Marine Lake Medical Practice
Marine Lake Health & Wellbeing Centre
Orrysdale Road
West Kirby
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0151 625 9171

A Study of Remternetug Versus Placebo in Early Alzheimer's Disease Participants at Risk for Cognitive and Functional Decline

Informed Consent Form

Welcome

We would like to invite you to take part in a research study of Remternetug in adults with early Alzheimer's Disease (AD). The purpose of this document is to help you learn more about this research study, so you can decide if it is right for you. Please take all the time you need to review this document. The study staff will review it with you and help answer any questions you may have now and during the study.

Who is responsible for this study?

Eli Lilly and Company is the sponsor of this research study and pays for the study costs. An independent research ethics committee and required regulatory body have reviewed this research study.

What is the purpose of this study?

The purpose of this research study is to learn more about remternetug, a possible new medicine for the treatment of early Alzheimer's disease (AD). About 1200 people globally will be in this study.

People with early AD have an abnormal protein in their brain but may or may not have some problems with their memory or thinking.

You may not have been told you have AD. If you participate in this study, your blood will be tested to see if you have an abnormal protein in your brain that could put you at risk for developing memory and thinking problems due to AD in the future.

The study aims to learn:

- Whether remternetug can delay the start or worsening of memory and thinking problems caused by AD.
- Whether remternetug works better than a placebo (a placebo is an inactive or "pretend" drug).
- The possible side effects of remternetug.

Is this study the best option for you?

You do not have to be in this study. There may be other choices for your condition, including not getting any treatment.

The study doctor can discuss other available options with you, including potential benefits and risks.

How long will this study take?

This study will take up to 5 years to complete.

What will happen if you join the study?

Throughout the study

Study activities might occur at the study doctor's office, your home, or other locations as specified for the study and as allowed by UK law.

The study doctor will talk to you about the specifics for this study covering topics such as:

- what current treatments you can continue,
- how the study will be done including what will be needed from you, and
- answer any of your questions.

If you have unexpected or troubling symptoms while you are in the study, contact your study doctor and, if you feel necessary, seek emergency medical care.

During the study, the study doctor may need to take blood from you for testing and monitoring purposes. The amount of blood is small, like what is taken during a regular visit to your doctor. To give you an idea, it's usually a few tablespoons or small tubes of blood. You should not donate blood from the time you enter the study until 20 weeks after your last dose.Tell your doctor right away if you or your sexual partner(s) become pregnant or plan to breastfeed, as the study doctor may ask for more information about the pregnancy and health of the child.

Participants who can get pregnant are not eligible for participation in this study.

If your sexual partner(s) can get pregnant, the following guidance applies:

- If your sexual partner(s) can get pregnant:
    - Birth control should be used during the study and for 20 weeks after receiving the last dose of study medication.
    - You should not donate sperm during the study and for 30 days after receiving the last dose of study medication.
- Tell your doctor right away if you or your sexual partner(s) become pregnant or plan to breastfeed, as the study doctor may ask for more information about the pregnancy and health of the child.

- The study doctor will review with you whether you may need to use birth control, which methods of birth control are required, or any other restrictions needed while you are in the study.

Screening Period

The first part of this study is the screening period. It lasts about 21 weeks depending on your personal health care situation.

The first part of the screening period will last for about 4 weeks.

During this time, you will have some tests and activities, including:

- Collection of your personal information.
- A blood sample taken for laboratory tests.
- Discuss how you are feeling.
- Questions related to the study.

During this time, you can expect about 1 blood sample, but you might need to have more.

Your blood sample will be tested for P-tau. P-tau is a blood test to identify an abnormal protein in your brain associated with AD. P-tau is not yet approved for use in all countries, including the UK but the sponsor is allowed to use this for research because it is needed for the study.

Depending on the results of the P-tau test, your blood may also be tested for *APOE,* a gene that is associated with risk for AD.

If your P-tau result is negative then,

- your blood sample will not be tested for the APOE gene
- you will not have the option to request the APOE gene result
- you will have to discontinue your participation in the study

If your P-tau result is positive then,

- your blood sample will be tested for the APOE gene
- you will have the option to request the APOE gene result, which may be disclosed by a genetic counselor, and
- you will proceed to the second part of the screening.

The second part of the screening period will last for about 17 weeks.

During this time, you will have some tests and activities, including:

- Medical and surgical history, including medicines, vitamins, and herbal supplements you take.
- Discuss how you are feeling.
- Blood sampling and urine collection taken for laboratory tests.
- Electrocardiogram (ECG).
- Magnetic-resonance imaging (MRI).
- Questionnaires related to the study (some with recordings of your audio and video).

During this time, you can expect about 1 blood sample, 1 ECG, and 1 MRI, but you might need to have more.

This period will help the study doctor figure out whether you can continue to the next part of the study.

Treatment Period

This period of the study lasts for about 78 weeks. This is when you get either remternetug or placebo to compare how well they work. We refer to these all together as "study drug." Neither you nor your study doctor will know which study drug you are getting. The likelihood that you will receive the drug being studied will depend on how the study is set up and is determined by chance. You will have a 50% chance of receiving placebo and a 50% chance of receiving remternetug.

During this time:

- You will take study drug for about 78 weeks by injection under the skin (subcutaneous injection).
- Your first two doses will be one injection each. Afterwards, the remaining doses will be two injections each.
- You will receive injections every 8 weeks for the first 32 weeks followed by every 4 weeks for the remaining treatment period.
- You and your study partner will be properly trained and provided with instructions to administer the study drug by injection under your skin.
- You may have the study drug administered by yourself or your study partner at a convenient location (such as your home).
- You will have some tests/activities including:
  - Discuss how you are feeling and any medicines you have taken
  - Vital signs like blood pressure, temperature, and pulse rate
  - Height, weight, and physical examination (including assessment of brain and nerves)
  - Blood sample and urine collection taken for laboratory tests
  - MRI

Questionnaires related to the study (some with recordings of your audio and video).

During this time, you can expect about 6 blood samples and 5 MRIs, but you might need to have more. Ask the study doctor if you want to know more.

Observation Period

This period of the study lasts for about 3 years.

During this time,

- If you received all doses during the Treatment period, you will not receive any study drug.
- If you did not receive all your doses during the Treatment Period, you may receive doses in the Observation period.
- You will have some tests/activities including:
  - Discuss how you are feeling and any medicines you have taken.
  - Vital signs like blood pressure, temperature, and pulse rate
  - Blood sample and urine collection taken for laboratory tests
  - MRI
  - Questionnaires related to the study (some with recordings of your audio and video).

During this time, you can expect about 2 blood samples and 3 MRIs, but you might need to have more. Ask the study doctor if you want to know more.

Follow-Up Period

The follow-up period of the study lasts for about 20 weeks and is a single visit.

During this time:

- You will no longer receive the study drug.
- You will have some tests/activities including:
  - Discuss how you are feeling and any medicines you have taken.
  - Blood sample taken for laboratory tests and urine collection
  - MRI
  - A questionnaire related to the study.

You can expect about 1 blood sample and 1 MRI during the follow-up period, but you might need to have more. Ask the study doctor if you want to know more.

Open-Label Extension Period

After the Observation Period, if you were getting placebo, you may have the opportunity to receive remternetug. At that time, your doctor will discuss if you can participate and will talk about further details with you.

Could you be harmed by joining the study?

The study doctor will talk to you about any recommended or required lifestyle restrictions. There may be some unknown risks to you and any potential embryo, fetus, or breastfeeding child. There may be risks of interactions with other medicines you are taking, including certain kinds of birth control. Your study doctor can discuss your specific risks in more detail.

No matter what treatment you receive as part of the study, you may not receive any medical benefits. This means that your condition may not improve or may get worse.

Provided below are known potential risks if you participate in this study.

Risks for drug being studied

Clinical Study Exposure

A total of 1301 people have taken the study drug in clinical trials. Of these,

- 100 (remternetug N = 81; placebo = 19) were healthy adults
- 1201 (including an estimated 62 who took placebo) were adults with AD.

Risks for All Studies

Of the 1201 study participants with AD who have received study drug, the following side effects were reported (in order of higher to lower frequency):

- **Very common** (10 or more out of 100 participants):
  - swelling in the brain, and
  - small areas of bleeding in the brain or lining of the brain.
- **Common** (1 to 9 out of 100 participants):
  - headache
  - COVID-19
  - fall
  - nose and throat infection
  - dizziness
  - urinary tract infection
  - pain in the joints
  - loose watery stools

- common cold
- anxiety
- cough
- high blood pressure
- confusion
- feeling sick to the stomach
- inflammation of the sinuses
- back pain
- feeling tired
- bruise
- flu
- redness of skin at the injection site
- pain in arms or legs
- bronchitis
- depression
- rash, and
- fainting or passing out

Of the 100 healthy participants who received a single dose of remternetug injection into the vein or under the skin, only COVID-19 was reported by at least 2 participants.

Risks for Participants with AD

Treatments and procedures in this study may have unwanted or harmful effects (side effects). In studies of remternetug, participants had these important side effects:

Side effects in the brain: Swelling in the brain and small areas of bleeding in the brain or lining of the brain

- In individuals with AD, swelling in the brain or small areas of bleeding in the brain or lining of the brain can occur. Treatment with remternetug can increase this risk.
- MRI scans of your brain will be done routinely as part of this study to check if you have swelling in your brain or bleeding in or lining of the brain. If the MRI scans show swelling in your brain or small areas of bleeding in or lining of the brain, you may be asked to get extra scans of your brain. You may also be asked to discontinue study drug, temporarily or permanently.
- Swelling in the brain or small areas of bleeding in or lining of the brain were very common in people taking remternetug (10 or more out of 100 participants). The majority of these participants did not report symptoms; if symptoms are present, they generally resolve.

- Symptoms can include, but are not limited to
    - headache
    - worsening confusion
    - feeling sick to the stomach
    - vomiting
    - shaking and uncontrolled muscle movements
    - problems with your sense of balance (unsteadiness/dizziness)
    - visual disturbances
    - speech difficulties
    - disorientation (for example, difficulty understanding what is happening or where you are)
    - seizures, and
    - muscle weakness.
- Some symptoms may persist, which may require short or long-term treatment with medications, hospitalization, or physical therapy.
- Serious episodes of swelling in the brain or bleeding in the brain which resulted in hospitalization were common in those receiving remternetug (1 to 9 out of 100 participants). Some of these episodes were considered life-threatening or led to permanent bad outcomes. The chance of serious episodes is greater in people who have a brain condition of small areas of bleeding of the lining of the brain before taking remternetug; your doctor will make sure that you do not have this condition by checking your brain scan before you are allowed to begin the study.
- Some people who take medicines like remternetug along with blood thinners, and medicines used to treat blood clots, may have an increased risk of bleeding in the brain.
- Most people with AD have a gene (*APOE ε4*) that increases the risk of swelling in the brain and small areas of bleeding in the brain or lining of the brain. Treatment with remternetug can increase this risk.

Side effects in the brain: Larger areas of bleeding in the brain

- Serious and life-threatening episodes of larger areas of bleeding in the brain have occurred in people taking remternetug in studies. Such events were uncommon (less than 1 in 100 people).
- These episodes can be detected with an MRI scan of your brain.
- The risk of experiencing serious episodes of larger areas of bleeding in the brain may be increased in people who are taking blood thinners, and medicines used to treat blood clots.

Nonclinical Safety Data

The study drug has been studied in animals. There is no relevant additional information from these studies about unwanted effects of the study drug in humans.

Important Symptoms

It is important to notify the study doctor right away if you have any of the problems below, because they could indicate a serious problem.

Call the Study Doctor Right Away if you Have…	Because it may indicate…
For All Participants	
disorientation, worsening confusion, severe headache, seizure, shaking, speech disturbance, unsteadiness/dizziness, visual disturbance, muscle weakness, or vomiting	swelling in the brain, or bleeding in the brain or lining of the brain
chills, difficulty breathing, fever, itching, raised red spots on the skin, rashes, shortness of breath, or throat irritation	allergic reaction or immune system reaction

Current Medication

During the study, you will continue to take your current medication. Ask your study doctor about any risks that may be associated with your current medication(s). Your study doctor may suggest continuing the medication at the same dose or change the dose.

During the study, you may be asked to take medication to treat symptoms that may arise during the study. The study doctor will discuss any risks with you.

Risks for study procedures

This study will involve medical procedures that may have some risk for you. For example, pain or bruising after a blood sample. Other procedures are listed below with an explanation of the possible risks.

Blood Tests

For most people, needle punctures for blood samples do not cause any bad problems. However, sometimes they may cause bleeding, bruising, discomfort, infections and/or pain where you had the blood sample taken. You may also feel dizzy.

Electrocardiograms (ECGs)

There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.

MRI Scans

Generally, there are no bad effects of an MRI scan. But you should not have the scan if you have any metal objects in your body. For example, you might have metal in your body if you have a metal plate in your leg after a break. You may also have metal in your body if you have been exposed to metal fragments during welding. You should tell the study doctor, or MRI staff if you have any tattoos since some older tattoo ink may contain metal. Some people who do not like to be in small spaces might feel bothered by an MRI. You may also be bothered by the noise the scanner makes. You will be given ear plugs to reduce the noise of the scanner.

Subcutaneous Injection (Injection under the skin)

For most people, needle punctures for injections do not cause any serious problems. Sometimes they may cause bleeding or bruising where the injection is given. Sometimes people complain of discomfort, infections and/or pain at the site of the injection. Infection may happen with injections because the needle breaks the skin. Then germs can get into the skin underneath. Injections may cause abscesses or skin and soft tissue infections. Additionally, if a blood vessel is hit by the needle, the risk of infection will be even greater if germs are taken into the blood system.

Cognitive Testing and Questionnaires

Some people may feel embarrassed or upset while completing the questionnaires. Some people may become upset, frustrated, bored, or tired when doing tests for memory and thinking.

***APOE* Result Disclosure**

Your APOE result may show that you have a gene that may mean you have an increased risk for developing symptoms of AD, such as problems with memory or thinking. In addition, because genes are passed down from parents to children, your APOE genotype gives information about the possible genotypes of your biological family members and their potential risk for developing symptoms of AD. It is difficult to predict how you, or your family members might feel about your results. Some individuals feel anxiety or depression when thinking about the possible risk of AD. You may find that your family members have different opinions about genetic testing and learning APOE results. You may want to consider having a discussion with your family members before requesting your APOE result. APOE testing can impact you family members. A person's APOE gene type depends on their parents' gene types and which types were passed on to them. Each parent passes 1 of their 2 types of the APOE gene to a child.

Additional materials will be available to explain APOE to you and the implication of potential results for you and your family members. This information will help inform your decision to request the APOE results.

If requested by you, the PI will submit a request to obtain the APOE result.

Disclosure of the APOE result is to occur with supporting genetic counselling provided by the PI or designee to go into more details about the implications of the results for you and your family members.

Risks for medical device(s)

Read the "instructions for use for the prefilled syringe for remternetug" before using the prefilled syringe for remternetug.

Could something change while you are in the study?

The study doctor or the sponsor may remove you from the study. This may be because of a bad reaction, or you did not follow the study plan. It could also happen if the sponsor or the study doctor learn new information about the safety of the study drug or the study**.**

If new information is learned that may affect your decision to stay in the study, the study doctor will tell you promptly. If you are removed from the study or choose to not continue, the study doctor will discuss any issues with you and answer any questions.

What will happen if you lose capacity to consent during the study?

The investigator is responsible for ensuring continued capacity to consent for participation. If capacity is lost, then you will need to be reconsented with your legally authorized representative.

Changes may occur to the information contained in the consent document, including updates to the risks, that may require re-consent. If this occurs, re-consent must be appropriately obtained using the updated approved ICFs in accordance with sponsor and ERB consenting guidance.

The investigator or the investigator's representative will explain the updated information, including the risks and benefits, to the participant, or if applicable, the participant's legally authorized representative.

Also note that a participant may withdraw from the study at any time at the request of the participant or the participant's legally authorized representative.

How will Your Samples be Used?

Samples from your body will be collected from you. Please see the table below for more information about how your samples will be used and who will have access to them.

Type	Purpose	Length of time stored	Who may use it or see your data	Notes
Blood	**P-tau**: To confirm that you can be in the study. ***APOE***: If P-tau result is positive, *APOE* will be tested to determine if you have a gene that indicates a possible risk for developing AD. To develop new tests to help researchers understand AD.	Up to 7 years after all participants have finished the study	Study researchers and others*	
Blood and urine	To confirm that you can be in the study and monitor your health.	Until tests are done and confirmed	Only researchers in this study	You may be tested for hepatitis or other diseases. If blood tests say you have one of these diseases, researchers will contact you. Certain results may be required to be shared to others based on UK law.
Blood	To see how fast your body breaks down the study drug.	Up to 1 year after all participants have finished the study	Only researchers in this study	
Blood	To learn more about AD or how people respond to the study drug.	Up to 7 years after all participants have finished the study	Study researchers and others*	Biomarkers are substances in the body that can tell researchers about a condition. For example, cholesterol in the blood can be a biomarker for heart disease.
Blood	To learn how the study drug works for you or to help find out why people react to drugs differently. To better understand AD. To make new genetic tests.	Up to 7 years after all participants have finished the study	Study researchers and others*	DNA tells your body how cells should be built and work. Some of these instructions tell your body how to react to drugs. The results of the genetic testing will never be tied to one single person.
Blood	To determine if your body produces antibodies against the study drug.	Up to 15 years after all participants have finished the study	Only researchers in this study	Antibodies are substances the body produces to recognize and protect against foreign substances and organisms, such as viruses.

*"Others" refers to a third party organization who will be required to sign a written agreement to protect your samples and uses the samples as agreed to in this consent form. Third party organizations can be business partners and can also be internal Lilly scientists.

All samples will ultimately be destroyed based on laboratory procedures, laws, regulations, or international laboratory standards.

Will you have costs or be reimbursed for joining the study?

You will receive the study drug, treatments, and procedures that are directly related to the study at no cost. Depending on how your healthcare is paid for, you may have some personal expenses. The study staff can explain further.

Reasonable travel and additional overnight stay expenses (wherever applicable) related to your participation in this study will be reimbursed. We will also provide reimbursement for your refreshments for all hospital visits that are over 3 hours long. If you withdraw from the study early, you will be reimbursed for these expenses for the portion of the study that you completed. You may also receive an inconvenience fee for your time and effort for participating in the study.

The study staff will provide information and review more details around how reimbursement will be received.

Your samples may help with the development of other items, such as products or procedures, that may be worth money to the sponsor. You will not receive any rewards or benefit from this.

What happens if you are harmed during the study?

If the study plan is followed correctly, you follow the directions of the study doctor and staff, and you are physically injured as a direct result of a study procedure or drug, the sponsor or insurance for the study will pay the medical expenses for the treatment of that injury.

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

The sponsor, Eli Lilly and Company Limited, agrees to abide by the Association of the British Pharmaceutical Industry (ABPI) guidelines on clinical trial compensation. The sponsor will pay compensation where the injury probably resulted from:

- a drug being tested or administered as part of the trial protocol;
- or any test or procedure you receive as part of the trial.

The sponsor will not compensate you if an injury results from a procedure carried out which is not in accordance with the protocol for the study. Your legal right to claim compensation for injury, where you can prove negligence, is not affected. Your study doctor can give you a copy of the ABPI guidelines.

If you have a concern about any aspect of this study, you should ask to speak to one of the study team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or GP surgery.

Who can answer any questions you have?

The table below shows who you can contact for questions during the study.

Name	Role	In case of	Contact details/ Additional Information
Dr James Perry	Study doctor of the site	Questions, problems or concerns	Phone N° 01516259171 Email cmicb-wi.researchmlmp@nhs.net
Mandy Williams Anne Crutchley	The study staff	Questions, problems, or concerns	Phone N° 01516259171 Email cmicb-wi.researchmlmp@nhs.net
Ethics committee that reviewed and approved the trial. To protect your safety, rights, well-being and dignity.	CA, Patient rights representative, ethics committee	Questions about your rights as a participant in a study	The East Midlands - Nottingham 2 Research Ethics Committee has given a favourable opinion of the study

How to learn more about this study

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. Requirements to join the trial and countries participating can be found on this Web site.

Information can also be found at www.euclinicaltrials.eu/search-for-clinical-trials/ with study number 2024-515656-20-00.

When the study is over, a summary of the results will be made available. The study doctor can provide more details about when and where you can access the results.

INVOLVEMENT OF THE GENERAL PRACTITIONER / FAMILY DOCTOR

With your permission, your GP will be informed that you are taking part in a study so that your study doctor and your GP can provide proper medical care. We may also contact your GP to obtain your relevant medical history.

WILL YOUR TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Yes. All information about you will be kept confidential. Eli Lilly and Company Limited is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in accordance with the Data Privacy statement included with this document. In order to undertake this study Eli Lilly will act as Data controller. This means that we are responsible for looking after your study information and using it properly. Eli Lilly and Company Limited will keep your study information for 15 years or for as long as it is required for legitimate business purposes.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Some of your information may not be available to you until the study has been completed. To safeguard your rights, any data that is sent away from your study site will be identified by a code and not by your name / NHS number. The minimum amount of data necessary will be collected for the purpose of the study. If you withdraw from the study, the sponsor will keep the coded information about you that we have already obtained and use it for the purposes outlined in this consent form. This is necessary to ensure the scientific integrity of the study and to follow legal and other requirements on how information is used in research studies. If you allow it, we may also continue to collect information about you from your study doctor. If you do not want any further information about you collected and provided to the sponsor for the purpose of this study, you may let your study doctor know that you withdraw your permission. Your study doctor will then need to inform the sponsor in writing of your decision and will update your medical records accordingly. In addition, you would no longer be able to participate in the study.

You can find out more about how we use your information by contacting your study doctor. Your study doctor will act as liaison with Eli Lilly for any questions you may have. You can also find out more about how we use your information by contacting us directly atPrivacy@lilly.com.

will collect information from you and/or your medical records for this research study in accordance with our instructions.

[NHS/other site] will keep your name, NHS number and contact details [add other identifiers] confidential and will not pass this information to Eli Lilly and Company Limited. [NHS/other site] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Eli Lilly and Company Limited and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Eli Lilly and Company Limited will only receive coded information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[NHS/ other site] will keep identifiable information about you from this study for 15 years after the study has finished.

There are also types of information that your doctor must share with others. If something happens to a person in the study that could harm them or someone else, your doctor will share this information with only the people that need to know. Examples of this are bad treatment or something that is against the law.

Your personal health information will be stored in limited-access databases. Your health information will be used and disclosed in accordance with the Data Privacy Statement included with this document. Steps are taken to reduce the risk of your personal health information being misused or accessed by unauthorized people. However, these risks cannot be eliminated.

Your study data will be saved for as long as it is needed for legitimate business purposes according to the sponsor's records retention policies and applicable laws and regulations.

If you have concerns about how your information has been handled, please contact the Information Commissioners Office (ICO) (Information Commissioner's Office (ICO) The Helpline number for the Data Protection Officer is 0303 123 1113.

Sponsor request for confidentiality.

The information in this informed consent document is intended to help you determine whether participating in this study is right for you. You may wish to discuss this information with others for the purposes of helping you decide whether to participate in the study or as needed for medical treatment. You are asked to treat this information as confidential and to inform any others with whom you share this information that it is confidential. During the course of this study, you and/or a family member or caregiver of yours may learn, or have access to, proprietary information of the Sponsor, including study drug information. Proprietary information should be maintained as confidential. Please ask your study doctor for more specifics if you have a question about the nature of any particular information.

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Joining the study is your decision

To become part of this study, please sign,date and initial the boxes below.

Signing this page means that:

- I understand all of the information I have been given about this study, all my questions have been answered and I have had time to think about it. ☐
- I understand that I choose to be part of the study, and it's okay if I decide not to join or change my mind later. ☐
- I have given my free and informed consent to be part of this research study. ☐
- I agree to the use and/or return the study drug only as instructed by my study doctor and study staff. ☐
- I give permission ("consent") to the use, disclosure, and transfer of my study-related personal information ("study data") as described in "How is your data protected and used?", in particular the protected characteristics. ☐

Signature of Study Participant	Date (must be written in by study participant)
Study Participant first and last Name (print or type)	
Signature of Legal Representative	Date (must be written in by legal representative)

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Legal Representative first and last Name (print or type)

Describe relationship to study participant or other basis for legal authority

If applicable:
I witnessed that the information in the consent and any other written information was accurately explained to, and apparently understood by, the study participant or the legally authorized representative, and that informed consent was freely given by the study participant or the legally authorized representative:

Signature of Impartial Witness

Date must be written in by impartial witness)

Impartial Witness first and last Name (print or type)

I have explained the study (such as the purpose, risks, benefits, and the activities) to the study participant before the study participant voluntarily agreed to participate.

Signature of Person Conducting Informed Consent Discussion

Date (must be written in by person conducting discussion)

Person Conducting Informed Consent Discussion first and last Name (print or type)

1 copy for participant; 1 copy for researcher site file; 1 copy to be kept in medical notes.

Attachment 1- Data Privacy Statement

By signing the consent document for this study, you are giving permission for your personal health information and study data to be used and shared as described in this Data Privacy Statement. Your personal health information includes information from your existing medical records needed for this study and new information created or collected during the study.

If you agree to participate in the research study, your personal health information will be used and shared in the following ways:

• The study doctor and staff will send your study-related health information ("study data") to the sponsor of the study, its associated companies and its representatives ("the sponsor"). The sponsor conducts business related to clinical research in many countries around the world so this may involve sending your study data outside of the UK and Europe. Other countries may have privacy laws that do not provide the same protection as the laws in this country and the EU. However, the sponsor will respect the terms of this Data Privacy Statement in all countries.

• The sponsor will use the study data for research purposes to support the scientific objectives of the study described in the Patient Information Sheet and Consent Form. They will also use your data to assess the safety or efficacy of any medication or treatment included in the study and to better understand the disease(s) included in the study. Your data may also help the sponsor to improve the design of future studies.

• Your 'pseudonymised' (non-identifiable) study data, either alone or combined with data from other studies, may be shared with regulatory authorities in this country and other countries including the United States.

• Study data that does not identify you may be published in medical journals or shared with others as part of scientific discussions.

• Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor and regulatory authorities in this country and/or other countries including the United States.

The sponsor works with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partner signs a contract that requires it to protect your study data to the same level and in the same way that the sponsor has agreed to protect your data.

You may request to see and copy your personal health information related to the research study for as long as the study doctor or research institution holds this information. However, some of your study related health information may not be available to you until after the study has been completed. This is to ensure the study retains its scientific credibility.

Your study data will be kept for as long as it is needed for legitimate business purposes according to the sponsor's records retention policies and applicable laws and regulations.