

NCI Community Oncology Research Program – Kansas City (NCORP-KC)

Study Title for Study Participants: Targeted Treatment for Advanced Squamous Cell Lung Cancer

Official Study Title for Internet Search on

<http://www.ClinicalTrials.gov>:

S1400, “A Biomarker-Driven Master Protocol for
Previously Treated Squamous Cell Lung Cancer (Pre-Screening Step)
Lung-MAP Study”

What is the usual approach to my lung cancer?

Squamous cell lung cancers make up about one-fourth of non-small cell lung cancer. Various chemotherapy drugs have been shown to improve survival for patients with advanced squamous cell lung cancer. Most patients, for example, will be treated at first with cisplatin or carboplatin in combination with a second chemotherapy drug such as gemcitabine, paclitaxel, docetaxel, or vinorelbine. In addition, immunotherapy has been recently FDA approved for patients with previously untreated squamous cell lung cancer whose tumors have high expression of a marker called PD-L1, as well as for patients who previously received chemotherapy and then had progression of their cancer.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above
- You may choose to take part in a different study, if one is available
- Or you could decide not to be treated for cancer, but you may want to get comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Why is this study being done?

The purpose of pre-screening is to obtain a sample of your tumor while you are on your current cancer treatment. If you agree to the prescreening, your tumor sample will be tested by a lab for specific genes and proteins. You will continue with your current treatment as long as it is continuing to help you. However, if your tumor begins to grow, prescreening will make it easier for you to take part in one of the treatment studies matching your tumor to an appropriate study drug. We do not know how accurate this screening will be in matching your tumor type to a drug to treat your tumor. Before you decide to get treatment on the study, you will be given information about the treatment and you will be asked if you wish to take part in this research study. You may choose not to take part in the treatment study assigned to you.

We expect that between 500 and 800 patients will be screened for this study each year. We also expect that about 300 to 500 patients per year will go on to receive treatment on one of the assigned treatment studies.

What are the study groups?

The study has two steps: the initial pre-screening step where we will examine your tumor tissue and the sub-study treatment step which will be discussed in a separate consent form.

The treatment studies are called sub-studies. There will be many sub-studies that are open for patients at a given time. The sub-study that you will be offered will depend on a combination of the results of the testing done on your tumor sample, which sub-studies are available if your tumor begins to grow, and whether you are ready to get treatment on this study.

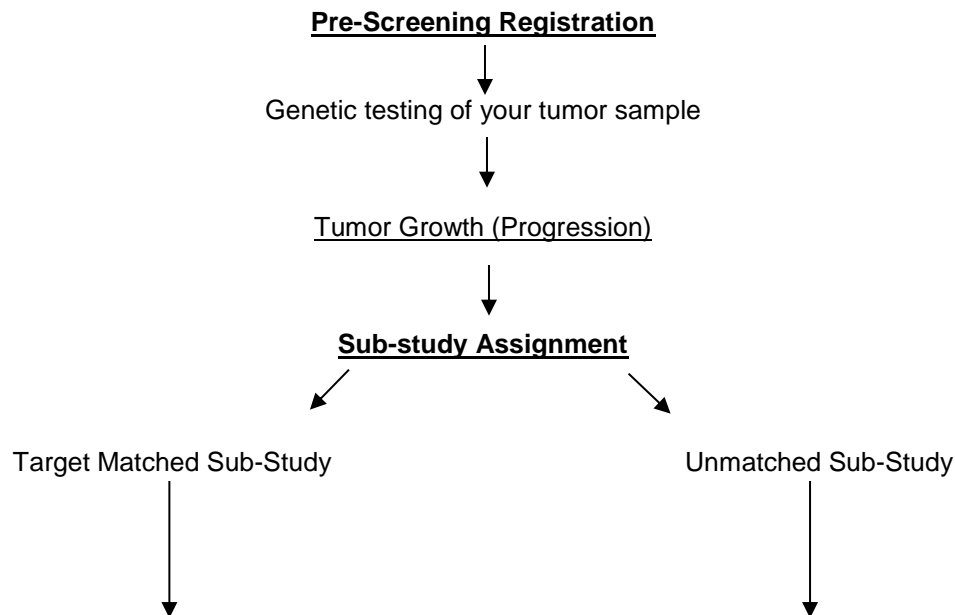
The testing done on your tumor sample is examining the presence or absence of certain biomarkers. These biomarkers are changes in genes or proteins in cancer cells that may be associated with cancer growth.

If your tumor begins to grow, you will be assigned to a sub-study. If your tumor has just one biomarker and there is a sub-study designed for that biomarker, you will be assigned to that sub-study. If your tumor has multiple biomarkers with sub-studies designed for them, you will be assigned to one of the related biomarker sub-studies randomly (by chance). There is also a sub-study available if your tumor does not have any of the biomarkers being tested or you were not eligible to participate in other sub-studies.

You will have to meet additional requirements before you can begin treatment on one of the sub-studies. If you don't meet those requirements, you may be re-assigned to another sub-study. If you don't meet the requirements for any assigned sub-study, you won't be able to begin treatment on a sub-study and will receive treatment without going on a sub-study. This will be decided between you and your study doctor.

The study chart below is to make the study design clearer to you. Start reading at the top of the chart and read down, following the arrows.

This chart is meant to help you understand the study.



If your tumor has just one biomarker with a sub-study designed for that biomarker, you will be assigned to that sub-study. If your tumor has multiple biomarkers with sub-studies designed for them, you will be assigned to one of the related biomarker sub-studies randomly (by chance).

How long will I be in this study?

The amount of time for the pre-screening step will depend on if and when your tumor begins to grow. The amount of time you will be on treatment depends on which sub-study you are in and how your disease responds to treatment. Even if you do not take part in any of the sub-studies for treatment, your study doctor will check your health status for this study every six months for up to three years.

What extra tests and procedures will I have if I take part in this study?

Before you begin the study, a small piece of tumor sample, which was already removed by surgery or biopsy, will be sent to special laboratories for the study. This tumor sample is required in order for you to take part in this study because the research on the sample is an important part of the study. The result of this testing will determine which sub-study you will be offered.

If there is not enough tissue left from a previous surgery or biopsy, you are required to have a biopsy to get more tissue before you can be screened for this study. A separate consent form will be needed for this biopsy. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.

If any tumor is left over, it will be stored in the Biobank and used for the laboratory studies within any sub-studies you may be enrolled in. The samples will be kept until there are no additional sub-studies for you to enroll in or they are used up, whichever happens first. The laboratory studies will be discussed in the sub-study consent form. If any tumor is left over after

the laboratory studies and there are no additional sub-studies for you to enroll in, and if you agree, it will be stored for biobanking. This will be discussed in the section on optional studies below.

Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. Results of the pre-screening test (including which study treatment you are eligible for) will be reported to your study doctor once your tumor begins to grow. The results will be reported to your study doctor even if you are not enrolled into a sub-study. Your doctor will discuss these results with you. Neither you nor your health care plan/insurance carrier will be billed for the collection or testing of the tumor tissue that will be used for this study.

What possible risks can I expect from taking part in the screening part of this study?

If you choose to take part in the pre-screening part of this study, there is a risk that:

- As with all medical screening tests, there is a chance of a false positive or a false negative result. A “false positive” refers to the identification of a biomarker that is not present. A “false negative” is the failure to find a biomarker that indeed exists. The tests have been designed to ensure that the possibility of incorrect results is low. Either a false positive or a false negative test would mean that your treatment assignment would not include the correct targeted treatment. However, because we do not know whether targeted treatment will work for you, we cannot say whether an incorrect treatment assignment would be worse.
- If you have to have another biopsy to get more tissue, you may have bleeding or infection. You may have pain and bruising at the biopsy site, which can be treated with regular pain medication. Also, you may have the biopsy and still not have enough tissue to go on the study. Rarely, patients may experience partial lung collapse that may require a chest tube or even a breathing machine.
- You may lose time at work or home and spend more time in the hospital or doctor’s office than usual.
- You may be asked sensitive or private questions which you normally do not discuss.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur. There are laws against misuse of genetic information, but they may not give full protection. The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The new law prevents discrimination from health insurers and employers. This law does not cover life insurance, disability insurance and long-term care insurance.

- There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.

Let your study doctor know of any questions you have about possible risks. You can ask the study doctor questions about risks at any time.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if the study approach to genetic screening of your tumor sample to help select treatment drugs is better than the usual approach, so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

There is no cost to you or your insurance associated with this screening or if you have to have an extra biopsy to collect more tissue for this screening (the biopsy cost will be provided in this case at a standard rate). However, if testing of your tumor sample shows that you are eligible for one of the treatment studies, you and/or your health plan/insurance company will need to pay for the costs of caring for your cancer while in this treatment study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health

plan or insurance company to find out exactly what they will pay for. Other costs will be addressed in more detail in the consent form for the treatment you are offered.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, SWOG, and the drug and device companies supporting the study.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Where can I get more information?

You may visit the NCI Web site at <http://cancer.gov/> for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Note to Informed Consent Authors: The above paragraph complies with the new FDA regulation found at 21CFR50.25(c) and must be included verbatim in all informed consent documents. The text in this paragraph cannot be revised.]

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ (*insert name of study doctor[s]*) at _____ (*insert telephone number*).

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records, nor will you or your study doctor know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say ‘no’ to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for each of the following studies.

1. Future Contact

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes No

2. Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems. Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this part of the study, the researchers would also like to ask your permission to store and use your samples and health information for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called “biobanking”. The Biobank is being run by SWOG and supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

- 1) If there is tissue left over after the laboratory studies and there are no additional sub-studies for you to enroll in, your tissue and some related information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up.
- 2) About 1 tablespoon of blood will be collected from a vein in your arm within 42 days of being assigned to a sub-study.
- 3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
- 4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
- 5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

- 1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
- 2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

- 3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The law prevents discrimination from health insurers and employers. This law does not cover life insurance, disability insurance and long-term care insurance. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

- 1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
- 2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and SWOG staff with access to the list must sign an agreement to keep your identity confidential.
- 3) Researchers to whom SWOG sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- 4) Information that identifies you will not be given to anyone, unless required by law.
- 5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, (*insert name of study doctor for main trial*) at

3. Optional Research Survey Study

Please note: This section of the informed consent form is about an additional research study that is being done with people who are taking part in the main study. You may take part in this additional study if you want to. You can still be a part of the main study even if you say 'no' to taking part in this additional study.

If you decide to take part in this additional study, you may withdraw your consent at any time without affecting your participation in the main trial. Regardless of your decision, there will be no penalty to you. You will not lose any of your regular benefits and this will not affect your medical care.

We are interested in learning what you know about genes, gene changes, cancer, and what you might like to learn about your personal gene changes. We would like your permission for a researcher to contact you by phone or email and ask you questions about that. You will receive a phone call or email from a researcher within a month after signing consent. The researcher < potential future option: or online survey > will ask you the questions on the survey provided. The survey will take approximately 30 minutes to complete. You will be sent a \$20 Amazon gift card to thank you for your time spent answering the survey questions. This payment will be sent to the address provided below within 30 days after completing the survey.

We will only use your contact information to schedule the call, conduct the interview, and send you the gift card. The information you give to us will be assigned a study ID number. That study ID number will not have your name or any other personal identifying information associated with it. Your responses will be added to other study participant responses and they will remain anonymous. The information that links your name with the study ID number and the signed consent forms will be confidentially maintained by the Fred Hutchinson Cancer Research Center and only certified investigators will have access to it.

If you have questions or concerns about this additional research study, please call Study Co-Chair, Dr. Josh Roth, at 206-667-7867. If you want to talk to someone about your rights as a research participant, who doesn't work on the study, please call Karen Hansen, Director of Institutional Review Office, Fred Hutchinson Cancer Research Center at 206-667-4867.

You can say "yes" or "no" to the following study without affecting your care. Please mark your choice.

I give permission for a researcher to contact me by phone <potential future option: or by email – Please circle which you prefer > to administer the Lung-MAP (S1400GEN) Patient Survey questionnaire.

Yes ___ No ___

Please print your contact information below if you choose to participate in the optional survey research study:

Name _____

Address _____

Telephone Number _____ home cell _____

Best time of day to call you: _____ am _____ pm

Email address _____

Signature _____ **Date** _____

For Site Use Only:

(Complete for "Yes" responses):

Treating Investigator: _____

SWOG Patient ID: _____

Institution: _____

Patient Initials (L, FM): _____

PI Email address: _____

Staff Name: _____

Staff Phone #: _____

Staff Email address: _____

This is the end of the section about optional studies.

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Screening Step of this Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant _____

Participant's signature _____

Date of signature _____

Person obtaining consent _____

Person obtaining consent signature _____

Date of signature _____

Specimen Consent Supplemental Sheets

How are Specimens Used for Research?

Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by SWOG. Your doctor does not work for SWOG, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

Why do people do research with specimens?

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

What type of research will be done with my specimen?

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

How do researchers get the specimen?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact SWOG and request samples for their studies. SWOG reviews the way that these studies will be done, and decides if any of the samples can be used. SWOG gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. SWOG will not send your name, address, phone number, social security number or any other identifying information to the researcher.

Will I find out the results of the research using my specimen?

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

Why do you need information from my health records?

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to SWOG. If more information is needed, SWOG will send it to the researcher.

Will my name be attached to the records that are given to the researcher?

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

How could the records be used in ways that might be harmful to me?

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members.

How am I protected?

SWOG is in charge of making sure that information about you is kept private. SWOG will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

What if I have more questions?

If you have any questions, please talk to your doctor or nurse, or call our research review board at (Insert IRB's Phone Number).

