EudraCT number:	2020-006073-30
Study medicine:	PF-07321332
Sponsor of the study:	Pfizer Inc.
Research organisation:	Pfizer Clinical Research Unit (PCRU), Route de Lennik 808, 1070 Brussels
Medical Ethics Committee:	The evaluating Belgian Ethics Committee (to be determined)
Principal Investigator (study doctor):	Dr. Lien Van Eyck
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I. Information vital to your decision to take part in 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 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 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 make a decision with full awareness of all the implications. This is called giving "informed consent".

Please read these few pages of information carefully and ask the investigator or his/her representative any questions you want. 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 and approved by one Ethics Committee and the federal agency for medicines and health products.
- Your participation is voluntary (your choice) 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 processed 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 21).

Objectives and description of the study protocol

We are inviting you to take part in a clinical study involving PF-07321332 which will include up to approximately 60 participants, including among these, 6 Japanese participants, if the optional Japanese cohort (Part 2 optional Cohort 7) is conducted.

1. AIMS OF THE STUDY

PF-07321332 is a new oral medicine that is currently being developed as an oral treatment in patients with COVID-19, a new, potentially fatal, respiratory infection caused by the novel coronavirus, SARS-CoV-2.

The aim of this study is to evaluate the safety and tolerability of single and multiple doses of PF-07321332 compared to placebo in healthy participants.

This is the first time PF-07321332 will be given to humans.

The study is made of 3 parts:
- Part 1 : single escalating doses
- Part 2 : multiple escalating doses
- Part 3 : food effect

The purpose of Part 1 of this research study is:
- To assess the safety and tolerability of a single dose of PF-07321332.
- To measure how much of PF-07321332 is in your blood after you take a single dose of PF-07321332.
- In one cohort (Cohort 1 Period 2), the amount of PF-07321332 and PF-07321332 metabolites in your blood, urine and feces will be measured.
- If we cannot achieve a sufficient amount of PF-07321332 in your blood, we could assess safety and tolerability of a single dose of PF-07321332 in combination with ritonavir (optional). Ritonavir would act as a booster by increasing the amount of PF-07321332 in your blood.
- Similarly, we would measure how much of PF-07321332 is in your blood after you take a single dose of PF-07321332 in combination with ritonavir (optional).
- To determine the amount of PF-07321332 in your blood after you take PF-07321332 as tablet compared to PF-07321332 as an oral suspension (optional).
- To find out the amount of PF-07321332 in your blood after you take a single dose of PF-07321332 as tablet with food (optional).

The purpose of Part 2 of this research study is:
- To assess the safety and tolerability of multiple ascending doses of PF-07321332.
- To measure how much of PF-07321332 is in your blood and urine after you take multiple ascending doses of PF-07321332.
- To assess the safety and tolerability of multiple ascending doses of PF-07321332 in combination with ritonavir (optional).
- To measure how much of PF-07321332 is in your blood and urine after you take multiple ascending doses of PF-07321332 in combination with ritonavir (optional).
- The amount of PF-07321332 metabolites in your blood may be also measured.

Part 3 is optional. The purpose of Part 3 of this research study is:
- To compare the amount of PF-07321332 in your blood after you take different formulations (tablet and suspension).
- To find out the amount of PF-07321332 in your blood after you take a single dose of PF-07321332 as tablet(s) with and without food.
- To assess the safety and tolerability of PF-07321332 administered as suspension and as tablet(s).
- To evaluate the sensory and taste of the PF-07321332 oral suspension.

2. LEGAL STATUS OF THE STUDY MEDICINES

PF-07321332 is a new investigational medicine. A new investigational medicine is one that is currently not approved for sale in Belgium.

Ritonavir is approved in Belgium and is available by prescription for the treatment of human immunodeficiency virus (HIV) infection and is given in combination with other medicines.

3. POSSIBLE SIDE EFFECTS

3.1. PF-07321332 RISKS

To date, PF-07321332 has not been administered to humans.

The safety of PF-07321332 has been studied in animals. In these animal studies, no significant risks or safety events of concern were identified, and PF-07321332 did not cause adverse effects at any of the dose levels that will be used in clinical studies. Based on the studies done in animals with moderate to high doses of PF-07321332, potential risks from treatment with PF-07321332 include increased respiratory rate (number of breaths per minute), small reductions in heart rate, small increases in blood pressure, vomiting, changes in movement and small changes in some blood laboratory measures that play a role in the blood clotting system or in inflammation.

During clinical studies of PF-07321332 you will be monitored for changes in respiratory rate, heart rate or blood pressure, as well as for the occurrence of other symptoms or side effects. Blood and urine samples will be taken on a regular basis to measure and evaluate for any changes in laboratory test results.

The effects of PF-07321332 on reproduction are unknown. At this time, it is not known whether PF-07321332 can cause harm to the foetus or whether it is secreted in human milk. Therefore, PF-07321332 should not be administered to pregnant women or women who are breastfeeding. An appropriate method of contraception is required.

Since the use of PF-07321332 is investigational for the treatment of COVID-19 when taken alone or in combination with other medications, there may be other risks or side effects that are unknown. Human clinical and animal studies do not always predict the side effects of experimental medicines that people may experience. There may be rare and unknown side effects, including reactions that may be life-threatening and could result in sickness or death.

3.2. RITONAVIR RISKS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Also, the side effects of ritonavir when used with other antiviral medicines are dependent on the other medicines.

Very common: may affect more than 1 in 10 people:
- upper or lower stomach ache
- vomiting
- diarrhoea (may be severe)
- feeling sick (nausea)
- flushing, feeling hot
- headache
- dizziness
- pain in the throat
- cough
- upset stomach or indigestion
- a tingling sensation or numbness in the hands, feet or around the lips and mouth
- feeling weak/tired
- bad taste in the mouth
- damage to the nerves that can cause weakness and pain

- itching
- rash
- joint pain and back pain

Common: may affect up to 1 in 10 people
- allergic reactions including skin rashes (may be red, raised, itchy), severe swelling of the skin and other tissues
- inability to sleep (insomnia)
- anxiety
- increase in cholesterol
- increase in triglycerides
- gout
- stomach bleeding
- inflammation of the liver and yellowing of skin or whites of the eyes
- inflammation of the pancreas
- increase in urination
- reduced kidney function
- seizures (fits)
- low levels of blood platelets
- thirst (dehydration)
- abnormally heavy periods
- wind (flatulence)
- loss of appetite
- mouth ulcer
- muscle aches (pain), tenderness or weakness
- fever
- weight loss
- laboratory test results: changes in blood test results (such as blood chemistry and blood count)
- confusion
- difficulty paying attention
- fainting
- blurred vision
- swelling of the hands and feet
- high blood pressure
- low blood pressure and feeling faint when getting up
- coldness in the hands and feet
- acne

Uncommon: may affect up to 1 in 100 people
- heart attack
- diabetes
- kidney failure

Rare: may affect up to 1 in 1,000 people
- severe or life-threatening skin reaction including blisters (Stevens Johnson syndrome, toxic epidermal necrolysis)
- serious allergic reaction (anaphylaxis)
- high levels of sugar in the blood (hyperglycemia)

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/ provided by the PCRU after the study has ended.

4. TREATMENTS ADMINISTERED DURING THE STUDY

As this research study will be the first time the study drug will be given to people, the dose of the study medicine to be used to treat patients in the future is not yet known. The highest daily dose that could be administered during this study will not exceed 3000 mg.

Each participant will be included in one of the following cohorts:

Part 1 (Cohorts 1 and 2) – single escalating doses:

Each cohort will consist of up to 4 treatment periods (Periods 1 to 4).

In each period, participant will receive a single dose of PF-07321332 or placebo, so that each participant will receive up to 2 active doses and 2 placebo doses or 3 active doses and 1 placebo dose during the study.

PF-07321332 or placebo will be administered as an oral suspension.

Periods 3 and 4 are optional periods and may be used to:
- Administer different doses of PF-07321332.
- Administer PF-07321332/placebo with ritonavir.
- Administer PF-07321332/placebo as tablet(s).
- Administer PF-07321332/placebo with a high-fat/high-caloric breakfast.

Cohort 1:

The planned treatments are:

Cohort 1 Period 1: 150 mg of PF-07321332 or placebo, on Day 1.
Cohort 1 Period 2: 1500 mg of PF-07321332 or placebo, on Day 1.
Cohort 1 Period 3 (optional): 150 mg of PF-07321332 or placebo with ritonavir 100 mg, on Day 1. Ritonavir 100 mg will also be administered in the evening of the day before (Day -1) and in the evening of Day 1 (3 doses in total).
Cohort 1 Period 4 (optional): 1500 mg PF-07321332 or placebo as tablet(s), on Day 1.

Cohort 2:

The planned treatments are:

Cohort 2 Period 1: 500 mg of PF-07321332 or placebo, on Day 1.
Cohort 2 Period 2: 3000 mg of PF-07321332 or placebo, on Day 1.
Cohort 2 Period 3 (optional): 300 mg of PF-07321332 or placebo with ritonavir 100 mg, on Day 1. Ritonavir 100 mg will also be administered in the evening of the day before (Day -1) and in the evening of Day 1 (3 doses in total).
Cohort 2 Period 4 (optional): 500 mg PF-07321332 or placebo with a high-fat/high-caloric breakfast, on Day 1.

For all cohorts of Part 1:

If a dose level is tolerated without significant side effects and the levels in the blood are acceptable, then the dose in later groups or periods may be increased.
The planned doses may change based on the results of the previous periods and cohorts.

It is planned that dosing will occur under fasted condition, unless the results of previous periods indicate that the study medicine needs to be taken with food.

If the study medicine is taken in fasted condition:
- You will be asked to take the study medicine after an overnight fast (no eating) of at least 10 hours.
- You will not receive a breakfast as you will need to fast until roughly 4 hours after taking the study medicine.
- You will not be allowed to drink for 1 hour before and 1 hour after you are given the study medicine.

Some of these restrictions may not be applicable, if the study medicine is given with a standard or high-fat/high-caloric breakfast.

In case of dosing under standard or high-fat/high-caloric breakfast condition:
- After an overnight fast (no eating) of at least 10 hours, you will be asked to eat a standard or high-fat/high-caloric breakfast, in its entirety within approximately 20 minutes, before taking the study medicine.
- You will not be allowed to eat until roughly 2 hours after taking the study medicine.
- You will not be allowed to drink for 1 hour after taking the study medicine.

Neither you nor the Investigator site staff will know whether you are receiving PF-07321332 or placebo during the period in progress, but the staff will be able to obtain the study medicine identity if necessary.

PF-07321332 or placebo will be administered in a random distribution determined by computer, which is also called randomization.

Part 2 (Cohorts 3 and 4, optional Cohorts 5 and 6 and optional Japanese Cohort 7) – multiple escalating doses:

Part 2 of this study will start after the same or higher blood levels of PF-07321332 during a 24-hour period are found to be safe and well tolerated in Part 1 of the study.

Each cohort will consist of one treatment period, in which the participant will receive multiple doses of PF-07321332 or placebo for 10 days.

PF-07321332 or placebo will be administered either as an oral suspension or as tablet(s).
PF-07321332 or placebo will be administered either two times a day (every 12 hours) or three times a day (every 8 hours).
If the administration is twice a day, PF-07321332/placebo can be administered with ritonavir 100 mg tablet.

The planned treatments are:

Cohort 3: 500 mg of PF-07321332 or placebo three times a day from the morning of Day 1 until the morning of Day 10 inclusive.

Cohort 4: 1000 mg of PF-07321332 or placebo three times a day from the morning of Day 1 until the morning of Day 10 inclusive.

Optional Cohort 5: 150 mg of PF-07321332 or placebo with 100 mg of ritonavir two times a day from the morning of Day 1 until the morning of Day 10 inclusive. On Day 10 evening, only ritonavir will be administered.

Optional Cohort 6: 300 mg of PF-07321332 or placebo with 100 mg of ritonavir two times a day from the morning of Day 1 until the morning of Day 10 inclusive. On Day 10 evening, only ritonavir will be administered.

For optional Cohort 7 (Japanese cohort), the dose will be equal to or lower than the highest dose found to be safe and well tolerated in the previous cohorts of Part 2. The frequency of administration and meal condition will be based on the results of the previous cohorts of Part 2.

<u>For all cohorts of Part 2:</u>

The planned doses as well as the dosing frequencies and meal condition may change based on the results of the previous cohorts.

The next dose regimen will be administered only if the previous dose regimen was safe and well tolerated.

It is planned that dosing will occur under fasted condition, unless the results of previous cohorts indicate that the study medicine needs to be taken with food. If the study medicine is taken in fasted condition, you will not be allowed to eat for at least 7 hours before taking the morning dose of the study medicine and for at least 2 hours before taking the afternoon and/or evening dose(s). On Days 1, 5 and 10 you must fast until roughly 4 hours after taking the study medicine in the morning. On other days and afternoon and/or evening doses, you will not be allowed to eat for approximately 2 hours after taking the study medicine.

On the morning dose of Days 1, 5 and 10, you will not be allowed to drink for 1 hour before and 1 hour after you are given the morning dose of the study medicine.
On other days and afternoon and/or evening doses, there is no water restriction.

Some of these restrictions may not be applicable, if the study medicine is given with a standard meal.

In case of dosing under standard meal condition:

- Morning dose:
  - After an overnight fast (no eating) of at least 7 hours, you will be asked to eat a standard breakfast, in its entirety within approximately 20 minutes, before taking the study medicine.
  - You will not be allowed to eat until roughly 2 hours after taking the study medicine.
  - On Days 1, 5 and 10, you will not be allowed to drink for 1 hour after taking the study medicine. On other days, there is no water restriction.

- Afternoon and/or evening dose(s):
  - You will be asked to eat a snack, in its entirety within approximately 10 minutes, before taking the study medicine.
  - There is no food restriction after taking the study medicine.
  - There is no water restriction.

Neither you nor the Investigator site staff will know whether you are receiving PF-07321332 or placebo during the period in progress, but the staff will be able to obtain the study medicine identity if necessary.

PF-07321332 or placebo will be administered in a random distribution determined by computer, which is also called randomization.

Part 3 (Optional Cohort 8) – food effect:

This cohort will consist of 3 treatment periods.

The planned treatments are:

Treatment A: A single dose of PF-07321332 oral suspension, fasted, on Day 1
Treatment B: A single dose of PF-07321332 oral tablet(s), fasted, on Day 1
Treatment C: A single dose of PF-07321332 oral tablet(s), fed, on Day 1

The dose will be determined depending on the results of the previous cohorts from Parts 1 and/or 2. The dose will be equal to or lower than the highest dose found to be safe and well tolerated in Part 1.

You will receive all 3 treatments (A, B and C), one in each study period.

Treatments A and B:
It is planned that treatments A and B administration will occur under fasted condition, unless the results of Part-1 and/or Part-2 indicate that the study medicine needs to be taken with food.

- You will be asked to take the study medicine in the morning, after an overnight fast (no eating) of at least 10 hours.
- You will not receive a breakfast as you will need to fast until roughly 4 hours after taking the study medicine.
- You will not be allowed to drink for one hour before and one hour after you are given the study medicine.

Some of these restrictions may not be applicable, if the study medicine is given with a standard meal.

In case of dosing under standard meal condition:
- After an overnight fast (no eating) of at least 10 hours, you will be asked to eat a standard breakfast, in its entirety within approximately 20 minutes, before taking the study medicine.
- You will not be allowed to eat until roughly 2 hours after taking the study drug.
- You will not be allowed to drink for 1 hour after taking the study medicine.

Treatment C:
- After an overnight fast (no eating) of at least 10 hours, you will be asked to eat a high-fat/high-caloric breakfast in its entirety within approximately 20 minutes, before taking the study medicine.
- You will not be allowed to eat until roughly 2 hours after taking the study medicine.
- You will not be allowed to drink for 1 hour after taking the study medicine.

The planned treatments will be administered in a random distribution determined by computer, which is also called randomization.

Course of the study

Part 1 (Cohorts 1 and 2):

For participants in Cohorts 1 and 2, the study is planned to last for approximately 13 weeks.

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

- A screening examination
- Up to 4 treatment periods (Periods 3 and 4 are optional). Each period will consist of up to 7 days and 6 nights in the PCRU (Pfizer Clinical Research Unit).
  There will be an interval of at least 5 days between each dosing. You may be asked to remain in the PCRU between periods.
- The follow-up phone call will take place approximately 28-35 days after the last administration of the study medicine.

Part 2 (Cohorts 3 and 4, optional Cohorts 5 and 6 and optional Japanese Cohort 7):

For participants in Cohorts 3 to 7, the study is planned to last for approximately 10 weeks.

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

- A screening examination
- 1 treatment period consisting of 13 days and 12 nights in the PCRU (Pfizer Clinical Research Unit).
- The follow-up phone call will take place approximately 28-35 days after the last administration of the study medicine.

Part 3 (Optional, Cohort 8):

For participants in Cohort 8, the study is planned to last for approximately 10 weeks.

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

- A screening examination
- 3 consecutive treatment periods consisting of 8 days and 7 nights in the PCRU (Pfizer Clinical Research Unit). There will be an interval of at least 2 days between each dosing.
- The follow-up phone call will take place approximately 28-35 days after the last administration of the study medicine.

1. COVID-19 ASSESSMENTS

Before being allowed to enter to the PCRU, you will undergo a questionnaire, temperature check and test to screen for COVID-19. During the study period, you will undergo temperature checks and an additional test for COVID-19 on the fifth day after admission. More information on COVID-19 measures during this study are included in the additional COVID-19 consent document.

2. SCREENING EXAMINATION

Before being allowed to take part in the study, you will undergo a medical examination, specifically an ECG (triplicate for Parts 1 and 2 and single or triplicate for Part 3) as well as blood pressure, oral temperature, respiratory rate and heart rate measurements. Blood and urine samples (**for which you must have been fasting for at least 4 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.

3. 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:

Part 1 (Cohorts 1 and 2):

- Physical examination: at admission.
- Detection of drugs in urine: at admission.
- Continuous cardiac monitoring (see section "Specific features of the study" on page 18) on Day -1 during at least 2 hours (Period 1 only) and on Day 1 during at least 8 hours at each period.
- Triplicate ECG: up to 36 measurements.
- Measurement of supine blood pressure, heart rate, respiratory rate and oral temperature: up to 36 measurements.
- Administration of the study medicine (see the section "Treatments administered during the study" page 7).
- Blood and urine samples for laboratory tests: up to 20 samples of each (for which you will have to be fasting for at least 4 hours, except for the sampling taken at 6 hours post-dose).
- Blood pregnancy test if you are a woman of child-bearing potential: at admission and at discharge.
- Blood samples to determine the amount of PF-07321332: up to 56 samples.
- Banked Biospecimen blood sample: 1 sample.
- Blood samples for metabolite profiling: 5 samples (**Cohort 1 Period 2 only**).

- Urine and feces sample: 1 sample of each before receiving the study medicine (**Cohort 1 Period 2 only**).
- Urine and feces sample collection up to 120 hours for metabolite profiling (**Cohort 1 Period 2 only**).

Part 2 (Cohorts 3 and 4, optional Cohorts 5 and 6 and optional Japanese Cohort 7):

- Physical examination: at admission.
- Detection of drugs in urine: at admission.
- Triplicate ECG: 10 measurements.
- Measurement of supine blood pressure, heart rate, respiratory rate and oral temperature: 10 measurements.
- Administration of the study medicine (see the section "Treatments administered during the study" page 7).
- Blood and urine samples for laboratory tests: 8 samples of each (for which you will have to be fasting for at least 4 hours, except for the sampling taken at 6 hours post morning dose on Day 5).
- Blood pregnancy test if you are a woman of child-bearing potential: at admission and at discharge.
- Blood samples to determine the amount of PF-07321332: up to 34 samples.
- Blood samples for metabolite profiling: 6 samples.
- Banked Biospecimen blood samples: 2 samples.
- Urine sample: 1 sample (on Day 1 only before receiving the study medicine).
- Urine sample collection up to 12 hours on Day 10.

Part 3 (Optional, Cohort 8):

- Physical examination: at admission.
- Detection of drugs in urine: at admission.
- Single or Triplicate ECG: 4 measurements.
- Measurement of supine blood pressure, heart rate, respiratory rate and oral temperature: 4 measurements.
- Administration of the study medicine (see the section "Treatments administered during the study" page 7).
- Blood and urine samples for laboratory tests: 2 samples of each (for which you will have to be fasting for at least 4 hours).
- Blood pregnancy test if you are a woman of child-bearing potential: at admission and at discharge.
- Blood samples to determine the amount of PF-07321332: 31 samples.
- Banked Biospecimen blood sample: 1 sample.
- Completion of taste assessment questionnaire: 4 times.

For all cohorts:

For safety reasons, 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 PCRU within 24 hours if we need to call you in for an additional 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 levels 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.

Contraception, pregnancy and breast-feeding

1. FOR WOMEN ONLY:

Women of non-childbearing potential:

You may participate in this study provided that:

- You are between 18 and 60 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).
- OR you have an ovarian failure.

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:

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

You must fulfil at least 1 of the conditions below:
- You have had a bilateral tubal occlusion
- You have a non-hormonal IUD
- You have a hormonal IUS
- You have a (progestogen-only) hormonal implant
- Your partner has undergone a vasectomy at least six months ago

These contraception methods will have to be started at least 28 days before the start of the study and will have to be continued until minimum 28 days after last administration of study medicine.

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, at admission and at discharge.

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. However, you will have to continue your contraception until 28 days after the last administration of the study medicine.

Egg donation is not allowed for the entire duration of the study and for a minimum of 28 days after the last administration of the study drug.

2. FOR MEN ONLY:

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

If you are abstinent from heterosexual intercourse with a female of childbearing potential as your preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent, you do not have to use contraception.

If you have a partner and you are not abstinent, you may take part in this study on condition that you use condoms during your participation in the study and for at least 28 days following the last administration of the medicine.
To prevent, among other things, the possible transfer of the medicine through the semen during the study.

In addition to that, if your partner is a woman and she is of childbearing potential, she will have to use one of the following contraception methods:

- IUD or IUS
- hormonal contraception

If you have had a vasectomy more than six months ago, or if your partner is post-menopausal or surgically sterilised, OR has had bilateral tubal occlusion, she will not need to use the contraception methods set forth above.

Taking the study medicine could bring about an unknown risk for an embryo, foetus or could negatively affect the quality of the sperm. It is important that you tell us if your partner is pregnant or if you plan to conceive during the study and up to at least 28 days after the last administration of the medicine. You commit to inform your partner about your taking part in this study and the potential risks for an embryo or foetus.

You cannot donate sperm until at least 28 days after the last administration of the medicine.

3. PREGNANCY FOLLOW UP

Any pregnancy during the study, either from a female participant or from the female partner of a male participant, or within at least 28 days after the 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.

<u>Risks associated with the evaluation procedures specific to the study</u>

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. ECG

The risks from an ECG can include skin irritation and a rash from the gel that is used or from wearing or removing the patches or shaving. If anything abnormal on ECG is seen, it may be necessary for you to have continuous ECG monitoring for some time for your own safety. This might mean that you are not able to move around very easily.

3. FASTING

Fasting could cause symptoms such as: dizziness, headache, stomach discomfort, fainting, and/or possibly hypoglycemia (low blood sugar).

4. TESTING OF DNA AND/OR RNA (BANKED BIOSPECIMEN BLOOD SAMPLE(S))

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, as such tests are not for the purpose of diagnosing or treating medical conditions. However, you can request your results (if any) and they will be provided to you, if possible. 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 orally or in writing. If you do so orally, your withdrawal shall be documented for liability reasons.

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 10 mL blood samples will be collected at Day 1 of Part 2 and a 4 mL blood sample will be collected at Day 1 of Period 1 in Part 1 and Part 3. These samples will be used to study biological substances in your sample(s), including your genes. This will help us learn more about the study drug and to investigate safety biomarkers.
These samples are called “Banked Biospecimens”
The sample will be held by Pfizer for up to 25 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 Sponsor may share the samples and/or data derived from them with third parties (such as other researchers and collaborators at other institutions and companies) consistent with the uses described above.

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.

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

1. 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 PCRU 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,

and
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:

- For the optional Japanese Cohort only: You don't have 4 biological Japanese grandparents who were born in Japan.
- You have received COVID-19 vaccine within 7 days before screening or have received only one of the 2 required doses of COVID-19 vaccine.

2. COMMON EXCLUSIONS TO MOST OF THE STUDIES

You may not take part in this study if:

- You are outside of the age limits (18-60 years) or weight limits (minimum of 50 kg), or you are outside of the limits of the Body Mass Index (17.5 - 30.5 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).

- 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 (platelets) 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

1. BLOOD VOLUME

The total quantity of blood taken during the study will be up to approximately 480 mL for Part 1, 290 mL for Part 2 and 160 mL for Part 3.
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.

2. STANDARD BREAKFAST/SNACKS (PART 2 ONLY – COHORTS 3-7)

If dosing is done under fed condition, you may be given a standard meal (breakfast and snack) before taking the study medicine.

You will be served breakfast 30 minutes before taking the study medicine. You must eat everything that you are given. You will have to eat regularly during 20 minutes and finish the breakfast approximately 10 minutes before taking the morning dose of the study medicine.

You will be served a snack 20 minutes before taking the study medicine. You must eat everything that you are given. You will have to eat regularly during 10 minutes and finish the snack approximately 10 minutes before taking the afternoon and/or evening dose(s) study medicine.

3. STANDARD BREAKFAST (PART 1 COHORTS 1 AND 2 AND PART 3 COHORT 8)

If dosing is done under fed condition, you will be given a standard breakfast before taking the study medicine.

You will be served breakfast 30 minutes before taking the study medicine. You must eat everything that you are given. You will have to eat regularly during 20 minutes and finish the breakfast approximately 10 minutes before taking the study medicine.

4. HIGH-FAT/HIGH-CALORIE BREAKFAST (PART 1 COHORTS 1 AND 2 AND PART 3 COHORT 8)

When the effect of food on the uptake of the study medicine will be evaluated, you will be given a high-fat/high-calorie breakfast before taking the study medicine.
The high-fat breakfast will include eggs, minced beef, whole milk, fried potatoes, and bread and butter.

You will be served breakfast 30 minutes before taking the study medicine. You must eat everything that you are given. You will have to eat regularly during 20 minutes and finish the breakfast approximately 10 minutes before taking the study medicine.

Please be aware that no vegetarian participants will be allowed to take part in Parts 1 and 3 cohorts where intake of a high-fat/high-caloric breakfast is required.

5. TASTE QUESTIONNAIRE (PART 3 ONLY – COHORT 8)

Immediately, 5, 10 and 20 minutes after receiving the PF-07321332 oral suspension in Part 3 (one period only), you will have to answer a questionnaire comprising rating scales aimed at qualifying the gustatory characteristics (bitterness taste and tongue/mouth burn sensation) of the PF-07321332 oral suspension.

6. TELEMETRY (PART 1 ONLY – COHORTS 1 AND 2)

Telemetry consists of a painless continuous recording of your heart activity. For this, you will wear a small case which will be linked to 10 electrodes (similar to ECG electrodes) placed on your chest. The apparatus itself is connected by a wireless link to a central computer that analyses your heart activity and enables us to monitor it in real time. Telemetry will be recorded for a minimum of 8 hours. Two hours will be also recorded in the same condition before the dosing (Period 1 only).

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.

Double Blind study: Neither the participant nor the Investigator site staff will know whether you are receiving study medication.

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 and metabolites 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.

Suspension: Liquid mixture containing solid particles.

Triglycerides: lipids in blood.

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

You must inform the study doctor or his/her representative 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 the evaluating Ethics Committee, 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 study - or your rights as a participant in a clinical study, you may contact during office hours the evaluating Ethics Committee or the federal ombudsman service: https://www.health.belgium.be/en/federal-ombudsman-service-patients-rights.

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 or his/her representative.

Information will also be made available in the EU database: https://www.clinicaltrialsregister.eu

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

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").

Insurance

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 Ltd., 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. 27).

You have the right to consult, correct or request deletion of your Personal data by writing to the following address: 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. This consult falls under the responsibility of the study doctor.

If you want to ask for removal of Your Personal Data, please send a signed and dated letter to 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 in 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 25 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.

PARTICIPANT AGREEMENT AND CONSENT FORM

Principal Investigator	Dr. Lien Van Eyck

1. I freely agree to take part in this study.
2. I have received full explanations from the staff 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 above-mentioned study.
3. I have been given enough time and 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. Results of blood study samples will not be communicated to me but I can choose to request my results (if any) and they will be provided to me, unless if they can no longer be linked to me. 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 and safety biomarkers. The sample will be held in a Pfizer-designated facility for up to 25 years.
   I understand that there are no plans to communicate to me the research results of the banked sample(s). However, I can request my results (if any) and they will be provided to me, if possible.
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 17). 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 21) and as further described in the Annex ‘Supplement related to personal data protection (page 27). 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) Fort Part 1: I shall receive the sum of **€ 4610.00** (four thousand six hundred ten euros) for my participation in the whole Part 1.
For Part 2: I shall receive the sum of **€ 2380.00** (two thousand three hundred eighty euros) for my participation in the whole Part 2.
For Part 3: I shall receive the sum of **€ 1515.00** (one thousand five hundred fifteen euros) for my participation in the whole Part 3.

This compensation is only for your participation in the study and not for risk of damage.

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 other 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 I enter the study at a later stage than the beginning of 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 and as further described in the Annex 'Supplement related to personal data protection. (page 27).

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.

SUPPLEMENT RELATED TO PERSONAL DATA PROTECTION

Content

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 EU 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 account number.**
- **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:

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

The individuals and groups listed above (assigned by "a" through "f") 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 (a, d);
- provide you with reimbursement for your time, effort and certain expenses related to your participation (a, d);
- verify that the study is conducted correctly, and that study data are accurate (a, b, d, e, f);
- answer questions from IRB(s), IEC(s), or government or regulatory agencies (a);
- assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any eConsent module used for the study and your comprehension of the eConsent process (a,b,c);
- contact you during and after the study (if necessary) (a);
- 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 (a);
- 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) (a,b,f); and
- answer your personal data protection requests (if any) (a).

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-07321332;
  - Understanding the study and the study results; and
  - Assessing the safety and efficacy of PF-07321332.

- **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-07321332 (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.

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. The Sponsor undertakes to respect the conditions in the General Data Protection Regulation (GDPR). 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 Privacy Steward, at the following address: 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

These rights derive from the GDPR.

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-07321332, 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 after the sample can no longer be associated with you. In those cases, it would not be possible to remove and destroy your biological samples and any related data. You agree that after the investigation the traceability of your samples will be removed; in other words that your samples can no longer be associated with you.