



Do you have advanced squamous cell lung cancer?

Talk with your doctor about the Lung-MAP research study.

<p>USUAL CARE</p>	<p>If you have the type of lung cancer called squamous cell lung cancer that is advanced – Stage IV that may have spread to other organs – usual care often involves chemotherapy. Even when initial chemotherapy works, lung cancer often returns. You would then be eligible to receive different therapies. These are known as “second-line” or “third-line” treatments.</p>
<p>PURPOSE OF THIS STUDY</p>	<p>The Lung-MAP study is a large clinical trial that is testing new treatments for patients who have advanced-stage squamous cell lung cancer. There are many different changes to a person’s cancer genes that can cause squamous cells to grow out of control. Researchers have developed new drugs that might “target” these genetic changes better and with fewer side effects. The Lung-MAP study hopes to learn if the drugs that target the genetic changes in the cancer cells will slow or stop the squamous cell lung cancer from growing.</p> <p>Lung-MAP is focused on advanced squamous cell lung cancer because there are few effective treatments for these patients, particularly those who don’t respond to chemotherapy.</p>

<p>WHAT IF MY TUMOR DOES NOT HAVE THE GENETIC CHANGE?</p>	<p>For some patients, their tumor will not match the genetic changes that are being tested in the trial. However, these patients may be able to join the “non-match” sub-study in Lung-MAP.</p> <p>This sub-study tests drugs that may help the immune system fight the cancer cells. Patients will be randomly assigned to one of two groups. Both offer a drug, nivolumab, which is approved for safety and effectiveness by the U.S. Food and Drug Administration for patients with advanced squamous cell lung cancer. One group of patients will be treated with nivolumab alone; the other will receive nivolumab plus another drug, ipilimumab.</p>
<p>BENEFITS OF TAKING PART IN THIS STUDY</p>	<p>It is not possible to know at this time if the study drugs are better than the usual treatment approach, so this study may or may not help you. However, this study will help researchers learn things that will help people in the future.</p>
<p>RISKS OF TAKING PART IN THIS STUDY</p>	<ul style="list-style-type: none"> • We may need to take another biopsy of your tumor, which may cause some bleeding, pain, or bruising. You may also develop an infection. • You may have side effects from the drugs used. • There may be privacy risks. We have strict rules and procedures in place to protect your identity, but we cannot guarantee that your identity will never become known.
<p>COSTS OF TAKING PART IN THIS STUDY</p>	<p>Study sponsors pay for the genetic testing of your tumor tissue and the investigational drug. You and your insurance company will need to pay for other care costs. Check with your insurance company to find out what it will and will not pay for. Patients who enroll in Lung-MAP will not be compensated.</p>
<p>YOU CAN STOP AT ANY TIME</p>	<p>If you change your mind about taking part in this study for any reason, you can stop at any time.</p> <p>We also may ask you to stop the study if we believe it is in your best interest, if new information becomes available, if you do not follow the study rules, or if the study is stopped.</p>

For more information ask your doctor or go to www.lung-map.org



S1400 Lung-MAP Study: Patient Questions and Answers

WHAT IS LUNG-MAP?

Lung-MAP is a large clinical trial, or research study, testing several new treatments for patients who have advanced-stage squamous cell lung cancer and whose cancer has continued to grow even after being treated with standard therapy. Lung-MAP is focused on squamous cell lung cancer because it is common and hard to treat. There are few effective treatments for squamous patients, particularly those who don't respond to chemotherapy.

Squamous cell lung cancer accounts for about 25 to 30 percent of non-small-cell lung cancer. Squamous cells are thin, flat cells that line the airways of the lungs. In advanced stage patients, the cancer has usually spread to other organs in their body.

While squamous cell lung cancer starts in a single group of cells, it is not a single disease. There are many different changes to a person's cancer genes that can cause squamous cells to grow out of control and become cancerous. Recently, researchers have developed new drugs that might "target" these genetic changes better and with fewer side effects.

With Lung-MAP, researchers test DNA from each patient's tumor to see if the patient has a genetic change in the cancer cells that may be causing the cancer to grow. If a change is detected in a patient's tumor, and if they meet other requirements, the patient will be eligible to get the drug that targets that specific genetic change. They will not get a placebo.

WHAT IF I DON'T HAVE A GENETIC CHANGE?

For some patients, their tumor will not match the genetic changes that are being tested in the trial. However, these patients may be able to join the "non-match" sub-study in Lung-MAP.

This sub-study tests drugs that may help the immune system fight the cancer cells. Patients will be randomly assigned to one of two groups. Both offer a drug, nivolumab, which is approved for safety and effectiveness by the U.S. Food and Drug Administration for patients with advanced squamous cell lung cancer. One group of patients will be treated with nivolumab alone; the other will receive nivolumab plus another drug, ipilimumab.

WHY IS THIS STUDY BEING DONE?

The purpose of the Lung-MAP study is to learn if the drugs that target the genetic changes in the cancer cells will slow or stop the squamous cell lung cancer from growing. For the non-match sub-study,

researchers want to compare the effects – good and bad – of using nivolumab alone and with another immune therapy drug.

CAN I JOIN LUNG-MAP?

Only you and your doctor can decide if Lung-MAP is right for you. Eligible patients have been diagnosed with advanced-squamous lung cancer, and have received at least one dose of chemotherapy. Lung-MAP patients must be at least 18 years old. Ask your doctor about Lung-MAP, also known as S1400.

WHAT WILL HAPPEN IF I JOIN THIS STUDY?

A sample of your tumor tissue will be sent to a lab for genetic testing. Based on those screening results, and if you meet other requirements, you can participate in a Lung-MAP research sub-study.

HOW WILL YOU GET THE TUMOR MATERIAL TO TEST?

For most patients, the research team can use tumor tissue from a past biopsy or surgery. In some cases, though, your doctor may need to perform another biopsy.

WILL I LEARN THE RESULTS OF MY TUMOR SCREENING?

Yes. Results of your genetic testing will be reported to your study doctor, who will discuss these results with you.

IF I WANT TO JOIN THIS TRIAL, HOW DO I FIND A PARTICIPATING CENTER?

Lung-MAP is open at more than 700 sites across the United States. To find a participating center near you, visit the Lung-MAP page on the ClinicalTrials.gov website. A list of these institutions is also available on the Find a Location page.

HOW IS LUNG-MAP DIFFERENT FROM OTHER CLINICAL TRIALS?

Lung-MAP has a few unique features.

First, it's not a single clinical trial. It's several sub-studies tackling a single disease and testing many treatments for it. These trials are sometimes called "umbrella" or "master protocol" trials. "Lung-MAP" is short for "lung cancer master protocol."

Lung-MAP is the first large-scale precision medicine trial launched with support from the National Cancer Institute. With precision medicine, doctors use information about the genes, proteins, and other features of a person's cancer to diagnose and treat the disease with precise treatments that target their cancer. The hope is that these targeted treatments will prove to be more effective than current treatments and have fewer side effects.

Lung-MAP is also special because it brings together many partners. SWOG manages the trial in collaboration with the National Cancer Institute, Friends of Cancer Research, and the Foundation for the National Institutes of Health. Other partners include pharmaceutical companies and the genomic analysis company Foundation Medicine.

The wide availability of the trial – with hundreds of sites across the country – gives many patients access to the latest treatments in their community.

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