Lung Cancer Screening

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Lung Cancer: World's leading cancer killer

1,825,000

new diagnoses globally

Annual global cancer mortality

Lung

Cancer	Mortality
Ovary	14,270
Cervix	266,000
Prostate	307,000
Esophageal	400,000
Breast	522,000
Colorectal	694,000
Stomach	723,000
Liver	746,000
Lung	1,590,000

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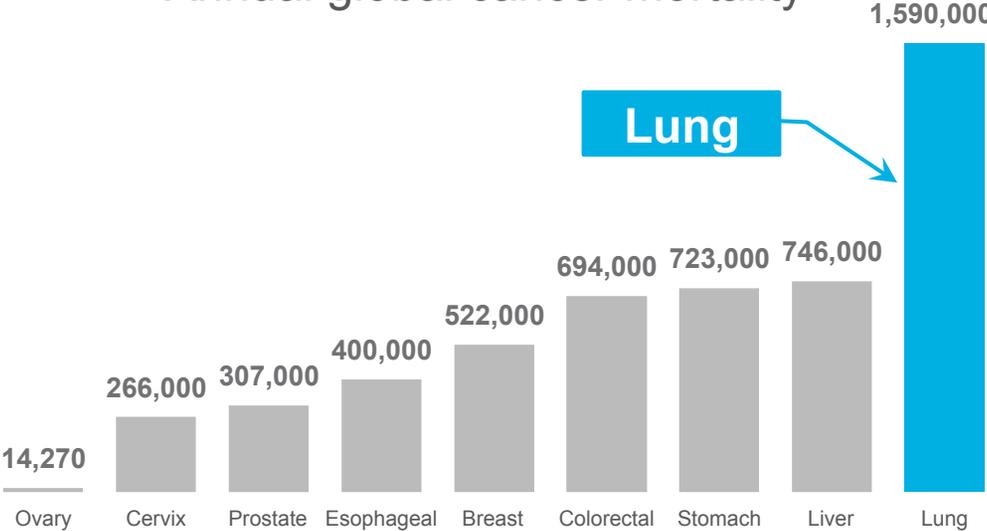
Source: Am Cancer Soc. *Cancer Facts & Figures* 2015. Atlanta: American Cancer Society; 2015.

Detecting lung cancer early saves lives
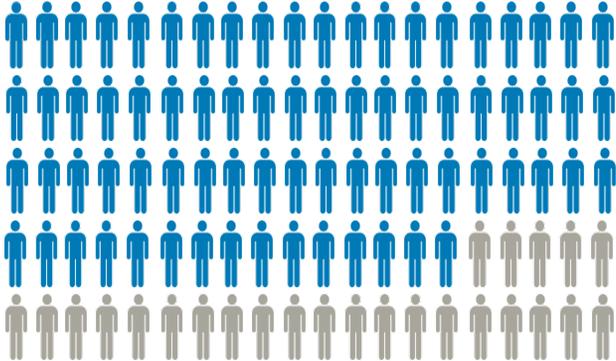
3 out of 4
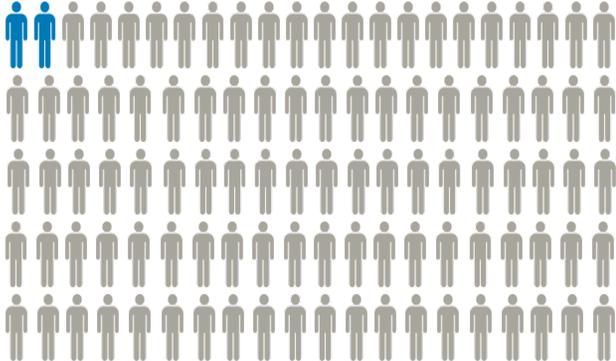*survive 5 years if*
asymptomatic with
Stage I

2 out of 100
survive 5 years if
diagnosed with
Stage IV

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Cost of lung cancer treatment continues to rise

$18B
Projected annual treatment costs in 2020

$12B

2010   2015   2020

Source: J Natl Cancer Inst. 2011; 103:1-12 (Mariotto)
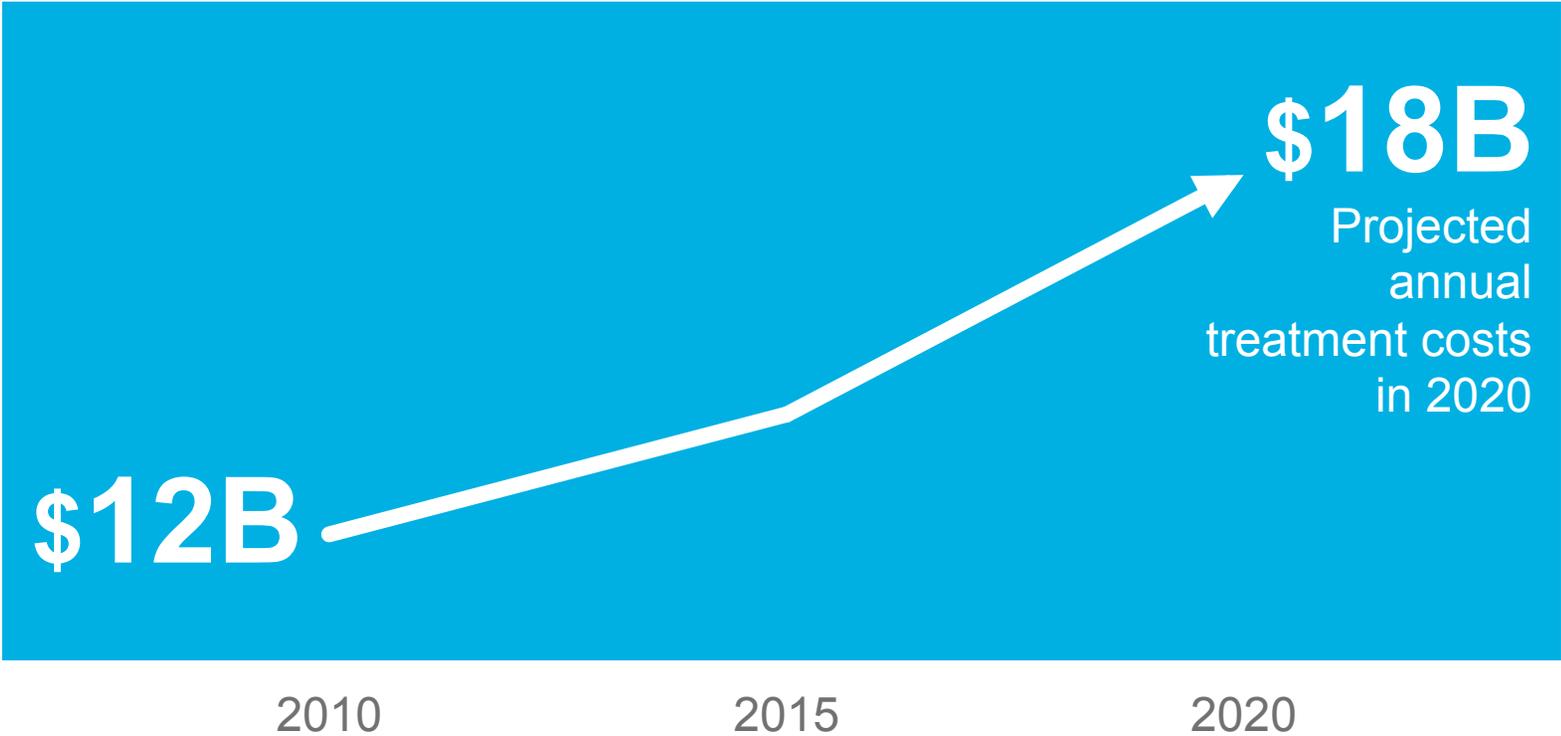
Significant screening opportunity in large smoking populations

42M
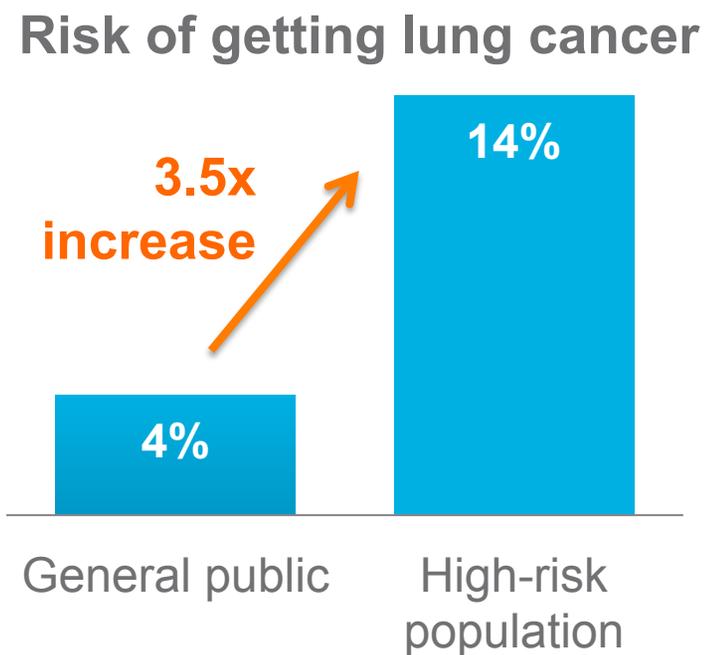current or former smokers in US

967M
current or former smokers worldwide

Source: U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014.

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>130M people worldwide in addressable high-risk population

High-risk, 30-pack year smoking population
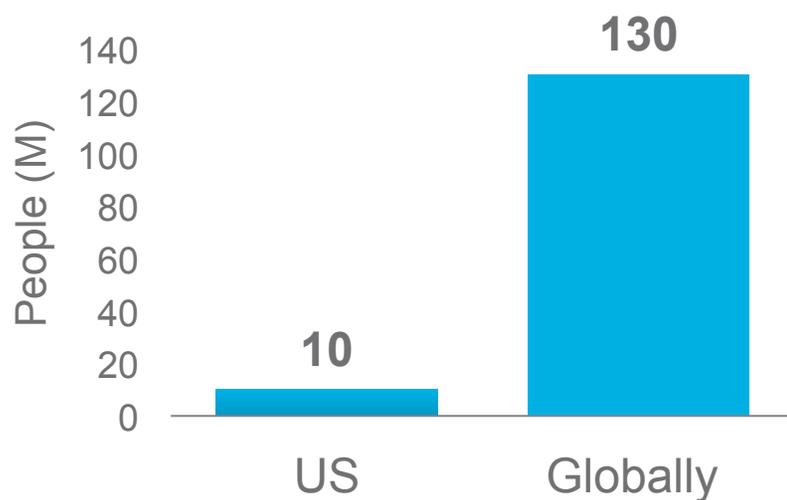
85%

of new diagnoses occur in current or former smokers

Source: U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014.

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National lung screening trial established low dose CT reduces mortality by 20%

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812   AUGUST 4, 2011   VOL. 365   NO. 5

Reduced Lung-Cancer Mortality with Low D...
Tomographi...
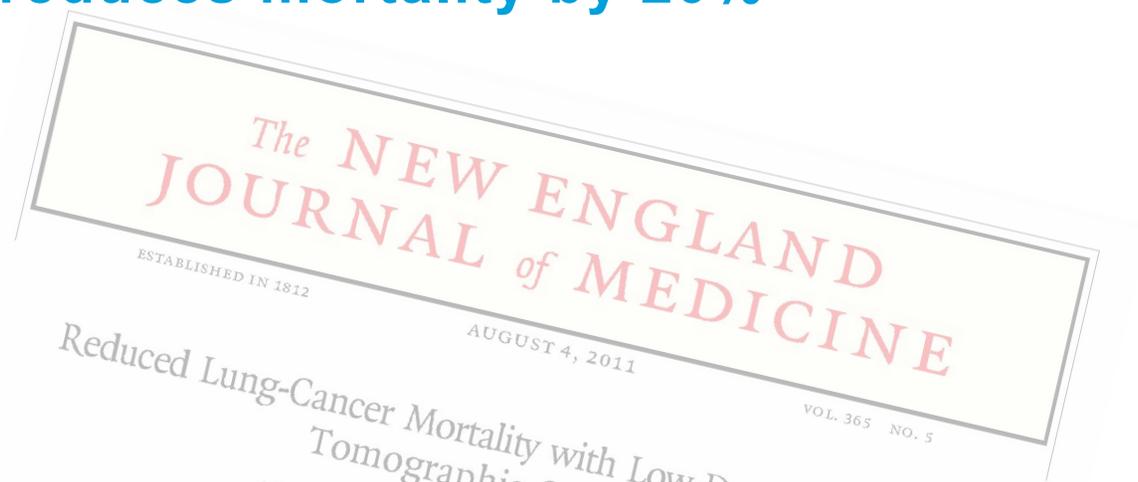
53,000+ high-risk smokers

24.2% positive, of which 96.4% were false positives

METHODS
From August 2002 through April 2004, we en...
lung cancer at 33 U.S. medical ce...
dergo three annual s...
gle-view...

...eening Trial (NLST) was conducted to determine whether ...with low-dose CT could reduce mortality from lung cancer.

...dose CT detects many tumors at early stages. ...landscape of lung-cancer screen-... ...g. The advent of low-

...orts to

The members of the writing team (who are listed in the Appendix) assume re-sponsibility for the integrity of the article. Address reprint requests to Dr. Christine D. Berg at the Early Detection Group, Division of Natio...

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Recommending LDCT screening despite challenges and costs

Regulatory Approval	U.S. Preventive Services TASK FORCE		CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Limitations To LDCT	Sensitivity 94%	Specificity 73%	Positives that are benign nodules 96%

Impact of Follow-up	Often harmful and invasive	~$3,600 per positive result	Radiation exposure

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Exact Sciences is well-positioned to tackle today's screening problem

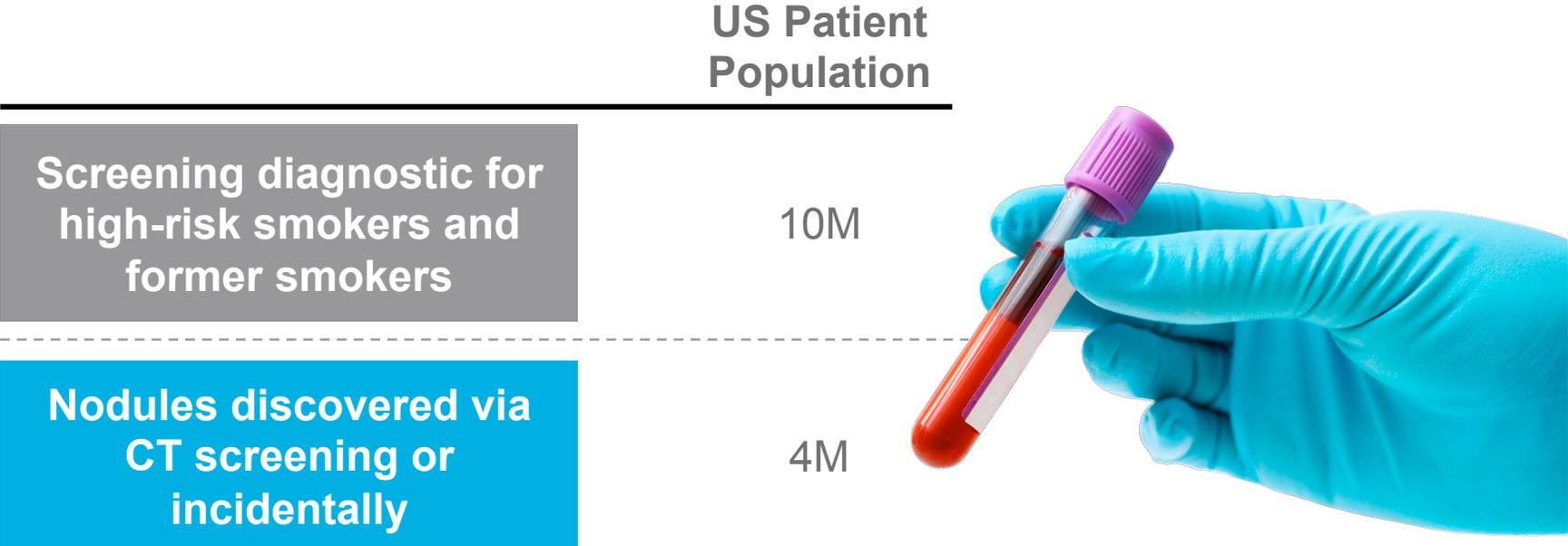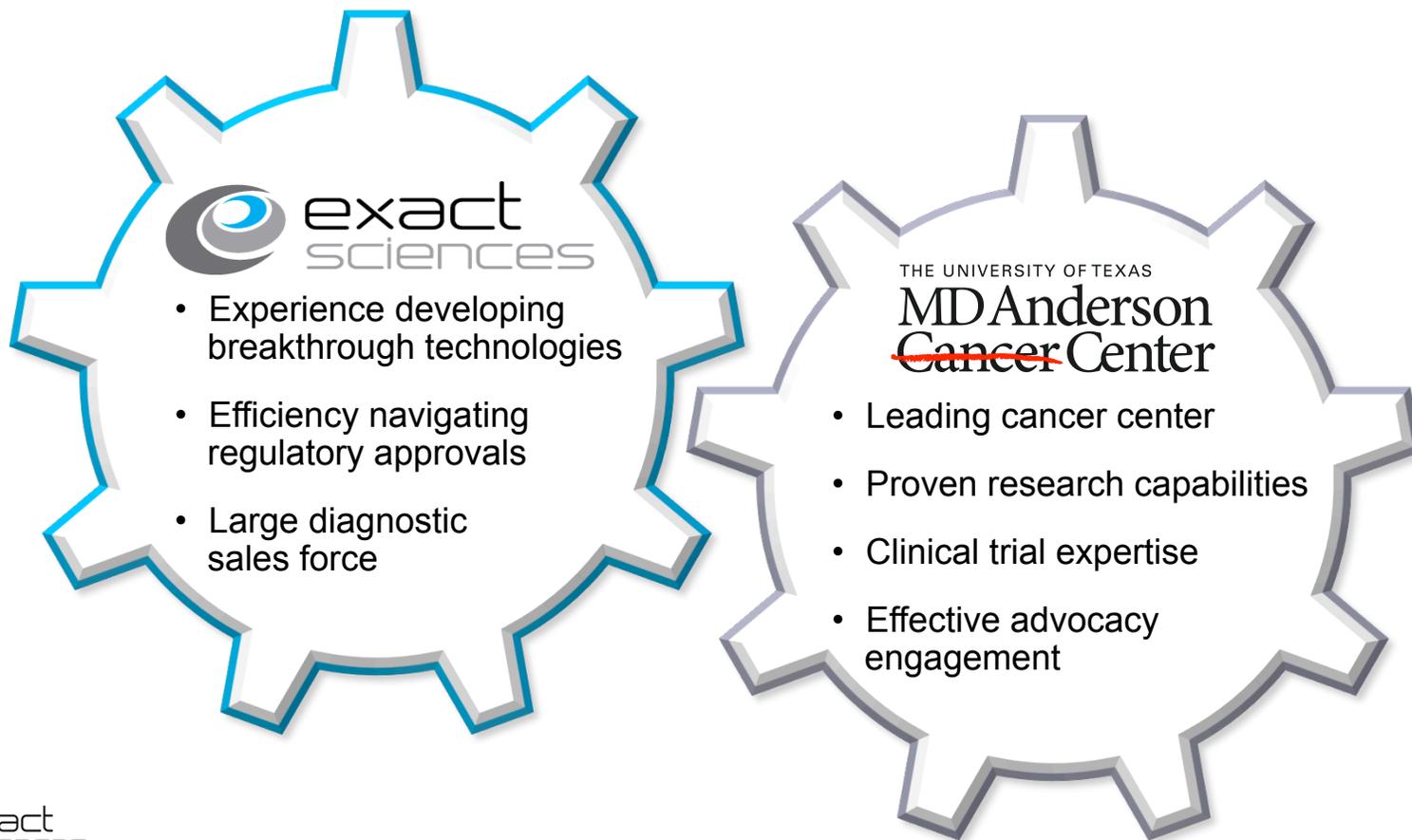|	
Scientific Capabilities	Agnostic to biomarkers; robust panel capability
Ability to Collaborate	History collaborating with Mayo Clinic
Clinical Trial Execution	DeeP-C was a 10,000 patient clinical trial
FDA/CMS Experience	Pioneered parallel review with Cologuard®
Commercial Capability	200-person primary care sales force

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Bringing blood-based tests to large populations

	US Patient Population
Screening diagnostic for high-risk smokers and former smokers	10M
Nodules discovered via CT screening or incidentally	4M

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Exact Sciences joins forces with MD Anderson

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- Experience developing breakthrough technologies
- Efficiency navigating regulatory approvals
- Large diagnostic sales force

THE UNIVERSITY OF TEXAS
MD Anderson
~~Cancer~~ Center

- Leading cancer center
- Proven research capabilities
- Clinical trial expertise
- Effective advocacy engagement

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Lung Cancer Screening

Sam Hanash, MD, PhD
Director, MD Anderson McCombs Institute for Early Detection and Treatment of Cancer

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THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

MD Anderson Moon Shots Program

- A bold plan to improve survival rates for many of the deadliest cancers

- $3B spend over next 10 years

- Addresses all aspects of cancer care

- Lung cancer leads the initiative

- Program also includes breast, ovarian, prostate cancers and leukemia

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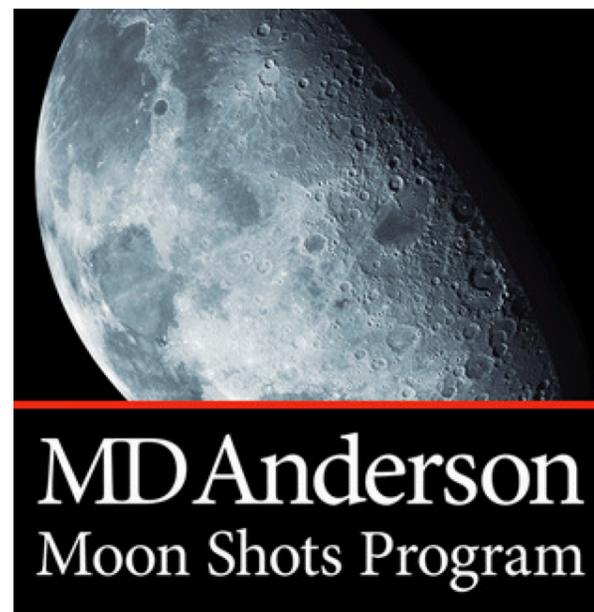
Detecting lung cancer early through connection to blood

- Typically takes >3 years for lung cancer to progress from nodule to late-stage cancer

- Proof-of-concept established by MD Anderson showing good sensitivity, excellent specificity

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Rationale for using blood to detect lung cancer

Cancer signatures found in blood

Identified common signatures through analysis of blood samples from patients with lung cancer

Assessed accuracy and effectiveness of markers in distinguishing between patients with and without lung cancer

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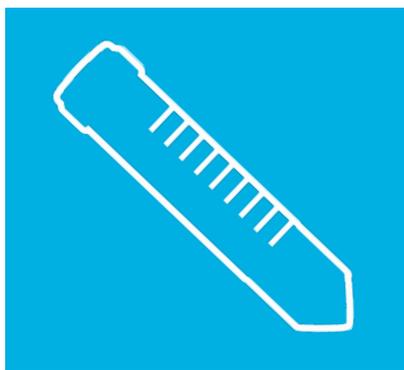
Discovery and validation of biomarkers through cancer continuum

Blood collected 3-5 years prior to diagnosis

Blood collected 6-18 months prior to diagnosis

Blood and tissue collected at diagnosis

Protein signatures of risk

Early detection signatures

Molecular classification

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Current assets available to partnership

Access to blood collected prior to diagnosis from >1M existing high- and average-risk people, newly diagnosed patients and patients with nodules

Integrating tumor tissue findings with findings from blood

Joint R&D initiatives to develop biomarkers

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Initial data show promising performance

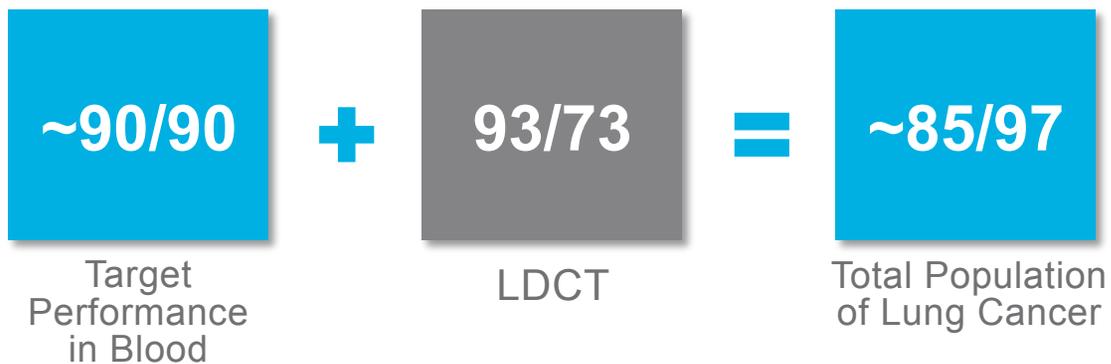MD Anderson initial biomarkers for lung cancer detection among smokers:

Specificity	95%
Sensitivity	65%

Panel optimization ongoing with additional biomarkers
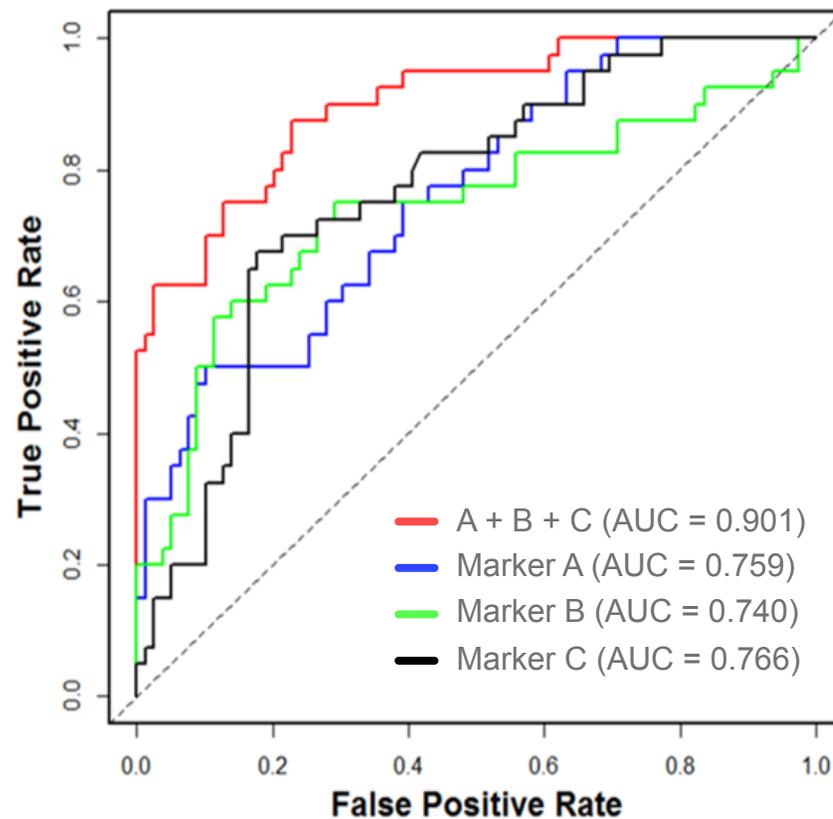
Proven approach and multi-marker assay

Modeling Sensitivity/Specificity for Lung Cancer

Paving the path for lung cancer screening for high-risk individuals

✓ Discovery

- Best-in-class protein markers
- Deep sequenced methylation markers
- Database mutations

Product Development

- Establish and validate biomarker panel

Clinical Validation

- Evaluation in clinical trial patients
- 15,000+ patient clinical trial
- Multiple US and international sites

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Paving the path for lung cancer screening for high-risk individuals

Regulatory Review

FDA approval

- Execute on regulatory review and approval

Insurance Coverage

CMS/ USPSTF

- Secure reimbursement by Medicare and commercial payers

Commercialization

Product launch

- Process tests using sole-sourced lab
- Utilize existing sales force to build awareness
- Conduct targeted marketing campaigns

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Monitoring population for nodules will compound annually to reach more than 20M

- ~4M patients with nodules added annually

  – 3.5M nodules detected incidentally

  – 800K nodules detected from high-risk screening

High follow-up, high positive LDCT attrition
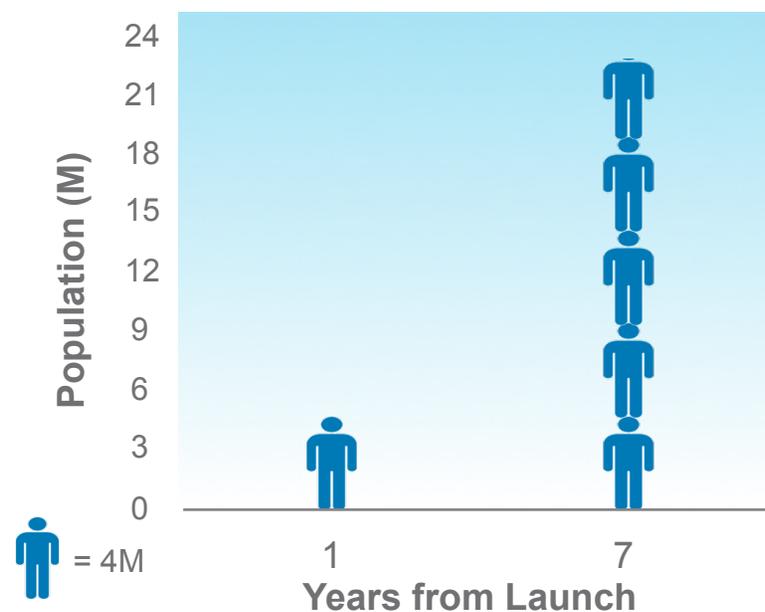
Market opportunity for early detection of lung cancer in high-risk individuals

	US Opportunity (Tests)	Global Opportunity (Tests)
Screening	10M	20M
Diagnostic	20M	40M
Total	30M	60M

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