Dementia Trials Accelerator

Participant Information Sheet

We are inviting you to join the Dementia Trials Accelerator, an initiative that connects people with medical researchers quickly.

One in three people born in the UK this year will develop dementia in their lifetime. Currently, there is no cure, and there are limited treatment options to slow the spread of the disease or lessen symptoms. The Dementia Trials Accelerator is supporting the government's Dame Barbara Windsor Dementia Goals programme to expand the options available for people to participate in crucial research.

If you join, you will receive feedback about your own health and researchers might contact you later to ask if you'd like to take part in studies about dementia or other brain health issues.

Before you decide, it's important to understand why we're establishing the Dementia Trials Accelerator and what it means for you. Please read this carefully and talk to someone you trust before you decide to join.

What is the purpose of this Dementia Trials Accelerator?

Dementia is a collection of symptoms resulting from damage to the brain which includes a decline in cognitive function that goes beyond what we would expect to happen as someone ages normally. There is still a lot we do not know about dementia and its causes and why some people end up with these symptoms. Dementia impacts about 1 million people in the UK right now, a number which will increase as the population continues to age.

The drugs and treatments we have now are not very good at stopping someone from getting dementia or slowing down dementia once someone has it. Early research shows that by using new and innovative methods this could change.

Scientists need to do research studies and clinical trials to understand if the treatments work. These studies are very important, but not many people in the UK have taken part in them so far. It's especially hard to do trials for dementia, because finding the right people to take part takes a lot of time and money.

The Dementia Trials Accelerator wants to help find people faster for research about dementia and other brain health issues. Brain health research is about figuring out how the brain works, what happens when things go wrong, and how to help people live healthier, fuller lives. It includes understanding how the health of other parts of the body, like the lungs, gut, and heart, influence our brain.

The Dementia Trials Accelerator will collect and store information like names, contact details, test results, and clues in the blood called "biomarkers" that may be linked to dementia. By

collecting and storing this information before a study takes place, researchers can quickly find if someone is a good match for their study and invite them to take part.

The data collected for the initiative will also be used for research about the potential causes and risks for brain related illnesses, including dementia, Alzheimer's, and Parkinson's. This research would be done on deidentified data and samples.

Who is running this Dementia Trials Accelerator?

The project is currently funded by the Medical Research Council, which supports science and health research in the UK. The work of the Dementia Trials Accelerator is currently run by Health Data Research UK (HDR UK) and the UK Dementia Research Institute (UK DRI) in partnership with researchers at Imperial College London (Imperial), including those running the REACT study. You will be kept informed of any changes in organisations involved in the Dementia Trials Accelerator.

Why have I been invited to take part?

You have been invited to take part in this project because:

- You are part of the Imperial REACT study cohort and are between the ages of 50 and 90.
- You agreed that we could invite you to take part in further research studies.
- You currently live in the UK.

You are not eligible to participate if:

- You are unable to consent to join the Dementia Trials Accelerator.
- You are currently not living in the UK or are about to move away.
- You don't want to be contacted about future research studies that might test a new treatment, including medicines, for helping with memory problems like dementia.

What is involved

Joining this initiative involves three things:

1. **Registering online. Here you will be asked to:**

- Confirm you are eligible for the Dementia Trials Accelerator and agree to join. If you have any questions about joining, you can email contact@support.dementia-trials-accelerator.org or call 0118 403 2366.

- Complete a short online questionnaire, which will ask you questions about yourself, including your name, age, sex, ethnicity, education and employment status, your overall mental and physical health, your medical history, your family medical history, followed by a memory, thinking and daily skills test.

- Book an appointment to complete the in-person assessment. You will be able to pick a time and location that are convenient for you. This can be booked online.

  This will take about 40 minutes to complete. You can reach out to us for help registering by emailing contact@support.dementia-trials-accelerator.org or calling 0118 403 2366.

2. **Visiting an assessment centre that is most convenient to you to:**

- Verify your identity. We will ask you to tell us your name and show something with your name on it (like an ID, bank card or a bus pass).

- Complete a consent form to join the Dementia Trials Accelerator. You will have a chance to ask any questions that you have about the initiative.

- Have your height, weight and blood pressure measured.

- Have a blood sample (approximately 20 ml, about three tablespoons) taken from your arm.

- Complete a test checking your memory, thinking and daily skills and how well you can follow instructions. Your whole appointment will take about 30-40 minutes.

3. **Follow-up from the Dementia Trials Accelerator:**

- You may be asked to repeat the questionnaire and test online annually to follow how your health, any symptoms and your lifestyle have changed. You may also be asked to provide saliva or blood sample.

  After the appointment you will receive a link to your feedback.

- If you are unable to attend your appointment, we will still keep your data on file and may contact you to reschedule or for future follow-up.

Will I receive any of my results?

Yes, you will receive a report of your results. This will include your height and weight, blood pressure, and body mass index (BMI) and whether these are within normal range. It will also include health advice about what these measures mean and what to do to keep healthy.

You will be able to choose if you want to know the results of your online memory, thinking and daily skills test. If you say yes, we will explain what the results mean. The tests are not clinical tests for diagnosing dementia or other diseases which affect memory, thinking, reasoning, language, or ability to do day to day tasks. If you have concerns about your results, you should see your GP or doctor.

You will not be given the results of your blood biomarkers, or the genes and proteins which we think might be linked to dementia. The biomarkers we are testing for are thought to be

linked to dementia. They cannot predict if someone will get dementia, and we still do not know enough about them to provide you insights on what they might mean for you.

How do I sign up for the Dementia Trials Accelerator?

If you choose to take part, please complete the registration process online. If you are unable to complete the registration process online, you can do so over the phone.

Further information about the Dementia Trials Accelerator is given in your personal invitation, which also includes your personal registration ID. Please follow the instructions in your invitation or you can contact us:

Phone: 0118 403 2366

Email: contact@support.dementia-trials-accelerator.org

Website: www.dementia-trials.org

Do I have to take part?

No. Joining the Dementia Trials Accelerator is entirely up to you. Even if you do decide to take part, you can change your mind at any time without giving a reason.

If you decide to sign up but later change your mind and want to withdraw, you can withdraw online through the www.dementia-trials.org or by contacting the Dementia Trials Accelerator team by emailing contact@support.dementia-trials-accelerator.org.

If you decide not to take part or withdraw at any time, it will not affect your ability to continue to take part in other research now or in the future.

How will this research help others?

The Dementia Trials Accelerator initiative helps connect people who want to take part in dementia research with the researchers who need their help. This can make it faster to find new treatments for people who have dementia or might get it in the future.

How will I benefit from joining the Dementia Trials Accelerator?

You can choose to receive some of your results. You might be asked to join a research study or clinical trial to help prevent or treat dementia. Whether you're invited depends on the rules for that study. Not everyone will be asked or be able to take part. If you are invited, you will get more information about the study before you decide.

You might not get any direct benefit from the research done with your samples and information. But your participation could help other people who have dementia or might get it one day. The use of your samples and data may lead to the development of new drugs, treatments or tests by both commercial and academic organisations.

What are the possible risks or side-effects of taking part?

During your visit, you will do some tests and activities. Sometimes, these can make you feel a little tired. If you do feel tired, you can take a break or tell the staff.

When we take your blood, you might get a small bruise on your arm where the needle went in. You might also feel some discomfort while the blood is being taken, but it won't last long. The people taking your blood are trained and know how to do it safely.

How will the Dementia Trials Accelerator tell me about other studies I can join?

Other researchers will give us details about what type of people they are looking for to join their studies. If you might be a match based on the data and samples that you provided, we will contact you to give you information about the research study or clinical trial. We will also explain how you can take part. We will never share your personal information, including your contact details, with other research studies unless you give us permission to do so.

You do not have to join any research studies if you choose not to.

The information you share with us as part of this initiative will **only be used for the purpose of health and care research or to contact you about future options to participate in research**. It will not be used to make decisions about your healthcare or future services available to you, such as insurance.

There is more information about how your personal data will be used and stored as part of the Dementia Trials Accelerator in the privacy policy: www.dementia-trials.org.

Confidentiality

Researchers who analyse data cannot see your name or contact details. Results that are published will never identify you. Only approved researchers can access de-identified data for health and care research that serves the public interest. All studies must also be approved by the Dementia Trials Accelerator Access Committee, which includes members of the public.

We never share your personal contact details with other study teams unless you give us permission by signing up to be contacted about that research study or clinical trial. The team will contact you with information to help you make your decision.

What will happen to my samples?

We will study your blood to look for things like genes, proteins, and small molecules. This helps us understand if they have anything to do with getting dementia in the future.

We will keep all information about you safe and secure. Your samples will be stored at secure locations while the Dementia Trials Accelerator is ongoing.

We will send one sample to the Biomarker Factory, a laboratory in London run by the UK DRI for analysis of the proteins mentioned above.

One sample will be used to extract your DNA and store it for future analysis, which could include the whole sequence of your genome. Your genome is your body's 'instruction manual' that contains the information needed to make you, run you and repair you.

Remaining samples will be stored in freezers at Affinity Biomarker Labs. The samples and other non-identifiable information will be made available to other academic and commercial organisations in the UK and overseas to carry out analyses for research purposes only. This will only be done if the research studies are approved by a special group called a Dementia Trials Accelerator Access Committee and any applicable charge is paid. An access committee helps protect people's private information by making sure that only trusted researchers can use your information for approved purposes. The Access Committee includes representatives from organisations running the Dementia Trials Accelerator and participant and public representatives.

Who will have access to my samples and data?

So that the maximum information can be obtained from your participation in this initiative we may make your samples and data available to other researchers. Researchers who wish to access information or samples from the Dementia Trials Accelerator will have to apply to the Dementia Trials Accelerator Access Committee. We never share your personal contact details with other studies unless you give us permission by signing up to be contacted about research study or clinical trial. The team will contact you with information to help you make your decision.

Linkage to medical records

It is important that researchers understand as broadly as possible the factors concerning your health now, and in the future to identify as accurately as possible what puts people at greater risk of developing dementia, or other brain health related illnesses. We therefore require your consent to link data (such as your GP health records) held by UK NHS bodies and other UK public health bodies to the data held in the Dementia Trials Accelerator. This will provide information on the long-term health status of the participants.

Some examples of the data we might request include your GP records, medical notes, and details of hospital episodes. We will use current and historic data available now, and that which becomes available in the future.

You can withdraw this consent at any point.

What will happen to the results of this project?

The results of this project may be shared in many different ways, such as being published in medical journals, presented at meetings of scientists and reported to both the organisations running the Dementia Trials Accelerator and the Health Research Authority who oversee and review how research takes place in England. No personally identifiable information about you will be made available outside of the project team.

Who has reviewed and approved the Dementia Trials Accelerator project?

To protect your interests, all research is reviewed by an independent group of people called a Research Ethics Committee. This project was given a 'favourable opinion' by the South Central – Berkshire B Research Ethics Committee.

Contact details

If you have further questions before deciding whether to take part, please contact the Dementia Trials Accelerator team on 0118 403 2366 or email us at contact@support.dementia-trials-accelerator.org.

Thank you for reading the information sheet!

A copy of the participant information sheet and Informed Consent forms be downloaded online.

Your Data

HDR UK, UK DRI, Imperial and Affinity Laboratories Limited (Affinity Biomarker Labs) will act as the joint data controller for the storage and processing of personal data for this initiative. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you.

Data we collect about you
Personal data means any information about an individual from which that person can be identified. We collect, use, store and transfer different kinds of personal data:

Category	Details
Identity data	including first name, last name, date of birth, NHS number, mobile phone number.
Contact data	such as your email address, address, home and mobile telephone number and social media address.
Communications Data	including your communication preferences.
Technical data	such as internet protocol (IP) address, browser type and version and operating system and platform. Please see our cookie policy for further details.
Demographic and Diversity Data	such as date of birth, location, sex, gender identity, ethnicity, language preferences, qualifications, employment status, caring responsibilities
Health data	such as physical activity, medical history, daily activities, lifestyle habits, physical measurements such as weight and blood pressure, cognitive abilities

We use different methods to collect data from you including through:

- Direct interactions. You may give us your personal data by filling in a form on our website, attending an in-person assessment centre, corresponding with us by phone, email, social media or otherwise, when you sign up to our newsletter or register for an event.
- Automated interactions. As you interact with our website we may collect technical data by using cookies or similar technologies. Please see our cookie policy for further details.
- Third parties. When you register for an in-person assessment centre, sign up to an event or complete a survey via a third-party platform such as Inuvi, Eventbrite or Microsoft Teams, we will obtain your registration details from the platform operator.

People within the Dementia Trials Accelerator project team (see section 'Sharing your information with others') will use this information to do the activities outlined in this Participant Information Sheet or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate.

People who do not need to know who you are, like the people handling your samples, will not be able to see your name or contact details. Your data will have a code number instead.

We will need to use information from you and your records held by the NHS and other public health and social care bodies for this project. This information will include your initials, name, contact details, and NHS number.

Imperial College London is the establishment responsible for management of the tissue bank and is responsible for looking after your blood samples. HDR UK, UK DRI and Affinity Biomarker Labs are also responsible for looking after your information. We will keep all information about you safe and secure by:

- Data to be stored in a dedicated secure environment which underpins security measures.
- Data will be stored in ISO 27001 certified and/or Cyber Essentials accredited environment.
- Robust pseudonymisation has been implemented to prevent identification
- Access controls have been implemented to ensure only key personnel can access the data.
- We will write any reports in a way that no-one can work out that you took part in the study.

We use personally-identifiable information to conduct and facilitate research to improve health care and services. We have to ensure that it is in our legitimate interests, in the public interest or to comply within the law when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct the work outlined in the Participant Information Sheet.

Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.
- HDR UK and UK DRI - "legitimate interests"; as charities with the fundamental purpose of advancing health research in the UK, HDR UK and UK DRI have a legitimate interest in facilitating brain health related research. This means we can only use data in ways you would expect. We do this by providing information to you about how your data will be used and have completed a legitimate interests assessment to be clear how this work has a clear purpose, is necessary and balanced with your rights regarding your information.

- Affinity Biomarker Labs - “for compliance with a legal obligation" - in order to store your samples legally under the Human Tissue Act, Affinity Biomarker Labs must store relevant data.

Where special category personal information is involved (most commonly health data, biometric data i.e. fingerprints or facial recognition and genetic data, racial and ethnic data etc.), all organisations rely on “scientific or historical research purposes or statistical purposes.

Where we process personal data on the basis of a legitimate interest, then – as required by data protection law – we have carried out a balancing test to document our interests, to consider what the impact of the processing will be on individuals and to determine whether individuals’ interests outweigh our interests in how we collect and use the data. You can obtain more information about this balancing test by using the contact details at the end of this document.

International transfers

We may share data about you outside the UK for:

- Research related purposes to third-party organisations who have requested the data for research purposes and are approved to by the Dementia Trials Accelerator Access Committee to access to your data.

- Where necessary to provide access to a data processor / service provider who will utilise your personal data as instructed by us.

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.

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:

- Utilising organisations based within countries which 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 which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner’s Office (ICO) website - www.ico.org.uk

- We utilise the UK International Data Transfer Agreement (UK IDTA) or EU Standard Contract Clauses (SCCs) plus UK Addendum and undertake Transfer Risk Assessments.

- 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. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website - Personal data breaches: a guide | ICO

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above. Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

The following will be responsible for processing the data and samples provided to the Dementia Trials Accelerator:

- Other Imperial College London, HDR UK, UK DRI and Affinity Biomarker Labs employees (including staff involved directly with the research project or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London HDR UK, UK DRI and Affinity Biomarker Labs agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above).

- Biomarker analysis organisation. The Biomarker analysis site will analyse your blood sample for proteins. They will match your sample with a code unique to you, which will include a number and a bar code. This will be saved in their data inventory system and the results be returned to the Dementia Trials Accelerator to be added to the central data repository.

- In-person appointment provider (Inuvi). We will transfer your contact details, so they can remind you of your appointment. Inuvi will collect the data and samples provided at your in-person appointment. This will include your contact details, blood sample, blood pressure, height, weight, and an in-person cognitive test. They will store your personal data in their case management system. However, they transfer the data collected at the appointment based on what we told you in the participant information sheet.

- Online thinking and memory test provider (H2 Cognitive Designs LTD (H2CD) via the Cognitron platform). After completing the online thinking and memory test, your results will be shared with the provider so they can score your test. This data will be saved in their data inventory system and the results be returned to the Dementia Trials Accelerator to be added to the central data repository.

Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

Commercialisation

Samples / data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties without your consent. If we were approached by a future study or commercial company we would contact you to ask if you were willing to participate.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the Dementia Trials Accelerator. Your data will not be shared with a commercial organisation for marketing purposes.

Data Retention

We will only retain your personal data for as long as reasonably necessary to fulfil the purposes we collected it for.

Where we process personal data for marketing purposes or with your consent, we process the data until you ask us to stop and for a short period of 30 days after this (to allow us to implement your requests). We also keep a record of the fact that you have asked us not to send you direct marketing or to process your data so that we can respect your request in future.

Where we process personal data for provision of research services, we retain it for as long as is outlined in the participant information sheets/study protocol.

The 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 may need to keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of our work. 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 research or if you ask us to delete information which we are

required by law or have compelling legitimate interests to keep. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your other records, like your NHS records. If you do not want this to happen, tell us and we will stop.

If you wish to exercise any of these choices, please contact dataprotection@hdruk.ac.uk.

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, by contacting Dementia Trials Accelerator team either;

- by sending an email to contact@support.dementia-trials-accelerator.org, or
- by ringing us on 0118 403 2366 or
- On our website www.dementia-trials.org

What if something goes wrong?

Imperial College London, HDR UK and UK DRI hold insurance policies which apply to this initiative. If you experience harm or injury as a result of taking part, you will be eligible to claim compensation from an organisation without having to prove that organisation is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this process then you should immediately inform the Dementia Trials Accelerator team on 0118 403 2366 or contact@support.dementia-trials-accelerator.org.

How to make a complaint

If you wish to raise a complaint on how we have handled your personal data, please contact:

- HDR UK Data Protection via email at dataprotection@hdruk.ac.uk and/or via post at HDR UK Data Protection, 215 Euston Road, London, England, NW1 2BE

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

About the organisations

HDR UK is a limited company registered in England and Wales under company number 10887014. Its registered office is at 215 Euston Road, London, England, NW1 2BE.

UK DRI is a limited company registered in England and Wales under company number 1179589. Its registered office is at 338 Euston Road, London, NW1 3BT.

Imperial is a public research university of Exhibition Road, Faculty Building, London SW7 2AZ, Charity number 1179589).

Affinity Biomarker Labs is a limited company registered in England and Wales under company number 10566588. Its registered office is at Suite 602 Cumberland House, 80 Scrubs Lane, London, NW10 6RF.