The facts

79% Almost 80% of lung cancer is diagnosed after it has spread to other organs[1]

19% 5-year survival rate[1]

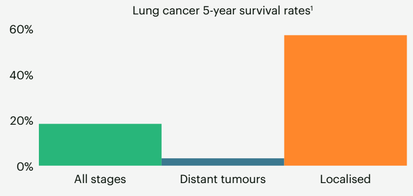
52% 52% of patients die in the first year after diagnosis[1]

CT scanning is the gold standard for lung cancer screening, but is only available in the US and for patients at very high risk of lung cancer.[2] CT screening has high sensitivity if repeated annually, but poor specificity and low positive predictive value (PPV) and accuracy.[3]

Early detection of lung cancer enables earlier intervention and saves lives.[3]

The impact

Intervention in the early stage of disease, while it is still localised, improves the 5-year survival rate for lung cancer by more than 3 times to 56% of patients.[1]



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)

*Early*CDT®—Lung

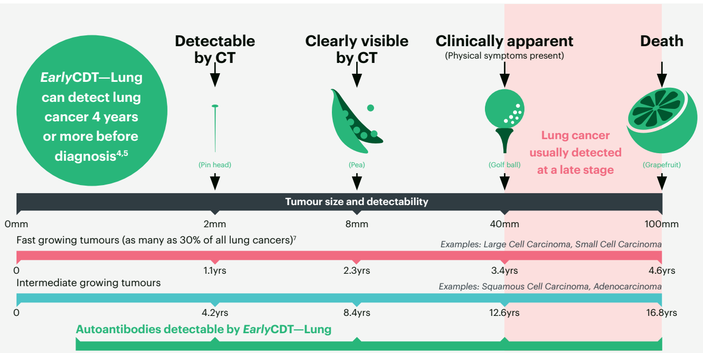
Detecting cancer early using *Early*CDT—Lung

***Early*CDT—Lung** is a rule-in test for lung cancer, helping to identify which patients are at highest risk of having a lung cancer. As a simple blood test, ***Early*CDT—Lung** can be used to detect lung cancer early, when a patient is at increased risk of the disease and CT screening is either not available or the patient is not eligible.

***Early*CDT—Lung** measures blood levels of seven autoantibodies against specific tumour-associated antigens. These autoantibodies have the potential to signal the presence of cancer four years or more before clinical diagnosis via standard pathways.[4,5]

***Early*CDT—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 ongoing ECLS trial, conducted by the National Health Service (NHS) in Scotland, is evaluating ***Early*CDT—Lung** in 12,210 high-risk patients, making this the largest-ever controlled, randomised controlled trial for biomarker-based early detection of lung cancer. Interim results from the study demonstrate a 55% stage shift: 75% of all lung cancers found (n=16) have been at stage 1 or 2; in normal practice in Scotland, 80% of lung cancers are diagnosed at stage 3 or 4.[6]



Who do I test?

***Early*CDT—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: a history of emphysema/COPD, first degree relative family history, or 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 *Early*CDT—Lung?

The overall accuracy is 92%.[8] ***Early*CDT—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)[9]
***Early*CDT—Lung** (High)[8,9,10]	**97%**	**1 in 5**
***Early*CDT—Lung** (Moderate & High)[8,9,10]	**92%**	**1 in 10**
CT Screening (Annual)[3]	73%	1 in 25
Mammography[11]	92%	1 in 26
Cologuard®[12]	84%	1 in 27

Assumed cancer rates[13]: ***Early*CDT—Lung** & CT Screening = 1.2%, Mammography = 0.8%, Cologuard® = 0.6%

● True Positive = cancer ● False Positive = no cancer

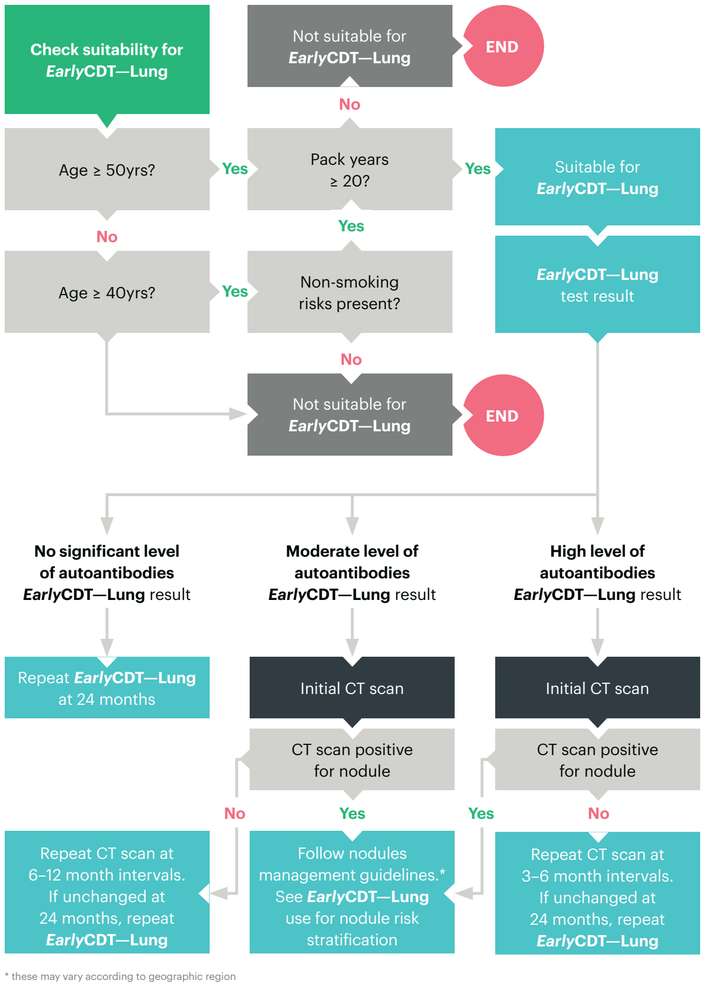
How will *Early*CDT—Lung benefit my patients?

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.

A personalised report reflecting the estimated risk of your specific patient as calculated based upon age, gender, smoking history and their ***Early*CDT—Lung** test result is available online at *http://oncimmune.com/smoking-calculator*

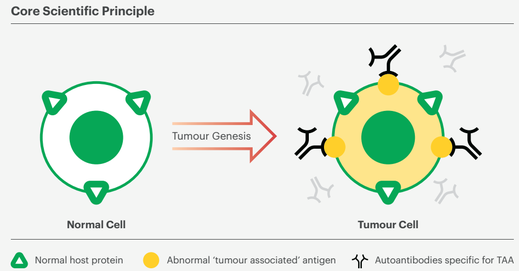
How to use *Early*CDT—Lung



* these may vary according to geographic region

How does *Early*CDT—Lung work?

***Early*CDT—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.[1,2] 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 and in Oncimmune's CLIA laboratory in Kansas, US.



More than **155,000 tests** have already been performed for patients worldwide, which represents tests ordered by more than **2,000 clinicians**. ***Early*CDT—Lung** detects all types and stages of lung cancer and has led to the detection of numerous early stage lung cancers. ***Early*CDT—Lung** is now available in many countries. Please see the list of test providers at *http://oncimmune.com/distributors/*

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10 Healey GF, Lam S, Boyle P, et al. Signal stratification of autoantibody levels in serum samples and its application to the early detection of lung cancer. *J Thorac Dis.* 2013;5(5):618–625.
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13 Positive Predictive Value – the number of positive test results required to detect a cancer.

* Exception: basal cell carcinoma. See ***Early*CDT—Lung** FAQs

Oncimmune®

*Early*CDT®—Lung

A simple blood test to aid in the risk assessment and early detection of lung cancer in high-risk patients.

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