

Screening for Lung Cancer: Challenges and Obstacles **THE I-ELCAP EXPERIENCE**

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THORACIC ONCOLOGY SESSION I



Today's Challenges and Obstacles Same as we faced in 1992

- Recruitment
- Updating the protocol using latest innovations in scanners and AI, including criteria for enrollment
- Identification of appropriate staff and training
- Identification of bottlenecks or problems to be solved
- Communication of results
- Expansion of the screening program and pointers to new directions (i.e., identification of subgroups not well represented and how to reach them)

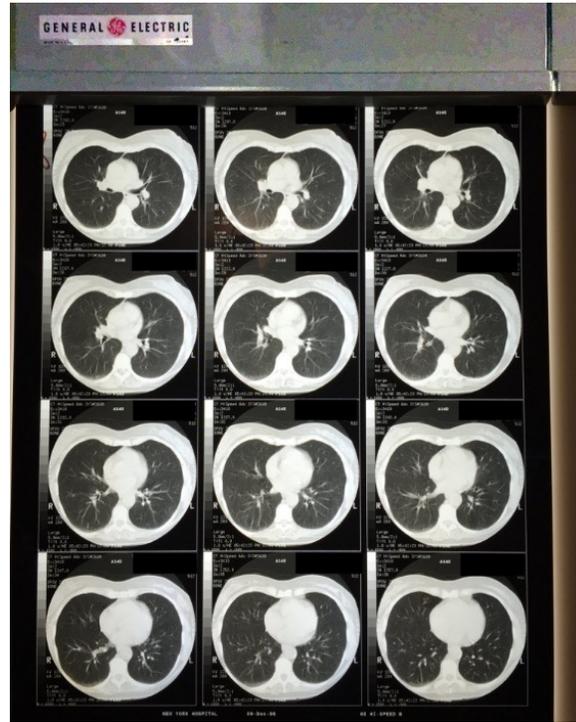
CRITICAL QUESTIONS in 1992

- How to reduce deaths from lung cancer?
 - When we find the lung cancer earlier we know that early treatment could result in a **cure**
 - We wanted to learn how early low-dose CT screening could find lung cancers compared to CXR
 - How to get funding for a preliminary study
 - Morgan et al. What is the definition of cure in non-small cell lung cancer? Oncol Ther

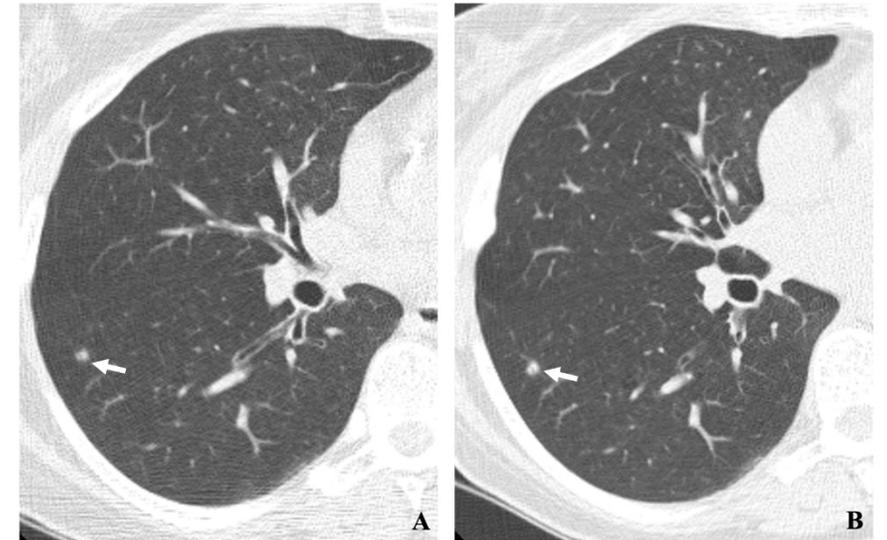
2021; 9:365-371

CT IMAGING IN 1992

12 tiny images on 1 x-ray film
Low dose acquisition just introduced
24-30 images on 2-3 x-ray films



Today more than 1000 axial images
as well as coronal and sagittal images



12 images on 1 X-RAY

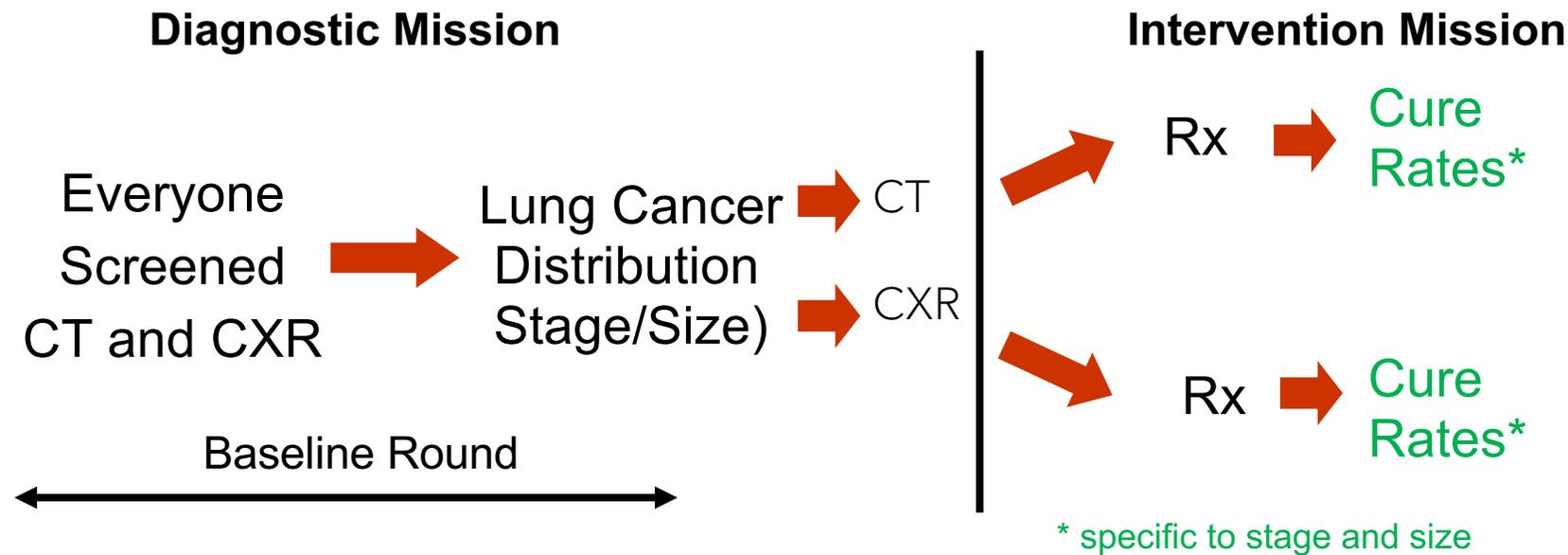
Early Lung Cancer Action Project: 1990-1998

- Explored methods
 - AI: Article in **Business Week**. Searching for lung cancers instead of tanks: May 23, 1994
 - Henschke CI, Yankelevitz DF, Mateescu I, Brettle DW, Rainey TG, Weingard FS. Neural networks for the analysis of small pulmonary nodules. Clin Imaging 1997; 21:390-99 PMID:9391729
- Volumetric assessment of growth of nodules
 - Reached out to engineers at Cornell University, Center of Excellence in Computing:
 - Started to work with Anthony Reeves PhD
 - Early Repeat CT Imaging for Evaluation of Solitary Lung Nodules. NCI R01-78905. 9/99-8/02
 - Yankelevitz DF, Reeves AP, Kostis WJ, Zhao B, Henschke CI. Small pulmonary nodules: volumetrically determined growth rates based on CT evaluation. Radiology. 2000; 217:251-6
- Programmed a management system using Statistical Analysis System (SAS)

The ELCAP Approach in 1992-1999

1000 participants, aged 60+ and at least 10 pack-years of smoking

CT found 27 cancers of which 23 (85%) were Stage I
vs. CXR found 7 cancers of which 4 (57%) were Stage I



Lung Cancer Screening Promises Big Benefits, Big Costs

4 NOV 2010 • BY [ELIOT MARSHALL](#)

"the greatest single reduction of cancer mortality in the history of the war on cancer,"

says James Mulshine, vice president for research at Rush University Medical Center in Chicago, Illinois and cancer researcher associated with the pro-screening advocacy group, the Lung Cancer Alliance



Study design

Screening protocol

Pathology protocol

Regimen of screening

Lung cancer size, stage, cure rate



Additional discoveries

Nodule growth & detection

Mediastinal masses

Emphysema

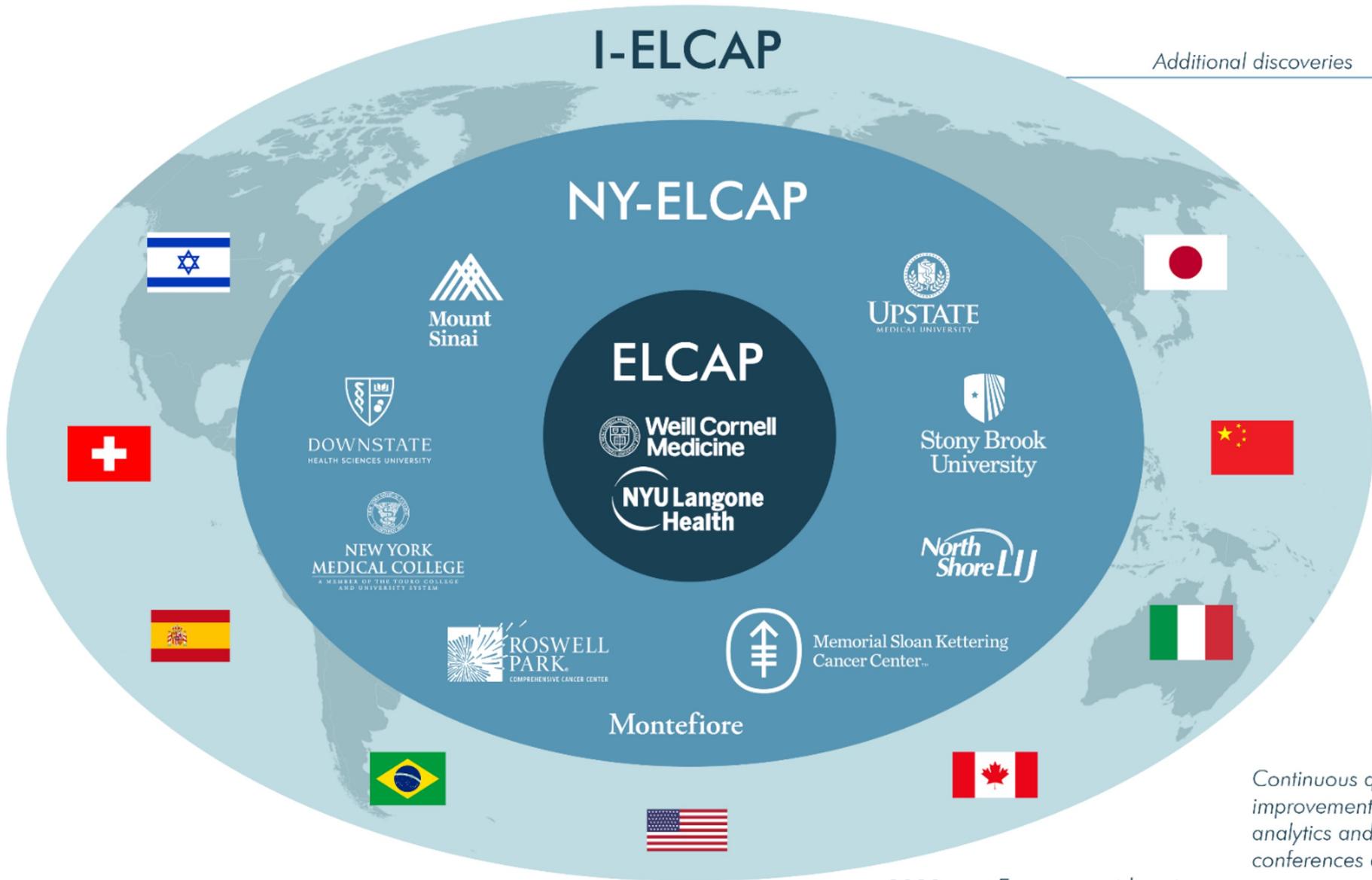
Coronary Artery Ca++

Breast diseases

I-ELCAP

NY-ELCAP

ELCAP



1992

2023

Future considerations

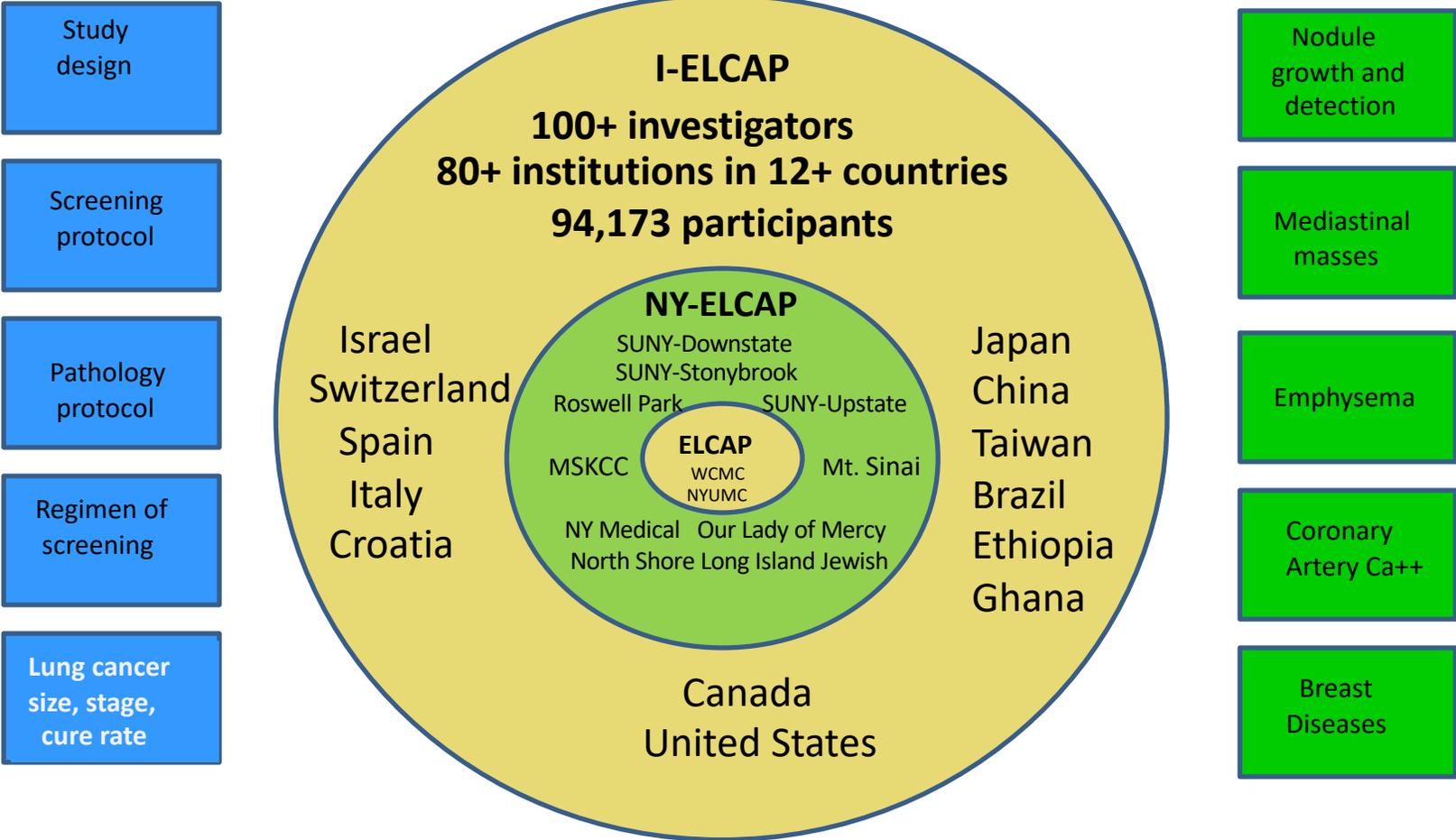
Continuous quality improvement via computer analytics and international conferences every 6 months

Key Components of Screening Program

- Screening intervals
- Separate the protocols for baseline and repeat screenings
- Nodule definitions
 - Solid, part-solid, nonsolid
 - Peri-fissural and costal pleural nodules
- Measurement of nodules
- Nodule growth assessment
- Thresholds for noninvasive and invasive diagnostic workup
- Management System for the entire screening process

ELCAP to NY-ELCAP to I-ELCAP: 1992-2024

Individualized CT screening depending on indicators of risk, e.g., current smokers, former smokers, never smokers

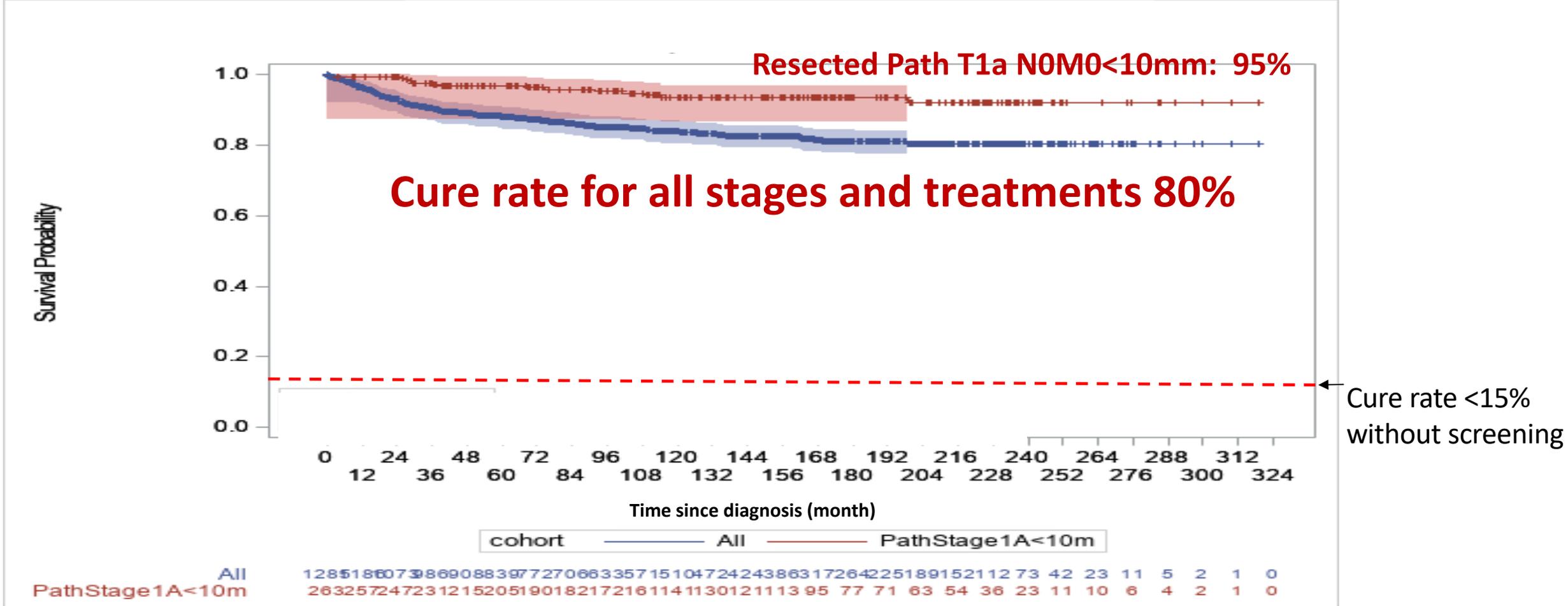


Computer Analytics

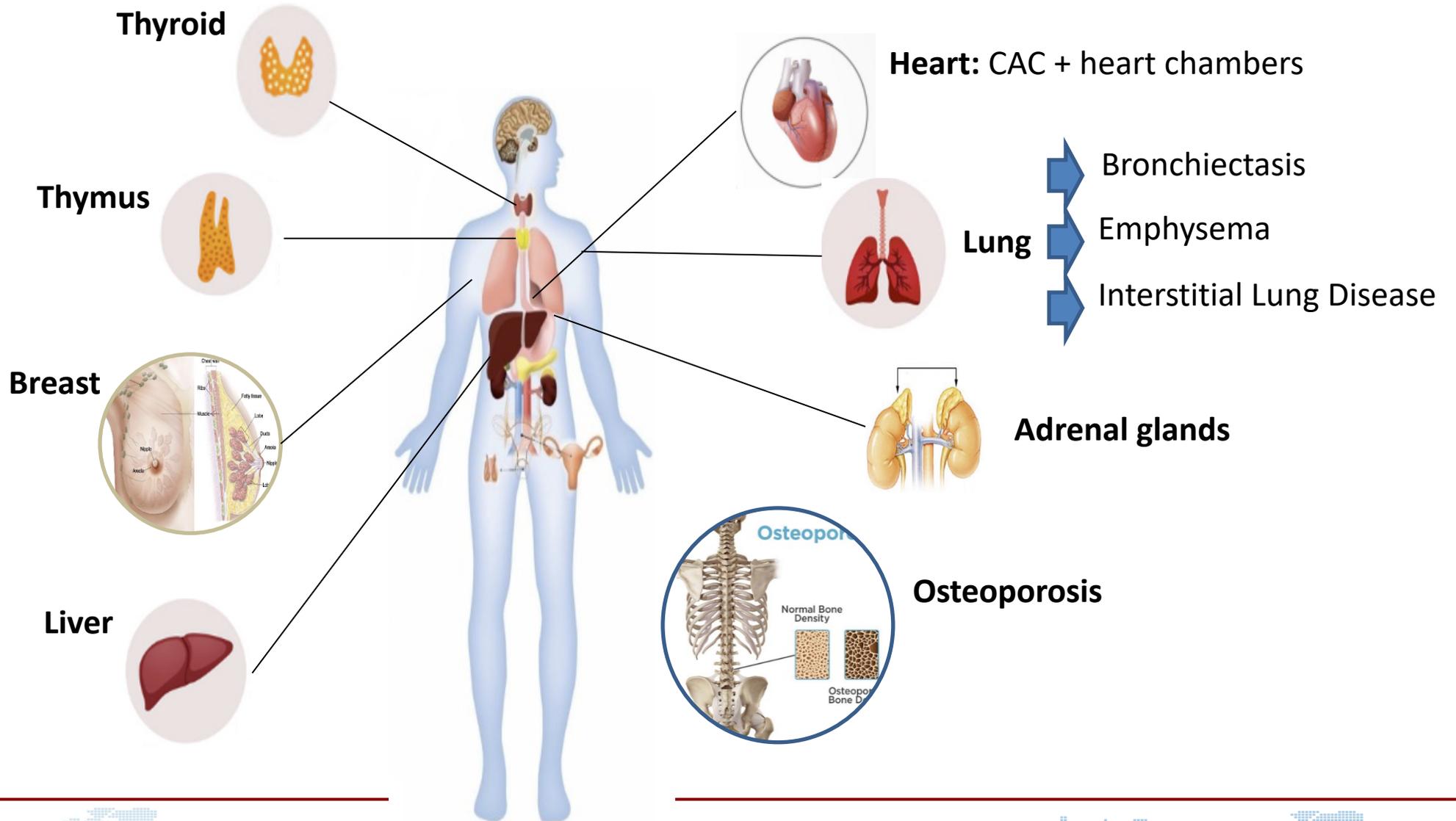
Conferences @ 6 months

Continuous Quality Improvement

WE CAN INCREASE LUNG CANCER CURE RATE BY LDCT SCREENING (Radiology 2023)



LDCT is an Annual Health Check

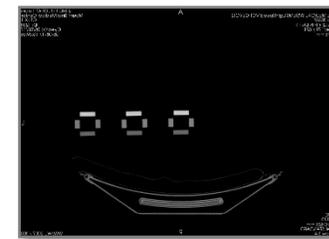
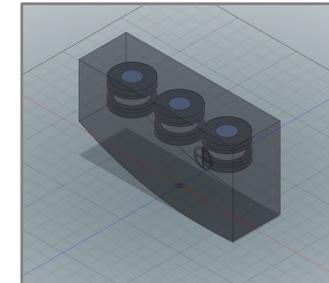
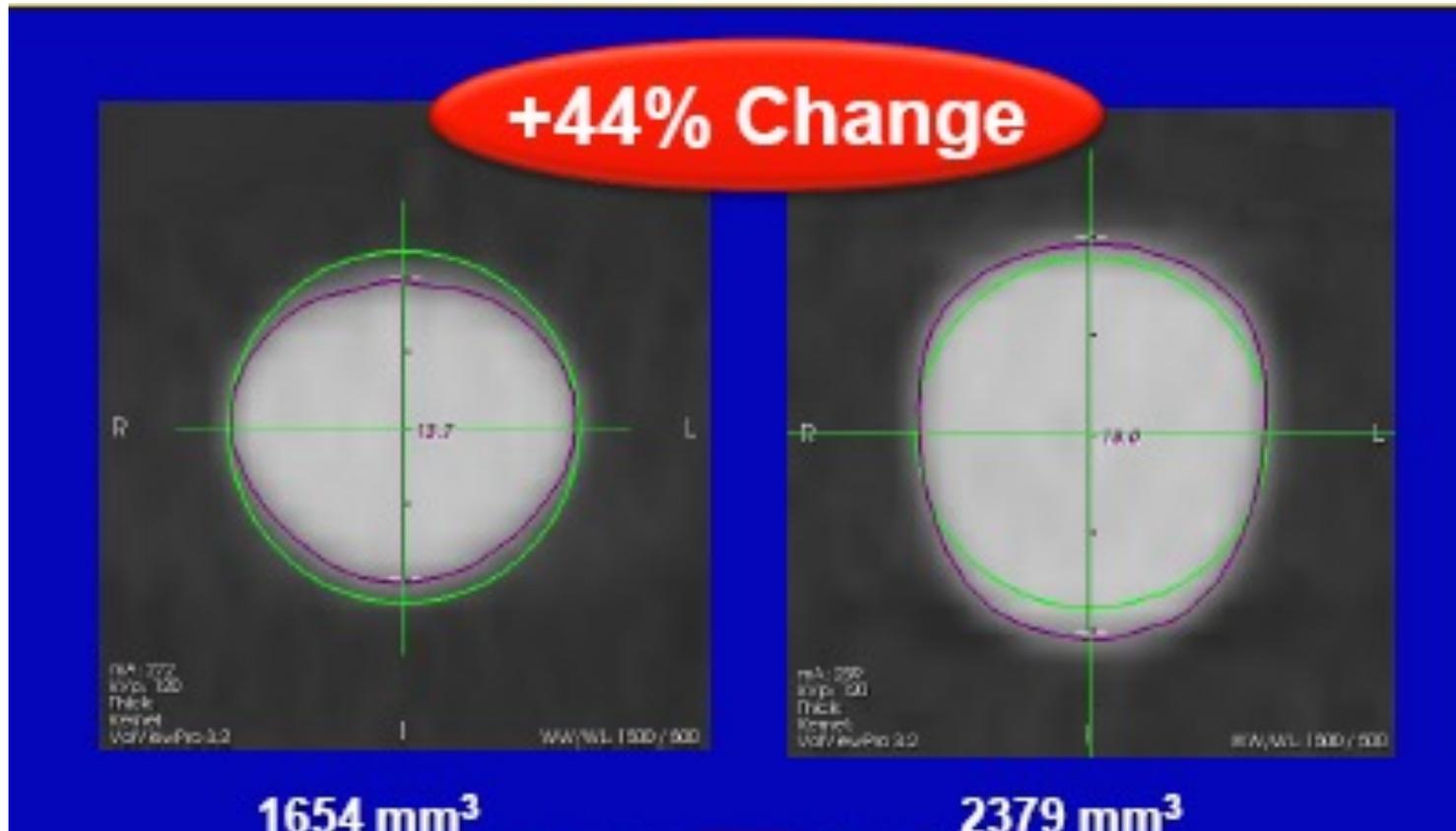


Global Lung Cancer Statistics in 2020

- 2.2 million people were diagnosed with lung cancer
- One fifth (1/5) of all deaths from cancer were due to lung cancer
 - Almost twice as many deaths as 2nd most (colorectal cancer) or 3rd most (liver cancer) cancer
- Lung cancer has a higher economic burden than any other cancer
- Without LDCT screening, the cure rate for lung cancer is low

Today Nodule Growth Assessment Still Limited by Measurement Accuracy

RSNA/QIBA
Performance
Certification



Check Each
Time Scanner
or Protocol
Changes
and Once
Per Year

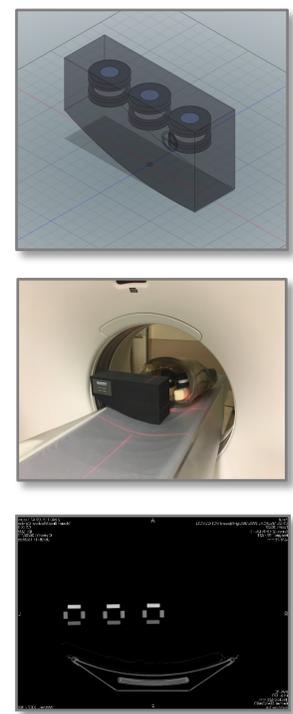
Within seconds of repeat CT, 44% change at a VDT rate of 172 days

Updated I-ELCAP Management System Optimizes Screening Efficiency and Quality

+ Screening Performance Reports For National & Local Administrators



Administrative and patient management screens from the I-ELCAP system, including a 'Lung Screening Intake Form' and various data tables.



Automated CT Image Quality Performance Report from Accumetra. The report includes scanner and protocol settings, performance assessment status, and measured image quality characteristics with associated graphs.

Scanner and Protocol Settings

Manufacturer	GE MEDICAL SYSTEMS	Tube kVp	120.00
Scanner Model	Revolution CT	Tube mA	15.00
Scanner Series	SLNCT	Scan Protocol	SLN
Scan Date	07/08/17	Scan Spacing	0.625
Scan Name	STANDARD	Pitch	0.99

Measured Image Quality Characteristics

The QIBA CT Small Lung Module Profile requires that CT image quality performance is verified for a fundamental image quality characteristic throughout the acquired CT image data. The performance of each of these characteristics is reported from scanner to scanner to enable a hospital to compare with other hospitals and to monitor the performance of their own CT scanner. The DICOM CT scan plots to within acceptable limits for this analysis (n=215).

Pulmonologist

Teaching Files

Software interfaces for Pulmonologist and Teaching Files, showing detailed data and analysis tools.

AI

Pathologist

Oncologist

Software interface for PatientAI, showing patient information and screening details.

Radiation Oncologist

Software interface for PatientAI, showing patient information and screening details.

CT Evaluation Form

ScreeningPLUS Home Case Review Reports About Logout XXX

DOE9000004,JOHN 999-99-9999 DOB: 03/02/2000
CT Evaluation Form

Scan Nodules Emphysema/Coronary Calcifications Other Abnormalities Impression & Follow-Up

Scan information

*CT study date: 01/01/2000

Signing radiologist: [dropdown] Radiologist: [dropdown]

Clinical information

Include in impression

CT scan performed at outside institution

*Type of exam: Baseline Annual repeat Follow-up (not annual repeat)

Import AI+ Data Revert AI+ Data

Only select Baseline if there is no prior CT or there is a prior CT scan more than 3 years ago

*CT protocol: [dropdown]

Nodules

READ before completing the Nodule Grid

- BASELINE: Include all nodules ≥ 6.0 mm in average diameter. Others are OPTIONAL.
- ANNUAL REPEAT: Include all NEW nodules ≥ 3.0 mm in average diameter.
- For BASELINE CT, all nodules are new unless there is a CT more than 3 years earlier.
- For BASELINE CT, the nodules will automatically be sorted with the largest non-calcified nodules with a solid component coming first.
- Note: hilar masses and focal consolidation should be included in the nodule grid.
- The same nodule ID will be used on all subsequent CT and other forms. NEW nodules, even if LARGER, must follow nodules already listed.
- For nodules recommended for biopsy or antibiotics, list the reason in the comments field in the corresponding column.

+ Add nodule

Nodule ID	Image 1	Image 2
	Nodule 1	Nodule 2

	Nodule 1	Nodule 2
* Is it new? [?]	-	-
* Endobronchial? [?]	-	-
* Most likely location? [?]	RML	LUL
* Nodule seen in series [?]	[input]	[input]
* Nodule seen in images [?]	[input] - [input]	[input] - [input]
* Nodule status [?]	-	-
* Nodule consistency [?]	Solid	Solid
* Length (mm) [?]	18.3	9.9
* Maximum width (mm) [?]	13.3	4.9
Mean diameter (mm) [?]	-	-

Structured Report Form Is Auto Filled In By A FDA Cleared CT Lung Nodule AI System

Translated into a Radiology Report

ScreeningPLUS Home Case Review Reports About Logout XXX

DOE9000004,JOHN 999-99-9999 DOB: 03/02/2000 AGE: 21 GENDER: F

CT Evaluation Report

Participant Name: DOE9000004,JOHN

Study ID: XXX9000004

Type of Examination: Baseline low-dose CT

Examination Date: 01/01/2000

Date of Birth: 03/02/2000

Report:

Comparison CT Scans: None

Description: CT examination of the entire thorax was performed at low-dose CT settings. Images were obtained at 0.5 mm slice thickness. Multiplanar reconstructions were performed.

Lung Nodules:

RML Nodule 1 is noncalcified, solid, 18.3 mm x 13.3 mm (average diameter of 15.8 mm), smooth edges, (Series 1, image 100-102).

LUL Nodule 2 is noncalcified, solid, 9.9 mm x 4.9 mm (average diameter of 7.4 mm), smooth edges, (Series 1, image 200-202).

Emphysema: None.

Pleura: No pleural effusion.

Coronary Artery Calcifications: none in left main, none in left anterior descending, none in circumflex, and none in right coronary.

Other Cardiac Findings: None.

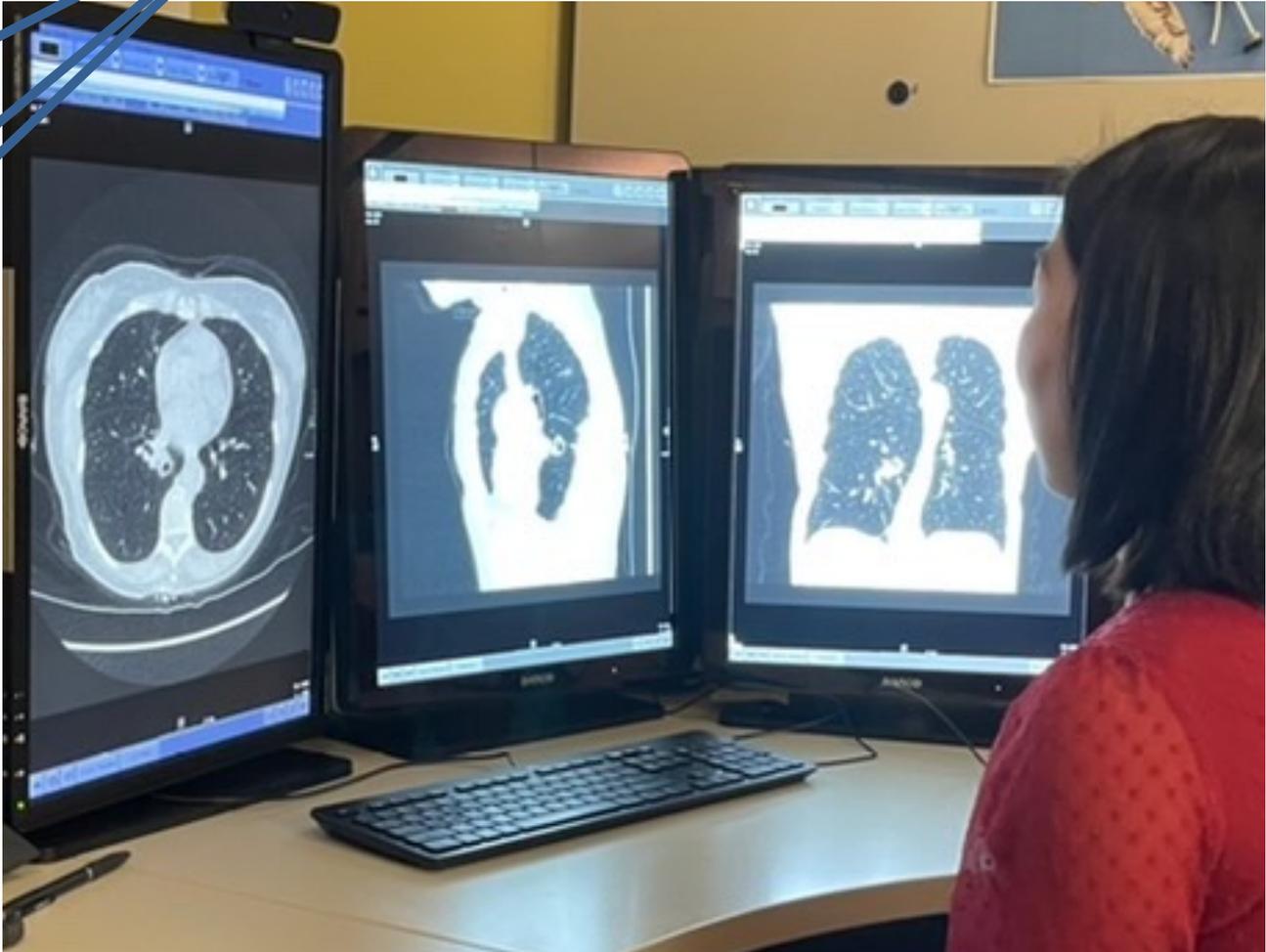
Editable Report That Is Automatically Sent To The EHR and PACS Via HL7

SCREENINGPLUS: updated I-ELCAP Mgt System

AI Results Now Auto-Fill The Nodule Grid

The screenshot shows a web browser window with the URL <http://demo.va-pals.org:9080/v...>. The interface includes a navigation menu with options: Scan, Nodules, Emphysema/Coronary Calcifications, Other Abnormalities, and Impression & Follow-Up. Below the menu, there are two columns for 'Nodule 1' and 'Nodule 2'. Each column contains a small image of a nodule and a corresponding data entry form. The forms are filled with values, and some fields have dropdown menus or checkboxes. The data for Nodule 1 and Nodule 2 is as follows:

Field	Nodule 1	Nodule 2
Is it new?	Newly seen	Newly seen
Endobronchial?	No	No
Most likely location?	RLL	RLL
Nodule seen in series #	2002	2002
Nodule seen in images	53	96
Nodule status	Unknown	Unknown
Nodule consistency	Solid	Solid
Length (mm)	19.5	11.9
Maximum width (mm)	14.8	10.5
Mean diameter (mm)	17.1	11.2
Height (mm)		
Volume (mm ³)	2040.4	832.4
Solid comp. of part-solid	length x width	length x width
Solid mean diameter(mm)	-	-
Smooth edges	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> Yes
Spiculated	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Yes
Calcifications	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes





1st Conference on Integrating Early Detection of Heart and Lung Disease through Low-Dose CT

*“Scientific Think-Tank Event Exploring New Frontiers in Averting
Preventable Premature Deaths through AI-enabled Early Detection”*

Together with

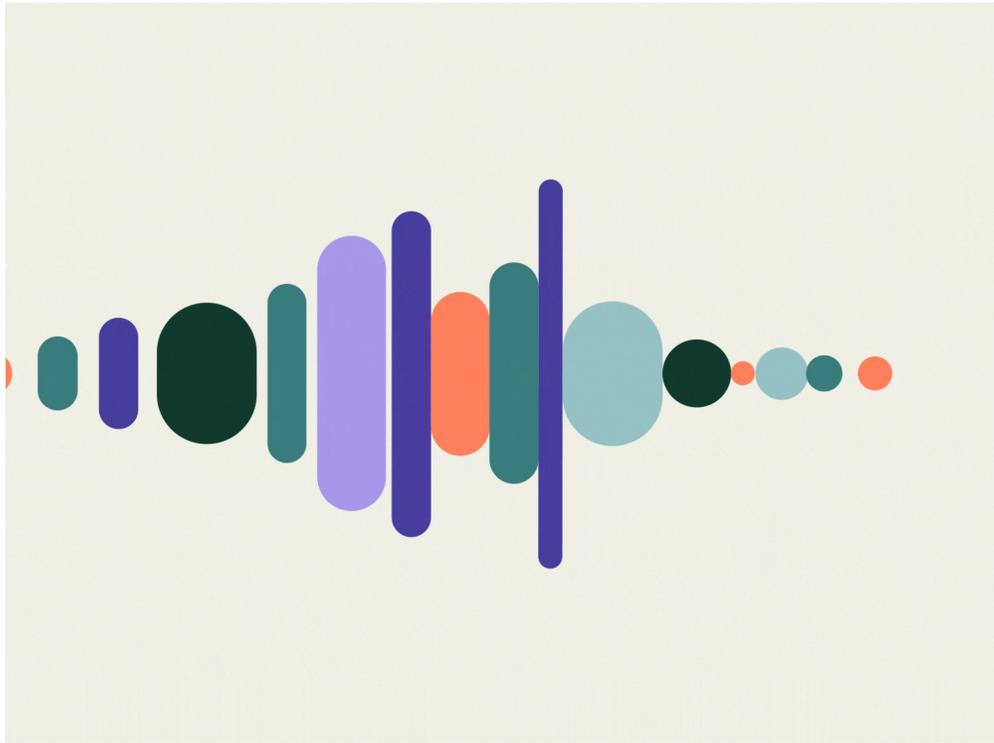
**46th International Conference on
Screening for Lung Cancer**

**14th Conference on Early Lung
Cancer Research on Treatment**

Integrating Cardiac
and Lung Screening

September 19-21, 2024

New York Academy
of Medicine in
New York City



I-ELCAP AIRS:

Automated Image Reading System



An Open Source
automated image reading
system (AIRS) that
determines **no clinical
change has occurred –
no new nodules and
no nodule size change**

I-ELCAP AIRS Team



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PI of AIRS



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Founder/CEO Paraxial and Accumetra
Former head of CAD/AI for GE & Kitware
Founder of VTK and ITK imaging toolkits
AI Development Subcontract to AIRS



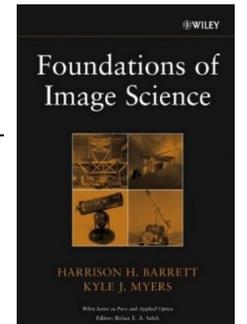
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Lead Engineer to AIRS



Rowena Yip, MPH
Senior Biostatistician at Mount Sinai
I-ELCAP Lead Statistician
Lead Statistician to AIRS

The I-ELCAP AIRS Team

- ❖ CH and DY developed automated nodule analysis in 1998
- ❖ This technology was licensed to GE in 2001, where RA was head of CAD/AI development at GE Research
- ❖ Nodule analysis (Lung VCAR) was brought by GE to FDA in 2004 where it was evaluated in the division headed by KM
- ❖ KM has extensive experience on image quality evaluation
- ❖ RY and AJ have worked with all members for many years
- ❖ In summary:
 - ❖ **The I-ELCAP AIRS Team has been working together on papers, conferences, and projects for many years**
 - ❖ **The I-ELCAP AIRS Team has been developing the AIRS concept for years**



I-ELCAP AIRS will:

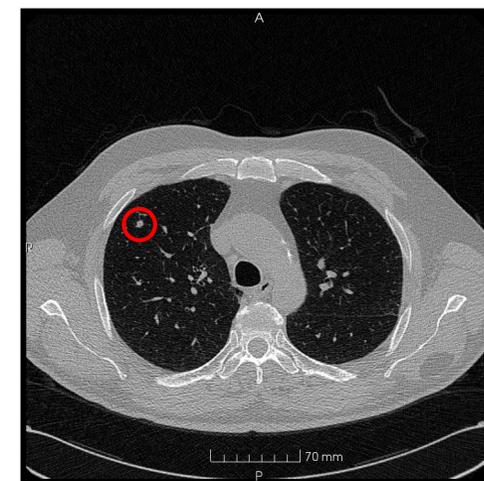
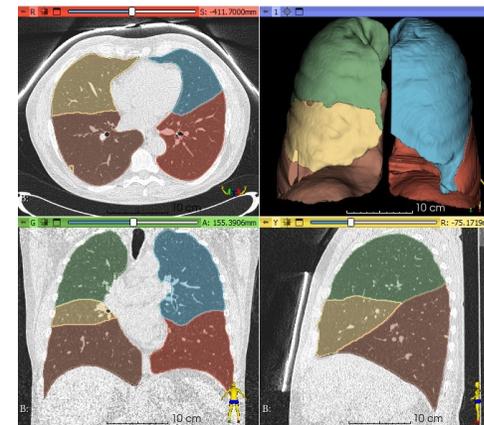


- Act as a **first-read** for annual LDCT scans – **radiologists would not need to spend time** reviewing these annual scans
- **Majority of scans** in an established screening program **will be annual LDCT scans**
- Will apply for FDA approval to facilitate clinical use

Imagine What Could be Accomplished

If sites around the world had access to this tool it would:

- Dramatically reduce the burden on radiologists, especially in low and moderate income countries
- Allow for automation of the entire screening process by connecting to a management system, such as the open source VAPALS-ELCAP/ScreeningPLUS system
- Standardize quality of scan interpretations



The NEW ENGLAND
JOURNAL of MEDICINE

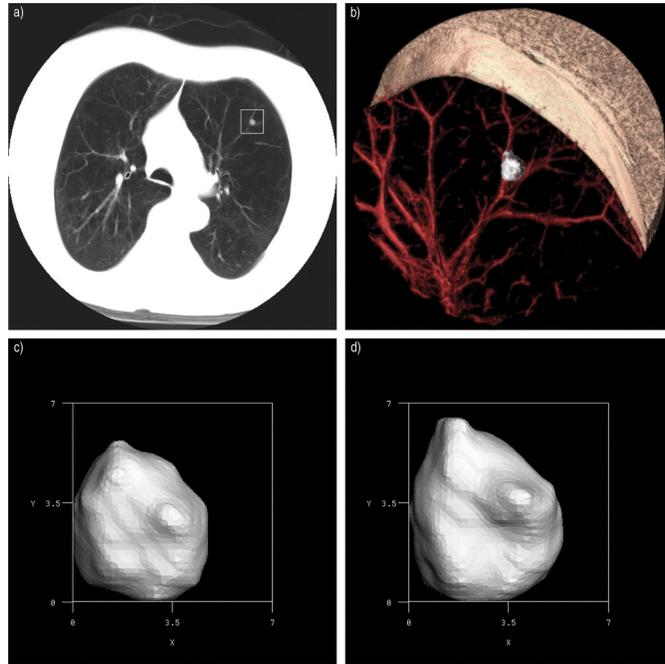
ESTABLISHED IN 1812

OCTOBER 26, 2006

VOL. 355 NO. 17

Survival of Patients with Stage I Lung Cancer
Detected on CT Screening

The International Early Lung Cancer Action Program Investigators*



Why I-ELCAP Because...

We have the largest database of lung screening CT scans: > 90k participants, 300k CT scans worldwide

We are leaders in lung screening
(started in 1992!)

We are leaders in automated medical imaging – first patent on volumetric analysis of nodules

Welcome New Members

- Croatia, first national screening program in European Union starting in 2019: Dr. Miroslav Samarzija
- Egypt: Dr. Ola Khorshid and HSW Mikhael
- Ethiopia: funded by BMSF: Dr. Wondo Bekele
- Ghana: Dr Alfred Yawson and Dr. Jane Afriyie-Mensah



The I-ELCAP Investigators Worldwide

Future Developments

Leveraging the infrastructure from the current program, we are seeking collaborations to develop:

- Enhanced automated accurate methods for determining growth rates of pulmonary nodules and their probability of malignancy
- Tools to easily link the comprehensive management system with institutional EMRs
- Comprehensive risk assessment tools
- New software tools for comprehensive health checks of cardiac illness, lung illness and personalized measures of health

Thanks and Acknowledgements

- **The efforts of all the I-ELCAP Investigators and their teams**
We express our deepest gratitude to the many physicians, nurses, patient coordinators, academicians, and technical and administrative staffs whose dedicated and meticulous work over the past decades has provided the platform on which I-ELCAP research is built.
- **Our very, very special thanks to the thousands of screening participants**
who have allowed us to follow their progress over the years so that others could benefit from the information gleaned from their experiences. We greatly appreciate their generosity of spirit.

EARLY DIAGNOSIS AND EARLY TREATMENT

A new era in Preventive Health

