.

For more information about the Eastern Cooperative Oncology Group (ECOG), visit [ecog.org](http://ecog.org).

