The facts

79% of lung cancer is diagnosed after it has spread to other organs[1]

10-15% is the 5-year survival rate of patients diagnosed with late stage lung cancer[1]

55-70% of patients die within the first year of diagnosis[2]

CT scanning is the gold standard for lung cancer screening, but it is not available everywhere and is often limited to patients at very high risk of lung cancer.[3] CT screening has high sensitivity if repeated annually, but poor specifity and low positive predictive value (PPV) and accuracy.[4]

Early detection of lung cancer enables earlier intervention and has been proven to save lives.

The impact

Intervention in the early stage of disease, while it is still localised, improves the 5-year survival rate for lung cancer by almost 3 times to 64% of patients.[5]

Lung cancer 5-year survival rates[5]

All stages	
Distant tumours	
Localised	

(Chart axis: 0%, 20%, 40%, 60%)
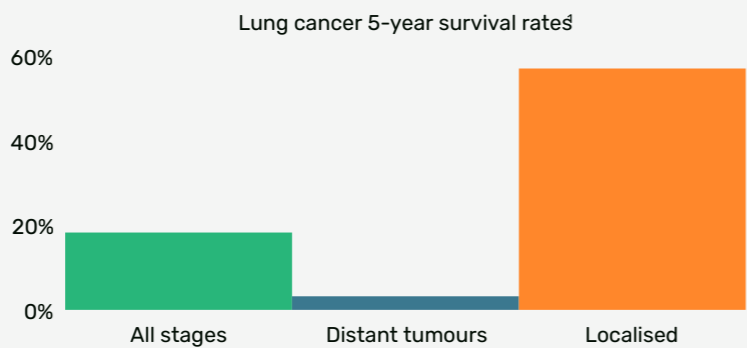
1.2%

The Challenge
The challenge is how to find the 12 lung cancers in a population of 1,000 high-risk patients early, before symptoms appear (1.2% prevalence = 12 cancers in 1,000).[4,***]

***Prevalence estimate of approximately 1.0–1.3% based on baseline lung cancer detection rates in high-risk participants undergoing low-dose CT screening in the National Lung Screening Trial (NLST).[4]

EarlyCDT® LUNG

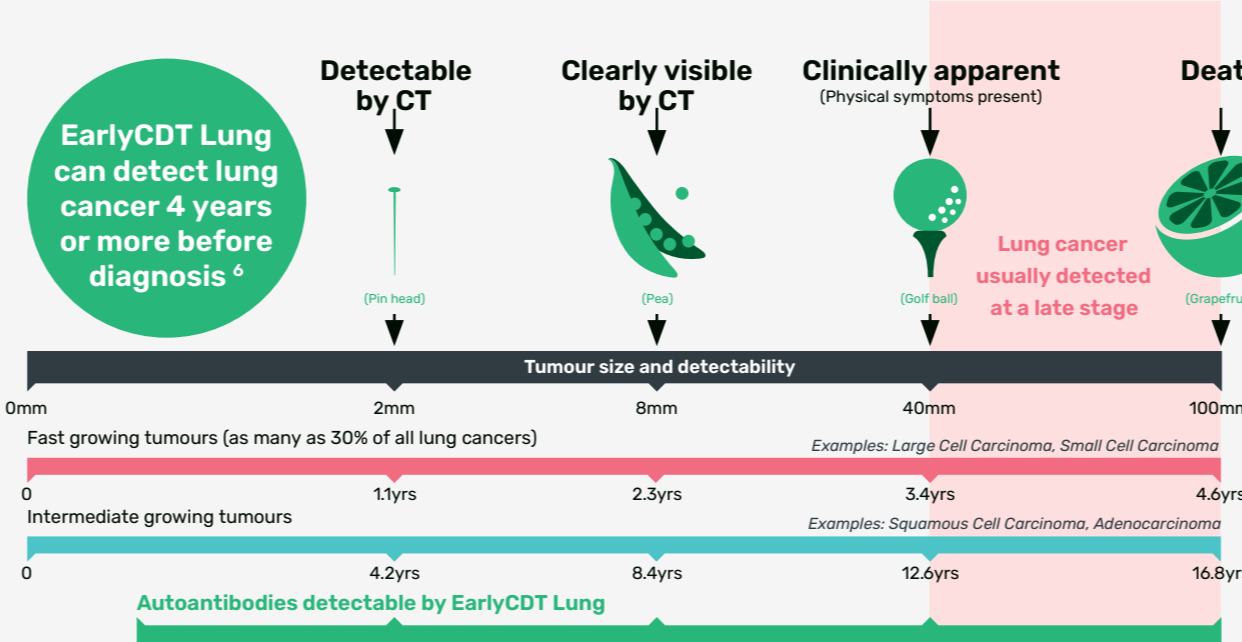### Detecting cancer early using EarlyCDT Lung®

EarlyCDT Lung is a rule-in test for lung cancer, helping to identify which patients are at the highest risk of having a lung cancer. As a **simple blood test**, EarlyCDT Lung can be used to detect lung cancer early in high-risk patients, triaging them into CT screening. This approach is particularly beneficial in situations where access to CT scanning is limited or unavailable.

EarlyCDT Lung measures **blood levels of seven autoantibodies** against specific tumour-associated antigens. These autoantibodies have the potential to signal the presence of cancer **on average four years** before clinical diagnosis via standard pathways.[6]

EarlyCDT Lung has high accuracy and PPV, due to its high specificity. A positive (Moderate or High Level) test result should be followed up by CT scanning. A No significant Level of Autoantibodies Detected test result does not mean that the patient does not have, or will not develop, lung cancer.

The groundbreaking ECLS trial, the largest-ever randomised controlled trial for biomarker-based early detection of lung cancer, recruited 12,210 high-risk patients. At the two-year follow-up, the trial demonstrated a **37% reduction in late-stage presentation**.[7] The five-year follow-up data clearly showed improved cancer mortality in the tested group compared to controls, **evidencing the benefits from early intervention**. Currently, no other IVD biomarker test for lung cancer can match these survival outcomes, positioning this test as a pioneering advancement in lung cancer detection and patient care.[8]

Health economic evaluations of EarlyCDT Lung have determined that the **test is cost effective** in the US and UK healthcare systems.[9,10]

Detectable by CT — **Clearly visible by CT** — **Clinically apparent** (Physical symptoms present) — **Death**

EarlyCDT Lung can detect lung cancer 4 years or more before diagnosis[6]

(Pin head) — (Pea) — (Golf ball) — (Grapefruit)

Lung cancer usually detected at a late stage

Tumour size and detectability

| 0mm | 2mm | 8mm | 40mm | 100mm |

Fast growing tumours (as many as 30% of all lung cancers)
Examples: Large Cell Carcinoma, Small Cell Carcinoma

| 0 | 1.1yrs | 2.3yrs | 3.4yrs | 4.6yrs |

Intermediate growing tumours
Examples: Squamous Cell Carcinoma, Adenocarcinoma

| 0 | 4.2yrs | 8.4yrs | 12.6yrs | 16.8yrs |

Autoantibodies detectable by EarlyCDT Lung

This illustration is based on widely accepted clinical guidelines and staging systems used by radiologists, pulmonologists, and oncologists worldwide. The sizes provided are general guidelines, and individual patient cases may vary significantly based on tumor biology, location, imaging technology, and clinical context.

Who do I test?

EarlyCDT Lung® is recommended for high-risk patients – those who are at risk of lung cancer due to a combination of age, gender, smoking history and other risk factors. Other key risk factors include environmental exposures (radon, dust, asbestos, radioactive substances).

The patient should be at least 50 years old with 20+ pack-years smoking history, or 40–49 years old with 20+ pack-years smoking history, and at least 1 additional risk factor. Patients should not have a history of any type of cancer.**

How accurate is EarlyCDT Lung?

The overall accuracy is 92%.[11] EarlyCDT Lung performs favourably when compared with other established cancer detection tests. Depending on the level of autoantibodies in the blood compared to cut-off values, the test results are reported as High Level, Moderate Level and No Significant Level of Autoantibodies Detected.
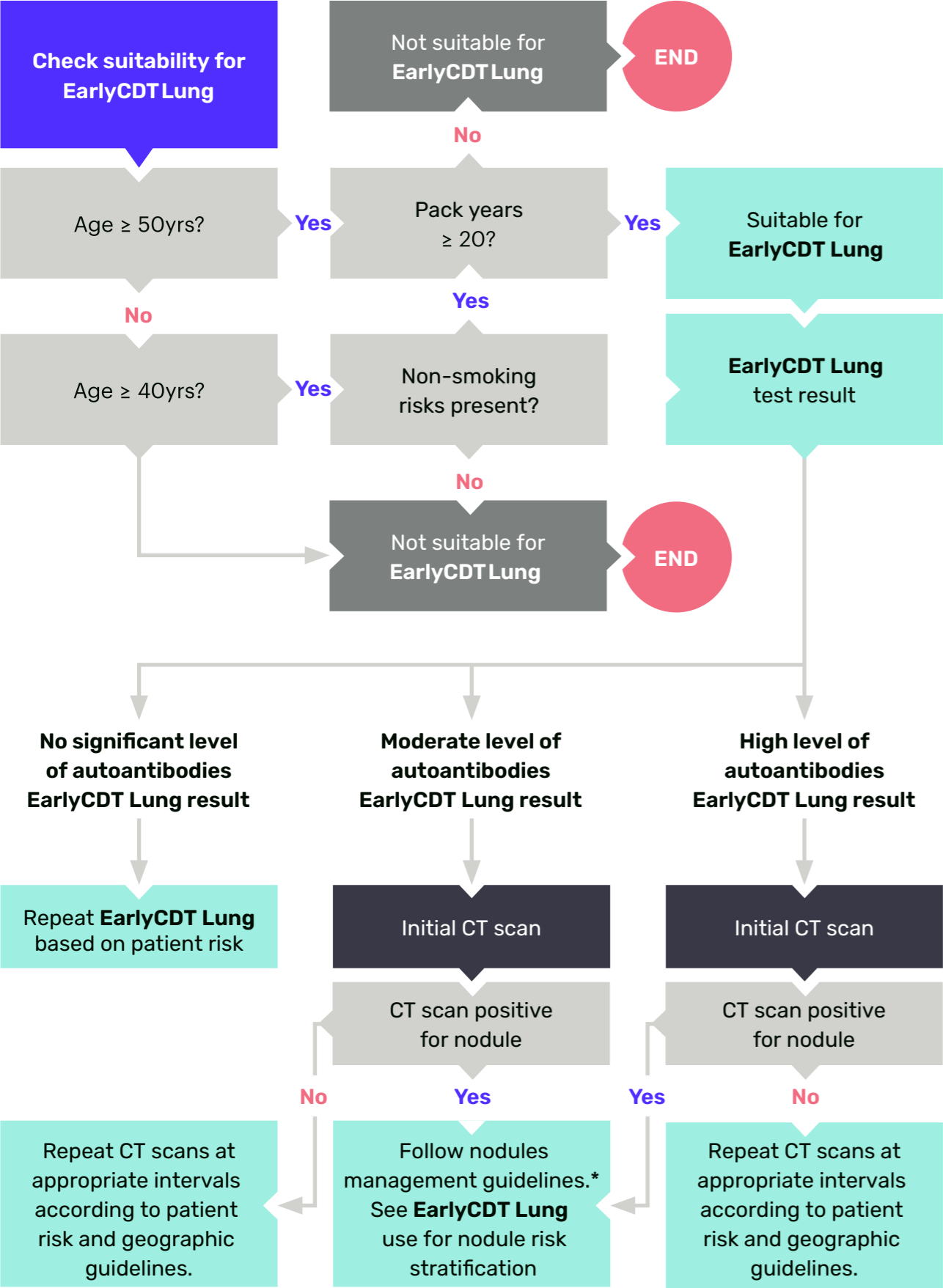
	Accuracy	Performance (PPV)[12]	
EarlyCDT Lung (Moderate & High)[11,12,13]	92%	1 in 15	
Mammography[14]	92%	1 in 26	
Cologuard®[15]	84%	1 in 27	

Assumed cancer rates : **EarlyCDT Lung** & CT Screening = 1.2%, Mammography = 0.8%, Cologuard® = 0.6%

● True Positive = cancer   ● False Positive = no cancer

Positive Predictive Value – the number of positive test results required to detect a cancer

How will EarlyCDT Lung benefit my patients?

A typical high-risk patient: 65 year-old male with a 45 pack-year smoking history

If this patient has a **No Significant Level of Autoantibodies Detected** test result, his estimated 1-year risk of having lung cancer is essentially unchanged from his pre-test risk status of **1.2%**.

If he has a **Moderate Level** test result, his estimated 1-year risk of having lung cancer nearly triples to **3.5%**.

If his test result is **High Level**, his estimated 1-year risk of having lung cancer is **19.3%**, an increased risk of over 16 times.
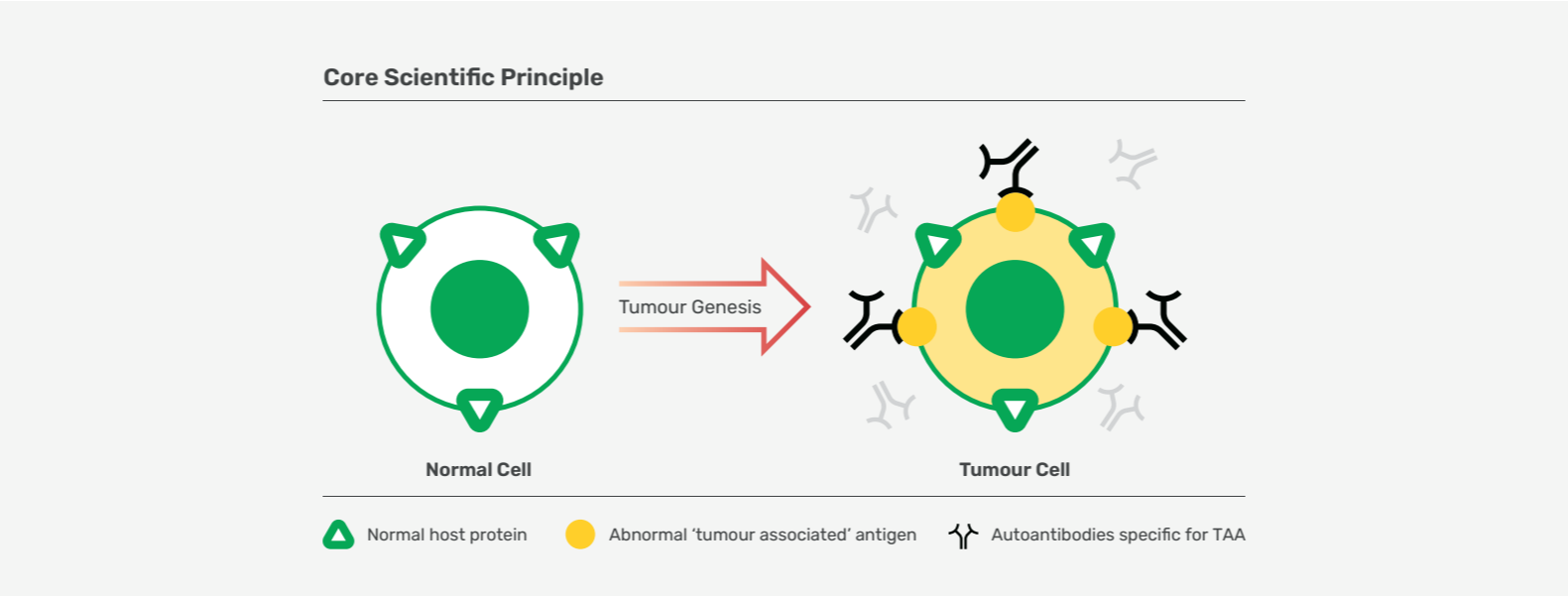
How to use EarlyCDT Lung®

Check suitability for EarlyCDT Lung

Age ≥ 50yrs? — **Yes** → Pack years ≥ 20? — **Yes** → **Suitable for EarlyCDT Lung**

No ↓

Age ≥ 40yrs? — **Yes** → Non-smoking risks present?

Pack years ≥ 20? — **No** → Not suitable for **EarlyCDT Lung** → **END**

Pack years ≥ 20? — **Yes** (down)

Non-smoking risks present? — **Yes** → **EarlyCDT Lung test result**

Non-smoking risks present? — **No** → Not suitable for **EarlyCDT Lung** → **END**

EarlyCDT Lung test result branches:

No significant level of autoantibodies EarlyCDT Lung result
→ Repeat **EarlyCDT Lung** based on patient risk

Moderate level of autoantibodies EarlyCDT Lung result
→ Initial CT scan → CT scan positive for nodule
— **No** → Repeat CT scans at appropriate intervals according to patient risk and geographic guidelines.
— **Yes** → Follow nodules management guidelines.* See **EarlyCDT Lung** use for nodule risk stratification

High level of autoantibodies EarlyCDT Lung result
→ Initial CT scan → CT scan positive for nodule
— **Yes** → Follow nodules management guidelines.*
— **No** → Repeat CT scans at appropriate intervals according to patient risk and geographic guidelines.

* these may vary according to geographic region

How does EarlyCDT Lung® work?

EarlyCDT Lung measures blood levels of a panel of seven autoantibodies to tumour-associated antigens that are linked to lung cancer. The seven autoantibodies have been shown to be elevated for all types of lung cancer, and from the earliest stage of the disease. Unlike the tumour antigens themselves, the autoantibody levels can be measured easily and accurately, based upon the signal magnification created by the body's immune response to cancer. The test runs on a simple enzyme-linked immunosorbent assay (ELISA) platform, which is widely available in hospital laboratories around the world.

Core Scientific Principle

Normal Cell — Tumour Genesis → Tumour Cell

△ Normal host protein   ● Abnormal 'tumour associated' antigen   ⵟ Autoantibodies specific for TAA

Over 200,000 tests have already been performed for patients worldwide and led to the detection of numerous early stage lung cancers.[8,9] EarlyCDT Lung is now available in many countries, see earlycdt.com for further details.

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** Exception: basal cell carcinoma

CE 2797

EarlyCDT®
LUNG

A proven simple blood test for detecting lung cancer in high-risk patients up to four years before symptoms appear.