Participant Information Sheet & Informed Consent Form

AttackMS – Natalizumab for the treatment of people with inflammatory demyelination suggestive of multiple sclerosis, or definite multiple sclerosis, at first presentation

Version Number and Date: V6.0, 25 June 2025

Chief Investigator: Prof. Klaus Schmierer

Study Sponsor: Queen Mary University of London

Principal Investigator: [INSERT]

IRAS Number: 1003822

Invitation

You are being invited to participate in the AttackMS Study. This information sheet will explain why you have been invited, why the research is being done and what it will involve, should you decide to take part. Taking part in this study is voluntary – It is up to you whether or not you wish to take part.

A member of our team will go through this information sheet with you in some detail and answer any questions you may have. If you wish, please talk to your friends, relatives, your General Practitioner (GP) or another healthcare professional about the study. Please take time to read through this document carefully and ask the study team, if any information in this document is unclear or if you require further information. Contact details of the study team can be found in the section titled “Who can I contact if I have any questions about this study?”.

Why am I being invited, and do I have to take part?

You have been invited to take part in this research study because you have shown symptoms suggestive of "Clinically Isolated Syndrome of demyelination" (CIS) or "Multiple Sclerosis" (MS) at first presentation. As a result, your clinician and/or other members of your clinical care team think you might be suitable to participate in this research.

It is your choice whether to take part or not. If you decide that you do not wish to take part in AttackMS, your medical care will not be otherwise affected. If you do take part, you can withdraw from the study at any time with or without giving a reason.

What is the purpose of the study?

MS is a disease of the central nervous system affecting over 150,000 people in the UK and more than 2.8 million worldwide. Left untreated, MS leads to chronic disability in the majority of cases.

CIS is a common first manifestation of MS: There is a more than 80% chance of MS in somebody presenting with CIS, provided one or more "lesions" characteristic of inflammatory demyelination can be detected on a magnetic resonance imaging (MRI) of the brain. The presence of at least *two* such lesions is an inclusion criterion for this study. Inflammatory demyelination is the process by which cells of your body's own immune system attack the insulation sheath (= myelin) of nerve fibres (= axons) in the central nervous system.

Once a diagnosis of MS has been confirmed, many people with this disease will be eligible for what is called "disease-modifying treatment" (DMT) on the NHS. Such treatment targets the immune cells that are involved in the inflammatory attack against the myelin sheaths and nerve fibres. However, while in a small number of cases, a diagnosis of MS can be made instantaneously, it regularly takes week, months and, sometimes even longer, to reach a formal diagnosis of MS. This diagnostic delay inevitably leads to delays in starting disease-modifying treatment.

The AttackMS trial aims to speed up the assessment process and start you on an DMT earlier in the process.

AttackMS will test whether:

(i) It is feasible to recruit participants with a diagnosis of CIS at high risk of MS, or definite MS, at first presentation for treatment within 14 days of symptom onset and
(ii) Such early treatment improves myelin repair at 3 months, as measured using a special MRI technology called magnetisation transfer ratio (MTR).

What would taking part involve?

Natalizumab (Tyruko®) is a medication currently approved by the Medicines and Healthcare products Regulatory Agency (MHRA) as a disease-modifying treatment for adults with rapidly evolving severe (RES) relapsing MS. In treating people with first presentation of CIS or MS, AttackMS aims to advance our mechanistic understanding of Natalizumab. We are looking to test safety and efficacy of treatment with Natalizumab 300mg, given through a needle in a vein (intravenous infusion), over 8 weeks compared to a placebo.

We are aiming to recruit 40 people across three sites in London to take part in this study. If you agree to participate, you will be in the study for 24 weeks (less than 6 months); this includes the time that you will receive treatment and follow up visits.

AttackMS is randomised trial. This means that for the first 12 weeks of the study, a computer will decide,by 50:50 chance, whether you receive Natalizumab or a placebo. The placebo isa saline solution with no active substance, and this is used as a control. During this time, both you and the study team will be blinded to your treatment allocation. In other words, neither yourself nor the clinical team involved in your care will be aware whether you are receiving Natalizumab or a placebo. The study is blinded to ensure we make a scientific and fair comparison between Natalizumab or placebo. From week 12 onwards, all participants will receive Natalizumab until 4 weeks before the end of the study, which will be week 24.

In case of a medical emergency, we can find out at any time during the study which treatment you have been allocated. If you are withdrawn from the study and/or the study medication during the blinded part of the study, you have the right to be informed which treatment you received (Natalizumab or placebo) at the end of the study, unless this information needs to be known earlier for safety or health reasons.

What will happen to me if I decide to take part?

You will be given as much time as you need to decide whether or not you would like to participate in the study.

Once you have read this information sheet and have your questions answered, you will be invited to attend the first study visit (screening visit) at the hospital.

Visit 1 (Screening Visit)

At this visit you will be asked to sign an informed consent form, confirming you understand the information in this document, and are happy to take part in the study. You will get to keep a copy of your signed informed consent form.

Please note that giving your consent will not guarantee your participation in the study. Your health status may change, for example, if some test results show you are not suitable for the study.

At this visit the study team will perform the following screening procedures:

- Obtain your informed consent (signing the informed consent sheet)
- Collect your medical, drug and disease history, including some demographic information
- Examine and record the following: your height, weight and vital signs (including blood pressure, heart rate, temperature and respiratory rate)
- A physical examination
- A Specialised Neurological Examination - Expanded Disability Status Scale (EDSS)
- Limb Function Tests - 9 Hole peg test (9-HPT) and Timed 25-Foot Walk Test (T25-FW)
- A Cognitive Test - Symbol Digit Modalities Test (SDMT)
- A Visual Function Test - Sloane Low Contrast Visual Acuity test (SLCVA)
- Ask you to complete a MS specific questionnaire - Neurological Fatigue Index (NFI-MS)
- Collect a blood and urine sample
- Perform lumbar puncture for collection of cerebrospinal fluid, if deemed clinically necessary. This can be performed at this visit or at a later time.

- Review your diagnostic brain and, if available, spinal cord MRI scans

This visit should last approximately 90 minutes.

Visit 2 (Baseline and Randomisation Visit)

At this visit, your eligibility for the study will be confirmed. During this visit, we will repeat some of the assessments completed at the first visit, as well as carry out further assessments. We will complete the following

- Ask you to attend the Queens Square MS Centre, UCL Institute of Neurology, Queen Square, WC1N 3BG for a brain MRI scan
- Check your vital signs, ask how you are feeling and review if there are any changes to your current medications.
- Complete an eligibility (inclusion and exclusion) criteria assessment, using your screening visit assessment results, to check if you are eligible to participate in AttackMS.
  - If you are assessed to not be eligible for the study, your involvement in the study would end at this point.
  - If you are assessed as eligible for the study, you will be randomised to either Natalizumab or a placebo.
- Review any adverse events that may have happened since the screening visit
- Ask you to complete a visual function test - Visually Evoked Potential (VEP)
- Ask you to complete an eye test - Optical Coherence Tomography (OCT)
- Collect a blood sample
- Administer infusion of Natalizumab or a placebo
  - Natalizumab or a placebo is given in a dose of 300mg and administered by intravenous infusion during the AttackMS study
  - Each Natalizumab or a placebo infusion will be administered, for approximately 1 hour and you will be observed throughout this time
  - You will also be observed after the infusion for approximately 1 hour and this observation is for signs and symptoms of hypersensitivity reactions

This visit consists of two parts, your MRI at the Queen Square MS Centre and your visit to the trial site where all other interventions will take place. The MRI should take no longer than one hour; the visit to the trial site should take approximately 90 minutes, including your infusion.

Following Visits

You will be asked to attend a visit at your hospital, approximately every 4 weeks for 5 months (remaining duration of the study). The procedures and assessments will differ depending on the visit timepoint.

Visit 3 (Week 4) we will:

- Check your vital signs, ask how you are feeling and review if there are any changes to your current medications
- Review any adverse reactions (serious/non-serious) you have had
- Perform a specialised neurological examination
- Ask you to perform limb function, visual function and cognitive tests
- Ask you to complete an MS specific questionnaire

- Collect a blood sample
- Administer Natalizumab or placebo infusion

This visit should last no longer than 90 minutes, including your infusion.

Visit 4 (Week 8) we will:

- Check your vital signs, see how are feeling and review if there are any changes to your current medications
- Review any adverse reactions (serious/non-serious) you have had
- Collect a blood sample
- Administer Natalizumab or placebo infusion

This visit should last no longer than 90 minutes, including your infusion.

Visit 5 (Week 12) we will:

- Check your vital signs, ask how you are feeling and review if there are any changes to your current medications
- Review any adverse reactions (serious/non-serious) you have had
- Perform a specialised neurological examination
- Ask you to perform limb function, visual function and cognitive tests
- Ask you to complete an MS specific questionnaire
- Collect a blood sample
- Administer infusion of Natalizumab
- Ask you to attend Queens Square MS Centre, UCL Queen Square and Institute of Neurology for a brain MRI scan
- Discuss your further management after completion of AttackMS

This visit should last no longer than 120 minutes, including your infusion.

Visit 6 (Week 16) we will:

- Check your vital signs, see how are feeling and review if there are any changes to your current medications
- Review any adverse reactions (serious/non-serious) you have had
- Collect a blood sample
- Administer Natalizumab

This visit should last no longer than 90 minutes, including your infusion.

Visit 7 (Week 20) we will:

- Check your vital signs, see how are feeling and review if there are any changes to your current medications
- Review any adverse reactions (serious/non-serious) you have had
- Collect a blood sample
- Administer Natalizumab

This visit should last no longer than 90 minutes, including your infusion.

Visit 8 (End of Study/Week 24) we will:

- Check your vital signs (including blood pressure, heart rate, temperature, respiratory rate), record your height and weight
- Perform a physical examination
- Review any adverse reactions (serious/non-serious) you have had
- Review your current medications
- Collect a blood sample
- Perform a specialised neurological examination
- Ask you to perform limb function, visual function, eye and cognitive tests
- Ask you to complete an MS specific questionnaire
- Ask you to attend Queens Square MS Centre, UCL Queen Square and Institute of Neurology for a brain MRI scan
- Collect a blood sample

This visit consists of two parts, your MRI at the Queen Square MS Centre and your visit to the trial site where all other interventions will take place. Both the MRI as well as your visit to the trial site should take no longer than 60 minutes each.

What will happen if I want to withdraw from the study?

You have the right to withdraw completely from the study at any time, without the need to provide a reason, and your future care will not be impacted by your decision to withdraw. If you choose to withdraw, you have the option of withdrawing from study treatment only and continuing with study visits or withdrawing completely (withdrawing from both study treatment and visits).

If you choose to withdraw, you will be asked to attend an early withdrawal visit.

If you withdraw completely, we will stop the medication and all data and sample collection. However, we will use the data collected up to and including your withdrawal visit. If you withdraw from the study treatment only, you can still attend the follow up visits, which would include coming for the assessment visit at week 24 and we may ask you to take a pregnancy test.

The table on the next page shows the procedures and assessments that will occur at each visit of the study.

AttackMS: Schedule of Assessments										
Study Procedures	**Visit 1 (Screening)**	**Visit 2 (Baseline and Randomisation)**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8 (End of Trial)**	**Early Withdrawal**	**Unscheduled Visit**
		Week 1	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24		
	-14 days	n/a	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days		
		M 0	M 1	M 2	M 3	M 4	M 5	M 6		
Informed Consent Form	X									
Medical History, Drug History, Demographic information & Concomitant Medication	X									
Vital signs	X	X	X	X	X	X	X	X	X	
Height and Weight	X							X	X	
Physical Examination	X							X	X	X
Specialised Neurological Examination - Expanded Disability Status Scale (EDSS)	X		X		X			X	X	
Limb Function Test - Nine-Hole Peg Test (9-HPT)	X		X		X			X	X	
Limb Function Test - Timed-25 Foot Walk (T25-FW)	X		X		X			X	X	
Cognitive Test - Symbol Digit Modalities Test (SDMT)	X		X		X			X	X	
Questionnaire - Neurological Fatigue Index-MS (NFI-MS)	X		X		X			X	X	
Visual Function Test - Sloane Low Contrast Visual Acuity Test (SLCVA)	X		X		X			X	X	
Inclusion and Exclusion		X								
Randomisation		X								
Concomitant Medication Review		X	X	X	X	X	X	X	X	
Adverse Events Review		X	X	X	X	X	X	X	X	
Review of Brain and Optional Spinal Cord MRI	X									
Brain MRI*		X			X			X	X	
Visual Function Test - Visually Evoked Potentials (VEP)*		X						X	X	
Eye Test - Optical Coherence Tomography (OCT)*		X						X	X	
Blood Tests	X	X	X	X	X	X	X	X	X	
Urine Test	X									
Natalizumab or Placebo		X	X	X						
Natalizumab					X	X	X			
***Brain MRI, VEP, and OCT only need to be completed at early withdrawal visit if feasible. Lumbar Puncture may be performed at one of your study visits.**										

What will happen to my blood samples?

Samples will be sent to the following laboratories for processing:

- Your local NHS Trust laboratory:
  - Biochemistry, urinalysis, CSF OCB (*at visit 1*)
  - Full Blood Count (*at visit 1, 5, and 8)*
  - Hepatitis B & C, human immunodeficiency virus (HIV), syphilis serology, thyroid function test and immunoglobulins (M, G, A) (*at visit 2*)
- Queen Mary University of London (QMUL) Centre for Neuroscience and Trauma Neuroimmunology Laboratory:
  - Serum neurofilament light chain (sNfL) (biomarker samples).
- Central laboratory - Medicover (MICS) Syneovo Lab, Pache Protopopescu no 81, 021408 Bucharest, Romania (www.medicover-jcv-portal.com) for:
  - John Cunningham Virus (JCV) testing *(at visit 1, 8, and early withdrawal visit, if applicable)*

Some samples will be analysed immediately – these will be the 'eligibility' samples (the ones that are key for the decision whether or not you are eligible to take part). These samples will be analysed and discarded according to the Trust protocols. Biomarker samples will be processed and stored for analysis at the end of the study – these are the samples which will tell us if there has been any effect from the study drug. All samples collected during the study will be stored securely and destroyed after analysis. With your permission, we will retain some samples for future laboratory-based, ethics committee-approved research.

Are there any restrictions?

You can continue with your daily routine activities as normal while participating in this study. However, if you take part in the study you should ensure to:

- Stop taking other disease-modifying therapies for MS
- If you are a woman of child-bearing potential, you must use highly effective contraceptive measures during the study course. This is important because Natalizumab may harm a developing embryo and not all risks are known at this time. Highly effective contraceptive measures include:
  - True abstinence
  - Oral contraceptive (combined or progesterone only)
  - Intrauterine device (IUD)
  - Injectable progesterone
  - Levonorgestrel implant
  - Transdermal contraceptive patch
  - Tube sterilisation
  - Male partner vasectomy or other medical condition causing azoospermia
- If you are a woman of child-bearing potential, you must not be breastfeeding

What are the known risks of the study?

The highest incidence of adverse reactions identified from placebo-controlled trials in MS patients with Natalizumab given at the recommended dose, are reported as dizziness, nausea, urticaria (hives) and rigors (muscle stiffness) associated with infusions.

Other common side effects include:

- Urinary tract infection
- Nasopharyngitis
- Hypersensitivity
- Headache
- Sickness
- Joint pain
- Fever
- Tiredness

Very rare side effect include:

- Progressive Multifocal Leukoencephalopathy (PML), an infectious disease of the central nervous system caused by John Cunningham (JC) virus

MRI Scans

MRI scan uses strong magnetic fields and radio waves to produce an image. For most patients, the risks or side effects associated with having an MRI are minimal. However, because the MRI scanner uses strong magnets, you cannot have an MRI scan if you have certain metal implants such as a pacemaker in your body. You will be asked questions prior to your scan to make sure you can safely have an MRI scan. Some people experience anxiety and claustrophobia prior to or during the scan. Should this be the case, and so severe that you are unable to have an MRI, you cannot take part in this study.

Some people experience side effects from the Gadolinium-based contrast including injection site pain, nausea, itching, rash and headache.

If you feel ill in any way at any point in the study, you must tell your doctor or the research nurse who can then determine the best course of action. If this happens, the medication may be stopped immediately, and you will be treated appropriately.

If you choose to participate, you will be given a card (similar in size to a business card), which will have the important details of the study. You should always carry it and show it to any doctor or nurse who is treating you. If you lose this card, contact the research nurse for a replacement.

What are the possible benefits of taking part?

The treatment given in this study may or may not provide medical benefit to you. Whatever the outcome, the information we gather from this study may help us improve the treatment of people with MS in the future.

What are the possible disadvantages and risks of taking part?

Natalizumab is a relatively safe, convenient, highly effective disease modifying treatment approved for people with highly active relapsing MS. The treatment must be initiated and

continuously supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions, in centres with timely access to MRI.

You may have side effects from the drugs or procedures used in this study, as described above. Side effects can be mild to severe and even life threatening, and they can vary from person to person. Talk to your study doctor right away, if you have any of the following during the study:

- Symptoms that are new or have worsened
- Changes in your prescribed or over-the-counter medications (including herbal therapies)
- Visits to the doctor or hospital, including urgent care accident and emergency visits

What if new information becomes available?

During the study, you will be told in a timely manner about any new information or changes in the study course, such as an extension of the study period. When you have been informed and if you have agreed to continue in the study, you may be asked to sign a new consent form.

Expenses and payments?

If you decide to take part, the study medication will be provided to you free of charge. You will not be paid for your participation in this study. Travel expenses (public transport whenever possible) will be covered.

Will I be able to continue taking the study drug once the study finishes?

Once your participation in AttackMS is over, you will return to standard of care. You may continue treatment with Natalizumab provided, at the point of leaving the study, you fulfil the eligibility criteria for such treatment supplied by the NHS. You may also be eligible for other disease-modifying treatments for CIS/MS. We will start the discussion with you from visit 5 (week 12) about treatment options available to you after completing your participation in AttackMS.

How have patients and the public been involved in this study?

We discussed the study on numerous occasions with members of the public (people with MS and others) on The MS blog (https://multiple-sclerosis-research.org/). We have also received input through a focus group of people with MS who had been diagnosed within the preceding two years. Their comments helped us design this study. As part of our public and patient involvement (PPI) strategy, we will have one person with MS on each our Trial Steering Committee and Trial Management Group throughout the study. This will ensure that AttackMS remains aligned with the interests of people with MS and the wider public.

What will happen to the results of the research study?

Your data may be presented and published nationally and internationally. We will also publish results in scientific peer-reviewed journals and present them at research conferences. Only fully anonymised results will be presented and published, and you will not be identified in any report or publication.

Once the study has ended, you can make a request if you wish to know the treatment group you were in.

It is the responsibility of the Chief Investigator to ensure that all information provided to the public domain, including in peer-reviewed publications, is accurate.

Future Research

If you are eligible to take part in this study, the Principal Investigator (PI) may approach you to take part in future research. Your participation in future studies is optional and your decision will not affect the care you receive in this study, or as standard of care.

Who has reviewed the study?

The study has been reviewed and approved by a Research Ethics Committee (REC), the Health Research Authority (HRA), and MHRA. These groups ensure that research protects your interests. This study has been reviewed and given favourable opinion by London – Surrey Boards Ethics Committee.

How will we use information about you?

We will need to use information from you, your GP, and other healthcare professions involved in your clinical care team or your medical records for this research project. This information will include your:

- Full name
- Initials
- NHS and/or local hospital number
- Contact details
- Date of birth

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Queen Mary University of London is the sponsor of this research. Queen Mary University of London is responsible for looking after your information. We will share your information related to this research with the following types of organisations:

- Research Collaborators - Your data from MRI, OCT and VEP assessments will be shared with research collaborators for analysis in the study.
- Biobank - If you consent to further research, as per the Human Tissue Act (HTA), your samples including study data will be held in a biobank.
- Clinical Care Team - MRI scans collected as part of the trial can be made available to your clinical care team at the end of the trial. Should you wish for your MRI scans not to be shared, please make sure you indicate this on the consent sheet.

We will keep all information about you safe and secure by:

- Providing you with a participant identification (ID) number. All data that will be collected on forms and sent to the Sponsor will have your participant ID number and not your

name, local hospital number, or NHS number. The only information the sponsor will receive about you personally will be your initials, gender, and date of birth.
- Entering your personal and medical information onto a secure server within the study electronic data capture system (OpenClinica EDC). This will be entered by your clinical care team and handled securely in accordance with the data protection law to ensure that all information about you is handled in the strictest confidence. To randomise and enroll you in the study we will enter your initials and date of birth on the randomisation system (Sealed Envelope) and OpenClinica EDC.
- Pseudoanonymising any data to be processed.
- *Holding all personal information obtained for the trial securely and treating it as strictly confidential.* All data will be stored on paper and electronically and will only be accessible by authorised personnel associated with the study.
- Preventing sharing of your personally identifying information with third parties not directly involved with this research.

International Transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Contractual obligations to share study data with funders, which are based outside of the UK.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following organisation:

- Study funder (Sandoz)

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- The countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
  We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 25 years. The study data will then be fully anonymised and securely archived or destroyed. **What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already had.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Your electronic data will be saved in a secure server within the study electronic data capture system (EDC), and your samples and associated data will be stored securely at the Blizard Institute, Queen Mary University of London as per the Human Tissue Act (HTA).

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- The leaflet available at www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to [site to localise with PALS email], or
- By ringing us on [site to localise with PALS phone number]

Under what legal basis are you collecting this information?

Queen Mary University of London processes personal data for research purposes in accordance with the lawful basis of 'public task'.

Please read Queen Mary's privacy notice for research participants containing important information about your personal data and your rights in this respect. If you have any questions relating to data protection, please contact Queen Mary's Data Protection Officer, Queens' Building, Mile End Road, London, E1 4NS or data-protection@qmul.ac.uk or 020 7882 7596.

Who is organising or sponsoring the research?

The trial is sponsored by Queen Mary University of London.

The research is coordinated by the Pragmatic Clinical Trials Unit at Queen Mary University of London. Professor Klaus Schmierer is the Chief Investigator and has overall responsibility for the study. The study is funded by Sandoz (who are also providing Natalizumab).

What should I do if I have any concerns about this study?

If you have any concerns about the manner in which the study was conducted, or any possible harm you might suffer in the first instance, please contact the PI responsible for the study, who do their best to answer your questions.

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The study team can give you details of the right Data Protection Officer. If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Alternatively, or in addition, you can contact the Independent Patient Advice and Liaison Service (PALS) at your hospital by contacting them via email [site to insert local PALS email] or their telephone number [site to insert local PALS telephone number].

Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

Who can I contact if I have any questions about this study?

If you have any questions, please feel free to ask a member of the research team. Please keep this copy of the AttackMS participant information sheet.

If you would like to ask any questions or receive more information about the study, then please contact one of the following:

Study Doctor: _____

Study Nurse: _____

Telephone Number: _____

Emergency Number (24 hours) _____

Thank you for taking the time to read this information sheet

INFORMED CONSENT FORM

AttackMS Study: Natalizumab for the treatment of people with inflammatory demyelination suggestive of multiple sclerosis, or definite multiple sclerosis, at first presentation

Chief Investigator: Prof. Klaus Schmierer

IRAS ID: 1003822	EudraCT: 2021-002255-11

Participant ID Number	**XXX-XXX**
Site ID	**XXX**
Principal Investigator	**[**Insert**]**

Thank you for your interest in this research.

Should you wish to participate in the study, please consider the following statements. Before signing the consent form, you should initial all or any of the statements that you agree with.

	Statement	Please initial box
1	I confirm that I have read the participant information sheet (PIS) dated __/____/___ version __.__ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Initials
2	I understand that my participation is voluntary and that I am free to stop taking part in the study at any time, without giving any reason and without my medical care or legal rights being affected.	Initials
3	I understand that my study data will be securely stored for 25 years, in a pseudo-anonymised form. When shared with other researchers, my data will be completely anonymised.	Initials
4	I understand that I can access the information I have provided and request destruction of that information at any time.	Initials
5	I understand that if I lose the capacity to consent at any point during the study, additional tests will not be conducted for research purposes. In such a case, I agree for the researchers to use any previously collected research data and any further data collected as part of routine clinical practice.	Initials
6	I understand I will be given a unique participant identification (ID) number to ensure my data is pseudonymised.	Initials
7	I understand that researchers may contact me to follow up on my health status and remind me of upcoming study visits.	Initials

8	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the research team, study sponsor or delegate, regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.			Initials
9	I understand that the information and samples collected will be used for medical research only, including academic publications, and may be shared anonymously with other researchers.			Initials
10	I agree to my GP being informed of my participation in the AttackMS trial.			Initials
11	I understand what is involved in in the AttackMS study and agree to participate.			Initials
	Optional	Please tick one		
		Yes	No	
12	I agree for my blood samples and data to be stored and used for future ethically approved biomedical research			Initials
13	I understand that I may be contacted by the research team in the future to be invited to take part in future studies. I understand that I would not have to take part in any upcoming research if I did not wish to.			Initials
14	I agree for my MRI scans conducted as part of the trial to be shared with my clinical care team at the end of the study.			Initials

Your signature confirms that you are willing to participate in this research.

Participants full name: _____

Signature: _____ Date: D D - M M M - Y Y Y Y

Witness's full name *(if applicable)*: _____

Signature: _____ Date: D D - M M M - Y Y Y Y

DETAILS OF PERSON CONSENT OBTAINED BY:

Must be a physician and signed on the site delegation log

Investigator's full name: _____

Signature: _____ Date: D D - M M M - Y Y Y Y

Original to be kept in the Investigator Site File, 1 copy in hospital notes, 1 copy to the patient, 1 copy to the Trials Office