

Alliance A0151216
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Update #4

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

Genetic Testing For Patients with Resectable or Resected Lung Cancer

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:

Protocol A151216: Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)

WHAT IS THE USUAL APPROACH TO MY CANCER?

Your lung cancer tumor has either been removed or will be removed by a surgeon. As part of your normal treatment, you may receive chemotherapy or radiation therapy to reduce the chance of the cancer coming back. Today, therapy is not based on tumor genetic testing, but this trial is trying to see if tumor genetic testing would be helpful at guiding treatment in patients such as you. The treatment you will receive, chemotherapy and possibly radiation therapy, is based on current standard therapy that patients with your type of cancer receive.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS SCREENING STUDY?

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

- you may choose to have standard therapy without having any tumor genetic testing;
- you may choose to take part in a different research study if one is available
- or you may choose not to receive additional treatment for your cancer at this time

WHY IS THIS SCREENING STUDY BEING DONE?

The purpose of this research study is to examine lung cancer patients' surgically removed tumors for certain genetic changes, and to possibly refer these patients to a treatment study with drugs that may specifically target tumors that have these genetic changes.

Genetic testing will be done to learn if your tumor has any of these genetic changes. These tests will look at the genetic material of the tumor cells. All tissues in the body are made up of cells. Those cells contain DNA, which is your unique genetic material that carries the instructions for your body's development and function. Cancer can develop when changes in

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certain genes cause those cells to divide in an uncontrolled way and, sometimes, to travel to other organs.

We are interested to see if your tumor tissue might have several different genetic changes. For example, in patients with a type of lung cancer called non-squamous lung cancer we are interested in looking for one of two genetic changes:

- Genetic changes in ALK (this will be referred to as ALK)
- Genetic changes in EGFR (this will be referred to as EGFR)

ALK and EGFR are both proteins found on the surface of cells. If your tumor is found to have one of these genetic changes you may be invited to participate on a trial that will look at drugs which may target tumors that have these specific genetic changes. There will be about 8300 people taking part in this screening study by having genetic tests of their tumors. However, it is believed that about one in ten people (approximately 800 people) will have a tumor with a genetic change, either in ALK or EGFR, that is required to be present in order to be invited to participate in one of the treatment studies. Your doctor will provide you with additional information on these clinical trials if your cancer is found to have a genetic change in ALK or EGFR.

If your tumor is not found to have the genetic changes in ALK or EGFR, your doctor will provide you with other options for your care and you will be followed for 5 years. A doctor or research staff will contact you every 6 months for 5 years to determine the status of your cancer and your overall health. This will help doctors better understand what happens to patients receiving the standard treatment for the disease.

There is another study that your site may be participating in, which will require you to get tested for genetic changes in PD-L1. The PD-L1 testing is similar to the EGFR and ALK testing described above. If your site is participating in this other study and you have a certain type of cancer called squamous cell lung cancer you will have the PD-1 testing. Also, if your site is participating in this other study and your tumor will then undergo the PD-L1 testing. Your doctor will talk to you about these different tests and the different studies you might participate in.

Another purpose of this research study is to learn more about cancer and why treatments may be more effective or even stop working with some tumors or in certain patients. After your tumor tissue is screened, if there is any tissue left, the remainder of your coded tissue samples will be sent to a National Cancer Institute (NCI)-sponsored storage facility, currently known as the Biospecimen Core Resource (BCR). The samples will be processed there and portions of your samples then will be sent to different types of laboratories, all within the NCI facility, as part of this project. Additionally, if your cancer comes back and there is biopsy tissue available for analysis, this too will be studied in that way. One type of laboratory will analyze your DNA by a method called sequencing. Other types of laboratories will study other biochemical material from your samples by different methods. The remaining portions of

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your samples, if any, will be stored at the BCR for possible future use in research related to cancer or, perhaps, in other research projects. Please check a box below to show whether or not you would like to have your tissue be used for future research:

1) My samples and related information may be kept at the BCR for use in future health research.

YES NO

Information from analyses of your samples and your medical information, which may include genetic information, will be put into databases along with information from the other people who volunteered for this project. These databases will be accessible by the Internet in two ways:

- Some of the results from the analysis will be added to the results from other participants and put in a completely public database, available to anyone on the Internet. This information will not be specific to you or any other participant.
- The other database is private, and will include person-by-person coded genetic, biochemical and medical information. The results in this database will be available to the global biomedical research community, but the access is controlled. Only researchers who have received approval from an NIH Data Access Committee will be authorized to access this database.

Your individual results from this research project will not be given back to you or put into your medical records.

If research from this project is published in professional journals, it will not include traditionally-used identifying information, such as your name, address, telephone number, or social security number. Some publications from this project will be found at the www.cancergenome.nih.gov website.

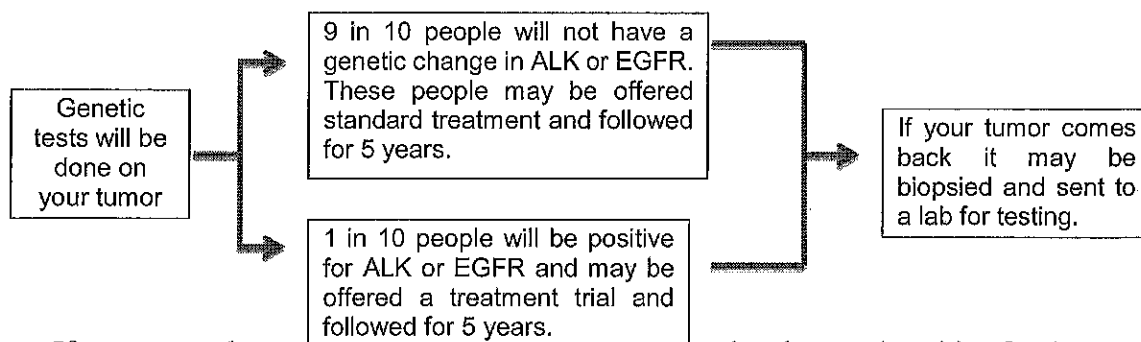
If you or your doctor requests the return of your samples from the laboratory, every effort will be made to return the samples if there is any remaining.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.

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If your tumor has already tested positive for the genetic changes in ALK or EGFR, you will be asked to submit a tissue sample for re-testing centrally. Regardless of the results of the re-test, you will be invited to participate in the appropriate treatment trial.

If your site is participating in the PD-L1 study and you have non-squamous cell lung cancer with no genetic change in EGFR and ALK your tumor will then be tested for PD-L1. The results of this test will be sent to your doctor.

Patients with squamous cell lung cancer will not have the EGFR and ALK testing. They will be tested for PD-L1. The result of this PD-L1 test will be given to your doctor.

WHAT ARE THE POSSIBLE TREATMENT STUDIES I COULD BE OFFERED BASED ON THE RESULTS OF MY GENETIC TEST?

For patients with non-squamous cell lung cancer: On this study, your tumor will be screened for genetic changes. Only about 1 in 10 patients will have the genetic changes required to be offered the EGFR or ALK treatment study. There are 2 different studies with 2 different drugs targeting tumors with certain genetic changes that you will be referred based on your genetic test.

- If your tumor has a genetic change in ALK, you may be offered the opportunity to participate in a clinical trial that will randomize you to receive either standard treatment plus crizotinib or no treatment. This is the ALCHEMIST-ALK study (E4512).
- If your tumor has a genetic change in EGFR, you may be offered the opportunity to participate in a clinical trial that will randomize you to receive standard treatment plus erlotinib or no treatment. This is the ALCHEMIST-EGFR study (A081105).

If your tumor does not have genetic changes in either ALK or EGFR, your physician will help you decide what treatment you will receive and the investigators will continue to follow your progress for 5 years as part of this study. Certain hospitals will have a trial available for those patients who do not have genetic changes in either ALK or EGFR. If your hospital

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has this trial open, your tissue that was already tested for the EGFR and ALK will then be tested for a genetic change in PD-L1. Your doctor will talk to you about whether or not you can be treated on this other trial, which will randomize you to either receive nivolumab or not have any treatment and be followed by the doctor (EA5142).

For patients with squamous cell lung cancer: Your tumor will be tested for genetic changes in PD-L1 only. Your doctor will then evaluate you to see if you could be treated on a trial which will randomize you to receive either nivolumab or not have any treatment (EA5142).

If your cancer comes back you will be asked to have a biopsy if that is appropriate for your medical care. Generally, tissue is needed by your doctor to determine your diagnosis. If tissue is available it will be sent to researchers to further study the genetic changes in your tumor. This is because tumors can change during treatment and investigators are interested in seeing what these changes are.

HOW LONG WILL I BE IN THIS SCREENING STUDY?

Patients who go onto one of the treatment studies described in this consent will be followed on that study. If you do not go onto one of the treatment studies a researcher from your hospital will contact you every 6 months for 5 years to check on the status of your cancer and overall general health. Your biopsy may still be used for future research if you consent.

WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS SCREENING STUDY?

Most of the exams, tests, and procedures you will have are part of the usual care for your cancer.

You will need to have the following extra exams, tests and procedures to find out if you can be in the research study:

- At the beginning of the study the researcher may ask you some extra questions about family and personal history.
- You will have about 2 tablespoons of blood drawn as part of this research study. The blood will be obtained at the beginning of the study to help the researchers study genetic changes. The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. One blood sample will be processed to collect your non-tumor genetic information and will be used to compare to the tumor genetic testing. The other 2 blood samples will be used in the future, to study circulating tumor DNA in the blood. To help you make your decision, additional information is included in the "Risks" section of this consent.
- Tumor tissue collected at the time of your surgery will be sent to a central laboratory for genetic testing.

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- You may be offered the opportunity to participate in a treatment trial related to this screening study. Before enrolling on a trial, you will be asked to provide a consent for that specific trial. As part of that process, extra exams or procedures required for that trial will be explained.

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS SCREENING STUDY?

If you choose to take part in this research study, there is a risk that:

- Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.
- While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a relative) in another database and be able to identify you (or your relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.
- Since some genetic variations may suggest the possibility of future health problems of you and your relatives, this information might be of interest to employers, health providers, insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative).
- While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. In 2008, the federal government established the Genetic Information Nondiscrimination Act (GINA), a law that prohibits genetic discrimination in employment and health insurance. It is important to note that while this law protects you from certain kinds of genetic discrimination, there are exceptions. For example, GINA does not apply to employers with fewer than 15 employees. Additionally, this law does not protect you from genetic discrimination in life, disability, or long-term care insurance. [Note to PI/IRB: insert state/local laws reference that may

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offer additional protections to safeguard patients' genetic information and prevent genetic discrimination.]

- There also may be other privacy risks that we have not foreseen. Even if you withdraw from this study the data collected and entered into a database will still be available for public viewing.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS SCREENING STUDY?

- This research study may help researchers learn things that may help other people in the future.
- Your study doctor will be given your genetic test results for ALK and EGFR.
- The results of your genetic test results for ALK and EGFR may allow you to enroll in a treatment study.
- If you participate in the PD-L1 testing the results will be shared with your doctor, who may evaluate you for a treatment trial.

CAN I STOP BEING IN THE SCREENING 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.

If you withdraw, we will stop collecting any of your information and will no longer distribute your samples to anyone – they will be discarded. However, please understand that, even if you do withdraw, once your samples have been distributed to the participating research centers and your information transferred to the databases, it will not be possible to discard your samples or remove your information from this research project.

If you withdraw from this project, it will in no way affect the care you receive from this hospital.

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

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- If the study is stopped by the sponsor, IRB or FDA.

WHAT ARE MY RIGHTS IN THIS SCREENING STUDY?

Taking part in this research 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 NCI Community Oncology Research Program Institutional Review Board at 913-948-5588.

WHAT ARE THE COSTS OF TAKING PART IN THIS SCREENING STUDY?

You or your health plan/insurance company will need to pay for the surgery and collection of the tumor. The screening testing done on the biopsy tumor tissue will be paid for by the National Cancer Institute (NCI) as part of this study. Before you decide to be in the research study, you should check with your health plan or insurance company to find out exactly what they will pay for.

If after treatment your cancer comes back, you will be asked to have a diagnostic biopsy, unless your doctor determines the biopsy is not appropriate for your medical care. If you choose to have the biopsy, the remaining tumor tissue from your diagnostic biopsy not used for diagnostic purposes will be submitted for research genomics. The research genomics will be paid for by the NCI, but you or your health plan/insurance company will need to pay for the biopsy and collection of the tumor.

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

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS SCREENING STUDY?

If you are injured or hurt as a result of taking part in this research study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for your injury. Your insurance company may not be willing to pay for research 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 seek recovery for any injuries or damages even though you are in a research 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

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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.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The Alliance;
- The Alliance Data Monitoring Committee, a group of experts who regularly review the progress of the study;
- The local Institutional Review Board (IRB), a group of people at this institution who review the research study to protect your rights;
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), involved in keeping research safe for people;
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials;
- The National Clinical Trials Network (cancer research groups who endorse this study);
- Cancer Genetics, the laboratory doing the EGFR and ALK testing, will also be getting a copy of your pathology report, which is a report describing the tumor that was removed.

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.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS SCREENING 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)

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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 THIS SCREENING 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 screening study and possibly be referred to a subsequent treatment trial based on the results of my genetic tests.

Participant _____

Participant's signature _____

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Date of signature _____

Person obtaining consent _____

Signature of person(s) conducting the informed consent discussion _____

Date of signature _____

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