Master Informed Consent Form

[Investigator name]

[Investigator address or affiliation]

[Investigator telephone number]

[IRB/IEC name]

Study Title: Efficacy, Safety and Pharmacokinetics of 3 Doses of REC 0/0559 Eye Drops for the Treatment of Stage 2 (Moderate) and 3 (Severe) Neurotrophic Keratitis in Adult Patients

Protocol Number: REC0559-B-001

Sponsor: Recordati Rare Diseases

Name of Doctor Administering Consent: [Name of doctor]

Important

This informed consent ("permission") form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that are not clear to you.

Joining a study is an important decision. You should ask the study team any questions you may have about the study and this informed consent form before making a decision to participate.

Also, you may have your primary doctor call the study doctor to ask any questions he/she feels are necessary to evaluate the study and your possible participation in it.

You may take home an unsigned copy of this informed consent form to think about it or discuss it with family or friends before making your decision to take part in the study.

Why is this study being done?

Recordati Rare Diseases is conducting a research study of an investigational drug (also known as the "study drug") called REC 0/0559 as a possible treatment for moderate to severe neurotrophic keratitis (NK). An investigational drug is a drug that is under evaluation and that has not yet received a marketing authorisation from the United States (US) Food and Drug Administration (FDA) or European Medicines Agency (EMA). You are being asked to take part in this study because you have been diagnosed with NK.

Your participation in this study is voluntary. If you decide not to take part in this study, you can continue with your current medical care.

The main purpose of this study is to learn how well the study drug works and how safe it is compared with vehicle (similar to a placebo) and to find out what dose should be used in humans. A vehicle looks the same as the active study drug but does not contain any active study drug. Researchers use a vehicle to see if adding or not adding the study drug works better and is safe. REC 0/0559 has been tested in animals and on a small group of patients suffering from NK, and these data have been used to predict what doses of the drug will be safe in humans.

NK is a degenerative corneal disease involving the surface and the deeper layers of the cornea. The initial small damage of the cornea increases and becomes deeper. This condition is called corneal ulcer. Associated symptoms are not frequent and can include red eye, decrease of vision, or blurred vision. Healing can be difficult and deep corneal ulcers may perforate. This condition requires immediate surgical intervention to preserve the eye.

It has been shown that recombinant human nerve growth factor (rhNGF) eye drops could promote corneal healing. The study drug REC 0/0559 belongs to this class of drugs and is expected to shorten the time of corneal healing and help recovery.

The study has received favourable/positive opinion by the Ethics Committee [insert name as applicable] and an authorisation from the applicable competent authorities [insert name as applicable] according to the legislation in force.

How many people will take part in this study?

This study will take place in approximately 45 centres in 7 countries, with about 108 people with NK participating.

How long will my participation in this study last?

You will be in this study for approximately 12 weeks, and you will be asked to come to the study centre at least 10 times over this period.

What will happen during this study?

The study is divided into 3 time periods: a screening period of up to 3 days before first treatment administration, an 8-week treatment period, and a 4-week follow-up period. During each study period, you will have 1 or more visits with your study doctor at the centre.

The screening visit may last for over 4 hours and the related procedures may take place over 1 to 3 days before the first treatment administration(Visit Day 1).

Visit Day 28 and Visit Day 56 will take over 4 hours.

All other visits during the treatment period are expected to last approximately 2 to 3 hours.

The follow-up visit will last about 1 to 2 hours.

You will be asked to come to the study centre for an early termination visit if you discontinue the study during the treatment period.

Before any study-related tests and procedures can be done, you will be asked to read and sign this informed consent form. After you sign this informed consent form, the study will begin with a screening visit. The purpose of the screening visit is to determine if you meet the requirements to take part in this study. If you do not meet the requirements, the study doctor will explain why and will discuss with you other treatment options.

If the study doctor determines that you meet all of the requirements to be in the study, you will be randomly assigned (like the flip of a coin) to receive either the study drug or vehicle. You will have a 75% (3 in 4) chance of receiving REC 0/0559 and a 25% (1 in 4) chance of receiving vehicle. You will not be told which treatment you are receiving. The study doctor and any other people involved in the study will not know whether you are receiving study drug or vehicle. However, this information will be given to the study doctor if it becomes necessary for your safety.

If you are assigned to receive REC 0/0559, you will be treated with 1 of the following dose levels:

- 5 µg/mL 4 times a day
- 25 µg/mL 4 times a day
- 50 µg/mL 4 times a day

The escalation of the dose is planned during study along with the recruitment of new patients, and based on the opinion of the independent committee assessing the safety of study treatment on an ongoing basis. You will not be able to choose your dose level in either part of the study. You will be allowed to continue some of the medications you were taking prior to study entry, such as artificial tears without preservatives, some anti-glaucoma eye drop without preservatives or some antibiotic drops.

The study doctor or study staff will give you instructions on how to take the study drug. You will need to administer 1 drop of study drug to your affected eye (the "study eye") 4 times each day, starting in the morning, 4 hours apart + or – 30 minutes, during the 8-week treatment period. You will be given enough study drug to last until the next scheduled visit.

Each single container is to be used once only. If a drop does not reach your eye, you can administer a second drop into the eye from the same container. This means that during one day you will use 4 containers. You should administer any other medications in your eye at least 15 minutes (1 hour is recommended) before or after you administer the study drug.

The used (opened) and unused study drug containers should be collected and brought to the site during next study visits. Please do not throw away the used (opened) containers.

Study Procedures and Assessments

A description of the procedures and assessments that will be performed during the study, including the screening visit, is shown below. In addition to the visits described below, the study doctor may ask you to come in for extra visits, if necessary for your safety.

Blood samples are planned to be collected 3 times during study for safety assessments. Additional collections of small blood samples will take place at 2 visits, to test the amount of study drug in your blood. The total volume of blood collected during study is expected to be approximately 21 mL (about 1 ½ tablespoons). Some subjects will be required to provide additional blood samples to measure the amount of study drug in the blood, and they will have to sign an additional Pharmacokinetic Testing consent form to participate in the study.

A urine sample will be collected for women during screening, the final/early termination visit, and the Day 84 visit to check whether you are pregnant.

	Screening	Treatment Period								Follow-Up Period		ET
Study Day	**Day -3 to Day 1**	**Day 1**	**Day 3**	**Day 7**	**Day 14**	**Day 21**	**Day 28**	**Day 42**	**Day 56**	**Day 70**	**Day 84**	
Visit Number	**Visit 1a [a]**	**Visit 1b [a]**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**	**Visit 10**	
Sign informed consent, review eligibility, collect medical history and demographics [b], measure height	X											
Questionnaire about how your disease affects your life and activities		X					X		X			X
Assign study treatment		X										
Measure blood pressure, heart rate; physical examination; questions about any side effects you may have and medicines you are taking	X	X	X	X	X	X	X	X	X	X	X	X
Measure weight	X								X			X
ECG [c]		X					X		X		X	X
Questions about symptoms and discomfort in your affected eye		X	X	X	X	X	X	X	X	X	X	X
Vision test using a letter chart	X			X	X	X	X	X	X	X	X	X
Have a slit lamp eye examination and pictures of your eye with and without dye (fluorescein)	X		X	X	X	X	X	X	X	X	X	X
Test for sensitivity of the cornea	X								X		X	X
Examination of the inner structures of the eye (fundus examination)	X			X					X		X	X
Test for dry eye (Schirmer test)	X											
Blood samples for safety tests		X					X		X			X

	Screening	Treatment Period								Follow-Up Period		
Study Day	**Day -3 to Day 1**	**Day 1**	**Day 3**	**Day 7**	**Day 14**	**Day 21**	**Day 28**	**Day 42**	**Day 56**	**Day 70**	**Day 84**	**ET**
Visit Number	**Visit 1a [a]**	**Visit 1b [a]**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**	**Visit 10**	
Urine pregnancy test, for women who can become pregnant	X								X		X	X
Sample to measure the amount of study drug in your blood		X [d]		X [d]			X		X			
Receive study drug kits		X		X	X	X	X	X				
Administer study drug and record time in study diary		→										
Collection of used and unused study drug containers				X	X	X	X	X	X			X
Review study drug diary			X	X	X	X	X	X	X			X

[a] Procedures in Visit 1a may take place on Day -3, Day -2, Day -1 prior to V1b, or on the same day (Day 1) prior to randomisation. If they take place on the same day, the measurement of blood pressure and heart rate, physical examination, and questions about any side effects you may have and medicines you are taking do not have to be repeated.

[b] Demographics: date of birth, gender, colour of eyes, and ethnic origin.

[c] ECG: An ECG (or "electrocardiogram") is a test that measures the electrical activity of the heart. A technician will place patches on your chest that will be connected by wires to a machine. The machine will record the electrical activity of your heart. After 24 patients have been enrolled in the study, the independent committee assessing the safety of study treatment may decide to discontinue ECG examination. The study doctor will inform you if the examination is still required or not.

[d] Samples to measure the amount of study drug in the blood are only taken for some participants on Day 1 and Day 7. If you are required to provide these samples you will sign a separate Pharmacokinetic Testing informed consent form.

The following procedures will be performed during the study:

Questionnaires: 2 questionnaires will be used, one related to your quality of life and visual functioning and another one to assess your ocular symptoms and symptoms related to the tolerability of study treatment. You will be interviewed by your study doctor or nurse to complete these questionnaires.

A visual acuity test: This is used to determine the smallest letters you can read on a standardised chart. This test is done on each eye, and one at a time.

Slit lamp examination: Your doctor will use a slit lamp to look into your eyes. A slit lamp is an instrument consisting of a high-intensity light source that can be focused to project a thin sheet of light into your eye. Using this exam, the doctor can microscopically examine the eye for any abnormalities or problems. This examination will be done during each visit.

Corneal photography: At all study visits images of your eye/eyes will be made and sent to a central reading centre for review and evaluation. You will be asked to place your chin on the camera's chin rest and your forehead against a support bar to keep your head still during the test. The pictures of the front part of your eye will be taken. The same procedure will be repeated after the small amount of fluorescein dye is administered on the surface of the eye.

Fluorescein stain test: a dark orange dye called fluorescein is placed onto the outer surface of your eye, by a piece of blotting paper. You will be asked to blink several times to allow the dye to spread over the surface of the cornea. Your eye surface may have a transient light yellow appearance. The ophthalmologist will then shine a cobalt-blue light onto your eye through a slit lamp, and examine the eye surface.

Corneal sensitivity test done using a Cochet–Bonnet aesthesiometer: This device uses a single nylon thread, touching the cornea with various forces. The filament is lightly placed on to the cornea by the study doctor. You will be asked to report when you can feel the thread touching your eye surface.

Fundus examination: This is a noninvasive procedure to see inside of the eye and determine the health of the structures inside your eye. This procedure may require administration of ophthalmic drops dilating the pupil.

Schirmer test: you will be asked to look up, and the examiner will gently insert a thin strip of filter paper inside the lower lid of your eye(s). The strips are left in place for 5 minutes. Blinking normally or keeping your eyes lightly closed does not interfere with the test, but you should avoid squeezing or rubbing your eyes. Closing the eyes too tightly during the test will increase tearing, altering the results. After 5 minutes, the filter paper is removed. The doctor then assesses how far the tears have travelled on the paper.

What do I have to do?

During the study, you will have the following responsibilities:

- Tell your study doctor if you have any allergies, including drug allergies. If you are unsure, ask your primary doctor.
- Attend all scheduled visits.
- Take the study drug as directed.
- Fill out the study drug diary as directed. The study staff will show you how to do this.
- Return any used and unused study drug and containers as instructed by the study staff.
- Follow the study doctor's instructions about whether or not you may continue to take your regular prescribed medications or over-the-counter medicines during the study period. You will be allowed to continue some of the medications you were taking prior to study entry, such as artificial tears without preservatives, some anti-glaucoma eye drop without preservatives or some antibiotic drops.
- Tell the study doctor of any changes to your current medications, illnesses or injuries, unexpected or troublesome side effects, or problems that occur during the study.
- Tell the study doctor if you plan to have an elective surgery or any other medical treatment or procedure.
- If you receive ophthalmic drops dilating the pupil as part of the study procedures, you should not perform activities such as driving or operating machinery unless you feel your vision is clear, and it is safe to do so.
- You should continue to make regular visits to your primary doctor or any other special doctors you were seeing before starting the study because being in the study does not replace regular medical care.
- Make sure that the study drug is kept out of the reach of children and people who have a limited capacity to read or understand. You are the only person who should take the study drug.
- Contact the study doctor if you find you have any questions about the study after you sign this form.
- You must use a reliable form of contraception during the study. If you become pregnant while you are in the study, be sure to tell the study doctor as soon as possible.

What are the benefits of being in this study?

There is no guarantee that you will receive any benefits. However, you will be helping others by contributing to medical research. You may feel that you are benefiting in the following ways:

- The study drug may help to promote healing of the cornea and relieve your symptoms.

What are the risks and possible discomforts?

Any study has risks, which may include things that could make you sick, make you feel uncomfortable, or harm you. You might experience side effects related to the study drug while participating in the study. These side effects may be mild or serious. The study team may give you medicines to help reduce side effects. In some cases, side effects might be long lasting or

permanent and may even be life threatening. All participants in the study will be watched carefully for any side effects. The independent committee will periodically review all data about medical events occurring during study treatment administration. This committee will inform the Sponsor if any safety issue occurs that can affect the study conduct.

Taking part in this study involves some risks and possible discomfort to you as noted below.

Possible risks of the study treatment:

- If you are assigned to take vehicle, or if the study drug does not work for you, you may see an increase in your NK symptoms. The study doctor might propose another medicine or treatment procedure in this case, and ask you to remain under observation.
- The study drug may cause unpleasant side effects or reactions. No side effects were reported in a limited number of patients with NK who received the study drug in an exploratory setting (not as part of a research study). However, as the present study is the first prospective thorough evaluation of the study drug in patients, some side effects may be still unknown.
- In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment with eye drops containing phosphates. REC 0/0559 and vehicle contains phosphate as an excipient.
- Because the study drug is investigational, there may be risks and side effects that are unknown. All drugs have a possible risk of an allergic reaction.

Possible risks of study procedures:

- Blood samples: Taking blood from your arm may cause faintness and/or swelling, pain, redness, bruising, bleeding at the collection site, or infection (infection rarely happens) at the site where the needle is inserted.
- Electrocardiogram (ECG), (in case the examination is done) : Skin irritation is rare but could occur during an ECG from the electrode patches or gel that are used.
- Fluorescein stain test: You may feel a slight stinging sensation when the dye is first applied but after a short time the dye will feel like normal liquid on the eye and will no longer be uncomfortable.
- Corneal sensitivity test: There is a minimal risk of corneal erosion during this test. The feeling of the filament touching the eye surface may start to be unpleasant during examination.
- Pupil widening: The eye drops routinely used to widen your pupils for examination of the back of your eye may make you sensitive to light for as long as the pupils are widened (you may wish to use tinted glasses or sunglasses to shield your eyes from bright lights and the sun). This effect could last for a few hours. It is possible that the eye pressure may increase and this may be associated with nausea, discomfort, and blurred vision.

This may occur in some participants, but it is uncommon. You will not be able to drive for several hours after the application of these drops. You should therefore be prepared to have someone, such as a family member, to transport you if you must return home sooner than your ability to drive is re-established.

- Schirmer test: This test can be mildly irritating or uncomfortable.

Additional possible risks:

- The following side effects were reported for patients with NK taking medications that work in a similar manner to the study drug, but they may or may not apply to REC 0/0559: eye pain; inflammation of the eye; pain in the eyelid; abnormal sensation and discomfort in the eye, including feeling that there is something in the eye; increase of tears (this could include symptoms such as discharge in the eye); inflammation of the eyelid with twitching and redness; redness of the conjunctiva (mucous membrane that covers the front of the eye and lines the inside of the eyelids); sensitivity to light; irritation in or around the eye; headache; excessive growth of blood vessels into the cornea (can affect vision); or infection (abscess) of the cornea with pus and swelling.

Pregnancy/Birth Control

Women

Taking the study drug may involve unknown risks to a pregnant woman, an embryo, foetus (unborn baby), or nursing infant. Therefore, if you are pregnant, planning to become pregnant, or are breastfeeding a child, you cannot take part in this study.

Before entering the study, a pregnancy test will be done for all women who are able to become pregnant. Pregnancy tests will be repeated during the study to monitor if pregnancy has occurred.

During the study, if you are able to become pregnant, you must use a highly effective method of birth control while you are taking part in this study and for 4 weeks after you finish the study treatment. If you are already using a method of birth control, the study doctor or study staff will discuss with you whether or not your current method of birth control is acceptable for use during this study. Methods of highly effective birth control include surgery (blocking or destroying part of the fallopian tubes), hormonal contraceptive, patch, vaginal ring, intrauterine device, or intrauterine hormone-releasing system. If you are abstinent as part of your preferred and usual lifestyle for the total duration of the study and for 4 weeks after you finish the study you are not required to use an additional birth control method.

If during the study you become pregnant, you should tell the study doctor as soon as possible. The study drug will be stopped, and your involvement in this study will end. The Sponsor will ask to collect data related to your pregnancy and your baby's health conditions.

Men

It is not known if the study drug could damage sperm and consequently a foetus. Therefore, male participants should be surgically sterile (vasectomy) or use condoms during the study and for 4 weeks after the end of study treatment. Male participants whose partners are not of childbearing potential are not required to use condoms.

If during the study your partner becomes pregnant, you should tell the study doctor as soon as possible. The Sponsor may like to receive updates on the progress of the pregnancy and its outcome as well as on the health condition of your baby. If your partner agrees to this, she will be asked to sign a separate informed consent.

What if there are new findings?

If new findings that would affect your safety and willingness to participate in the study are identified while you are in the study, you will be told as soon as possible so you can decide whether to leave the study or continue. If you continue, you will be required to sign a new informed consent form.

What other options are available if I do not take part in this study?

You do not have to take part in the study to treat your NK. There are other options of therapies, such as partial or total tarsorrhaphy (a surgical procedure in which the eyelids are sewn together), amniotic membrane transplantation, use of special contact lenses called scleral or corneal contact lenses, conjunctival flap, and corneal transplantation. The therapy choice depends on the disease severity and the local standards of care. You can ask the study doctor for more information on the other available options.

In some countries there have been approved topical eye drops containing cenegermin (Oxervate®) for the treatment of individuals with NK. Your primary doctor or the study doctor can answer any questions that you have about other treatments.

You should also contact your primary doctor to ask about other research currently being done in the treatment of NK.

Who is paying for this study?

This study is being funded by Recordati Rare Diseases. The study doctor will be paid for his/her work in this study.

What are the costs?

The study drug will be given at no cost to you, and you will not be charged for any study doctor visits, laboratory work, tests, or procedures that are needed for the study.

Will I be paid for being in the study?

Recordati Rare Diseases appreciates your involvement in this study. You will receive no payment for taking part in this study, but you will be reimbursed for transportation, meals, or parking payments related to visiting the study centre upon provision of receipts.

What if I get sick or hurt?

In accordance with country regulation, the Sponsor of the research has subscribed an insurance guaranteeing its civil liability. A contract was issued with the company:

Name and address of the insurance company:

_____

Policy number: _____

This insurance policy covers injuries and damages caused in connection with the conduct of the study and that you may incur as a patient participating in the study.

<Additional information will be added per country-specific requirements. Instructional text to be left in final Master document, as this is to be completed by country SSU.>

Can I leave the study after it has begun?

Yes. Taking part in this study is voluntary, and you can leave the study at any time for any reason. There will also not be any penalty or loss of benefits to which you are entitled if you decide not to take part or if you decide to leave the study.

If you decide to leave the study, you should contact the study doctor who will explain the safest way to end participation, which may involve the completion of some final tests and examinations. You should also contact your primary doctor so he/she can provide you with the best course of continuing care.

The study doctor or Recordati Rare Diseases can remove you from the study, without your permission. Possible reasons for doing so include the following:

- any change in your medical condition that might make continuation in the study harmful to you
- pregnancy, if you are a woman who is able to become pregnant
- your failure to follow the study doctor's instructions
- discovery that you do not meet the study requirements anymore
- cancellation of the study
- administrative purposes

What will happen to the samples that I provide?

Your blood samples will be coded before being shipped to a central laboratory named *<for EU, use the following:* Eurofins Central Laboratory, B.V. (Bergschot 71, 4817 PA Breda, The

Netherlands)> <*for US, use the following:* Eurofins Central Laboratory LLC (2430 New Holland Pike, Lancaster, PA 17601, USA)>. The blood samples that you give for safety testing will be used only for specific tests that are needed for this study. Your samples will be destroyed at the latest 6 months after the study results have been finalised. Your samples will be tested and destroyed according to the standard procedures of the laboratory.

Samples taken to measure the amount of study drug in your blood will then be shipped to Syneos Health Bioanalytical (Syneos Health Clinique inc., 2500 Einstein Street, Québec, QC, G1P 0A2, Canada) and will be stored there until they are analysed. Your samples will be destroyed at the latest 6 months after the study results have been finalised. Your samples will only be used for study-related purposes. No other analyses will be performed without your approval and the approval of the Ethics Committee. You have the right to refuse permission for these additional tests to be done, and you may (at any time) request that your samples are destroyed.

What happens when this study stops?

When the study stops, you will be under the care of your primary doctor who will decide the best way to treat your NK. The study drug will no longer be available to you.

You have the right to be informed of the overall results of the study.

Will my records be kept private?

To participate in this study, you must read and sign the Privacy Notice at the end of this form (see Appendix 1).

What if I have a question or concern?

You should feel free to ask questions about the study and your rights as a subject before, during, and after the study.

Whom can I call?

If you have any questions about this study or if at any time you believe that you have a research-related injury or a reaction to the study drug, you should contact <*insert study doctor's name*> by telephone at <*insert his/her telephone number*>. If you have any questions regarding your rights as a research subject, you may contact <*insert IRB/IEC name*> by telephone at <*insert IRB/IEC telephone number*>.

Important

Do not sign this informed consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
Signing your name to this informed consent form means that you voluntarily agree to take part in this study.
This agreement can be withdrawn at any time; although, data collected up to that point are legally allowed to be used.

Consent to Participate

By signing this informed consent form, I agree to the following:

- I have read, and I understand, this informed consent form.
- I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.
- I understand the risks of taking part in this study as described in this informed consent form.
- I understand that there is no guarantee that I will receive any benefits from taking part in this study.
- I freely consent to be treated with REC 0/0559 under the study doctor's care.
- I confirm that all information that I have given about my medical history is correct to the best of my knowledge.
- I understand that I am free to withdraw from the study at any time for any reason. I will tell the study doctor if I decide to withdraw so that my participation may end in an orderly manner, and my future care can be discussed.
- I understand that I will be told of any new information that might relate to my willingness to continue in the study.
- I will tell the study doctor if I have any physical or psychiatric ("mental health") symptoms or problems.
- I understand that I will receive a signed and dated copy of this informed consent form for my records.

My consent to participate in this study does not take away any legal rights in the case of negligence (carelessness) or other legal fault of anyone who is involved with this study.

_____
Name of participant (print)

_____ _____
Signature of participant Date (dd/Mmm/yyyy)

_____ _____
Signature of study doctor or person administering consent Date (dd/Mmm/yyyy)

Impartial Witness (if needed)

I am an impartial witness and was present during the entire informed consent discussion. I attest that the information in this informed consent form was accurately explained to, and apparently understood by, _____, and that he or she freely gave consent to participate.

_____
Name of impartial witness (print)

_____ _____
Signature of impartial witness Date (dd/Mmm/yyyy)

Appendix 1: Privacy Notice

Identification of Data Controller: During the study, the Sponsor will direct the collection and use of your personal information (data) needed for the study. The Sponsor is the data controller of your personal data under applicable data protection laws. You can contact the Sponsor's data protection officer at:

groupDPO@recordati.com
Recordati RD, represented by
Data Protection Officer
Recordati S.p.A.
Via Civitali, 1
20148 Milano, Italy

The study centre may also be considered as a data controller of your personal data under applicable data protection laws. You may contact the study doctor using the contact information for the study doctor on the first page of this informed consent form. *<If relevant>*You can contact the study centre's data protection officer at: *<Study centre to provide contact information>*.

If you have any questions or would like to see the data collected about you for this study, you should contact the study doctor.

Data to be Collected and Processed: The study staff will collect data about you for the study. These data may include your name or initials, date of birth, gender, colour of the eyes, contact details, and information needed for reimbursement processing. In addition, the following sensitive personal data about you may be collected: health and ethnic origin.

How Your Personal Data Will be Used: The personal data collected about you will be recorded in your study file by the study staff to run the study and to monitor your safety as a participant. Your personal data may be processed on a computer and/or on paper. The collection of these data is necessary to conduct the study and comply with applicable laws. You will not be able to participate in the study if you fail or refuse to provide your information.

There are laws about the recording, forwarding, storage, and analysis of your personal data, including sensitive personal data. These laws require your voluntary and explicit consent before you participate in the study. If you do not consent to the collection and use of your personal information, you will not be able to be in the study

Results of this study may be presented at meetings or in publications; however, your identity will never be shared. Your personal data will not be used for any direct marketing purposes.

Storage of Your Personal Data: According to legal requirements, your personal data will be stored in the study databases and/or paper files for whichever time period is longer, as required by applicable laws:

- at least 15 years after the study ends, OR
- at least 2 years after the drug being studied has received its last approval for sale, OR
- at least 2 years after the drug's or device's development has stopped.

Transferring the Personal Data to a Third Party: To keep your identity private, all data that is sent or provided outside of the study centre will show only a coded identification number instead of your name. Only the study doctor and authorised personnel will be able to connect this code to your name. They will use a list that will be kept in a secure place to link this code to your name in case of an emergency. The coded data from the study showing your involvement (including uncoded personal information) will be provided to the Sponsor and other individuals and/or companies that act on the Sponsor's behalf, including Syneos Health. Also, your medical records (including uncoded personal data) may be reviewed by the Sponsor and other individuals and/or companies that act on the Sponsor's behalf, including Syneos Health; government agencies in countries where the study drug may be considered for approval (such as the US FDA); [IRB/IEC name], a group that reviews and approves studies; and independent auditors for the purposes of confirming your participation in the study, monitoring your safety during the study, and monitoring the conduct of the study. Further, your personal information may be disclosed in response to lawful requests by public authorities, including those to meet national security or law enforcement requirements.

If your personal data are shared with other companies that are located outside of the country where you live, the Sponsor will make sure your data are protected as required by your country's data protection laws. Some of these other companies may be located in countries whose data protection and privacy laws may be less strict than in your own country, including the United States and _____. You may contact the study doctor to get more information about the precautions used to protect your personal data outside of your country. You may also ask the study doctor for a copy of those precautions.

With your permission, the study doctor will tell your primary doctor about your role in this study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. A description of this clinical study will also be available on the European clinical trials database at https://www.clinicaltrialsregister.eu as required by European Law. This website will not include information that can identify you. At most, this website will include a summary of the results. You can search this website at any time. [Country adaptation if applicable: Information about

what will happen to the results of the research and how the results will be made available to participants should be added.]

Your Rights as a Data Subject: If you live in the European Union (EU) or a country that provides these specific rights for individuals, you have the right to access and correct the data collected about you during the study and submit any questions or concerns about the collection or processing of your personal data. If applicable, you may also have the right to request

- the deletion of your personal data,
- restriction on or objection to the processing of your personal data, and
- the receipt of your personal data (data portability) (starting 25 May 2018 in the EU).

You may make these requests by contacting the study doctor. You may also have the right to file a complaint regarding the handling of your personal information with your local data protection authority.

You have the right to withdraw your consent for the processing of your personal data at any time. However, data collected before you remove your consent is still legally allowed to be used. If you withdraw your consent, you will no longer be able to take part in the study.

Consent Language

Consent to the Collection, Processing, and Use of Personal Data

By signing below, I agree that:

(1) My personal data, including sensitive personal data, can be collected, used, and archived for purposes of carrying out the study as described in this Privacy Notice;

(2) My personal data, including sensitive personal data, can be transferred to and shared with other companies both within and outside of the European Economic Area (EEA), including to countries that may not have the same level of data protection as the EEA, as described in the Privacy Notice;

This consent is valid unless you change your mind and provide a written notice to the study doctor.

_____
Name of participant (print)

_____ _____
Signature of participant Date (dd/Mmm/yyyy)