## Developing a Pan-European Technical Standard for a Comprehensive High-quality Lung Cancer CT Screening Program. An ERS Technical Standard

#### Appendices

Appendix A: Search strategy

#### SCOPE:

narrative review on pre-defined key steps in LDCT lung cancer screening programmes

- a. Capacity and infrastructure requirements
  - i. capacity (personnel and equipment)
  - ii. infrastructural
- b. Clinical governance, roles and responsibilities
  - i. clinical governance
- c. Invitation methods
  - i. invitation methods
- d. Participant pathway
  - i. pathway
- e. Risk assessment for entry into screening programmes
- f. Low Dose Computed Tomography Acquisition and Reading
  - i. parameters for image acquisition?
  - ii. reading of CT imaging?
- g. CT interval and surveillance
- h. Non-attendance and Exiting the Programme
  - i. non-attendance?
  - ii. exiting the programme?
  - Communication of results
    - i. participants?
    - ii. information given on participants?
- j. Data management
  - i. requirements for data management?

### LIMITS:

i.

Systematic Reviews

Cohorts of 50+ cases

Guidelines

Statements

RCTs

Government and Society documents

European languages

#### SEARCH STRATEGIES:

- RCTs in LDCT lung cancer screening DETeCCTS\_update\_2020 library : large equation with focus on document type, time limit from 2020 (update of previous systematic review by Thierry Berghmans and Valérie Durieux) = 20 new documents (plus previous systematic review(s) accessible for us)
- 2. Real life publication in LDCT lung cancer screening DETeCCTS\_focus\_RL library : large equation with focus on real life, time limit from 2010 = 1340 documents (no time limit: 1663 documents)
- 3. Risk assessment: DETeCCTS\_RA library : equation for risk assessment, time limit from 2015 = 570 documents
- 1. Information on RCTs in lung cancer screening

(exp mass screening/ or exp early diagnosis/ or screening.tw or early diagnos\*.tw) and (lung neoplasms/ or bronchial neoplasms/ or carcinoma, bronchogenic/ or carcinoma, non-small-cell lung/ or small cell lung carcinoma/ or pancoast syndrome/ or lung neoplasm\*.tw or lung cancer\*.tw or lung carceroma\*.tw or lung tumour\*.tw or lung tumor\*.tw or pulmonary neoplasm\*.tw or pulmonary cancer\*.tw or pulmonary carceroma\*.tw or pulmonary tumour\*.tw or pulmonary tumor\*.tw or pulmonary tumor\*.tw or bronchial neoplasm\*.tw or bronchial carceroma\*.tw or bronchial carcinoma\*.tw or bronchial tumor\*.tw or bronchial carceroma\*.tw or bronchial carceroma\*.tw or bronchial tumor\*.tw or bronchial tumor\*.tw or bronchogenic tumour\*.tw or bronchogenic carcinoma\*.tw or bronchogenic tumour\*.tw or bronchogenic tumor\*.tw or pancoast\* syndrome\*.tw or pancoast\* tumor\*.tw or pancoast\* tumor\*.tw) and (exp Tomography, X-Ray/ or Tomography Scanners, X-Ray Computed/ or CT\*.tw or Scan\*.tw or Tomograph\*.tw or Tomodensitometr\*.tw) and (smokers/ or exp smoking/ or tobacco/ or exp "Tobacco Use"/ or exp tobacco products/ or smoker\*.tw or tobacco smok\*.tw or tobacco consumption.tw or cigaret\*.tw or high risk\*.tw)

AND (comparative study.ti or controlled clinical trial.ti or randomized controlled trial.ti OR rct.ti OR phase iii.ti or clinical trial, phase iii.pt or comparative study.pt or controlled clinical trial.pt or randomized controlled trial.pt)

From 2020 = 20 (25/11/2021)

2. Information on real life publications in lung cancer screening

(exp mass screening/ or exp early diagnosis/ or screening.tw or early diagnos\*.tw) and (lung neoplasms/ or bronchial neoplasms/ or carcinoma, bronchogenic/ or carcinoma, non-small-cell lung/ or small cell lung carcinoma/ or pancoast syndrome/ or lung neoplasm\*.tw or lung cancer\*.tw or lung carcinoma\*.tw or lung tumour\*.tw or lung tumor\*.tw or pulmonary neoplasm\*.tw or

pulmonary cancer\*.tw or pulmonary carcinoma\*.tw or pulmonary tumour\*.tw or pulmonary tumor\*.tw or bronchial neoplasm\*.tw or bronchial cancer\*.tw or bronchial carcinoma\*.tw or bronchial tumour\*.tw or bronchial tumor\*.tw or bronchogenic neoplasm\*.tw or bronchogenic cancer\*.tw or bronchogenic carcinoma\*.tw or bronchogenic tumour\*.tw or bronchogenic tumor\*.tw or pancoast\* syndrome\*.tw or pancoast\* tumor\*.tw or pancoast\* tumour\*.tw) and (exp Tomography, X-Ray/ or Tomography Scanners, X-Ray Computed/ or CT\*.tw or Scan\*.tw or Tomograph\*.tw or Tomodensitometr\*.tw) and (smokers/ or exp smoking/ or tobacco/ or exp "Tobacco Use"/ or exp tobacco products/ or smoker\*.tw or tobacco smok\*.tw or tobacco consumption.tw or cigaret\*.tw or high risk\*.tw)

From 2010 = 1340 (25/11/2021)

### 3. Information on risk assessment

(lung neoplasms/ or bronchial neoplasms/ or carcinoma, bronchogenic/ or carcinoma, non-small-cell lung/ or small cell lung carcinoma/ or pancoast syndrome/ or lung neoplasm\*.tw or lung cancer\*.tw or lung carcinoma\*.tw or lung tumour\*.tw or lung tumor\*.tw or pulmonary neoplasm\*.tw or pulmonary cancer\*.tw or pulmonary carcinoma\*.tw or pulmonary tumour\*.tw or pulmonary tumor\*.tw or bronchial neoplasm\*.tw or bronchial cancer\*.tw or bronchial carcinoma\*.tw or bronchial tumour\*.tw or bronchial tumor\*.tw or bronchogenic neoplasm\*.tw or bronchogenic cancer\*.tw or bronchogenic carcinoma\*.tw or bronchogenic tumour\*.tw or bronchogenic tumor\*.tw or pancoast\* syndrome\*.tw or pancoast\* tumor\*.tw or pancoast\* tumour\*.tw) and (smokers/ or exp smoking/ or tobacco/ or exp "Tobacco Use"/ or exp tobacco products/ or smoker\*.tw or tobacco smok\*.tw or tobacco consumption.tw or cigaret\*.tw or high risk\*.tw) and (risk model\*.tw or Risk Assessment/ or Risk assessment\*.tw or Risk prediction model.tw or Assessment tool.tw or Prediction score.tw or Bach.tw or Liverpool Lung Project.tw or LIP.tw or Spitz.tw or Two-stage clonal expansion.tw or TSCE.tw or Model for African Americans.tw or Lung cancer in Korean men.tw or Hoggart.tw)

From 2015 = 570 (25/11/2021)

Appendix B: Flow diagram of article screening results



# Appendix C:

Topics identified by TF members as essential components of a Lung Cancer Screening program

| Торіс  | Questions  |
|--|--|
| Capacity and infrastructure                  | What are the requirements in terms of capacity (personnel and equipment) in order to deliver a CT screening program for lung cancer? |
| requirements                                 | What are the infrastructural considerations that may influence the delivery of a CT screening program for lung cancer?               |
|  | What are additional services within a CT screening program for lung cancer?  |
| Clinical                                     | What clinical governance standards apply to CT screening?  |
| governance,<br>roles and<br>responsibilities | Which roles form part of clinical governance of programs?  |
| Participant                                  | What are the components that are included in the participant pathway?  |
| Pathway                                      | What components are regarded as crucial?   |
| Invitation                                   | What invitation methods have been used successfully in screening for cancer?   |
| methods                                      | Which invitation methods are the most effective?   |
| Risk assessment for entry into               | What methods are used to assess the risk of lung cancer in potential participants?   |
| screening<br>programs                        | Which risk assessment methods may be applied to select eligible participants?  |
| Smoking cessation                            | What is the optimum strategy for integration of smoking cessation into LCS programs?   |
| Non-   | What methods have been applied to address non-attendance?  |
| attendance and<br>Exiting the<br>Program     | Which methods are most effective   |
|  | What are the options for exiting the program?  |
| LDCT   | What are the accepted parameters for image acquisition?  |
| Acquisition,<br>Reading and<br>Reporting     | What are the standards for reading of imaging?   |
|  | What are the standards applied to interpretation and reporting?  |
| CT interval and surveillance                 | What intervals have been applied between scans?  |
|  | What are the implications of different intervals?  |
|  | What circumstances may influence the choice of interval?   |

| Communication<br>of results | What methods are used to communicate results to participants?<br>What impacts do the methods used, and content of, the information given on<br>participants? |  |
|-----------------------------|--|--|
| Data<br>management          | What are the requirements for data management?   |  |
|                             | What data are collected?   |  |
|                             | How are data analysed?   |  |
|                             | How are data managed and what are the options?   |  |

Appendix D: Core roles and responsibilities in the governance of a LCS program.

| Title of role  | Function  | National /<br>local / both |
|--|---|----------------------------|
| National Screening<br>Advisory Body                          | Evaluates the effectiveness and cost effectiveness and makes national recommendations   | National                   |
| National Cancer Board<br>/ Team                              | Translates recommendations for screening, national cancer plans into a national LCS program                                       | National                   |
| National LCS Steering<br>Committee or<br>Collaborative Group | Develops protocol, advises on all aspects of the program including outcome and quality assurance data                             | National /<br>Local        |
| Local LCS Steering<br>Committee                              | Direct oversight of the local program ensuring adherence to protocol (whether national or local)                                  | National /<br>local        |
| Director / Lead of local<br>programme                        | Takes overall responsibility for local delivery of LCS including adherence to the agreed protocol and quality assurance standards | National /<br>local        |
| Lead Radiologist(s)  | Responsible for adherence of radiology team to defined standards  | National /<br>local        |
| Lead Clinician(s)  | Responsible for adherence of the clinical team managing indeterminate, incidental and positive findings from LDCT                 | National /<br>local        |
| Lead Assessor(s)   | Responsible for ensuring the correct selection and recruitment process  | National /<br>local        |

#### Appendix E: An example lung cancer screening participant pathway



Appendix F: Additional desirable features of semi-automated volumetry

- 1. Facility to measure nodule volume on nodules not identified by CAD.
- 2. Facility adjust segmentation in a semi-automated fashion when necessary.
- 3. Facility to accept or reject CAD identified nodules.
- 4. Ability to track nodules consistently.
- 5. Ability to measure and record diameter where segmentation has failed.
- 6. Provision of percentage volume change and volume doubling time calculations compared to all previous scans.
- 7. Ability to detect, segment and measure subsolid nodules.

Appendix G: Minimum required dataset items

| Centers for Medicare & Medicaid Services <sup>257</sup> |                                    | NHS England Targ           | NHS England Targeted Lung Healthcheck Program <sup>10</sup>   |  |
|---|------------------------------------|----------------------------|---|--|
| Data Type   | Minimum Required Data Elements     | Data Type                  | Required Data Elements  |  |
| Facility  | Identifier                         | Demographic<br>data        | Participant ID, LSOA, sex, age, GP Practice code, CCG code,<br>marital status, ethnicity, main language   |  |
| Radiologist(reading)                                    | National Provider Identifier (NPI) | Co-morbidities             | COPD, IHD, Cancer (date of previous cancer diagnosis), other medical diagnoses  |  |
| Patient   | Identifier                         | Lung Health<br>Check (LHC) | Dates of letters/ telephone contact<br>ID of person contacting participant<br>LHC date<br>LHC assessor ID<br>Symptoms<br>WHO/ECOG Performance Status<br>Height, weight, BMI<br>LDCT consent & ID of person taking consent |  |
| Ordering Practitioner                                   | National Provider Identifier (NPI) | Smoking history            | Smoking Type, Age started smoking, Date stopped smoking,<br>Total quit period (years), Average number smoked<br>daily, Number of years smoked, Estimated Pack Years,  |  |

| CT scanner               | Manufacturer, Model.  | Risk assessment      | All LLP v2 variables   |
|--------------------------|---|----------------------|--|
|                          |   |                      | All PLCOm2021 variables  |
| Indication               | Lung cancer LDCT screening absence of signs or symptoms of lung cancer  | Exclusion criteria   | Unable to lie flat, Weight >200Kg, Previous thoracic CT <12<br>months ago, does not have capacity to consent to LDCT,<br>Not physically fit, Participant declined  |
| System                   | Lung nodule identification, classification and reporting system   | Smoking<br>cessation | <ul> <li>Smoking Cessation Offered, Consent to be referred for smoking cessation.</li> <li>Outcomes of smoking cessation, including quit data at 3 months</li> </ul>   |
| Smoking history          | Current status (current, former, never).<br>If former smoker, years since<br>quitting.<br>Pack-years as reported by the<br>ordering practitioner.<br>For current smokers, smoking<br>cessation interventions available. | Screening            | Date<br>Scanner ID<br>Radiation dose<br>Reader 1 ID/ reader 2 ID<br>CAD used<br>Nodule data/ risk assessment<br>Incidental findings<br>Screening outcome/ recommendation<br>Onward referrals/ reason for these |
| Effective radiation dose | CT Dose Index (CTDIvol).  | Diagnostics          | Diagnostic/ staging tests  |

|   |                                     |          | Outcome                               |
|---|-------------------------------------|----------|---------------------------------------|
|   |                                     |          | TNM stage if lung cancer              |
|   |                                     |          | Treatment if lung cancer              |
| Screening   | Screen date                         | Outcomes | Death within 30 days of any procedure |
|   | Initial screen or subsequent screen |          | Date of death                         |
|   |                                     |          | Cause of death                        |
| LDCT: low-dose computed tomography; LSOA: Lower Super Output Area; GP: General Practitioner; CCG: Clinical commissioning group; COPD: chronic obstructive pulmonary disease; IHD: ischaemic heart disease; WHO/ECOG: World Health Organisation/ Eastern Cooperative Oncology Group; BMI: body mass index; LLP: Liverpool Lung Project; PLCO: Prostate, Lung, Colorectal and Ovarian cancer; CAD: computer-aided detection; TNM: tumour, |                                     |          |                                       |
| node, metastasis  |                                     |          |                                       |