

Participant Information and Agreement to Take Part Form

A research study looking at how different doses of study medicine (Inno8) works in the body of people with haemophilia A

Final Version 2.0

Administrative information:

Study ID:	NN7442-8454	Date:	22-August-2025
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Official name of the study:	Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Multiple Ascending Peroral Doses of Inno8 in People with Haemophilia A		
Research sponsor contact information: Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd, Denmark			
Information about the study will be made available at www.novonordisk-trials.com , euclinicaltrials.eu , and potentially in other regional or local registries <add other national/regional registries, if applicable>.			
A description of this clinical study will also be available on http://www.ClinicalTrials.gov . This Web site will not include information that can identify you. You can search this Web site at any time.			

The visit schedule and study related activities are presented in the table below. For more information, see Section 3 **What will you need to do if you take part?**

This table shows visit schedule and the study related activities.

Visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Timing of visit (days)	-28	1	2	3	4	5	6	7	8	9	10	11	17	23	29	36	46
Visit to the clinic, home visit or phone visit									 or 	 or 							
Personal information																	
Body measurements																	
General health check																	
Check heart (ECG)																	
Blood samples																	
Urine test																	
Take study medicine																	
Fasting overnight until 30-35 minutes after study medication																	



Visit to the clinic



Home visit



Phone visit

Participant Information and Agreement to Take Part Form

A research study looking at how different doses of study medicine (Inno8) works in the body of people with haemophilia A

You are invited to take part in a research study

You are free to decide if you want to take part in this study or not.

- Before a medicine can be prescribed by doctors, it must be tested. This is to see if it is safe and if it works as we expect it to.
- This is called a ‘research study’. In this document we will call it a ‘study’.
- In this study we will be looking into how different doses of study medicine (Inno8) works in the body of people with haemophilia A.
- The company doing this study is called Novo Nordisk. Novo Nordisk is a company that develops medicines.
- Before you decide if you want to take part in the study, it is important that you understand:
 - why we do the study
 - the possible benefits and harms
 - what you will have to do
 - the rights you have
- This participant information will help you decide if you want to take part. Please take your time to read the document carefully. You may wish to talk to your study doctor, study staff, family or friends before deciding.
- Please ask the study staff if there is anything that is not clear or if you want more information.
- If you decide to take part in the study, you need to sign the ‘Agreement to take part form’ at the end of the document.
- If you decide not to take part, your current and future medical care will not be affected.

Please read the rest of this participant information. It gives you more information about the study.

What is in this document?

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Who to contact

If you have any questions, concerns or complaints about this study, please talk to your study doctor:

Study doctor’s name: <Doctor’s name>

Working address: <Doctor’s address>

Contact phone number: <Doctor’s phone no.>

Other contact person’s name: <Contact name>

Working address: <Contact address>

Contact phone number: <Contact phone no.>

Important things that you need to know

This is a summary of the important things you need to know about the study.

- This study will test how different doses of study medicine (Inno8) work in the bodies of people with haemophilia A.
- The purpose of the study is to see if Inno8 is safe to use for people with haemophilia A.
- The study medicine is a new medicine that cannot yet be prescribed by doctors.
- The study medicine is a tablet. You will get 1 tablet of the study medicine daily for 10 days. All tablets must be swallowed whole with half a glass of water (120 millilitres) after an overnight fast of at least 10 hours and at least 30 minutes before the first meal or drink of the day.
- Like all medicines, the study medicine may have side effects.
- The study will last for about 11 weeks.
- You will have 17 visits in total. Of these, 14 are clinic visits and 3 are phone calls with the clinic. 2 of the 14 clinic visits could take place in your home.
- Blood samples will be taken at all 14 clinic visits.
- You should not take part in this study if you:
 - have any disease or condition other than haemophilia.
 - are receiving treatment preventing you from bleeding.
 - have previously had a reaction to any ingredient of the study medicine.
 - have a blood pressure, a pulse or blood tests that are not normal.
- In case you experience bleeds, these can be treated with additional haemostatic medication as agreed with your doctor. However, Novo Nordisk will not cover the cost for treatment of bleeds.

1 Why are we doing this study?

We are doing this study to see if the study medicine (Inno8) is safe to use in people who have the disease haemophilia A. This is the first study where Inno8 will be given to people with haemophilia A.

Haemophilia is a bleeding disorder that some people are born with where they bleed longer than usual. People with haemophilia A have too little of a certain component in their blood called clotting factor VIII (8) which helps to form blood clots to stop bleeding.

Usually, medicines to treat haemophilia A are injected with a needle into a vein or under the skin. Some people with haemophilia A develop a resistance to these treatments by producing a type of protein called inhibitors which stop the medicines from working.

This study and later studies will be done to test if people with haemophilia A, with or without inhibitors, can take their medicine as a tablet (Inno8) instead of injections.

Also, the information we collect can help us better understand:

- Haemophilia A or related diseases.
- How the study medicine works in the body.
- How to improve the treatment of people with haemophilia A or related diseases.

What will this study look at?

This study will mainly look at:

- How safe the study medicine is at different doses. This will be done by looking at any side effects that may happen and by looking at the results from the blood samples.
- How fast and for how long the medicine works at different doses. This will be done by measuring the concentration of the study medicine in the blood at different time points.
- How the study medicine works in the body at different doses. This will be done by looking at results from the blood samples.

How many people will take part?

20 men across the world will take part in this study.

2 Deciding if you want to take part

Why are you being asked to take part in the study?

You are being asked to take part because:

- You are a man aged 18-64 years.
- You weigh 45 kg or more.
- You have haemophilia A with or without inhibitors.

What happens if you say 'yes'?

You will need to sign a form agreeing to take part. We call this an 'agreement to take part form'.

- This form is at the end of this document.
- You will be given a copy of this participant information and the signed form to take home and keep.

What happens if you say 'no'?

You are free to say no – the choice is yours. If you do not take part in the study, your current and future medical care will not be affected. Your study doctor will talk to you about other possible treatments, their benefits and harms.

What happens if you change your mind and no longer want to take part?

You can decide no longer to take part in the study at any time – you do not have to give a reason.

- Your future medical care will not be affected if you stop taking part.
- You will continue to be treated as you were before you started this study.
- If you decide to stop taking part during the study, information about you that has already been collected can still be used for research. This is required by the health authorities to make sure that the results for the entire study can still be used.

Taking part in other studies

You cannot take part in this study if you are already taking part in another study that is testing a medicine or treatment. You must also not join other studies that are testing a medicine or treatment if you decide to take part in this study. This is to protect your safety and the outcome of this study.

3 What will you need to do if you take part?

How will you take the study medicine?

You will take 1 tablet of the study medicine (Inno8) daily for 10 days. All tablets must be swallowed whole with half a glass of water (120 millilitres) after an overnight fast of at least 10 hours and at least 30 minutes before the first meal or drink of the day. The 2 first days you will take the pill in the company of medical staff at the clinic. The next 7 days you will take the pill at home. The last day you will again take the pill at the clinic when you attend visit 11. It is important that you do not take the pill at home before going to the clinic for visit 11.

The doses in this study have been decided based on a study in people without haemophilia A. The doses have been chosen so that they are safe, but they may not prevent you from bleeding. If you should start bleeding during the study, the doctors will make sure you get treatment.

The study medicine will first be given to one group of study participants at a low dose. Then, in a second group of participants, 2 people will get the study medicine at a higher dose. These people will be observed for 3 days before giving the same dose of the study medicine to the rest of the people in that group. This is done to make sure that the dose is safe to take and to make sure that no acute reactions happen.

During the study, you need to store and take the study medicine as told by your study doctor.

What are your responsibilities?

If you take part in this study:

- You should not eat any foods containing poppy-seeds 2 days before visit 2, see visit schedule.
- You should not smoke more than 5 cigarettes per day (or the corresponding amount of nicotine containing products) from the first visit until the last visit.
- You are advised to not change your normal way of moving and working out from the first visit until the last visit, as it can affect the study results.
- You should not take any medicines other than the study medicine (except routine vitamins, and occasional use of paracetamol (acetaminophen) and ibuprofen) from the first visit until the last visit.

- You should not take part in any other study from the first visit until the last visit.
- You must attend visit 2, 3 and 11 fasting (see visit schedule).
- You must take the tablet once daily.
- You must take the tablet in the morning after an overnight fasting. Fasting is defined as no food or liquid, except for water, for at least 10 hours before you get the study medicine. No water or medicines taken by mouth are allowed 1 hour before dosing.
- At the day of visits 2, 3 and 11, you should take the study medicine at the clinic. It is important that you do not take the study medicine at home on these days.
- You must swallow the tablet whole with half a glass of water (120 millilitres).
- You should not split, crush or chew the tablet, as it is not known if it affects how the study medicine is taken up by the body.
- You must close the bottle with tablets right after taking the daily dose. If the bottle is left open for more than 30 minutes, the tablets must be thrown out.
- After taking the tablet, you will have to wait for 30–35 minutes before having the first meal or drink of the day or taking other medicines by mouth.
- You must inform the study doctor immediately if you start to experience a bleeding episode anytime during the study period.
- You must agree with the study doctor what medication you use to treat a bleeding episode at home.

How long does the study last for?

The total time you will be in this study is about 11 weeks.

- Up to 4 weeks at the start – to check that you can take part in the study.
- 10 days where you will be taking the study medicine daily and be looked at by medical staff.
- 5 weeks after your last dose of the study medicine – to check on your general health.

What will happen at the different visits in the study?

During the study, you will be asked to:

- come to 14 visits at the clinic, 2 of these visits can maybe take place at your home.
- have 3 phone calls with the study doctor or staff.

During the visits, various tests and examinations are carried out, such as checking blood pressure, pulse, body temperature, and respiratory rate or taking blood samples. The individual tests and examinations usually take between 5-20 minutes, in exceptional cases even longer.

It is important that you come to all the visits for the study doctor to check your health and follow how the study medicine is working on you.

You may be asked to come for extra visits. For example, if you have any side effects that the study doctor needs to evaluate.

The amount of time you will be at the clinic at each visit may vary. This is because the tests and checks will differ at each visit. There will be:

- 2 visits (visit 2 and 11) that will most likely take 9 hours.
- 9 visits (visit 1, 3, 8, 9, 10, 12, 16, 17 and either visit 5 or 6) that may take about 2 hours. Visit 9 and 10 may be scheduled as a home visit, where a registered nurse from the clinic attends your home to collect information and blood samples. Home visits can only be offered if allowed by the clinic.
- 3 visits (visit 13, 14 and 15) that may take about 1 hour.
- 3 phone calls (visit 4, 6 and 7) that may take about 15 minutes.

Talk to your study doctor if you want to know more about this.

Tests and checks

You can check the visit schedule in the beginning of the document to get an overview of what will happen at all the visits. During the study you will have the following tests and checks:

- At 1 visit, you will have your height and body weight measured (visit 1).
- At 11 of the visits, you will have a general health check done (visit 1, 2, 3, 5, 8, 9, 10, 11, 12, 16, and 17). This includes measuring your blood pressure, pulse, body temperature, and respiratory rate.
- At 8 of the visits, your physical condition will be checked (visit 1, 2, 3, 8, 9, 12, 16 and 17).
- At 3 of the visits (visit 2, 3 and 11) you cannot eat for 10 hours before the visit (see more instructions in the section called 'What are your responsibilities?').
- At 6 of the visits, you will have an electrocardiogram (ECG). This is a test to check your heart (visit 1, 2, 3, 12, 16 and 17).
- At 6 of the visits, you will have a urine sample taken (visit 1, 2, 5, 11, 12 and 17).
- At all the clinic and home visits you will have blood samples taken (multiple times during visit 2, 3 and 11). A total of about 500 millilitres of blood will be taken during the study (which means about half a litre). Your blood samples will be used to perform routine laboratory tests, including a test for HIV, measure the amount of Inno8 in your body and perform tests on how the study medicine works.
- The blood sample taken at the very first visit to the clinic will also be used to perform a genetic test. This is to check if you are at risk of getting blood clots in your vessels. If so, you cannot take part in the study. You can say no to the genetic test and still be in the study, but an additional laboratory test will have to be done instead. Talk to the staff at the clinic about this.
- You will be informed about the results of the HIV test and the genetic test.

When doing tests, the laboratory equipment may automatically provide additional routine results not needed for the study. Such results will not be reported to Novo Nordisk. Abnormal values will be reported to your study doctor who will discuss them with you, if relevant for your health.

4 What do you need to know about the study medicine?

The study medicine is a new medicine called Inno8. You will take 1 tablet of the study medicine per day for 10 days.

The study medicine will be given at 2 different doses in this study. The exact doses to be given in the study will be decided based on results from an earlier study. You will get the same dose during all 10 days where the study medicine is taken.

Which study dose will you get?

Which dose you will get depends on which group you are in - group 1 or group 2. You and the study staff will know which dose of study medicine you get.

About Inno8

Inno8 is a medicine that acts like clotting factor VIII (8) in the body. Clotting factor helps the body to stop bleeding. People with haemophilia A have too little clotting factor VIII in their blood and can therefore bleed for a longer time than usual. Inno8 can help people with haemophilia A.

5 What are the possible side effects or harms of taking part?

Your study doctor will watch for any health problems that may happen while you are taking part in this study.

- As with all medicines, side effects may happen.
- If side effects happen, they will be treated, if needed.
- You may be asked for an extra blood sample or clinical test if you have any side effects that the study doctor needs to look at.

Tell your study doctor or the study staff about any side effects or health problems you have while taking part.

Tell the study doctor or staff even if you do not think that the study medicine caused the side effects.

Side effects of study tests and checks

Blood sampling

During this study, small amounts of your blood will be taken. This allows the study doctor to see how you are doing and if the study medicine works.

- You may feel a little discomfort, bruising, bleeding or swelling where the needle goes in.
- There is also a very small risk of infection where the needle goes in.

Side effects of Inno8

These are side effects we know about from other medicines similar to Inno8. We do not know whether or how often these side effects may happen during or after treatment with Inno8.

Hypersensitivity reaction (a reaction of the immune system)

Hypersensitivity reactions (a reaction of the immune system) may occur upon administration of a medicine. Hypersensitivity reactions may show as allergic reactions:

Allergic reactions

Signs of mild allergic reactions may include:

- rash, redness, hives and itching.

Signs of a serious allergic reaction may include:

- breathing difficulty, swelling, light-headedness, fast heartbeat, sweating and loss of consciousness or rapid swelling under the skin in areas such as the face, throat, arms and legs.

If you experience signs of a serious allergic reaction, you should seek immediate medical help and inform your doctor straight away.

Serious allergic reactions can be life threatening if throat swelling blocks the airway.

Blood clots

Clots in arteries:

This can lead to heart attacks or strokes – which can cause death. Blood clots can also affect your kidneys or gut.

Signs may include:

- severe chest pain
- feeling short of breath
- feeling confused
- trouble with speech or movement
- pain in your stomach area.

Blood clots in your arteries are more likely to happen if you:

- are smoking

Clots in veins:

Clots can be formed in the veins of your legs, arms, lungs, liver, kidneys. This could lead to clots in the lungs ('pulmonary embolism') – which can cause death.

Signs may include:

- difficulty in breathing
- red and painful swelling in the leg.

Blood clots in your veins are more likely to happen if you:

- are smoking

If you experience any signs of a blood clot, you must seek immediate medical help and inform your doctor straight away.

Thrombotic microangiopathy

This condition has been seen in a few cases in patients with haemophilia A, using a medicine with the same kind of action as Inno8. The condition

was seen when the drug was combined with another medicine containing various coagulation factors known as activated prothrombin complex concentrates (aPCC). Thrombotic microangiopathy is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs.

Get medical help right away if you have any of the following signs or symptoms during or after treatment with Inno8:

- fever
- fatigue or weakness
- paleness
- confusion, stroke or seizures
- red dots or bruises on the skin (for example on the legs) or mucous membranes (for example in the mouth)
- yellowing of skin and eyes
- severe stomach or back pain
- nausea or vomiting
- decreased urination, foamy or red-coloured urine

Driving and using machines

Inno8 has no known effect on the ability to drive or use machines.

Pregnancy – information for men

Men

There are no contraceptive requirements for participation in this study.

6 What might the benefits be to you?

You may or may not benefit from taking part in this study or taking the study medicine.

- You may benefit from having tests, checks and talks with your study doctor.
- The information we get from you during the study may help you or other people with haemophilia A in the future.
- The results may also show that you have other illnesses that may not have been found if you did not take part in this study. If so, you will be told.

You will not have to pay for the following things – while you take part in the study:

- Study medicine.

7 Who is involved and more information about taking part

Who is paying for this study?

Novo Nordisk, a company that makes medicines, is paying for this study.

Novo Nordisk will pay for:

- the cost of the study medicine,
- the tests and checks,
- the time spent by the study doctor and staff and
- use of the clinics.

However, Novo Nordisk will not provide or reimburse treatment for bleeding episodes.

Will you receive any payments?

- *In case no payments of participants in relation to taking part in the study are allowed locally, insert: You will not receive any money for your time spent at the clinic or for taking part in the study.*
- *Alternatively, if allowed by local regulation and approved by the Research Ethics Committee/Institutional Review Board, insert a statement concerning reimbursement of participant's expenses or other payment relevant for the study in local context, for example: You can receive money for some of your expenses related to taking part in the study: <list here what will be reimbursed, for example the overnight stays near the clinic during the treatment period, costs for transportation to and from the clinic, absence from work due to clinic visits, meals in connection with travelling to and from the clinic, etc..>*
If a stipend for participation is locally accepted by authorities, insert: You will receive a payment for participation in the study.
- *The following text should be used in all countries: You will not receive any money to cover for the treatment of bleeds that may occur during the study.*

Who has reviewed, appraised and/or approved this study?

The study has been reviewed, *appraised and/or approved* by:

- an independent committee called a *Research Ethics Committee/Institutional Review Board* and
- *the national health authority in your country.*

What treatment will you get when you stop taking part?

At the final visit your study doctor will discuss the choices for your future medical care with you. After the end of the study, Novo Nordisk will not give you any free medicines or extra care.

What if new information becomes available during the study?

During the study, your study doctor will let you know as soon as possible if there is new information important for you. This might be information about:

- the study medicine
- the study visits
- the possible benefits and harms.

You can then decide if you want to stay in the study:

- If you stay in the study, you may be asked to sign a new 'agreement to take part form' (like this one).
- If you stop taking part in the study, the study doctor will discuss your options for future medical care and treatment.

What if you decide to stop taking the study medicine?

You can stop the study medicine at any time and still be in the study. This means you would stop taking the study medicine – but still come to all the clinic visits and have the tests performed. This will help us to understand the study results better. Every participant's information is important for the overall success of the study. Also, you may benefit from the clinic visits. It is up to you if you decide to keep coming or not. If you decide to stop taking your study medicine, please talk to your study doctor before making any changes. This is to make sure the study medicine is stopped in a safe way.

What if the study doctor decides to stop the study medicine?

The study doctor may stop you from taking the study medicine at any time – even if you want to carry on. The doctor may ask you to stop the study medicine:

- for your safety – for example if your body has a bad reaction to the study medicine
- if the study medicine is not the best choice for you
- if your illness becomes worse

What if you decide to stop taking part in the study?

If you decide to stop taking part, please talk to your study doctor before making any changes to your study medicine. This is to make sure that the study medicine is stopped in a safe way.

- You will be asked to come for a final visit (visit 17). This will be to check your health and any effects of the study medicine on your body up until that point.

What happens to your samples if you decide to stop taking part in the study?

If you wish, you can ask the study staff to arrange for any stored blood samples to be destroyed.

What if Novo Nordisk or the health authorities decide to stop the study?

Novo Nordisk, the health authorities or the *Research Ethics Committee/Institutional Review Board* may end the study early at any time. This could be done for safety or other reasons. If this happens, you will be told by your study doctor. The study doctor will talk to you about your options for future medical care.

What if something goes wrong?

If you are harmed as a direct result of taking part in this study or taking the study medicine, Novo Nordisk will make sure that you have the needed medical care available in your country. *Some countries have other mandatory 'Compensation for injury' clauses or indemnity statements approved by Corporate Legal that can replace this paragraph.*

Tell your study doctor straight away if you feel that you may have been harmed as a direct result of taking part in this study.

8 How will information collected about you be used and who can see it?

What information about you will be collected?

During the study, your study doctor will collect information about your health and certain types of personal information. This may include your name, age, year of birth, contact information, body weight, blood pressure, sex and race. This may also include your and your family's haemophilia history, details on bleed history and haemophilia treatment. The study staff may also collect information relevant for the study from other health care professionals. The information will be written down in your personal medical file at the clinic.

Who will be able to see your information?

Novo Nordisk (the data controller) is responsible for your information collected during the study. All parties who have access to your information are responsible for ensuring your privacy:

- Your study doctor and Novo Nordisk will make sure that your information cannot be looked at by people who are not allowed to.
- Novo Nordisk will protect your identity in all presentations and publications.

To make sure that the study is done correctly and to check the results, the following people will also be able to see your study information at the clinic and the list which links you to your participant number:

- Novo Nordisk staff such as monitors and auditors
- *Research Ethics Committee/Institutional Review Board* and health authorities.

In some cases, Novo Nordisk staff (such as monitors and auditors) and health authorities may do the checks remotely. For example, via direct access to electronic systems or by video calls. During the checks, they will ensure to keep your information private and protect your identity. They will use a secure Internet connection. They will not record the activity.

Information collected during the study can be shared with the following people. They will be able to see information collected during the study without being able to identify you directly:

- Novo Nordisk staff and consultants, IT-suppliers, research organisations or laboratories working for Novo Nordisk

- *Research Ethics Committee/Institutional Review Board* and health authorities

We may also share the information we collect during this study with other researchers who are not part of the study. We will only share the information to find out more about the study medicine, haemophilia A or related diseases and to help improve medical care and science.

Your information, blood and other samples may be sent securely to other countries for testing and analysis. This information and samples will not include personal information, like name and contact information. The information cannot be directly linked to you. It will only have your participant number on it. Novo Nordisk will take measures to ensure that this information is protected both during transfer and while it is being tested and analysed.

If your information is transferred out of the European Union/European Economic Area, such transfer of personal data will either be subject to Novo Nordisk binding corporate rules or the European Commission's standard contractual clauses. You can request a copy of the measures applying to the transfer of personal data by contacting privacy@novonordisk.com.

How do we ensure your privacy?

The study doctor will share your information with Novo Nordisk without sharing your identity. Your study doctor will keep a code list. This list links you to your participant number. The code list may be used to identify you, if needed.

How will we use the information we collect?

We collect your information for several reasons. When doing so we follow the relevant privacy laws:

- We collect the information to learn how the medicine works and learn more about haemophilia A or related diseases. The legal basis for this is our legitimate interests to understand and develop medicines and scientific research.
- Scientific research in health is a regulated activity. Novo Nordisk will inform health authorities about the study results and how the study is performed and documented. The legal basis for this is to meet the legal obligations of Novo Nordisk and for reasons of public interest in the area of public health.
- Novo Nordisk may share new knowledge and information with health authorities outside Europe and the scientific community. The legal basis for this is our legitimate interests and for reasons of public interest in the area of public health.

How long will your information be stored?

The information from the study must be stored for 25 years by your study doctor after the study has ended or longer as required by local law. Hereafter, the code list which links you to your information will be destroyed.

After the study has ended, Novo Nordisk will store your information from the study for 25 years or longer as required by local law, or as long as the information contributes to scientific purposes or product safety.

Blood and other samples will be sent to different laboratories for testing:

- Samples will be destroyed either after they have been tested or when the report on the full results of the study is final. If the test result is not normal, then a part of the sample may be kept for up to two years or according to local regulations.
- Antibody samples will be stored for further testing – for up to 15 years after the end of the study. An antibody is something that your body may produce which can stop the medicine from working. The antibody samples may also be used, within this drug-development project, to improve how we test for antibodies and to further look into how your immune system reacts to treatment.
- Blood samples taken for analysis of pharmacokinetics (PK) may be stored for up to 5 years after the end of the study. PK means that we are looking at how the study medicine is broken down in the body. The stored PK samples may be used to improve the tests we use for measuring the study medicine and its 'break-down' pieces in the body, and to make sure the tests work the right way.
- Blood samples taken for analysis of biomarkers may be stored for up to 5 years after the end of the study. A biomarker is a marker of how the study medicine works in the body. The stored samples may be used to improve the way we test for biomarkers, for example by developing new ways of testing.

What will happen with the study results?

It is important to us to make the study results available to the public. Sometime after the study has ended, you can find a summary of the results on the Internet at www.novonordisk-trials.com.

Later, you can also find the results on these/this Internet site(s):

- euclinicaltrials.eu
- [<add other national/regional registries, if applicable>](#).

The results will not include information that can identify you.

You can ask your study doctor after the end of the study to get information about the overall results of the study. Later on, Novo Nordisk will follow local rules for sharing information with public.

If the study staff lose contact with you

It is very important that you keep in contact with the study doctor or staff. If the study staff loses contact with you during the study, your study doctor may ask for information about you from elsewhere. This might include:

- family members or other people who you have given the names of to the study staff
- your family doctor
- other health care professionals, medical records and publicly available records.

9 Who can you talk to for more information?

Information about the study

If you have any questions, concerns or complaints about this study, please talk to your study doctor *or contact person*. The contact information can be found in the section 'Who to contact' at the beginning of this documents.

This includes if you feel you have been harmed as a direct result of taking part in the study.

Information about your rights and ethics

You may have questions about:

- your rights as a person taking part in a study.
- how your personal information is handled.
- the study itself (including concerns or complaints).

If so, you may contact *<include name, address and phone number to an independent institution/body according to local practise that can guide the participant in terms of their right as a participant and possibilities in case they want to complain about their care/injury as a direct result of participation in the study, for example the Research Ethics Committee/Institutional Review Board', Patient Ombudsman, national health authority etc.>*

Novo Nordisk will follow the data protection laws about how to protect your information (including the EU General Data Protection Regulation [GDPR]).

You have the right to:

- see and get a copy of your information
- ask to limit the use of your information
- ask to have information corrected.

You can contact your study doctor for more information about your rights.

If you have any questions, concerns, or complaints as to how Novo Nordisk is using your personal information, you can contact your study doctor. You may also contact Novo Nordisk's Data Protection Officer at privacy@novonordisk.com. Please note that only the study doctor has access to your personal information. As Novo Nordisk cannot identify you, Novo Nordisk will only be able to provide you information about the general study set-up. If you would like to get information specific about you, please first contact the study doctor.

The [Country] Data Protection Authority is responsible for making sure that laws about

personal information are followed in [Country]. If Novo Nordisk A/S is the sponsor and there isn't a local Data Protection Authority this should be 'Danish/Denmark'. For more information about your rights, or if you wish to make a complaint, you can contact [Data Protection Authorities contact information].

Thank you for taking the time to read this participant information.

If you have decided to take part, please fill in the 'Agreement to take part form' on the next pages.

10 Agreement to take part form

By signing this form, I agree with all the following statements:

Taking part

- I have been given spoken and written information about this study.
- I have read and understood the information given to me.
- I have had enough time to think about taking part.
- I have had the chance to ask questions – and all my questions have been answered.
- I understand that I do not have to take part and that I am free at any time to stop taking part. Also, that I do not have to give a reason and that this will not affect my future medical care.

Information about me

I understand the following points:

- A number of people can see my personal medical file. This is to make sure that the study is done correctly, and that all information is recorded correctly. All personal details will be kept private. The people who can see my information are:
 - Novo Nordisk staff, consultants, *Research Ethics Committees/Institutional Review Boards* and health authorities will be able to see my medical file.
 - IT-suppliers, research organisations or laboratories working for Novo Nordisk will be able to see information collected during the study without being able to identify me directly.
- Sometimes, checks may have to be made remotely, for example by video calls, by direct access to electronic systems or by sending my information electronically.
- Information collected by Novo Nordisk during the study is stored electronically in a database and may be shared with other researchers who are not working on this study. The information can also be sent to other countries.
- If I decide to stop taking part during the study, information already collected cannot be deleted. This is required by the health authorities to make sure that the results for the entire study can still be used.
- The results of this study will be made publicly available.
- I accept that the study staff may get information related to the study from people like other health care professionals. They may also look at publicly available information.

About this form

- I will get a copy of this participant information and this signed and dated form.
- I agree to take part in this study.

Please now turn over to sign the form.

To be completed by you

I agree with all of the statements on this form and would like to take part in the study:

Signed:

Date:

Name (print):

To be completed by the study staff seeking the agreement to take part

(to be signed by the study doctor or appropriately medically qualified designee)

By signing this form, I confirm that the entire agreement to take part process has been conducted before any study procedures have taken place. Furthermore, I certify that the participant has not expressed any objections to taking part in the study:

Signed:

Date:

Name (print):

To be completed by impartial witness, if applicable

Signed:

Date:

Name (print):

Genetic testing

To be completed by you

I agree with all of the statements on this form regarding genetic testing and allow my sample to be used for genetic testing:

Signed:

Date:

Name (print):

To be completed by the study staff seeking the agreement to take part

(to be signed by the study doctor or appropriately medically qualified designee)

By signing this form, I confirm that the entire agreement to take part process has been conducted before any study procedures for genetic testing have taken place:

Signed:

Date:

Name (print):

To be completed by impartial witness, if applicable

Signed:

Date:

Name (print):