Study Partner Information and Consent Form
I5T-MC-AACQ
Investigating the Effect of Different Donanemab Dosing Regimens on ARIA-E and Amyloid Lowering in Adults with Early Symptomatic Alzheimer's Disease

Introduction

You are being asked to participate in this research study because you are the study partner or caregiver of someone who has agreed to participate in Study I5T-MC-AACQ (AACQ). Before you decide if you want to take part, it is important for you to understand why the research is being done, how your information will be used, what the study will involve, and its possible benefits. Please take time to read the following information carefully.

Study partners play a very important research role in this clinical study. You must be willing to accompany the study participant to the research center for all the visits in which a study partner is needed. You must be willing to take the telephone calls if necessary. If any problems arise between visits, you must contact the study staff and follow their guidance for what to do. In addition, as someone who has the opportunity to observe the study participant in his or her day-to-day settings, you will be expected to be alert to the behaviors of interest in this study and to answer questions asked of you by study staff in an objective and accurate manner during study visits.

You should not sign and date the form until you understand all of the information presented in the following pages and all of your questions about the research have been answered. If you would like to, you may review the Study Participant Informed Consent document for more detailed information about the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Purpose

This study is being carried out to see

- How different donanemab dosing regimens compare in their **safety** (any side effects the participant might experience) in treating people with AD (Alzheimer's Disease)
- How different donanemab dosing regimens compare in their **effectiveness** (decreasing the amount of amyloid biomarker in the participant's brain) in treating people with AD

In study AACQ, all participants will receive donanemab at different dose levels and frequency. Neither you, the participant, nor study doctor will know at what dose level or frequency the participant is receiving donanemab.
At certain visits in the first 14 weeks of the study, the participant might receive placebo instead of donanemab to preserve the blind for the different dosing regimens. A placebo is an infusion that looks like the study drug (donanemab) but has no medicine.
The participant will receive donanemab or placebo through an infusion into their vein about every 2-4 weeks.

Study Procedures

The study partners are required to accompany the participant for signing the consent form. Visits requiring the collection of side effects and concomitant medications must have a study partner available by telephone if not accompanying the participant at a visit. By signing this form, you consent to the study doctor and his or her staff collecting and using personal data about you for the study (study data). This includes: your birth year, your sex, and your relationship with the study participant.
If a study partner must withdraw from study participation, a replacement may be allowed at the investigator's discretion. The replacement will need to sign a separate informed consent form on the first visit that they accompany the participant. The length of the visit varies, but in general, visits will last 3-7 hours (longer visits include MRI and/or PET imaging). Visits can be completed on different days, and someone other than you may accompany the study participant for some of the testing and examinations.

Risks

There are no additional risks to you to help answering questions about the side effects the participant may have and any medications the participant is taking.

Possible Benefits

The findings from this research study may not have a direct beneficial effect on the individual care of the study participant. Your consent to take part may also not directly benefit you, but the study research team and other doctors may learn important new things about the treatment effects of the study drug. The findings may help improve treatment for other people who have cognitive and functional problems related to Alzheimer's disease and help reduce the burden of caregiving.

Participation in the Study

You are under no obligation to take part in this study. If you begin the study and later no longer wish to participate, you can withdraw at any time. However, the study participant cannot be in this study without a study partner. If you are unable or unwilling to participate, he or she may also need to leave the study.
If any new information on the study drug becomes available which may influence your decision to continue in the study, you will be told in a timely manner.
If you or the study participant wants to leave the study early for any reason, please tell the study doctor or study staff. You will not have to give a reason for leaving the study early; however, you

and the subject will be asked to come for a visit that occurs only if the study participant stops the study early and for a follow-up visit. You will not waive any of your legal rights by withdrawing from the study.
You and the study participant may have to leave the study early even if you or the study participant wants to continue. This could happen if:

- Due to safety issues, the study doctor or study staff believes that it is best for you or the study participant to stop being in the study.
- You or the study participant do not follow instructions about the study, resulting in safety concerns.
- The sponsor (Eli Lilly and Company) stops the study for any reason.

Reimbursement

You are invited to voluntarily take part in an optional program to reimburse you for your study inconvenience and travel expenses. You do not have to participate, and you can also decide to stop participating any time

Privacy

By signing the consent document for this study, you are giving permission for your personal information and study data to be used and shared as described in this Data Privacy Statement. The study doctor and staff will handle your personal information in a confidential manner.

By signing this form, you consent to the study doctor and his or her staff collecting and using personal data about you for the study (study data). This includes: your date of birth, your sex, and your relationship with the study participant. Your consent to the use of study data does not expire, but you may withdraw your consent at any time by notifying the study doctor in writing. If you do this, you will not be allowed to stay in the study.

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

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

- The sponsor will use the study data for research purposes to support the scientific objectives of the study described in the Patient Information Sheet and Consent Form. They will also use your data to assess the safety or effectiveness of any medication or treatment included in the study and to better understand the disease(s) included in the study. Your data may also help the sponsor to improve the design of future studies.
- Your non-identifiable study data, either alone or combined with data from other studies, may be shared with regulatory authorities in this country and other countries including the United States. It may also be shared with the Ethics Committee that reviewed this study.
- Study data that does not identify you may be published in medical journals or shared with others as part of scientific discussions.

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

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

Contact Information for Help

In the event of an emergency, dial +44 (0)1483 388 020 immediately.

In case of a study-related injury or if you have any questions or concerns now or at any time in the trial, please contact Dr. Nicholas Mannering, Phone No. +44 (0)7510034286.

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

Re:Cognition Health, Compliance Team on 020 3355 3536 or compliance@re-cognitionhealth.com.

Signatures

By signing and dating this Study Partner Information and Consent Form, you authorize your participation in this study and the use of study data (see Attachment 1).

Study Partner Information and Consent Form
Attachment 1
Signatures

To become a part of this study, you must sign and date this page.

Only sign this consent after:

- You have read all of the information in this Study Partner Information and Consent Form and you have had time to think about it.
- All of your questions have been answered to your satisfaction.
- You voluntarily agree to be part of this research study, and to do the following:
  - to follow the study procedures,
  - to provide necessary information to the study doctor, nurses, or other staff members, as requested, and
  - allow the study doctor and the sponsor to use and disclose your personal information as described in this document.

You may freely choose to stop being a part of this study at any time. You will receive a copy of this signed Study Participant Information and Consent Form to keep.

Study Partner:

Signature of Study Partner	Date (Study Partner must personally date)
Study Partner Name	

Individual Conducting Consent Discussion:

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

Signature of Individual Conducting Informed Consent Discussion	Date (individual conducting informed consent discussion must personally date)

Name of Individual Conducting Informed Consent Discussion