Study Participant Information Sheet and Informed Consent Form (Part 2)

Study Title:	Efficacy and tolerability of tasipimidine after 3 repeated bed-time doses in patients with insomnia disorder with a 4-week extension part
Protocol Number:	3110012
EU CT Number:	2022-502483-21-00
Sponsor:	Orion Corporation Orionintie 1, FI-02200 Espoo, Finland
Principal Investigator /Study Doctor:	<Print name of Principal Investigator>
Site Number:	<Site Number>
Site Name and Address / Study Center:	<Site Name and Address>

1.0 Introduction

In this consent form, "you" refers to the person participating in the study.

Orion Corporation (the Sponsor) is running a research study to see if a yet to be approved test medicine, named tasipimidine, will help in the treatment of insomnia (sleeplessness) and how safe it is to use in people.

You are being asked if you would like to take part in this research study because you have insomnia.

This information sheet is provided to allow you to make an informed decision on whether you would like to take part in the study. Take as much time as you need and discuss this information with who you wish to help you decide. You are free to ask questions at any time. Your participation is voluntary, if you do not want to take part you do not need to do anything, and your doctor will discuss what other treatments are available to you. If you do decide to take part, you will have to sign the consent form but you can still withdraw your consent at any time and you do not have to give any reason. You will receive a copy of the signed consent form. You do not have to sign this consent form, but if you do not, you will not be allowed to participate in the study.

2.0 Study Design

The study will be conducted in two parts: Part 1 at the study clinic (sleep laboratory) and part 2 both at the study clinic and at home. The planned number of subjects is 272 in total (128 in Part 1 and 144 in Part 2). You are being invited to participate in part 2 of the study.

Your Study Doctor will explain when, how often and how to take the medicine(s).

There will be placebo and tasipimidine (study medicine) groups that will be running in parallel. However depending on the clinical (safety) data there might be between 1 and 4 different dosing groups. You may receive a placebo which looks like the tasipimidine but contains no medicine and is not expected to have any effect to allow the Sponsor to see if tasipimidine works similar to or better than the placebo.

The study is double blind, which means that neither the participant nor the study doctor or site personnel that is involved in the study will know whether the participant is receiving the test medicine or placebo. For practical reasons the dose level of tasipimidine is single-blind, meaning that the study doctor and other study site personnel involved in the study conduct will know the dose level you will be receiving (the same amount of test medicine or placebo will be given), but you will not be informed. You will be

randomly assigned to either placebo or tasipimidine group. The allocation ratio will depend on the safety data that will be received from part 1 of the study.

3.0 Study Activities and Time Commitment

Your participation in the study will last maximum80 days.

What will happen at the different visits in the study?

In the duration of maximum 6 weeks, you will be requested to go to the clinic for three screening visits;

At your first visit your study doctor will check to see if you are suitable to take part in the study. This will involve completing some procedures and tests, including taking some blood and urine samples (see Table below). If you are suitable to take part in the study, you will be asked to come back for the further visits and will have some further procedures and tests (including taking blood and urine samples). You will also have the opportunity to ask questions and will have sufficient time to decide whether or not to participate in the study. A signed and dated written informed consent will be obtained.

For the next two screening visits you will be asked to stay overnight at the clinic. The nights should be performed within 4 days from each other.

At the beginning of the treatment period you will stay at the clinic for three consecutive days and nights where one dose of the study drug in the form of oral solution will be administered each evening by the study personnel and you will be under their surveillance. You may leave the study site on Day 2 and Day 3 morning and come back for the same evening if there are no significant decreases in your blood pressure or other adverse effects in connection to the morning orthostatic test. These will be evaluated by your study doctor and if he considers that it is in your best interest, you will have to stay at the study site until Day 4. If your study doctor allows you to leave the study site on Day 2 and Day 3, you must refrain from napping.

During the third night at the study site you will be woken after 4h from lights off for orthostatic test. In addition several blood samples for safety assessment will be drawn during this night. To enable the blood collection and to lessen the discomfort an intravenous cannula may be inserted into a suitable vein.

The study doctor will evaluate if it is safe for you to proceed the study treatment at home for the next 4 weeks. This will be done on Day 4 after the 16h physical examination. The evaluation is based on adverse events, orthostatic test results, other vital signs and all available safety data. Your study doctor will explain how you should take the study medicine at home. You will proceed to take the study medicine on the evenings of Days 4-26 and record the intake in the eDiary. After 2 weeks you will have to visit the study clinic for safety assessment. Between 2nd screening PSG night and Day 1, between Day 7 and 14, between Day 20 and 27 and during the first night after stopping the treatment you will have to use home EEG Somfit (electroencephalogram) device. It is preferrable that you do that when at home on 5 consecutive nights on three separate occasions.

On Day 27 you will return to the site and stay at site for 2 nights. The PSG recordings will take place in sleep laboratory setting during these last 2 nights of the treatment period. You may leave the study site on Day 28 morning and come back for the same evening.

During all site visits you will be allowed to consume only food and drinks offered by the site personnel. Light evening snack will be offered 2h before dosing.

After the second PSG screening night you will be offered the opportunity to use Oura ring throughout the study. The Oura ring is a non-invasive ring worn on one of the fingers acting as a sleep tracker and will collect information for your sleep duration, blood pressure, heart rate variability, respiratory rate etc. The data will be transferred via Bluetooth to a smartphone application. Oura ring should be used at minimum of 7 days between screening PSG night 2 and Day 1 and will be continued until end of study visit (details in the below table). In case you agree to use the Oura ring a separate ICF will be provided.

The end of study visit (last visit) will take place 5-10 days after the study treatment.

You will be asked to return the Oura ring and the home EEG (Somfit) device. The study personnel will ask for your feedback on both devices.

Throughout the whole study you will be asked to complete different questionnaires like morning questionnaire (sTST, sWASO, sLSO) or evening questionnaire. You will use the TrialMax eDiary app to complete these. Not all of these questions are to be answered when at site or at home. In the table below you will see the exact schedule for completing the full list of questionnaires. There is a separate set of questionnaire called MINI (Mini International Neuropsychiatric Interview) which will be completed by the site personnel, as well as the ISI (Insomnia Severity Index) and C-SSRS (Columbia Suicide Severity Rating Scale) which will be completed while at the site using a Slate tablet.
The information on morning sleepiness is collected by asking you how you feel and by placing a mark on an 11-point numeric rating scale.

In total approximately 140 ml of blood will be taken from you during the study. Your samples will be tested by [insert central lab name and country]. If you are a woman capable of having children, you will be required to have pregnancy tests during the study to make sure you are not pregnant.

Information about what tests will be done and when they will be done are shown in the table below.

Protocol activities	Screening period Max. 6 weeks				Treatment period 28 days									Post-treatment period 5-10 days		
	Scr. visit	Scr. PSG night 1[1]	Scr. PSG night 2[1]	Before Day 1	Day/ night 1	Day/ night 2	Day/ night 3	Day 4	Days 5-13	Day 14 ± 2 d	Days 15-26	Day/ night 27 ± 3 d	Day/ night 28	Day/ night 29	Day 30	EOS
At site	x	x	x		x	x	x	x		x		x	x	x		x
At home				x				x	x		x			x	x	
Informed consent	x															
Demography and substance use	x															
Weight, height and BMI	x															
12-lead ECG	x				x			x		x				x		x
Day-time orthostatic test	x	x	x		x	x	x	x		x		x	x	x		x
Night-time orthostatic test							x									
Polysomnography		x	x		x	x						x	x			
Continuous ECG by PSG system		x	x		x	x						x	x			
Continuous 12-lead ECG							x	x								
Continuous BP monitoring		x	x		x	x	x					x	x			
Laboratory safety assessments																
Haematology and chemistry	x				x			x		x				x		x
Urinalysis	x				x			x		x				x		x
Serology	x															

Protocol activities	Screening period Max. 6 weeks				Treatment period 28 days									Post-treatment period 5-10 days		
	Scr. visit	Scr. PSG night 1[1]	Scr. PSG night 2[1]	Before Day 1	Day/ night 1	Day/ night 2	Day/ night 3	Day 4	Days 5-13	Day 14 ± 2 d	Days 15-26	Day/ night 27 ± 3 d	Day/ night 28	Day/ night 29	Day 30	EOS
Pregnancy test for females of child-bearing potential[2]	x				x					x		x				x
Blood sample for PG/CYP2D6 genotype	x															
Drug screen	x	x	x		x	x[3]	x[3]					x	x[3]			
Alcohol breath test	x	x	x		x	x[3]	x[3]					x	x[3]			
Physical examination	x				x			x		x				x		x
Insomnia history and diagnosis	x															
Insomnia Severity Index (ISI)	x											x				
Mini International Neuropsychiatric Interview (MINI)	x															
C-SSRS	x							x		x				x		
Study treatment (at site)					x	x	x					x	x			
Study treatment (at home)								x	x	x	x					
Morning questionnaire: sTST, sWASO, sLSO; morning		x	x	x		x	x	x	x	x	x	x	x	x	x	

Protocol activities	Screening period Max. 6 weeks				Treatment period 28 days									Post-treatment period 5-10 days		
	Scr. visit	Scr. PSG night 1[1]	Scr. PSG night 2[1]	Before Day 1	Day/ night 1	Day/ night 2	Day/ night 3	Day 4	Days 5-13	Day 14 ± 2 d	Days 15-26	Day/ night 27 ± 3 d	Day/ night 28	Day/ night 29	Day 30	EOS
sleepiness scale																
Evening questionnaire: IDSIQ				x		x	x	x	x	x	x	x	x	x		
Home EEG device (Somfit)		x		x[4]					x[4]	x[4]	x[4]			x		x
Wearable device: Oura (optional)	x		x	x	x									x		x
Blood samples for PK							x	x								
Blood sample for exploratory assessments					x											
Medical history and current medical conditions	x															
Adverse events	x															
Concomitant treatments	x															

[1] Screening PSG nights should be within 4 days from each other
[2] Optional for permanently sterilised or postmenopausal females
[3] For subjects who have not stayed at the study site during daytime
[4] For 5 nights between screening PSG night 2 and Day 1, between Day 7 and Day 14, and between Day 20 and Day 27

Additional Test Clarifications:

- Demography - sex, ethnicity and racial group (if reported by patient), age and birth year
- Substance use – your doctor will ask you about the use of nicotine, alcohol, caffeine and drug abuse
- BMI – Body Mass Index, derived from the weight and height of a person
- Orthostatic test – your doctor will measure the heart rate and blood pressure when you have been laying down for at least 5 min and 1, 3 and 5 min after standing up. During the PSG nights the test will be completed both in the evening before lights off and in the morning after the lights on. You will be also woken up during the 3rd night to perform this test.
- CYP2D6 genotype tests – A blood sample will be taken to test your DNA for the activity of the gene of the enzyme called CYP2D6. This enzyme is important for metabolizing many types of drugs. This genotyping test tells how fast the liver will convert tasipimidine. The result can be: a) Slow metaboliser b) Intermediate metaboliser: The gene is less active c) Normal metaboliser: The gene is active, d) Ultra-rapid metaboliser.
- Serology – blood sample will be tested for antibodies to rule out the following infections: (HIV, Hepatitis B and Hepatitis C)
- C-SSRS - Columbia Suicide Severity Rating Scale – this is clinical interview to assess your mental health
- Mini International Neuropsychiatric Interview (MINI) – this is a psychiatric examination and will help us identify the participants with psychiatric conditions
- Insomnia Severity Index (ISI) – this test consists of seven questions and will help the study doctor to assess the severity of patient's insomnia
- Evening questionnaire: Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ) contains 14 questions related to i.e. alertness/cognition; negative mood; tiredness/sleepiness.
- Morning questionnaire consist of sTST (self-reported Total Sleep Time), sWASO (subjective Wake After Sleep Onset), sLSO (subjective Latency to Sleep Onset) and Morning sleepiness scale.
- PSG (Polysomnography) is done using equipment that records your brain waves, the oxygen level in your blood, heart rate and breathing. It is used from evening until morning to assess your sleep.
- Pharmacogenomic (PG) test – a blood sample will be taken to test your DNA and help us understand tasipimidine's effect on the body and how your body handles tasipimidine.
- Blood sample for exploratory assessments will be utilized for the identification of both disease and drug response biomarkers.
- If you agree to use the Oura ring for this study, you will be sized during the screening visit
- Home EEG device (Somfit) will be used to record your sleep data

3.1 Digital Technology Platform - eDiary

A mobile application (app), called TrialMax eDiary will be used in this study. You will use the app to complete certain study questionnaires. You will be asked how you slept, how you feel, if you are worried or frustrated, do you feel energetic, do you feel depressed etc. All information collected through the app will be secured, ensuring protection of your personal data, as described in the privacy section of this document. You need to be able to work with smartphones to complete study questions within the app.

In order to use the TrialMax app, the site will register you. It is important that you are the only one who can access the app, thus you must ensure login credentials are kept confidential and known only by you. You must not share your login and password with anyone, including the study staff, your family and friends.

The study staff will inform you of where to find instructions for the eDiary. Once you open the app, you will need to complete the training with sample questions before you will be able to answer the study questionnaires. Your study staff will also support and train you if you have any difficulties.

In case you do not agree to use, or you do not have a personal device suitable for the study, please inform your study staff and you will be provided with a smartphone for use during the study.

In the event you are provided with a smartphone, this will be given to you during site visit and the study staff will train you how to use it.

Once you are no longer part of the study, you will not be able to access the app (your access to the app will be removed). The data remains available for people responsible for its analysis in a way which does not identify you. If the device was provided by Sponsor, please return the device to site in accordance with instructions given to you by your study staff. Any personal information on the device will be removed once you return it.

If you use your personal device, you are encouraged to remove the app from your device at the end of the study. If you need any support, please contact your study staff.

There is a helpdesk service that is accessible to you 24 hours/day, 7 days/week where people speak <include local language> if you need assistance. The helpdesk is managed by Signant Health. You can reach the Helpdesk at any time, however, all medical questions should be directed to your study staff. When you contact helpdesk no personal information about you will be recorded

3.2 Wearable devices

Two wearable devices are used in this study: home EEG device Somfit (mandatory for use) and Oura ring (voluntary for use).

This study involves collection of certain data through the wearable EEG device(Somfit). This is a device which collects information on your physiological data, pulse, peripheral arterial tone, snoring etc. and will assist the medical professionals toreceive more information about your sleep disorder.

The study staff will give you the device set at the study site and will instruct you on how to use the device. They will also assist you with downloading the Somfit app onto your smartphone and connecting it to your home EEG device (Somfit), as you will then continue using this device at home.. This device should be used only for study purposes. The study staff will answer any questions you have about the device and will provide you instructions for use

There is a helpdesk service where people speak <language> if you need assistance. The helpdesk is managed by Siesta You can call the Helpdesk for any technical questions, however, all medical questions should be directed to your study staff. When you contact helpdesk no personal information about you will be recorded.

You should use the device in accordance with instructions given by your study staff. Information collected with the home EEG device (Somfit) will be first transferred via Bluetooth to Somfit app. Then from the Somfit app the collected data will be sent to a secure online platform where people responsible for analysis of this data will be able to see it. All data shared through the platform will be coded so that you cannot be identified. You will be linked to your device through the unique number assigned to you.

Once you are no longer part of the study, you should return the device to the site, in accordance with instructions given to you by your study staff.

If you agree to use the Oura ring for this study, you will find the information about this device in the Optional Device ICF. In that case you will also need to provide the courier with your personal contact information to ship the device to your home address.

Genetic Testing

As part of this study, during the screening visit a blood sample for DNA extraction will be taken and will be tested and analyzed. DNA is the material in your body's cells (genes) that pass on characteristics that are inherited from one generation to the next (like hair and eye color). DNA will be extracted from your blood sample in a laboratory and analyzed to produce genetic information. Your genetic information can be used to study whether your response to treatment with tasipimidine and any side

effects that you may have developed are related to your genetic identity or based upon your genetic makeup. This area of research is called “pharmacogenetics” because we are striving to understand how genes influence the different responses that people have to the same drug. The goal of this research is to find variations in DNA that will help identify persons with insomnia that will have the best response with tasipimidine or to identify persons who will have fewer side effects in order to maximize their benefit from tasipimidine.

4.0 Risks

Some procedures that will be done during the study may carry some risks, these are given below, and your study doctor can provide more information to you.

Procedure	Risk
Blood Sample	• Mild pain, discomfort due to swelling or bruising around the injection site • Light-headedness and fainting (uncommon) • Small risk of infection at the injection site or a small clot
Insertion of intravenous cannula	• Mild pain, discomfort at the insertion site
ECG	• The sticky pads placed on your chest may cause skin irritation
PSG	• Attached electrodes and probes may cause discomfort and disturb sleep
Home EEG Somfit	• Can cause mild discomfort as the device has a probe attached to the forehead. In some cases there could be a skin irritation
Oura ring	• Skin redness or irritation

5.0 Possible Side Effects

We do not know all the possible side effects of the study medicine(s). Like all medicines, the study medicine(s) can cause side effects, although not everybody gets them. The most common or presumed adverse effects of the study drug are the decrease of blood pressure, dizziness and fainting when standing up.

You will be monitored for the duration of your time in the study and you should tell your study doctor about any changes in your health while taking part in the study. For example, you might feel dizziness when standing up, or difficulty standing up. Therefore, as a safety measure, in case you wake up during the night and want to visit the restroom, you will be asked to call the site staff have them escorting you there. It is also better to raise slowly and sit on the side of the bed for a while before standing up. You will be carefully instructed for situations where you feel dizziness when rising from the bed at home.

Your study doctor will assess and record the causality and severity of all adverse events. The causality assessment checks whether the adverse event is related or not-related to the study drug. As for the severity, the adverse events could be divided into three groups:

- Mild: Discomfort noticed, but it does not affect normal activity.
- Moderate: Discomfort sufficient to reduce or affect normal daily activity.
- Severe: Incapacitating with inability to work or perform normal daily activity.

Most side effects are usually mild to moderate. However, some people may experience serious side effects and may require treatment.

In addition, the sedative effect of the study medicine might be present during the next day and can have an effect on your ability to drive or operate machines. Your ability to drive on Day 4 will be assessed by the study doctor.

6.0 Potential Benefits

There is no guarantee that you will receive any benefit from taking part in this study. Tasipimidine may favour sleep and could potentially be useful in the treatment of insomnia but in this trial the study drug will be administered for only 3 nights at the study site and 4 weeks at home, which is expected to improve symptoms of insomnia disorder oryour condition may remain the same. It is also possible that you will only receive placebo.

Information obtained from the study may help in the development of better treatments for insomnia.

7.0 Pregnancy

As the Sponsor does not know the effect of the study medicine on an unborn baby, you should not become pregnant during the study. The effects of study medicine on a nursing infant are unknown. If you are pregnant or breastfeeding, you cannot participate in the study.

Female and male participants must adhere to highly effective contraception if they are sexually active and not permanently sterilized.

If you become pregnant during the study, you must tell your study doctor immediately. If you agree, the Sponsor would like to follow up on the outcome of your pregnancy. You will be asked to sign a separate consent form for this follow-up.

8.0 Responsibilities

As a subject in this study, you have certain responsibilities. You will have to:

- Complete all required visits to the study center
- During the stay at the clinic, consume only those food and drinks that are offered to you
- Take the study medicine(s) as instructed by your study doctor
- Tell the study doctor your full medical history
- Tell the study doctor of any side effects and changes or new medical problems you suffer during the study
- Tell the study doctor if you become pregnant
- Complete questionnaires
- You should not use alcohol containing beverages 48h before the screening visit and entries to the study site until leaving the study site
- Consumption of caffeinated beverages containing more than 600 mg of caffeine per day or any caffeine consumption after 2 p.m. is discouraged during the rest of the treatment period and prohibited before all PSG nights.
- Consuming grapefruit juice on Days 1- 4 is forbidden from 48 h before the entries to the study site until leaving the study site and also discouraged during the 4-week home treatment
- Poppy seeds must be avoided from 72 h the screening visit and entries to the study site as it could compromise the results
- Intensive exercise is not recommended 96 h before the screening visit and entries to the study site until leaving the study site or longer if judged necessary due to safety reasons
- Sauna bathing is prohibited for 24 h after study treatment administration on Days 1 - 4
- Driving or operating machines is not allowed on Days 1 - 4(treatment days) and 16 hours after the last dose

All medications that are acting in brain are not permitted to be used during the study. Additionally, you should not start using any new medications during the study, if possible. Please, inform the study doctor about all medications that you are using or intending to start and discuss if they are allowed during the study

9.0 Compensation

You will not receive any payment for taking part in the study, but you will be reimbursed for reasonable travel costs incurred by taking part of the study. For the days that you have to spend in the clinic and

not being able to work you will be additionally reimbursed. A separate informed consent with details will be provided to you.

The Sponsor has a contract with the study doctor/study center who will receive payment for taking part in this study.

10.0 Insurance

The Sponsor has taken out an insurance policy for the study that complies with current local law. If you are injured or your health is affected, the Sponsor will pay all reasonable and necessary medical costs to treat the injury or illness, if the injury or health issue was directly caused by the study medicine(s) or study procedures.

Please note that taking part in this study may affect any personal insurance policies you have, such as health insurance, and you should contact your insurer to check if this is the case.

11.0 Voluntary Participation/Withdrawal

You can choose whether you want to take part in the study, and you can change your mind at any time and you don't have to give any reason. If you decide not to take part, or stop taking part after the study has started, this will not affect your future treatment and care. If you want to withdraw from the study you should contact your study doctor or study staff.

Your study doctor may also decide that you should no longer take part in the study if it is in your best interests or if you do not follow the instructions you receive for taking part in the study. The Sponsor, Ethics Committee or Regulatory Authority may also decide to stop the study at any time for any reason.

If you decide to no longer take part in the study, or your study doctor decides you should no longer take part you will be asked to attend a last visit to ensure it is safe for you to no longer be monitored by the study doctor. You can discuss alternative treatments or follow-up measures with your study doctor if you stop participating in the study.

You will not take part in the study after withdrawal.

If there is new information available on the study medicine(s) during the study which might make you change your mind about taking part in the study, you will be informed of this new information without delay.

12.0 Alternative Treatments

There are commonly prescribed medications for insomnia. Your study doctor will discuss with you treatment options including the benefits and risks, for your symptoms.

13.0 Who to Contact with Questions or Report a Possible Study Related Injury or Reaction

If you have any questions about the study or your rights, at any time, or think you have experienced an injury or reaction to the study medicine, you should contact your study doctor.

Study Doctor/Principal Investigator: Dr [insert PI name and contact information]

14.0 Confidentiality and Data Protection [Must be on its own page]

The words in **bold text** are in a glossary of terms found at the end of this section for reference.

14.1 What **personal data** is being processed?

Only **personal data** needed to run the study properly and safely will be collected.

In Finland, the legal basis for processing of the data for the purposes of the study is public interest and public interest in the area of health (EU GDPR 2016/679 Articles 6 (1)(e) and 9 (2)(i)). The legal basis for safety reporting and other reporting required by the regulatory authorities is the legal obligation to which Orion is subject and public interest in the area of health (EU GDPR 2016/679 Articles 6 (1)(c) and 9 (2)(i)).

In Poland, the legal basis of processing the personal data is the legal obligation to which Orion is subject. In regard to special categories of personal data like health data, processing of personal data is necessary for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of health care and of medicinal products, based on binding law.

Germany to add their country approved language

14.1 Who will be able to see your **personal data** and how will it be protected?

The Sponsor and those working on the study will only be given as much information from your medical records as is needed for the correct running of the study.

Coded Data

Your personal data is safeguarded by giving it a study-specific **subject ID number** and is called **coded data**. Your **coded data** will be accessed by people who are working for or on behalf of the Sponsor and its **affiliates** in connection with the study and external people such as the **EC** and **regulatory authorities** which reviewed and approved the study and to domestic or foreign competent authorities to apply for a marketing authorisation and for safety assessment for the product.

They will not be given your name, where you live or anything that could identify you. Your medical data and any samples will be labelled with your **subject ID number** only. Your **coded data** will be stored and analyzed under the **subject ID number**. In the case of emergency, the study site can trace the information back to you.

The Sponsor is responsible for all your **coded data** collected during the study. They are responsible for making sure all those working on the study comply with the data protection requirements for the collection, use and processing of **personal data** collected for this study.

Orion can use service providers to help in research and development. Orion can also transfer the personal data including biological samples stored in Orion's sample repository to another company in case Orion decides to sell or license the research project to another company. In these cases, all parties will continue to be bound by their obligations of confidentiality.

Non-coded data

[If the data will be collected from other healthcare providers and from personal registers that contain health information it should be listed in this section. Registers and the information collected from them should be identified. The study participant should be told that the study doctor can request the information using study participant's personal identity code.]

The **non-coded data** will be recorded by the study doctor in your medical records and medical chart and remain the responsibility of the study doctor.

To make sure the study is run properly and ensure data is recorded correctly it may be necessary for the following people to look at your non-coded data.

- Specific authorized employees of the Sponsor and persons acting on the Sponsor's behalf who are working on the study

- Representatives of any **Regulatory Authority**. These authorities may be from the regulatory bodies of European Economic Area (EEA), the USA or other countries, or people who have been authorized by these authorities to inspect the study data. The inspection is carried out under the supervision and responsibility of the study doctor.

14.2 How long will your coded data be kept for?

The **coded data** will be kept for a minimum of 25 years once the study has finished. It may be used and shared for similar future research purposes related to the use of tasipimidine but your privacy would continue to be protected as only coded data would be used. Your identity will be kept confidential.

Information collected during the course of the study will be stored in the study register as described in the Information Notice and used in the development of taspimidine and thereafter for as long as the information is relevant to patient care. All information is handled confidentially and according to the current laws and regulations. Your name will not be mentioned and your identity cannot be recognised in any of the drug companies' reports or publications.

14.3 Can you see the **personal data** collected and recorded about you?

You can speak with the study doctor to see your **personal data** that has been collected and to have any inaccurate information about you corrected. If requested, you can receive information from where the personal data has been collected and where the data has been transferred. In addition, the study participant has the right to request restriction of the use of his/her personal data.

If you decide to stop taking part in the study i.e. withdraw your consent to participate it is important to understand that your **coded data** (including the analyses of samples already taken but not analysed for the specific purpose of this study), collected up until the date when you stop taking part in the study, will remain as part of the study records and cannot be deleted. No new data will be collected and processed.

If you have concerns about the way your **personal data** has been used, please contact your study doctor whose contact details are above, who may contact the Sponsor's data protection officer if needed. If your questions relate to processing of personal data by Orion for this clinical study in general, you can also contact directly Sponsor's data protection officer as described in the Information Notice for this study. If they cannot address your concern, you can contact your country's data protection supervisory authority with your complaint as described in the Information Notice for this study.

14.4 Where will your **personal data** be sent?

The Sponsor or their representative may need to send your **coded data** to other countries, including the USA, where the data protection laws may not be as strict as in your country. The reason for sending the data is to support data analysis and applications to market new medicines made by the Sponsor. The Sponsor is required to protect your privacy and send any **coded data** in a secure way as required by law. You can ask them to provide more information about this through your study doctor.

14.5 How will your personal information be protected in the Digital Technology Platform and Wearables Devices

[This text should be included in addition to the standard ICF template] When you consent to this study, your personal informationwill be recorded and stored electronically. It is processed and encrypted then sent via the internet over a secure connection to the study-specific platform. As it is encrypted your personal information cannot be read by anyone not involved in the study. Your personal information may be processed by organizations the Sponsor has entrusted with technical, logistic, IT, storage and transmission services. Your study staff can provide you with more information about the app and data collected.

When you register, you will be presented the Terms of Use Agreement and Privacy Policy, where you can find more details on the use of the application. In case you do not agree with Terms of Use Agreement and Privacy Policy, you will not be able to create your account.

After all participants have completed the study, the app will be deactivated.

The data collected by the wearable devices (home EEG device (Somfit) and Oura ring) is transferred via Bluetooth connection on your smartphone to secure data storage. The access to this data storage is limited and protected by login and password. All data is coded so that you cannot be identified. You will be linked to your device through the unique number assigned to you. If you use the optional Oura ring, you will be presented with the Oura Privacy Policy where you can find more information on data protection.

14.6 Storage of biological samples

The biological samples including DNA and plasma samples are collected for exploratory research purposes to understand treatment response to tasipimidine. These samples will only be utilized in an exploratory fashion to identify biomarkers (genetic, proteins or metabolites) which can identify individual or population level responses to the therapy. The samples from the placebo study can also be utilized as (protein or metabolite) biomarker exploration tools for the progression of the disease. The samples will be stored in sponsor's sample repository for up to 20 years after which they will be destroyed. Possible future use of these biological samples will be confined to the scope of this study as described above. If sponsor desires to expand the restricted scope of this research, it will first seek approval from the ethics committee. If the new study is approved, you will be asked to sign another informed consent.

14.7 Future scientific research use

The data collected from this research study may be useful when discovering new disease indications for tasipimidine which are currently unknown. Your data can be used for further scientific research of Orion when studying tasipimidine, and can be disclosed to companies and/or research organizations conducting scientific research that can help to advance medical science and improve future patient care where such data is relevant. In these cases the data will always be in coded format (you will not be identified personally) or anonymized whenever possible. The data may also be transferred to countries outside the EEA for this purpose and the data transfer will be protected as described in the Information Notice for this study. The legal basis for processing data for further scientific use (whenever the data is not anonymized) is legitimate interest of Orion as outlined in the Information notice for this study and scientific research (EU GDPR 2016/679 Articles 6 (1)(f) and 9(2)(j)).

14.8 Where will study information be made publicly available?

The details about the study is available on the https://euclinicaltrials.eu/home Web site. After the end of the study a summary of the results will be published in lay language in https://euclinicaltrials.eu/home

Glossary

Affiliate	A person or organization officially attached to the Sponsor, for example the Sponsor offices in other countries
Coded Data	The participant is allocated an identification number and all data and samples related to that participant are held under this number.
Subject ID number	Identification number allocated to you that is included in the research study.
Non-coded data	Data which may directly identify you including parts of your medical records and charts relevant to the study.
Personal Data	Any information that can directly identify you, such as full name, address, date of birth, health information such as non-coded data or indirectly, such as coded data.
Regulatory Authority	A regulatory authority is a government agency set up to enforce safety and standards and to protect subjects

Participant Informed Consent Form

Efficacy and tolerability of tasipimidine after 3 repeated bed-time doses in patients with insomnia disorder with a 4-week extension part

I have received information on the abovementioned study and have had the opportunity to read the information and to ask questions and have received answers.

I am aware of:

- The processing of my personal data, to include but not limited to medical information and genetic data, as notified by this form and derived from the study
- The transfer of my personal data to countries outside of my own where data protection might differ from the data protection in my country
- The Sponsor and its representatives, as well as Regulatory Authorities, to compare data reported in the study to those contained in my medical records.
- I understand that using my personal device/ provisioned device means that the app will have access to my calendar, Bluetooth, camera

I have received and read the Information Notice of Orion Corporation attached to this information sheet.

I know that at any time and without giving any reason I can withdraw my consent and stop taking part in the study. This will not affect my future treatment and care.

I will receive a signed copy of this Participant Information Sheet and Informed Consent Form for my records.

With my signature I confirm my participation in this study and consent to being a voluntary study participant.

Signatures

Study Participant	
	Print Name
Signature	Print Date

Study Personnel Performing Consent	
	Print Name
Signature	Print Date

Principal Investigator	
	Print Name

Signature	Print Date