Artificial Intelligence in Mammography Study (AIMS)

Detailed Study Information Leaflet

This NHS screening centre is taking part in a research study that is trialling a new technology that assists cancer specialists, and has the potential to improve NHS breast cancer screening. Our goal is to provide you and other women with an even better cancer screening service in the future.

This research has received NHS ethical approvals to include anonymised scans (images) from all women attending this screening centre for the duration of the study. However, if you would prefer your images not to be included in the study, it is very easy to opt out of being part of this research before you attend or within 3 months of your screening visit, and your care will not be affected in any way.

It's really important for you to know that this study will have no impact on your care, and the screening service will continue to run as normal.

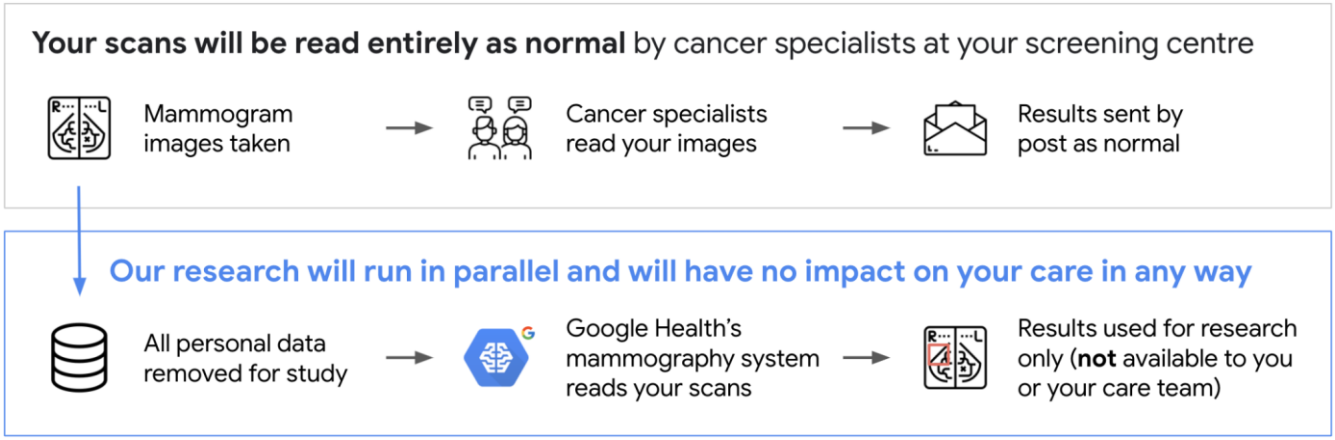
What is the purpose of the study?

1 in 8 women will be diagnosed with breast cancer during their lifetime. Breast screening aims to find cancers early, when treatment is more successful. In the UK breast screening programme, two cancer specialists (radiologists and radiographers) review the x-ray images (mammograms) taken during your visit. They decide if the mammogram is normal or whether further imaging or investigation is required. Any disagreements between the two specialists are reviewed further by a third specialist.

This research aims to test the ability of a new computer system developed by Google that uses a technology called artificial intelligence (AI) to help detect potential signs of cancer in the breast images (mammograms) that are taken during your screening visit. We have already completed a lot of research where we have shown that this technology is as good as an expert radiologist at identifying cancers on these scans. We believe that this technology has the potential to improve accuracy, safety, and patient experience of breast screening in the UK, and make the process more affordable for the NHS. It may also have a role in supporting NHS screening services and clinicians directly. We now need to understand how it works in a real world NHS setting.

In this study, we plan to test the AI system running 'silently' within the breast screening programme at your screening site. This means that the mammograms taken at your visit will

be read by the AI system but **the result will not affect your clinical care**. All mammograms will continue to be reviewed by cancer specialists as normal.



We will assess how the AI system can be integrated into the NHS screening pathway at Imperial College Healthcare NHS Trust and St. George's University Hospitals NHS Foundation Trust. We will test how quickly the AI can read the images and return results to the clinical site. Findings and lessons learnt from this study will help to design a screening pathway that may include AI as one of the readers. Our patients and their wellbeing are very important to us. We regularly conduct patient and public engagement workshops with a diverse group of participants. We value the feedback received from patients and members of the public and we receive their active input with study design and planning.

Why have I received this leaflet?

You have received this leaflet because you are a woman aged 50 to 70 years old undergoing routine breast cancer screening as part of the national breast screening programme at this centre. Everyone attending routine breast screening between 27-Nov-2023 and 22-Jan-2024 at your local mammography department will be informed of this study. We will include approximately up to 14000 women in this study overall.

Do I have to take part?

No. Your data (which includes images) will be used for the research study unless you decide to opt-out. As this study will use de-identified data (personal data such as your name, date of birth, and address will be removed and replaced by unique identifiers not derived or related to your data), we will not be collecting individual patient consent.

It is entirely up to you to decide if you do not want your data to be part of this study. Your care will not be affected in any way if you decide to opt-out of the study.

If you do decide to take part, there will be no further action required on your behalf. If you decide to take part, **you are still free to opt-out within 3 months of your screening visit**, and without giving a reason.

If you opt-out **before** your screening visit, your data and images will not be used for the study. If you opt-out **after** your screening visit, your data and images may have already been processed for the study, however we will confirm to you that your data and images have been deleted from our database and will not undergo further processing or be used for analysis.

If you would not like to take part in the study or you wish to withdraw from taking part at any time, please opt-out by phoning the research team on 0203 313 0147 or by visiting our website www.imperial.ac.uk/aiscreening. This will mean that we will not use your data or images for this study. You will not be disadvantaged if you choose to not take part in this study.

What will happen to me if I take part?

There will be no change in the order, timing or duration of your screening appointment by taking part in this study. Your images will be reviewed by at least two cancer specialists as normal and you will receive the results of this in the post. There will be no change in the time taken to receive your results.

For the research study, your data (which includes images) will be de-identified via pseudonymisation, meaning all your personal data such as your name, date of birth, and address will be removed, and replaced by unique identifiers, before transferred to the research team to be read by the AI system.

As this study does not involve any activities outside of your normal clinical care, you will not receive any payments or reimbursement of expenses for this study.

What do I have to do?

You do not need to notify anyone if you would like your data to be used for the study. If you would like to opt-out, please call us or visit our website using the details at the end of the leaflet.

Who is involved and why?

This study will take place across breast cancer screening centres within Imperial College Healthcare NHS Trust and St. George's University Hospitals NHS Foundation Trust. Royal Surrey NHS Foundation Trust and Google Health are also collaborative partners in this study.

Google Health was formed in November 2019. Their mission is to help everyone live more life every day through products and services that connect and bring meaning to health information. In partnership with clinicians, universities, and hospitals across the world, they have developed technology that uses artificial intelligence to assist in detecting cancer, predicting patient outcomes, preventing blindness and much more. Google Health aims to

partner with organisations such as the NHS to ensure we are building safe, inclusive, and equitable tools that meet the highest health data privacy and safety standards.

Google Health's AI system for mammography has been developed in collaboration with doctors that specialise in breast cancer screening in the UK to ensure the system is robust and effective in the NHS.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to taking part.

What are the possible benefits of taking part?

We do not anticipate any immediate benefits of taking part in this study. However, the information we get from this study will help us assess if artificial intelligence has the potential to improve future clinical care in the UK breast screening programme and worldwide, by providing more accurate reads, improving breast cancer detection, and by reducing the time to provide results to patients.

What do we do with your data?

For this study we will use the images taken during breast screening. We will also collect data such as your age, ethnicity, and the results of screening.

The clinical team at your screening centre will see your personal data such as your name, date of birth and hospital number as part of your clinical care records. To protect your privacy, all data (which includes images) will be de-identified via pseudonymisation, meaning your personal data will be removed and replaced with unique identifiers not derived from or related to it) before it is sent to the AI system. This means that the images cannot be connected to a specific individual.

For this study, the results from the AI system will be sent electronically to the hospital, and will be connected back to your hospital number. The results will only be available to the research team at the hospital, and will not be available to you or your NHS care team.

The study research team at your hospital and the research team from Royal Surrey NHS Foundation Trust may have access to your personal data, such as your name or NHS number in the process of de-identifying your data or while linking your data back to your hospital number. However, the study Sponsor (Imperial College London) and Google Health will only use de-identified data (which includes images) to perform the research and undertake study analysis.

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Where is the data going?

Once the data (which includes images) are de-identified, they are transmitted to the Google Health AI system for analysis. The AI system sends the result back to the screening site. The images or results are not stored by Google Health, meaning that Google Health cannot access your data once your images have been analysed and a result has been returned.

How will we use this information about you?

Imperial College London is the sponsor for this study and will act as the Joint-Controller with Imperial College London NHS Foundation Trust and St. George's University Hospitals NHS Foundation Trust for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for 10 years after the study has completed in relation to primary research data. The study is stated to finish in August 2024.

We will need to use information from you and your medical records for this research project. This information will include your name/hospital number/NHS number. People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that the 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 will not be able to see your name or contact details. Your data will have a unique identifier i.e., code number instead. We will keep all information about you safe and secure.

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

Will my clinical care team be informed of my involvement?

Your local mammography department will be told that your data will be used in this study. However, the results provided by the AI system will not be used for your clinical care in any way.

What will happen to the results of the research study?

When results from the study become available, a summary will be published on the study websites of the organisations involved in this study and in a medical journal and/or presented at a scientific conference. Findings will be shared with the NHS and the Breast Screening Programme. We will also present results at a formally designated Patient and Public Involvement and Engagement (PPIE) group whose interim and final meeting comments will be audited, presented to the research team and included in the final presentation of this work. Findings will also be disseminated through infographics and blogs aimed at the general public, with the assistance of our patient and public representatives. Your data (which includes images) or personal details will not be individually identified in any reports or

publications. Should you wish to see the results, or the publication, please contact us (details at the end).

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College 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 study then you should immediately inform your Site Investigator (Dr Mamatha Reddy, St. George's University Hospitals NHS Foundation Trust, mamatha.reddy@nhs.net; Dr Deborah Cunningham; Imperial College Healthcare NHS Trust, deborah.cunningham1@nhs.net) and the Project Lead (Prof. Hutan Ashrafian, Imperial College London, h.ashrafian@imperial.ac.uk). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

We do not anticipate any problems. However, if you have any concerns about the way you have been approached or treated by members of staff during the study, or wish to complain, please use the normal NHS complaint process. If you are still concerned and wish to complain, or query any aspect of the way you have been approached or treated by members of staff or about problems you may have experienced due to your participation in this study, contact the local mammography department lead and the Chief Investigator for this study, Prof. Ara Darzi. Additionally, the normal National Health Service complaints mechanisms are available to you.

Please contact the named study doctor at the end of this leaflet if you would like more information, or visit the Department of Health website: http://www.dh.gov.uk.

What happens when the research study stops?

Once the study ends, the AI system will no longer process data from the NHS sites involved in this study. The AI will not be immediately available to the NHS sites to use in clinical care.

Who is organising and funding the research?

Imperial College London (ICL) is the sponsor and has overall responsibility for this study. It is organised by the Institute of Global Health Innovation (IGHI). This study is being funded by an NHSx Accelerated Access Collaborative/NIHR grant.

You will not be paid for taking part in this study. Your doctor is not receiving any money or other payment for you to take part in the study.

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Who has reviewed the study?

This study has been submitted for review and approval to the National Health Research Authority, Research Ethics Committee, Confidential Advisory Group and Public Health England's Breast Cancer Screening Research Ethics Committee, and the. Imperial College London Research Governance Integrity Team (RGIT).

This study was given favourable opinion by the NHS Health Research Authority, East Midlands - Nottingham 1 Research Ethics Committee on 22 September 2022.

This study was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that this study should be supported, and the Decision Maker within the Health Research Authority approved this.

Legal basis

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest 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 and analyse the research study.

Our legal basis for using your personal 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. Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London rely/relies on "scientific or historical research purposes or statistical purposes

International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguard how your personal data is processed.

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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:

- Other Imperial College London employees (including staff involved with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London 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). 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 Research Collaborators / Partners in the study:
    - Imperial College Healthcare NHS Trust - research site and collaborator
    - St George's University Hospitals NHS Foundation Trust - research site and collaborator
    - Royal Surrey NHS Foundation Trust - technical research collaborator
    - Google Health - technology collaborator; only de-identified data (personal data removed and replaced with unique identifiers not derived from or related to it) will be shared for the purposes of running the artificial intelligence on breast screening mammograms

Potential use of study data for future research

If your data is used in this research study, the information collected either as part of the study or in preparation for the stud, may be provided to researchers running other studies at Imperial College London and 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.

What are your choices about how your information is used?

You can opt-out of being part of the study **within 3 months of your screening visit**, without giving a reason, but we may keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

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

You can find out more about how we use your information at

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from at www.imperial.ac.uk/aiscreening
- by asking one of the research team
- by sending an email to aimstrial@imperial.ac.uk

Complaint

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to aimstrial@imperial.ac.uk, or by ringing us on 0203 312 1310.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

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.

Contact for Further Information

If you want further information about the study, please contact our team on:

- aimstrial@imperial.ac.uk

You can also find information about the studies on the following website:

- www.imperial.ac.uk/aiscreening

For accessibility and inclusion - We also have an audio-friendly link to this information leaflet

- https://www.youtube.com/watch?v=_CIZn8XxjJU

A shorter version of this information leaflet is also available on our website in Polish, Portuguese, Spanish, Italian, Turkish, Tamil, Gujarati, Punjabi, Hindi, Urdu, Arabic, Korean, Cantonese, Mandarin.

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Thank you for taking the time to read this patient information leaflet.