Research Study Informed Consent Document

Study Title for Participants: Testing the use of nilotinib and paclitaxel as a treatment for patients with prior taxane treatment

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol EAY191-E4, ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients with Prior Taxane-Treated Solid Tumors (NCT #05554341)

Version Date: December 20, 2023

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have a solid tumor and have previously received a type of drug called a taxane to treat your cancer. The most common examples of taxane drugs are paclitaxel and docetaxel.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can the combination of the drugs nilotinib and paclitaxel cause your cancer to stop growing or shrink when you have already received paclitaxel (or another taxane drug treatment) in the past?

Please know that your eligibility for this trial may have been determined in part on the basis of a laboratory-developed test that has not been reviewed or approved by the FDA.

What is the usual approach to my cancer?

There is currently no agreed upon approach for treating patients with solid tumors who did not respond to prior taxane-based therapy. People who are not in a study are usually treated with surgery, radiation, or with drugs. Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will get the study drugs, nilotinib and paclitaxel, until your disease gets worse or the side effects become too severe.

After you finish your treatment, your doctor and study team will continue to ask you if you are experiencing any side effects, even if you start new treatments, for up to 3 years from the date you registered to this study. Your doctor or study team will contact you by phone or in person every 3 months for 2 years from the date you started on study and then every 6 months for 1 year.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the study drugs may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

There is also a risk that you could have side effects from the study drugs. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- Diarrhea, constipation, nausea, or vomiting
- Infection, especially when white blood count is low
- Anemia which may cause tiredness, or may require blood transfusions
- Pain, weakness, or numbness in the fingers and toes
- Change in heart rhythm, which in rare cases may lead to death

There may be some risks that the study doctors do not yet know about.

Benefits

The combination of nilotinib and paclitaxel has shrunk or stabilized tumors in a limited number of people with solid tumor cancers who have previously received a taxane drug. It is unlikely that it will work in everyone with your cancer or help you live longer. This study will help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (ECOG-ACRIN). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

This study uses a combination of drugs (nilotinib and paclitaxel). These drugs are approved for use on their own by the US Food and Drug Administration (FDA) for several different types of cancer, but the combination has not been approved by FDA. The purpose of this study is to test both the good and bad effects of giving the drugs, nilotinib, as a capsule you take by mouth, together with paclitaxel, given through a vein in your arm. Taking nilotinib and paclitaxel together could stabilize or shrink your cancer, but it could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drugs will shrink the cancer by at least 30% compared to its present size.

At least 20 people will be allowed to take part in this study. If at least 3 of the first 20 people in this study respond to treatment, an additional 20 people will be allowed to participate, for a total of 40 participants overall.

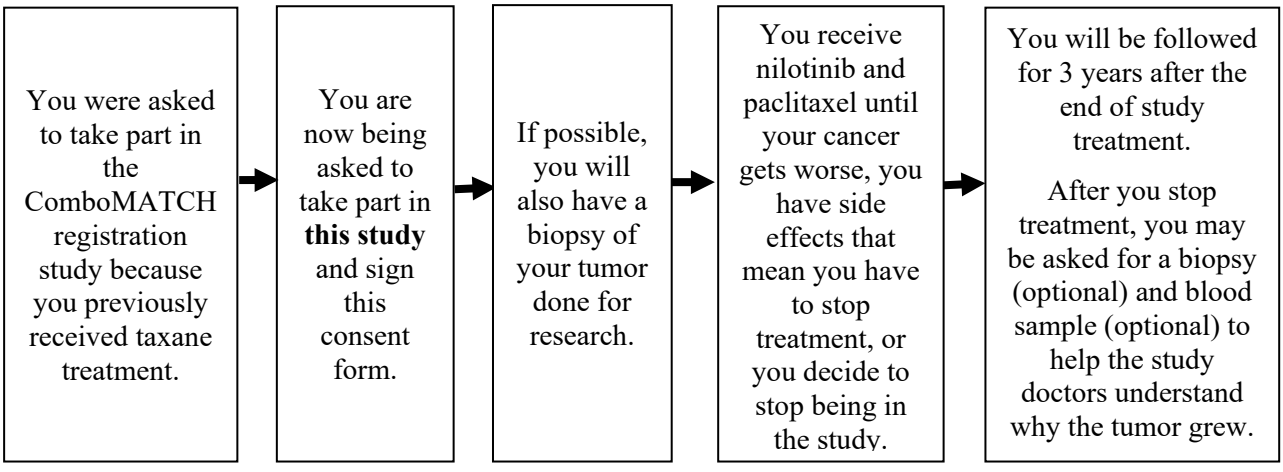
Another purpose of this study is for the study doctors to learn more about the characteristics of your disease that make it more or less likely to respond to treatment.

What are the study groups?

All study participants will get the same study treatment.

Treatment schedule: You will receive nilotinib as a capsule you take by mouth twice a day on every day of each cycle. You will also receive paclitaxel through a vein in the arm on days 1, 8, and 15 of each cycle. Each cycle lasts for 28 days. Study cycles will repeat until your cancer gets worse, you have side effects that mean you have to stop treatment, or you decide to stop being in the study. See the study calendar at the end of the consent form for more information.

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.



What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and

procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Physical exams done weekly during the first cycle of treatment and on the first day of each additional cycle (Cycle 2 and beyond).
- Vital signs done weekly every time you receive the drug paclitaxel.
- Blood counts done weekly every time you receive the drug paclitaxel.
- Electrocardiogram (ECG) prior to starting treatment and weekly for the first two weeks of treatment. You may have additional ECGs during the study based on how you are doing.
- For patients of childbearing potential: a pregnancy test within 8 days prior to registration to the study.

This study will use genetic tests that may identify changes in the genes in your tumor DNA or blood. We know that changes in some tumor genes play an important role in how cancers respond to drugs. Determining whether different tumor gene variations affect how the study drugs works against tumors will help scientists understand which patients might respond best to this drug combination.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- You will need to have a blood sample taken for the study. The blood sample will be taken before you start treatment with the study drugs. A blood sample will be drawn from a vein in your arm and will be sent to a central lab for research testing.

  This test is called Whole Exome Sequencing (WES). Your blood and tissue samples contain genes, which are made up of DNA (deoxyribonucleic acid), which serves as the "instruction book" for the cells that make up our bodies. Whole Exome Sequencing will determine the exact order of the base pairs (chemical letters) in your blood. This may help us understand how your cancer responds or does not respond to the study drugs.

  You and your study doctor will not get the results of this testing.

- If you have biopsiable disease and a biopsy can be done with minimal risk, you will also need to have a biopsy for the study prior to starting treatment with the study drugs. The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer.

  If you do not have biopsiable disease or a biopsy would not be minimal risk, you will need to have tumor tissue available from a recent biopsy.

Your tumor biopsy sample will be sent to a lab for research testing, including WES to determine the exact order of the base pairs (chemical letters) in your tumor, and RNA sequencing (RNA-seq) to determine what genes are being used by your tumor. This may help us understand how your cancer responds or does not respond to the study drugs.

You and your study doctor will not get the results of this testing. If you agree to take part in the study, you may need to sign a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.

What risks can I expect from taking part in this study?

General Risks

If you choose to take part in this study, there is a risk that the study drugs may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The study drugs used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 3 months after you have completed the study.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Biopsy Risks

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Depending on the location of the biopsy, injury to the organ that is biopsied may also occur. Rarely, an infection can occur. You may sign a separate consent form for the study biopsy that describes the risks in more detail.

Side Effect Risks

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drugs.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.

2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

This study is looking at a combination of the usual drugs used to treat this type of cancer plus a study drug. This different combination of drugs may increase your side effects or may cause new side effects.

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Tasigna is a difficult drug to dose because of the dietary requirements.

Possible Side Effects of Nilotinib

(Table Version Date: January 30, 2020)

COMMON, SOME MAY BE SERIOUS In 100 people receiving nilotinib, more than 20 and up to 100 may have:
• Change in heart rhythm • Cough • Infection, especially when white blood count is low • Anemia, which may require blood transfusions • Bruising, bleeding • Diarrhea, constipation, nausea, vomiting • Pain • Swelling and redness of the throat and sinuses (might not be caused by infection), which may cause difficulty breathing and swallowing • Headache, fever, tiredness • Itching, rash • Increased sweating, especially at night

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving nilotinib, from 4 to 20 may have:
• Heart attack, which may cause chest pain, shortness of breath • Swelling of arms or legs • Bleeding from multiple sites, including the brain • Internal bleeding, which may cause black tarry stool or blood in vomit • Prior liver infection that returns, which may cause yellow eyes and skin • Muscle weakness, spasm • Hair loss

RARE, AND SERIOUS In 100 people receiving nilotinib, 3 or fewer may have:
• Stroke, which may cause paralysis • Numbness and pain of arms and legs • Tumor lysis syndrome, which may cause kidney damage which may require dialysis

Possible Side Effects of Paclitaxel

(Table Version Date: October 14, 2020)

COMMON, SOME MAY BE SERIOUS In 100 people receiving paclitaxel, more than 20 and up to 100 may have
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require blood transfusions • Sores in mouth which may cause difficulty swallowing • Diarrhea, nausea, vomiting • Pain • Muscle weakness • Numbness, tingling or pain of the arms and legs • Hair loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving paclitaxel, from 4 to 20 may have:
• Abnormal heartbeat

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving paclitaxel, from 4 to 20 may have:
• Blood clot which may cause swelling, pain, shortness of breath • Damage to the lungs which may cause shortness of breath

RARE, AND SERIOUS In 100 people receiving paclitaxel, 3 or fewer may have:
• Heart attack or heart failure which may cause shortness of breath, swelling of ankles, and tiredness • A tear or a hole in the bowels which may cause pain or that may require surgery • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body

Additional Drug Risks

The study drugs could interact with other drugs and food. Nilotinib and paclitaxel interact with certain enzymes in your liver, and concurrent medications that need these liver enzymes to be effective or to be cleared from your system must be used very carefully. Other medicines may also affect the activity of these liver enzymes. Because of this, it is very important to tell your study doctors about all of your medicine before you start this study, including medicine you buy without a prescription at the drug store (over-the-counter remedy) or herbal supplements. Share this information with your family members, caregivers, other health care providers, and pharmacists.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study.
- Write down in your medication diary when you take the study drug at home.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 3 months after your last dose of study drugs. It is important you understand that you need to use birth

control while on this study and for 3 months after the study.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- the cost of the study drug paclitaxel.
- the costs of getting the nilotinib and paclitaxel ready and giving it to you.
- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The research biopsy done after enrollment to the study.
- The research studies done on the research biopsy for this study.

You or your insurance provider will not have to pay for the study drug nilotinib while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a

study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The ECOG-ACRIN Cancer Research Group is conducting this study. ECOG-ACRIN is a cancer research group that conducts studies for the National Cancer Institute. Your doctor is a member of ECOG-ACRIN or another group that is participating in this study. To help protect your privacy, ECOG-ACRIN has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, ECOG-ACRIN cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor (ECOG-ACRIN) and any company supporting the study now or in the future. This would include any organization helping the company with the study.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from

other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

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.

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 site study doctor[s])* at _____ *(insert telephone number)*.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number)*.

Optional studies that 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. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people with cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say "no" to any or all of these studies. There is no penalty for saying "no." You and your insurance company will not be billed for these optional studies. If you sign up for, but cannot complete any of these 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.

Optional sample collections for known laboratory studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

If you choose to take part in this optional study, researchers will:

1) Collect blood specimens for research to test levels of circulating tumor DNA (ctDNA) in your blood stream. This will allow researchers to determine whether any changes in the amount of ctDNA or changes in the tumor gene sequences found in ctDNA might affect how the study drugs work against tumors. Researchers will sequence your ctDNA to look for these changes.
2) Collect an additional, optional tumor biopsy specimen when your disease comes back or shows signs of coming back, to determine whether any tumor gene changes might affect how the study drugs work against tumors. Researchers will sequence your tumor DNA to look for these tumor gene changes.

Unknown future studies

If you choose to take part in this optional study, tissue from the biopsies collected as part of the main study will be stored for future research. Storing samples for future studies is called "biobanking." The biobank is being run by ECOG-ACRIN and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

Right now, we don't know what research may be done in the future using your tumor tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

What is involved in this optional sample collection?

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

1. Any tissue that was collected during your biopsy prior to starting treatment and that is left over after all of the mandatory research studies are completed will be sent to the biobank.
2. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information

in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find 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 and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

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

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

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 to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

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 (*insert telephone number of study doctor for main trial*).” who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial*).”

Please circle your answer below to show if you would or would not like to take part in each optional study:

Blood samples for known future studies:

I agree that my samples and related health information may be used for the laboratory studies described above.

YES NO

Additional biopsy for known future studies:

I agree that an additional biopsy may be done to obtain research specimens if my disease comes back or shows signs of coming back.

YES NO

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the 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 and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____

Study Calendar

Visit	Patient Activities
Visit 1: Screening (within 4 weeks prior to start of treatment unless otherwise noted) *may need to be repeated within 8 days before starting treatment	• History and physical examination* • Routine blood tests • Pregnancy test (if you are a woman who could become pregnant) within 14 days of starting treatment • Electrocardiogram • Imaging (CT or MRI; same method to be used at future visits) to look at your cancer within 6 weeks prior to start of treatment • Blood collection for research submission • Tumor biopsy or tissue submission from prior tumor biopsy for research submission
Visit 2: Start of treatment Cycle 1 (each cycle is 28 days or 4 weeks)	• Examination by your doctor • Side effects assessment • Routine blood tests • Electrocardiogram • Start study drugs Nilotinib and Paclitaxel o You will be given pill capsules of Nilotinib to take twice a day at home on every day of the cycle o You will receive Paclitaxel through an IV in your arm during your study visit
Visits 3, 4 and 5: Weekly during cycle 1 (visit 3 is one week after you start treatment, visit 4 is two weeks after you start treatment, and visit 5 is three weeks after you start treatment)	• Examination by your doctor • Side effects assessment • Routine blood tests • Electrocardiogram (Visit 3 only) • Continue taking Nilotinib at home • Receive Paclitaxel through a vein in your arm during your study visit (Visits 3 and 4 only)
Visits 6 and beyond: Start of cycle 2 and ongoing treatment evaluations You will come in weekly for 3 weeks and one week off every 4 weeks or 1 cycle	• Examination by your doctor • Side effects assessment • Routine blood tests • Imaging (CT or MRI; by same method as screening) every 8 weeks, or more frequent if clinically necessary • Blood collection for research submission (Visit 6 only, and only if you said yes to optional blood samples above) • Continue taking Nilotinib at home • Receive Paclitaxel at weekly study visits for the first three weeks of each cycle
End of treatment	• Side effects assessment
Only if you consented to additional blood samples	• Blood collection for research submission at end of treatment • Biopsy for research submission at end of treatment

and biopsy	
Follow up: Every three months up to two years, then every 6 months in the third year	• Examination by your doctor • Side effects assessment, if clinically necessary • Routine blood tests, if clinically necessary • Imaging (CT or MRI; by same method as screening), if clinically necessary