

Your role in improving the diagnosis of lung disease

Information Sheet and Privacy Notice

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.

This study aims to use a computer programme known as Artificial Intelligence (AI) to improve the diagnosis of Lung Cancer. NHS England has launched an ambitious programme of Lung Health Checks to help detect lung diseases, especially lung cancer, at an early stage to improve survival in those people where it is detected. The ambition of this study, DART, is to see if we can further improve some aspects of the Lung Health Check and help the NHS to make them available to more people.

1. Your contribution to the study

We wish to collect the health information generated by your attendance at the Lung Health Check centre. This will provide information related to the CT scan images and any biopsies or operations you might have on your lungs. This data will be given a code to replace any information that identifies you, and will be transferred securely to Oxford University Hospitals NHS Foundation Trust.

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 at the end of this document.

2. Privacy and safety

Research is a task that we perform in the public interest. It is important to help us understand more about illness and offer earlier and more effective treatment for people affected. 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.

Data will be held securely by Oxford University Hospitals NHS Foundation Trust. Details 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 we can link data received from different places, but they will be replaced with a study number before data and images are made available to the study team, who will be unable to recognise patients from the data they have available. When the study releases data for analysis, only the details needed for the analysis will be supplied, and these will have further protections such as use of different dates, and anonymised care locations and staff identifiers.

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

This study has been reviewed and approved by the Black Country REC, reference 21/WM/0278. For more information see www.dartlunghealth.co.uk .

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 support 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: 22/CAG/0010).

All cancer data is used for the cancer registry in the UK to help improve understanding of who is affected in the public interest and this information will give another essential layer for this much needed research.

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)).

3. If you don't want to take part

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 current 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.

4. How data will be used

Once we have anonymised data (removed the code, so there is no link back to you) we will work with academics in the University of Oxford and two companies, that we have been working with for a number of years.

1. We've been working with GEHC for 20 years to develop an AI tool to identify smoking related lung and health disease.
2. An Artificial Intelligence company – Optellum Ltd – is going 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.

3. 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.

All three companies are providing funding for staff, equipment and specimens to enable this research. It is also funded by CRUK and Innovate UK.

5. Why is DART developing Artificial Intelligence (AI)?

There have recently been great advances in computer Artificial Intelligence (AI) and that have been applied to characterising lung nodules detected on CT scans. AI is now being applied to histology (the microscopic study of tissues) 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, that is more accurate than healthcare professionals who currently read images, 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 way to CT scans. We will then be able to help pathologists diagnose lung cancer from slides and see if AI methods developed for CT and histology can be combined and used to improve AI for nodules shown on CT.

Patients with lung cancer often have damaged lungs from smoking and this often determines the type of treatment 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. Creating a risk model means that the service is focusing on people who are most likely to develop this illness and doing fewer tests/ using less resource on people who may be at no or low risk.

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.

6. Scientific background

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.

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 treatable. Unfortunately, the symptoms of lung cancer often only appear when the tumour is already large and has spread beyond the lung. As a result, more than 75% of people with lung cancer are diagnosed at a late-stage, when the 5-year survival rate is low .

Therefore, early detection and treatment of people without symptoms is crucial. Detecting lung cancer early when it is 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 chest x-ray; 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 harmless, 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 cause the patient no harm. However, 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.

7. Useful links and contacts

If you have further questions or are unhappy 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

RGEA.sponsor@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).

Contact details for your local site: **[insert preferred name, email, phone, website, etc]**

Research team

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List of co-investigators at <https://dartlunghealth.co.uk/team/>