

# Artificial intelligence in mammography study

<b>Submission date</b> 25/05/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/06/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/03/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

1 in 8 women will be diagnosed with breast cancer during their lifetime. It is a leading cause of cancer-related deaths among women worldwide. There is a need for rigorous large-scale studies to assess the performance of artificial intelligence (AI) for the diagnosis of breast cancer from breast scans (mammography). This should be done on diverse cohorts of women across multiple screening sites and on unenriched data representative of a true screening population. The aim of this study is to evaluate the performance of an AI system in detecting breast cancer on data representative of a true screening population.

### Who can participate?

Being a retrospective study, no participants are directly involved in the study. There will be no effect or change to any participant's care.

Retrospective study (Part A): Historical data from women 50-70 years old who had a mammography as part of the national breast screening programme. The study will evaluate the AI system based on its analysis of historical, de-identified cases from study sites.

Arbitration study (Part B): Participants in the reader study will be voluntarily recruited from participating sites. Readers must be either breast screening radiologists or film reading radiographers.

### What does the study involve?

Data will be collected from a mammography image database with patient consent. There will be no impact on patient care. The intervention is the AI system, assessed on de-identified retrospective breast screening cases and outcomes. The study will look at how specialists interact with the AI system in the arbitration clinic.

### What are the possible benefits and risks of participating?

The researchers do not anticipate any disadvantages or risks to taking part. They do not anticipate any immediate benefits from taking part in this study. However, the information from this study will help to 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 reducing the time to provide results to patients.

### Where is the study run from?

Imperial College London (UK)

When is the study starting and how long is it expected to run for?  
May 2021 to May 2024

Who is funding the study?  
National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
Clinical Trial Manager, a.sy@imperial.ac.uk

## Contact information

**Type(s)**  
Principal investigator

**Contact name**  
Prof Ara Darzi

**Contact details**  
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## Additional identifiers

**Integrated Research Application System (IRAS)**  
303782

**Protocol serial number**  
21SM7312

## Study information

**Scientific Title**  
Clinical validation of an artificial intelligence system to improve the quality, efficiency and experience of breast cancer screening

**Acronym**  
AIMS

**Study objectives**  
A novel AI system for breast cancer screening demonstrates the appropriate accuracy, safety, acceptability, and cost-effectiveness required for use as an independent reader within the NHS breast screening programme.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 14/02/2022, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8115; Nottingham1.rec@hra.nhs.uk), ref: 22/EM/0038

## **Study design**

Part A: retrospective diagnostic accuracy study; Part B: simulated usage of the AI system by readers in arbitration panels using retrospective data

## **Primary study design**

Observational

## **Study type(s)**

Screening

## **Health condition(s) or problem(s) studied**

Decision support in breast cancer screening

## **Interventions**

Data will be collected retrospectively from the OPTIMAM Mammography Image Database, with patient consent. There will be no impact on patient care. The intervention is the AI system, assessed on de-identified retrospective breast screening cases and outcomes. To understand how the AI system would perform within a "double reading" screening workflow, the study will look at how specialists interact with the AI system in the arbitration clinic.

## **Intervention Type**

Other

## **Primary outcome(s)**

Sensitivity and specificity of AI system cancer detection measured as the number of positive cases (cases considered positive if they received a biopsy-confirmed diagnosis of cancer within 39 months following the screening visit. Negative cases will require a negative result from the study screening visit, and another negative result at the subsequent screening visit at least 31 months later) compared to first, second and consensus reader decisions.

## **Key secondary outcome(s)**

1. Case recall rate, cancer detection, positive predictive value, negative predictive value, cancer detection rate, area under the receiver operating characteristic curve will be measured for AI system performance over the study dataset time period
2. Subgroup performance by factors including cancer type and grade, primary tumour size, patient age, breast density, prior cancer, prevalent and incident screens, ethnicity, device manufacturer, socioeconomic status, and screening site over the study dataset time period
3. Analysis of failure cases for the study dataset time period
4. Percentage of women that meet the eligibility criteria over the course of the study
5. Simulations of workforce impact assessment and health economic modelling over the study period
6. AI system localisation performance (if lesion position data available) over the study period
7. AI system performance in confirmed interval cancers (percentage of historical interval cancers

that the AI system flagged for recall, and qualitative agreement of the localisation in the original screening mammogram with the presence/absence of true radiological evidence) over the study period

**Completion date**

21/05/2024

## Eligibility

**Key inclusion criteria**

1. Women undergoing routine breast cancer screening (age 50-70 years) as part of the national breast screening programme from January 2016 onwards
2. Mammography images acquired using Hologic/Lorad, Siemens, or GE devices

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

50 years

**Upper age limit**

70 years

**Sex**

Female

**Total final enrolment**

0

**Key exclusion criteria**

Part A:

1. Women attending an assessment clinic or symptomatic clinic (i.e. not routine screening)
2. Women undergoing annual screening due to:
  - 2.1. High risk (lifetime risk >30% - e.g. faulty BRCA1, BRCA2, TP53)
  - 2.2. Moderate risk (lifetime risk 17-30%)
  - 2.3. Personal stratified follow up (e.g. indeterminate B3 lesions)
3. Presence of breast implants
4. Screens with incomplete (<4 standard screening views - e.g. due to abandoned screen)
5. Poor diagnostic quality imaging (which would be repeated)
6. Non-standard acquisitions beyond the routine 4 screening views
7. For negative or benign cases, women without a negative follow up screen approximately 3 years later (at least 31 months after initial screen), as this would preclude determination of a robust ground truth

Part B:

Same dataset as defined in Part A, with the same inclusion and exclusion criteria

**Date of first enrolment**

21/03/2022

**Date of final enrolment**

21/03/2024

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Teddington Memorial Hospital**

Hampton Road

Teddington

England

TW11 0JL

**Study participating centre**

**Surbiton Health Centre**

Ewell Road

Surbiton

England

KT6 6EZ

**Study participating centre**

**Edridge Road Community Health Centre**

Impact House

2 Edridge Road

Croydon

England

CR9 1PJ

**Study participating centre**

**Robin Hood Lane Health Centre**

Camden Road

Sutton  
England  
SM1 2RJ

**Study participating centre**  
**Queen Mary's Hospital**  
Roehampton Lane  
London  
England  
SW15 5PN

**Study participating centre**  
**Purley War Memorial Hospital**  
856 Brighton Road  
Purley  
England  
CR8 2YL

**Study participating centre**  
**Charing Cross Hospital**  
Fulham Palace Road  
London  
England  
W6 8RF

**Study participating centre**  
**St Mary's Hospital**  
Praed Street  
London  
England  
W2 1NY

**Study participating centre**  
**Ealing Hospital**  
Uxbridge Road  
Southall  
England  
UB1 3HW

**Study participating centre****Heart of Hounslow**

92 Bath Road  
Hounslow  
England  
TW3 3LH

**Study participating centre****Uxbridge Health Centre**

George Street  
Uxbridge  
England  
UB8 1UB

## Sponsor information

**Organisation**

Imperial College London

**ROR**

<https://ror.org/041kmwe10>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		10/03/2026	12/03/2026	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No