C3421010-1001	**A 2-PART PHASE 1, OPEN LABEL, STUDY WITH A 4-PERIOD,4- SEQUENCE, CROSSOVER DESIGN IN COHORT 1 AND A 2-PERIOD, 2-SEQUENCE CROSSOVER DESIGN IN COHORT 2 TO COMPARE THE SINGLE DOSE PHARMACOKINETICS OF FIVE DIFFERENT FORMULATIONS OF PF-06882961 ADMINISTERED ORALLY TO OTHERWISE HEALTHY ADULT PARTICIPANTS WHO ARE OVERWEIGHT OR HAVE OBESITY.**

EudraCT number:	2020-001016-24
Study medicine:	PF-06882961
Sponsor of the study:	Pfizer Inc.
Research organisation:	Pfizer Clinical Research Unit (PCRU), Route de Lennik 808, 1070 Brussels
Medical Ethics Committee:	Comité d'Ethique Hospitalo-Facultaire Erasme-ULB.
Principal Investigator:	Dr. Constantino Kantaridis
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I. Information vital to your decision to take part to the study

Introduction

You are being invited to take part in a clinical study to evaluate an investigational medicinal product. An investigational medicinal product is a medicinal product that is still being studied to evaluate its efficacy, safety or mode of action.

You will not personally derive any benefit from your participation in this study, but the results obtained could be very important for the development of medicines and treatments which will benefit other people.

Before you agree to take part in this study, we invite you to take note of its implications in terms of organisation and possible risks, to allow you to take a decision with full awareness of all the implications. This is called giving an "informed consent".

Please read these few pages of information carefully and ask any questions you want to the investigator or his/her representative. There are 3 parts to this document:

- the information essential to your decision,
- your written informed consent and
- supplementary information (appendices) detailing certain aspects of the basic information.

If you take part in this clinical study, you should be aware that:

- This clinical study is being conducted after having been reviewed by one Ethics Committee.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. However, even after having signed that document, you can stop participating in the study at any time, by informing the investigator of your decision.
- The data collected in the scope of the study are confidential and shall be process in conformity with the General Data Protection Regulation and the Belgian law of 30 July 2018 relating to the protection of natural persons with regards to the processing of their personal data. Your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You may contact the investigator or a member of his/her team at any time, should you need any additional information.
- If you have expressed a specific consent for this, your general practitioner will be informed of your participation in this study. He/she will also be informed when the study is complete.

Further information about the "Participant Rights" can be found in appendix (page 12).

Objectives and description of the study protocol

We are inviting you to take part in a clinical study involving PF-06882961 which will include around 32 participants.

1. AIMS OF THE STUDY

The purpose of this research study is to compare the amount of PF-06882961 in the blood following different formulations administered to otherwise healthy adult participants who are overweight or have obesity.

In addition, we will assess the safety and tolerability of single oral doses of PF-06882961.

2. LEGAL STATUS OF THE STUDY MEDICINES

PF-06882961 is a new investigational medicine. A new investigational medicine is one that is currently not approved for sale in Belgium.

PF-06882961 is currently being developed by Pfizer as a treatment for type 2 diabetes mellitus. This is a disease characterised by high glycemia (sugar level) in the blood. PF-06882961 is a study drug that is similar to some injectable drugs that are available to patients by prescription for the same indication. These drugs control the amount of glucose in the blood, delay emptying of the stomach, and decrease the food intake through increasing the feeling of being full.

3. POSSIBLE SIDE EFFECTS

As of 09 September 2020, there have been three completed studies with PF-06882961, including men and women of non-childbearing potential. In 2 of these studies, PF-06882961 was taken by healthy adult participants, and in the third study, PF-06882961 was taken by participants with type 2 diabetes. To date, PF-06882961 has been generally safe and well tolerated, and there have been no serious side effects reported related to dosing of PF-06882961.

In the first study, 25 healthy participants received single doses of PF-06882961 ranging from 3 mg to 300 mg by mouth, or a matching placebo. In these participants, who received either PF-06882961 or placebo, 100 side effects were reported. A majority of these side effects were deemed mild, except for 5 side effects that were reported as “moderate” in severity. The most common side effects were related to the gastrointestinal system and included nausea, decreased appetite, and vomiting.

In the second study, 12 healthy participants received single doses of PF-06882961 (of different formulations) ranging from 25 mg to 100 mg by mouth. In these participants, 30 side effects were reported, all of which were deemed mild. The most common side effects were headache, nausea and skin abrasion.

In the third study, participants with type 2 diabetes taking metformin were given PF-06882961 doses ranging from 10 mg twice daily to 120 mg twice daily (or matching placebo), or single daily doses up to 200 mg (or matching placebo), by mouth for 28 days. In this study, 73 participants received PF-06882961 and 25 received placebo. In these 98 participants, 319 side effects were reported, of which a majority (92%) were mild in severity, 7% were moderate in severity and 1% (2 of the 319) were severe. The most frequently reported side effects were nausea, dyspepsia (stomach upset), vomiting, diarrhea, headache, and constipation. Some participants experienced a mild increase in heart rate, ranging from 5-15 beats per minute, with most heart rate measurements in the normal range.

PF-06882961 has been dosed in rats for up to 6 months and in monkeys for up to 6 months. At the highest dose level given in the 4-week rat studies, there was evidence of mild to moderate damage to the heart and moderate to severe effects on the thymus gland (which helps with managing infection). In addition, rats given the highest dose level for 4 weeks developed mild to moderate stomach ulcers. At the highest dose of PF-06882961 in the 4-week rat study, the most severe finding was death in some

animals. The drug levels at this dose were more than 200 times higher than the highest dose planned in this study. There were no deaths related to PF-06882961 at lower doses in any of the rat studies. The findings above were not found in longer duration studies in rats. In the 6-month study in rats, the only adverse findings were limited to an organ called the Harderian gland that is only present in rats and is not present in humans. This finding in the Harderian gland was present at drug levels that were more than 50 times higher than the highest dose planned in this study and is not relevant to humans.

In the 6-month monkey study, 3 animals underwent early euthanasia, on Days 23, 50, and 106, after demonstrating adverse clinical signs including decreased food consumption, vomiting, loose stools, dehydration, and significant body weight loss, which was associated with damage to the heart and kidney. The damage to the heart and kidney occurred in the setting significant body weight loss and dehydration and were due to prolonged decreases food and fluid intake, rather than direct effects of PF-06882961. The heart and kidney damage were unique to this study and was not observed in the animals who survived to the end of this study or in other monkey studies in animals exposed for longer duration at similar doses. In the animals who survived to the end of the study, adverse findings that were considered related to PF-06882961 included body weight loss, vomiting, liquid stools, dehydration and intermittent tremors. However, these findings were reversible after PF-06882961 dosing was discontinued.

Cardiovascular changes, including changes in heart rate, blood pressure, and ECG, occurred in single dose and/or repeat dose studies in rats and monkeys; however, these changes were not considered adverse.

The highest dose of PF-06882961 that you will receive in this study will be 100 mg once per period. The highest dose of PF-06882961 planned in this study is lower than the dose level at which no adverse effects were observed in rats.

PF-06882961 is a study drug that is similar to some marketed injectable drugs. While some effects of those drugs were not reported in the animal studies for PF-06882961, potential risks of these marketed drugs in humans include thyroid tumors (that were reported only in rats and mice), inflammation of the pancreas, hypoglycemia (low blood sugar), effects on kidney function, gastrointestinal (GI) side effects and worsening of diabetic eye disease. In addition, a potential risk in patients with obesity from a related marketed injectable drug includes suicidal thoughts and behavior.

Other currently unknown risks and discomforts could appear. It is therefore very important that any new health problem is quickly reported to the doctor, regardless of whether or not you think it has to do with the study.

As with any study medicines research, unexpected side effects may occur. If any significant findings or side effects were to come to light during the course of this study, you would be notified.
In this case, you will be asked to sign either an addendum to the consent form or a new informed consent form.
The study medicines will not be available after the study has ended.

Course of the study

The study consists of 2 different cohorts:

- Cohort 1
- Cohort 2

Cohort 1:

For the participants in Cohort 1 the study is planned to last for approximately 6 to 11 weeks.

Several examinations or procedures will be required in connection with the study:

- A screening examination

- 4 consecutive treatment periods organised of 13 days and 12 nights in the Unit (from Period 1 Day -1 to Period 4 Day 3). You may be discharged after each period.

Cohort 2:

For the participants in Cohort 2 the study is planned to last for approximately 6 to 11 weeks.
Several examinations or procedures will be required in connection with the study:

- A screening examination
- 2 consecutive treatment periods organised of 7 days and 6 nights in the Unit (from Period 1 Day -1 to Period 2 Day 3). You may be discharged after each period.

1. SCREENING EXAMINATION

Before being allowed to take part in the study, you will undergo a complete medical examination, specifically an ECG as well as a blood pressure and heart rate measurements. Blood and urine samples (**for which you must have been fasting for at least 8 hours**) will be taken for laboratory tests and to screen for drugs. You will nevertheless be allowed to drink water.
A hormone test will be carried out for post-menopausal women and a pregnancy test will be carried out for women of childbearing potential.

You will also complete a questionnaire about your participation in clinical studies in the 365 days preceding this screening examination.

For hygiene reasons, you are requested to take a shower before this visit.
To make it easier for the ECG electrodes to adhere to the skin, we ask you not to apply a moisturizing cream on your body.

2. STUDY PERIOD

If you agree to take part in the study and meet all the conditions required to be enrolled in the study, you will undergo the tests and examinations described below:

Cohort 1:

- Physical examination: at admission (Period 1 only)
- Detection of drugs in urine: at admission.
- ECG: 5 measurements in total.
- Measurement of blood pressure and heart rate: 5 measurements in total.
- Administration of the drug (see the section “Treatments administered during the study” Page 5).
- Blood and urine samples for laboratory tests **(for which you must have been fasting for at least 8 hours)**: up to 8 samples in total.
- Pregnancy test, if applicable: up to 4 samples in total.
- Blood samples to determine the concentrations of PF-06865571: 52 samples in total.
- Banked Biospecimen blood sample: 2 samples.

Cohort 2:

- Physical examination: at admission (Period 1 only)
- Detection of drugs in urine: at admission.
- ECG: 3 measurements in total.
- Measurement of blood pressure and heart rate: 3 measurements in total.
- Administration of the drug (see the section “Treatments administered during the study” Page 5).

- Blood and urine samples for laboratory tests **(for which you must have been fasting for at least 8 hours)**: up to 4 samples in total.
- Pregnancy test, if applicable: up to 2 samples in total.
- Blood samples to determine the concentrations of PF-06865571: 26 samples in total.
- Banked Biospecimen blood sample: 2 samples.

For Cohorts 1 and 2:

For safety reason, we may add procedures at any time during the study in order to check on your health status.

Each participant will have a follow-up phone call 28 to 35 days after administration of the last dose of study medicine.

When participating to the study, you must be able to come to the Unit within 24 hours if we need to call you in for a check-up. We therefore ask you not to make any travel plans that will prevent you from respecting this condition.

The remainder of your laboratory test samples and of the samples used to determine the study medicine may be retained for storage up to 1 year following completion of the study. These samples shall be destroyed after this timeframe or earlier if not used. The samples may be used for evaluation of exploratory safety biomarkers, bioanalytical method, as well as for other internal exploratory purposes related to this study medicine. In addition, if you agree to take part to the Additional Research, your samples will be stored for a maximum of 50 years and used as described in the Additional Consent Document (p. 19).

3. TREATMENTS ADMINISTERED DURING THE STUDY

The planned oral treatments are:

Cohort 1:

Formulation A: one tablet of 100 mg PF-06882961, oval tablet used in patient studies (reference).
Formulation B: one tablet of 100 mg PF-06882961, round tablet potentially intended for patient studies (test).
Formulation C: one tablet of 100 mg PF-06882961, round tablet with larger particle size (test).
Formulation D: one tablet of 100 mg PF-06882961, round tablet with slower dissolution (test).

You will receive all treatments after an overnight fast (no eating) of at least 10 hours. You will not be allowed to drink for one hour before and one hour after you are given the study medicine.
You must stay fasted (no eating) until roughly 4 hours after taking the study medicine.
Each formulation (A, B, C and D) will be administered in a random distribution determined by computer, which is also called randomization.
In Periods 1 and 2, you will receive the formulations A and B. In Periods 3 and 4, you will receive the formulations C and D.
You will receive each formulation (A, B, C and D), one in each study period on Day 1.

Cohort 2:

Formulation A: one tablet of 100 mg PF-06882961, oval tablet used in patient studies (reference).
Formulation E: one tablet of 100 mg PF-06882961, round tablet potentially to be used in future clinical studies (test).

You will receive all treatments after an overnight fast (no eating) of at least 10 hours. You will not be allowed to drink for one hour before and one hour after you are given the study medicine.
You must stay fasted (no eating) until roughly 4 hours after taking the study medicine.

Each formulation (A and E) will be administered in a random distribution determined by computer, which is also called randomization.
You will receive each formulation (A and E), one in each study period on Day 1

Contraception, pregnancy and breast-feeding

1. FOR WOMEN ONLY:

At each visit to the Unit, we will check that you are using the appropriate contraception.

Women of non-childbearing potential:

You may participate in this study provided that:

- You are between 18 and 55 and
- You are post-menopausal (meaning that your last period was at least one year ago).
- OR ELSE you have been surgically sterilised (bilateral oophorectomy, bilateral salpingectomy, or hysterectomy).

If you do not fall into one of these categories (described above), you will be considered as capable of having children.

Women of childbearing potential:

You must fulfil one of the conditions:

- You have had a bilateral tubal occlusion
- You have a non-hormonal IUD
- You have a hormonal IUS
- Your partner has undergone a vasectomy at least six months ago.

These contraception methods must be used until minimum 28 days after last administration of study medicine intake.

Taking the medicine during the study could bring about an unknown risk for an embryo, foetus or breastfed baby. That is why you must have a negative pregnancy test during screening and at admission.

If you wish to discontinue your contraception during the study, you must inform us without delay. You will be withdrawn from the study if you discontinue your contraception.

2. FOR MEN ONLY:

You are not required to use birth control, because PF-06882961 is not likely to transfer to a partner through semen at pharmacological relevant levels.

3. PREGNANCY FOLLOW UP

Any pregnancy during the study, either from a female participant or the female partner of a male participant, or within at least 28 days after treatment with the study medicine stopped, should be reported to the study doctor or his/her representative immediately. The study doctor will ask if you/your partner or your pregnancy doctor is 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 study sponsor for safety monitoring follow-up.

Risks associated with the evaluation procedures specific to the study

1. BLOOD DRAWS

Blood draws may cause faintness, dizziness, inflammation of the vein (blood vessel), pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection.

2. TESTING OF DNA AND/OR RNA

Genes are pieces of DNA that, through material called RNA, give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. DNA, RNA, and proteins can be studied as part of genetic research. This study may involve studying your biology and whether a particular biological feature (including genes) is related to the effects or action of the study medicine or to a disease. This may include analysing all of your genetic information (called "whole genome sequencing"). Sequencing a gene is like reading a book one letter at a time. This is a very thorough way to learn about genes. The genetic analysis is for research purposes only and is not a medical test. This means that the medical importance of the results may not be known, or that they may not be related to any medical condition. The results of tests on your sample will not be given to you or the study doctor. If you do not want genetic testing to be done on your samples, you should not agree to participate in the research described in this document.

Benefits

You will not personally derive any benefit from your participation in this study, but the results obtained could be very important for the development of drugs and treatments which will benefit other people.

Withdrawal from the study

Your participation is voluntary, and you are entitled to withdraw from the study for any reason, without having to justify your decision. Nevertheless, it may be useful for the investigator and for the sponsor of the study to know if you are withdrawing from the study because the constraints or discomfort of the treatment are too great (too many uncomfortable side effects, for example).

You may be asked if this decision to withdraw is just to stop receiving the study medicine or also to stop taking part in study procedures and/or post treatment study follow-up. If you agree to continue with the follow up part of the study, information about your health will continue to be collected as described above in the procedures.

If you disagree to continue with the follow up part of the study, you must inform the study doctor in writing.

The sponsor will use information and samples already collected from you in the study before your withdrawal.

It is also possible that the investigator withdraws you from the study because he/she thinks it is better for your health or because he/she finds out that you are not following the instructions given to participants.

Finally, the competent national or international authorities, the ethics committee that initially approved the study or the sponsor may decide to interrupt or discontinue the study because the information gathered shows that the investigational treatment causes more side effects or more serious side effects than anticipated, or for any other reason, such as, for example, the decision to stop research and development of the study medicine.

Samples of biological material collected during the study

The sponsor of the study undertakes that the samples will only be used as defined in this section.

1. BANKED BIOSPECIMEN SAMPLE

A 4 mL and a 10 mL blood samples will be collected at Period 1 Day 1 in Cohort 1 and Cohort 2. This sample will be used to study biological substances in your samples, including your genes. This will help us learn more about the study medicine.
These samples are called “Banked Biospecimens”.
The samples will be held by Pfizer for up to 50 years. Research results will not be communicated to you or your doctor.
Specimens will be stored in a Pfizer-designated facility, which is currently located at 2910 Fortune Circle West, Suite E, Indianapolis, Indiana, 46241 in the United States.

The sample taken of your biological material is considered to be a “donation” and you should know that, as a matter of principle, you will not receive any financial benefit (royalties) related to the development of new therapies derived from the use of your donation of biological material and that could have commercial value.

If you withdraw your consent for participation in the study, you may contact the investigating physician to have the unused portion of your sample destroyed. The results obtained based on your samples before the withdrawal of your consent will remain the property of the sponsor of the study.

2. OPTIONAL USE OF YOUR SAMPLES

See section **“ADDITIONAL CONSENT REQUEST: USE OF BIOLOGICAL SAMPLES FOR ADDITIONAL RESEARCH”** Page 19.

If you take part in this clinical study, we ask you:

- To cooperate fully in the smooth running of this study.
- Not to conceal any information relating to your state of health, the medication you are taking or the symptoms you are experiencing.
- Not to take part in other clinical study involving an investigational treatment, be it a medicinal product, a medical device or a procedure, while taking part in this study.
- To carry the "emergency card" with you at all times. This is imperative for your safety in the event of emergency care in an institution that does not know you. This card states that you are taking part in a clinical study. It also mentions a telephone number that you may call in an emergency. You should return this card to us at the end of the study.

Contact

If you need further information, but also if you have problems or concerns, you can contact the Pfizer Clinical Research Unit on the following telephone number +32(0) 2/556 70 02.

II. Supplementary information

Restrictions

COMMON RESTRICTIONS TO MOST OF THE STUDIES

You should avoid all medications including non-prescription medicines bought, including vitamins, extracts of plants, homeopathic medicines and medicinal herbal teas, in the four weeks before the study, throughout the study and up to the day of final payment. If you fall ill and require treatment, please contact the Unit immediately. You will be told what treatment you may undergo or whether it is possibly preferable to discontinue the study.

You must also avoid consuming any alcoholic drinks, stimulants (such as coffee, tea, chocolate or beverages containing caffeine or theine), bread or cakes containing poppy seeds:

- from 24 hours before the screening examination until the results of your tests are known,

then

- from 24 hours before the start and throughout each study period.

You must also avoid any strenuous physical exercise:

- from 48 hours before the screening examination until the results of your tests are known,

and

- from 48 hours before the start and throughout each study period.

You must also avoid consuming tobacco-or nicotine-containing products from 24 hours before the start and throughout each study period.

Furthermore, you may not consume red wine, grapefruits or grapefruit juice or citrus fruit of the grapefruit type (pomelos, « Seville » oranges or bitter oranges) from 7 days before the start of the first period until the last day of the last period.

Exclusions

1. SPECIFIC EXCLUSIONS FROM THIS STUDY

You may not take part in this study if:

- You have a known participation in a clinical trial of PF-06882961.
- You have a personal or family history of thyroid cancer and/or cancers affecting endocrine glands.

2. COMMON EXCLUSIONS TO MOST OF THE STUDIES

You may not take part in this study if:

- You are outside of the age limits (18-55 years) or weight limits (minimum of 50 kg), or you are outside of the limits of the Body Mass Index (25 - 40 kg/m^2).
- You are regularly taking medications, or you are suffering from a chronic illness.
- You have an illness, or you have received treatment that may affect absorption of the medicines (for example a gastrectomy).
- You are suffering from asthma or from any allergy to a medicine.

- You are suffering from any treated or symptomatic, seasonal allergies (hay fever) during the study.
- You smoke more than 5 cigarettes a day or consume an equivalent quantity of tobacco / nicotine-containing products.
- You have taken part in another clinical study involving investigational medicines within the last 30 days.
- You have given blood or constituent elements of blood during the two months preceding the study or you intend to be a donor in the two months following the end of the study (Red Cross standard to guarantee blood cells regeneration). Giving plasma is allowed.
- You have taken or you are taking drugs.
- You think you are at risk of being infected with the AIDS virus, hepatitis B or C.
- You have a history of regular alcohol consumption exceeding 14 drinks/week (1 drink = 90 mL of wine or 240 mL of beer or 30 mL of spirit).

Supplementary information on the risks associated with participation in the study

Specific features of the study

BLOOD VOLUME

The total quantity of blood taken during the study will be approximately 265 mL for Cohort 1 and approximately 150 mL for Cohort 2.
The times for taking blood may change. Additional blood samples may be added provided the total volume of 550 mL is not exceeded.

Your body will quickly build up again this quantity of blood during the study.

Glossary

Bilateral oophorectomy: Ablation (surgical removal) of the ovaries.

Bilateral salpingectomy: Surgical removal of the fallopian tubes.

Bioanalytical method: Techniques used to measure the quantity of study medicine, metabolite, biomarkers or proteins.

Biobank: Reserve of biological samples.

Biomarker: A biomarker is a characteristic objectively measured and evaluated as an indicator of a disease or of the action of a medicine. Thus, for example, glucose is a biomarker for diabetes, and blood pressure is a biomarker for arterial hypertension (high blood pressure).

Body Mass Index: The Body Mass Index is calculated by dividing your weight (in kg) by your height (in m) squared. In practice, you just need to divide your weight by your height and then once again divide the result by your height. For example, if you are 1.70 m tall and you weigh 70 kg, your BMI index will be 24. This is calculated as follows: 70 kg / 1.70 m = 41 and 41 / 1.70 m = 24.

DNA: A molecule that is present in all cells, and which comprises the entire set of information necessary to the development and working of an organism. It is also the support of the heredity, because it is wholly or partly transmitted in the course of reproduction. It therefore carries the genetic information (the genotype) and constitutes the genome of living beings.

Hysterectomy: Ablation (surgical removal) of the uterus.

Metabolite: Compound resulting from the transformation of a medicine in a cell, in a tissue or in blood.

Pharmacokinetics (PK): Assessment of the evolution of study medicine concentrations in the blood before and after administration.

Plasma: The liquid portion of the blood that bathes the other blood components (red blood cells, white blood cells, platelets).

Protein: Biological molecule composed of amino acids brought to the body through food processing by digestion followed by assimilation by the intestines, among others.

RNA: A biological molecule that is present in practically all living organisms, including certain viruses. The RNA is a molecule that is chemically very similar to DNA and it is also in general synthesised in the cells based on a DNA matrix of which it is a copy. Living cells use RNA in particular as an intermediary support for the genes to generate the proteins they need. The RNA can fulfil numerous other functions and in particular intervene in chemical reactions taking place in the cell.

Type 2 diabetes mellitus: Type 2 Diabetes mellitus is a long-term metabolic disorder that is characterized by high blood sugar, insulin resistance, and relative lack of insulin. Common symptoms include increased thirst, frequent urination, and unexplained weight loss.

Additional information on protecting participants and their rights in each clinical study

You must inform the study doctor of:

- Any medicine or substance that you have taken in the last 28 days, that you are currently taking or that you intend to take;
- Any change in treatment that has taken place during the study;
- Any study exclusion criteria that would apply to you according to the information given by the doctor in charge;
- Any significant illness, past or present, including any consultation you have had with any doctor during the last six months, whether or not it resulted in medication or a medicine prescription;
- Your history of drug taking, alcohol consumption or smoking tobacco;
- Your participation in other clinical studies during the last 12 months.

Assistance or advice

This study has been submitted to an independent Ethics Committee 'Comité d'Ethique Hospitalo-Facultaire Erasme-ULB', which has issued a favourable ethical opinion as regards to its implementation. The Ethics Committees are responsible for the protection of the subjects who take part in clinical research in accordance with the Law of 7 May 2004 concerning experiments on humans.
However, the decision as to whether or not to participate in this study must be your own personal decision. Under no circumstances should you take the Ethics Committee's favourable opinion as an incentive to take part in this study.

If you have any questions, concerns or complaints concerning the role of the Ethics Committee or your rights as a participant in a clinical study, you may contact the Ethics Committee 'Comité d'Ethique Hospitalo-Facultaire Erasme-ULB', during office hours, dialling the following number: 02/555 37 07.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by legislation. This website will not contain information that can identify you. It will be no more than a summary of the general results of the study. You can check this website at any time. However, it may take several years before the research results are available online.

The ClinicalTrials.gov website is in English only. If you would like any help in understanding the contents of this website, please talk to your study doctor.

Participant rights

Before signing, do not hesitate to ask any questions that you consider useful. Take the time to discuss it with a person you trust if you so wish.

Your participation in this study is voluntary and you must remain free from any constraint. This means that you have the right not to take part to the study or withdraw from it, at any time, without giving any justification and without losing your legal rights, even if you previously agreed to take part to it.

If you decide to withdraw from the study, we ask you to inform the study doctor and to undergo some follow-up examinations so that we can be sure that you are in good health.
The doctor in charge of the study can decide to remove you from the study, if she/he deems that it would be harmful for you to continue to take part to it.
The study may also be discontinued further to the discovery of new information concerning the product or in the event that the Ethics Committee takes a new decision on the study.

You will be informed of any new data that may influence your decision to take part or not in the study.

If you agree to take part in the study, you must sign the informed consent form. The study doctor, or designee, will also sign this form and will thereby confirm that she/he has provided you with all the necessary information on the study. You shall receive a paper copy of that document.

Compensation and insurance

Your compensation for the inconveniences caused by your participation to the study will be available three weeks after the last contact (see point 12 of the "Participant Agreement and Consent Form").

Any clinical study carries a risk, however small it is. If you suffer damage as a result of your participation in this study, you (or in the event of death, your dependants) will be compensated for this damage by the study sponsor in accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004). You do not have to prove a fault for this. In this regard, the sponsor has taken out an insurance policy.

You are therefore asked to report any new health problem to the investigator before consulting another doctor, taking any other medication or receiving any other medical treatment. If, for any reason, you consult another doctor during this clinical study, you must inform him/her that you are taking part in a clinical study and present your clinical study participant card. This could be important in establishing a diagnosis and treating your complaints.

If the investigator believes that a link with the study is possible (the insurance does not cover the natural progression of your disease or the known side effects of your normal treatment), he/she will inform the study sponsor, which will initiate the declaration procedure to its insurance company. The latter will appoint an expert - if it considers it necessary - to assess whether there is a link between your new health problems and the study.

In the event of disagreement either with the investigator or with the expert appointed by the insurance company and also whenever you feel it is appropriate, you or - in case of death - your dependents may bring proceedings against the insurer directly in Belgium (Insurer: AIG Europe Limited, policy number: 3.300.389, contact: Karin Vergracht, Aon Belgium B.V.B.A, Tel: +32 (2) 730 99 51).

The law provides that the insurer may be summoned to appear either before the judge of the location where the event giving rise to the damage occurred, or before the judge of your domicile, or before the judge of the insurer's registered offices.

Provision has been made for insurance to cover research injury liability of the sponsor established in relation to the clinical trial.

Protection of your personal data

Your participation in the study means that you accept that the study doctor will collect data related to you (the "Personal Data") such as your name, postal address, email address, phone number, your date and place of birth, sex, age, your general practitioner's name (with your consent), bank details, as well as ethnic origin and data relating to your health status, and that the study sponsor (Pfizer) will use this Personal Data for research purposes as specified in this document, and for scientific and medical publications on that research (fully anonymously).

Your Personal Data will be collected, stored, accessed and otherwise processed in compliance with the applicable EU and Belgian laws on clinical trial, and with the applicable EU and Belgian privacy legislations as they may be amended or repealed and replaced from time to time (collectively referred to as "Data Privacy Laws") and as specified in the annex "Supplement related to personal data protection" (p. 21).

You have the right to consult, correct or request deletion of your Personal data by writing to the following address: Data Privacy Steward, Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels. Should communicating your Personal Data potentially jeopardise the results of the study, we may ask you to wait until the end of the study to access these Personal Data.

If you want to ask for removal of Your Personal Data, please send a signed and dated letter to Data Privacy Steward, Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels. Your data will be deleted by Pfizer and will no longer be stored or processed by us (except for your letter requesting the removal – see point G of the "Supplement related to personal data protection"). You will therefore not be able to participate to any of our future studies.

However, if you have taken part to a study or a screening, we will not be able to delete your data, but your file will be inactivated, and you will not be contacted again.

Monitoring of non-participation in other clinical studies

Our Pfizer Clinical Research Unit, located on route de Lennik 808, 1070 Anderlecht (Brussels) takes part in the « Verified Clinical Trials LLC (« VCT ») programme.

The law of 7 May 2004 relating to experiments on humans contains a provision (article 32), for the creation of a federal database containing a list of participants taking part in phase I studies.

The aim of this database is to enable us to ensure that participants are not taking part in several phase I clinical studies at the same time. In addition, this system will enable us to enhance your protection, as well as the quality of the data for the study that you will be taking part in.
To ensure the correct application of the law relating to experiments on humans and prior to the creation of the federal database, we decided to work with the company Verified Clinical Trials LLC ("VCT") located on Franklin Avenue, Suite 150, Garden City, New York 11530, USA.
This company manages the VCT database that is already used by several phase I clinical research units in Belgium, Germany, the Netherlands and the United States.

Verified Clinical Trials LLC ("VCT") is a secure system that respects data protection regulations. Besides, only authorised institutions conducting clinical studies are able to access the data. Your personal data will be supplied to the VCT server in encrypted form and will be stored on the Verified Clinical Trials LLC ("VCT") server in United States in encrypted form for a maximum of fifty years.

We will therefore supply the following to the VCT server:

- Your surname, first name, date and place of birth, nationality and sex.
- The start and end dates of the study, the exclusion period between two studies and the number and type of studies you are taking part in.

The result of the comparison with the existing data on the VCT server will enable us to determine whether or not you can be authorised to take part in a clinical study.

Your personal data will be collected and processed by Pfizer and VCT in the strictest confidence, in accordance with the applicable EU and Belgian privacy legislations as they may be amended or repealed and replaced from time to time (collectively referred to as "Data Privacy Laws") under the responsibility of PFIZER SA, Boulevard de la Plaine 17, 1050 Brussels.

Your personal data may be accessed by other PFIZER units around the world and PFIZER will always ensure that your data are processed confidentially and protected according to the strict criteria of Belgian legislation.

PARTICIPANT AGREEMENT AND CONSENT FORM	
Principal Investigator	Dr. Constantino Kantaridis

1. I freely agree to take part in this study.
2. I have received full explanations from the people in charge of the study about the nature, purpose and likely duration of the study, and about what is expected of me. I have also been informed of all the possible side effects. The information document, which was sent to me, is attached hereto and is an integral part thereof. I have informed the study doctor of my medical history, of the medications I may have taken, and of any other studies I may have participated in. In this regard, I was given the Study Information Leaflet pertaining to the abovementioned study.
3. I have been given the opportunity to question the study doctor on all aspects of the study and have understood the advice and information given as a result.
4. I have been informed that a blood sample will be taken for HIV, Hepatitis B and C screening. I have also been informed that a blood sample will be taken, to study biological substances including my genes, to help us learn more about the study drug. The sample will be held in a Pfizer-designated facility for up to 50 years.
   Research results will not be communicated to me or my doctor.
5. I agree to comply with any instruction given during the study and to co-operate faithfully with the study doctor and to tell him/her immediately if I suffer any change of any kind in my health or well-being or any symptoms of whatever kind.
6. I undertake to be present on the premises of the Pfizer Clinical Research Unit for the whole period spent in hospital, and also for the outpatient visits scheduled within the context of this study. I am aware of the fact that non-compliance with this obligation could be detrimental to my health if I experienced an undesirable effect and could not immediately gain access to the appropriate medical care.
7. I shall not donate blood during the study, nor for two months before or after the trial.
8. I undertake to comply with the study restrictions as they are mentioned under “II. Supplementary information” (Page 9). If a violation of these commitments were confirmed by laboratory tests, I could be excluded from the study.
9. I understand that data about me will be collected throughout my participation in this study and that the Investigator and the Sponsor of the study will guarantee the confidentiality of these data.

   I agree to my personal data being processed as described under “Protection of your personal data” in the section “Additional information on protecting participants […]” (Page 12). I also consent to these data being transferred to and processed in countries other than Belgium.
10. Although my name must never appear in the report of the study disclosed to third parties, I expressly authorise the company Pfizer to pass on the results of this study to the competent medical or pharmaceutical authorities, both Belgian and foreign, to technical advisers, whether or not linked to the company, and to publish the results.
11. It is understood that I am free to leave the study at any time without having to justify my decision and without losing my legal rights. However, I shall, in that case, continue to benefit from all treatments and check-ups my condition may require.

12. The company sponsoring the study confirms that:

i) I shall receive the sum of **€ 2200.00** (two thousand two hundred euros) for my participation in the whole **Cohort 1** of this study.

I shall receive the sum of **€ 1350.00** (one thousand three hundred and fifty euros) for my participation in the whole **Cohort 2** of this study.

If I need to withdraw from the study for medical reasons evaluated by the Investigator as related to the study, I shall however receive a full payment of the above-mentioned amount for my participation. If I withdraw from the study for medical reasons or other reasons not associated with my participation in the study, I shall receive a compensation proportional to the duration of my participation.

If changes are made to the original calendar of the study as provided at the time of first dosing, the compensation amount will be reviewed proportionally to the duration of the new calendar.

If my participation is ended for not respecting the restrictions, I shall be removed from the study, and my compensation amount shall be reviewed proportionally to the duration of my participation.

In addition, **I will be compensated for my travel expenses** (a lump sum) based on the journey from the address where I officially reside, and the number of journeys made.

ii) The sponsor has subscribed a no-fault insurance to cover injuries or significant deterioration in health or well-being in connection to my participation in the study.

13. I have been made aware of the reasons for which personal data will be processed and/or transferred as part of the study and of my legal rights concerning these personal data as described in the Participant Information Sheet.

Signatures:

In agreement, the participant:

_____
Printed name of participant

_____ _____
Signature of participant Date of signature§

§Participant/ impartial witness must personally date their signature.

Person Obtaining Consent:

I hereby confirm having provided the participant with all the necessary information about the study, without exercising any pressure to cause the subject to participate. I further confirm that I have handed over a copy of the Information and Consent Leaflet signed by the participant and by me, and that I am willing to answer any additional questions if necessary. I state that I work in compliance with the ethical principles set out in the "Helsinki Declaration" and the Belgian Law of 7 May 2004 concerning experiments on humans.

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion † Date of Signature

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

Consent for Participant Who Cannot Read:

The study participant has indicated that he/she is unable to read. One or more members of the study team read the consent document to the study participant, discussed it with the study participant, and gave the study participant an opportunity to ask questions.

_____
Printed name of impartial witness ‡

_____ _____
Signature of impartial witness Date of signature§

☐ Not applicable (*Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the participant cannot read.*)

§Participant/ 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 informed consent process if the participant cannot read, and who reads the informed consent and any other written information supplied to the participant. *See* Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.

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ADDITIONAL CONSENT REQUEST
USE OF BIOLOGICAL SAMPLES FOR ADDITIONAL RESEARCH
(OPTIONAL FOR PARTICIPANTS)

- The Sponsor would like your permission to use some or all of the samples collected in this study for additional research that may or may not be related to the study. This additional use of your sample(s) is called "Additional Research".
- If you decide to participate in this Additional Research, you do not have to provide any new samples because the sample(s) that have already been collected in the study will be used for this Additional Research.
- This request is optional, and you do not have to agree. You may take part in the study and contribute samples for use in the study even if you do not want your samples to be used for Additional Research.

PURPOSE OF THIS ADDITIONAL RESEARCH

The aim of this Additional Research is to use these biological samples and the data obtained from them to understand diseases and to advance science, including development of other medicines or treatments.

- This Additional Research might involve learning more about your biology. It may involve studying biological substances in your sample(s), including your genes.
- The Additional Research might include exploratory research of any disease or condition and is not limited to the disease or condition that is the focus of the study. It may not be possible to link the results of the exploratory research to individuals, including you. The sponsor does not plan to return information from this Additional Research to you or to the study Principal Investigator.

The sponsor may share the samples and data from them with other researchers and collaborators. Further information about this is explained in the privacy section below.

Specimens will be stored in a Pfizer-designated facility, for as long as they are useful for scientific research, which may be for up to 50 years.

POSSIBLE BENEFITS OF PARTICIPATING IN THIS ADDITIONAL RESEARCH

This Additional Research is for research purposes only. There is no direct benefit to you from taking part. Information learned from the Additional Research may help other people in the future and help in the development of new medicines or treatments.

WITHDRAWAL OF CONSENT

You can change your mind at any time about allowing your biological samples to be used for this Additional Research. Inform the study doctor that you would like to end your participation in the Additional Research.

COMPENSATION

You will not be compensated for taking part in this Additional Research.

The sponsor may use information from this Additional Research to develop products or processes from which the Sponsor could make a profit. There are no plans to pay you or provide you with any products developed from this Additional Research. The sponsor will own or have rights to all products or processes that are developed using information from your samples.

PRIVACY PROTECTION

See section "Protection of your personal data" (Page 13).

CONTACT INFORMATION

The medical team will answer your questions or concerns regarding the Additional Research before, during, and after the research study.

Please refer to the main consent for contact information if you need to reach the medical team or wish to speak with someone not involved with the Additional Research.

PARTICIPANT AGREEMENT AND CONSENT FORM FOR THE ADDITIONAL RESEARCH

1. I have read and understood the information about this Additional Research.
2. I have been given enough time and opportunity to ask about the details of the Additional Research and to decide whether or not to participate.
3. I voluntarily agree to take part in this Additional Research. I do not give up any of my legal rights by signing this consent document.
4. I have been informed that I will receive a signed and dated copy of this document.

First Name_____ Name_____ _____ Signature _____ Signature date	**YES, I AGREE** TO MY SAMPLE(S) BEING USED FOR ADDITIONAL RESEARCH
First Name_____ Name_____ _____ Signature _____ Signature date	**NO, I DO NOT AGREE** TO MY SAMPLE(S) BEING USED FOR ADDITIONAL RESEARCH

SUPPLEMENT RELATED TO PERSONAL DATA PROTECTION

Table of Contents

This **Supplement related to personal data protection** describes how we will collect, use, and share your personal data. It also describes your rights as data subject of whom personal data are being collected and processed. Your personal data shall be processed in compliance with the General Data Protection Regulation and the Belgian law of 30 July 2018 relating to the protection of natural persons with regards to the processing of their personal data.

A. What personal data may we collect about you during this study?

The study team and others assisting you with study-related care will collect information related to you (personal data), in the framework of the study. Amongst these personal data; some are sensitive data. These data may include:

- **Information that directly identifies you** such as your name, address, telephone number, e-mail address, date and place of birth, national ID number.
- **Your bank details.**
- **With your consent, the identification of your general practitioner.**
- **Sensitive personal data** 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 personal data that is needed for this study such as ethnic origin, genetic information, sexual orientations, HIV/AIDS, tuberculosis, dietary preferences.
- **Data from testing and analysis of biological samples** (such as blood or urine) **and images** (such as X-rays, CT-Scans, and medical photographs). This may also include genetic information.
- **Data captured from electronic devices,** if you complete the consent process using the eConsent tablet or if you use a mobile application or other digital tool during the study. This information may include data about your use of the eConsent tablet, application or tool, such as the length of time it takes you to complete the consent process, the number of times you scroll between pages or click on the hyperlinked items, your electronic signature. Mobile applications and other digital tools used in the study may have their own privacy policies. Those policies provide additional information about the data processing activities performed by the digital tools.

B. Who will use my personal data, how will they use it, and where will it be stored?

Any personal data collected about you during this study will be stored by the study team at your study site. The study team must ensure the confidentiality of your personal data.

Your personal data shall be accessed by:

- The study doctor and other study team members;
- The Sponsor and its representatives (including its affiliated companies);
- People or organizations providing services for, or collaborating with, the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or rights to the product under study;
- Government or regulatory authorities (including those in other countries); and
- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study.

The individuals and groups listed above will use your personal data 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 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), IEC(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 e-consent module used for the study and your comprehension of the e-consent process;
- contact you during and after the study (if necessary);
- follow-up on your health status, including using publicly available sources should the study team be unable to contact you using information held on file;
- protect your vital interests and/or the interests of your pregnant partner (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated); and
- answer your personal data protection requests (if any).

The study site will retain your personal data for the period necessary to fulfil the purposes outlined in the consent document(s). This period could be up to 25 years after the end of the study.

If you provide someone else's personal data (for example, an emergency contact or details of family medical history) you should make them aware that you have provided the information to us. We will only use such personal data in accordance with this informed consent and applicable law.

C. What happens to my personal data that is sent outside the study site?

Before the study team transfers your personal data outside the study site, the study site will replace your name with a unique code and remove all information that directly identifies you. We call this "**Coded Information**." The study site will keep the link between the unique code and your personal data confidential, and the Sponsor will not have access to that link. The Sponsor's employees and representatives are required to protect your Coded Information and will not attempt to re-identify you.

Your Coded Information will be used by the following persons:

- The Sponsor and its representatives (including its affiliated companies);
- People and/or organizations providing services to or collaborating with the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or the rights to the product under study;
- Other researchers;
- The IRB or IEC that approved this study;
- Government or regulatory authorities, if necessary;

The above parties may use your personal data for the following purposes:

- **Conducting the study**, including:
  - Examining your response to PF-06882961;
  - Understanding the study and the study results; and
  - Assessing the safety of PF-06882961.

- **Complying with legal and regulatory duties,** such as:
  - Ensuring the study is conducted according to good clinical practice;
  - Making required disclosures to IRB(s), IEC(s), or government or regulatory authorities;
  - Seeking approval from government or regulatory authorities to market PF-06882961 (it is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research); and
  - Sharing study data with other researchers not affiliated with the Sponsor or the study team (including through publication on the internet or other media). 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 or at educational meetings of other researchers. You will not be directly identified in any publication or report of the study. However, 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. Moreover, 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.

The Sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in the consent document(s). This period could be up to 25 years after the end of the study.

D. How are my biological samples and images handled?

If biological samples or images of you are taken during the study, those samples and images will be handled in the same way as your Coded Data. All samples will be treated as required by law. Sometimes your study site may be unable to remove information that can identify you from your images before sending images to the Sponsor and its representatives.

E. Can my personal data be used for other research?

Your Coded Information may be used to advance scientific research and public health in other projects that will occur in the future. At this time, we do not know the specific details of these future research projects. However, if your biological samples are collected, those samples, with their related data, will only be used for other research if you agree and confirm by signing the Additional Consent Request.

This other research may be conducted (1) in combination with data from **other sources**, (2) for **additional scientific research purposes** beyond objectives of this study, and (3) subject to **specific safeguards**.

- **Other sources**: Coded Information may be combined with data from other sources that are taken from outside typical research settings. These sources may include: coded electronic health records, claims and health care cost and payment data or databases, product and disease registries, data gathered through your phone, tablet, or other devices and mobile applications, social media, pharmacy data, biobanks, or patient engagement programs.
- **Additional scientific research:** Coded Information may be used to understand how to make new medicines, devices, diagnostic products, tools and/or other therapies that treat diseases and to improve future research. It may also be used to inform value, cost-effectiveness and pricing, and to optimize access to medicines.
- **Specific safeguards** will be used to protect your Coded Information, which may include:

    - Limited access to Coded Information to specific individuals who will be bound to keep this information confidential and will be prohibited from attempting to re-identify your Coded Information.
    - Use of security measures to avoid data alteration, loss and unauthorized access.
    - Anonymisation of the data by removing and/or replacing information from the Coded Information and/or destroying the link to the Coded Information.
    - Assessment of data protection systems to identify and mitigate privacy risks, if any, associated to each additional scientific research purpose.
    - When required by applicable law, verification that the scientific research has obtained the approval of IECs, IRBs, or other similar review groups.

F. How will my personal data be protected when transferred from the study site to the Sponsor?

Your personal data will be treated in compliance with applicable data protection laws. The Sponsor and Pfizer Clinical Research Unit (PCRU), part of Pfizer SA, are the data controllers of your personal data. The PCRU will be the data controller of your personal data and the Sponsor, will be the data controller of your Coded Information.

Some of the people using your personal data, including your Coded Information, may be based in countries other than those of the European Union (EU) and of the European Economic Area (EEA), including the United States. Data protection laws may be different in these countries. The European Commission has decided that some of these countries provide a level of data protection equivalent to the one available in the EU (the full list of these countries is available at this website: https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en).

The Sponsor and people working with the Sponsor will take steps to maintain the confidentiality of your personal data. If your personal data is transferred by the Sponsor from the EU, EEA, and/or Switzerland to other countries that have not yet been found by European Commission to meet requirements for the protection of personal data, the Sponsor has put in place standard EU data transfer agreements to protect your personal data. Please contact your study team to obtain a copy of these standard data transfer agreements.

G. What are my data protection rights? Whom may I contact about these rights or any concerns or complaints?

If you wish to exercise any of the rights described below or have concerns about how your personal data is being handled, it is best to contact the PCRU and not the Sponsor of the study. Generally, the Sponsor will not know who you are (by name) because the Sponsor only holds your Coded Information, which does not include your name or other information that can identify you. Please contact the PCRU, the study team representative or PCRU data protection officer, at the following address: Data Privacy Steward, Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels, Phone: 0800/99.256 or +32 2/556.70.02; Email: werespectyourprivacy@pfizer.com

- You have the right to access your personal data that is held about you by the study team. To ensure the integrity of the study, you will not be able to review some of the data until after the study has been completed.
- You have the right to correct or update your personal data.
- You have the right to limit the collection and use of your personal data under certain circumstances (for example, if the information is inaccurate).
- You have the right to receive your personal data in a in a structured, commonly used and machine-readable format (for example, in a readable text electronic file or chart) for your own purposes or for giving it to others. *You do not have the right to receive your personal data that have been used for public interest purposes (for example, for reporting incidents of disease to public health officials) or in the exercise of official authority vested in the Sponsor or the PCRU (for example, responding to information requests from public agencies or monitoring drug safety).*
- You have the right to request the deletion of your personal data if you are no longer participating in the study and you have withdrawn your consent to process your personal data as described in this document. *However, there are limits to the ability to honour a request to delete your personal data. Some or all of your personal data may be kept and used if deletion would seriously impair the study (for example, if deletion would affect the consistency of study results) or if your personal data is needed to comply with legal requirements.*
- You have the right to file a complaint with the data protection authority:

  Data Protection Authority
  Rue de la Presse 35, 1000 Brussels
  Tel.: +32 (0)2 274 48 00
  Fax: +32 (0)2 274 48 35
  Email: contact@apd-gba.be
  https://www.dataprotectionauthority.be/contact-us

H. What happens if I 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 by informing the study team of it.

If you stop taking part in the study and you do not inform the study team about your withdrawal, your contact information may be used by the study team to contact you and check whether you wish to continue in the study. If the study team is unable to reach you, the Sponsor may use publicly available records about your health to monitor the long-term safety of the study medicine. This will only be done if allowed by the law.

If you stop taking part in the study but do not withdraw your consent for the processing of your personal data, your personal data will continue to be used in accordance with this document and applicable law.

If you decide to withdraw your consent:

- You will no longer be able to participate in the study;
- No new information or samples will be collected about you or from you by the study team.
- The study team may still need to report any safety event about the medicine related to the study that you may have experienced due to your participation in the study;
- Your personal data, including your Coded Information, that has already been collected up to the time of your withdrawal of consent, will be kept and used by the Sponsor to guarantee the integrity of the study, to determine the safety effects of PF-06882961, to satisfy legal or regulatory requirements and/or for any other purposes permitted under applicable data protection laws.;
- Your personal data, including your Coded Information, will not be used for further scientific research. However, if your personal data has been anonymized so that the information does not identify you personally, that information may continue to be used for further scientific research (as described in Section E of this document), as permitted by applicable law; and
- Biological samples that have been collected but not analysed will no longer be used, unless permitted or required by applicable law.

  You have the additional right to request that any remaining samples that have been collected from you as part of the study be destroyed. You may exercise this right by communicating to the study team your wish to have the samples destroyed. The study team will then send your coded request to the Sponsor. In some countries, local laws or regulations may require that your samples be destroyed or de-identified if you withdraw from the study, regardless of whether you specifically make such a request.

  However, we cannot guarantee the destruction of all samples because some of the samples may no longer be traceable to you, they may have been entirely used up, or they may have been released to a third party. In those cases, it would not be possible to remove and destroy your biological samples and any related data.