Please note: This book does not replace your Informed Consent Form (ICF) but may help you better understand its contents. Please do not hesitate to ask the study staff any questions you have.

[Printcode]

Amgen - XALute Study - UYS book - 12-SEP-2025 - English (Principal) - V3.0

XALute

Understanding the XALute Study

A research study for adults with prostate cancer

Welcome to the study.

Clinical studies are important for finding new ways to treat illnesses. By allowing your study doctors and staff to be part of your cancer treatment journey, you are making an important contribution to prostate cancer research. What we learn in this study may help you and future patients like you.

In this guide, you will find an overview of the study and what to expect. There is important information on what to do if you don't feel well or have other changes in your health during this study.

Thank you for your time and contribution to the XALute Study. We could not make scientific progress without volunteers like you.

With our appreciation,
Your XALute Study Team and Amgen Inc.

Your study doctor: _____

Phone number: _____

Your study coordinator: _____

Phone number: _____

Email: _____

Once your study medicine is determined, write the name here:

_____

Scan the code or visit
www.xalutestudy.com for additional study resources.

Pin Code: 0509

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XALute

Study Overview

The study lasts up to 4.5 years (56 months), including a minimum of 3 years (36 months) of treatment and follow-up. It is divided into 5 parts.

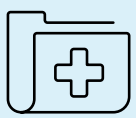
Screening	After you sign the Informed Consent Form, you'll have health checks and tests to see whether: • The study is right for you. • You qualify for the study.
Study Treatment	You'll be assigned by chance to an investigational study medicine and have health checks and tests according to a schedule.
End of Treatment Visit	You'll see your study doctor after you stop taking your investigational study medicine and before you begin any new cancer treatment.
Safety Follow-up	There will be 1 additional checkup about 30 days after your last dose of the investigational study medicine.
Long-Term Follow-up	The study staff will continue to check on you by phone and may ask you to come in for additional in-person visits and assessments.

How long you are treated will depend on how well your cancer responds and how well your body handles any side effects.

Screening Health Checks and Tests

You'll have health checks and tests to see whether the study is right for you and if you qualify for the study.

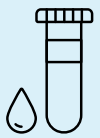
If you are able to be in the study, you'll start treatment within 4 weeks (28 days).



MEDICAL HISTORY

PHYSICAL EXAM

ECG HEART TEST

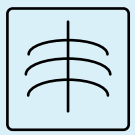


BLOOD TESTS

SALIVA TEST (OPTIONAL)*

QUALITY OF LIFE QUESTIONNAIRES

CT/MRI SCAN



BONE SCAN

OTHER ASSESSMENTS

*This test is optional and may not be available in your country.

Your health and well-being are the top priority.

Study Groups

You'll be placed by chance into either the investigational (test) group or the control group. You cannot choose your group. You will know which group you are in.

If you are in the control group, your study doctor will choose a standard treatment approved for treating prostate cancer. This may be chemotherapy or an androgen receptor pathway inhibitor.

Investigational (Test) Group 2 in 3 chance	**Control Group 1 in 3 chance**		
Xaluritamig	Cabazitaxel (chemotherapy)	OR	Abiraterone acetate or enzalutamide (androgen receptor pathway inhibitor)
1-hour infusion every week for 4 weeks, then every 2 weeks	1-hour infusion every 3 weeks		1 or more pills once a day

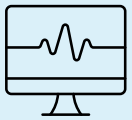
No matter which group you are in, you are equally valued in this study.

Visits During the Study Treatment Period

While you are taking your investigational study medicine, visits may include some or all of these health checks and tests.

HEALTH QUESTIONS

PHYSICAL EXAM

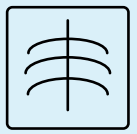


ECG HEART TEST

BLOOD TESTS

QUESTIONNAIRES

CT/MRI SCAN



BONE SCAN

EDIARY CHECK (ABIRATERONE ACETATE OR ENZALUTAMIDE GROUP ONLY)

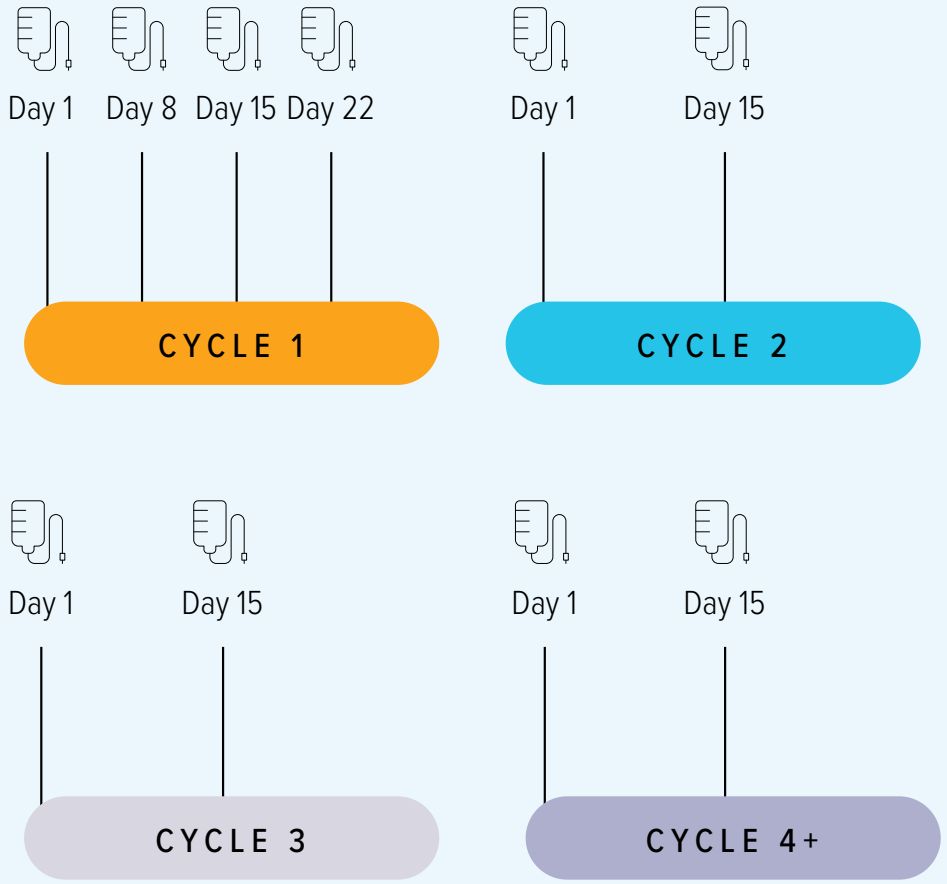
If you experience any health changes or side effects, call your study doctor right away. Do not wait for your next visit.

Schedule of Visits: Xaluritamig Group

The infusion schedule for xaluritamig is done in 4-week cycles.

In Cycle 1, there will be 4 weekly infusions, with the dose increasing each week.

After weekly infusions in Cycle 1, xaluritamig infusions will be given every 2 weeks.



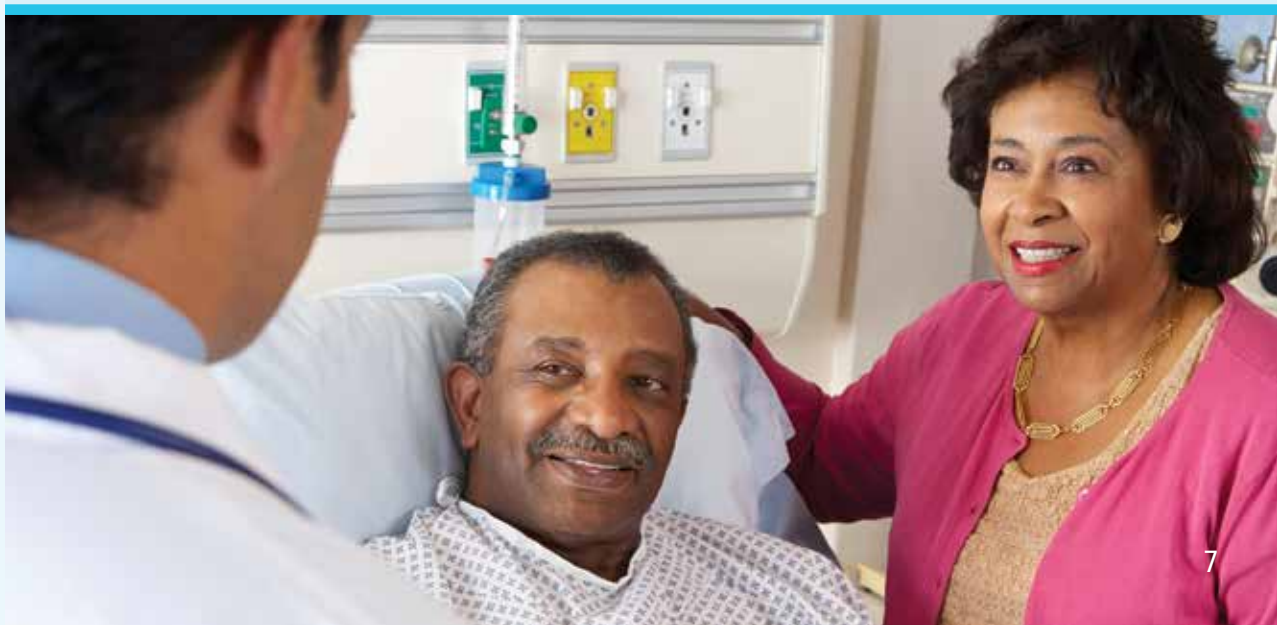
Schedule of Visits: Xaluritamig Group

On Cycle 1 Day 1, you will be hospitalized for your first xaluritamig infusion. You will need to stay at least 16 hours after the infusion for monitoring.

Your study doctor will check to make sure it is safe for you to leave the hospital. You and your caregiver will need to stay within 1 hour's distance from the hospital until 24 hours have passed after the infusion.

For the next 3 weekly infusions (Cycle 1 Days 8, 15, and 22), you'll receive the infusion as an outpatient. The study staff will monitor you for a minimum of 1 to 2 hours after the infusion. If your study doctor feels you need closer monitoring, you may be hospitalized.

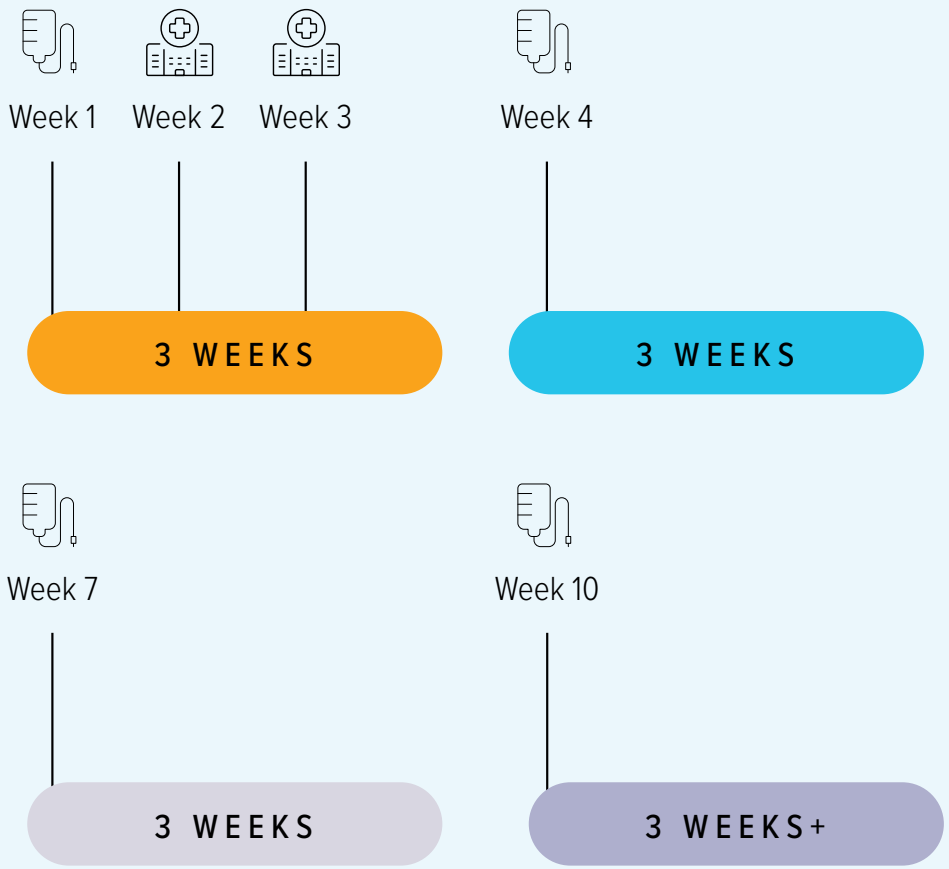
For Cycles 2 and beyond, there are no minimum monitoring requirements. Your study doctor will determine how long you need to be monitored after the infusion.



Schedule of Visits: Cabazitaxel Group

Cabazitaxel will be given as an infusion every 3 weeks. How long you stay on treatment will depend on how well your cancer responds and how well your body handles any side effects.

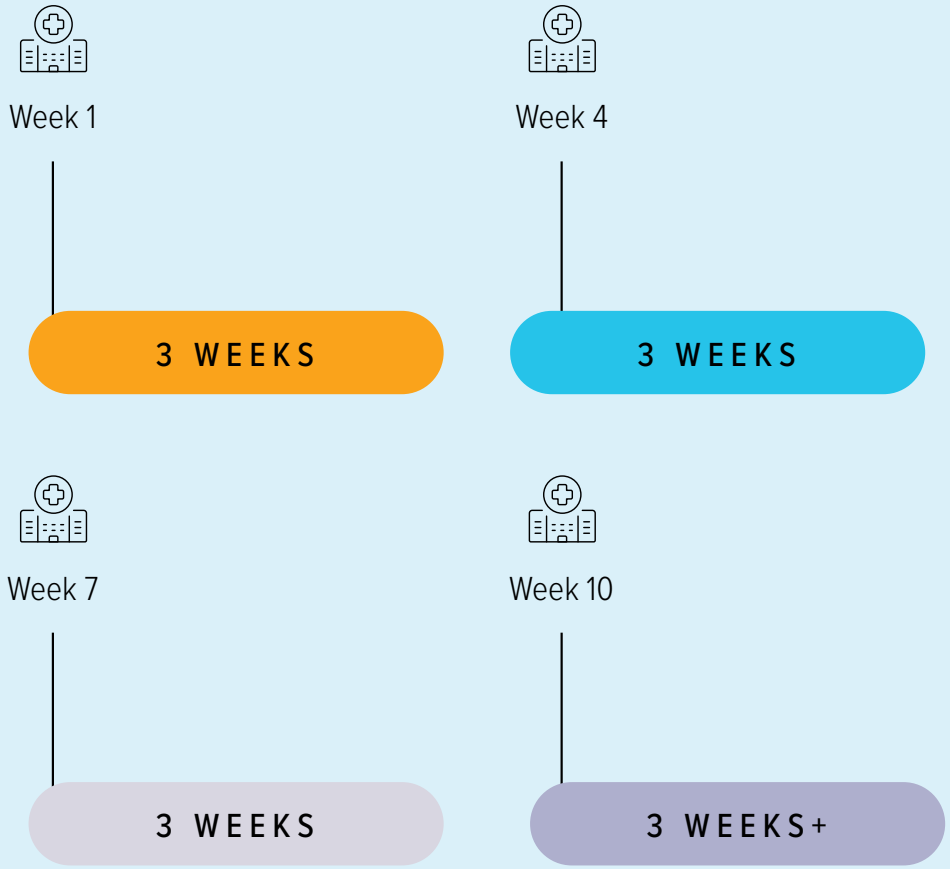
Cabazitaxel infusions will be given every 3 weeks.



Schedule of Visits: Abiraterone Acetate/ Enzalutamide Group

Abiraterone acetate or enzalutamide is an oral medicine you take daily at home. How long you stay on treatment will depend on how well your cancer responds and how well your body handles any side effects. You'll visit the study clinic every 3 weeks.

Abiraterone acetate/enzalutamide is taken every day with study visits every 3 weeks.



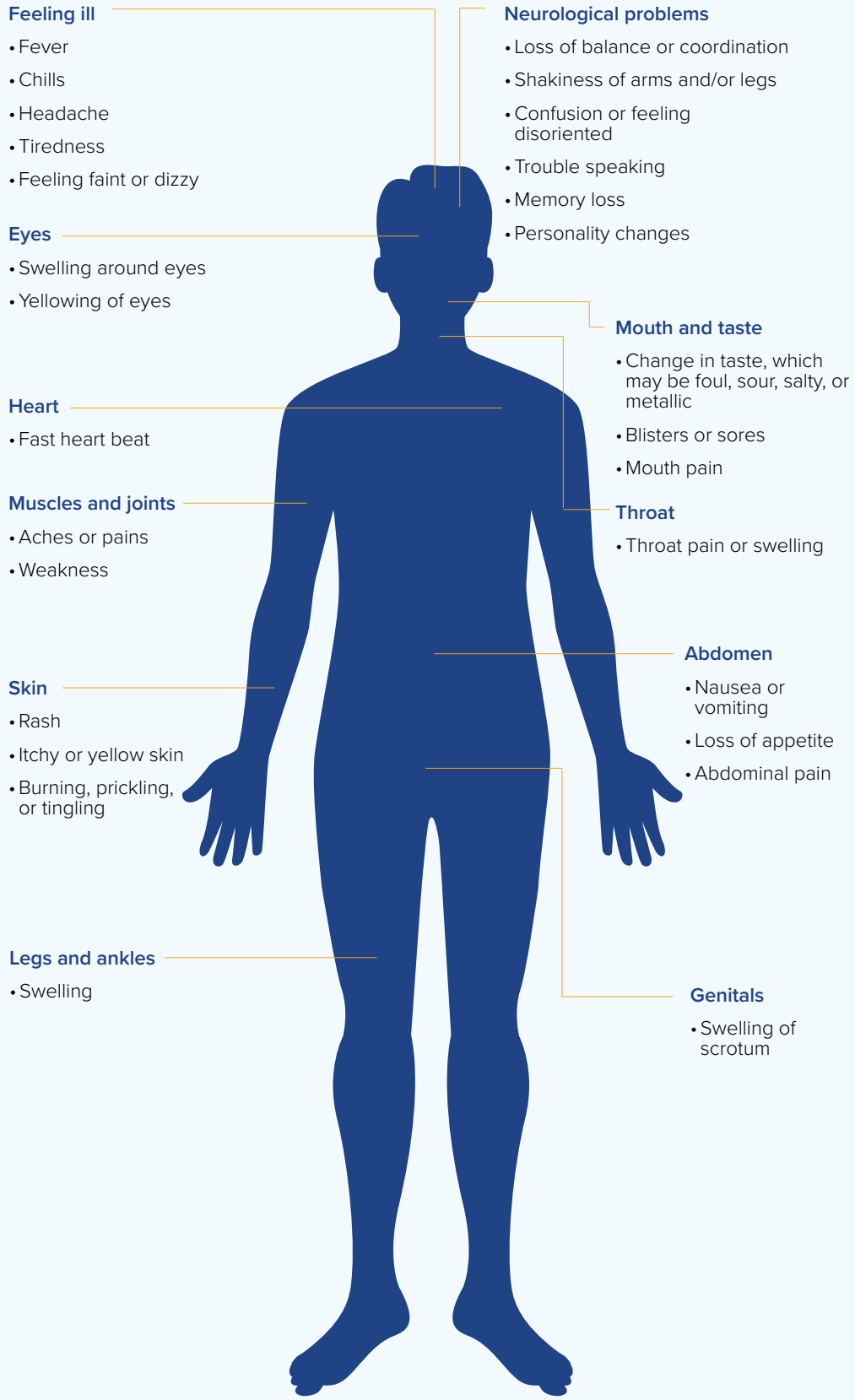
Side Effects

As with any medicine, there may be side effects from the investigational study medicine. It's important you know what to watch out for and report any symptoms or changes in how you feel to your study doctor right away. Prompt diagnosis and treatment can help side effects go away.

If you are in the xaluritamig group, it's important to be aware of certain side effects that can be caused by immunotherapy. The side effects result from dying cancer cells that release their contents into the blood and cause inflammation as your body aggressively attacks the cancer. For more information, please see your wallet card, safety flyer, and caregiver brochure.

Report any side effects to your study doctor.

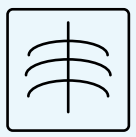
Please see your Informed Consent Form and talk to your study doctor to learn more about the possible side effects from your study medicine.



Imaging Scans

Imaging scans will be done to see how your cancer is responding to the investigational study medicine.

CT and MRI scans create images of the inside of the body so that your study doctor can monitor your cancer. CT scans use X-rays while MRI scans use magnetic waves. Your study doctor will determine which type of scan is best for you. A contrast agent may be used with either type of scan.



A bone scan is a nuclear scanning test that allows your study doctor to see problem spots in your bones. A small amount of radioactive substance will be injected into your bloodstream.

CT or MRI scans and bone scans will be done every 8 weeks for the first 48 weeks, then every 12 weeks until your cancer progresses.

Questionnaires and eDiary

The study includes questionnaires that will help your study doctor assess your condition. You may be asked to complete the questions on a hand-held device at the site or at home.

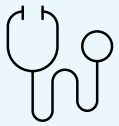
If you are taking pills at home, you'll be asked to record your doses in an electronic dosing diary (eDiary). Complete it at the same time every day.

Please follow the instructions for using electronic devices in this study. Answer questions to the best of your ability.

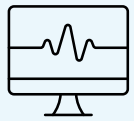
Your responses will help us understand your unique experience with prostate cancer, providing valuable information beyond tests and lab results. Your perspective and opinions matter, and may help doctors and patients in the future make the best possible treatment decisions.

Follow-up

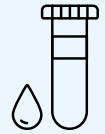
A Safety Follow-up Visit will take place about 30 days after you stop taking your investigational study medicine.



PHYSICAL EXAM



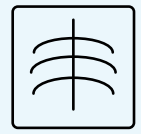
ECG HEART TEST (IF APPLICABLE)



BLOOD TESTS

QUALITY OF LIFE QUESTIONNAIRES

CT/MRI SCAN



BONE SCAN

After this visit, you will be in the Long-Term Follow-up Period. Every few months, the study staff will call you or ask you to come to the study clinic. They will ask about your health and any new cancer treatments, and they will possibly ask you to come for additional assessments. You may be asked to complete questionnaires by phone.

It is very important for the study team to have your correct contact information. The information collected during follow-up allows for a complete and accurate picture of your journey with prostate cancer.

Expectations and Responsibilities

For your health and safety, it's important to follow these instructions:

- Attend all clinic visits and complete all procedures.
- Notify the study staff as soon as possible if you are unable to attend a study visit.
- Tell the study staff if your contact information changes (address, phone number, email).
- Carry your emergency contact information card with you at all times.
- Tell your study doctor or the study staff about any changes in health even if you think they are not important.
- Tell the study doctor or the study staff about any medicines you are taking, have recently taken, or are planning to take, including herbal remedies, supplements, and medicines you take without a prescription.
- Bring this Understanding Your Study book and your study hand-held electronic device to every visit.

Leaving the Study

Participating in this study is 100% your choice, and you may choose to stop at any time.

If you want to leave the study, talk to your study doctor about your options, which include:

- Stopping the investigational study medicine but continuing with study tests, procedures, or follow-up.
- Stopping the investigational study medicine, tests, and procedures, but allowing the study staff to follow up with you by telephone to see how you are doing.
- Receiving no more contact related to the study.

By continuing to share information with your study doctor about how you are doing after you stop treatment, even if only by telephone contact, you will be helping other men with prostate cancer. The information we learn from you could help extend the lives of others.

Study Visit Tracker

Use the table to plan and track your appointments.

Date/Time	Notes

Study Visit Tracker (cont)

Date/Time	Notes

Glossary

Blood tests: Blood will be collected from your vein with a needle. The blood samples will be used for routine lab tests, to measure prostate-specific antigen (PSA) levels, to monitor your cancer, and possibly for additional testing to understand how your body handles the study medicine.

Bone scan: A bone scan is a nuclear scanning test to find certain problems in the bone which are affecting the bone's attempts to heal. A small amount of radioactive substance will need to be injected into your bloodstream to help see the bone scan results.

CT scan: A computed tomography (CT) scan is a specialized X-ray test that takes images of the body. You may need to have an injection of contrast material to make certain areas of your body show up more clearly in the images.

ECG heart test: An electrocardiogram (ECG) test is done to check how your heart is working. For this test, you will lie down and small sticky pads will be attached to your skin. The pads are connected by wires to a computer that will pick up signals every time your heart beats.

eDiary check: If you are in the abiraterone acetate/enzalutamide group, you will be asked to record information about each dose you take. The study staff will lend you a device. Complete the eDiary on the device at the same time every day. The study staff will check that you are completing it correctly. Bring the device to every study visit.

Health questions: At each visit, the study staff will ask about your health and any changes since the last visit. Tell them about any medical events you have had outside of the study, such as hospitalizations, doctor visits, procedures, and possible side effects. Report anything that is bothering you, even if you think it is not related to your cancer or the investigational study medicine.

Glossary (cont)

Medical history: The study doctor and/or study staff will ask you about your health now and in the past, including surgeries and treatment of your prostate cancer. It's ok if you cannot remember all the details. Information can be obtained from your medical records.

MRI scan: Magnetic resonance imaging (MRI) scans use strong magnetic fields and radio waves to produce an image of the inside of the body. There are no known harmful effects from the strong magnetic field used in MRI scans. MRI scans cannot be used for imaging if you have metal in your body, such as a pacemaker, implant, or shrapnel.

Physical exam: You'll have a routine physical examination at Screening and other study visits. This includes measuring your blood pressure, heart rate, breathing rate, temperature, and blood oxygen levels. Depending on your symptoms, your study doctor may check your reflexes and your nerve and muscle function.

Quality of life questionnaires: You'll be asked to complete questionnaires about your general health. The questionnaires will be completed on an electronic tablet at the study clinic or on a handheld device at home. The study staff will lend you a device to use at home.

Saliva test: You may be asked to participate in optional genetic research. If you agree, a sample of your saliva will be collected. Your DNA will be tested to help researchers study how genes affect prostate cancer or the way the investigational study medicine works.