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Investigator: Dr. Nicholas Mannering **Centre number**: 2004 **Contact for queries** If you have any questions about this study, you can contact: **Daytime:** Clinical Trials Team on 01483 388 020 **Out of hours:** Dr. Nicholas Mannering on 07510 034 286	**Re:Cognition Health** **29 Fredrick Sanger Road** **Surrey Research Park** **Guildford** **GU2 7YD** **Tel: +44 (0) 1483 388 020** **Re:Cognition Health Complaints Department. Details can be obtained from 020 3355 3536**

Exploratory platform trial on Anti-Inflammatory agents in Alzheimer's disease (EXPLAIN-AD): A randomised, placebo-controlled, multicenter platform study to evaluate the efficacy, safety, tolerability and pharmacokinetics of various anti-inflammatory agents in patients with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease.

Why is this study being done?

We would like to invite you to be part of a research study. A research study is a way to test new medicines to see if they work just as well or better than placebo (a treatment that has no known medical effect). This form tells you about this research study and the choice that you have to take part in it. You can ask any questions that you have at any time.

This information document is made up three sections:

1. questions and answers about the study
2. a quick-reference summary of what is involved in taking part
3. a Consent Form

Please take some time to read this information carefully. We ask that you keep it confidential but you may discuss it with your family, friends and GP if you wish, before making up your mind. If anything in this Information Sheet is not clear, or if you have more questions, please ask the doctor who gave it to you.

1 WHY HAVE I BEEN GIVEN THIS DOCUMENT TO READ?

You are invited to participate in a clinical research study to find out if the anti-inflammatory drug Canakinumab (ACZ885) is safe and has beneficial effects (can improve memory and thinking abilities) in people who have mild cognitive impairment or Alzheimer's disease.

Before you decide whether to take part, you need to understand why the research is being done and what it will involve. This informed consent form tells you about the study that you are being asked to participate in.

Your decision to participate in this study is voluntary. This means:

- You are free to decide to participate in this study or not
- You are free to stop study treatment and study-related activities at any time and without the need for giving any reason
- If you do not want to participate in this study, then this decision will not affect your medical care

2 WHAT IS A CLINICAL RESEARCH STUDY?

A clinical research study is a study involving humans to answer specific health questions.

Carefully conducted clinical research studies are the safest and most efficient way to find treatments that work in people and to establish new ways to improve health care. There are two goals of clinical research:

1. To find a treatment that may be better or safer than currently available treatment.
2. To gain knowledge that may benefit others, even though at this time no one can be sure that this research treatment will be helpful for you.

WHAT IS THE PURPOSE OF THIS CLINICAL RESEARCH STUDY?

The pharmaceutical company named Novartis sponsors this clinical research study. The purpose of the study is to determine the effects of anti-inflammatory treatment on memory and thinking.

Anti-inflammatory treatments are those that bring down inflammation and swelling. The anti-inflammatory treatment used in this study is called Canakinumab (ACZ885).

This study will also see if anti-inflammatory treatment has an effect on "biomarkers" in your body. Biomarkers are important biological 'indicators' which can be measured in samples taken from your body, such as blood and cerebrospinal fluid (CSF).
This study will also look at how safe various experimental anti-inflammatory treatments are and how well they are tolerated.

There are certain tests/questions you must complete to find out if you meet the requirements to be in the study. You must also have a reliable "study partner" in order to participate. This study partner should be someone you have frequent contact with (at least several days a week) and someone who can attend all study visits with you. If you do not meet these requirements, you cannot take part in the study. If this happens, you can talk to your Study Doctor about other options.

The first anti-inflammatory treatment being studied is called Canakinumab (ACZ885) and has not yet been approved by the Medicines Healthcare Regulatory Authority (MHRA) for the treatment of people with your medical condition. Canakinumab (ACZ885) is currently not "on the market" (available for you to receive a prescription for and/or to buy) in any country for Alzheimer's disease.

WHAT IS ALREADY KNOWN ABOUT THE DRUG BEING TESTED?

Canakinumab (ACZ885) has been studied in mild asthma, psoriasis, gouty arthritis, rheumatoid arthritis, and in people with a history of previous heart attack, in 82 studies that included 14,062 participants. Canakinumab (ACZ885) is approved as a treatment for several diseases that are associated with inflammation in various body parts and organs.
Canakinumab (ACZ885) has not been studied in Alzheimer's disease. Thus, we do not know whether it will work for you. Your condition may improve, may get worse, or there may be no change.

The study is being organised and funded by Novartis Pharma AG, Lichstrasse 35, 4056 Basel, Switzerland and is being run by the medical staff in hospital out-patient clinics. Novartis will make payments into your study doctor's hospital research fund to cover the costs of this study.

3 WHO WILL TAKE PART IN THIS STUDY?

About 86 patients with early signs of cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease, aged between the ages of 45 and 90 years are being asked to participate in this study in 4 countries, worldwide.

4 WHO CANNOT TAKE PART IN THIS STUDY?

As with any new drug, we do not know whether Canakinumab (ACZ885) can harm an unborn or breast-fed baby. Therefore, pregnant or breast-feeding women cannot take part in this study.
If there is any possibility that you might become pregnant, you will be tested for pregnancy at the start of the study and again at the end of the study.

5 HOW LONG WILL I BE IN THE STUDY?

Your study participation will last for about 12 months and during that time you will visit the Study Doctor about 11 times. Most study visits should take between 2 to 4 hours.

6 WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Your Study Doctor will not perform any procedures associated with the study before you have signed the consent document. However, your Study Doctor may talk to you about the study to find out if you might be interested in knowing more and reading the information about the study. Finding out more information does not mean that you have to join the study. You can chose to not take part.

If you do choose to take part, you will be asked to visit the hospital more often than usual. At any time, your Study Doctor may need to contact your GP to get more information about your health. During the first 2 months of your participation in the study, you will complete tests or procedures during a "Screening" period. The purpose of this Screening period is to make sure you meet all of the requirements in order to participate in the study. You will have to go to the study site at least 3 times during this Screening period in order to complete all of the tests and procedures. The last visit of the Screening period is called the "Baseline" visit.

Once you are confirmed to be eligible you will then start the study. You will visit the study site every 4 weeks for about 5 months. These site visits are called:

- Day 1, Day 29 (Week 4), Day 57 (Week 8), Day 85 (Week 12), Day 113 (Week 16), and Day 141 (Week 20).

You will also be asked to return to the hospital for two further visits on Day 171 (Week 24) and Day 281 (Week 40; this is the end of participation in the study).

If any other health problem shows up

It is possible that the health checks carried out before and during the study could show up a problem that you didn't know about. If this happens, you will be referred for suitable treatment and you may be told that you are not able to take part in the study.

We will let your GP know

By signing this consent you agree for us to let your GP know that you are taking part in the study. Your study doctor may need to contact your GP to obtain more information about you. Please ask your study doctor if you would like a copy of any correspondence.

Access to medical records

It may be necessary to access your original medical records. These may be stored by your GP or hospital. As a result of COVID-19, it may be necessary to access your records over the internet. Security measures will be in place to protect your information.

By signing this form, you agree that your original medical records will be accessed as part of the study.

Travel Insurance

When you apply for travel insurance, insurers will typically ask questions about your health in order to make an accurate risk assessment. The insurer will often ask questions about any pre-existing health conditions and medical treatments for those conditions. Where an insurer asks about your participation in clinical research trials, the insurer must ensure the question is clear and you should answer it accurately and honestly.

Whilst having a condition itself may attract additional costs to travel insurance taking part in a clinical trial is not something that would be expected to lead to increased premiums, penalties or insurance refusal. If you find that you are denied insurance or your premiums increase purely on the grounds of participation in this study, please raise this with you Study Doctor so that this can be investigated further with the Association of British Insurers.

7 WHAT STUDY TREATMENT WILL I RECEIVE?

During the study treatment period, you may receive either one of the following study treatments by chance, which will be given by two subcutaneous (under the skin) injections every month, for 6 months:

- Canakinumab (ACZ885): You have a 1 in 2 chance of getting this treatment.
- Placebo: You have a 1 in 2 chance of getting placebo, which has no active ingredients

You will get the study treatment by subcutaneous injection. This is an injection under the skin.

You will receive either Canakinumab (ACZ885) or placebo using randomisation. Randomisation means that you are put into one of two groups by chance. The randomisation process for this study is a 50% chance of either Canakinumab (ACZ885) or 50% chance of placebo – like flipping a coin.

You will receive either Canakinumab (ACZ885) or placebo on Days 1 and 29. Your Study Doctor will then either increase your dose of Canakinumab (ACZ885) or continue placebo administration on Day 57. You will continue on either 300 mg Canakinumab (ACZ885) or placebo every 4 weeks until Day 141, which will be your last dose of study treatment. The study treatment will be given by two subcutaneous injections at each clinic visit.

The placebo is used to make sure that any changes study participants report in the study are not happening just by chance.

Neither you nor your Study Doctor will know what treatment you are getting. However, if a serious problem with your health happens, the Study Doctor can find this out to decide on any necessary actions.

During the study, other medications that you might be taking for mild Alzheimer's disease will continue for your standard of care. At this time, there are no approved treatments for mild cognitive impairment.

During the study treatment, you will have the following tests and procedures:

Test or Procedure	**Description**	**How often will this be done?**
Vital signs	Basic measurements such as body temperature, weight, blood pressure, pulse rate, etc.	At each visit.
Medications taken	You will be asked about any medications you are taking and any changes in those	At each visit.
Suicidality assessment questionnaire	A questionnaire to see if you are at risk of hurting yourself.	At each visit except Baseline.
Electrocardiogram	This measures the electrical activity of your heart.	At Screening, Day 1, Day 85 (Week 12), Day 171 (Week 24), and Day 281 (Week 40).
Physical and neurological examination	Your study doctor will check your skin, your eyes, ears, nose, throat, lungs, heart, nervous system and general appearance.	At each visit **except** Baseline and Day 281 (Week 40).
Blood and urine tests	Tests that are part of the general safety assessment including pregnancy and/or fertility test for those who may be able to become pregnant.	At each visit.
Alcohol and drug test	Blood and urine tests for alcohol and drug use.	At Screening only.
Tuberculosis, HIV and Hepatitis tests	Blood tests for HIV and hepatitis and blood or skin test for tuberculosis.	At Screening only.

Inflammation blood test	Blood test to determine how much of a marker of inflammation is in your blood.	At Screening and Day 281.
Demographics	Information that includes your year of birth, sex, ethnicity, family history of Alzheimer's disease, number of years of education, and ApoE genotype if your doctor has that information in your medical record).	At Screening only.
Participant questionnaires and tests of memory and thinking	Certain tests and questionnaires will assess your memory and thinking, lifestyle, ability to perform daily activities, and any symptoms of depression that you may be experiencing. Some tests will be done with pen/paper and some tests will use a tablet to capture the answers.	At each visit **except** Day 281 (Week 40).
Study partner demographics	Information that includes your study partner's relationship to you, their frequency of contact with you, their age and gender, and their judgement of your experience with mobile and tablet technology.	At Screening only, or at any point during the study if there is a change in your study partner.
Study partner questionnaires	Interviews with your study partner will assess your memory/lifestyle/ability to perform daily activities, and behavioral changes you may be experiencing. Study staff will capture answers to all study partner questionnaires on a tablet.	At Baseline and at each visit **except** Day 281 (Week 40).
Cerebrospinal fluid (CSF)	A lumbar puncture ("spinal tap") is	At Screening and at Day 85 (Week 12).

taken	performed in your lower back (lumbar region) to collect a sample of cerebrospinal fluid (CSF, the fluid that surrounds the spine and the brain) to detect biomarkers associated with Alzheimer's disease and inflammation.	
Study drug administration/dispensing	You will receive 2 subcutaneous (under the skin) injections.	Day 1, Day 29 (Week 4), Day 57 (Week 8), Day 85 (Week 12), Day 113 (Week 16), and Day 141 (Week 20).

In between visits to the study site, you and your study partner will complete brief assessments at home. These will be completed on an electronic tablet, which will be handed to you and your study partner at the Baseline visit.

Test or Procedure	**Description**	**How often will this be done?**
At-home assessments of memory and thinking	You will complete a few assessments at home on a tablet to monitor any changes in memory and thinking abilities. The assessments are game-like and will be completed on a tablet.	2 times (on 2 separate days) starting at the Baseline visit, leading up to Day 1. 2 times (on 2 separate days) in the week leading up to Day 57 (Week 8). 2 times (on 2 separate days) in the week leading up to Day 85 (Week 12).
At-home study partner questionnaire to monitor mood and behaviour	Your study partner will complete questionnaires on the tablet to help monitor any changes in mood and behaviour. This questionnaire is also completed at clinic visits.	At least 2 times (on 2 separate days) starting at the Baseline visit, leading up to Day 1. At least 3 times (on 3 separate days) during the week leading up to Day 29 (Week 4).

		At least 3 times (on 3 separate days) during the week leading up to Day 57 (Week 8). At least 3 times (on 3 separate days) during the week leading up to Day 85 (Week 12).
Feedback survey	You and your study partner will be asked a few questions about your thoughts and feedback on the at-home assessments and the use of the tablet to complete these assessments.	This will be made available on the tablet for you and your study partner to complete after 2 of the at-home assessments are done.

Important information on the electronic tablet and the at-home assessments is included in the next section.

Important requirements for study conduct:

You should tell your Study Doctor about all medications that you are taking including dietary supplements and herbal remedies. You should also talk to your Study Doctor about your alcohol consumption (if any) and your smoking habits (if any).

At your screening visit, you will have a blood draw to test for certain markers ("biomarkers") that are associated with inflammation. At a later screening visit, you will then have a lumbar puncture ("spinal tap") to test your cerebrospinal fluid (CSF) for biomarkers that are associated with Alzheimer's disease, called amyloid and tau. If you have very low levels of the inflammation biomarker in your blood, you will not be able to participate further in the study. In addition, if the levels of amyloid in your CSF are not low enough, and/or the levels of tau in your CSF are not high enough, you will not be able to participate further in the study.

If you choose to take part in the study, you will need a study partner. This can be a spouse, family member or friend who knows you well or a caregiver who knows you well. The study partner will need to review the informed consent document and agree to provide information and agree to complete questionnaires that describe your memory, mood or general well-being. If your study partner is no longer able to participate, you will be asked to find a new study partner or caregiver to continue in the study.

At your baseline visit, your study partner will be provided with an electronic tablet to take home. **Your study partner must also bring the electronic tablet to every study visit.** Both you and your study partner will complete at-home assessments on the tablet. You should treat it carefully and must return it at the end of your participation in

the study. If you have any questions about using the tablet or if you lose the tablet, please contact your study site immediately.

Additional information on how and when to complete the at-home assessments on the tablet will be provided to you by the study staff. If you or your study partner forget to complete any of these assessments, please let the study staff know as soon as possible. The study staff may also contact you in cases where assessments are missed or incomplete.

Participant Reported Outcomes (PROs):

As part of the medical examination during your clinic visit, you will be asked to complete certain Participant Reported Outcome measures. Your Study Doctor will review your answers to the Columbia Suicide Severity Rating Scale (C-SSRS), also called the 'Suicidality assessment questionnaire', as part of the medical examination during your clinic visit. Your Study Doctor may discuss your answers with you, or update your care based on your answers.

Trial Feedback Questionnaire

After completing some of the 'at-home assessments', the Sponsor of this study (Novartis) will ask you some questions to collect your feedback about your experience using the electronic tablet for the 'at-home assessments' in this study. These questions will appear on the tablet and may be completed at any point after two 'at-home assessments' are completed and before you return the tablet to the study site.

8 WHAT BIOLOGICAL SAMPLES WILL BE COLLECTED DURING THE STUDY?

Biological samples (this may include blood, urine samples and cerebrospinal fluid), will be collected from you at various times during the study for tests and research called "biomarker analysis". A "biomarker" is an indicator that gives information about your health or your response to treatment. These biomarker samples will be used to help answer scientific questions related to Canakinumab (ACZ885) effect on cells or organs in your body, as well as impact on your disease. These samples will also be used to try to understand your disease better.

Approximately 250 mL (about 17 tablespoons) of blood will be collected for lab tests during your participation in this study. This is less than the amount taken for a blood donation. These samples are used to research how the study treatment (Canakinumab) is processed by your body. Samples will also be used to understand whether your body has an immune response against the treatment and also the effect the study treatment has on your body and/or your disease.

Your samples may also be used to measure proteins that may be related to your disease or affected by your study treatment. This includes a protein that shows

inflammation and it is often at higher levels in the blood when there is inflammation. As mentioned in the section called 'Important requirements for study conduct', the Study Doctor will look at your levels of inflammation markers in your blood at your screening visit and, if you do not have moderate or high levels, you will not be able to participate in the study.

You will have approximately 12 mL (about 2 teaspoons) of cerebrospinal fluid (CSF) taken at two time points in the study (screening and Day 85 visit). The CSF sample will be tested for biomarker proteins, antibodies and antigens. These tests will be used to understand how the study drug effects biomarkers in your brain and if the study drug is able to reduce inflammation in your brain. Inflammation may have an effect on brain health and the process of aging of the brain.

Your CSF samples will also be used to measure biomarkers that are associated with Alzheimer's disease. These biomarkers are called amyloid and tau. As mentioned in the section called 'Important requirements for study conduct', if after undergoing the lumbar puncture at the screening visit, it is determined that the amyloid and/or tau levels in your CSF are not indicative of Alzheimer's disease, you will not be able to participate in the study.

No tissue samples will be collected for this study.

If Health Authorities require the Sponsor to do more testing on your samples, such tests will be done, where possible.

9 CAN I STOP MY STUDY TREATMENT OR DECIDE NOT TO CONTINUE IN THE STUDY?

Please inform your Study Doctor or Study Staff if you decide you do not want to continue taking the study treatment. You will be asked to return to the hospital clinic as soon as possible to check how you are. You must return any study equipment (e.g. electronic Tablet) to the clinic.

You may decide that you want to stop study treatment and also do not want to come to any further visits and do not want to have any further assessments or contact by the study Doctor, and do not want Novartis to analyse any blood samples or other biological samples already collected. This is considered as withdrawal of your consent for participation in this study. If this is what you want, then it is important that you inform your Study Doctor of your decision to withdraw your consent Novartis will continue to retain and use any research results that have already been collected for the study evaluation. No further study-related activities will take place.

The choice to withdraw from the research study will not affect your future medical care.

10 ARE THERE ANY REASONS THAT MY STUDY TREATMENT OR MY STUDY PARTICIPATION MAY BE STOPPED EARLY?

The Study Doctor may stop your participation in the study or stop your use of study treatment for any important reason and will discuss your options with you. Some examples of reasons to stop are:

- You need another treatment that is not allowed in this study
- You experience side effects from the study treatment(s) that you or your Study Doctor find unacceptable
- The Study Doctor thinks that keeping you in the study might be harmful and is not in your best interest
- You are female and become pregnant
- You are unable or unwilling to follow study instructions
- The Sponsor decides to stop this study
- You no longer wish to continue in the study

If your participation stops early for any of these reasons, you may be asked to have some of the study procedures done at your final study visit. These may include physical and neurological examination, blood specimens taken for laboratory tests including pregnancy testing for women of child-bearing age, full blood count to check your red blood cell and white blood cell status, blood test to check that your liver and kidneys show normal enzyme levels, urine testing for infection, and an ECG to check your heart rate. The Study Doctor will also ask you questions about your mood and how you feel. Some of these questions may make you feel sad or concerned. You should talk to the Study Doctor if you feel like this after answering the questions about your mood.

11 WHAT WILL HAPPEN AFTER I COMPLETE THE STUDY?

Your Study Doctor will receive a summary of the study results after the study is completed and all data examined. The Study Doctor may share these results with you.

After the study is completed, a summary of the results will be publicly available at www.novartisclinicaltrials.com, www.ClinicalTrials.gov, and/or at the European Clinical Trials Database (EudraCT, https://eudract.ema.europa.eu/).

These websites will not include information that can identify you. At most, the websites will include a summary of the results. You can search the websites at any time. A summary of the results may be published at conferences or in journals. If the results of the study are presented to the public, you will not be named. Some authorities may ask that the Sponsor disclose study data for transparency reasons. However, the data shared will not identify you.

After the study is completed, your Study Doctor will receive a summary of your individual study results. If you want to know your study results, you should talk to your Study Doctor.

You will not own any data or discoveries made during the study; this will be owned by the Sponsor.

12 WILL I HAVE ACCESS TO STUDY TREATMENT AFTER THE STUDY ENDS?

You will not be given study treatment after your time in the study ends.

13 WHAT ARE THE POSSIBLE BENEFITS TO ME IF I CHOOSE TO TAKE PART IN THIS STUDY?

Taking part in this research study may not benefit you directly, but we may learn new things that could help treat patients in the future.

14 WHAT ARE THE POSSIBLE RISKS TO ME IF I CHOOSE TO TAKE PART IN THIS STUDY?

There is a possibility that you will experience side effects from the study treatments and/or procedures done. Not all of the possible side effects of the study treatment are known at this time.

It is very important that you tell the Study Doctor if you have any complaints, side effects, or had other doctor visits or hospitalisations outside of the study.

The risks listed in the table below, were identified in lower doses of Canakinumab (ACZ885) administered subcutaneously (under the skin injection).

Known risks associated with Canakinumab (ACZ885):

Very Common Side Effects: happens to about 1 in 10 people	
Infections, including; Respiratory tract infections, viral infection (cold and flu), sinusitis, rhinitis Pneumonia Ear infection Cellulitis (skin infection) Gastroenteritis (inflammation in your intestines) Urinary tract infection (water infection)	Upper stomach (abdominal) pain Injection site reaction (redness, pain, itching, swelling) Joint pain (Arthralgia) Creatinine clearance decreased (waste cleared through kidneys) Presence of protein in your urine (Proteinuria) Low number of white blood cells (leukopenia)
Common Side Effects: happens to about 1 in 100 people	
Vulvovaginal candidiasis (vaginal and vulval yeast infection) Dizziness/vertigo Back and musculoskeletal pain	Fatigue Low number of white blood cells (neutropenia)
Uncommon Side Effects: happens to about 1 in 1,000 people	
Acid reflux Platelet count decreased	

If you or your partner become pregnant during the study, the possible risks to an unborn child or nursing infant are as follows: unknown.

Important points about side effects:

- Your Study Doctor cannot predict who will or will not have side effects.
- Extra care will be taken to monitor the side effects that are not always apparent; your study doctor will ask you about any unusual symptoms. Blood samples will be taken for safety assessments throughout the study.
- Most side effects are expected to go away once the study medication is stopped. However, in some cases the side effects may be serious, long lasting and permanent or possibly lead to death.
- If you do experience a serious side effect dosing with study medication will be stopped and you will be checked regularly for the progress of side effects. This may require extra visits and examinations including blood tests. The study medication *may* be re-started at a lower dose after the side effects improve or disappear.

Important points about how you and your Study Doctor can make side effects less of a problem:

- Tell your Study Doctor if you notice or feel anything different.
- Your Study Doctor may treat the side effects or adjust the study treatment to try to reduce side effects.
- Ask your Study Doctor for more information about potential risks and side effects from study treatment.

Blood samples

Blood samples will be taken from you and there is a risk of bruising and/or infection at the site of the needle puncture. You should talk to your Study Doctor if you take blood thinners such as warfarin or if you know that you have dizzy spells during previous blood tests for your usual clinic visits.

Cerebrospinal Fluid (CSF) collection

A CSF sample will be taken from you using a lumbar puncture at two time points during the study. You may feel some stinging, pain and/or some pressure during the procedure.

Post-lumbar puncture headaches occur in around 1-2% of subjects but are generally mild and require no treatment or treatment with mild painkillers (e.g. paracetamol). Other problems you might have after the procedure can include feeling lightheaded or dizzy, a slight risk of infection, a slight risk of bleeding in the spinal canal and risk of brain swelling.

Please ask your Study Doctor any questions you have about this procedure.

Other risks

In rare instances, a nurse, Study Doctor, or laboratory technician, may be exposed to your blood, tissue or body fluids by needle injury, cut, or damaged skin. If this happens (or if required by the study protocol), it may be necessary to test your sample for certain viral infections including Hepatitis B and C and HIV. If possible, this will be done on a sample already available. The result will be shared with the person who was exposed to your blood, tissue, or body fluids – thus making it possible for that person to receive proper monitoring and treatment, as needed. The Study Doctor will provide results of your tests and advise on the next steps. Confidentiality of the results of your tests will be respected at all times.

15 WHAT DO I NEED TO KNOW ABOUT BIRTH CONTROL AND PREGNANCY?

Please see Appendix 1 for information about birth control and pregnancy.

16 WHAT ARE MY RESPONSIBILITIES AND ARE THERE ANY COSTS FOR ME IF I AGREE TO JOIN THE STUDY?

You will be reimbursed reasonable travel expenses for getting to and from the hospital including standard class rail travel and bus travel so please keep your receipts. If you are travelling by car, you will be reimbursed at 45p/mile, so please keep a note of your mileage. Car parking fees will be reimbursed so please keep your receipts.

For visits lasting longer than 3 hours you will be reimbursed up to £10 for light refreshments. If a caregiver attends the study visit with you, they may also be reimbursed reasonable travel costs and expenses.

If you agree to participate in this study, you have the following responsibilities:

Related to study appointments/visits and procedures:

You will need to:

- Carry with you at all times a card (the same size as a credit card) which the study doctor will give you at your first visit. Cards like this are given to everyone who takes part in this kind of study; they include phone numbers to contact in any emergency.
- Follow instructions given to you by the Study Doctor and Study Staff.
- Attend all of your study appointments. If it is necessary to miss an appointment, you must contact the Study Doctor or Study Staff to reschedule your appointment.
- Complete your required study activities as instructed, such as filling in questionnaires or diaries
- Any equipment provided to you for the purpose of this study must be returned at the end of the study (e.g. electronic tablet).

Related to side effects and other medications you may be taking:

- You must tell your Study Doctor or Study Staff if you have any unusual symptoms, any side effects, and other doctor visits, or planned hospital admissions that you may have.
- You must tell your Study Doctor about any medications you currently take or may take during the course of the study, including prescription medicines, over the counter medicines and vitamins and supplements.
- If you are taking other medications, they may need to be stopped or the dose reduced to manage side effects. This is to avoid a mix-up of effects between the other medication and the study treatment. Your Study Doctor will discuss this with you.

You will not have to pay for the study treatment.

17 WHAT OTHER CHOICES ARE AVAILABLE FOR ME?

You do not need to join this study in order to be treated for your mild cognitive impairment due to Alzheimer's disease/mild Alzheimer's disease. If you decide not to join this study, the Study Doctor will discuss other treatment options and their potential risks and benefits with you.

18 WHAT IF I BECOME INJURED BECAUSE I PARTICIPATED IN THIS STUDY?

If you are not happy with the general care and treatment you receive during the study, please speak first to your study doctor or nurse, who will try to resolve the problem.

He/she should also tell you about the hospital/clinic's standard complaints procedure in case you wish to take the matter further.

If you develop any health problem or suffer harm during the study, you should contact the Study Doctor. If you think you may have been harmed by the study medication, or otherwise by taking part in the study, Novartis Pharmaceuticals (the company organising the study) should compensate you according to the Clinical Trial Compensation Guidelines issued by the *Association of the British Pharmaceutical Industry (ABPI)*, as follows:

- if your injury is attributable to the administration of the study medication; or
- If you were harmed by any procedure which is part of the study, which you would not have had but for your inclusion in the study.

You can get a copy of the guidelines from your hospital / clinic or visit:-

Telephone 020 7930 3477 or visit http://www.abpi.org.uk/contact-us/

19 WHAT IS PERSONAL DATA AND WHAT HAPPENS WITH IT?

During this clinical study, the Study Staff will collect certain information/data about you that is called “Personal Data”.

What is Personal Data and who can see it?

What is Personal Data?	Who can see it?
Examples include: • Your name, full date of birth, gender • Address and phone number • Medical condition and medical history • Images (such as X-Rays, scan results, photographs) • Biological samples (such as blood and tissue)	• The Study Doctor/Study Staff • Very few of the Sponsor’s authorised employees who need to check that all the data is correct • Vendors (people who work on the study for the Sponsor, such as a Contract Research Organisations [CROs]) • Health Authorities (government groups who make sure that clinical studies are conducted according to established quality and safety standards)

Your “Personal Data” will be kept confidential at the Study Site.

All of these people are trained to keep data confidential. They use your personal data to ensure the study was run properly and make sure these data are correct.

What is Coded Data and who can see it?

The Study Doctor will replace the parts of “Personal Data” that can identify you, such as your name and address, with a Participant ID. This ensures that all this information about you becomes “Coded Data”.

What is Coded Data?	Who can see it?
Examples include: • Participant ID • Your gender, age and year of birth • The data, biological samples, collected during the study	• The Study Doctor and study staff • The Sponsor and their staff • The Sponsor’s collaborators (such as researchers who work with the Sponsor)

where information that can identify you has been replaced by your Participant ID. • Genetic data	• Organisations that provide services to the Sponsor, like the CROs • Health Authorities' employees located in different countries around the world. Examples of these health authorities are the FDA (Food and Drug Administration) in the US, the EMA (European Medicines Agency) in Europe • Ethics Committees.

By using Coded Data, it is very unlikely that anyone other than the Study Doctor and Study Staff can identify you.

The Sponsor only keeps the Coded Data and is required to combine the data of all study participants. The Sponsor may use the combined Coded Data to assess the safety and efficacy (how well it works) of the study drug and submit it to Health Authorities for the approval of the drug.

The Coded Data cannot be used to contact you or affect your care or any other decisions about your life. Your Coded Data will not become part of your health record.

The people/organisations listed in the table above may be located in countries outside of Europe, but during the transfer, the Sponsor will ensure the protection and privacy of the Coded Data as required by law.

By law, the Sponsor must keep all study data for at least 25 years.

The collection and use of Personal Data and Coded Data by the Sponsor is necessary for scientific research purposes, as well as the Sponsor's legitimate interests in performing the study.

Subject to laws and regulations, you have the right to:

- review, correct certain Personal Data, and obtain a copy at the end of the study;
- get the Personal Data you provided in a standard electronic format (the law calls it right of portability);
- oppose the use of the Personal Data;
- lodge a complaint with the Information Commissioner's Office.

It is not possible to erase your Personal Data or Coded Data which has already been collected as the study data needs to be complete, correct, and available for Health Authority purposes. Please remember that the Sponsor does not keep Personal Data. The Sponsor only keeps the Coded Data. If you wish to exercise any rights regarding Personal Data, you should contact your Study Doctor.

For any queries related to Coded Data, you can contact your Study Doctor/site staff.

20 HOW LONG WILL MY BIOLOGICAL SAMPLES BE KEPT?

Your Biological Samples will be coded with a unique number and stored under Novartis control for a maximum of 15 years (some samples may be stored for much less time). The study doctor will be alerted to medically significant important changes in your laboratory results, should they occur.

21 HAS THE STUDY BEEN APPROVED?

Yes. Fast Track Research Ethics Committee has reviewed and approved this research study. The Research Ethics Committee includes healthcare professionals as well as non-medical people. All members of the committee are completely independent from anyone organising the study.

22 WHERE CAN I GET MORE INFORMATION?

If you have more questions about this study, you can contact the study doctor whose name and number are on the front page of this Information Sheet and on the Consent Form.

Patient advice and liaison services (PALS)
The Patient Advice and Liaison Service, known as PALS, has been introduced to ensure that the NHS listens to patients, their relatives, carers and friends, and answers their questions and resolves their concerns as quickly as possible. Your local PALs can be located online: https://www.nhs.uk/Service-Search/Patient%20advice%20and%20liaison%20services%20(PALS)/LocationSearch/363

Complaints Department: 020 3355 3536

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

Investigator: Dr. Nicholas Mannering **Centre number**: 2004 **Contact for queries** If you have any questions about this study, you can contact: **Daytime:** Clinical Trials Team on 01483 388 020 **Out of hours:** Dr. Nicholas Mannering on 07510 034 286	**Re:Cognition Health** **29 Fredrick Sanger Road** **Surrey Research Park** **Guildford** **GU2 7YD** **Tel: +44 (0) 1483 388 020** **Re:Cognition Health Complaints Department. Details can be obtained from 020 3355 3536**

Exploratory platform trial on Anti-Inflammatory agents in Alzheimer's disease (EXPLAIN-AD): A randomised, placebo-controlled, multicenter platform study to evaluate the efficacy, safety, tolerability and pharmacokinetics of various anti-inflammatory agents in patients with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease.

Please initial each box to confirm that you have read, understood and agreed each of the numbered points.

1	I have read and understood this Information Leaflet **version 02.03.02 dated 07-Sep-2021** and I have had the time to consider it and the opportunity to ask questions.	1
2	I understand that taking part in the study is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.	2
3	I have read and understood the information on the use of my Personal Data and Coded Data, and the use of my biological samples (such as blood and biological samples), as described in this document.	3
4	I agree that my confidential medical records can be accessed for the study.	4
5	I agree to my GP being told that I am taking part in this study and providing requested information relevant to my participation.	5.
6	I agree to take part in the above study.	6

When you have initialled all the above boxes, please complete the first box below (including the date) yourself:

Name of **Patient** (CAPITALS):	
Date:	Signature:
Name of **Doctor** taking consent (CAPITALS):	
Date: Time:	Signature:
Name of **Impartial Witness** (if applicable):	
Date:	Signature:

Patient number:	**Patient's initials:**

Original to be kept in the study Investigator Folder; Second original or a copy of the original to be given to the patient. The Information Sheet and Consent Form are one entire document and must not be separated. The Consent Form should be printed and used as a single page.

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Appendix 1 (to be read as appropriate).

You have read the information sheet Titled: Main version 02.03.02 dated 07-Sep-2021 however as you are of child bearing potential you are being asked to read this additional information

Animal studies have shown no potential safety concerns associated with the study drug. Studies in marmoset monkeys showed no maternal or foetal effects and no effects on male fertility. Although the study drug showed no effects on the developing foetus, women who are of child-bearing age should discuss the study drug and recommended birth control measures with the Study Doctor.

We do not know whether the study treatment(s) may harm an unborn or nursing baby. If you are pregnant, trying to become pregnant, or breast-feeding, you cannot be in the study.

If you are female and are able to have a baby, you must use the right type of birth control. The Study Doctor will discuss the birth control methods approved for the study and the period of time they will be needed after your last study treatment. If you become pregnant, you must tell the Study Doctor immediately. The study treatment will be stopped, and you will be asked to read and sign another consent form to let the Study Doctor ask about your pregnancy.

1. If you are male, your Study Doctor will advise you on the use of condoms and the period of time they will be needed after your last dose of study medication. You must agree not to father a child and not to donate sperm during this time. If your partner becomes pregnant, you must tell the Study Doctor immediately,

and your partner will be asked to read and sign another consent form to let the Study Doctor ask her about her pregnancy.

1. If you are a woman who could become pregnant:
You will be asked to have a pregnancy test at the screening visit, at every study visit and at end of the study. If you think you may have become pregnant during the study, you must tell the doctor immediately.

As a female participant in the study it is important that you use a highly effective form of birth control method (contraception) if you are sexually active and may become pregnant.

Highly effective methods of birth control have a less than 1% chance of unwanted pregnancy during one year, if used according to the instructions of the manufacturer. Please discuss with your Study Doctor the most appropriate birth control method for you that also respects your cultural and religious situation.

Examples of highly effective birth control methods are:

Total abstinence (no sexual relations), when this is in line with your preferred and usual lifestyle choice. Periodic abstinence like calendar, ovulation, temperature method, post-ovulation methods, and withdrawal are not acceptable methods of contraception.

- Female sterilisation (surgical removal of both ovaries with or without hysterectomy), total hysterectomy (surgical removal of the uterus and cervix), or tubal ligation (getting your “tubes tied”) at least six weeks before taking study treatment.

- Your male partner has already been sterilised at least 6 months prior to screening. The sterilised male partner should be your sole partner.

- Barrier methods of contraception: condom or occlusive cap (diaphragm or cervical/vault caps) with a spermicidal foam/gel/film/cream/vaginal suppository.
- Use of oral (oestrogen and progesterone), injected, or implanted hormonal methods of contraception or or other forms of hormonal contraception that have comparable efficacy (failure rate <1%), for example hormone vaginal ring or transdermal hormone contraception or placement of an intrauterine device (IUD) or intrauterine system (IUS).

In case you are using an oral contraception as a woman, you should be stable on the same pill for a minimum of 3 months before starting study medication.

If you become pregnant or suspect being pregnant during study treatment you must inform your Study Doctor and you have to stop ongoing study treatment immediately. You will not be allowed to continue study treatment if you are pregnant. Your Study Doctor will medically follow your pregnancy until delivery to monitor you and your child`s safety.

2. If you are a man whose partner could become pregnant:
As a male participant in the study you must agree to use a condom during intercourse and not to father a child during the study. Vasectomised men must also use a condom in order to prevent delivery of the drug via seminal fluid.
In addition, it is advised that your female partner uses a highly effective form of birth control method (contraception) if she is sexually active and may become pregnant. In case you father a child while in this study you are asked to report the pregnancy to the Study Doctor. Consent from your partner will be needed to allow your Study Doctor to medically follow this pregnancy until delivery to monitor the mother`s and child`s safety. If you think your partner may have become pregnant during the study, you must tell the doctor immediately.

Please initial each box to confirm that you have read, understood and agreed each of the numbered points.

1	I have read and understood this Appendix 1 to the main Information Sheet **version 02.03.02 , dated 07-Sep-2021** and I have had the time to consider it and the opportunity to ask questions.	1
2	I agree to my participation/continued participation in the study	2

When you have initialled all the above boxes, please complete the first box below (including the date) yourself:

Name of **Patient** (CAPITALS):	
Date:	Signature:
Name of **Doctor** taking consent (CAPITALS):	
Date: Time:	Signature:
Name of **Impartial Witness** (if applicable):	
Date:	Signature:

Patient number:	**Patient's initials:**

Original to be kept in the study Investigator Folder; Second original or a copy of the original to be given to the patient. The Information Sheet and Consent Form are one entire document and must not be separated. The Consent Form should be printed and used as a single page, document.

Investigator: Dr. Nicholas Mannering **Centre number**: 2004 **Contact for queries** If you have any questions about this study, you can contact: **Daytime:** Clinical Trials Team on 01483 388 020 **Out of hours:** Dr. Nicholas Mannering on 07510 034 286	**Re:Cognition Health** **29 Fredrick Sanger Road** **Surrey Research Park** **Guildford** **GU2 7YD** **Tel: +44 (0) 1483 388 020** **Re:Cognition Health Complaints Department. Details can be obtained from 020 3355 3536**

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Optional consent for additional research using your Coded Data and biological samples

During or after the clinical study, the Sponsor may want to use the Coded Data, including your biological samples (such as blood and tissue) for additional research. The purpose of the additional research would be limited to:

- help better understand how the study treatment works;
- learn more about your disease;
- help develop ways to detect, monitor, and treat related human diseases;
- improve the way we conduct clinical studies.

The specific details of such additional research are not known right now but examples of what this might involve are using your Coded Data and biological samples: to test new approaches or biological markers that are or may be relevant to your disease; and, to compare the benefits and risks of the treatment with data about other treatments. The Sponsor alone, or with other scientists or partner companies around the world may use and combine coded data with data from other people to support additional research projects and to help science and public health to advance.

The Coded Data will remain private and it is very unlikely that you can be identified. The Sponsor limits the number of people who can see the Coded Data. This will help ensure that the Coded Data will only be used for the purpose of scientific research.

The Coded Data cannot be used to contact you or affect your care or any other decisions about your life. You will not own any data or discoveries made from the

additional research; the Sponsor will own these data. Your Coded Data will not become part of your health record.

You are not required to sign this consent if you do not want to participate in this optional additional research.

Please note: if you want to withdraw your consent for additional research, you should write to your Study Doctor. In this case, the Coded Data will not be used for additional research anymore but it will still be used for the study purposes.

Optional consent for additional research using your Coded Data

Please tick one of the boxes below to indicate whether you consent to the use of your biological samples and the use, access, and sharing of your Coded Data for the purposes described above:

☐ I consent ☐ I do not consent

Name of **Patient** (CAPITALS):	
Date:	Signature:
Name of **Doctor** taking consent (CAPITALS):	
Date: Time:	Signature:
Name of **Impartial Witness** (if applicable):	
Date:	Signature:

Patient number:	**Patient's initials:**

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Consent from Study Partner/Caregiver:

As a relative/close friend of the person signing this consent form, you may receive information explaining your role in support to your relative/close friend participation in this study. We request you sign this consent to confirm the following:

Please initial each box to confirm that you have read, understood and agreed each of the numbered points.

1	I have read this informed consent form **version 02.03.02 , dated 07-Sep-2021** as signed by the Study Participant that I will support;	1
2	I declare that I am prepared and agree to undergo interviews regarding my relative/close friend;	2
3	I am aware that I will need to complete questionnaires in-clinic and at-home using a tablet as described in Section 7 of this informed consent document, including but not limited to, information about my relation to the Study Participant;	3
4	I am aware that I will need to provide demographic information about myself as described in Section 7 of this informed consent document;	4
5	I am expected to report any changes that I observe in the Study Participant to the Study Doctor or staff for the duration of the study, including mental status, behaviours or other health-related findings;	5.

6	I have received information about my role as a Study Partner, and answers to all my questions;	6
7	If the Study Participant is signing an updated version of the informed consent, I am aware that I will need to read the updated version and sign the consent form present in the updated version.	7

When you have initialled all the above boxes, please complete the first box below (including the date) yourself:

Name of **Study Partner /Caregiver** (CAPITALS):	
Date:	Signature:
Name of associated participant: _____ Associated participant number: _____	
Name of **Doctor** taking consent (CAPITALS):	
Date: Time:	Signature:

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Additional consents for replacement Study Partner/Caregiver (if needed):

As a relative/close friend of the person signing this consent form, you may receive information explaining your role in support to your relative/close friend participation in this study. We request you sign this consent to confirm the following:

Please <u>initial</u> each box to confirm that you have read, understood and agreed each of the numbered points.

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Date:	Signature:
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