**Your role in improving the diagnosis of lung cancer**

**Information sheet**

**Oxford University is leading a project to improve the diagnosis of lung cancer called “The Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases”, commonly known as DART.**

The DART study has a main aim of using Artificial Intelligence (AI) to improve the diagnosis of Lung Cancer.

If our research is successful, we will be able to identify nodules that are not cancers and are harmless so we can speed up the time to diagnose lung cancer in patients with small nodules on CT scans that are early lung cancers. We may also be able to remove the need for other investigations such as lung biopsies in some patients, which will make investigating patients for suspected lung cancer safer and allow the NHS to reach more people for Lung Health Checks.

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, please tell us using the contact details below.

In the UK, lung cancer is the third most common cancer (~48,000 cases per year) but is the most lethal cancer and is responsible for 21% of all cancer deaths (~35,000 deaths per year). The number of patients with lung cancer has increased over the past decade.

If found at an early stage, lung cancer is curable. Unfortunately, the symptoms of lung cancer often only appear when the tumour is already large and has spread beyond the lung. Consequently, more than 75% of people with lung cancer are diagnosed at a late-stage, when the 5-year survival rate is very low at less than 5%.

Therefore, early detection and treatment of asymptomatic patients is crucial. Detecting lung cancer early when it is small and seen on a CT scan as a small nodule is now recognised as the best way to do this. These CT scans may be carried out for a variety of reasons: to assess a lung nodule seen on a CXR; if a patient has symptoms suggestive of lung cancer; or for other clinical indications such as chest pain; or as part of a lung cancer screening programme.

Once a nodule is detected on CT, it is critical to determine if it is benign, as the vast majority of nodules detected on CT are not due to cancer. About 97% of all nodules seen on CT scans performed for lung cancer screening are not due to a cancer and are just a benign incidental nodule that causes the patient no harm, but, to be absolutely sure it is not cancer, they often require multiple scans and sometimes even biopsies and surgery to find out if they are a cancer. These additional tests and biopsies cause great patient anxiety, take time and are expensive.

NHS England have launched an ambitious programme of Lung Health Checks to help detect lung diseases, especially lung cancer, early and improve survival in those people where it is detected. The ambition of this study, DART, is to see if we can further improve some of the aspects of the Lung Health Check and help the NHS to make them available to more people.

There have recently been great advances in computer Artificial Intelligence, AI, and these have also been applied to characterising lung nodules detected on CT scans. AI is also now being applied to histology slide specimens, because these can be digitised to produce images similar to CT scans.

We aim to develop an Artificial Intelligence software programme that can interpret CT scans and if there is an abnormality tell us how likely it is to be cancer. This will speed up the time to diagnosis and reduce the numbers of additional scans and biopsies that might be needed in future. Our biggest aim is to see if having a scan via a Lung Health Check centre can reduce the need for any additional tests. We have already developed an AI programme for small nodules on CT scans discovered when patients have scans for other reasons. This study looks to compare the accuracy of it against diagnoses by doctors but each AI programme needs to be developed for specific patient groups. Therefore it is important to gather and analyse data from the majority of people who have a scan which shows they do not have cancer, as well as from the few whose early cancer can be picked up and treated.

We also aim to develop AI for histology so that specimens from lung biopsies and resections can be analysed in a similar fashion to CT scans. We will then be able to help pathologists in diagnosing lung cancer from slides and see if we can combine the AI methods we develop for CT and histology, and use this new AI method to improve the AI for nodules seen on CT.

Patients with lung cancer often have damaged lungs from smoking and this damage often determines the type of treatment that patients may have, because very damaged lungs can make surgery or radiation treatment unsafe. We have developed a technique that appears to be able to predict this damage from CT scans, but this requires computer scientists to do this manually over days. We plan to turn this into an AI technique, so that it can happen in seconds, and can be used on all lung CT scans performed for any cause including lung cancer screening.

Additionally, 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.

Researchers in Oxford have developed a risk model – QRisk, that is used by GPs to determine the risk of and need for investigation in millions of patients attending GP surgeries in England for diseases such as cancer and coronary artery disease, but is not specific for lung cancer. We aim to develop a similar risk score for patients who may be invited for Lung Health Checks.

Your involvement – We wish to collect the information from you that is generated by your attendance at the Lung Health Check centre. This will provide us with information related to the CT scan images and any biopsies or operations that you may have on your lungs. This data will be given a code in place of information that identifies you, and will be transferred securely to Oxford University Hospitals NHS Foundation Trust. Once we have anonymised (removed the code, so there is no link back to you) we will work with academics in the University of Oxford and with two companies, that we have been working with for a number of years.

1. An Artificial Intelligence company – Optellum Ltd – to develop the AI algorithms. We have been working with Optellum for 6 years and have already developed one AI programme, and now wish to develop an AI programme specifically for nodules identified when scanning patients at Lung Health Check Centres.

2. Roche Ltd – We have been working with Roche for many years in the University, and the DART team have been working with them for 2 years. They have developed a scanner that digitises slides to produce images that we can analyse in a similar fashion to CT scans. We aim to develop an AI programme that is able to tell from scanned slides whether the sample is cancer or not and if it is a cancer, what type.

This study has been reviewed and approved by the

West Midlands Black Country Research Ethics Committee, reference 21/WM/0278.

. For more information see [www.dartlunghealth.co.uk](http://www.dartlunghealth.co.uk/).

Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

The legal basis for the processing and storage of personal data for DART is that it is ‘a task in the public interest’ (article 6(1)(e)) and, that sensitive personal data is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (article 9 (2) (j), based on Article 89(1)).

Data will be held securely by Oxford University Hospitals NHS Foundation Trust. Demographic data such as names, addresses and postcodes will be deleted automatically from the data sources if received. NHS and hospital numbers will be held separately and securely so that we can link data received from different sources, but they will be replaced with a study number before data and images are made available to the study management team, who will not be able to recognise patients from the data they have available. When the study releases data for analysis, only the kinds of data required for the analysis will be supplied, and those datasets will have further protections such as shifted dates, and anonymised care locations and staff identifiers.

Importantly, whilst the information received is specific to each trial participant, no individual person will be identifiable in any publication arising from this work. Your personal data will not be shared with any third parties and will not be used for any automated decision making or profiling.

Under Section 251 of the NHS Act 2006, we have permission to conduct this study without consent.

We have special permission to conduct the DART study without study-specific consent (i.e. link, transfer, process and analyse the data) from the Confidential Advisory Group. This permission is given under Section 251 of the National Health Service Act 2006 and its current regulations, the Health Service (Control of Patient Information Regulations 2002) (CAG reference number: [To be added]).

**What to do next?**

If you decide at any time that you do not want your data to be used in this way you can withdraw it without affecting your medical care, by contacting your local site (details below) quoting either your NHS number (preferred), or your name and date of birth if you don’t know it. The study team will then remove all your data from the database.

Data protection regulation provides you with control over your personal data and how it is used. Further information about your rights with respect to your personal data is available at <https://compliance.admin.ox.ac.uk/individual-rights> or by contacting the study team using the details below. The University’s data protection officer can be reached at data.protection@admin.ox.ac.uk.

If you have further questions or are not happy with the way your data has been handled, please contact the study team using the contact details below. Alternatively, you can contact the study sponsor on 01865 616480 or ctrg@admin.ox.ac.uk. You have the right to lodge a complaint with the Information Commissioner’s Office (0303 123 1113 or [www.ico.org.uk](http://www.ico.org.uk)).

Contact details for your local site

[insert preferred name, email, phone, website, etc]

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Lung Health Checks

[Each to add own preferred contact details]

Blackburn with Darwen and Blackpool

Bradford with Craven

Cheshire and Merseyside

Corby

Coventry

Doncaster and Bassetlaw

Hull

Liverpool

Luton and Thurrock

Newcastle and Gateshead

RM Partners (London)

Salford

Southampton

Stoke

West Yorkshire and Harrogate