Oncimmune®

Oncimmune

Beating cancer, one test at a time

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Oncimmune®

A leader in the development and commercialisation of immunodiagnostics for the screening and detection of cancer

Oncimmune®

Foundation for success

Proprietary immunogenic protein library
Over **8,000** proteins
patented | advanced | highly validated

200+ patents
granted and pending
47 territories

38 reviewed
publications
91 peer-reviewed
presentations

12,209
in **NHS** trial

£69.5 million
invested

Europe, US, China
69 staff

Lung & liver tests launched
3+ more in the pipeline

£42+ million
minimum sales
commitments

Validated multi-format performance
central lab, IVD kit and multiplex bead

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Company overview

- Newly appointed management team that has already delivered on core strategic objectives
  - Maintain focus on core business of developing and commercialising clinical tests for early detection of single types
  - Unlocking the existing technology platform through strategic partnerships and acquisitions
- Strategic partnership agreement with US-focused Lung Cancer Specialist, Biodesix, Inc. for EarlyCDT Lung valued at up to $28 million over next five years with lump sum payments and direct cost savings
- Acquisition of Protagen Diagnostics AG (March 2019)
  - Established revenue-generating company with existing partnerships with leading pharmaceutical multinationals
  - Will accelerates Oncimmune's biomarker discovery process
  - Stratification tools will support drug development, improve treatment strategies and patient management
- Strong Intellectual Property (over 200 patents granted and pending patents)
- Regulatory progress: local regulatory approvals – CLIA laboratory, 510k De Novo3(2019); CE marked kit in EU; NMPA application progressing
- Listed on London Stock Exchange AIM market (ONC:LN)
- Offices in London (UK); Nottingham (UK); Dortmund (Germany); Kansas City (USA); and a partner representative office in Shanghai (China)

De Novo3 classification under section 513(f)(2) of the Federal Food, Drug and Cosmetic Act (the FD&C Act). This process provides a pathway to Class I or Class II classifications for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

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Core scientific principle

Early cancer detection based on autoantibodies

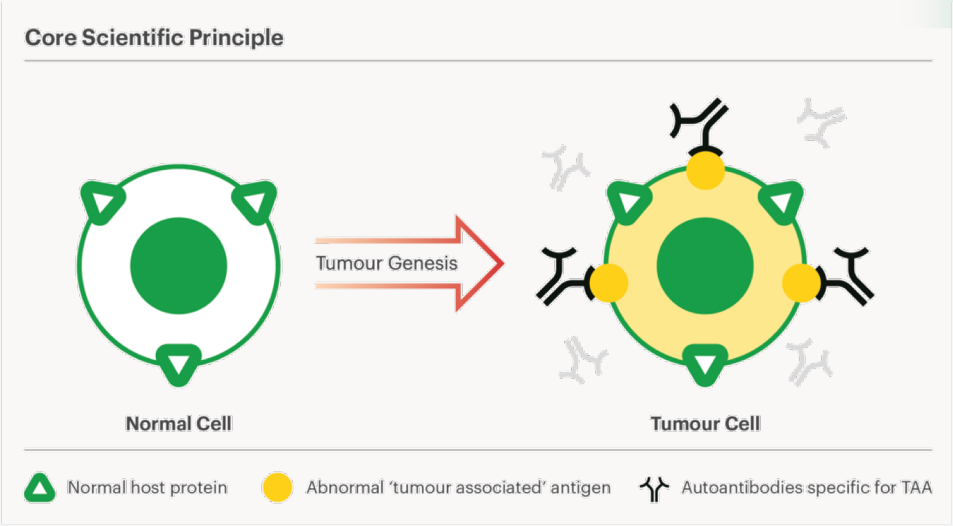
- Autoantibodies produced early in tumour formation – can be detected years ahead of clinical diagnosis[3,4]
- Absent or low concentrations in healthy & benign groups
- Patients with lung cancer can mount an immune response with autoantibodies providing an early measurable signal

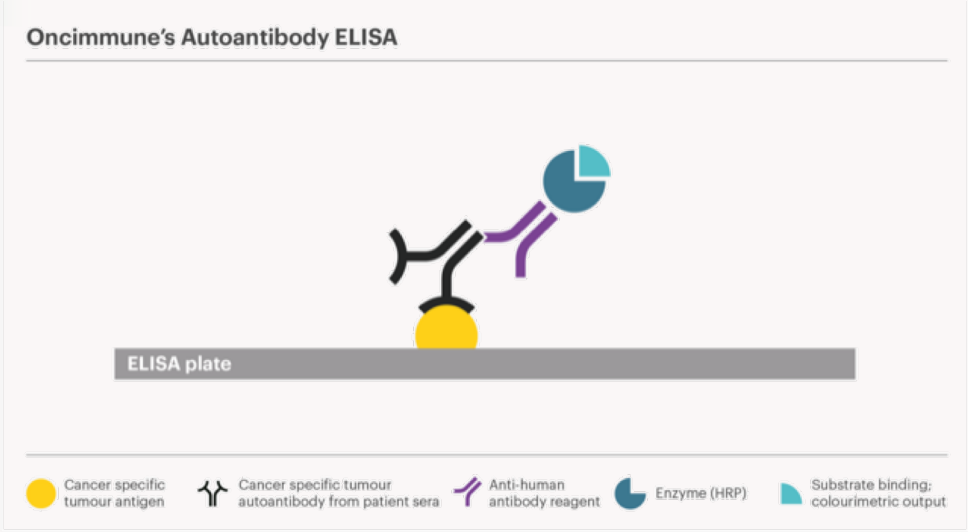
Proven cancer detection methodology

Antibody capture technology

Proprietary immunogenic protein library

- Over 8,000 immunogenic proteins
- Enzyme-Linked ImmunoSorbent Assay (ELISA)
- Multi-analyte panels developed to cover disease heterogeneity
- Cut-offs established to return a positive result on single analyte





3 Zhong L, et al. Profiling tumour-associated antibodies for early detection of non-small cell lung cancer. *J Thor Oncol* 2006; 1:513-519.
4 Jett J, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKCTOCS cohort. *J Thor Oncol* 2017; 12(11):S2170.

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Early detection landscape

1. Early detection potential in multiple cancers

GUARDANT · freenome · GRAIL · Volition · Savicell™

2. Retrospective evidence of performance indicating downstream potential for survival impact

CellMax Life · immunovia · Thrive.

3. Launched application with evidenced performance in highly prevalent cancer with clinical unmet need

veracyte · OncoCyte™ · MDxHealth

4. Prospectively evidenced application with positive impact on outcomes in existing clinical unmet need

Oncimmune® · exact sciences · epigenomics

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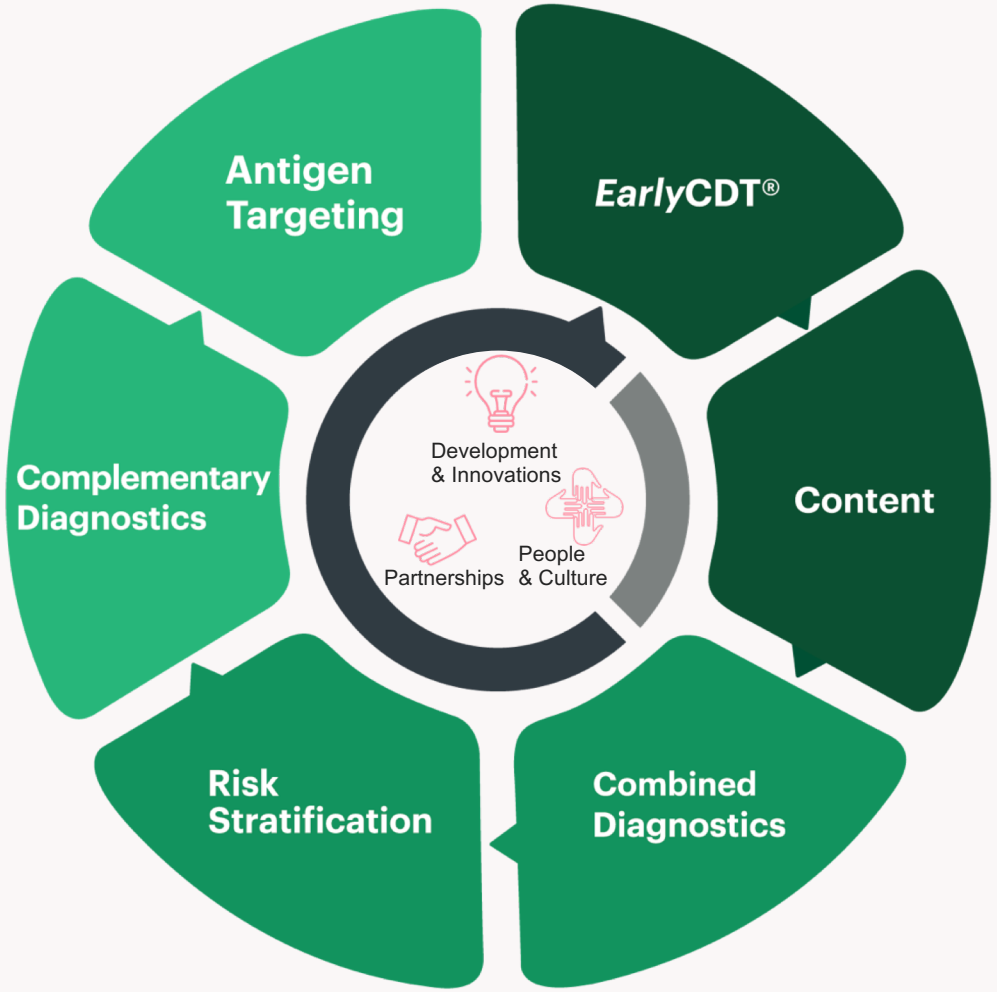
Unlocking the broad value of our technology through our core strengths



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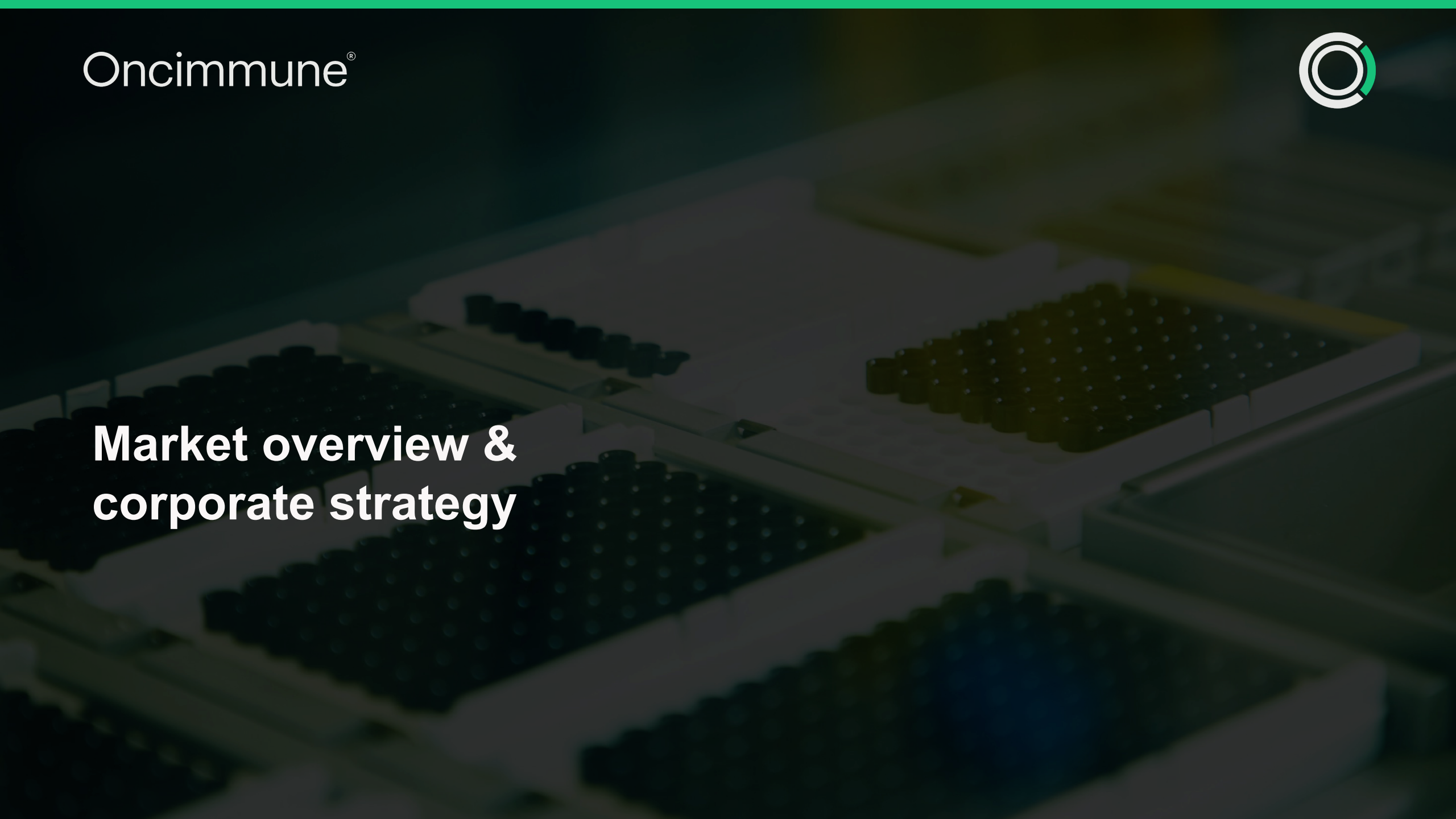

Market overview & corporate strategy

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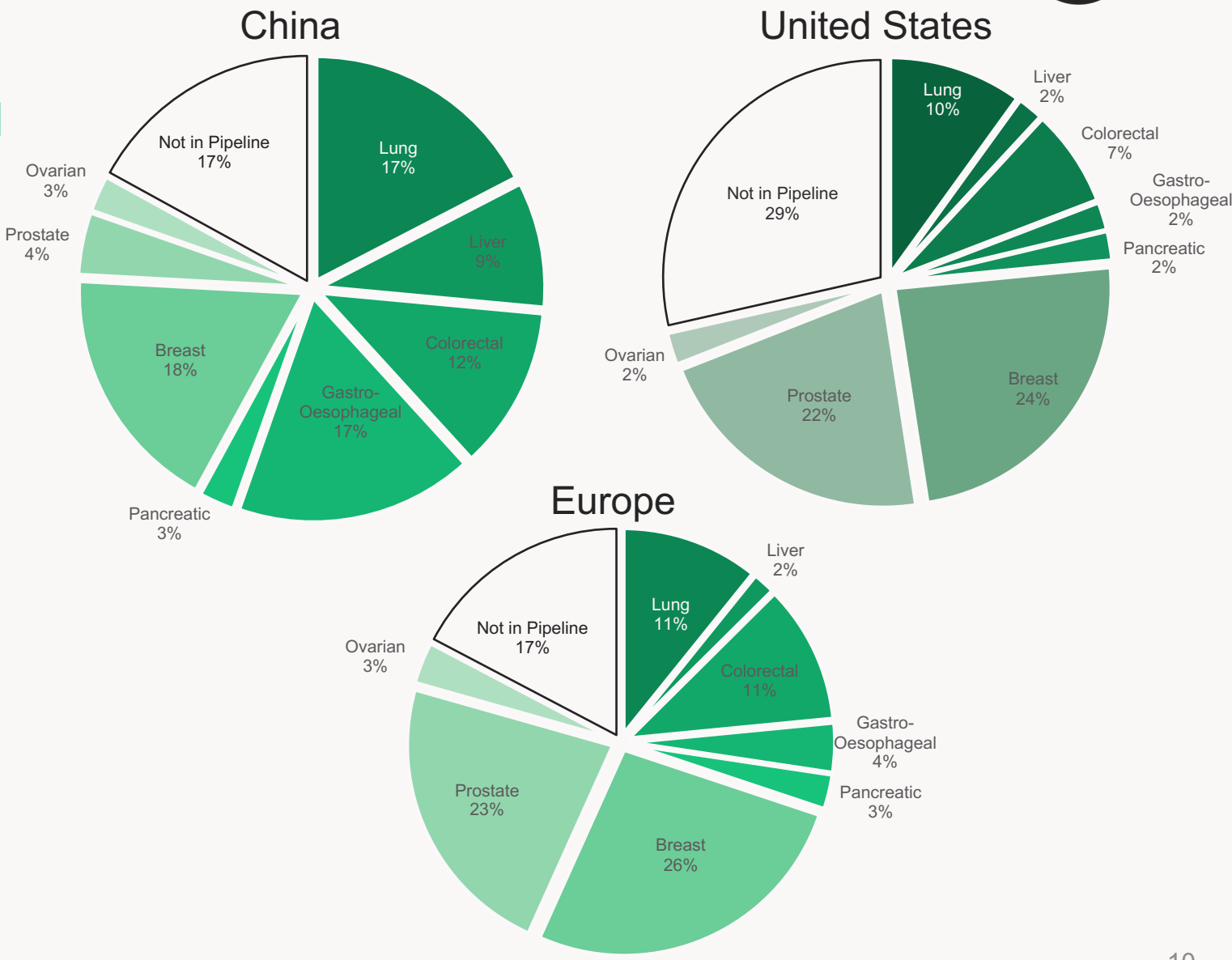
Portfolio and pipeline designed to address many cancer types

2,100,000 lung

&

840,000 liver

new cancer cases annually



Cancer incidence – age standardised rate for all cancers (inc NMSC)[5]

5 International Agency for Research on Cancer, WHO; The Global Cancer Observatory, Globocan 2018 https://gco.iarc.fr/today/home

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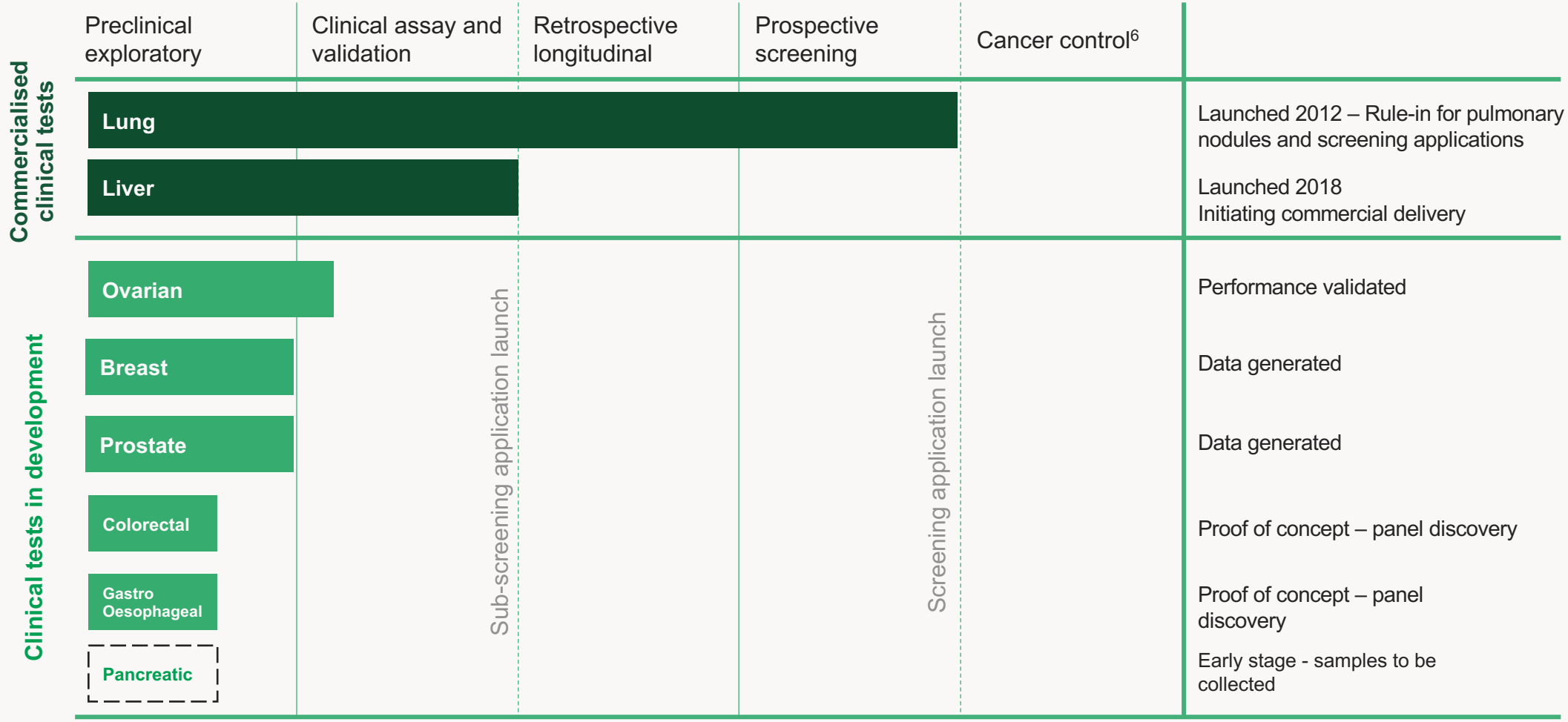
EarlyCDT clinical test portfolio & roadmap



6 Pepe et al. Journal of the National Cancer Institute 2001;93:1054-61

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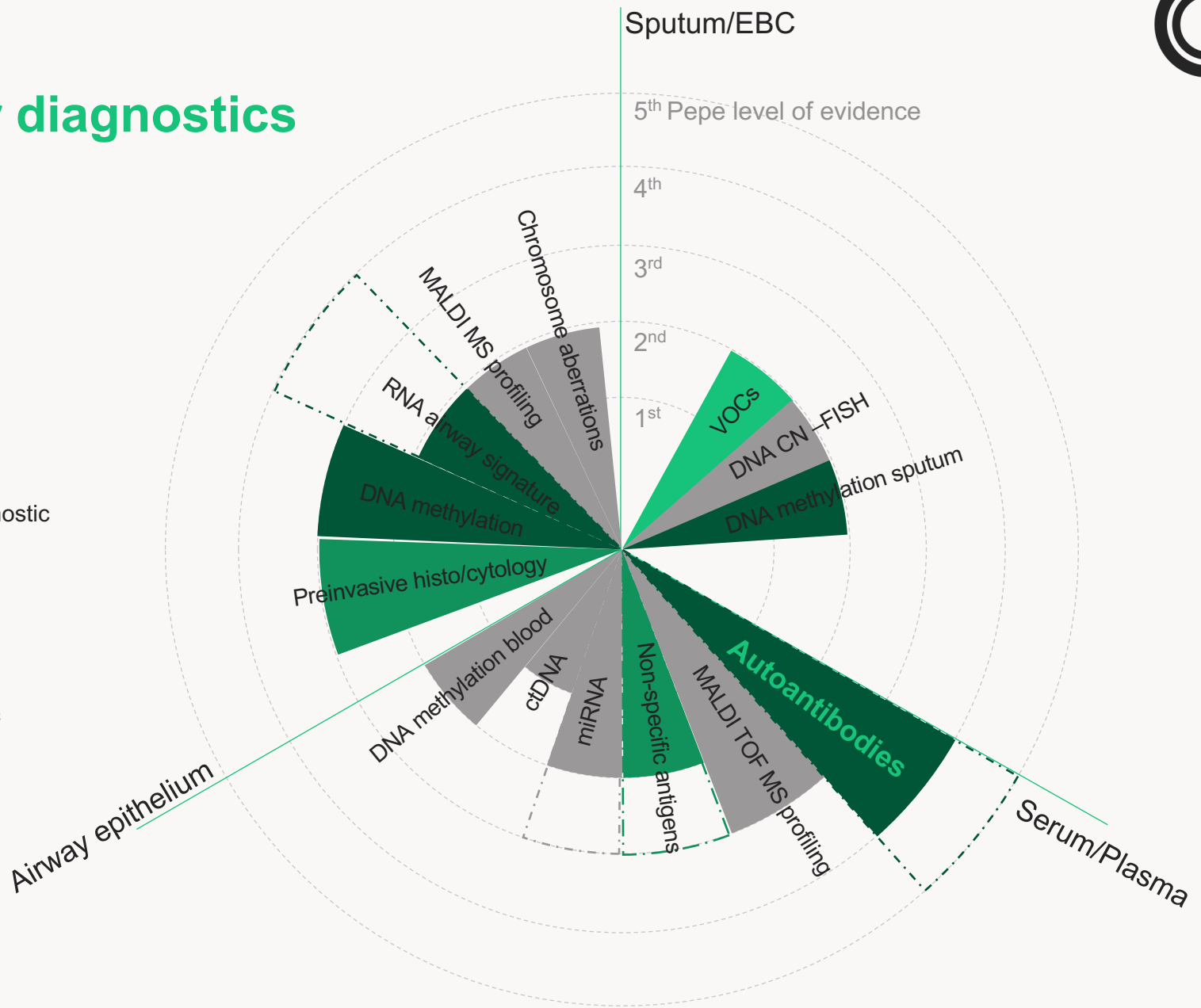
Progress of biomarker diagnostics

- 1st generation clinical biomarkers
  - Minimal benefit
  - Poorly reimbursed
  - Increased risk
  - A data trend
  - Descriptive
- 2nd generation clinical biomarkers
  - Known benefit - subset
  - Value-based reimbursement
  - Unique to person multi-measures
  - Predictive, prescriptive and potentially prognostic
- 3rd generation clinical biomarkers
  - Great potential benefit
  - Challenging reimbursement mechanism
  - A personal profile
  - Predictive, prescriptive and likely prognostic
- 4th generation clinical biomarkers
  - Transformational benefit to rapid diagnosis
  - Unknown reimbursement mechanism
  - N=1, longitudinal, dynamic personal profile
  - Predictive, possibly prescriptive



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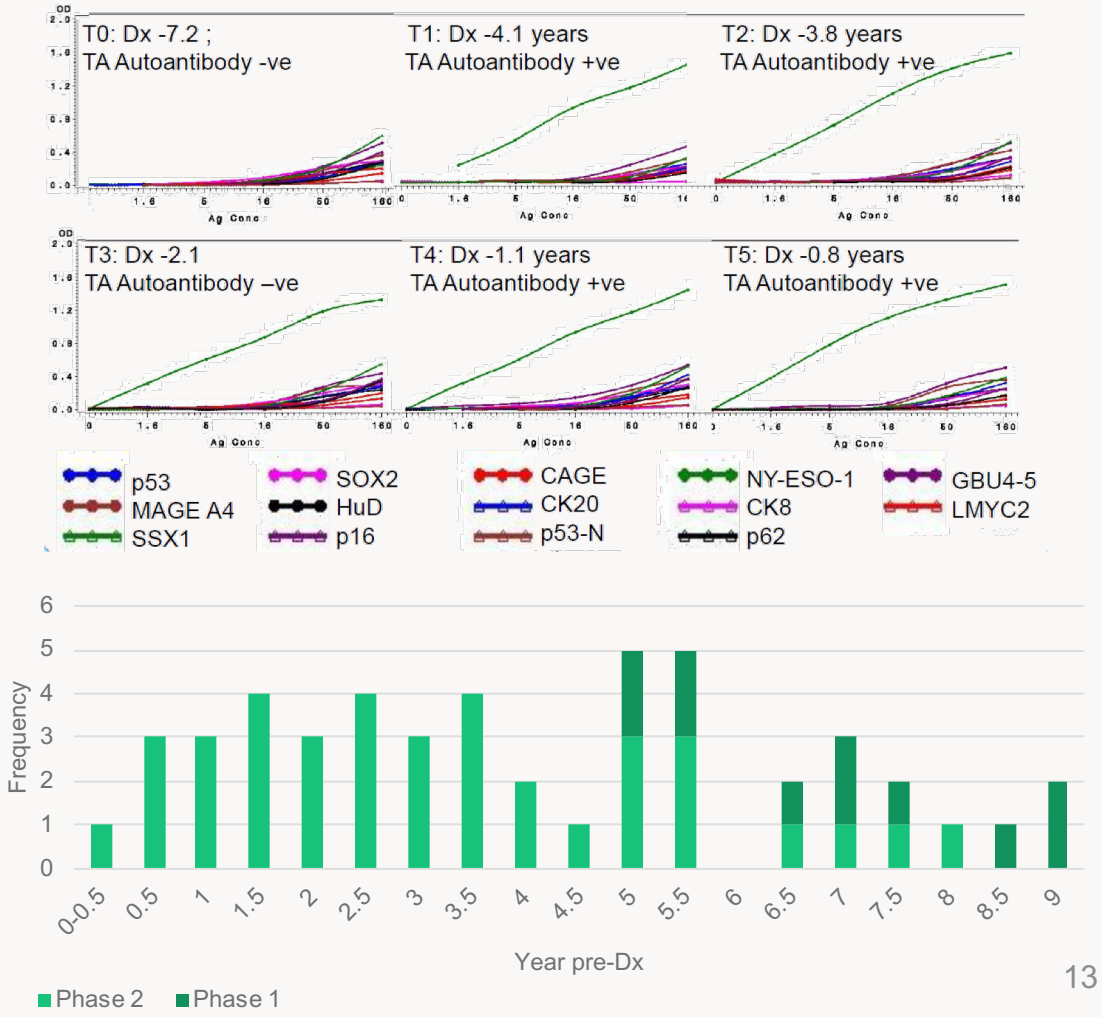
EarlyCDT – scientifically proven earlier detection technology

Longitudinal study of autoantibody detection lead time

- 202,000 women followed for 14 years (UKCTOCS)
- 142 lung cancer cases with longitudinal sampling up to 10 years prior to diagnosis
- Median detection of lung cancer by EarlyCDT Lung four years before standard diagnosis



Intended Uses

1. **Reflex test on human patients to further assess the risk of lung cancer being present where indeterminate lung nodules have been detected but have not been diagnosed as malignant**
2. Primary screen of human patients at high risk of lung cancer:
   - ≥50 years of age with at least a 20 pack year smoking history
   - 40-49 years of age with at least a 20 pack year history plus at least one additional risk factor

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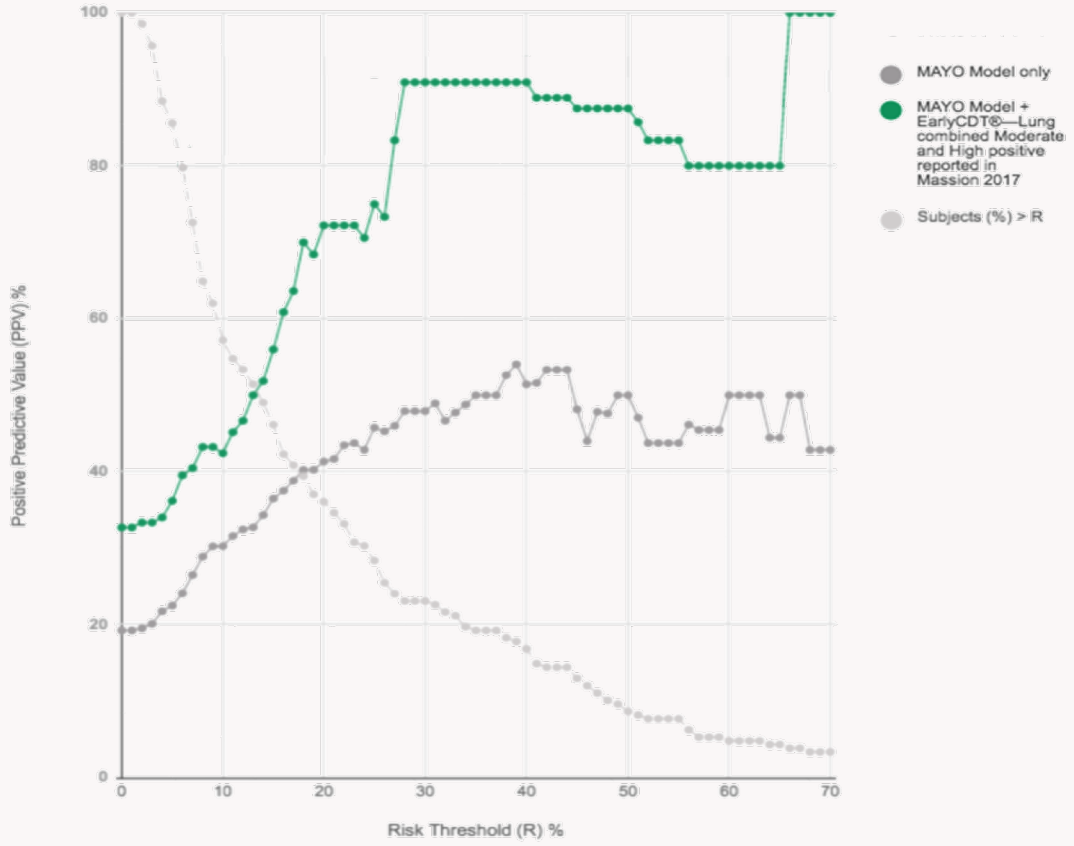
Application as a rule in test for indeterminate pulmonary nodules

EarlyCDT Lung vastly improves predictive risk of imaging in lung cancer

Improved diagnostic performance of MAYO CT risk model in combination with EarlyCDT Lung[10]



10 Massion et al 2017 J Thor Oncol, 12: 3 578-84

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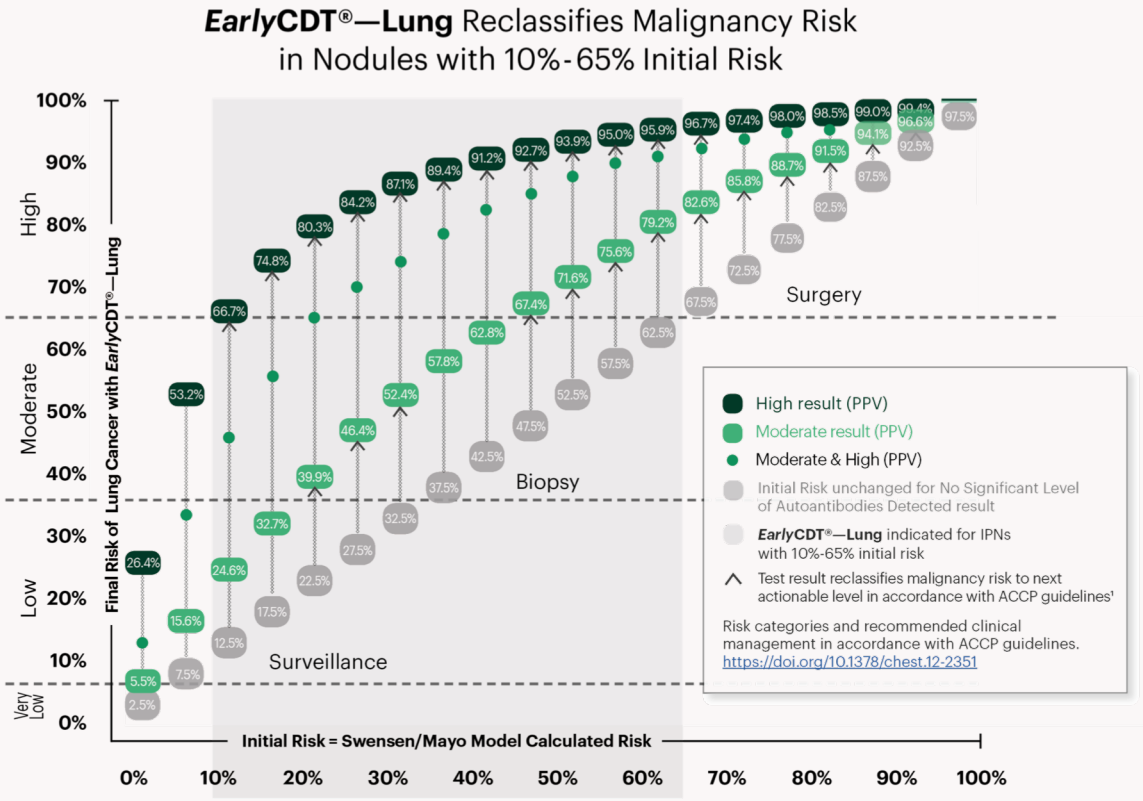
Pulmonary nodule risk assessment with EarlyCDT Lung



A nodule risk calculator combining the Swensen/Mayo model with ***Early*CDT®—Lung** is available at http://oncimmune.com/nodule-calculator

1. Risk calculations: Healey GF, Macdonald IK, Reynolds C, et al. Tumor-Associated Autoantibodies: Re-Optimization of ***Early*CDT®—Lung** Diagnostic Performance and its Application to Indeterminate Pulmonary Nodules *J Cancer Ther.* 2017; 8:506-517.

- "High level" result
  - Accurately requalifies moderate risk patients with this result into high risk
  - Alters recommended course of action to intervention
- "Moderate level" result
  - Qualifies a patient at an additional 25% risk of disease
  - Most patients with this result will be moved to intervention

Intended Uses

1. Reflex test on human patients to further assess the risk of lung cancer being present where indeterminate lung nodules have been detected but have not been diagnosed as malignant
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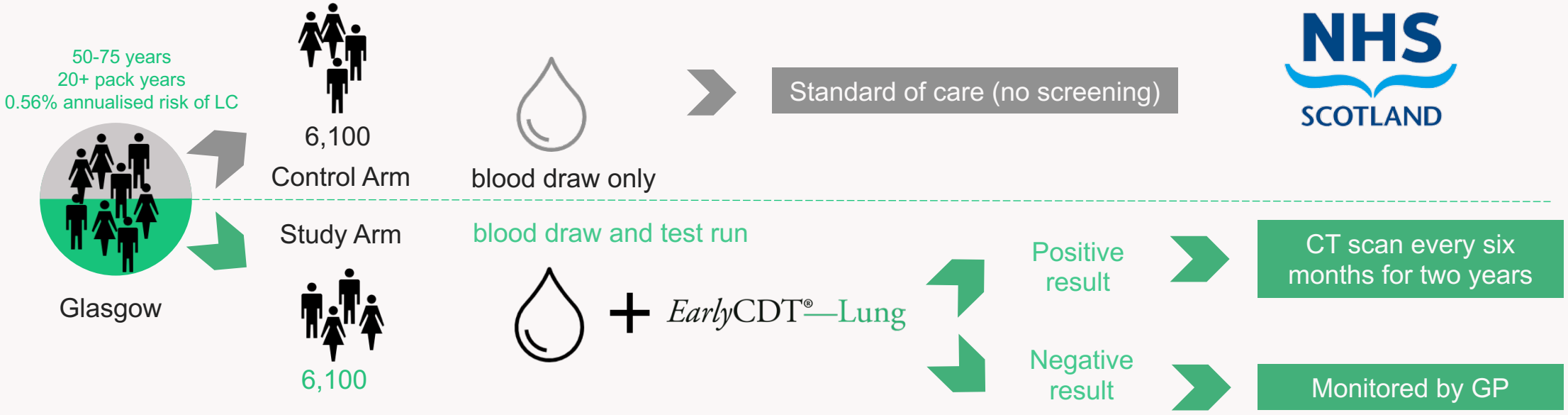
ECLS[12] study in collaboration with NHS Scotland – top line results met primary end point

- Primary endpoint: assess the effectiveness of EarlyCDT Lung test in reducing the incidence of patients with late-stage lung cancer at diagnosis compared with standard clinical practice



- It is estimated that 18.7% of the world's population will be smokers by 2028[13]; Scotland alone has over 800,000 smokers[14]
- We estimate early stage detection saves c.£40,000 in treatment costs per patient[15]

12 ECLS: Early Cancer detection test – Lung cancer Scotland. Believed to be the largest
13 Tobacco Free Initiative WHO; Global Report on trends in tobacco smoking 2000-2025 Trends, Second Edition
14 Mid-year Population Estimates Scotland (Mid-2017); Fastfacts – Smoking in Scotland No.1 (published in October 2018 by Ash Scotland)
15 NHS

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Decrease in frequency of late stage detection

Number of late stage lung cancers at diagnosis 2 years after randomisation

2 year follow-up

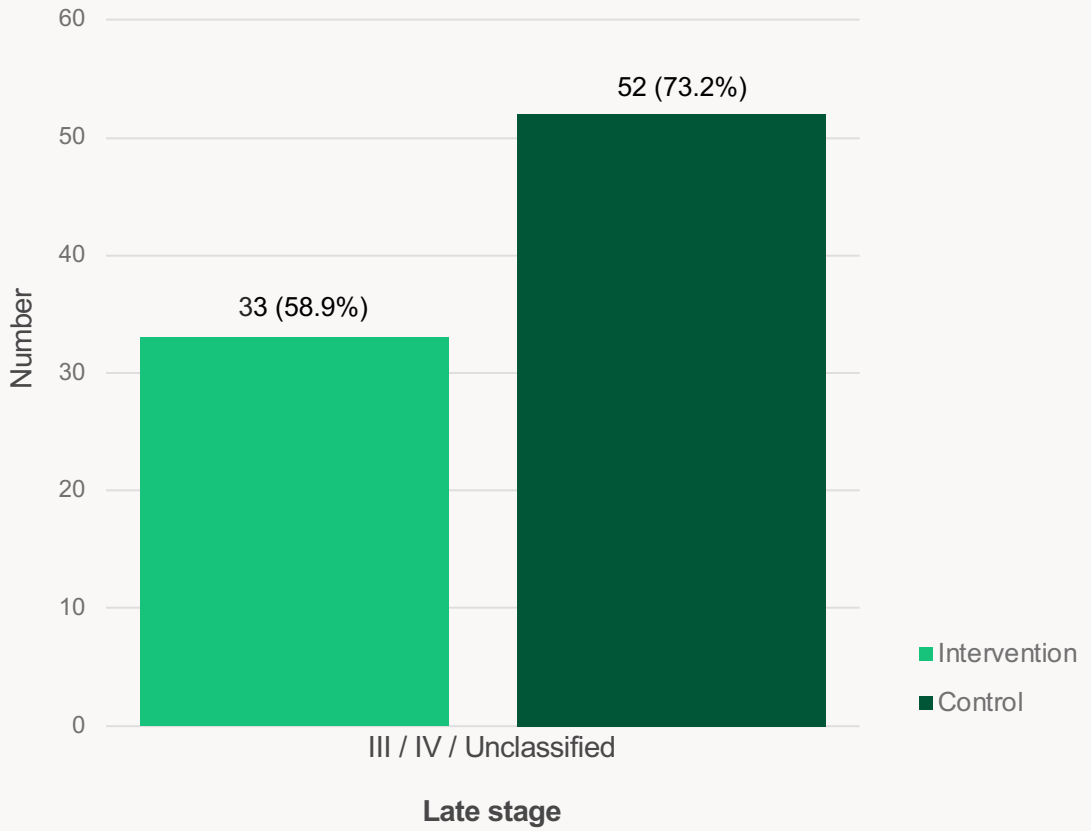
Specificity 90.4%

Sensitivity 32.7% all
52.2% early

1 year follow-up (post-hoc)

Specificity 90.4%

Sensitivity 45.5% all
69.2% early



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Performance and positive predictive value

EarlyCDT

	Early stage	Overall
Sensitivity	59.3%	40%
Specificity	90.2%	
PPV	4.0%*	

Double positive; EarlyCDT followed by CT

	Early stage	Overall
Sensitivity	55.7%	37.6%
Specificity	97.3%	
PPV (double positive)	12.2%	

* PPV CT in NLST at 1.2% annualised risk of lung cancer = 3.8%

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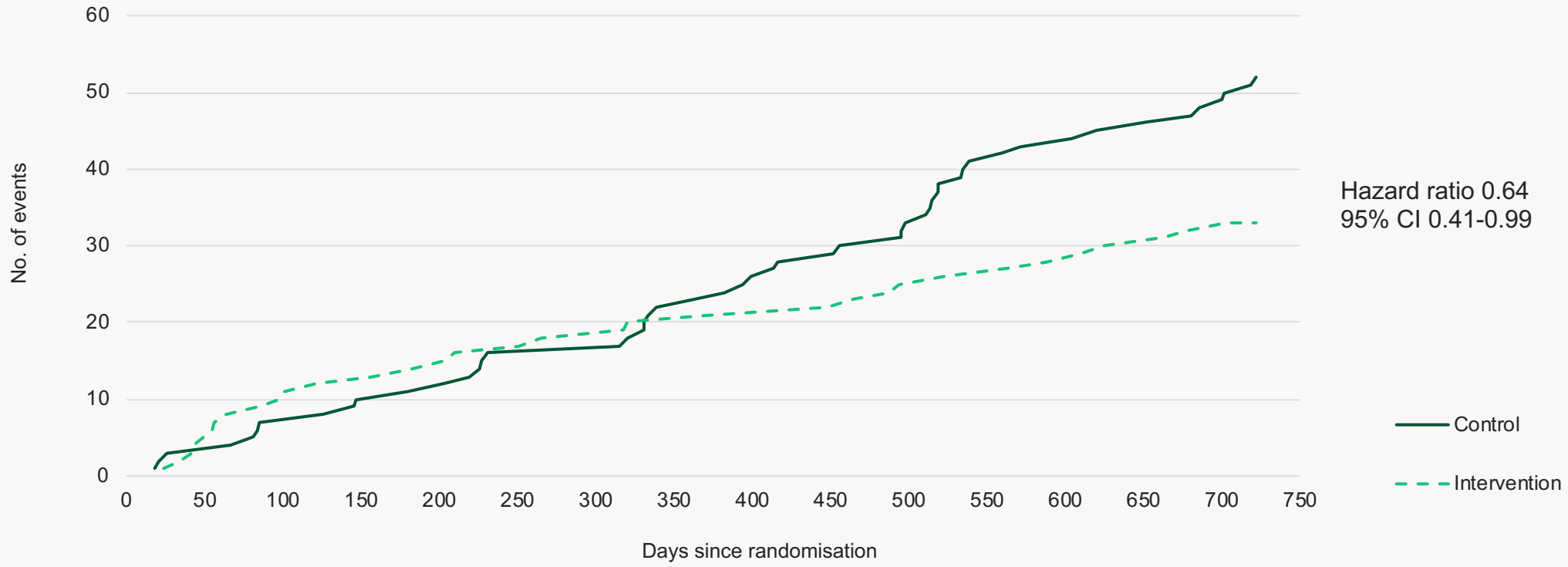
Analysis of primary endpoint

Diagnosis of stage 3/4 and unspecified lung cancers 2 years after randomisation



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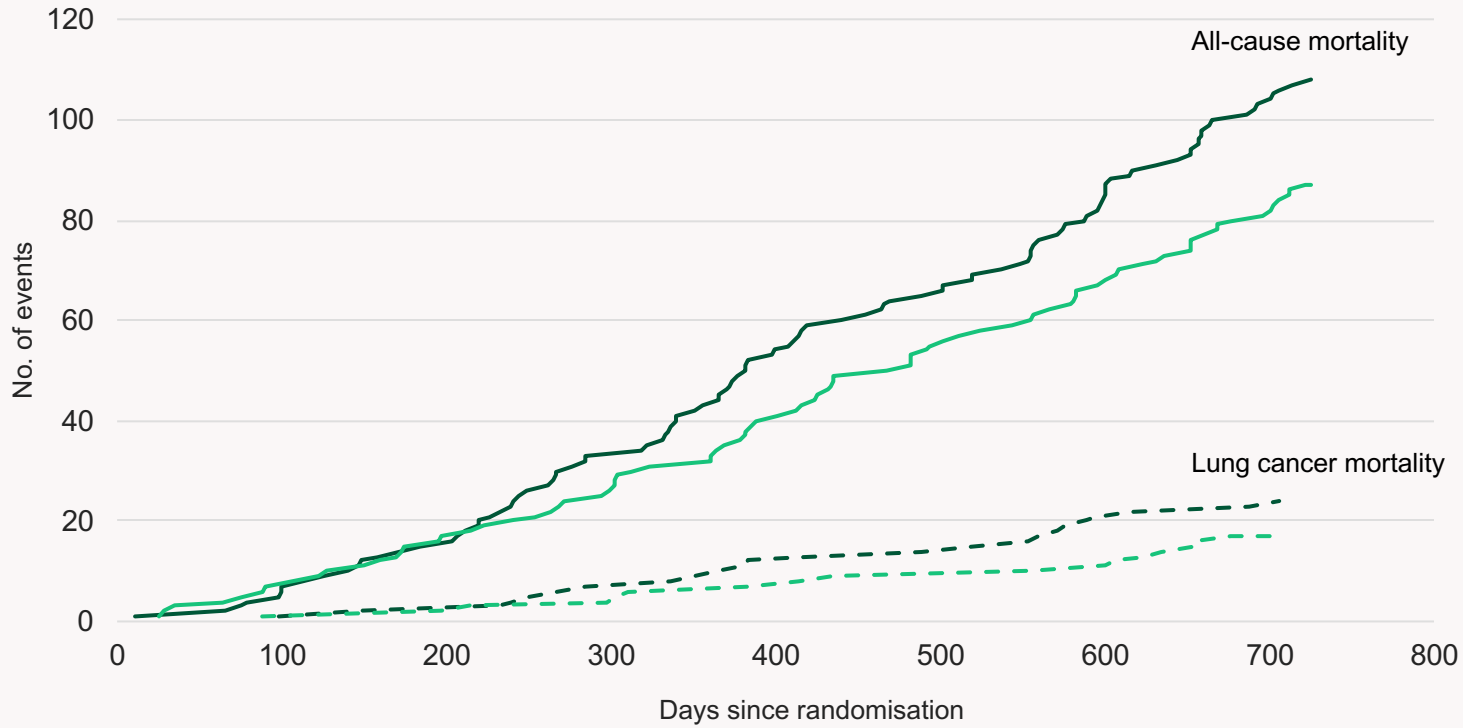
Encouraging trend in mortality benefit

Mortality 2 years after randomisation



- Trend towards reduced mortality rates in intervention group after just two years of follow-up since enrolment
  - All cause 87 v. 108
  - Lung cancer 17 v. 24
- Interaction with health service for lung cancer screening helps to identify and address comorbidities
- Planned mortality analyses
  - at 3 years (data already collected, awaiting analysis)
  - at 5 years

Control

Intervention

Follow on activities for ECLS

- A submission on the full ECLS study is being prepared for a leading peer-reviewed medical publication
- Preparations are underway to move to a larger population based evaluation in up to 200,000 patients to assess the implications of diagnosis with EarlyCDT Lung on survival and mortality in real-world setting
- Each participant will be tested with EarlyCDT Lung, to be supplied by Oncimmune on negotiated commercial terms

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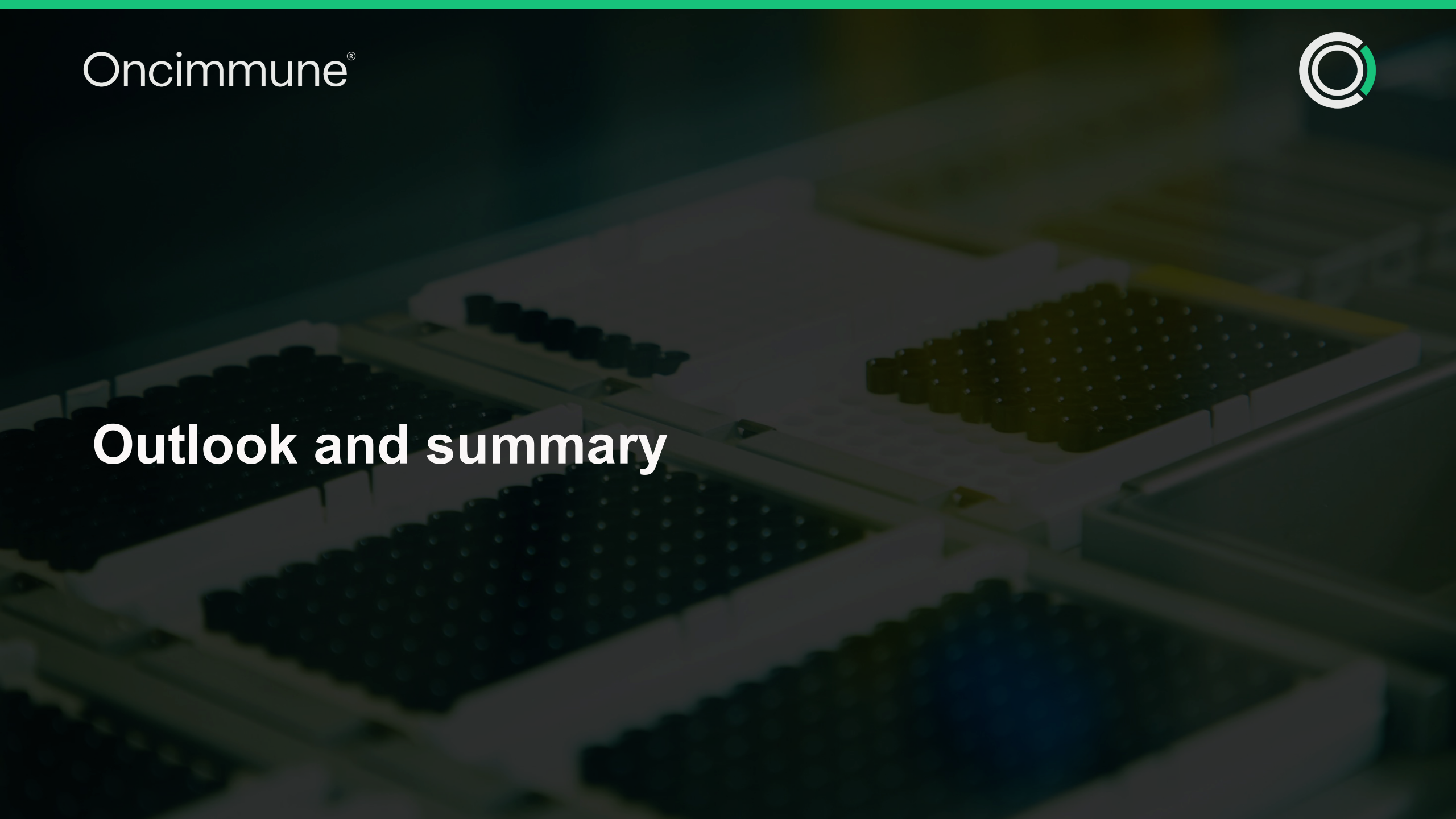

Outlook and summary

Commercial update

- Currently distribution agreements in force across 18 countries globally, with minimum sale commitments of £42m+ over next 5 years – most require initial regulatory approvals – expect sales to build towards the end of these agreements
- Recently signed strategic commercial agreement for EarlyCDT Lung in the US with Biodesix – valued at up to $28 million over next 5 years
- Recently signed distribution partnership with R-Pharm in Russia for use of EarlyCDT Lung in screening – valued at up to £5 million plus £3.5 million investment by R-Pharm
- Our Spanish distributor signs Quirónsalud Group and Vithas Group, Spain's largest private private hospital groups – launched EarlyCDT Lung as a nodule and screening test

Commercial update

- Gene Group agreement signed to sell EarlyCDT Lung in Hainan, China ahead of NMPA approval and product shipped
- Emerging revenues reflects the early stage of portfolio of distribution agreements
  - Cash (c.£5m) at year end will be materially above expectations
  - Operating costs for FY2019 materially lower than expectations
- Protagen integration progressing well with the first commercial service contract since acquisition having been signed and a growing pipeline of opportunities
- Landmark ECLS study: Results presented at the 2019 World Conference on Lung Cancer
  - Selected as top seven abstract and present at the Presidential Symposium
- Phase V population-based evaluation using EarlyCDT Lung expected to follow ECLS Study and deliver material revenues and profits

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Summary

- Phase 5 population-based evaluation using Early CDT Lung expected to follow ECLS Study and deliver material revenues and profits
- Tumour-related antibody platform with proprietary 8,000+ immunogenic protein library at its core
- Strong IP with 200 granted and pending patents covering 47 territories, two commercial tests and over £42m+ of sales commitments
- Outstanding delivery capability underpinned by a combination of leading development and innovation; growing pipeline of multi-industry partnerships and acquisitions – Biodesix and Protagen
- A high-potential platform with the capability to drive rapid revenue growth through supporting critical clinical decision making across the care pathway
- Strength of Oncimmune's platform and breadth of addressable cancer detection opportunities, means significant medium term potential to deliver value to shareholders
- Strong pipeline of early cancer detection across the board

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