PARTICIPANT INFORMATION AND CONSENT

TO TAKE PART IN A CLINICAL RESEARCH STUDY

Full Study Title: A Double-blind, Randomised, Placebo controlled, Two period Cross-over Study to Evaluate the Efficacy and Safety of Orvepitant in Chronic Cough in Patients with Idiopathic Pulmonary Fibrosis

Short Study Title: A study to find out if orvepitant is safe to use and reduces the severity of cough in patients with idiopathic pulmonary fibrosis

We invite you to take part in a research study

Before deciding whether to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Discuss it with your doctor, your friends and relatives if you wish.

You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors.

Some terms may be unfamiliar to you. Ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- We want to find out how well orvepitant (the study drug) works in patients with idiopathic pulmonary fibrosis (IPF) who have chronic cough.
- Orvepitant is an investigational medicine, meaning it is not yet approved for use.
- You have been invited to take part because you have chronic cough associated with IPF.
- If you decide to take part, you will meet with the study team eight times for between 1 and 4 hours each time. You will have some tests done and complete questionnaires about your symptoms.
- A diary needs to be completed every day for approximately 13 weeks.
- At three visits during the study, you will have a cough monitor fitted that you will need to wear for 24 hours. This device records your coughing over that time period.
- You will take study drug once a day for two 4-week periods (Treatment Period A and B). In one of these 4-week periods you will take orvepitant and in the other you will take placebo (tablets that look like orvepitant but contain no active drug)
- You will take part in the study for up to about 17 weeks.
- It is your decision whether to take part. You may stop taking part in the study at any time.

Study Sponsor

This study is sponsored by **NeRRe Therapeutics Limited** (NeRRe). **Pharm-Olam** International is working with NeRRe to help manage this study.

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If you have any questions about this study, please talk to the doctors who organise it: Dr **<name>** or Research Nurse **<name>** on **xxxxx xxx**

1. Why are we doing this study?

We are testing an investigational medicine called orvepitant as a treatment for chronic cough associated with idiopathic pulmonary fibrosis (IPF), a condition that causes scarring of the lungs. An investigational medicine does not yet have a license to be marketed or sold. It is still being tested to see if it works and to make sure that it is safe.

The chronic cough associated with IPF is often a dry and unpredictable cough, although a cough with sputum/phlegm can also occur, especially when waking from sleep. One possible explanation for cough in people with IPF is that the cough pathway has become too sensitive. This oversensitivity may be caused by changes in the lungs (caused by the fibrosis) that affect the nerve cells that control coughing. One of the chemicals in the body that controls the cough reflex is called Substance P and blocking the effects of this chemical may make the cough pathway less sensitive.

There are no treatments approved for treating chronic cough, but some options are available.

Orvepitant is being developed by NeRRe as a treatment for different types of chronic cough. It stops the signals produced by Substance P and so may reduce chronic cough. It is hoped that orvepitant may provide long-lasting control of chronic cough and a better quality-of-life.

Orvepitant has been given to more than 900 people so far including around 250 patients with unexplained chronic cough. We are doing this study to see if orvepitant reduces cough in people with IPF. We also want to make sure that orvepitant is safe.

This study will take place in around 30 locations worldwide. It will include about 88 participants to start with but may include up to 108 participants in total.

2. What is involved in taking part in this research?

a) Am I eligible to take part in the study?

All research studies restrict who can be in the study. These restrictions are to do with age, type of disease, other medical conditions, and other medications that you might be taking. The study doctor will check your medical history, confirm that you have chronic cough associated with IPF and do tests to see if you meet the other requirements for this study. If you do not meet the requirements, you will not be able to take part.

If you are currently taking medicines to control your chronic cough you may still be eligible for the study. You will have to agree to stop taking these medicines for a time before this study. The time between when you stop the current medicines and when you can take the study drug varies according to the medication type. Additionally, there are some drugs that you cannot take during the study. Your study doctor will discuss with you any drugs that you need to stop or cannot take.

b) What treatment will I get if I decide to take part?

The study has two different treatment periods (A and B). The study treatment is taken once a day, in the evening before bedtime, for 28 days in each of the two treatment periods. In one treatment period you will take an orvepitant tablet and in the other you will take a placebo tablet. A placebo is a dummy treatment. It looks the same as orvepitant but does not contain any active medication.

To make the comparison between orvepitant and placebo as fair as possible, the study is "double blinded." This means that neither you nor the study doctor will know which treatment you are taking. In an emergency situation the study doctor can find out which treatment you are taking.

There will be a 3-week period between the first and second treatments (called the wash-out period) during which you will not take any study medication. We are testing two different doses of orvepitant (10 and 30 mg).

Neither you nor your study doctor will be able to choose the dose of orvepitant or the order you receive the treatments. Instead, you will be randomly allocated to the dose of orvepitant and to get either orvepitant or placebo first. This is like drawing straws to decide the dose and the treatment order. We do this because it helps to make sure that the results are not biased (favouring one treatment over another).

This randomisation means there are four possible combinations of dose and order of treatment you might receive:

- Orvepitant 10 mg first then placebo second
- Placebo first then orvepitant 10 mg second
- Orvepitant 30 mg first then placebo second
- Placebo first then orvepitant 30 mg second

If you forget to take a dose in the evening it may be taken any time up until 9 am the following morning. After this time the dose should not be taken.

You will also be given a small card with details of this study, and you should carry it at all times. In case of an emergency, the details on the card can be used by a healthcare professional to find out about the study and the study medication.

c) What will I have to do?

If you take part in this study, you will be asked to follow the study procedures and attend all the study visits. There will be a screening period of up to 4 weeks with one visit at the end to see if you are eligible to take part. If you are eligible, you will then continue in the study for about 13 weeks, taking your total study participation to about 17 weeks.

You will need to meet with the study team six times and have two phone or video call discussions. These meetings and calls are known as visits. In some instances, there may be a need to repeat a visit. The visits will last for between 1 and 4 hours. During the visits you will have discussions with the study team to assess your health and at most you will have some medical tests done.

You will be asked to complete an electronic diary (eDiary) **once** a day, in the evening. You will start completing the diary before you start study medication and will continue to complete it once a day for 13 weeks altogether. It is important that you complete this every day. The diary looks like a mobile/cell phone and is used to rate your coughing and other IPF symptoms. It should take just a minute or two to complete each day and the device will send you a notification to remind you. Your study nurse or doctor will show you how to use the eDiary.

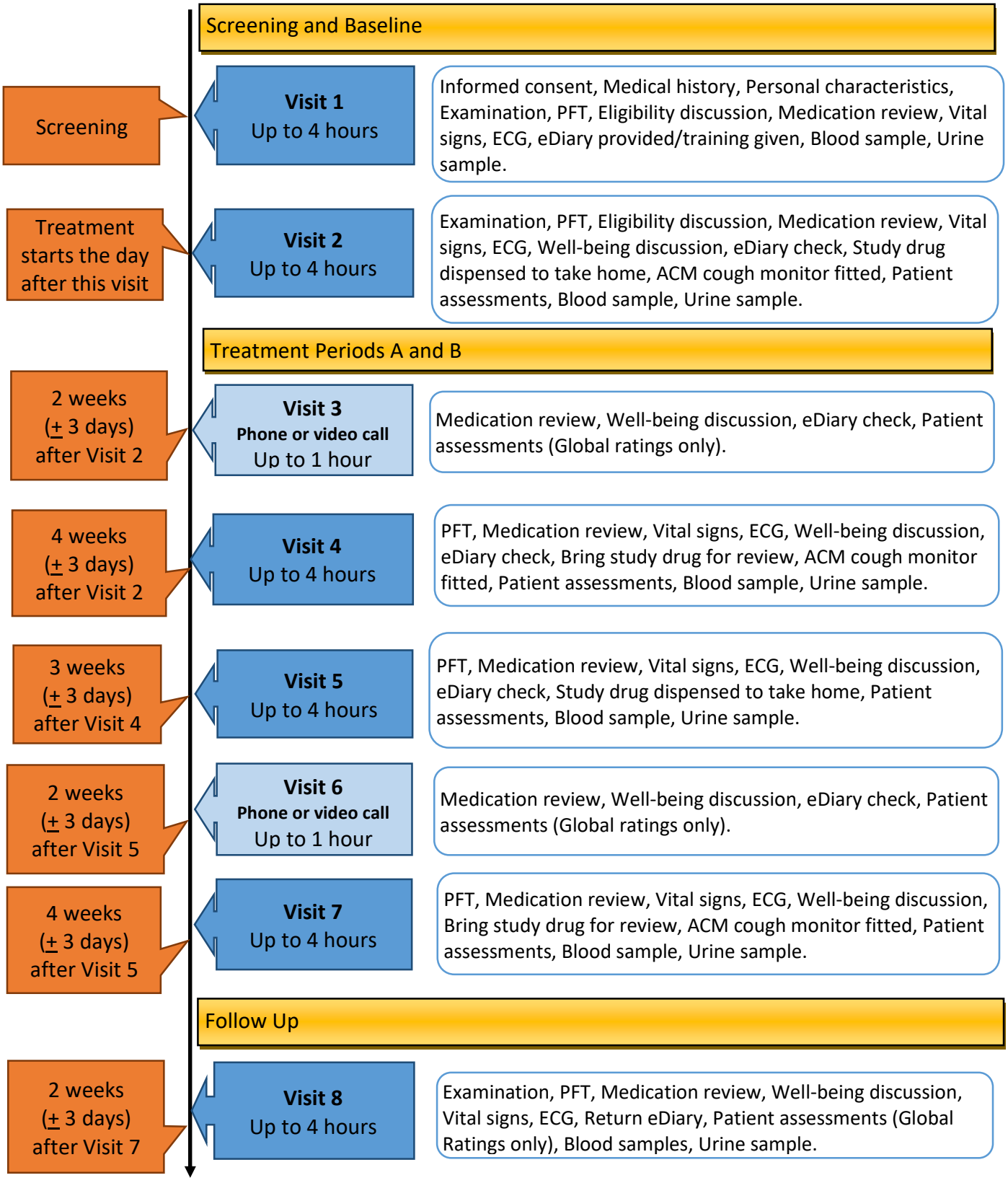
The diagram on the next page shows when you have the visits and what you will be asked to do at each visit. This is followed by a brief description of each assessment and task (Pages 6 and 7).

Throughout the study you should tell the study doctor about any symptoms or side effects and any medications taken.

All visits and tests shown below are just for this study and they may be extra to those that you would have in your routine care.

Your family doctor will be told that you are taking part in this study. Your study doctor might ask to obtain your medical history from your family doctor.

This diagram shows when the visits will take place and what procedures will be done at each visit.



Informed consent: If you agree to take part, first you will be asked to sign this form to record that you understand the study and agree to take part in it. No study-related procedures will be done before you sign this consent form.

Personal Characteristics: You will be asked your sex, date of birth, and ethnicity.

Eligibility discussion: You will be asked about your cough and your general health.

Well-being discussion: You will be asked about medicines you take and how you are feeling. You will also be asked if you have had any new health problems.

Examination: The study doctor will examine you. At the first visit this will be a full physical examination but at later visits will be more limited according to what symptoms you may be experiencing.

Pulmonary function test (PFT): This is a test to see how well your lungs work by measuring how much air you inhale, how much you exhale, and how quickly you exhale. You should not take any long-acting bronchodilators (drugs that cause widening of the bronchi part of the lungs) at least 24 hours before this test and short-acting bronchodilators at least 12 hours before the test. You will have this test on 6 occasions.

Vital signs: Your blood pressure, temperature, heart rate, and oxygen saturation (how much oxygen is in your blood) will be measured. At some visits your weight will also be measured.

Electrocardiogram (ECG): This is a painless test that shows how your heart is working. During the ECG, you will sit or lie on a bed/couch for several minutes with sensors called electrodes, which are sticky patches, taped to your arms, legs, and chest. The ECG will be performed after you have rested for 5 minutes.

Cough monitoring (ACM): At three visits you will wear a cough monitor (clipped to your clothes) for 24 hours. You will also be given a paper form to record the time you were asleep when wearing the cough monitor. The monitor records the number of times you cough over the time you are wearing it. It is important to follow the instructions about the cough monitor and that you always keep it on (except when showering). At the end of the 24 hours, you will either return the monitor to the clinic or collection of the monitor will be arranged. **Please note**: In addition to your coughing, the monitor will record what you say. However, the coughs are counted automatically and what you say will not be listened to by anyone else.

Blood samples: On 6 occasions, blood samples will be collected from your arm with a needle. These will be extra to any blood samples that you would have in your usual care. The blood samples help assess the safety of orvepitant. There will also be blood samples to measure the amount of orvepitant in your blood and samples to see the effect of orvepitant on some markers of IPF disease. Each sample will be between 14 and 33 mL (approximately 3 to 7 teaspoons) and during the whole study, about 156 mL (31 teaspoons) of blood will be taken.

Urine sample: On 6 occasions you will be asked to give urine samples. Your urine will be tested to measure your overall health.

EDiary Assessments: You will complete all of the following using your eDiary each day. Completion should take no more than a minute or two:

- IPF Coughing Severity Scale: You will rate how severe your coughing was in the past 24 hours at its worst.
- Early Morning Cough Scale: You will rate how severe your coughing was first thing in the morning (on waking or rising).
- Rest of the Day Cough Scale: You will rate how severe your coughing was during the rest of the last 24 hours (excluding waking or rising) at its worst.
- Urge to Cough Scale: You will rate how severe your urge to cough was in the past 24 hours at its worst.
- Cough Frequency Scale: You will rate how often you have coughed in the past 24 hours.
- Shortness of Breath Scale: You will rate how severe your shortness of breath was over the past 24 hours at its worst.

Patient Questionnaire Assessments: You will complete some or all of the following at most visits:

- Leicester Cough Questionnaire (LCQ): measures how your cough affects your quality of life (physical, psychological, and social).
- Hull Airway Reflex Questionnaire (HARQ): assesses how sensitive your airway is.
- Kings Brief Interstitial Lung Disease Health Status Questionnaire (K-BILD): asks about the symptoms of lung diseases like IPF more generally (psychological, breathlessness, and chest symptoms)
- Patient-reported Outcomes Measurement Information System Sleep Disturbance Questionnaire (PROMIS SD): asks about sleep disturbance.
- Hospital Anxiety and Depression Scale (HADS): measures anxiety and depression.
- Global ratings of your cough: You will be asked about the current status of your cough and if your cough has changed over the course of the study.

Additional visits

If your study doctor believes that you should have an extra visit(s) to assess your health, for example because you have experienced a new symptom or side effect, you may be asked to come for an additional visit. You may have some extra tests at these visits. These will be explained to you at the time.

About a quarter of the study participants will be asked to take part in an interview with a trained researcher at the end of the study (after Visit 7). The purpose of the interview is to hear about your understanding of the questions you answered during the study. It will last about an hour and will take place by telephone or video conference. The interviews will be recorded, and your replies included in a report. Nothing on the recording or in the report will identify you by name. You can decline to take part in the interviews but still take part in the rest of the study.

d) If I agree to take part, what will my responsibilities be?

During the study, your responsibilities will be to:

Activities:

- Attend all of your study visit appointments.

Health Assessments

- Complete the eDiary **once** a day and bring it with you to all visits.
- Wear the ACM cough monitor for three 24-hour periods and return it to the clinic as per the study doctor's instructions.
- Complete the questionnaires and scales at each visit, as necessary.

Medications

- Take the study drug every day for each of the two 4-week treatment periods.
- Keep your study medication safe and not allow anyone else to take it. You must bring your study drug bottles (whether empty or containing unused medication) to every visit.
- Tell the study doctor about other medicines you are taking, or any changes to your medications throughout the study. You shouldn't take any over the counter medicines without discussing them with the study doctor first.

Your health

- Tell the study doctor about any illnesses, injuries, side effects, or problems you have.
- Tell the study doctor if you plan to have any surgery, medical treatments, or procedures.
- If you feel unwell, stop any activity that may cause injury to yourself or any other person.
- Do not drive or operate machinery if you feel sleepy.
- You must not use recreational or illegal drugs during the entire study.

Contraception

- If you are a man whose partner can have children, you must use a condom during the study and for 30 days after the last dose of study drug. The study doctor will discuss this with you. You must let the study doctor know straight away if you think that your partner might be pregnant either during the study or for up to 30 days after the last dose of study drug.

e) What happens when the research study stops?

After you finish the study, you will return to your normal care straight away. Orvepitant is not yet approved, so it will not be possible to let you carry on taking it after the study ends.

f) Will I be reimbursed to take part in the study?

You will be paid up to £652 for your time and inconvenience taking part in this study.

You will be able to claim money back for reasonable transport costs for travelling to and from the clinic, including taxi fares. If you would like to do this, please ask your study doctor.

If you do not complete the study, you will be paid for your commitment to the study up to that point.

NeRRe Therapeutics is paying the **(name of Institution or site)** for their work in this study.

The Chief Investigator for the study, Professor Birring from King's College Hospital, London, created several of the patient questionnaires being used in the study. Both Prof Birring and King's College Hospital will receive fees for the use of these questionnaires.

g) What will happen to my blood samples?

We will send your blood samples to a laboratory for testing, which may be outside of your country. Tests will be done that measure your overall health, the level of orvepitant in your blood, and the effects of orvepitant. When we test the blood samples, we may find information important to your health. If this happens, the study doctor will discuss the findings with you. You may be referred to another health care professional if required.

Blood samples will be stored securely and confidentially. They will be kept until the end of the study. After this time, they will be destroyed. Samples will only be labelled with your study number. No personal information will be kept with the samples.

3. What are the possible benefits of taking part?

We do not know if taking part in this study will help your coughing. You may benefit in the following ways:

- Taking orvepitant may (or may not) improve your coughing.
- Your general health will be assessed and monitored during the study.
- Results from this study may be used to develop future treatments for chronic cough associated with IPF.

4. What are the possible disadvantages and risks of taking part?

a) Risks of taking orvepitant

The doses of orvepitant chosen for this study are thought to be safe based on the data from tests in animals and from clinical studies to date. However, we do not know all the risks of taking orvepitant. One of the reasons we are doing this study is to make sure that orvepitant is safe.

You could get side effects that have not been reported before. It is also possible that you will have no side effects.

In addition, the study drug may not control your coughing.

Orvepitant has been given to around 900 study participants. The following are some of the more common safety issues from previous clinical studies that seem to be due to treatment with orvepitant:

- Fatigue
- Somnolence (sleepiness)
- Dizziness

Other safety findings from clinical studies and which may be linked to orvepitant include palpitations (feeling the heart beating in the chest), headache, paraesthesia (pins and needles), diarrhoea, insomnia (difficulty getting to sleep), anxiety and abdominal (stomach) pain.

***** Please tell the staff immediately if you do experience any "side effects" while taking part in this clinical study, even if minor. *****

b) Study procedure risks

There are risks and side effects with some of the tests done in this study:

- You may get swelling, pain, redness, bruising or infection in your arm where blood samples are taken. Taking blood samples can also make you feel dizzy or faint.
- ECG pads may cause some local irritation and may be uncomfortable to remove.
- You may feel mild discomfort in your arm while the blood pressure cuff is inflated.
- The pulmonary function test is generally a safe test although you may feel short of breath or dizzy for a moment after you perform the test. It may also make you cough. Rarely, the test triggers severe breathing problems.

5. What if something goes wrong?

If you have any questions about this study, you can speak to the study team:
Name: _____ Telephone: (_____) _____

If you are calling after hours or on a weekend, you may contact:
Name: _____ Telephone: (_____) _____

If you have questions about your rights as a research subject, you should contact the individual below:
<<Insert name of Patient Advice and Liaison Service, e-mail address and telephone number>>
Name: _____ Telephone: (_____) _____

If you are unhappy and want to make a formal complaint, you can contact:
Name: _____ Telephone: (_____) _____

If you think you have an injury caused by taking part in this study, you should speak to the study team.

NeRRe will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).

We will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the trial protocol
- Any test or procedure you received as part of the trial
- Any payment would be without legal commitment. (Please ask if you wish more information on this)

We would not be bound by these guidelines to pay compensation where:

- The injury resulted from a drug or procedure outside the trial protocol
- The protocol was not followed.

Please ask your study doctor if you would like any further information.

By agreeing to take part in this research project you are not waiving any of your legal rights nor discharging the study doctor, the Sponsor, or the institution of their civil and professional responsibilities.

6. If I do not take part in this study, what will happen?

We do not know if taking part in this study will improve your chronic cough more than other treatments.

You do not have to take part in this study to have your symptoms treated. If you have any questions about other treatments, you can ask your personal doctor or the study doctor. Your family doctor can discuss the advantages and risks of this treatment with you.

7. If I want to stop my participation in this study, what will happen?

You can choose not to continue in the study at any time and you do not have to give a reason. If you decide to stop taking part in the study, this will not affect any of your care. If you want to stop taking part in the study, you should contact the study doctor. If you do not tell the study doctor that you want to stop taking part in the study, information about you will continue to be collected from your medical records.

If you want to stop taking part in the study, you can choose from the following options:

- You can stop taking treatment but keep in contact with us to let us know your progress. Information (including blood samples) collected may still be used if you agree to this.
- You can stop taking treatment and have no more contact with us. You can let us use information (including blood samples) already collected.

If you do want to stop taking part in the study, you will be asked to have a safety follow up visit. This visit will take place as soon as possible after you stop taking the study drug. It is important that you do have this visit so that we can check your health status.

The study doctor or NeRRe may stop you taking part in the study for any reason. If this happens, we will explain the reasons and arrange for your usual care to restart. Examples of when this could happen are:

- New information is found that means it is in your best interests to stop taking part
- You do not follow the instructions given by your study doctor

If the study is stopped for any other reason, we will tell you and arrange for your usual care to restart.

If you stop taking part in the study for safety reasons, you will be asked to visit the research clinic for final tests.

8. Privacy and Confidentiality

a) Why is my personal data processed and how will it be kept confidential?

The processing of your data is necessary for the Sponsor to comply with its legal obligations. Your personal information will be used for the purpose of this study and may also be used for the purpose of future scientific research activities that are currently unknown. Any future use will be consistent with the general research purposes for which the personal data were originally collected.

All reasonable efforts will be taken to keep all medical records and research materials that could identify you confidential. All data which are collected and obtained for the purpose of the study will only be stored, evaluated, and possibly forwarded, in pseudonymized form. Pseudonymized means that neither your name nor initials will be documented, only a number code. The code which is required to match the coded data with your name is accessible only to the study doctor and his/her study staff, monitors and auditors, as required. If the results of this study are published in the medical literature, you will not be identified by name.

b) What information is being collected and what are my rights?

In addition to the usual medical records and basic personal information (such as name contact details, sex, weight), specific health data are recorded by the study doctor for this clinical study, as described in the previous sections. You have the right to request access to, correction of, or erasure of your health information. You can also request restrictions on or object to the processing of your health information or request the portability of your health information.

If you would like to make any such requests, contact the Data Protection Officer listed below. The site's and/or NeRRe's ability to comply with your requests will be limited by the requirements of the study, the policies of the site and NeRRe, and applicable laws and regulatory requirements. For more information about your rights related to your health information, you can contact the Site´s Data Protection Officer at **<<insert a dedicated telephone number, and a dedicated e-mail address>>**.

The Clinical Data Privacy Manager for NeRRe Therapeutics is:

Name: Susan Seymore;

Email: clinicalDPM@nerretherapeutics.com

c) Who will have access to my data?

Your study doctor and their staff who have access to your personal data. In addition, NeRRe and Pharm-Olam staff and vendors (for example database companies or central laboratories) will also have access to your coded data. By signing this form, you understand that medical information about you obtained during this study may be made available to authorised representatives of foreign health agencies (Regulatory Agencies) for the purpose of ensuring that the medical

information was collected ethically and accurately. It may also be available to other public authorities in response to lawful requests and law enforcement requirements. You also understand that this medical information may be made available to the Sponsor or persons acting on behalf of the Sponsor (including contractors) for the purpose of conducting the trial and analysing study results, the ethics committee (a group that reviews study safety and ethics and to ensure patients' rights are not violated) or study personnel who may be evaluating the results of this study.

The coronavirus (COVID-19) pandemic may prevent Sponsor or Pharm-Olam representatives, or other agents designated by the Sponsor, from visiting the site to review critical data in your medical records that refer to your safety and the main study endpoints. Current guidance by research authorities allows for your data generated for this study to be reviewed remotely during the COVID-19 pandemic provided that:

- This remote review takes place in a safe and secure manner
- if your data are transferred outside of the UK, the sponsor will ensure all relevant safeguards, such as standard contractual clauses, are in place to protect your personal, coded data.

d) Will my data be transferred to other countries?

Your data will be processed and used in IT systems in other countries and may be transferred outside the United Kingdom to other countries where personal data protection laws may be less strict. However, appropriate safeguards will be implemented for data transfers, if required, such as agreements and other mechanisms issued by the data protection authorities. This includes the company undertaking the end of study interviews (LORA Group LLC) which is located in the United States. An agreement between NeRRe and LORA requires LORA to manage your data to the standards required by UK data privacy laws. Your data and samples will also be sent for processing to Denmark, Italy and the United States.

If you would like to learn more about this, you may contact the Site Data Protection Officer /Sponsor´s Clinical Data Privacy Manager.

Under the data protection law (Data Protection Act 2018) of the United Kingdom, the Sponsor and the Site will be responsible as "joint-controllers" for ensuring that your information is safeguarded.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by US law. It will also be available on the EMA Clinical Trial Register on https://www.clinicaltrialsregister.eu/, and other national or international web sites. These websites will not include information that can identify you. At most, the web sites will include a summary of the clinical study and its results. You can search these web sites at any time.

e) How long will my data be stored?

The data collected during this study will be stored for at least 25 years after completion or termination of the study. After that, your personal data will be deleted if this does not contradict the legislative requirements for their storage.

Your samples will be stored in a secure laboratory until testing is performed at the completion of the trial, and then the Sponsor will destroy your blood.

If you withdraw your consent for participating in this study, your personal data collected before you withdrew your consent may still be used for the purpose of the study. After you have withdrawn your consent for participation, no further data, samples and/or images, will be collected from you for the purposes of this study unless you agree otherwise. For example, you agree to have further tests and examinations. If you do agree to have further data collected after you have withdrawn your consent, these study data may also be used for the purpose of the study.

If you stop participating in this study, you may ask that your samples not be used by contacting the study doctor. If you ask for this, your samples will be destroyed once all protocol-defined procedures are completed. NeRRe and its authorised representatives (including contractors) may continue to use the samples collected during your participation in the study for tests and procedures approved for this trial.

If at any time during this study you feel that you have not been informed enough about the privacy rights about your health information, or you feel that the privacy of your health information has not been protected, you may contact the abovementioned Data Protection Officer. You also have a right to lodge a complaint with your country's supervisory data protection authority.

You also have a right to lodge a complaint with the Information Commissioner's Office (ICO).

Tel.: 0303 123 1113

Website: https://ico.org.uk

f) What will happen to the results of the study?

When the study has finished, data will be analysed by qualified people to find the results, and potentially apply for a license to market this drug for treatment of patients with coughing due to IPF. You have the right to be told about the overall results of the study and you may receive the study results directly. You will not be able to be identified in any results.

The results will be available to the public in one or more of the following ways:

- Scientific papers in academic journals.
- Presentations at conferences and seminars.
- Applications for a license to sell the medicine.
- On public clinical trial databases: http://www.ClinicalTrials.gov or https://www.clinicaltrialsregister.eu

g) Who has reviewed the study?

International guidelines exist to ensure clinical studies are performed properly and ethically. All studies are performed to these international standards. This study has been reviewed by the **<<insert name>>** Research Ethics Committee as well as the appropriate regulatory authorities and will be conducted to those standards.

9. CONSENT STATEMENT OF PARTICIPANT

Study Protocol: ORV-PF-01

Participant Study Identification Number: _____

	Please initial the boxes below to indicate your approval
I agree to participate in the study. I have thoroughly read, understood, and had a full explanation of all the information in this consent form. I understand that I am not required to participate in this research study, I am free to withdraw at any time, and that my current medical care will not be affected by these decisions.	
I agree that my family doctor (GP) will be informed of my participation in this trial.	
I understand and agree that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, agents of the Sponsor such as Pharm-Olam, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that I will receive and may keep a copy of this signed and dated consent form.	
I have not waived any of the legal rights that I would have if I were not a participant in a research study.	
I understand that—for reasons of public interest in the area of public health, for archiving purposes in the public interest, for scientific research purposes, or for statistical purposes—my personal, coded data will continue to be processed after the completion of the study or after I withdraw from the study, if necessary.	
I understand that—for the purpose of conducting the study—my personal, coded data may be transferred outside of the UK to other countries where personal data protection laws may be less strict.	
I understand that my personal, coded data will be processed as described in this informed consent form.	
I understand that the cough recording device could record my private conversations during the study, but that the information from those conversations will not be used in the study.	

If asked, I consent to taking part in the interview at the end of the study (Note, you can decline the interview but still take part in the rest of the study).	YES ☐ NO ☐

I understand that I will receive and may keep a copy of this signed and dated consent form.

Signature of Participant	Date (dd/mmm/yyyy)	Printed Name of Participant

10. STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION

I, the undersigned, certify that to the best of my knowledge, the subject signing this consent form had the study fully and carefully explained and clearly understands the nature, risks, and benefits of participation in this research study.

Signature of Investigator (or other Person Obtaining Consent)	Date (dd/mmm/yyyy)	Printed Name of Person Obtaining Consent

Your signed consent form will be filed in the Study Site File and you will receive a copy to take home