

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

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

Plain English Summary

<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

Study website

<https://dartlunghealth.co.uk>

Contact information

Type(s)

Principal Investigator

Contact name

Prof Fergus Gleeson

ORCID ID

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

Contact details

Department of Oncology

University of Oxford

Old Road Campus

Research Building

Oxford

United Kingdom

OX3 7DQ

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fergus.gleeson@oncology.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

301420

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 hypothesis

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

Secondary study design**Study setting(s)**

Community

Study type(s)

Other

Participant information sheet

<https://dartlunghealth.co.uk/patients/> see Downloadable documents

Condition

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/10/2020

Overall study end date

31/07/2023

Eligibility

Participant inclusion criteria

Participants attending NHSE targeted lung health checks

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

300,000

Participant exclusion criteria

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

Recruitment start date

01/10/2020

Recruitment end date

31/07/2023

Locations

Countries of recruitment

England

United Kingdom

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

Sponsor details

Joint Research Office
1st floor, Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB

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ctrng@admin.ox.ac.uk

Sponsor type

University/education

Website

<https://www.ukri.org/>

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

Publication and dissemination plan

Planned publication in a high-impact, peer-reviewed journal

Intention to publish date

30/09/2023

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?
HRA research summary			28/06/2023	No	No