

# Providing data so computer systems can help with the early identification of lung diseases, leading to more rapid treatment and better survival rates

<b>Submission date</b> 03/03/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/05/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-develop-and-test-a-computer-programme-to-help-to-improve-the-diagnosis-of-lung-cancer#undefined> (added 05/05/2022)

### Background and study aims

In the UK, lung cancer is common with a very low 5-year survival rate as most patients are diagnosed at a late stage. Early detection on a CT scan when the cancers are small and seen as a nodule has been shown to improve survival.

DART will work with NHS England's ambitious Lung Cancer Screening programme using CT to collect clinical, CT and histology data for research aimed at improving lung cancer diagnosis and screening using artificial intelligence, AI.

If DART is successful, using artificial intelligence we will speed up the time to diagnose lung cancer whilst also identifying incidental harmless nodules on CT. DART aims to: remove the need for other investigations such as lung biopsies, making investigations safer and quicker; help pathologists diagnose lung cancer using; help patients by providing their doctors with more information on lung and heart function; improve patient selection for lung cancer screening.

DART aims to improve screening using AI, resulting in the avoidance of additional tests and biopsies which cause great patient anxiety, take time and are expensive.

DART will develop an AI algorithm for histology so that specimens from lung biopsies and resections can also be analysed in a similar fashion to CT scans.

Patients with lung cancer often have damaged lungs from smoking making surgery or radiation treatment unsafe. DART plans to develop an AI technique that can be used on all lung CT scans performed. As smoking can cause heart disease, patients screened for lung cancer often have heart disease. DART aims to use AI to see if we can identify this from their CT scans.

We will develop a specific risk model for Lung Cancer Screening selection, that outperforms published risk models that have been developed in academic institutions but are not used in clinical practice.

Who can participate?

To aid our research, it is important to gather data from as many people attending Lung Health Checks as possible. However, if you do not want your data included, now or at any time, please tell us using the contact details below

What does the study involve?

Computers will be to conduct additional analysis of scans and data from those attending lung health checks. It will not require any extra time or visits and will not interfere in any way with the standard health care.

Personal information will be kept private, but an NHS research laboratory will be able to link a patient's your data (health records, scans, biopsies and resections) accurately.

What are the possible benefits and risks of participating?

There are no health risks to participating. We will anonymise data by removing the code before it is used by researchers so there is no link back to patients, who will never be identified in research or publications.

There are no immediate benefits to participants, but participation will contribute towards:

- If found at an early stage, lung cancer is curable
- DART will develop an Artificial Intelligence software programme that is faster and accurate to assist doctors to interpret CT scans and detect cancer
- This will speed up the time to diagnosis and reduce the numbers of additional scans and biopsies that might be needed in future.
- As smoking can cause heart disease, patients screened for lung cancer often have heart disease, and we aim to use AI to see if we can identify this from their CT scans as well.

Where is the study run from?

The study is run from the University of Oxford (UK)

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

Data will be collected from lung health checks between 1st October 2020 and 31st July 2023

Who is funding the study?

The study is funded by UK Research and Innovation

Who is the main contact?

Prof Fergus Gleeson, Professor of Radiology, University of Oxford, [fergus.gleeson@oncology.ox.ac.uk](mailto:fergus.gleeson@oncology.ox.ac.uk)

## Contact information

**Type(s)**

Principal investigator

**Contact name**

Prof Fergus Gleeson

**ORCID ID**

<https://orcid.org/0000-0002-5121-3917>

**Contact details**

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Old Road Campus

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Oxford

United Kingdom

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[fergus.gleeson@oncology.ox.ac.uk](mailto:fergus.gleeson@oncology.ox.ac.uk)

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

301420

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

PID15885-A002-SP001, IRAS 301420, CPMS 51308

## Study information

**Scientific Title**

The integration and analysis of Data using Artificial intelligence to improve patient outcomes with Thoracic diseases

**Acronym**

DART

**Study objectives**

To develop an artificial intelligence prediction model for malignancy in pulmonary nodules detected on CT scans based on nodule characteristics including histology, and patient clinical risk profiles using machine deep learning models.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 24/02/2022, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 21/WM/0278, CAG 22/CAG/0010

**Study design**

Retrospective data collection

**Primary study design**

Other

**Study type(s)**

Other

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

Early diagnosis of lung cancer

**Interventions**

Data will be collected retrospectively from Lung Health Check centres, with patient consent. There will be no impact on patient care.

**Intervention Type**

Other

**Primary outcome(s)**

1. Diagnosis of cancer measured by expert opinion using Targeted Lung Health Check spreadsheets and CT scans, collected from patients attending lung health checks first visit.
2. Diagnosis of cancer measured by AI model using Digital images collected from the CT scan.

**Key secondary outcome(s)**

1. Diagnosis of cancer determined by expert histology opinion from resection and biopsy specimens
2. Diagnosis of cancer determined by the AI model from the digitised resection and biopsy specimens

**Completion date**

31/07/2023

**Eligibility****Key inclusion criteria**

Participants attending NHSE targeted lung health checks

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Patients who request to not be included in any studies as part of the NHS opt out.

**Date of first enrolment**

01/10/2020

**Date of final enrolment**

31/07/2023

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****University of Oxford**

Old Road Campus Research Building

Oxford

United Kingdom

OX3 7DQ

**Study participating centre****Lancashire Teaching Hospitals NHS Foundation Trust**

Preston Road

Chorley

United Kingdom

PR7 1PP

**Study participating centre****Bradford Teaching Hospitals NHS Foundation Trust**

Bradford

United Kingdom

BD9 6RJ

**Study participating centre**

**Liverpool Heart and Chest Hospital NHS Foundation Trust**

Thomas Drive  
Liverpool  
United Kingdom  
L14 3PE

**Study participating centre**

**Kettering General Hospital**

Rothwell Road  
Kettering  
United Kingdom  
NN16 8UZ

**Study participating centre**

**University Hospitals Coventry and Warwickshire (UHCW) NHS Trust**

Clifford Bridge Rd  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**

**Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust**

Doncaster Royal Infirmary  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**

**Hull University Teaching Hospitals NHS Trust (HUTH)**

Anlaby Rd  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**

**Luton and Dunstable University Hospital NHS Foundation Trust**

Lewsey Rd  
Luton  
United Kingdom  
LU4 0DZ

**Study participating centre**

**Royal Brompton & Harefield Clinical Group, Part of Guy's and St Thomas' NHS Foundation Trust**  
Sydney Street  
London  
United Kingdom  
SW3 6NP

**Study participating centre**

**Salford Royal Foundation Trust**  
Stott Lane  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**

**University Hospital of North Staffordshire**  
Princes Road  
Stoke-on-trent  
United Kingdom  
ST4 7LN

**Study participating centre**

**The Newcastle upon Tyne Hospitals NHS Foundation Trust**  
Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**

**Gateshead Health NHS Foundation Trust Laboratory**  
Queen Elizabeth Hospital  
Sherriff Hill  
Gateshead  
United Kingdom  
NE9 6SX

**Study participating centre**  
University Hospital Southampton NHS Foundation Trust  
Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

## Sponsor information

### Organisation

Research Governance, Ethics & Assurance Team (RGEA), University of Oxford

### ROR

<https://ror.org/001aqnf71>

## Funder(s)

### Funder type

Government

### Funder Name

UK Research and Innovation

### Alternative Name(s)

UKRI

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

De-identified data will be shared with academic and industrial partners as approved by the CI

### IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes