WELCOME LETTER

Dear Sir or Madam,

Thank you for considering participating in this research study (also known as a clinical study). You are provided with a separate consent document to help you make your decision. The consent document explains **what you can expect to happen during this study**.

Your participation in this study is **completely voluntary (your choice)**. Take as long as you need to make your decision. You can choose to take part in the study now, and then change your mind at any time. Please keep in mind that even if you choose to participate, it may turn out that you do not meet the study's entry requirements.

We encourage you **to talk with your family, caregivers, doctors, and study team** about taking part in this study and whether it is right for you. The study team will answer any questions you have about the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

If you choose to participate in this study, **you will be asked to sign the consent document** prior to taking part in the study to let the study team know your decision.

You will receive a signed copy of the consent document for your records. Please keep the consent document for your reference.

We appreciate that you are thinking of taking part in this study.

Sincerely,

_____

Study Doctor

TO BE PRINTED ON HOSPITAL HEADED PAPER

MAIN PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title:	A Phase 1/2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single Escalating Doses of PF-07868489 in Healthy Adult Participants and, Additionally, Clinical Activity of Repeat Doses in Participants with Pulmonary Arterial Hypertension
Protocol Number:	**C5001001**
IRAS Number:	**[IRAS ID]**
Name of company sponsoring the study:	**Pfizer Inc.**
Study Doctor:	**<Insert Doctor Name>**
Study Site Number:	**<Insert Site Number>**
Participant Number:	
Contact Person:	**<Insert site contact person>**
Site Address:	**<Insert Site Address>**
Phone Number (Normal Business Hours)	**<Insert Site Daytime Number>**
Phone Number (24 hours or Emergency Phone)	**<Insert Emergency Number>**
Patient Rights Advocate:	**<Insert PALS or equivalent contact details>**

Contents

Each and every person plays a powerful role in clinical research

Every approved medicine and vaccine we have today was tried and tested in a clinical study. With your participation, and the help of countless others, we are working toward developing therapies to improve the lives of people worldwide. From all of us dedicated to that goal at Pfizer, thank you for your interest in this research. We could not do it without you.

Brief Summary of Study

You are being invited to take part in a study that is sponsored by Pfizer (the "**Sponsor**"). The Sponsor is providing funding to [the study doctor/institution] to conduct the study.

This study is being conducted in 2 parts [Part A & Part B]. In Part A, the study drug was given to healthy adult people and was generally well tolerated, without any safety issues being identified. You are being invited to participate in Part B of this study because you have pulmonary arterial hypertension (PAH). This study will explore the effect of multiple doses of study drug (PF-07868489) in adult people with PAH. This research study is different from your regular medical care. The purpose of research is to gather information to advance science and medicine and does not replace your regular medical care. For those who complete this C5001001 study, you may be offered the opportunity to participate in a separate study that would allow you to continue taking the study drug.

You will be asked to take part in the study for about 41 weeks, i.e. about 10 months. You will be assigned to receive study drug or a placebo (a placebo does not contain any active ingredients) as 2 injections under the skin. You will receive study treatment 6 times. This is to say that at 6 different site visits, study site staff will administer study drug. You will take the study drug or placebo in addition to continuing to be treated with at least 2 PAH treatments that you're already taking to treat your condition.

Your study doctor will determine whether you are eligible for the study. The study will involve a Screening, Treatment, and Follow-Up period. You will be required to visit the study doctor at the study site for all study visits. You will be asked to provide biological samples (such as blood or urine) and undergo procedures that might be different from a regular medical examination. These tests are to monitor your health during the study and to see what effects the study treatment will have on you. The procedures will include blood tests, ECGs, measurements of your heart rate, blood pressure, breathing rate, temperature, collection of your answers to patient questions, a 6-minute walk test, and a right heart catheterisation (not performed at each visit, but done 2 times during the study).

No potential risks associated with the use of study drug have been identified in studies in healthy participants or animals conducted to date. Like other protein antibody drugs, there is a potential for allergic reactions to the study drug. This is not a complete list of risks or discomforts; you may also experience some other potential risks that are unknown at this time. A more complete list of risks and discomforts is provided later in this consent document.

It is possible that your condition or health may improve, worsen, or stay the same because you are taking part in this study. There is no guarantee that you will benefit in any way. However, your participation in this study may benefit future patients. You will continue to receive standard clinical care for your PAH while you are in this study. The study doctor will discuss alternative treatments and procedures that may be available to you, and their risks and benefits.

Taking part in this study is voluntary (your choice). There is no penalty or change to your regular medical care if you decide not to participate. You can choose to take part in the study now, and then change your mind at any time without losing any benefits or medical care to which you are entitled. We encourage you to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for you. The study team will answer any questions that you may have about the study.

You will receive a signed copy of this consent document for your records. Please keep this consent document for your reference.

Introduction and Purpose of Study

You are being invited to take part in a study that is sponsored by Pfizer (the "Sponsor") because you have PAH. The Sponsor is providing funding to [the study doctor/institution] to conduct the study.

The purpose of this study is to learn about the effects of the study drug (PF-07868489) and to test the safety (the impact of the study drug on your body) of the study drug while you remain on your regular medications for the treatment of PAH. The study drug is an investigational drug because it is not approved for use in this country. In this study, the study drug is being compared with a placebo. The placebo looks like the study drug but does not contain any active ingredients. Researchers will compare the results of taking the placebo to the results of taking the study drug to see if there are any differences. Please note, in the remainder of this consent, references to "study drug" will refer to PF-07868489 and placebo, unless PF-07868489 is specifically noted.

This study will be the first time the study drug will be given to people with PAH.

This research study is different from, and does not replace, your regular medical care. As such, if you participate in this study, you may have additional visits, procedures, extra laboratory tests, and/or follow a modified treatment plan.

It is up to you to decide if you want to take part in this study. You can ask your study doctor or study team any questions you have before you decide whether you want to take part in this study.

Your personal information will be protected during this study in the manner described in the accompanying Privacy supplement.

This study has been reviewed and given a favourable opinion by <Insert name of REC> Research Ethics Committee.

If you decide to take part, the first thing you will be asked to do is to sign this informed consent document. You will get a signed copy to take home.

A. About the Study

1. Number of Study Participants

There will be about 36 people with PAH entered into Part B of this study at approximately 52 research sites in approximately 14 countries.

2. Length of Study for Participants

People taking part may be in this study for a maximum of 10 months. If you are enrolled, you will need to visit the research site at a minimum of 9 times or a maximum of 12 times during the study.

The difference in the number of site visits, is whether you choose to participate in a separate extension study in which you will not need to complete the follow up period in this study.

3. Process for Selecting Study Participants

After you sign this consent document, the study will start with a screening visit. This is to learn about your medical history and to check if you meet the study requirements. If you do not meet the study requirements, you will not be able to take part. The study doctor will explain why you did not qualify. If you meet the study requirements, you will be enrolled into the active treatment period to receive PF-0786849 or placebo. Further details about the study drug, study assignment, and procedures for this study are provided below.

As part of screening, you must complete all 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 tobacco use history.
- Give your past and current medication and treatment history. This includes any prescription drugs or over-the-counter (non-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, heart rate, breathing rate, and temperature) will be measured.
- Electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart.
- Complete a breathing test.
- HIV (human immunodeficiency virus), 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 immune deficiency 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 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.
- Blood tests for aPTT and PT-INR (tests of your blood’s ability to clot).
- Blood tests for tuberculosis (TB).

- Urine to test for drugs of abuse (illegal and prescription).
- Females able to have children will have a blood and/or urine pregnancy test.
- Females less than 60 years of age who have not had a period for at least 12 months in a row will have a blood hormone test to confirm they cannot have children.
- The use of proper contraception will be reviewed if you are a woman able to have children.
- Medical exam. This may be done at screening or when you check-in for the study.
- You will be asked “How do you feel?”
- You will be asked to complete some questionnaires on a tablet.
- Perform a 6-minute walk test.
- After it’s confirmed that you meet all the other requirements, then a Right Heart Catheterization (RHC) will occur. A description of this procedure and its possible risks are explained in Appendix A. The results of a RHC which were obtained as part of your medical care before this consent was signed may be provided to the Sponsor, or third-party vendor of the Sponsor’s, and be used to check whether you may be eligible for the study as long as it occurred within 12 weeks of signing this document.

4. Study Drug(s)

The study team will provide you with each dose of the study drug (up to 6 doses) while you are at the site. It is to be given to you as 2 injections under your skin of the abdomen (preferred) or the thigh or back of the arms.

If you participate in the study, you will be assigned by chance (like the flip of a coin) to receive the study drug PF-07868489 or a placebo. You will have a 50% (1 in 2) chance of receiving the study drug (PF-07868489) or receiving the placebo. The drugs will look alike, whether it is the placebo or the active study drug. No one (including you, your general practitioner (GP) and the study team) can choose the group you will be in. This is a double-blind study, which means that you and the study team will not know whether you are receiving the study drug or the placebo. This is done to avoid bias in the research. In case of urgent need, the study doctor can find out which drug you are receiving.

5. Post-Study Access to the Study Drug

After your participation in this study is complete, you may be invited to participate in a separate extension study that will allow you to continue to receive PF-07868489 for a certain (and possibly limited) length of time. If you are eligible for the extension study, you will be given a separate consent form and an opportunity to ask questions about whether to join that extension study. You are free to decline participation in the extension study. Whether you ultimately decide to join the extension study will not impact your eligibility to participate in this study. All participants who join the extension study will receive PF-07868489. No one will receive placebo in the extension study.

6. Study Tests, Procedures and Assessments

In this research study, you will have certain tests, procedures, and assessments. The study doctor may ask you to come in for additional tests, procedures and assessments, if necessary, to protect your health.

A brief overview of the study tests, procedures, and assessments is provided in the below table. A more detailed description of the tests, procedures and assessments that will be required in this study can be found in Appendix A *Study Tests, Procedures, Assessments and Associated Risks Details*.

Screening/Treatment Period:

Tests, Procedures, Assessments Description	Frequency
Informed consent	*1 time*
Review Inclusion/exclusion criteria	*1 time*
Medical history, demography	*1 time*
Medical exam	*7 times*
Randomisation	*1 time*
Height	*1 time*
Body weight	*4 times*
Vital signs	*9 times*
12-Lead ECG	*5 times*
Spirometry/breathing test	*1 time*
Pulse oximeter to measure oxygen saturation in the blood	*9 times*
Right heart catheterisation	*2 times*
Contraception check	*9 times*
Blood collections	*9 times*
Pregnancy test for women if applicable	*9 times*
Urine drug test	*1 time*
Study drug injection	*6 times*
Assess for any injection reactions	*continuous*
6- minute walk test	*9 times*
Complete questionnaires	*9 times*
Report changes in health and/or medications	*continuous*

Biological Samples

A company hired by the Sponsor may be involved in the collection, transportation, or storage of these samples.

You must provide biological samples in order to take part in this study. These samples taken from you may be sent to or stored in a foreign country. Additional samples may be collected depending on the results of your laboratory tests (e.g., if there are abnormalities that need confirmation or

follow-up) or if a replacement sample is needed. Biological samples, except Retained Research Samples, may be stored for up to 15 years after the end of the study.

The total amount of blood that is planned to be collected in Part B is approximately 390 mL or 26 tablespoons. In order to monitor your safety appropriately, your study doctor may choose to collect additional samples, however the total volume of blood samples will not exceed 550 mL or 37 tablespoons during any period of 56 consecutive days.

Stopping Study Drug and Impact on Study Tests, Procedures and Assessments

If for any reason you are asked to stop taking the study drug or you want to stop taking the study drug, you will be given the Early Discontinuation and will continue with the Follow-Up Procedures.

Early Discontinuation**:**

Tests, Procedures, Assessments Description	Frequency
Medical exam	*1 time*
Body weight	*1 time*
Vital signs	*1 time*
12-Lead ECG	*1 time*
Pulse oximeter to measure oxygen saturation in the blood	*1 time*
Contraception check	*1 time*
Blood collection	*1 time*
Pregnancy test for women if applicable	*1 time*
Assess for any injection reactions	*1 time*
6- minute walk test	*1 time*
Complete questionnaires	*1 time*
Report changes in health and/or medications	*1 time*

Follow-up Period:

Patients that do not enter the separate extension study at Week 24 will undergo the procedures for the Follow-period. Your follow-up period is scheduled to include 4 visits to the site. Following those 4 visits, the study doctor may ask you to come back for an additional visit/s to check on your well-being.

Follow-up Period:

Tests, Procedures, Assessments Description	Frequency
Medical exam	*3 times*
Body weight	*1 time*
Vital signs	*3 times*
12-Lead ECG	*1 time*
Pulse oximeter to measure oxygen saturation in the blood	*2 times*
Contraception check	*4 times*

6-minute walk test	*2 times*
Blood collection	*3 times*
Complete questionnaires	*3 times*
Report changes in health and/or medications	*1 time*

7. Possible Risks and Discomforts

Taking part in this study has some risks. The study drug(s) or procedure(s) may make you feel unwell or uncomfortable or could harm you.

Side effects might be mild or serious. The study doctor may determine that you need additional procedures or medicines to help manage the side effects.

It is important that you report all symptoms and side effects to the study team as soon as they happen, even if you feel the study drug or procedure was not the cause.

Risks from PF-07868489

PF-07868489 is an antibody that binds to a protein known as BMP9 (bone morphogenetic protein 9). BMP9 is produced by the liver and plays a role in controlling the growth of blood vessels in the lungs. Problems with BMP9 signalling are believed to contribute to the development of the disease “pulmonary arterial hypertension” in which pulmonary blood vessels become blocked. This can lead to heart failure and, eventually, death. PF-07868489 is predicted to improve pulmonary arterial hypertension by blocking harmful BMP9 activity in the lungs.

As of July 2024, PF-07868489 or placebo has been given as single escalating SC doses up to 800 mg to approximately 40 healthy people in Part A of this study. Therefore, only limited data about the safety, toleration, and potential side effects of PF-07868489 in humans are available. There have been no deaths or treatment-related severe side effects reported in available data. The most common side effects have been mild to moderate reactions at the site of injection of study treatment, and headaches. No safety risks have been identified and the overall safety profile in humans is consistent with a potential overall favourable benefit-risk relationship.

Studies have been conducted in animals to try to identify risks that may occur in people given PF-07868489.

PF-07868489 has been tested in rats and monkeys to see if it would likely be safe to give to people and to identify any possible undesirable side effects. No side effects were identified in these studies even at the highest dose tested. Those doses produced levels of PF-07868489 in the blood of the animals that are over 10 times the maximum levels expected in human clinical trials. Animal studies cannot entirely predict symptoms that may arise after administration of PF-07868489. There may be rare and unknown side effects, including reactions that may be life threatening.

To minimise and monitor for possible risks associated with administration of PF-07868489, we are only giving PF-07868489 to people in a controlled clinical setting in early clinical studies.

PF-07868489 may cause the body to form antibodies (proteins in the blood that identify and help destroy invaders, like bacteria) to the drug. Any foreign protein (including any other antibody drug) can cause these antibodies to form – this is not specific to PF-07868489. These antibodies could affect the potential for you to be treated successfully with PF-07868489 or similar drugs in the future. It may also increase your likelihood of becoming allergic to this or similar drugs in the future. PF-07868489 may also cause reactions at the site of injection.

All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue, or neck. Other allergic reactions may include rash, hives, or blisters.

At this time, it is not known whether PF-07868489 can cause foetal harm when administered to pregnant women. Animal reproductive studies have not been conducted with PF-07868489. It is also not known whether PF-07868489 can affect the ability of males or females to have children, or whether PF-07868489 is secreted in human milk. For this reason, pregnant and women nursing an infant cannot take part in early clinical studies with PF-07868489, and women who are able to have children will need to use appropriate contraception to prevent pregnancy.

Risks from Study Procedures

A description of the possible risks and discomforts associated with the tests, procedures and assessments required in this study can be found in Appendix A *Study Tests, Procedures, Assessments and Associated Risk Details*.

Other Risks

There may be other risks that are currently unknown because the study drug is still being developed (or is experimental).

All drugs have a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. You should get medical help right away or call your local emergency number and contact the study doctor if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing or swelling of the face, mouth, lips, gums, tongue, or neck. Other allergic reactions may include rash, hives, or blisters.

7a. Contraception and Pregnancy-Related Risks

Use of Contraception

If you are a male:

In this study male participants are not required to use any contraceptive methods because the chance that study drug could be transferred to a female partner by semen is very low. However the study doctor or designee may review contraceptive methods with you.

If you are a female:

There is evidence from animal studies or gene studies that suggests there may be a serious risk to a pregnancy if you become pregnant. If you are able to have children and you are sexually active, you must use contraception consistently and correctly during the study and for at least 15 weeks after the last dose of study drug. At each of your study visits, the study doctor or designee will discuss with you the need to use effective contraception consistently and correctly.

You will need to affirm your consistent and correct use of at least 1 of the selected methods of contraception. You are asked to immediately notify the site if you stop using contraception.

If abstinence (not having sexual intercourse at all) is your usual and preferred lifestyle, and both you and the study doctor agree that it is your selected method of contraception, you must continue not to have sexual intercourse otherwise you may become pregnant.

The effects of PF-07868489 on sperm, a pregnancy, a foetus, or a nursing child are not known.

Pregnancy-Related Risks

You cannot participate in the study if:

- You are pregnant, planning to become pregnant, or breast-feeding a baby.

The study drug may have unknown risks that could harm you, your partner, a foetus, or a breast-feeding baby.

Pregnancy Follow-Up

If you or your partner become pregnant during the study or within 15 weeks after you have stopped taking the study drug, tell the study doctor immediately. Also tell the health care provider(s) taking care of you/your partner during the pregnancy that you took part in this study.

The study doctor will ask if you/your partner or your health care provider(s) are willing to provide updates on the progress of the pregnancy and its outcome. If you/your partner agree, this information will be provided to the sponsor for safety follow-up.

8. Possible Benefits of Participation

Your participation may help future patients by increasing our understanding of PF-07868489 and PAH. It is possible that your condition or health may improve, worsen, or stay the same because you are taking part in this study. There is no guarantee that you will benefit in any way.

9. Other Options Instead of this Study

Instead of taking part in this study, you may choose to receive treatment with other PAH drugs that have been approved for use in the United Kingdom, including the current standard of care for treating PAH. The study doctor will discuss with you the major risks and benefits of the standard of care and any alternative treatments.

Participant Responsibilities & Rights

10. Special Instructions for Study Participants

You must:

- Be willing and able to follow all scheduled visits, instructions about the study drug, lab tests, and other study procedures. If you do not follow the instructions, your visit may have to be rescheduled and/or you may not be allowed to continue to participate in this study.
- Tell the study team if you have already taken part in this study (at this site or any other location), have taken part in any other study during the past year, or are now taking part in any other study or want to take part in another study. Participating in more than one study or site at the same time could put your safety at risk.
- Follow instructions you are given by the study team and discuss all prescription and non-prescription medications, supplements, or vaccines before you take them.

- Notify the study team if you move and provide your new contact information.

You should also tell your regular doctor that you are taking part in this study.

11. Process for Participants who Wish to End Study Participation

You can stop being in the study at any time. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study doctor if you decide to stop so that you can end participation in the safest way. The study doctor will explain what other steps may occur.

While you are participating, the study doctor will tell you in a timely manner if new information is learned that could change your mind about being in this study.

The study doctor may also decide to take you off the study drug and/or remove you from the study (even if you do not agree) in the following situations:

- You are unable or unwilling to follow the instructions of the study;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to be in the study; or
- The study is stopped by the Sponsor, a research ethics committee (REC) (a group of people who review the study to protect your rights), or by a government or regulatory authority.

Information about your health will continue to be collected and used as described in the Follow-up Procedures section above and in the privacy section.

You may request that any samples that have been collected from you as part of the study be destroyed, and in some countries, local laws or regulations may require that your samples be destroyed regardless of whether you specifically make such a request. However, we cannot guarantee the destruction of samples because, for example, the samples may no longer be traceable to you or the samples may have been used up.

12. Study-Related Injuries

You will also be given a card with important emergency contact information, including a 24-hour phone number. Show this card to any health care provider if you seek emergency care during this study. This card includes information about the study that will help the health care provider treat you.

If you experience a research injury, emergency medical treatment will be provided at no cost to you. A research injury is any physical injury, illness or disability caused by:

1. administration of the Pfizer study medicine; or
2. any study procedure that would not have occurred but for your inclusion in the study.

Compensation may be available for such research injuries, depending on a number of factors including the seriousness of the disease, the likelihood of adverse reactions, any warnings given, the risks and benefit of established treatments relative to these of the study medicines and compliance with study directions.

In assessing claims for compensation regarding any injury caused by taking part in this study, Pfizer follows the terms of the guidelines of the Association of the British Pharmaceutical Industry ("ABPI") a copy of which is available on request. The complaints procedure of the hospital where the trial is being conducted is also available.

13. Costs for Study Participants

You will not have to pay for the study drug or study-related procedures and visits.

Talk to the study doctor if you have any questions about costs resulting from participating.

14. Payment for Taking Part in the Study

You will be reimbursed by the study site or a third-party vendor (Illingworth Research Group) working on behalf of the Sponsor for reasonable expenses (such as parking, meals, travel) you may have while taking part in this study. For extended study visits e.g. Right Heart Catheterisation and for certain visits where questionnaires are required to be completed in an e-diary, a stipend may be provided.

The study team will provide you with more details on the payment/reimbursement timing and method and the need to retain receipts if necessary.

The Sponsor may use information and biological samples resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this study. The Sponsor will own all products or processes that are developed using information and/or biological samples from the study.

15. Maintaining Confidentiality and Use of Medical and Research Records

Medical and research records collected during this study will be stored by the study team at your study site and may also be stored on a third-party cloud-based platform paid for by the Sponsor. These medical and research records will be reviewed to verify that clinical trial procedures and/or data are correct.

Your medical and research records may be accessed by:

- Your study doctor and other study team members;
- The Sponsor and its representatives (including its affiliated companies);
- People, or organisations providing services for, or collaborating with, the Sponsor;
- Other researchers, including researchers involved in the study at sites other than the one at which you are participating in the study;
- Any organisation that obtains all or part of the Sponsor’s business or rights to the product under study;
- Government or regulatory authorities including those located in other countries; and
- REC overseeing this study.

In order to keep records that identify you confidential, the study site will replace your name with a unique code. The records and information labelled with the code are called “**Coded Information**.” The study site will keep the link between the code and your name confidential. Your information will

be transferred to the Sponsor using the unique code assigned to you. The Sponsor's employees and those with whom your Coded Information is shared are required to protect your Coded Information and will not attempt to re-identify you.

Your personal information will be collected, used, and shared (together called "processing") in compliance with applicable privacy laws.

There may be times when additional information about your medical tests, any hospitalisations, or a medical event that has occurred to you during the study will need to be sent to a committee engaged by the Sponsor to assess the research study's progress, safety, and, if needed, to see if the study drug is working. These committees might include a data safety monitoring committee or an adjudication committee, are separate from the study site, and may be located outside your country. Any directly identifying information, such as your name, will be removed on all medical and research records sent to this committee through this process.

You will also be provided a separate Privacy supplement (which is considered part of this consent document) that further describes how your information, biological samples, and/or images will be processed and your privacy rights.

16. Contact Information and Links to Additional Study Information

The study team will address any questions, concerns, or complaints you may have before, during, and after you complete the study. Contact information for your study site and study doctor is listed on the first page.

If you have any questions about your rights as a study participant or would like to speak with someone not directly involved in the study, you may contact <Insert contact details of PALS or equivalent>

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

A summary of the results of the clinical trial, and a summary presented in terms understandable to a layperson, will be made available in the EU clinical trial database [Clinical Trial Information System (CTIS)] accessible at https://euclinicaltrials.eu, no matter what the study's outcome. To the extent possible, these summaries will be made available in the EU clinical trial database when the summaries become available. This website will not include information that can identify you. The EU clinical trial number is 2024-514064-17-00.

The study results, when available, may also be found on www.pfizer.com and https://www.clinicaltrialsregister.eu/. If you need assistance to understand the content in a different language, please ask a member of the study team.

If you need assistance to understand the content in a different language, please ask a member of the study team.

The Sponsor will provide the study doctor with information about the study results when all participants have completed the study.

In addition, a plain language summary of the study results will be made available on Pfizer.com. This information will be provided no matter what the study's outcome. However, your individual overall study results will not be given to you, your doctor (if different from the study doctor), your family, your employer or any insurance company. If any exploratory research is done, it may not

be possible to link any results from that exploratory research to specific individuals, including you. The Sponsor does not plan to return information from any exploratory research to you, the study doctor, or your doctor (if different from the study doctor).

TO BE PRINTED ON HOSPITAL HEADED PAPER

INFORMED CONSENT FORM

Study Title:	A Phase 1/2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single Escalating Doses of PF-07868489 in Healthy Adult Participants and, Additionally, Clinical Activity of Repeat Doses in Participants with Pulmonary Arterial Hypertension
Protocol Number:	**C5001001**
IRAS Number:	**[IRAS ID]**
Name of company sponsoring the study:	**Pfizer Inc.**
Study Doctor:	**<Insert Doctor Name>**
Study Site Number:	**<Insert Site Number>**
Participant Number:	
Contact Person:	**<Insert site contact person>**
Site Address:	**<Insert Site Address>**
Phone Number (Normal Business Hours)	**<Insert Site Daytime Number>**
Phone Number (24 hours or Emergency Phone)	**<Insert Emergency Number>**
Patient Rights Advocate:	**<Insert PALS or equivalent contact details>**

Please initial each box:

Agreement to Participate and to Process Data	Initial
I confirm I have read (or, if I cannot read, a study team member has read to me) and understand participant information sheet version 01/01/00 dated 16-Oct-2024	

for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I acknowledge that I have received a copy of the Privacy Supplement dated 09 Apr 2024 and I have read and understood the Privacy Supplement. I understand that taking part in the study will require the processing (including collection, use, transfer, storage, analysis and reporting) of my personal information, as explained in the Privacy Supplement. I understand and agree to the processing of my personal information within and outside my country of residence for health care, medical research and/or regulatory purposes.	
I understand that taking part is voluntary and that I am free to stop taking part in this study or to withdraw my consent to the processing of my personal information at any time. I do not need to give any reason and my regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my personal information held at that time may be kept to comply with laws and regulations and to maintain the integrity of the study. I also understand that my biological samples may not be able to be destroyed because they may no longer be traceable to me, may have already been used, or may have been given to a third party.	
I agree to the study team accessing my medical history, including information from medical records and test results and any medical treatment I receive during the course of the study, and if necessary, contacting my doctor or any other health care providers treating me for access to such information.	
I consent to my General Practitioner (GP) being informed of my participation in this study. I also consent for my GP to contact the study team	
I understand that the Sponsor and/or others working with or on behalf of the Sponsor, research ethics committees (RECs), and regulatory agencies may need access to personal information about me generated at the study site or collected by the study team for the study and any other research. I agree that they may have access to my personal information.	
I do not give up any of my legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document.	
I agree to take part in the above study.	

I have had enough time to read this consent document (or, if I cannot read, an Impartial Witness‡ has read it to me) and have had the opportunity to ask questions. All of my questions have been answered to my satisfaction. I have been told that my participation is voluntary and I can refuse to participate or withdraw at any time. I agree to take part in the study.

I also acknowledge that I have received a copy of the Privacy supplement.

Printed name of participant

Signature of participant | Date of signature (dd-Mmm-yyyy)§

§ Participant must personally date their signature.

Consent for Participant Who Cannot Read or Cannot Write:

The study participant has indicated that he/she/they is/are unable to read or is unable to write. I read the consent document to the study participant and one or more members of the study team discussed it with the study participant and gave the study participant an opportunity to ask questions. The information in the consent form was accurately explained to, and apparently understood by, the study participant, who provided informed consent to participate in the study.

Printed name of impartial witness ‡

Signature of impartial witness | Date of signature (dd-Mmm-yyyy)§

§ Impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the entirety of the informed consent process if the participant cannot read or cannot write, and who reads the informed consent document and any other written information supplied to the participant. Refer to the Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance; EU Clinical Trial Regulation 536/2014 Art. 29(1).

Person Obtaining Consent:

Printed Name of the Person Conducting the Consent Discussion

Signature of the Person Conducting the Consent Discussion †

Date of consent discussion (dd-Mmm-yyyy) †

† The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and personally date the consent document during the same discussion when the participant signs the consent document.

Thank you for your participation

Your participation in this study matters. Your study team is here to support you throughout your journey with us, and we at Pfizer want to sincerely thank you for your time and commitment to this research.

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

1. PRIVACY SUPPLEMENT

UK PRIVACY SUPPLEMENT (version 9 Apr 2024)

This Privacy Supplement describes how the study site and the Sponsor will collect, use, transfer, store, analyse and share your personal information (called "processing") to conduct the study based upon its legitimate interests in (1) ensuring high standards of quality and safety in medicinal products and (2) conducting and publishing research. It also describes your privacy rights.

A. What information may be collected about you during this study?

In order to conduct the study, your study team will collect information about you. Information about you may include personal information that directly identifies you, demographics, and sensitive information such as your medical history and data from this study (including diagnoses, treatment, genetic information, sex, race, and ethnicity). If required by this study, the study team may also collect biological samples from you and take images or make audio/video recordings of you.

Information may be collected from electronic devices if you use a mobile application or other digital tool during the study. You should review the main consent document as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

If you provide an emergency contact or details of family medical history, you should inform that person or those persons you have done so and that their information will be used as described in this document.

B. How will your information be used?

Your information will be treated in compliance with applicable data protection laws. Any information collected about you during this study will be entered into records, including health records, maintained by the study team at your study site. The Sponsor is the controller for any information collected about you by the site for purposes of conducting the study and is also the controller of your coded information once it leaves the site. The study site will retain your information for the period necessary to fulfil the purposes outlined in this Privacy Supplement, in the main consent document, and/or for the maximum period permitted by applicable law, which could be at least 25 years after the end of the study.

Your information may be accessed and used by:

- The study team;
- The Sponsor (including its affiliated companies) and its representatives, for example, study monitors and auditors;
- People and/or organisations providing services to or collaborating with the Sponsor;
- Any organisation that has or obtains rights to the product under study or that obtains all or part of the Sponsor's business;
- Other researchers, including researchers involved in the study at sites other than the one at which you are participating in the study;
- Regulatory authorities, including those located in other countries, such as the United States Food and Drug Administration; and

Typically, your name will be removed from your information before it is sent outside the study site. As described in the main consent document, your name will be replaced with a unique code before your information (and/or your biological samples, images and/or audio/video recordings, if collected as part of the study) leaves the study site. This information is referred to as your "Coded Information." Data generated using biological samples, images and/or audio/video recordings of you if collected during the study, will be handled in the same way as your Coded Information, unless otherwise stated in this Privacy Supplement or the main consent document. Sometimes the study site may be unable to remove information that can identify you from your images, meaning that the images shared with others may be identifiable as yours.

The study site will upload your information (which will not include any information that personally identifies you) to a designated secure electronic system maintained by a third party engaged by the Sponsor. The Sponsor and/or the Sponsor's representatives will use this secure system to review and verify study data as they would at the study site. The Sponsor is the controller of the information uploaded to this electronic system. These uploaded records will be kept for the period necessary to fulfil the purposes outlined above and in the main consent document, as required by applicable law and/or for the maximum period permitted by applicable law on the secure electronic system.]

The individuals and groups listed above will use your information, including your Coded Information, to:

- conduct this study;
- comply with legal or regulatory requirements, including for all of the purposes listed in the main consent document that you were provided and to seek approval from government or regulatory agencies to market study drug;
- publish the study results;

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

The Sponsor may be required to provide information gathered from this study, including your Coded Information, to regulatory authorities for public disclosure. In such cases, the Sponsor will take steps to minimize the risk that you could be re-identified.

Some of the people and/or organisations using your information may be based in countries other than your country of residence, including the United States. When transferred to countries with legal standards that have not been found by the European Commission to offer an adequate level of protection of personal information, the Sponsor uses officially approved agreements (called Standard Contractual Clauses) to ensure a similar degree of protection is afforded. A copy of the agreement may be obtained by contacting your study team.

The Sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in this Privacy Supplement and in the main consent document, indefinitely or the maximum period permitted by applicable law after the end of the study.

C. Can your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, be used for other research?

Yes. The Sponsor may use and has a legitimate interest in using your Coded Information and biological samples, images and/or audio/video recordings, if collected as part of the study, in the future 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 research projects; however, your Coded Information and 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, images and/or audio/video recordings used in any other research and may include: (a) limiting access to individuals bound by duties of confidentiality; (b) taking steps to minimize the risk that you could be re-identified; and (c) obtaining approval of ethical review boards. Furthermore, if your Coded Information and biological samples, images and/or audio/video recordings, if collected as part of the study, are anonymised such that they can no longer be identified with you, they may be used for other research purposes.

D. What are your rights to your personal information?

You may request access to your personal information, to correct, delete or restrict its processing; however, these rights are limited, as your information needs to be managed in specific ways in order for the research to be reliable and accurate or to comply with

legal duties. The right to object to further research may also be limited by applicable law. To exercise any of these rights, contact the [Institution] (please see the **contact information at Page 1** of the main consent document) and not the Sponsor. However, you may find contact details for the Sponsor's data protection officer at DPO.Pfizer.com. You also have the right to file a complaint with a Data Protection Authority in the place you live, work or where any breach of data protection law may have occurred. Contact details of UK and EU Data Protection Authorities can be found by consulting the list here: http://ec.europa.eu/justice/data-protection/article-29/structure/data-protection-authorities/index_en.htm.

E. What happens to your information, and biological samples, images, and/or audio/video recordings that may be collected as part of the study if you do not wish to continue with the study?

As noted in the main consent document, you are free to stop taking part in this study at any time. If you stop taking part in the study and you do not tell the study team, your contact information may be used by the study team to contact you, your family or your personal doctor, or to search publicly available records to find out how you are doing. These uses of your information may continue until the Sponsor determines the study is complete, which may take many years. Your information will continue to be used in accordance with the main consent document, this Privacy Supplement and applicable law, as the Sponsor needs to manage your information in specific ways in order for the research to be reliable and accurate. The Sponsor, may continue to use your Coded Information even if you stop taking part in some or all of the study activities as necessary for the Sponsor (a) to comply with its legal and regulatory obligations; (b) for the Sponsor's legitimate interests in guaranteeing the integrity of the study and ensuring high standards of quality and safety of its products and advancing public health and scientific research and publishing the results of its studies; and (c) any other purposes permitted under applicable data protection and privacy laws.

No new information, biological samples, images and/or audio/video recordings will be collected about you or from you by the study team, unless you have told the study team that you agree to provide new information or samples. Even if you do not agree to the collection of new information or samples, the study team may continue to report any adverse effects or other safety event that you experience due to your participation in the study to the Sponsor.

In the event the Sponsor has already removed all information that could reasonably be used to identify you, it may use all resulting anonymised data for any purpose.

Any biological samples that have been collected about you or from you will be handled as described in the "Process for Participants who Wish to End Study Participation" section in the main consent document.

APPENDIX A: STUDY TESTS, PROCEDURES AND ASSESSMENTS AND ASSOCIATED RISK DETAILS

In this research study, you will have certain tests, procedures, and assessments. The study doctor may ask you to come in for additional tests, procedures, and assessments, if necessary, to protect your health.

Demographic Questions

- Demographic questions ask for personal information, such as your name, date of birth, race, ethnicity, etc. We collect race and ethnicity data to help us understand which participants are involved in our clinical trials and help us provide better drug treatments for individuals across all races and ethnicities.
- While collection of demographic information does not expose you to physical risk, collection of such information may result in a loss of your privacy if the information is lost or stolen.

Health and Medication Questions

- Health and medication questions ask about your health, medical history, quality of life, medications, and sexual history or practices, as well as the PF-07868489.
- These questions may be sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after responding to these questions, you should tell the study doctor.

Questionnaires

- Questionnaires are to be completed by you (self-reported) to help to better understand your view of your health status and the effectiveness of the treatment.
- Questionnaires are to be completed by the site with your input to help understand your level of fatigue and shortness of breath before and after each 6-minute walk test.
- Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, you should tell the study doctor.

Medical Exam

- Medical exam is an examination of certain body systems such as the heart and lungs.
- There are no known risks associated with a medical exam.

Blood Pressure

- Blood pressure test measures the pressure in your arteries as your heart pumps.
- The test is usually painless, however as the blood pressure cuff squeezes your arm while it inflates it may be uncomfortable. This feeling lasts only a few seconds.

Vital Signs

- Vital signs may include blood pressure, body temperature, heart rate, and respiratory rate.

- See Blood Pressure Risk above; no other risks are associated with the measuring of vital signs.

ECG (Electrocardiogram)

- An ECG (electrocardiogram) is a test that records the electrical activity of the heart. A technician will place sticky patches on your chest, arms and legs that are connected by wires to a machine. These patches collect a signal that measures your heart activity.
- The risks from an ECG can include skin irritation and a rash from the gel that is used or from wearing or removing the sticky patches.

Blood Sample

- Blood sample is the process of collecting blood for specific tests from a vein through a needle. The needle is connected to a small tube in which the blood is stored until it is tested. You will need to fast (not eat or drink anything) for at least 4 hours prior to a blood sample.

- A blood sample may cause faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection.

Viral, Microbiological, Bacteriological or Antibody Tests (HIV, HCV, HBV, tuberculosis, etc.)

- You will be required to undergo HIV, Hepatitis C (HCV), Hepatitis B (HBV) and tuberculosis testing as a part of the study procedures at the screening visit. The study doctor might be required to disclose the results of these tests to local health authorities, depending on the country in which you live and the local laws that apply.
- 11 mL (about 2 ¼ teaspoons) of your blood will be taken to test for hepatitis (looking for signs of inflammation of the liver, or viral infection of the liver known as Hepatitis B or C infection). Your blood will also be used to check if you have human immunodeficiency virus (HIV) infection, a condition that lowers your body's defence system to fight illnesses and causes your vital organs to stop functioning. HIV tests are required unless not allowed by health authorities in your country (per local guidelines).
- The results of all your blood tests, just like all other laboratory test results, will be provided to the Sponsor. Positive HIV and Viral Hepatitis test results may be reportable to local health authorities according to local laws. Your blood test results must be negative for you to take part in this study.
- Collection of 4 mL (about ¾ teaspoon), less than a teaspoon of blood to test for tuberculosis (TB). Positive TB results may be reportable to local health authorities according to local laws.
- You may be required to undergo HBV DNA tests if your study results have a particular outcome. The results of these tests may be reported to health officials depending on the country in which you reside and the local laws that are applicable.
- See Blood Sample Risk above.

Immunogenicity Samples

- A blood sample will be taken to determine if your body has produced substances (antibodies) against the study drug. This sample may also be used to develop and/or evaluate the test procedures used to measure study drug, immunogenicity, and/or biomarkers, as well as for other internal exploratory purposes.
- See Blood Sample Risk above.

Pharmacokinetics (PK) and Pharmacodynamics (PD)

- Pharmacokinetics (PK) Samples: A blood sample will be taken to measure the amount of study drug in your blood. This sample may be used to determine how the study drug is changed and eliminated from your body after you take it. This sample may also be used to develop and/or to evaluate the test procedures used to measure study drug, immunogenicity, and/or biomarkers, as well as for other exploratory purposes.
- Pharmacodynamics (PD) Samples: Blood samples will be taken to try to understand the relationships between amount of study drug in your blood and how your body responds to the study drug may be evaluated.
- See Blood Sample Risk above.

Biomarker Analysis

- Blood samples will be collected at different points in the study to try to get an understanding of the effects of study drug on your body. These samples may also be used to develop and/or evaluate the test procedures used to measure study drug, immunogenicity, and/or biomarkers.
- See Blood Sample Risk above.

Injection / injection site reactions (ISR)

- The study drug (PF-07868489 or placebo) will be injected under your skin using a syringe with a needle.
- The risk of the injections can include a hypersensitivity reaction that may be immediate, although it usually appears within 24-48 hours after injection. ISR, by definition, includes the following: redness, swelling, itching, pain, inflammation, rash at the injection site. These injection site reactions will be monitored by your study doctor and/or study team.

Pregnancy Testing

- Pregnancy testing is a test in females of blood or urine to check for pregnancy.
- See Blood Sample Risk above and/or Urine Collection Risk below.

Urine Collection

- Urine collection may be done for laboratory tests.
- There are no known risks associated with a urine collection.

Lung function testing (spirometry)

- Lung function testing is a test during which you blow into a tube to see how well your lungs work.

- There is very little risk associated with having a lung function test. Some people may feel lightheaded or dizzy during the procedure.

Right heart catheterization

- This procedure involves using a special needle which is inserted in either the neck or groin vein to measure blood flow and heart function**.** It is often with local anaesthesia (to numb the skin). You may also receive a sedative (drug to help you be calm and comfortable).
- The procedure may cause some pain and discomfort. Although complications are rare, possible risks can include bruising, infection, nerve damage, pain, bleeding, and partial collapse of your lung if your neck or chest veins are used to insert the catheter. Other rare risks are abnormal heart rhythms, fluid buildup around your heart that affects its ability to pump blood effectively, air leaking into your heart or chest area (which rarely results in death) and damage to the main artery in your lung (this can result in serious bleeding and may require chest surgery to correct). And as with any invasive procedure there is a very low chance of complications that could result in death. A numbing drug may cause a burning feeling, rash, allergic reaction, redness or soreness where you receive the shot.
- As part of this procedure, it will be necessary to use X-ray guidance for the placement of the RHC needle (using a technique known as “fluoroscopy”). If you take part in this study, you will have two RHC procedures. These could be extra to those that you would have if you did not take part in the trial. The RHC procedure uses ionising radiation (from the X-rays used in fluoroscopy) to form images of your vessels and provides your doctor with important information about the pressure in your pulmonary artery. This is necessary to determine the effectiveness of the study drug. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer;. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Undergoing two RHC procedures in this study will increase the chances of this happening to you to about 50.05%, an increase of 0.05%.
- The RHC procedure and the associated risks will be reviewed in detail by the study doctor/doctor prior to performing the procedure.

Chest X-ray

- You may also need to undergo a chest X-ray at screening if you have previously been treated for TB. The chest X-ray would be necessary to ensure that it is safe for you to participate and the radiation risk is minimal.

6-minute walk test

- The 6-minute walk test measures how far you can walk in six minutes. In the rare case that a 6-minute walk test is incomplete or unusable, you may be asked to complete an additional 6-minute walk test at a different time.
- You may experience symptoms such as fatigue, shortness of breath, leg cramps, chest pain, sweating, or other symptoms associated with exercise.

Retained Research Samples

- Sample(s) of your blood will be collected, stored, and used to learn more about the study drug(s) and PAH. Biological substances in your sample(s), including your genes, may be studied. This may include analysing all your genetic information (called “whole genome sequencing”). These samples may be kept by the Sponsor for many years (no time limit).

- Also see DNA and/or RNA Analyses for other risks.

DNA and/or RNA Analysis

- Genes are pieces of DNA in our cells that determine how we look and affect the way our bodies work. DNA is a substance that helps make proteins which the cells in your body needs. RNA helps to carry information from your genes to help in the creation of these proteins. Parts of your genes are passed down from your parents. By studying your DNA and RNA using a variety of laboratory methods we can understand more about genes. This analysis is for research purposes only and is not a medical test. The results may have no known medical importance to you or your family.
- 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 discriminating against you. However, steps are in place to prevent a particular result from being linked to you and to prevent unauthorised people from even knowing genetic research was done.

APPENDIX B: TIMELINE GRAPHIC FOR PARTICIPANTS

Treatment Period Timeline

Study Visit Activities	Screening	Day 1	Day 8	Day 29	Day 57	Day 85	Day 113	Day 141	Day 169
Informed Consent	☒								
Medical Exam	☒	☒	☐	☐	☒	☒	☒	☒	☒
Height	☒	☐	☐	☐	☐	☐	☐	☐	☐
Weight	☒	☒	☐	☐	☐	☒	☐	☐	☒
Blood Collection	☒	☒	☒	☒	☒	☒	☒	☒	☒
Urine Collection	☒	☐	☐	☐	☐	☐	☐	☐	☐
ECG	☒	☒	☒	☐	☐	☒	☐	☐	☒
Vital Signs	☒	☒	☒	☒	☒	☒	☒	☒	☒
Spirometry/breathing test	☒	☐	☐	☐	☐	☐	☐	☐	☐
Pulse oximeter	☒	☒	☒	☒	☒	☒	☒	☒	☒
Right heart catheterization	☒	☐	☐	☐	☐	☐	☐	☐	☒
Pregnnacy check (women of child bearing potential)	☒	☒	☒	☒	☒	☒	☒	☒	☒
Contraception check	☒	☒	☒	☒	☒	☒	☒	☒	☒
Study drug injection	☐	☒	☐	☒	☒	☒	☒	☒	☐
Assess for any injection reactions	☐	☒	☐	☒	☒	☒	☒	☒	☐
6-minute walk test	☒	☒	☒	☒	☒	☒	☒	☒	☒
Complete questionnaires	☒	☒	☒	☒	☒	☒	☒	☒	☒
Report changes in health &/or medications	☒	☒	☒	☒	☒	☒	☒	☒	☒

Follow-up Period Timeline

Study Visit Activities	Day 197	Day 225	Day 253
Medical Exam	☒	☒	☒
Weight	☐	☐	☒
Vital signs	☒	☒	☒
ECG	☐	☐	☒
Blood Collection	☒	☒	☒
Pregnnacy check (women of child bearing potential)	☒	☒	☒
Contraception check	☒	☒	☒
6-minute walk test	☒	☐	☒
Pulse oximeter	☒	☐	☒
Complete questionnaires	☒	☒	☒
Report changes in health &/or medications	☒	☒	☒