

**INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY**

Sponsor / Study Title: Pfizer Inc / “A PHASE 1, OPEN-LABEL, RANDOMIZED, SINGLE-DOSE, 2-WAY CROSSOVER, PIVOTAL BIOEQUIVALENCE STUDY COMPARING 50-MG CHEWABLE DILANTIN® INFATABS® MANUFACTURED AT VEGA BAJA (PUERTO RICO) AND ASCOLI (ITALY) IN HEALTHY ADULT PARTICIPANTS UNDER FASTING CONDITIONS”

Protocol Number: A4121018

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INTRODUCTION

You are here today as a possible participant in a drug research study sponsored by Pfizer Inc. Taking part in this study is voluntary (your choice). The study staff will be available to answer questions before, during, and after the study.

The sponsoring company (the company paying for this study), Pfizer Inc, employs the study investigator conducting this study. Additional steps have been taken to manage the potential conflict of interest that this financial arrangement may create. Please speak with your study investigator if you have questions about this.

If you are not completely honest about your health history, you may be harmed by being in this study.

PURPOSE OF THE STUDY

Dilantin® Infatabs® will be referred to as the “study drug” in the rest of this consent document.

The purposes of this study are:

- To see how the study drug is tolerated, if there are significant side effects, and how healthy adult participants feel after taking single 50 mg oral (by mouth) doses
- To measure and compare the amount of study drug in your blood after taking a single 50 mg oral dose manufactured at 2 different sites
 - Pfizer Ascoli, Italy
 - Vega Baja, Puerto Rico

The study drug is an approved, marketed prescription medication used to prevent seizures in people with epilepsy. It may also be used to prevent and treat seizures that may occur in patients during or after brain surgery. Study drug will be given as a chewable tablet, but you will swallow it whole.

The current manufacturing site located in Puerto Rico is scheduled to be closed. This study is being done to support moving the manufacturing process to Italy.

ABOUT THE STUDY

Number of Study Participants

There will be about 34 people taking part in this study.

Length of Study for Participants

You will be in this study for about 44 days. This does not include the time between screening and dosing, which can be up to 28 days.

This study involves:

- 2 dosing periods with 2 separate admissions. Each dosing period has 4 overnight stays. You will not be able to leave the Clinical Research Unit (CRU) during that time
- 1 follow-up phone call about 4 weeks after the last dose

There will be at least 14 days between each dose.

Eligibility to Participate in Another Drug Study

Your eligibility to take part in another study depends on information from this study and previous studies. You may be eligible to receive a different study drug in another study as soon as 28 days after your last dose of study drug in this study. This is true for most drugs. Some drugs may stay in your body longer which means that you may have to wait longer before joining another study. These results are usually known after your last blood sample is tested. We will tell you this as soon as possible. We will also tell you if there is a longer than usual period of time that you should not be in another drug study after this one. Our goal is to keep you from doing anything that might potentially harm you.

Dosing Plan

The recommended daily dose of the study drug depends on individual patient needs. It is usually given 3 times a day. In this study, single doses will be given in each period.

One group of participants is planned.

Dosing is planned as follows:

STUDY TREATMENT SEQUENCE	NUMBER OF PARTICIPANTS	STUDY PERIOD	
		1	2
		STUDY DAY	
1	17	1	1
2	17	Study Treatment A	Study Treatment B
		Study Treatment B	Study Treatment A

Study Treatment A: Single 50 mg dose of study drug manufactured in Puerto Rico

Study Treatment B: Single 50 mg dose of study drug manufactured in Italy

Your study treatment sequence will be randomly assigned, like the flip of a coin.

Both you and the study staff will know which study treatment you are receiving.

There will be at least 14 days between each dose of study drug.

On Day 1 of each period, you will receive a single 50 mg dose of study drug from 1 of the manufacturing sites. You will fast overnight (nothing to eat or drink except water) for at least 10 hours before dosing.

Each dose will be taken with about 8 oz. (1 cup) of water. Each dose must be swallowed whole. We will check your mouth after each dose to make sure the study drug has been swallowed.

This is a research study. The study drug will be given to you only during the study and not after the study is over.

Study Process

Before any study procedures begin, you will be asked to read, sign, and date this consent document.

Screening

After you sign and date the consent document, you will begin screening. The purpose of the screening is to find out if you meet all of the requirements to take part in the study. Procedures that will be completed during the study (including screening) are described below. If you do not meet the requirements, you will not be able to take part in the study. The study investigator or study staff will explain why.

As part of screening, you must complete all of the items listed below:

- Give your race, age, gender, and ethnicity
- Give your medical history
 - You must review and confirm the information in your medical history questionnaire
- Give your drug, alcohol, and tobacco use history
- Give your past and current medication and treatment history. This includes any over-the-counter or prescription drugs, such as vitamins, dietary supplements, or herbal supplements, taken in the past 28 days
- Height and weight will be measured
- Vital signs (blood pressure and heart rate will be measured)
- Electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart
- Safety lab tests will be done from blood and urine samples. In addition:
 - Blood tests for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C
 - Blood test for HLA-B*1502
 - People who test positive for this gene may be at risk for a serious skin reaction with certain medications, including the study drug
 - Urine to test for drugs of abuse (illegal and prescription)
 - Females who have not had a period for at least 12 months in a row will have a blood hormone test to confirm menopause/child bearing potential
- The study investigator may decide to do an alcohol breath test
- The use of proper birth control will be reviewed (males only)

- Columbia Suicide Severity Rating Scale (C-SSRS), Lifetime will be done
 - This is an evaluation to see if you have had any suicidal thoughts or behaviors over the course of your lifetime
 - If you are having suicidal thoughts or feel in crisis, call the study investigator at the telephone number listed on the first page of this form, you can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by skilled, trained counselors. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services
- You will be asked “How do you feel?”

HIV and Hepatitis Testing

HIV, hepatitis B, and hepatitis C will be tested at screening. If anyone is exposed to your blood during the study, you will have these tests done again. If you have a positive test, you cannot be in or remain in the study.

HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). If your HIV test is positive, you will be told about the results.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

Having certain infections or positive test results may have to be reported to the State Department of Health. This includes results for HIV, hepatitis, and other infections. If you have any questions about what information is required to be reported, please ask the study investigator or study staff.

Although this testing is meant to be private, complete privacy cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

During the Study

The events below will take place throughout the study. If you would like to know when exactly these will take place, please ask the study staff.

- You will be asked about any updates to your medical history. This includes medication, drug, alcohol, and tobacco use
- A physical exam will be done when you check in to the CRU on Day -1 of Period 1
 - Physical exams may be done at other times during the study at the discretion of the study investigator
- Height and weight will be measured
- The use of proper birth control will be confirmed/reviewed (males only)
- Vital signs will be measured. Your oral temperature may also be measured
- ECGs will be collected
 - It may be necessary to shave or trim hair on your chest so that the patches for the ECGs will stick to your skin
 - Your chest may be marked with a pen to identify the correct areas for ECG patch placement
- You will be asked: “How do you feel?” each day
- An intravenous (IV) catheter may be placed in a vein in one of your arms for blood collection

- The study investigator may decide to do an alcohol breath test at any time
- You may be tested for COVID-19
 - COVID-19 testing will be done by collection of a swab sample
- Blood and urine samples will be collected at various times throughout the study
 - Safety Labs: The blood and urine samples will be used for safety labs including the following:
 - Urine samples to test for drugs of abuse
 - Any leftover serum or plasma (components of blood) from the safety lab samples may be stored and used to assess exploratory safety biomarkers or unexpected safety findings
 - Biomarkers are natural substances in your body that can be used to show how your body works
 - Samples to be used for this purpose will be kept for up to 1 year following completion of this study
 - Study Drug Levels: Blood samples will also be used to measure the levels of study drug
 - As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples may also be used for the following:
 - Metabolite identification (by-products or end products of a drug produced as the body processes a drug)
 - Evaluate safety aspects related to any concerns during or after the study
 - Check the laboratory test which measures the study drug
 - Other internal exploratory purposes
 - Retained Research Sample: A samples of your blood will be collected, stored, and used to learn more about the study drug
 - Biological substances in your samples, including your genes, may be studied
 - These samples may be kept by Pfizer for as long as the samples are useful for scientific research. This may be for many years without a specified time limit
- The C-SSRS (since last assessment) will be completed at various times
- You will receive a follow-up phone call about 4 weeks after the last dose of study drug
- For safety reasons we may add procedures at any time during the study to check on your health status
- You will be asked, “How do you feel?”

Blood Draws

Blood samples will be taken by individual needlesticks, or by a catheter. A catheter is a small tube that is placed in a vein in your arm to take blood when required. Catheters are used when ordered by the study investigator or when required by the study plan. They are not used at the request of the participant.

There will be about 33 blood draws. The total amount of blood drawn during the study will be about 170 mL. This is equal to about a little more than 5½ oz., or about a little less ¾ of a cup. For comparison, the standard blood donation is about 16 oz. (2 cups), once in any 56-day period.

As with all studies with blood draws, rest and good eating habits are recommended.

Possible Risks and Discomforts

Taking part in this study has some risks. The study drug or procedure(s) may make you feel unwell or uncomfortable or could harm you. If you do not understand what any of the side effects described below mean, please let us know. The study investigator or study staff will explain them to you.

It is important that you report all side effects that you have as soon as they occur. This is regardless of whether or not you believe they are caused by the study drug or your participation in this study.

If you are not honest about any side effects that you have during the study, you may be harmed by staying in the study.

Study Drug Risks

Risks or discomforts that may be caused by the study drug include:

- Thoughts or actions that may become worse including:
 - Thoughts about suicide or dying
 - Attempts to commit suicide
 - New or worse depression
 - New or worse anxiety
 - Feeling agitated or restless
 - Panic attacks
 - Trouble sleeping (insomnia)
 - New or worse irritability
 - Acting aggressively
 - Being angry or violent
 - Acting on dangerous impulses
 - Extreme increase in activity and talking (mania)
 - Other unusual changes in behavior or mood
- Difficulty falling or staying asleep
- Uncontrollable eye movements
- Abnormal body movements
- Sleepiness
- Nervousness
- Muscle twitches
- Jerky movements or tremors
- Decreased or abnormal muscle tone
- Abnormal sensations or funny feelings in the hands or legs
- Loss of coordination
- Confusion or slowed thinking
- Slurred speech
- Dizziness
- Headache
- Altered taste or a metallic taste
- Nausea
- Vomiting
- Constipation
- Unwanted hair growth
- Coarsening of facial features
- Enlargement of lips
- Overgrowth of gums
- Painful sores in the mouth or eyes
- Pain or curving of the penis

The study drug can cause the following serious side effects:

- Slowed heart rate
- Heart stop beating
- Swollen glands
- Sore throat that does not go away or comes and goes
- Fever
- Frequent infections or infections that do not go away
- Rash
- Joint pain or muscle pain
- Yellowing of the skin or eyes
- Pain in the upper right part of the stomach, which may be caused by damage to the liver
- Excessive tiredness or severe fatigue or weakness
- Unusual bruising or bleeding
- Loss of appetite
- Flu-like symptoms
- Slowed motor skills
- Increased blood glucose (sugar) levels in healthy and diabetic patients

The study drug may also cause serious skin side effects that Asians are more prone to including:

- Death
- Rashes
- Hives
- Swelling of the face, eyes, lips, or tongue
- Trouble swallowing or breathing
- Painful blistering of the skin and mucous membranes, including the eyes

In addition, the study drug may cause damage to the liver or blood disorders that may lead to death and:

- Weakness of bones or bones breaking
- Immune disorders including damage to small arteries
- Lupus erythematosus (an autoimmune disease in which the immune system attacks its own tissue) that can cause damage to:
 - Joints
 - Skin
 - Kidneys
 - Blood cells
 - Heart and/or lungs
 - Damage to circulating blood proteins that protect against infections
 - Some cancers

When study drug doses are too high, confusion may result including:

- Delirium (temporary mental state that may include confusion, anxiety, incoherent speech and hallucinations)
- Psychosis (a collection of symptoms that affect the mind where there has been some loss of contact with reality)
- Brain malfunction (encephalopathy)

- Rarely, permanent loss of lower brain function (irreversible cerebellar dysfunction)

Until you know how the study drug will affect you, you should use caution by:

- Avoiding stairs
- Not driving a car
- Not swimming or bathing in a tub
- Not working with machinery or at heights

Other Risks

The study drug is a marketed drug, but all of its side effects are not known. There may be rare and unknown side effects. These include reactions that may be life-threatening.

All drugs have a potential risk of an allergic reaction. If an allergic reaction is not treated quickly, it could become life-threatening. You should get medical help right away (by calling 911 or immediately going to an emergency room) if you think you have any of the following symptoms:

- Trouble breathing
- Wheezing
- Difficulty swallowing
- Swelling of the face, mouth, lips, gums, tongue, or neck

Other allergic reactions may include:

- Itchiness
- Rash
- Hives
- Blisters
- Palpitations (racing heart)
- Chest discomfort/tightness
- Muscle pains/stiffness

At times, the following may also be symptoms of an allergic reaction:

- Diarrhea
- Nausea
- Vomiting
- Abdominal pain

If a significant side effect occurs, the following may be done:

- Tests or treatment may be given as needed for your safety
- Depending on how severe your symptoms are, you may be seen by outside medical providers or a hospital. This would be for further evaluation and/or treatment
- The study investigator may notify your emergency contact as appropriate in the event of an emergency while you are taking part in the study

Additional Risks or Discomforts

Testing of DNA and/or RNA (deoxyribonucleic acid and/or ribonucleic acid)

Genes are pieces of DNA that give coded instructions for the body. Parts of the code are passed down from parents to their children.

The genes in your samples may be studied. This may include analyzing all of your genetic information. This is called “whole genome sequencing.” While collection of genetic information does not expose you to physical risk, collection of such information may result in a loss of your privacy if your genetic information is lost or stolen.

There is a very small chance that your genetic information could be misused by people not involved with the research, including to discriminate against you. However, steps are in place to prevent a particular result from being linked to you and to prevent unauthorized people from even knowing genetic research was done.

U.S. federal law prohibits discrimination in health insurance coverage and employment based on a person’s genetic data. However, U.S. federal law does not protect against discrimination when you are applying for:

- Life insurance
- Long term care insurance
- Disability insurance

You should talk to your regular physician or genetic counselor about the potential for genetic discrimination.

The results of tests on your sample(s) will not be given to:

- You
- The study investigator
- Any insurance company
- Your employer
- Your family
- Any physician who treats you

Blood Samples and IV Catheters (if used)

Possible side effects of having your blood drawn or an IV catheter inserted include:

- Bleeding at the site of the needle puncture
- Bruising
- Feeling faint
- Rarely, infection or blood clot
- Redness of the vein
- Inflammation of the vein
- Swelling
- Pain
- Nerve damage

- Vein irritation
- Local swelling
- Scarring

If you feel faint, tell one of the study staff immediately.

COVID-19 Testing

Collection of a swab sample may cause:

- Discomfort
- Sneezing
- Your eyes to water
- Gagging
- Possible nosebleed

There is a risk of COVID-19 infection when you are in close contact with the study staff or other participants during the study. However, safety procedures will be followed during the study to minimize the risk of COVID-19 transmission.

If you test positive for COVID-19, you cannot be in the study. If you have a positive result, it may be reported to the Connecticut State Department of Health and your local department of health. If you have any questions about what information may be reported, please ask the study investigator or study staff.

ECG

Possible side effects from having an ECG include:

- Irritation or rash from the adhesive on the patches

A rash may result in a long-lasting discoloration of your skin. If it is necessary to shave the area where the patches need to be, irritation from shaving may occur.

Fasting

Fasting could cause symptoms such as:

- Dizziness
- Headache
- Stomach discomfort
- Fainting
- Hypoglycemia (low blood sugar)

Use of Birth Control

Females unable to have children

Women in this study should not be able to get pregnant or be breastfeeding. You may take part in this study provided that you meet one of the following:

- Have had your uterus removed (documented)
- Have had both fallopian tubes removed (documented)
- Have had both ovaries removed (documented)
- Have not had a period for at least 12 months in a row with no other medical cause. You must have a blood hormone level confirming that you cannot get pregnant

Females permanently unable to have children due to a medical cause not listed above may be allowed to participate in the study at the discretion of the study investigator.

Males

You must agree to the following during the study and for at least 14 days before the first dose through 28 days after the last dose of study drug:

- Refrain from donating sperm

PLUS either

- Be abstinent from heterosexual intercourse as your preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent

OR

Must agree to use birth control/barrier as detailed below:

- Agree to use a male condom and should also be advised of the benefit for a female partner to use a highly effective method of birth control as a condom may break or leak when having sexual intercourse with a female able to have children who is not currently pregnant
- In addition to male condom use, a highly effective method of birth control may be considered in female partners able to have children of male participants

Highly effective methods of birth control (for female partners of male participants) include:

- Implantable progestogen-only hormone birth control
- Intrauterine device (IUD)
- Intrauterine hormone-releasing system
- Bilateral tubal occlusion (both tubes blocked) which includes bilateral tubal ligation (both tubes tied)
- Partner has a vasectomy (absence of sperm confirmed)
- Sexual abstinence – defined as refraining from heterosexual intercourse and is the preferred and usual lifestyle of the participant

Pregnancy-Related Risks

The study drug has potential pregnancy risks including harm to an unborn child. If it is taken during pregnancy, the baby is at risk for serious birth defects and is also at risk for bleeding problems right after birth. There have been several reported cases of malignancies (cancers), including brain tumors, in children whose mothers received the study drug during pregnancy. The study drug can also pass into the breast milk

The effects of the study drug on the following are not known and may involve unforeseeable risks:

- Sperm
- Breastfeeding child

Even if you use birth control during the study, there is a chance your partner could become pregnant. If your partner is pregnant or becomes pregnant during the study, the study drug or procedure may involve unforeseeable risks to the unborn child. A pregnancy test is not always right, especially in the early stages of pregnancy.

You cannot participate in this study if:

- You are a man whose female partner is currently pregnant or planning to become pregnant

If you want to stop your required birth control during the study, you should tell the study investigator **immediately**. You will be taken out of the study if you stop using birth control.

Pregnancy Follow-Up

If you or your female partner become pregnant during the study or within 28 days after your last dose of study drug, please:

- Tell the study investigator **right away**
- Tell the health care provider(s) taking care of you or your partner during the pregnancy that you took part in this study

The study investigator will ask if you, your female partner or their health care provider(s) are willing to provide updates on the progress of the pregnancy and its outcome. This information will be collected for safety monitoring follow-up.

PARTICIPANT RESPONSIBILITIES AND RIGHTS

Participant Responsibilities

- You must tell the study investigator if you previously took part in this study, have been in any other study in the past year, or are currently involved in any other study. This includes being in the follow-up visit period of another study
- You must agree to the scheduled visits, the study plan, lab tests, study procedures, and diet and activity restrictions (details listed later in this document)
- You must not have any significant medical or psychiatric condition including recent (within the past year) or active suicidal thoughts or behaviors, as determined by the study investigator, that may put your safety at risk or could have an effect on the study results
 - You must not have previous history of suicidal behaviors in the past 5 years

- You must not have any lifetime history of serious suicidal thoughts or behaviors or recurrent suicidal behavior
- You must not have porphyria or a family history of porphyria
 - Porphyria is a group of rare disorders with a buildup of natural chemicals (porphyrins) in the body
- You must not be shown to carry or be positive for the HLA B*1502 allele (a version of a specific gene)
- You may be asked to provide documentation of your childbearing status
- You must not have a history of hypersensitivity to the study drug or its inactive ingredients, or other similar anti-seizure medications
- You must not have had an illness with a fever within 5 days before the first dose of study drug
- You must not take any medications (including over-the-counter medications, such as medications for cold or allergies, antacids, herbal supplements, minerals, or vitamins) within 7 days before the first dose or at any time during the study
 - Before taking any drugs other than the study drugs, you must call the CRU for approval. It must first be approved by the study investigator
 - You must tell the study staff about any drugs taken during the study
- You must not take any investigational product (drug or vaccine) within 30 days or 5 half-lives (drug dependent) before the first dose of study drug or at any time during the study
- You must not have a history of excessive alcohol use or binge drinking and/or other illicit drug use within 6 months before screening
 - Binge drinking is defined as a pattern of 5 (male) or 4 (female) or more alcoholic drinks in about 2 hours
 - You should not drink more than 14 alcoholic drinks a week
 - A drink is defined as 8 oz. (1 cup) of beer, 3 oz. (6 tablespoons) of wine, or 1 oz. (2 tablespoons) of hard liquor
- You must not be using/taking any drugs of abuse (such as cocaine, opioids, etc.). Urine tests will be done to check for such drugs.
 - If a test is positive, you will not be allowed in the study
 - Urine collection may be monitored by a staff member of the same sex
 - You have the right to refuse to be monitored, but may be disqualified from the study
 - While in this study, please do not eat anything that contains poppy seeds. They may cause a positive drug test
- You must not use tobacco or nicotine-containing products in excess of the equivalent of 5 cigarettes per day
- You must not use tobacco- or nicotine-containing products for 24 hours before the first dose and while confined to the CRU
- Please let us know if you or a relative are a staff member of Pfizer. If so, you may not take part in this study if you or your relative are supervised by the study investigator or are directly involved with the study

Activity Restrictions

- You will need to stay in the CRU for 4 days starting with each check-in
 - You may need to stay in the CRU longer if you experience a longer study drug effect. This is for safety reasons
 - The study investigator or study staff will decide when it is safe for you to leave the CRU
- You must not do any strenuous exercise for at least 48 hours before each blood draw for safety labs. Examples of this include heavy lifting, weight training, or aerobics
 - Walking at a normal pace is allowed

- You may be asked to wear a device (similar to a wristwatch) that can be used to alert study staff in case of an emergency
- You cannot lie down for 4 hours after each dosing unless needed for study procedures
- You must not donate blood during the study

Diet Restrictions

- You must not eat or drink anything except water for at least 4 hours before each safety laboratory test and 10 hours before the collection of pre-dose study drug blood levels
 - Except for 1 hour before and 1 hour after dosing you may drink water freely
- You must not eat or drink anything with, red wine for 7 days before the first dose. Red wine is not allowed through the collection of the last blood sample for study drug
- You must not eat or drink anything with alcohol for 24 hours (or as stated above for red wine) before each check-in. Alcohol is not allowed through the collection of the last blood sample for study drug in each period
 - Study staff may check your breath for alcohol. If alcohol is found, you will not be allowed in the study
- You must not eat or drink anything with caffeine for 24 hours before each dosing. Caffeine is not allowed through the collection of the last blood sample for study drug in each period
 - Caffeine can be found in different foods and drinks. Some examples include chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®
- You must not eat or drink anything that has grapefruit or grapefruit-related citrus fruits for 7 days before the first dose. These are not allowed through collection of the last blood sample for study drug
 - Examples of citrus fruits that are not allowed are Seville oranges and pomelos
 - Fruit juices and smoothies may also contain grapefruit or these citrus fruits
- Lunch will be provided about 4 hours after dosing
- Dinner will be provided about 9 - 10 hours after dosing
- An evening snack may be allowed
- Meals (breakfast, lunch, dinner, and evening snack) will be provided at appropriate times on all other study days

Possible Benefits of the Study

This study is for research purposes only. There will be no direct benefit to you from taking part. However, information learned from this study may benefit other people in the future.

Alternatives to Participating in this Study

This study is for research purposes only. Your alternative is to not take part in the study.

Confidentiality

This section describes how we will collect, use, and share your personal information.

What personal information may we collect about you during this study?

The study staff will collect information about you. This information may include:

- **Information that directly identifies you** such as your name, address, telephone number, date of birth, and Social Security Number
- **Personal information** such as your medical history, data from this study (including study results from tests and procedures), demographics (for example, age and gender) and other sensitive information that is needed for this study such as race, ethnicity, sexuality, substance use disorders, mental health disorders, diagnoses and treatment, and HIV status
- **Data from testing and analysis of biological samples** (such as blood or urine). This may also include genetic information
- **Data captured from electronic devices** if you complete the consent process using the eConsent tablet. This information may include:
 - The length of time it takes you to complete the consent process
 - The number of times you scroll between pages or click hyperlinked items
 - Your electronic signature

Who will use my personal information, how will they use it, and where will it be stored?

Any personal information collected during this study will be stored by the study staff at the CRU. The study staff must keep your personal information confidential. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Your personal information will be accessed by:

- The study investigator and other study staff members
- Pfizer and its representatives (including its affiliated companies)
- People or organizations providing services for, or collaborating with, Pfizer
- Government or regulatory authorities (including the U.S. FDA and authorities in other countries)
- Advarra Institutional Review Board (IRB), the IRB that reviewed this study and any other committees responsible for overseeing the research

The individuals and groups listed above will use your personal information to conduct this study, and to comply with legal or regulatory requirements, including to:

- Determine if you are eligible for this study
- Provide you with reimbursement, as allowed by the study, for your time, effort, and certain expenses related to your participation
- Verify that the study is conducted correctly and that study data are accurate
- Answer questions from IRB(s) or government or regulatory agencies
- Assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any eConsent module used for the study and your comprehension of the eConsent process
- Contact you during and after the study (if necessary)
- Follow-up on your health status, including using publicly available sources (for example, public databases or the internet) should the study staff be unable to contact you using information held on file
- Protect your vital interests such as providing information to an emergency department of a hospital if you are being treated
- Answer your data protection requests (if any)

If you provide someone else's personal information, you should make them aware that you have provided the information to us. Examples of this information include:

- Emergency contact information
- Details of family medical history

We will only use such information in keeping with this informed consent and applicable law.

Text Messages

If you agree, the study staff, or a company working on behalf of Pfizer, may send text messages using an automated system to remind you of:

- Upcoming study appointments
- Other study-related information
 - Standard text messaging rates apply to all text messages. Message rates differ from carrier to carrier. Please contact your wireless phone provider to ask about the details of your plan
 - The contact information you have provided will be used for the sole purpose of communicating with you about the study
 - The text messages received through this program may appear on your mobile phone screen as soon as they are received. This may happen even when the phone is locked. These messages could be seen and read by others who are near your phone when the message is received
 - To discontinue receiving text messages, please contact the Pfizer New Haven CRU at 800-254-6398

You will be asked to make your choice at the end of this document.

What happens to my personal information that is sent outside the CRU?

Before the study staff transfers your personal information outside the CRU, the study staff will:

- Replace your name with a unique code
- Remove information that directly identifies you

This is called "**Coded Information.**" The link between the code and your personal information will be kept confidential by the study staff.

Your Coded Information will be used by the following:

- Pfizer and its representatives (including its affiliated companies)
- People and/or organizations providing services to or collaborating with Pfizer
- Any organization that obtains all or part of Pfizer's business or the rights to the product under study
- Other researchers
- Advarra IRB
- Government or regulatory authorities

The above parties may use your coded information for the following purposes:

- **Conducting the study**, including:
 - Examining your response to the study drug
 - Understanding the study and the study results and learning more about the study drug
 - Assessing the safety of the study drug
- **Complying with legal and regulatory duties** such as:
 - Ensuring the study is conducted according to good clinical practice
 - Making required disclosures to IRB(s), or government or regulatory authorities
 - Seeking approval from government or regulatory authorities to market the study drug
 - It is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research
 - Sharing study data with other researchers not affiliated with the study staff or Pfizer. This includes through publication on the internet or other ways. However, information that could directly identify you will not be made available to other researchers
- **Publishing summaries of the study results:**
 - In medical journals
 - On the internet
 - At educational meetings of other researchers

You will not be directly identified in any publication or report of the study. But some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that genetic and other information from the study that does not directly identify you be made available to other researchers for further research projects.

- **Improving the quality, design, and safety** of this study and other research studies

How are my biological samples handled?

If biological samples are taken during the study, those samples will be handled in the same way as your Coded Information. All samples will be treated as required by law.

Can my coded information and biological samples be used for other research?

Yes. Pfizer may use your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of this study, to support and advance other scientific research projects, including improving the quality, design, and safety of other research studies, research supporting public health aims, and developing medicines, vaccines, diagnostic products, and tools.

At this time, we do not know the specific details of these future research projects; however, your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, could be used in combination with data from other sources, not related to you or this study. Reasonable safeguards will be used to protect your Coded Information, biological samples, image and/or audio/video recordings used in any future research and may include:

- Limiting access to individuals bound by duties of confidentiality
- Taking steps to minimize the risk that you could be re-identified
- Obtaining approval of institutional review boards

Furthermore, if your Coded Information, biological samples, images and/or audio/video recordings, if collected as part of the study, have identifiers removed such that they can no longer be readily identified with you, they may be used for future research purposes.

Study-Related Injuries

You will also receive a card with information about this study. This information includes:

- The name or number of the study
- The CRU 24-hour phone number

You should keep this card with you in case you have a medical emergency. You can give this card to any healthcare provider if they need more information about the research study to provide the best treatment for you.

If you experience a research injury, the CRU will arrange for medical treatment at no cost to you. Pfizer will cover the costs of this treatment. A research injury is any physical injury or illness caused by being in this study. There are no plans to offer you payment for such things as:

- Lost wages
- Expenses other than medical care
- Pain and suffering

To help avoid injury, it is very important to follow all study directions. You can get more information about medical treatment for research injuries from the study investigator or study staff.

You must call the study investigator immediately if you experience a research injury. The number is listed on the first page of this consent document. A 24-hour answering service is available.

If you are treated for a research injury that is paid for by Pfizer, Pfizer or its representative will collect your:

- Medicare Health Insurance Claim Number or,
- Social Security Number

This is to determine your Medicare status. If you are a Medicare beneficiary, Pfizer will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services (CMS). This is in keeping with CMS reporting requirements. Pfizer will not use this information for any other purpose.

Legal Rights

You will not lose any of your legal rights by signing and dating this consent document.

Whom To Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of a research-related injury;
- Payment or compensation for being in the study, if any;

- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedure;

Please contact the study investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By mail:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00079421.

Link to Additional Information

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.

Payment for Taking Part in the Study

The amount of payment is based on a number of things including the length of the study. Travel pay for this study has been included in the payment.

You may be eligible for a travel and hotel bonus payment:

- \$0.20/mile per one-way trip to or from the CRU based on your home address
- For participants traveling long distances, a 1-night hotel stipend (\$150.00) for the night prior to your visit(s), if needed

All payments will be in U.S. dollars. Compensation may be provided on a loadable debit card or by paper check. Pfizer New Haven CRU reserves the right to determine method of payment.

U.S. Citizens: Payments may be considered taxable income. If you receive \$600.00 or more in taxable payments within a calendar year, your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1099). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 24% and receive a tax form (1099). If you prefer to

not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

Non-U.S. Citizens: Payments may be considered taxable income. Your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1042-S). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 30% and receive a tax form (1042-S). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

If at any time you test positive for drugs of abuse, you will not be paid for your visit. Further, if you test positive for drugs of abuse:

- You will not be allowed to be in this study
- You may not be allowed to be in any Pfizer New Haven CRU future studies

Screening Payments

The screening payment is listed below. You will receive this payment within 2 weeks of screening. If you leave the screening early, you will not be paid.

Screening Visit at CRU	\$175.00
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Additional payments are made if we ask you to return to the CRU to repeat any screening tests (\$100.00 per visit).

Study Payments

The payment for completing the entire study is listed below. Please be aware that:

- If you do not follow instructions (including those listed in the New Haven CRU House Rules), if you are late for blood draws, or if you miss procedures, your payment may be reduced. You will be paid a prorated amount based on the extent of your participation if:
 - You are not able to complete the study
 - You choose to leave the study
 - You are withdrawn from the study early by the study investigator for non-safety-related issues
 - The study is stopped early
 - You are qualified but not chosen to participate
- You will not be given the study completion bonus if you drop out of the study early
- Partial payments are planned during the study. Details will be provided at screening
- A final payment will be provided to you within 2 weeks of finishing the study
- Pfizer may use information resulting from the study or samples collected in the study to develop products or processes. Pfizer may make a profit from these. There are no plans to pay you or provide you with any products developed from this research. Pfizer will own all products or processes that are developed using information or samples from the study

The decision to admit you into the study is based upon results of pre-study requirements. No one is guaranteed a place in the study until the first dose is complete. Enough numbers of participants will be brought in to be sure we fill the study.

STUDY PARTICIPANTS			
Type of Activity	Payment per Activity	Total Number (Days/Weeks)	Total
Overnight Stay	\$225.00	8	\$1,800.00
Washout between periods	\$15.00	10	\$150.00
Duration of Follow-Up Period (Discharge to Follow-Up Call)	\$15.00	26	\$390.00
Follow Up Phone Call	\$100.00	1	\$100.00
Completion Bonus	\$720.00		\$720.00
Total Payment Part			\$3,160.00

BACK-UP PARTICIPANTS	
Type of Activity	Payment per Activity
Overnight Stay	\$300.00
Daytime Stay	\$190.00

Additional payments are made if we ask you to return to the CRU or to outside medical providers for additional tests (\$250.00 per visit). During times that you need to stay in the CRU, you will not be paid more for repeat or added tests.

Costs for Study Participants

The study drug, study-related procedures, and study visits will be provided at no cost to you.

Your Decision to be in the Study

Taking part in this study is voluntary. You cannot be forced to be in this study. You may leave the study at any time without penalty or loss of any benefits. Your future medical care will not be affected. The study investigator, Pfizer Inc, or the FDA may take you out of the study without your permission at any time for the following reasons:

- You do not follow the instructions of the study investigator
- We find out you should not be in the study
- The study is stopped
- The study becomes harmful to your health
- You do not follow the New Haven CRU House Rules

If you leave the study or if you are taken out of the study for any reason, you may be asked to return to the CRU for a final visit. You may have some end of study tests at this visit. This is to make sure it is safe for you to leave the study. The data collected to the point of your withdrawal remains part of the study database and may not be removed.

If you are withdrawn from the study, or decide to stop the study, you can ask that any unused samples that were collected be destroyed. If you would like to have this done, please contact the study investigator. However, your samples may not be able to be destroyed because:

- They may no longer be traceable to you
- They may have already been used
- They may have been given to a third party

New Findings

If there is new information about the safety of the study drug or changes in the study tests, we will tell you in a timely manner. You can then decide if you still want to be in the study.

AGREEMENT TO BE IN THE STUDY

PIMS # _____

This consent document contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent document, ask one of the study staff.

By checking each of the following, you are agreeing that the statements below are true: Please
Check

A.	This consent document is written in a language I understand	
B.	I understand the information in this consent document	
C.	I have been given enough time to ask questions and talk about the study	
D.	All of my questions have been answered completely	
E.	I have received enough information about the study	
F.	I agree that I was not pressured by the study investigator or the study staff to be in this study	
G.	I know that I can leave the study at any time without giving a reason and without affecting my health care	
H.	I know that my health records from this study may be reviewed by Pfizer Inc and by government officials	
I.	I know that I cannot be in another study while I am in this study	
J.	I have received the HIV, Hepatitis A, B, and C pamphlets and reviewed the information in them	

IF YOU DID NOT CHECK THE BOX NEXT TO ANY OF THE ABOVE QUESTIONS OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS, YOU SHOULD NOT SIGN AND DATE THIS CONSENT DOCUMENT

Text Messages:

Please check the box next to your choice.

Yes, I agree that the study staff may send me text messages as described in the Confidentiality section

No, I do NOT agree that the study staff may send me text messages as described in the Confidentiality section

- You will get a copy of this signed and dated Informed Consent Document (ICD) for your records
- You agree to participate in this study
- It is your responsibility to tell the study investigator about all changes in your physical or mental health during the study

Printed Name of Adult Study Participant (Name as appears on U.S./State Government-Issued ID)

Signature of Adult Study Participant

Date

Printed Name or Initials of Person Explaining Informed Consent

Signature of Person Explaining Informed Consent

Date