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Lung Health Check pilot: Ireland's flagship lung cancer screening trial

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ABSTRACT

Introduction Low-dose chest CT (LDCT) has demonstrated the ability to detect early-stage lung cancer (LC) and improve disease-specific mortality in high-risk individuals. Use of LC risk scores such as the Prostate, Lung, Colorectal, Ovarian Model Score ($PLCO_{M2012}$) improves the sensitivity, specificity and positive predictive value for LC screening. Screening programmes have identified that primary care participation, patient engagement and improved accessibility may enhance the success of LC screening. Currently, there is no LC screening programme in Ireland. This first pilot study of LC screening will investigate (1) the feasibility, including uptake, of LC screening in a community setting, based on primary care-based participant invitation with mobile CT scanning and (2) novel blood/breath biomarkers in high-risk individuals who participate in the LC screening trial, to identify biologic parameters that may supplement existing risk scores, to maximise LC early detection.

Methods and analysis In a pilot feasibility clinical trial, approximately 30 000 adults aged between 55 and 74 from participating general practitioner (GP) practices will be invited to a 'lung health check (LHC)' prescreening, involving a telephone assessment of eligibility and risk status, based on the $PLCO_{M2012}$/Liverpool Score V.2. High-risk individuals will be invited to the LHC, which will take place in a mobile unit strategically located in the community and include a respiratory disease assessment, baseline spirometry, smoking cessation advice, an LDCT and in a selected cohort, blood/breath/sputum biospecimen collection. Two rounds of screening will take place at an interval of 12 months.

Ethics, dissemination and registration details In this pilot feasibility trial, the uptake of LC screening using a community-based strategy among high-risk participants will be investigated. The study has been approved by Beaumont Hospital Research Ethics Committee and is registered with clinicaltrials.gov (NCT07099027). Novel features of our design include directly calling participants and our translational arm of the study, which will focus on blood/breath/sputum biomarkers associated with LC.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Lung cancer screening is recognised to reduce lung-cancer related mortality, but implementation challenges have limited widespread introduction

WHAT THIS STUDY ADDS

⇒ In this pilot study, we will explore the use of a community-based engagement strategy to foster uptake in lung cancer screening, with the primary aim of assessment of feasability

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ We hope this will provide a strategy for Ireland and other countries to develop successful national lung cancer screening programmes

INTRODUCTION

Lung cancer is the leading cause of cancer-related death in both men and women and leads to more deaths from cancer than breast, colon and prostate cancer combined.[1] Identifying those at risk for lung cancer with an early detection method such as a low-dose CT (LDCT) scan has been shown to reduce lung cancer mortality by 20%–26% in two large clinical trials across the USA and Europe.[2 3] A review of the evidence by public health experts has revealed significant issues with attendance and implementation of early detection programmes internationally, with few national lung cancer screening programmes in Europe. Barriers to uptake in screening programmes include a perceived avoidance of hospital facilities and a fatalistic attitude towards lung cancer screening in deprived communities.[4] In the UK Lung Screening (UKLS) trial, McDonald *et al* noted that the likelihood of lung cancer risk increased with socioeconomic deprivation, but conversely,

attendance at lung cancer screening fell.[5] Reducing barriers to participation is a critical challenge to the implementation of early detection programmes for lung cancer.

Researchers and clinical implementation groups in the UK have been leading initiatives aimed at addressing these issues through the launch of numerous implementation pilot trials that have led to the creation of high-quality and cost-effective programmes.[6–8] Their widespread success led to a recommendation by the UK National Screening Committee to recommend a national lung cancer screening programme in the UK in 2022.[9] The National Health Service (NHS) England programme plans to scan over a million participants per year by 2029 and identify 9000 extra lung cancer cases per year. These initiatives were designed in the context of the NHS, in which governance of primary care and hospitals is within the same remit. In the Republic of Ireland (ROI), general practitioners (GPs) operate as private enterprises with partial funding through the state. Therefore, using individual GP practices carries specific challenges within the ROI when recruiting participants.

In addition to the risk of lung cancer, approximately 50% of those who are lifelong individuals who smoke will develop chronic obstructive pulmonary disease (COPD) at some stage in their lives.[10] Despite this, 30% of those who present to hospital emergency departments with emergent COPD have had no formal diagnosis.[11] Smoking cessation advice and treatment can improve outcomes for this vulnerable population, highlighting the importance of incorporating a respiratory assessment and intervention programme into pilot screening programmes.[12] Finally, predictive algorithms used in this and other screening programmes remain imperfect, with a risk of overdiagnosis and thus potential harm.[13] We will use the Prostate, Lung, Colorectal, Ovarian Model Score ($PLCO_{M2012}$) and Liverpool Score V.2 (LLPv2).[13 14] In an exploratory analysis, we will compare the performance of these scores to other validated models, which will provide data for future larger validation studies of current and novel risk stratification strategies. Additionally, we will collect breath, blood and sputum samples from consenting participants to investigate novel genomic, immunological and proteomic signatures of lung cancer, which may ultimately be used to refine current lung cancer risk scores.

The Beaumont RCSI Irish Cancer Society Lung health check (LHC) pilot clinical trial will enrol participants at high risk for the development of lung cancer with the primary aim of exploring the feasibility of an LHC pilot which incorporates an LDCT, respiratory disease assessment and spirometry, smoking cessation advice and translational biospecimen collection for biomarker analysis in the ROI.

Box 1 Summary of primary endpoints and key secondary endpoints

Primary endpoint

⇒ The proportion of high-risk eligible participants aged 55–74 years who participate in a community-based LHC.

⇒ The proportion of invited participants who undergo telephone assessment.

Secondary endpoints

Diagnosis of lung cancer

⇒ Proportion of participants that attend a LHC visit who are subsequently diagnosed with lung cancer.

⇒ Number of participants referred to the hospital Rapid Access Lung Cancer Clinic, as a result of the LHC.

Clinical management outcomes

⇒ Frequency of detection and management of incidental findings from low-dose CT scan.

⇒ Detection and management of chronic obstructive pulmonary disease from baseline spirometry and respiratory health questionnaires.

⇒ Nodule detection rate (definitions as per British Thoracic Society guidelines).[13 14 17]

⇒ Smoking rates before and after a brief smoking intervention followed by opt-out referral to public health led community-based smoking cessation programme for those who currently smoke, as part of the LHC.

Translational outcomes

⇒ Identify genomic features of high-risk participants for the development of lung cancer, in breath, sputum and blood.

⇒ Identify proteomic features of high-risk participants for the development of lung cancer, in blood.

⇒ Immunological features of high-risk participants for subsequent development of lung cancer, in blood.

Health economic outcomes

⇒ Cost of establishing and running the LHC pilot (intervention costs).

⇒ Trial-based cost-effectiveness: cost-per-participant invited to screening/part taken in screening.

⇒ Model-based long-term cost-effectiveness.

⇒ Distributional cost-effectiveness.

LHC, lung health check.

METHODS AND ANALYSIS

In this study, our primary aim (see box 1 for endpoints) is to investigate the feasibility of an LHC pilot in the ROI. Additionally, we are seeking to:

Secondary aims

1. Identify the incidence, stage, treatment and outcomes of participants diagnosed with lung cancer through a mobile community-based screening unit.
2. To assess the uptake of smoking cessation interventions among those who smoke.
3. To estimate the proportion of participants with known or newly diagnosed respiratory disease and their management.
4. Identify breath, blood and sputum-based biomarkers for early detection of lung cancer.
5. Explore the optimal mechanism for the assessment of eligibility for lung cancer screening in ROI for further development of validation studies.

6. Explore the cost-effectiveness of lung cancer screening.

Invitation

Under the General and Data Protection Regulations in the European Union, primary care teams cannot share a patient's clinical details with a third party without explicit consent or only under very select circumstances. Given that primary care and secondary care in ROI are separate entities, these laws apply to our study. Thus, we attained a consent declaration from the Health Research Consent Declaration Committee (HRCDC) (24–005-AF1) for the sharing of selected primary care data for the purpose of identifying suitable participants based initially on age. This approach is slightly different from that used in national screening programmes, given that this is being conducted as part of a research study rather than standard clinical pathways. Centric Health primary care practices are a privately owned group of primary care practices in the catchment area of North Dublin and the North East region and are key collaborators on this project. They have a centralised electronic database with the availability of unified communal communications. Thus, we successfully attained an HRCDC consent declaration to allow Centric to share personal data with the study team in order to invite participants.

Participants aged between 55 and 74 years will be invited to participate in the LHC pilot study by letters and low-burden patient information leaflets sent from their GP. Prior to receiving invitation letters, potential participants will be notified by a text message from their GP in advance. The invitation letter includes the time and date when the participant will receive a phone call from the study team. The low-burden patient information leaflet includes a lay overview of the study and relevant information for the participant. The approach of the study team contacting the participant directly is not a standard approach in lung cancer screening pilots.[6 13] However, this pilot is a clinical trial and, as such, is restricted to participants who are registered patients of the GP partner.

When potential participants are contacted by the study team, their consent is sought prior to determining their eligibility and risk scores. The risk scores are the $PLCO_{M2012}$ and LLPv2, which will calculate lung cancer risk. The $PLCO_{M2012}$ and LLPv2 are both validated risk scores that predict the 10-year risk of the development of lung cancer based on sociodemographic, clinical and smoking characteristics.[13 14] Participants with a $PLCO_{M2012} \geq 1.51\%$ or LLPv2 $\geq 2.5\%$ will then be formally invited to a community-based LHC visit at a specific date, time and location.

Participants will be invited to attend the mobile LDCT unit, which will be at four locations that correspond with associated GP practice zones in the North Dublin and the North East region during this pilot. These locations were chosen to ensure ease of access for the participant cohort.

Community-based LHC locations

The Gaelic Athletic Association (GAA) is Ireland's largest sporting community-based organisation, with clubs throughout the country. To bring the LHC pilot away from the hospital environment and to a community setting, individual GAA clubs in the target areas were approached. In collaboration with local GAA clubs, the mobile screening units will be located in the grounds of these facilities.

Interventions

Participants who attend the LHC pilot mobile screening unit will be asked to participate in the following (see figure 1).

1. Respiratory Assessment questionnaire and quality-assured spirometry, Modified Medical Research Council Score and a brief consultation with a respiratory nurse.
2. Smoking cessation advice (brief intervention with a respiratory nurse and opt-out referral to a national smoking cessation programme).
3. LDCT scan (follow-up in 1 year (T1) if normal or sooner as clinically indicated (T0+3).
4. Collection of breath/blood/sputum samples for translational research in selected cohorts (optional and no follow-up).

Within this data collection, we are collecting data on ethnicity, education standards and financial self-assessment, which will provide surrogates of socioeconomic deprivation.

Smoking cessation and respiratory assessment

Smoking cessation is a key public health intervention for lung health. In this study, through collaboration with the Health Service Executive (HSE) Quit programme, participants who indicate that they currently smoke will have an initial, brief smoking cessation consultation on the mobile screening unit and will then be referred through an opt-out mechanism to the Irish HSE Quit programme. This is a free, local, personalised smoking cessation plan with one-to-one support. This is a critical part of the LHC pilot, as there is a body of evidence supported by guidelines that concurrent lung cancer screening and smoking cessation reduce lung cancer mortality.[15]

Unlike many other studies, a clinical pathway has been designed for participants who have previously undiagnosed airway obstruction (AO) on spirometry assessment (see online supplemental appendix 1). Participants will be automatically referred to their GP or a community respiratory physician, depending on the severity of AO and symptoms.

LDCT result and follow-up

Based on the LDCT result, one of the following items will be actioned (See figure 1).

1. A follow-up scan in 1 year (T1).

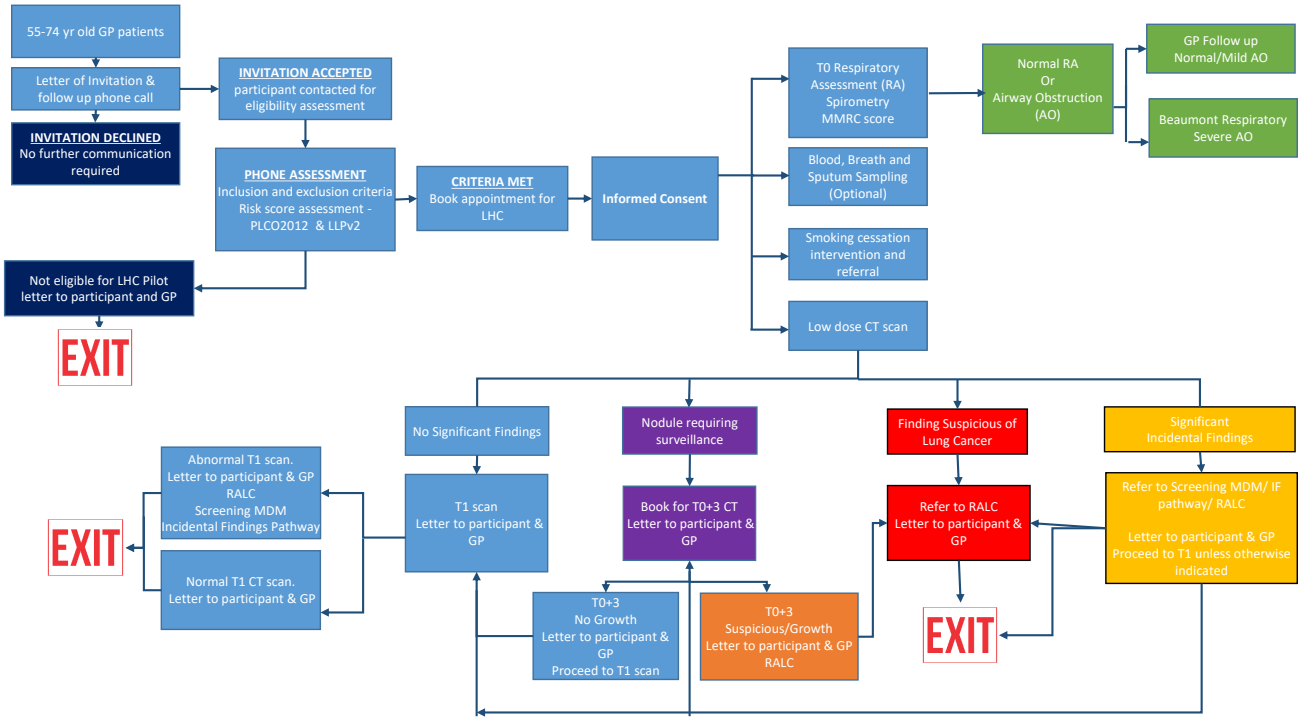

Figure 1 Study schema. Outline of patient journey through the LHC programme. COPD, chronic obstructive pulmonary disease; CAT score, COPD assessment test; GP, general practitioner; LHC, lung health check; MMRC, Modified Medical Research Council; MDM, multidisciplinary team meeting; $PLCO_{M2012}$, Prostate, Lung, Colorectal and Ovarian Model Score; RALC, Rapid Access Lung Clinic.

2. A follow-up CT thorax at a shorter time interval (3 months (T0+3)).
3. Referral to the RALCC for a suspicious nodule/lesion consistent with suspected lung cancer, as per the British Thoracic Society guidelines.
4. Further tests or visits for incidental findings identified on LDCT that are not related to lung cancer but require care in a hospital, community-based or GP setting. These participants will be referred to the relevant care pathways by the LHC team.

After T1 (scan after 1 year), participants will exit the pilot trial if there are no abnormalities requiring follow-up on imaging. Participants with outstanding lung or other findings will be referred to the relevant RALCC or other specialty clinic upon exiting the trial. CT scans will be read by a trained thoracic radiologist with artificial intelligence assistance. Incidental findings will be managed via a protocolised pathway based on NHS/European Respiratory Society best practice guidelines.

Endpoints

Primary endpoints

1. The uptake of high-risk eligible participants aged 55–74 years who participate in a community-based LHC.
2. The proportion of invited participants who undergo a telephone assessment.

Secondary endpoints

Secondary endpoints will explore lung cancer outcomes, clinical management outcomes, translational outcomes and health economic outcomes as outlined in box 1.

Statistical analysis

Sample size

In order to estimate the likely uptake among participants in the predefined catchment area for this trial in the ROI, we have calculated that we will need to invite a total of 13 933 participants who have ever smoked. This number is required to estimate the uptake of LHC, with a precision of 1% (ie, assuming a 95% confidence level±1%). This precision is based on the total number invited rather than respondents (via telephone or attendance). However, primary care electronic databases do not have sufficient medical history to determine if an individual has ever smoked. We will therefore need to invite more participants to identify high-risk participants (those with a smoking history). Based on the HRB National Drug and Alcohol Survey (2019/2020), we would expect 50.3% of people aged 50–64 years and 54.3% of people aged 65+ years to have never smoked (not eligible for inclusion).[3] Therefore, if we invited approximately 30 000 (initial population projection) participants between the ages of 55 and 74 years, we would expect a total of 13 933 invited participants to be eligible for LHC based on the

pilot trial's eligibility criteria. Based on an expected response rate of 30% from UKLC screening trial data, we expect 4179 participants to proceed to $PLCO_{M2012}$ or LLPv2 ≥2.5% scoring. Based on an expected 55% of participants with a $PLCO_{M2012}$≥1.51% or LLPv2 ≥2.5%, we would expect a total of 2298 participants to be eligible for enrolment. Finally, based on an attendance rate of 95% of those offered an appointment, we would expect a total of 2183 participants to attend the LHC pilot.

Data analysis plan

Descriptive analysis, such as proportions undergoing risk assessment, proportions responding to invitation and uptake/attending lung health screening, will be calculated with 95% CIs. Means (SD) and medians (IQR) will be used to describe continuous data. Factors collected at time of assessment/attendance, including age, gender, $PLCO_{M2012}$, LLPv2, educational level (primary, secondary and tertiary levels) and smoking status (current and former), will be examined in relation to LHC uptake/attendance using univariate and multivariable logistic regression. Clustering of participants within general practices will be adjusted for using multilevel regression. For comparison to non-screened participants, data on the detection of early-stage lung cancer (incidence and 1-year mortality) will be obtained from similar participants over the previous 3 years (or using data from the National Cancer Registry in Ireland (NCRI)). Incidence of early-stage lung cancer will be compared between the screened and non-screened (NCRI) participants using Poisson regression for incidence rate ratios and mortality rates (for 1-year survival) with 95% CIs.

Patient and public involvement (PPI)

PPI has been core to the goals of this research. This pilot is overseen by a 15-person steering committee, including patient representatives from the Irish Lung Cancer Community (SC and AMB). Patient partners have been involved in the design of the study and operational structure. A specific subcommittee, including patient representatives, was established to design participant and community engagement strategies to promote study recruitment, as well as review and edit patient-facing information. Patient representatives are co-investigators on this study and co-authors on this paper (SC and AMB). Initiation letters, low-burden patient information leaflets and study patient information leaflets were also reviewed by the National Adult Literacy Agency. Finally, PPI contributors will remain co-investigators and co-authors on all future research outputs, with a role in the interpretation of the results.

Biomarker collection

In tandem with our clinical outcomes, we are also investigating genomic, proteomic and immunological features of lung cancer, which are identified in blood, breath and sputum (see table 1). We will collect blood (plasma for proteomics: 10 mL; serum for proteomics: 10 mL; plasma for circulating tumour DNA (ctDNA) and buffy coat for peripheral blood mononuclear cells: 10 mL; exhaled breath condensate (EBC): 1 mL and 1–10 mL of sputum) to explore these aims.

We initially conceived that we would collect these biospecimens from all enrolled participants. However, blood specimens collected for plasma ctDNA must be processed within 2 hours of collection. Therefore, based on the community-based nature of mobile screening units, blood sample collection was rationalised with an expectation of collecting 400 samples over the duration of the pilot. A total of 25 mL of blood and 1 mL of EBC will be collected from four participants per day and transported directly to the research lab for processing. Finally, sputum samples will be collected from all participants following spirometry. Sputum samples will be stored at 4°C and then shipped on ice for storage at −80°C.

ETHICS AND DISSEMINATION

Ethics

The study will be conducted in accordance with ethical principles founded in the Declaration of Helsinki[16] and has been approved by the Beaumont Research Ethics Committee (REC 24/03).

Any proposed future research which is outside the scope of the study and which involves the use of samples from this study will be subject to a new application for review and approval by the research ethics committee. Changes to the protocol will require written ethics committee approval/favourable opinion prior to implementation, except when the modification is needed to eliminate an immediate hazard(s) to participants. The investigator will submit all protocol modifications to the ethics committee for review in accordance with the governing regulations.

The Royal College of Surgeons of Ireland (RCSI) is the study sponsor, with clinical responsibility for the study delegated to Beaumont Hospital. For the purpose of operations, Alliance Medical Diagnostics Ireland will supply an end-to-end operation of the LHC pilot.

The study will have independent oversight from the RCSI Clinical Research Centre, which will act as an independent data safety board that meets every 6 months to provide study oversight and will make recommendations where necessary. This independent data safety and monitoring board will review study progress and milestones and help to address any issues of study conduct at 6-monthly meetings or on an ad hoc basis at the discretion of the study principal investigators.

All data will be reviewed for legibility, completeness and logical consistency by study investigators before being entered on the study database. Data queries will be generated for the investigational site as required to clarify the data or request missing information. Any amended information will be entered into the database.

Table 1 Summary of study visits

	Phone prescreening (2–4 weeks after general practitioner invitation)	LHC visit 1 T0 (2–4 weeks after prescreening phone call)	LHC visit 2 T1 (1 year±4 weeks post-LHC visit 1)	Follow-up, if lung nodule* (T0+3) 3 month CT (3 months±2 weeks post-low-dose CT 1)	Follow-up, if lung cancer is suspected	Follow-up, if incidental findings on low dose chest CT	Follow-up, if no findings
Eligibility criteria	X						
$PLCO_{M2012}$ and LLPv2 ≥2.5%	X						
Participant demographics		X					
Assessment of smoking status		X					
Spirometry		X					
Respiratory questionnaires		X					
Respiratory nurse consultation		X					
Blood tests		X					
Breath/sputum test		X					
Smoking cessation advice		X					
Low-dose chest CT scan		X	X				
Low-dose chest CT scan 3 months after first CT				X			
Referral to rapid access lung clinic					X		
Referral to screening multidisciplinary team				X		X	
Referral to relevant clinical pathway						X	

LHC, lung health check; LLPv2, Liverpool Score V.2; $PLCO_{M2012}$, Prostate, Lung, Colorectal and Ovarian Model Score.

Dissemination

Our PPI contributors will assist in reviewing all participant and public-facing study results prior to sharing. In conjunction with our PPI contributors, we will also arrange a public information evening where the results of our research will be shared with interested members of the public when final results are available. Scientific results will be shared through abstract submissions and associated poster/oral presentations at international conferences and peer-reviewed journals. In addition to this, project outputs will be shared through partners in the EU4 Health funding programme—Strengthening the Screening of Lung Cancer in Europe (SOLACE).

No publication, abstract or presentation of any aspect of this study shall be made without the approval of the investigators. A predetermined procedure will be used to determine the authorship list of any publication or presentation, taking into account participation in the leadership, design and conduct of the study as well as patient accrual. This study is supported by the EU4Health SOLACE consortium and the Irish Cancer Society.

CONCLUSION

Lung cancer screening internationally has been hampered by the slow implementation of national programmes, infrastructure requirements and poor uptake. Ali *et al* detailed the self-reported barriers to non-participation in the UKLS trial.[5] These include practical and emotional barriers. In this study, the investigators aim to mitigate some of these factors to facilitate study participation. To remove physical barriers, screening units are located in community locations strategically located near participant GP practices. Emotional barriers identified in the UK studies were fear and an avoidance of lung cancer information. In this study, layered information originating from the participants' GP is a key communication pathway, ensuring the trust of the participant's physician is used. Additionally, the pilot study is promoted as an LHC, rather than a lung cancer screening.

The LHC pilot is modelled on successful studies in Manchester and Liverpool. However, a key notable difference between the UK and Irish systems surrounds the inclusion of GP practices. Unlike the UK public health

system, GPs in Ireland are private or semi-private organisations, not part of the public health system. Following consultation with stakeholders, we identified a solution of an HRCDC approval for the omission of patient consent on the grounds of public health interest. This approach may be applicable to other jurisdictions with similar data protection regulations (countries in the European Union).

In summary, we present the protocol for a lung cancer screening pilot, which is the first of its kind in Ireland. The pilot incorporates a respiratory assessment, spirometry and smoking cessation advice in conjunction with the investigation of genomic, proteomic and immunological biomarkers of lung cancer in breath, blood and sputum. It is intended that this study will provide critical data to guide the introduction of a national lung cancer screening programme in the ROI.

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Competing interests DOR—conference attendance: Pfizer, MSD and Servier; consulting: Janssen. KB—research funding from IQVIA and Novartis. JN—AstraZeneca: research funding, consulting/advisory board, data safety monitoring board, honoraria; Bristol Myers Squibb: research funding, consulting/advisory board, honoraria; Roche/Genentech: research funding, consulting/advisory board, honoraria; Amgen: research funding, consulting/advisory board; NGM Pharmaceuticals: consulting/advisory board; Takeda: consulting/advisory board; Pfizer: consulting/advisory board; Elevation Oncology: consulting/advisory board; Abbvie: consulting/advisory board; Kaleido Biosciences: consulting/advisory board; Mirati: research funding; Daiichi Sankyo: consulting/advisory board, data safety monitoring board, honoraria. AMB—Roche: steering committee (non-financial), honoraria; AstraZeneca: honoraria; J&J: honoraria. The remainder of the authors declare no conflicts of interest.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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