# Lung Cancer Screening:
## Clinical Trials, Screening Recommendations, and What's Next
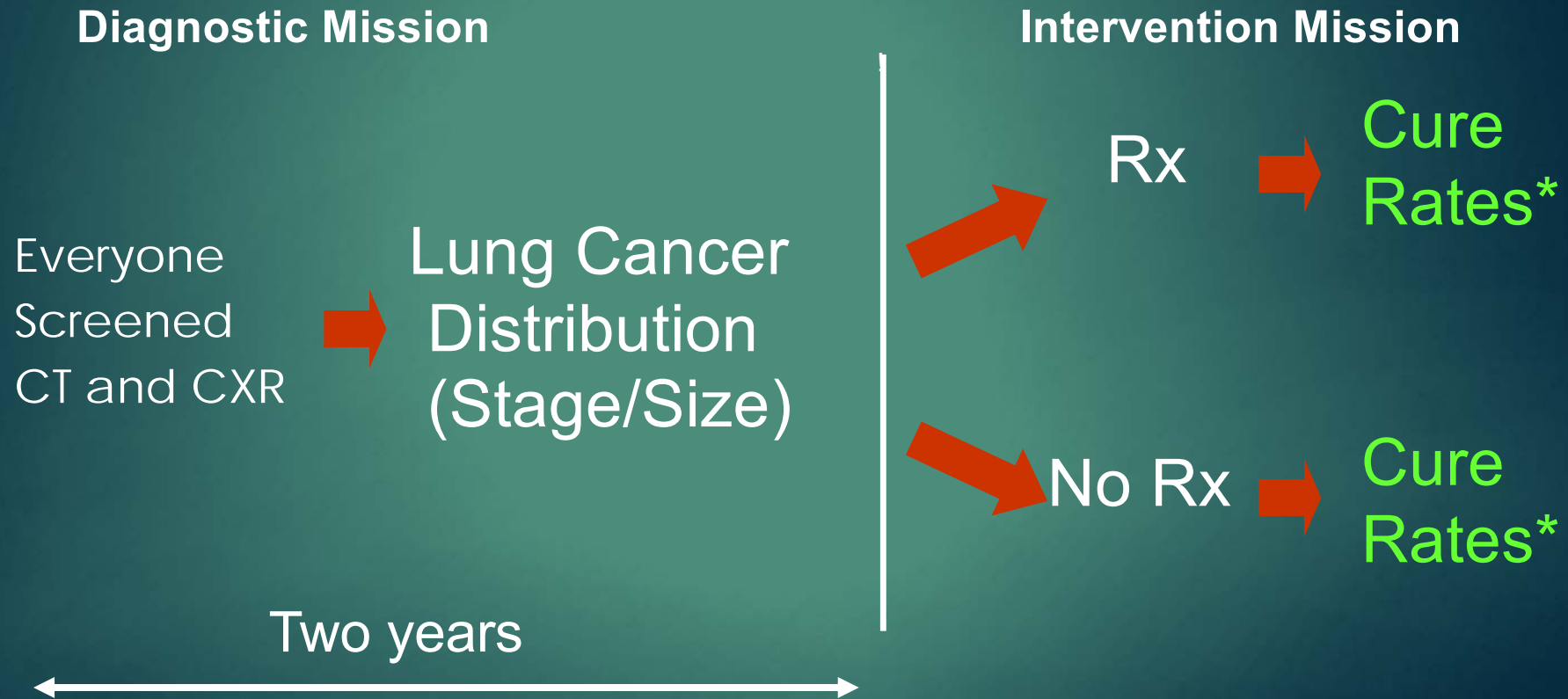
CLAUDIA I HENSCHKE PHD, MD

MOUNT SINAI HEALTH SYSTEM, NEW YORK, NY

# Disclosures

- I am a named inventor on a number of patents and patent applications relating to the evaluation of pulmonary nodules on CT scans of the chest which are owned by Cornell Research Foundation (CRF).

- As of April 2009, I signed away any financial benefit including royalties and any other proceeds related to the patents or patent applications owned by CRF.

- I am the President of the Early Diagnosis and Treatment Research Foundation

# The ELCAP Approach: *A cohort paradigm*
## *how to integrate technologic advances*

**Diagnostic Mission**

**Intervention Mission**

Everyone
Screened
CT and CXR

Lung Cancer
Distribution
(Stage/Size)
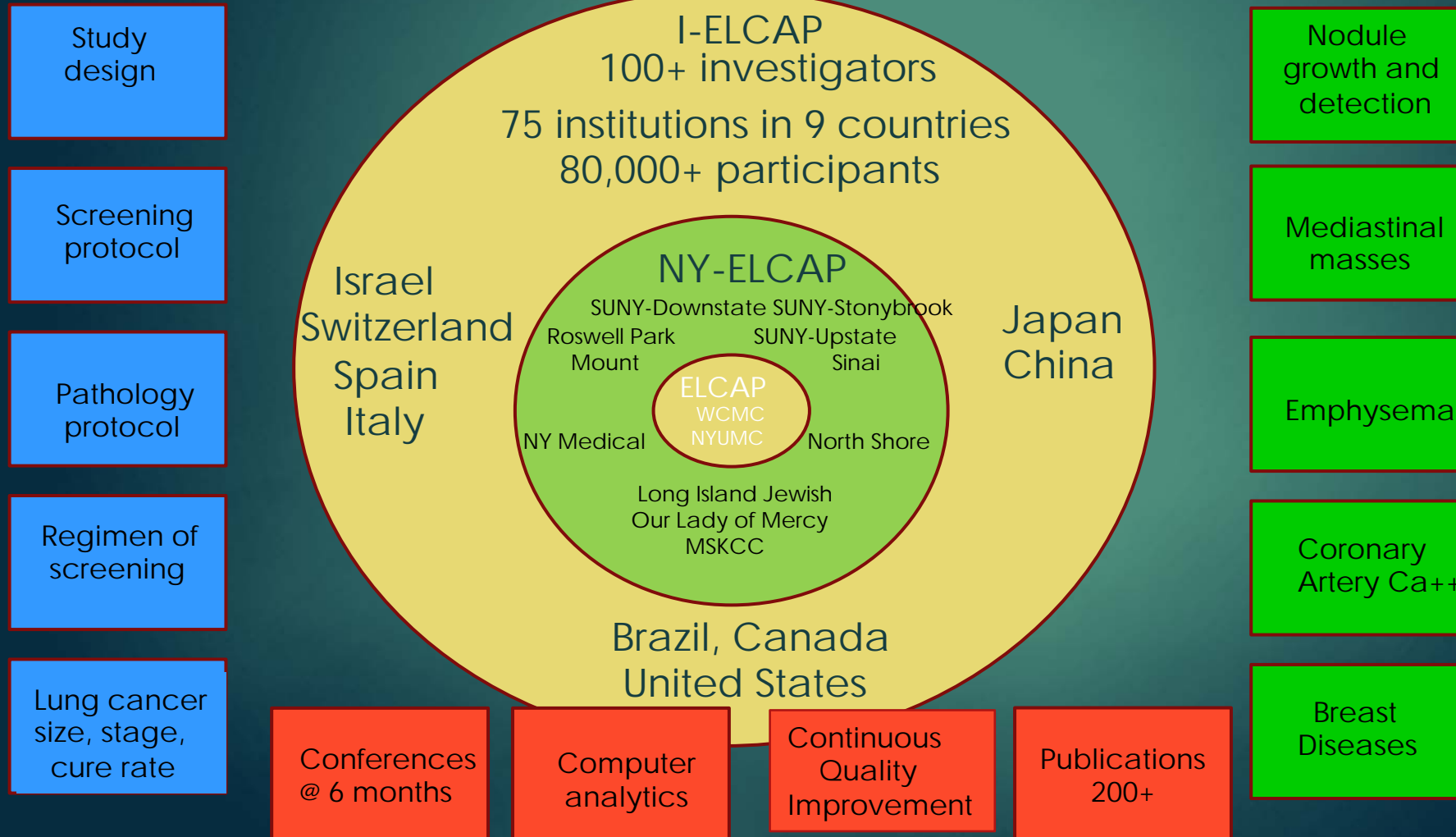
Rx

Cure
Rates*

No Rx

Cure
Rates*

Two years

* specific to stage and size

In future compare  CT with potential biomarkers or other tests

# Largest CT Screening Cohort in the World

ELCAP to NY-ELCAP to International-ELCAP

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

Study design

Screening protocol

Pathology protocol

Regimen of screening

Lung cancer size, stage, cure rate

I-ELCAP
100+ investigators

75 institutions in 9 countries
80,000+ participants

Israel
Switzerland
Spain
Italy

NY-ELCAP

SUNY-Downstate SUNY-Stonybrook
Roswell Park          SUNY-Upstate
Mount                          Sinai

ELCAP
WCMC
NYUMC

NY Medical              North Shore

Long Island Jewish
Our Lady of Mercy
MSKCC

Japan
China

Brazil, Canada
United States

We have been working with Delaware since the start of I-ELCAP

Nodule growth and detection

Mediastinal masses

Emphysema

Coronary Artery Ca++

Breast Diseases

Conferences @ 6 months

Computer analytics

Continuous Quality Improvement

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# ELCAP Management System

- Started in 1992, C Henschke programmed the first system

- In 2000, AP Reeves brought it into the web-based environment

- Now providing an open source system for the Veterans Administration and the world

# Goal of ELCAP in initial NCI grant

▶ Probability of detecting a noncalcified nodules (NCNs) on LDCT

▶ Probability of diagnosing lung cancer in an NCN

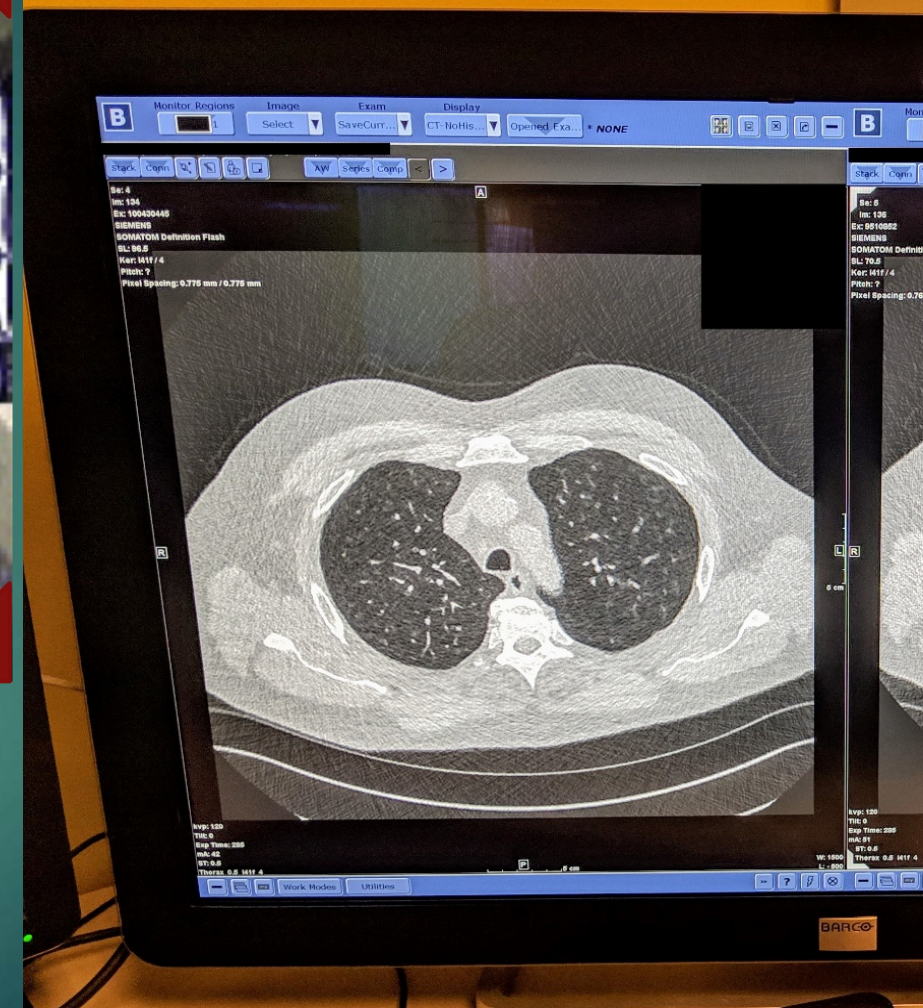▶ Probability of cure after treatment, given a diagnosis of lung cancer

1990's
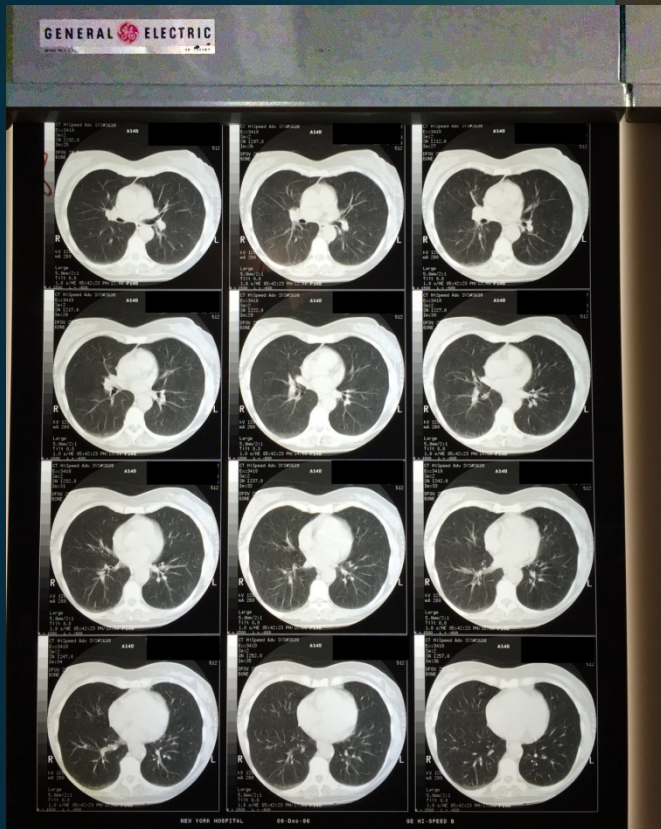
2000

After 2010

images on film

computer monitors

bigger monitors

# Goal of ELCAP in initial NCI grant

▶ Probability of detecting a noncalcified nodules (NCNs) on LDCT

  ANSWER: On initial CT scans in 1992-1999: 23% had NCNs

    On TODAYs CT scans:  > 50%

▶ Probability of diagnosing lung cancer in an NCN

  ANSWER:  Depending on smoking and age and round of screening:

    BASELINE: 1% to 3%

    ANNUAL REPEAT:  0.25% to 0.75%

▶ Probability of cure after treatment, given a diagnosis of lung cancer

  ▶ All cases diagnosed under screening:  80%

  ▶ Pathologic Stage I > 90%

# How to Differentiate Malignant from Benign NCNs: Volumetrics

- We introduced it in 1997 in NCI grant and publications in1999

  - Yankelevitz DF, Gupta R, Zhao B, Henschke CI.  Small Pulmonary Nodules: evaluation with repeat CT-preliminary experience. Radiology 1999; 212:561-6

  - Zhao B Reeves A, Yankelevitz DF, Henschke CI. Three-dimensional multi-criterion automatic segmentation of pulmonary nodules of helical CT images. Optical Engineering 1999; 38:1340-7

  - Kostis WJ, Reeves AP, Yankelevitz DF, Henschke CI. Three-dimensional segmentation of solitary pulmonary nodules from helical CT scans.  Proceedings of Computer Assisted Radiology in Surgery (CARS '99). (Eds: HU Lempke, MW Vannier, K Inamura, AG Farman). Elsevier Science 1999:203-7

  - 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

  - Kostis WJ, Yankelevitz DF, Reeves AP, Fluture SC, Henschke CI.  Small pulmonary nodules: reproducibility of three-dimensional volumetric measurement and estimation of time to follow-up CT. Radiology 2004; 231:446-52.

- Showed results and images to NLST and NELSON

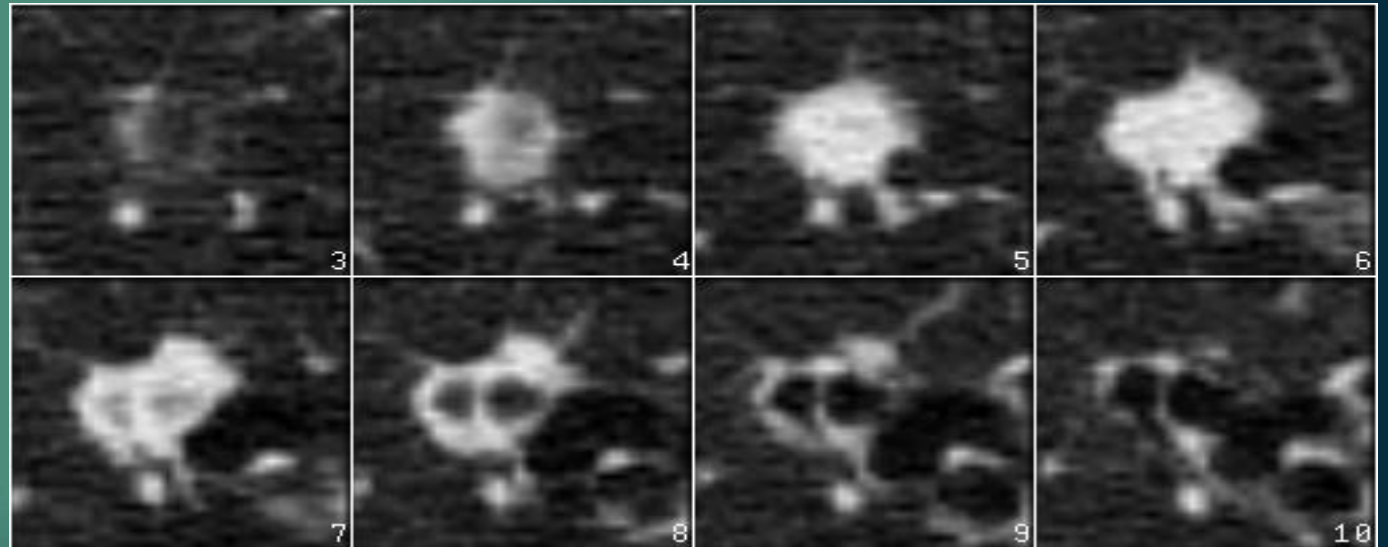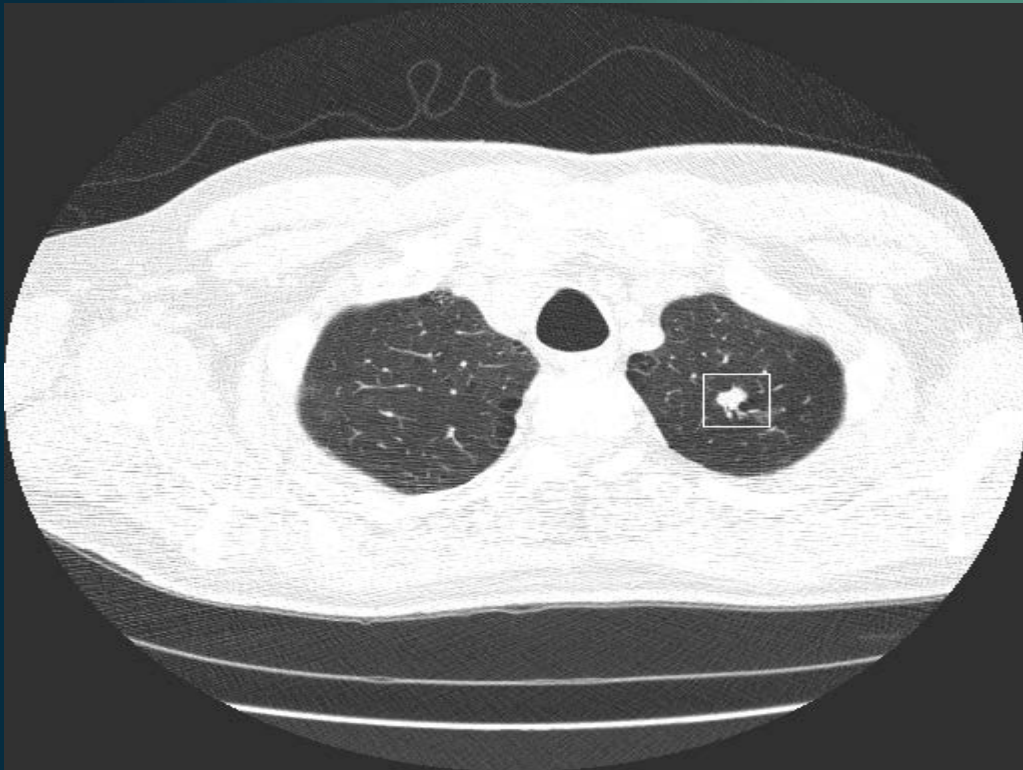- NELSON used and recommended volumetrics

# Baseline HRCT (CU0138)

Jun 17 1996, (X,Y) resolution: 0.68359 mm, Slice thickness : 1 mm
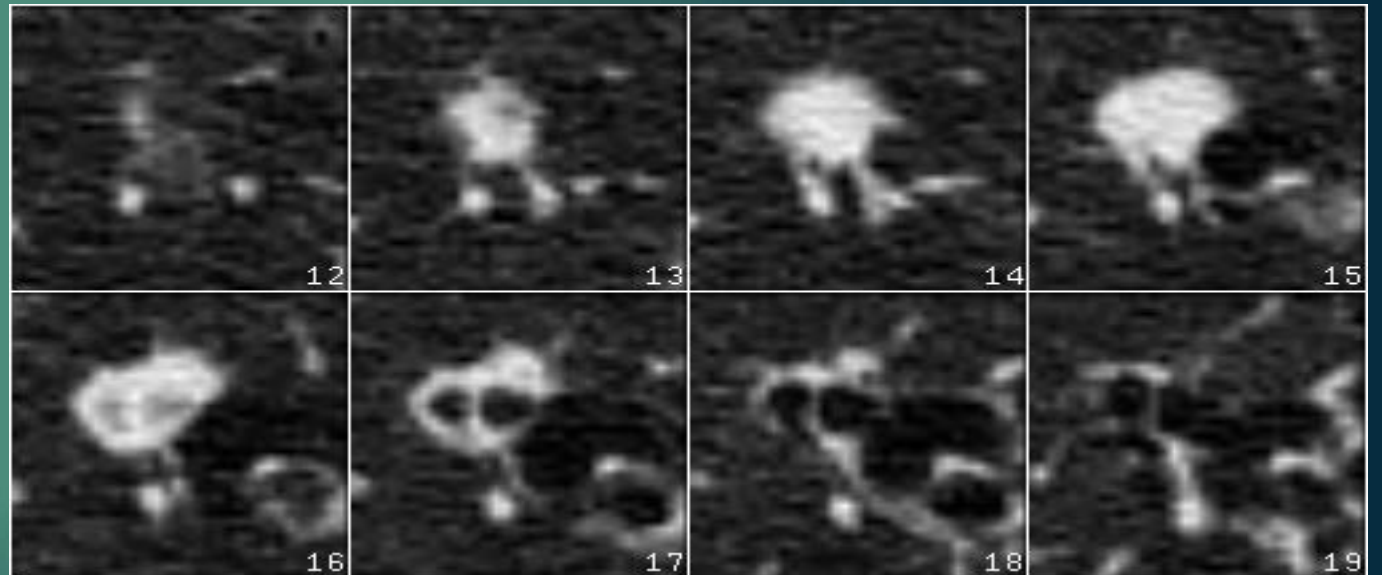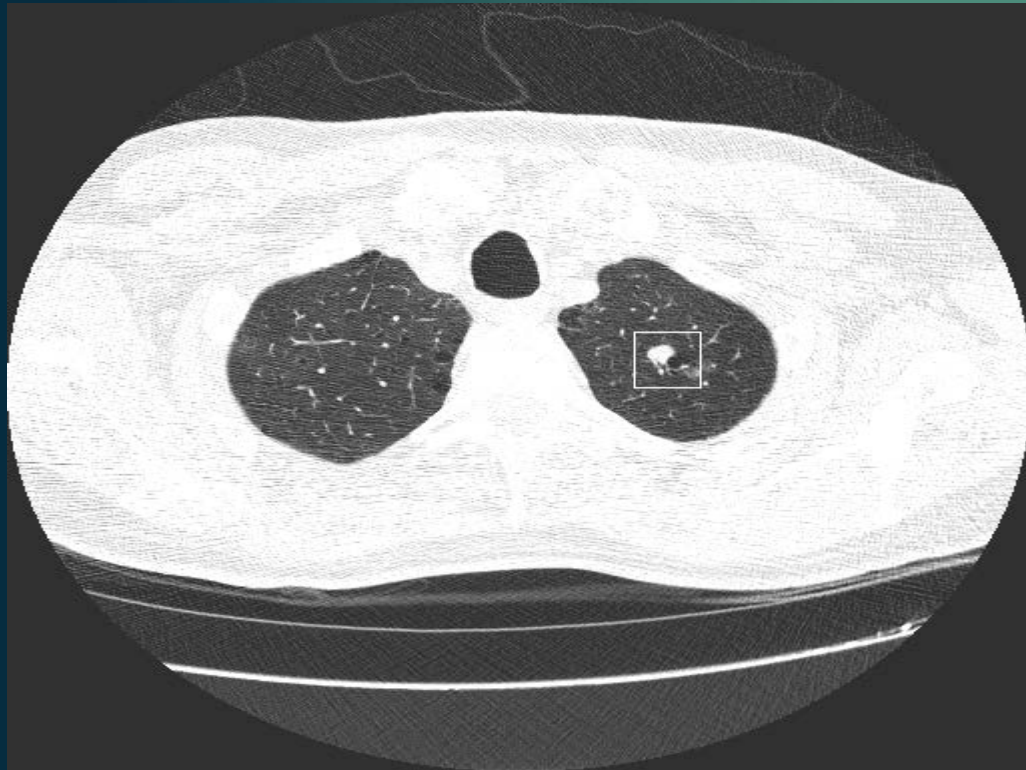


Images ©1998, ELCAP Lab, Cornell University Medical College

# Three Month Repeat HRCT (CU0138-2)

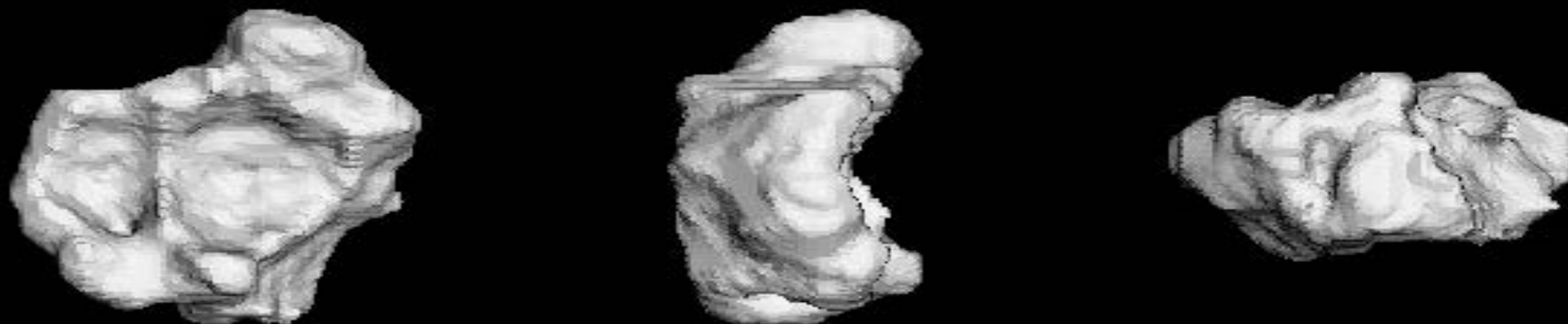Oct 25 1996, (X,Y) resolution: 0.68359 mm, Slice thickness : 1 mm
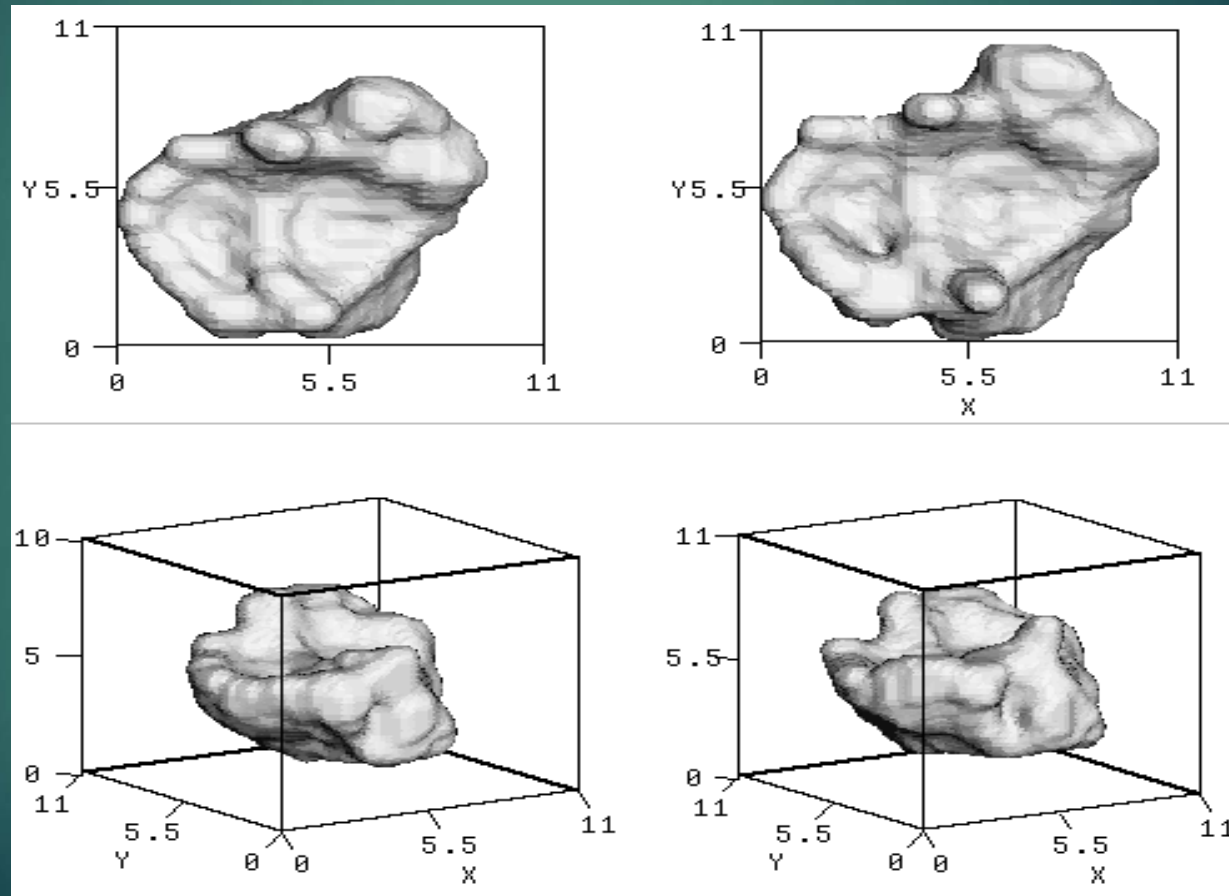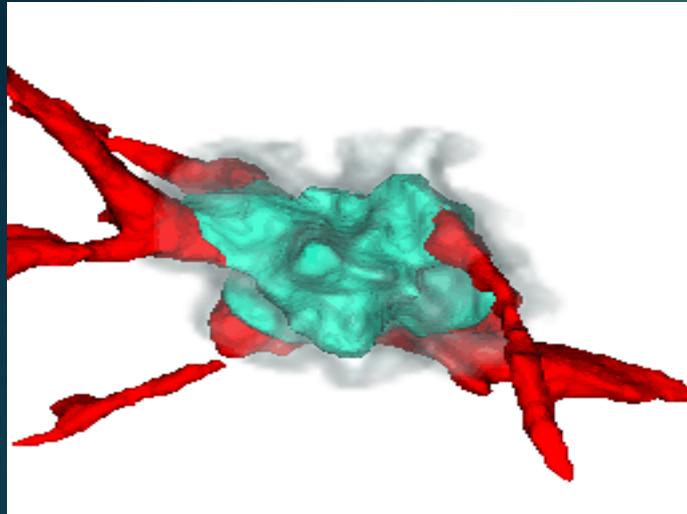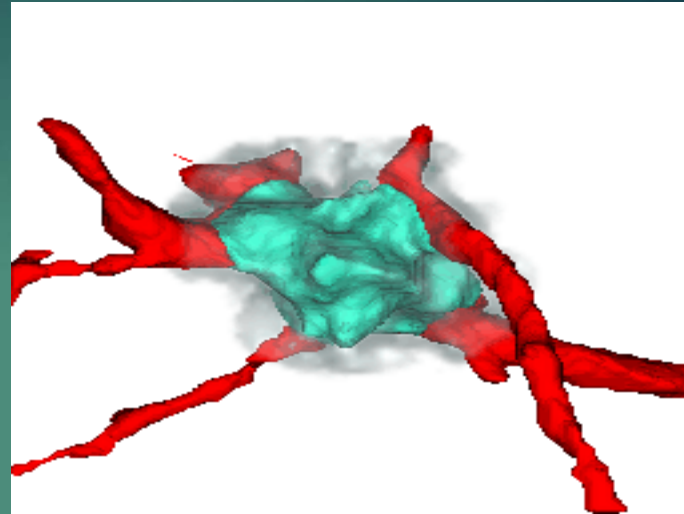
# Baseline and 3-month Repeat HRCT

Time 1

Time 2

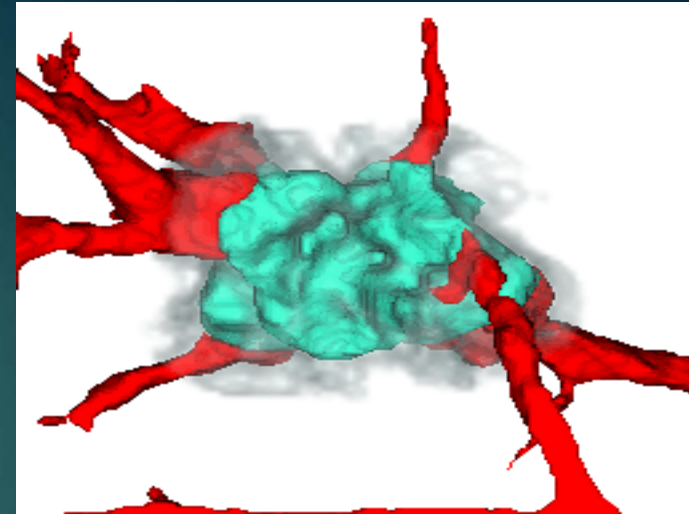# Comparison of Baseline and Three Month Repeat CT

T1

T2

T3

Axial Views
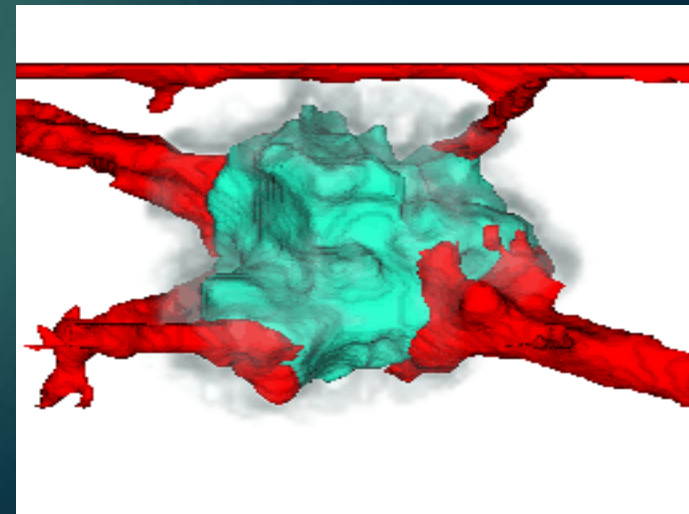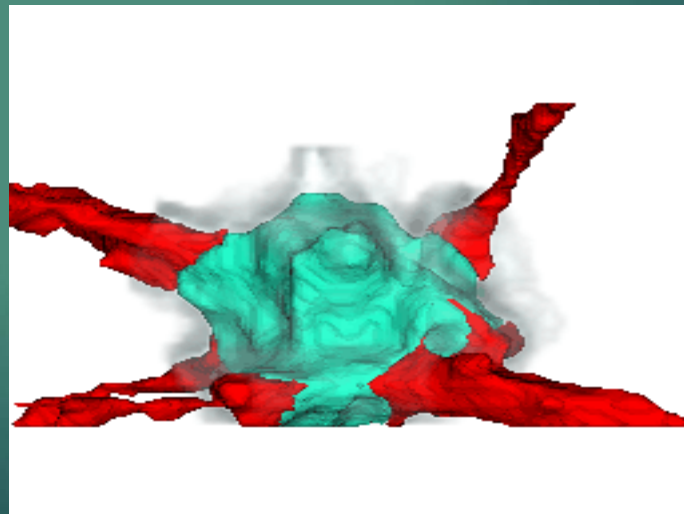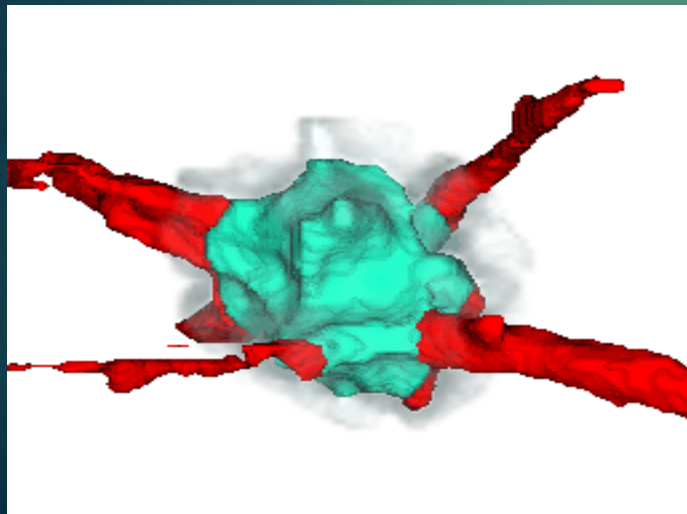
Coronal Views

# 2010: Roche ABIGAIL Study



Model A
Site 1

+44% Change

1654 mm$^3$       2379 mm$^3$

Model A
Site 2

+33% Change

1601 mm$^3$       2127 mm$^3$
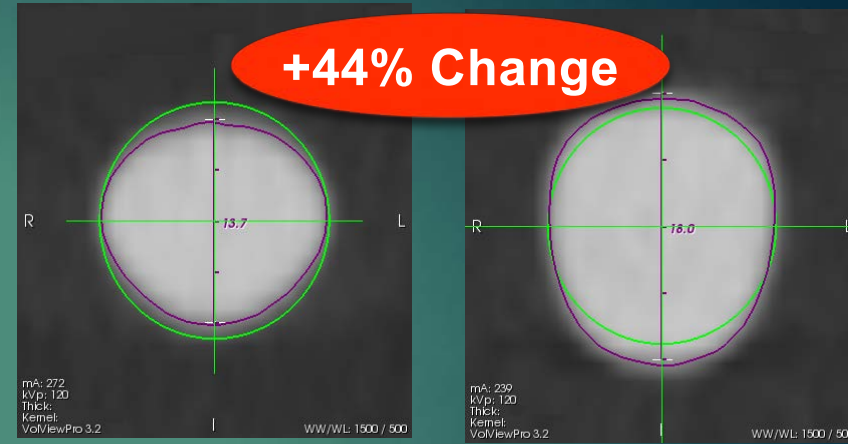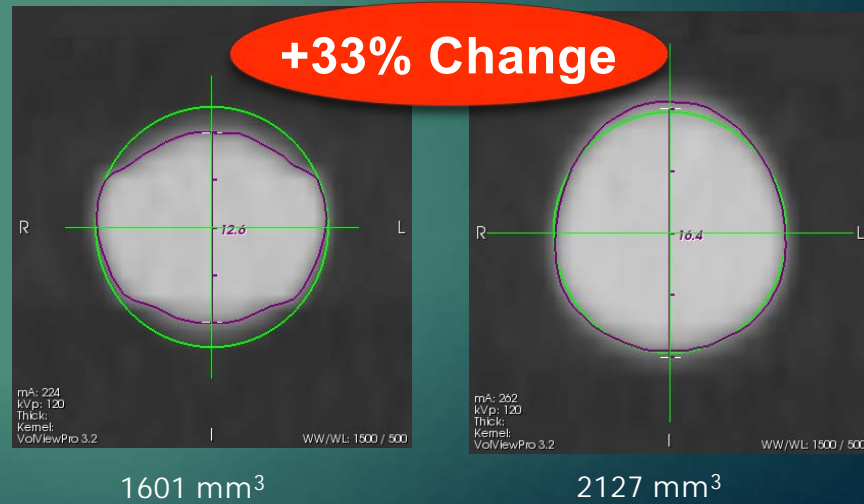
[J Med Imaging. 2016 Jul;3(3)]

Henschke CI, Yankelevitz DF, Yip R, Archer V, Zahlmann G, Krishnan K, Helba B, Avila R. Tumor volume measurement error using computed tomography imaging in a phase II clinical trial in lung cancer. J Med Imag 2016; 3:035505

# Measurement Uncertainty
# Within seconds, 44%
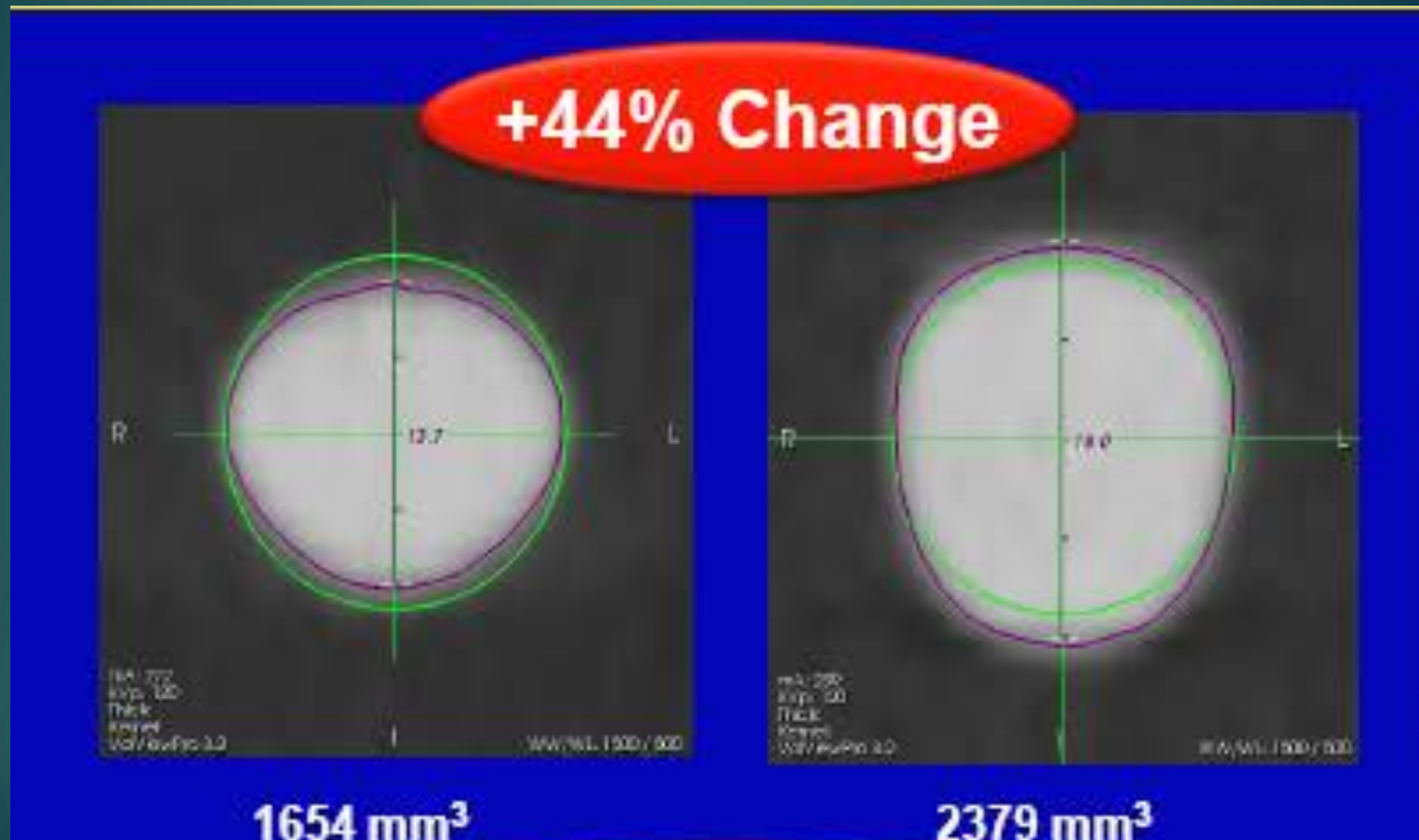


Perfect sphere had a 172 day volume doubling time

# HOWEVER, SERIOUS CONCERNS ABOUT MEASUREMENT ACCURACY

FDA Approved CT Scanner has one slice – considerable distortion

# 10-year Kaplan-Meier Lung Cancer Survival: NEJM 2006
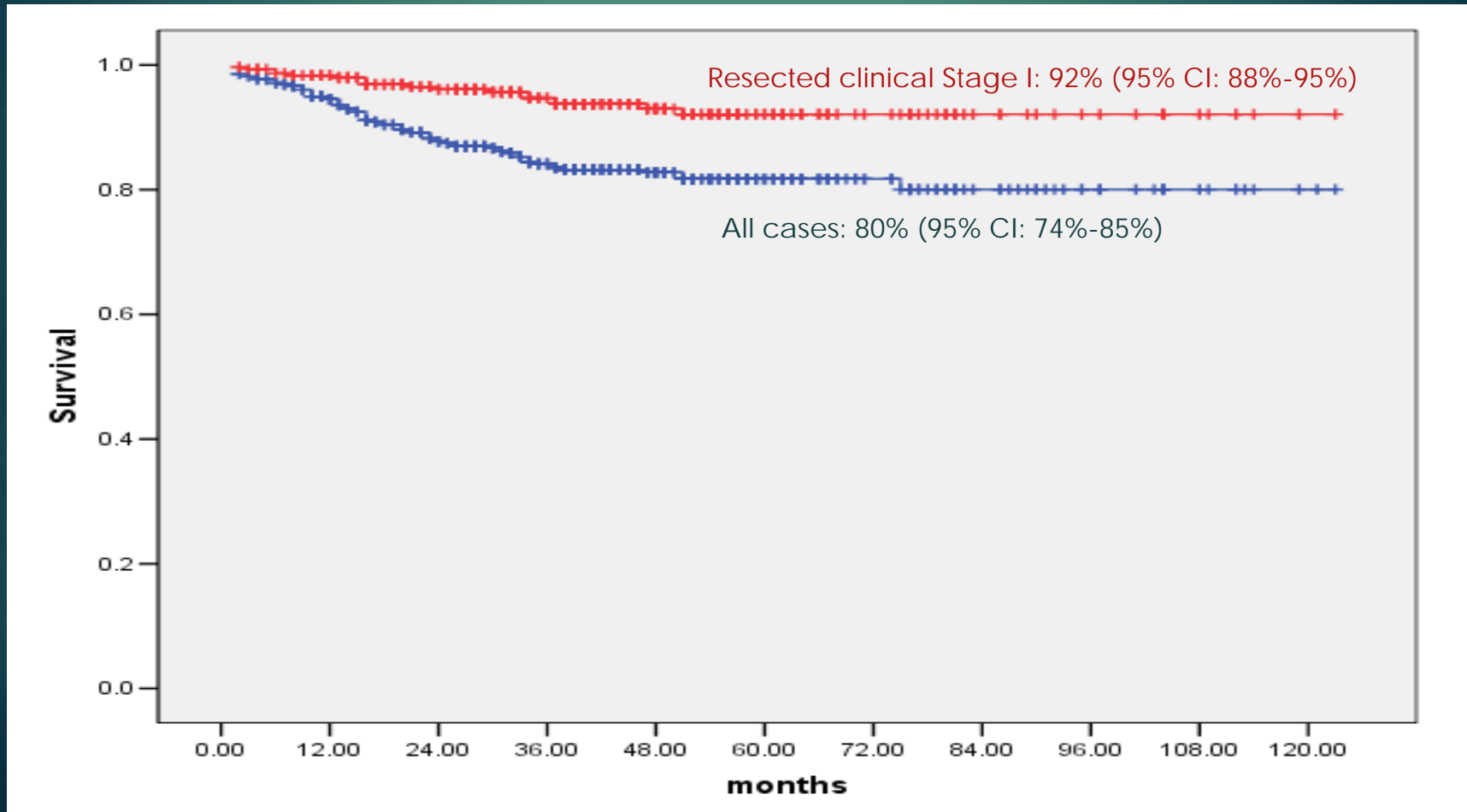
# 20-year Kaplan-Meier LC Survival Curve:
N = 1149
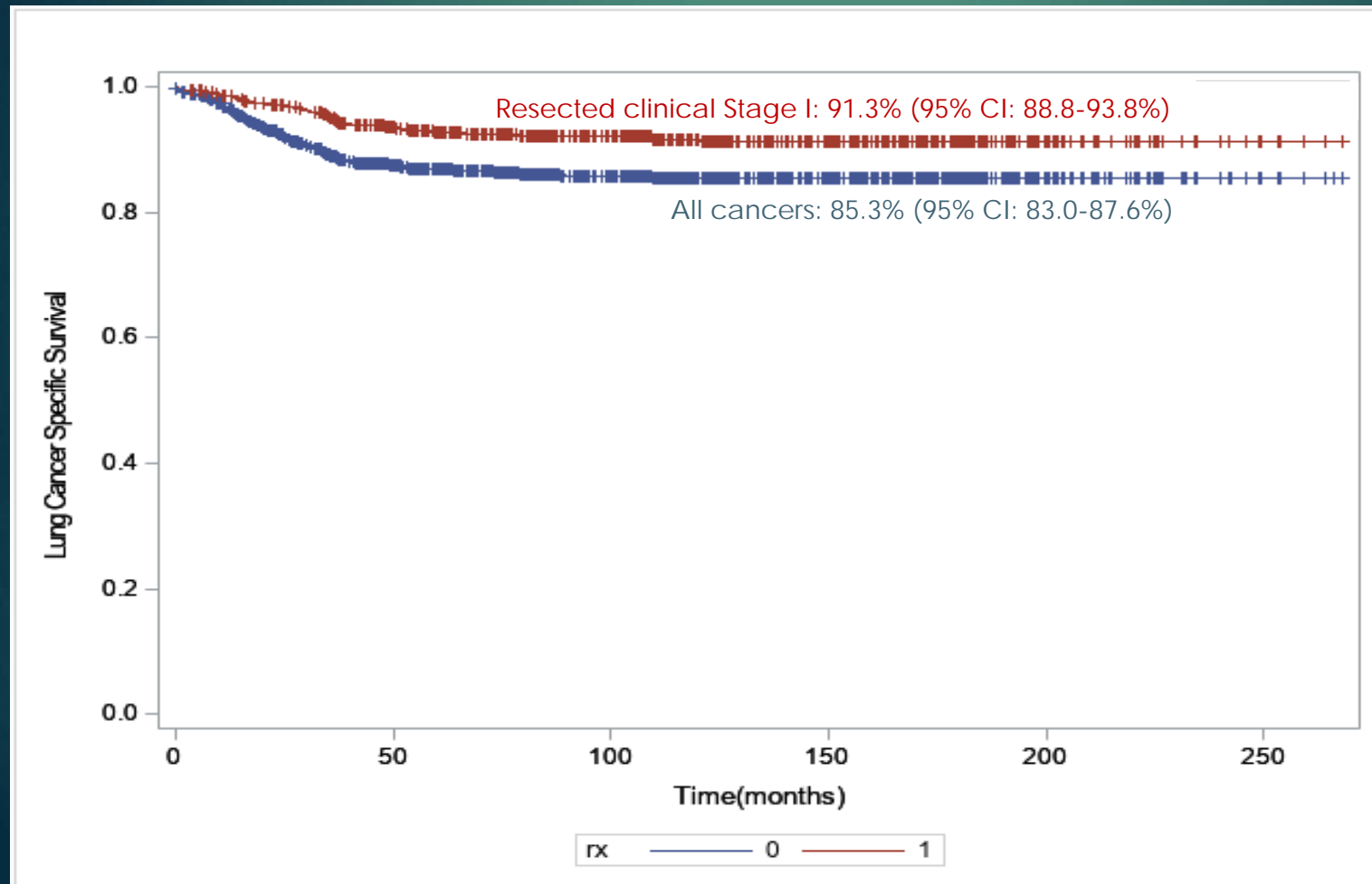
The protocol can reduce unnecessary tests and particularly invasive procedures

# I-ELCAP and NLST Survival Rates

The benefit of having a regimen of screening with continuous updates together with a web-based electronic structured management system is shown by the results below
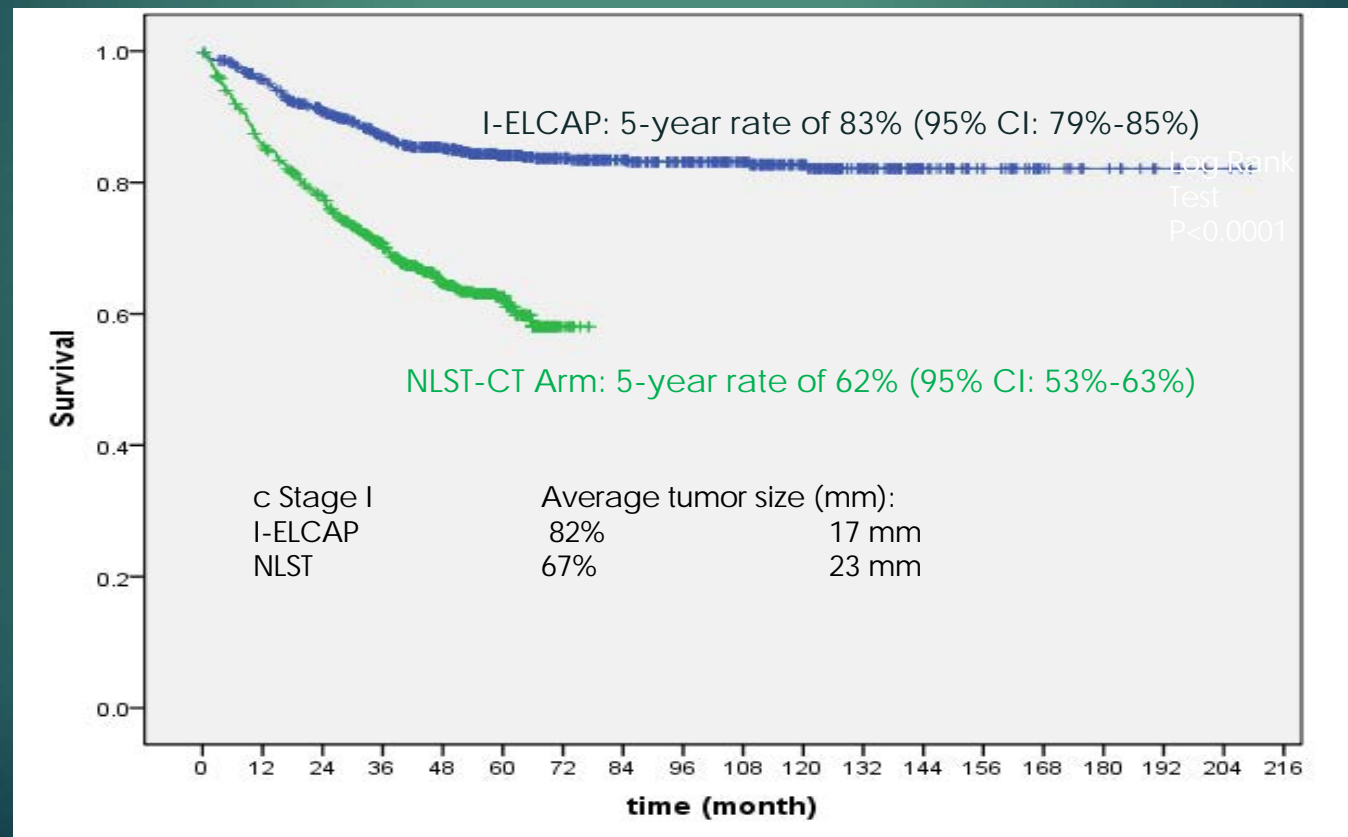
# Changes in Definition of Positive Result

- 1992:
  - Baseline: any noncalcified nodule (NCN)
  - Annual:  any new or growing NCN
- 2000:
  - Baseline: any NCN $\geq$ 5.0
  - Annual: any new or growing NCN $\geq$ 3.0
- 2016:
  - Baseline is a 2-step process for any solid NCN between 6.0-15.0, follow-up CT to assess growth rate
  - Annual: no change

# Subsolid Nodules: Part-solid and Nonsolid
## AAH – AIS – MIA – Lepedic predominant
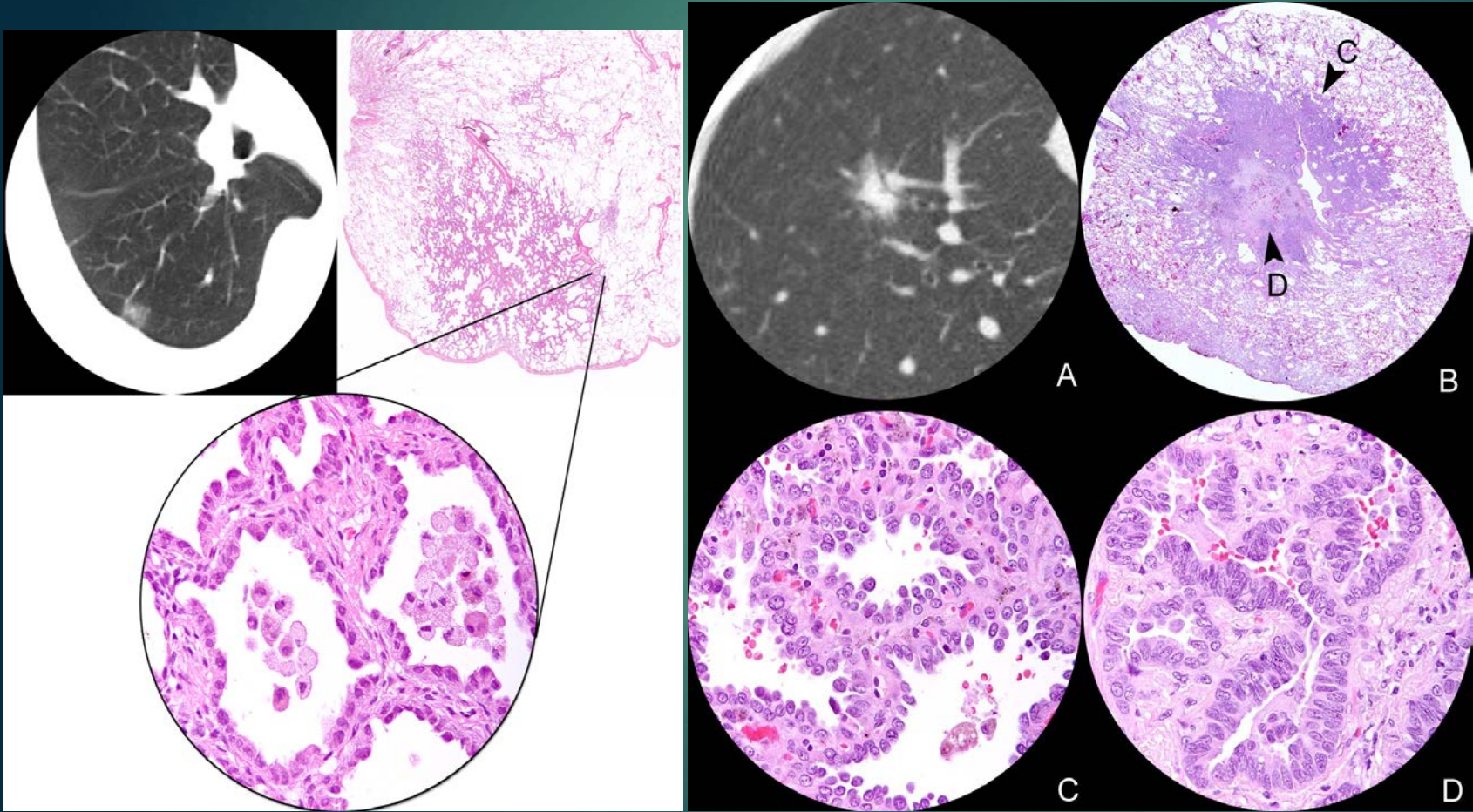


Nonsolid Nodule

Part-solid nodule

# International Early Lung Cancer Action Program Firsts



Ad-BAC 100% vs.
Ad-Mixed 95% (95%CI: 92%-98%)
vs. Adeno-Other 75% ((5%CI: 51%0100%
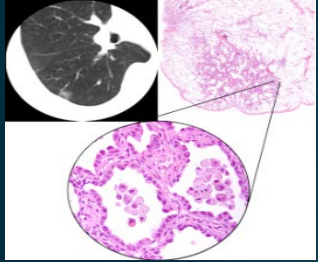
Long-term survival of solitary and multiple adenocarcinomas manifesting as subsolid nodules nodules

Vazquez et al. Lung Cancer 2009: 64: 148-54



Adeno by % BAC
Since then classified as
AIS, MIA, Adeno-BAC



Adenocarcinoma N0M0
Single 97% vs. Multiple 100%
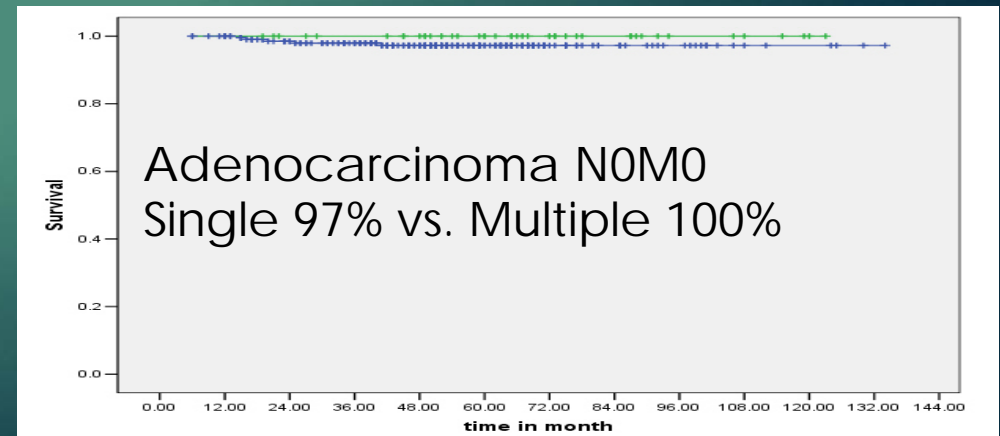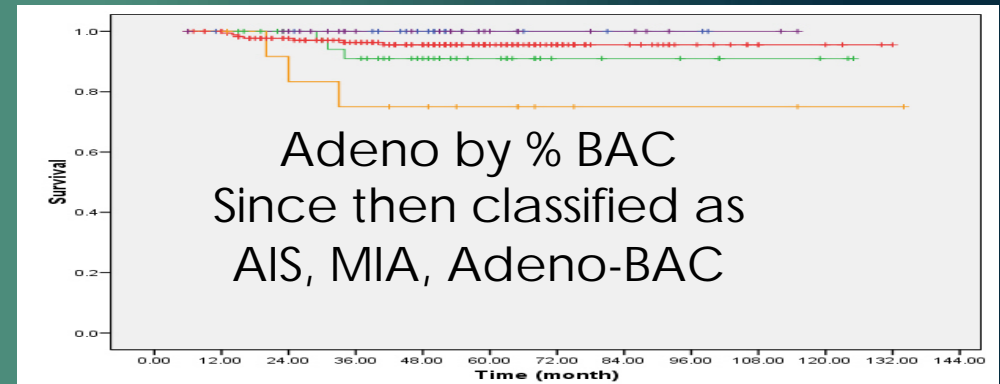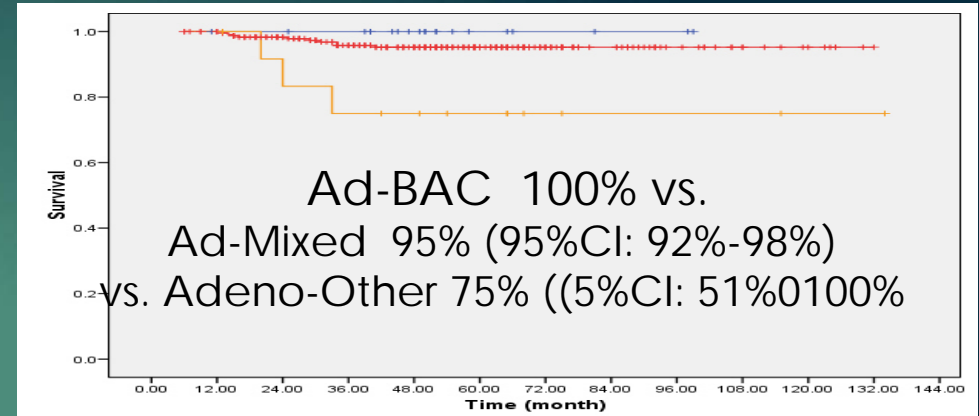
# For nonsolid nodules
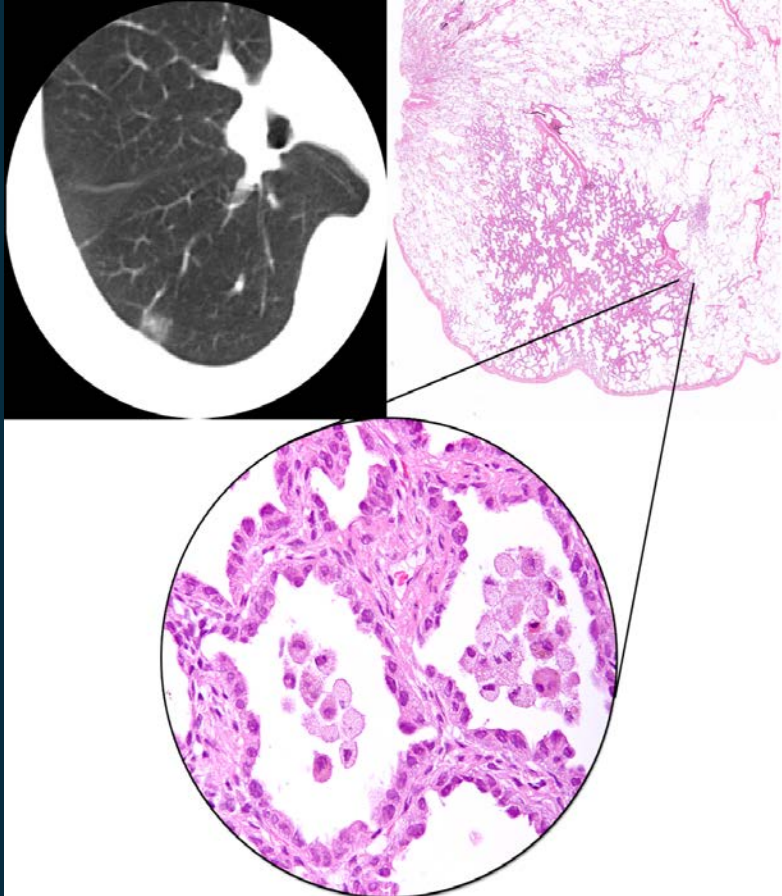


No further diagnostic tests

Only 1 year follow-up

Yankelevitz DF, Yip R, Smith JP, Liang M, Liu Y, Xu DM, Salvatore M, Wolf AS, Flores RM, Henschke CI for the IELCAP Investigators. CT screening for lung cancer: Nonsolid Nodules in Baseline and Annual Repeat Rounds. Radiology 2015; 277:555-64 PMID: 26101879

# For part-solid nodules
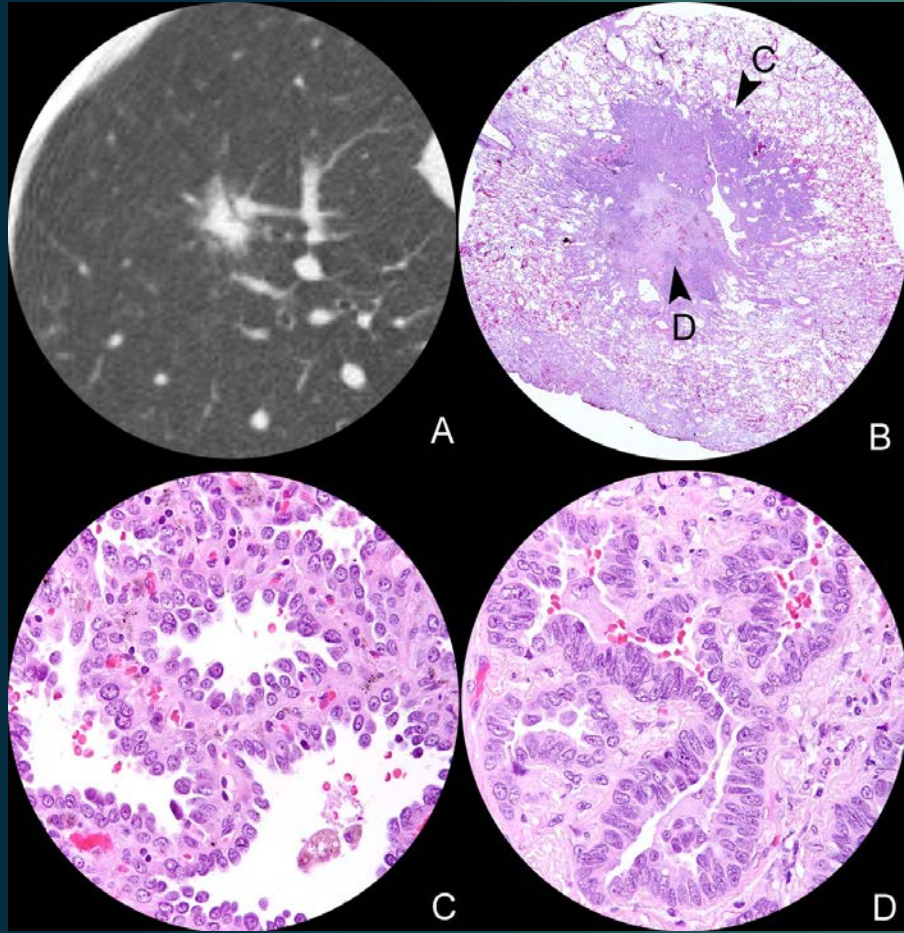


Follow-up based on
Solid component only

Same as solid nodules

Henschke CI, Yip R, Wolf AS, Flores RM, Liang M, Salvatore MM, Liu Y, Xu DM, Smith JP, Yankelevitz DF for the IELCAP Investigators.   CT Screening for Lung Cancer: Part-Solid Nodules in Baseline and Annual Repeat Rounds. AJR Am J Roetgenol 2016; 11:1-9

# Publications on Nonsolid and Part-solid Nodules

National Lung Screening Trial: Outcomes

▶ Yip R, Li K, Hu M, Jiranapatakul A, Henschke CI, Yankelevitz DF. Lung Cancer Deaths in the National Lung Screening Trial Attributed to Nonsolid Nodules. Radiology 2016; 281: 589-96 PMID: 27378239

▶ Yip R, Henschke CI, Xu DM, Li K, Jirapatnakul A, Yankelevitz DF. Lung Cancers Manifesting as Part-Solid Nodules in the National Lung Screening Trial. AJR Am J Roentgenol 2017; 208: 1011-1021 PMID: 28245151

Meta-analyses of Long-term Outcomes of Nonsolid and Part-solid Nodules

▶ Yip R, Wolf A, Tam K, Taioli E, Olkin I, Flores RM, Yankelevitz DF, Henschke CI. Outcomes of lung cancers manifesting as nonsolid nodules. Lung Cancer 2016; 97:35-42 PMID: 27237025

▶ Yip R, Li K, Liu L, Xu D, Tam K, Yankelevitz DF, Taioli E, Becker B, Henschke CI. Controversies on lung cancers manifesting as part-solid nodules European Radiology 2017; 4975-9 PMID: 28835992

# Baseline: frequency of positive result and dx of lung cancer among 21,136 recent participants

Henschke CI et al. Definition of a positive test result in computed tomography screening for lung cancer:a cohort study. Ann Intern Med. 2013; 158: 246-52
Yip R et al. Alternative definitions of positive test result based on the NLST. Radiology 2014:273:591-6
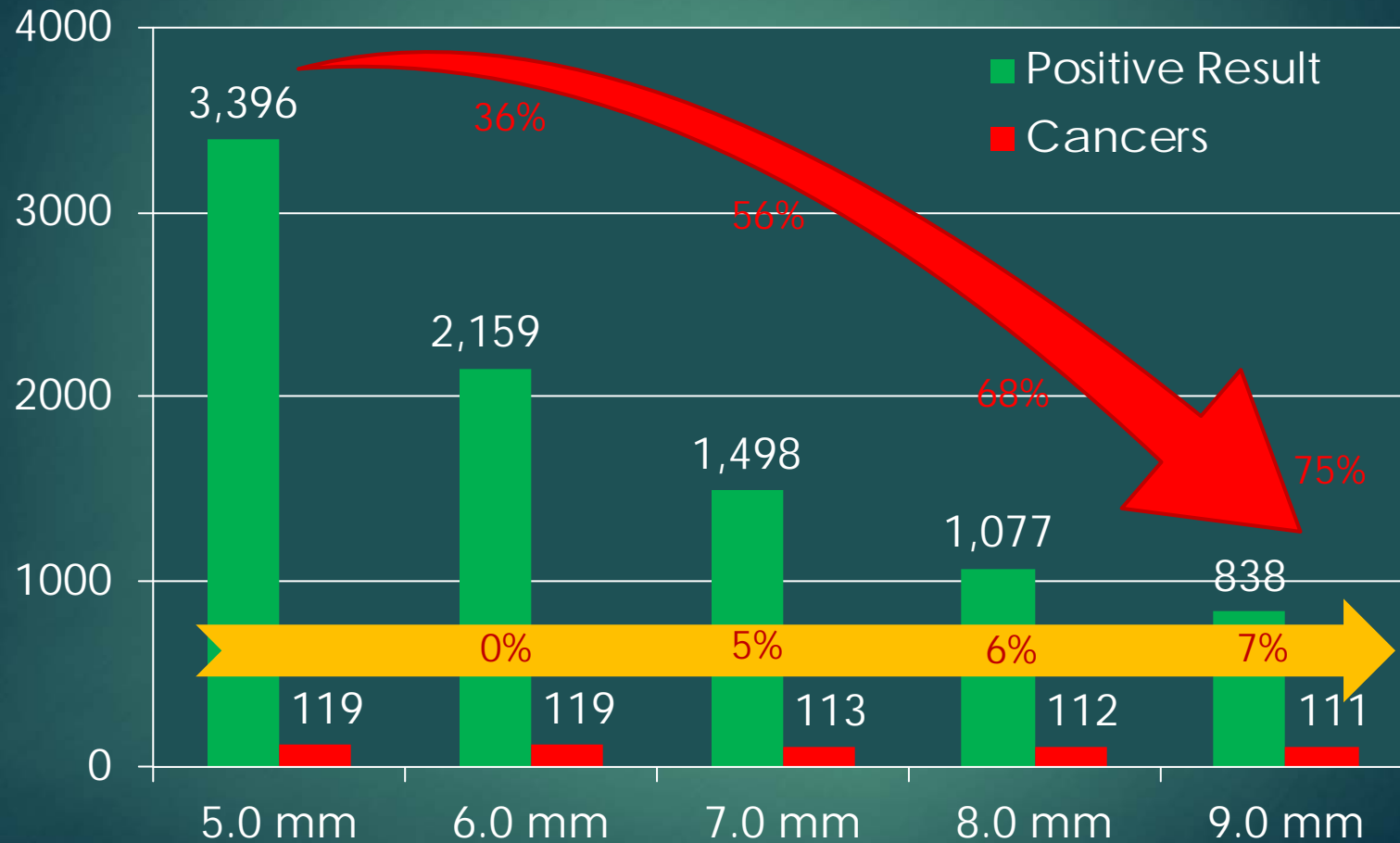
# Led to Guideline Changes

LUNG RADS, NCCN, I-ELCAP

# I-ELCAP Recommendations for Baseline Workup:
## Based on largest solid (solid component of PS) NCN

- ▶ Recommend annual repeat LDCT for all NCN (nonsolid, part-solid, solid)

- ▶ Unless

  - ▶ NCN (solid or solid component of PS) is 6.0 to 15.0 mm which demonstrates growth at a malignant rate on 3-month follow-up LDCT

  - ▶ NCN 15.0 +, then recommend biopsy

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# Largest CT Screening Cohort in the World
ELCAP to NY-ELCAP to International-ELCAP

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

Study design

Screening protocol

Pathology protocol

Regimen of screening

Lung cancer size, stage, cure rate

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# I-ELCAP, ACR-LungRADS, European baseline protocol comparison

| a. Immediate workup PET, biopsy, follow-up CT | I-ELCAP | ACR-Scenario 1 | ACR-Scenario 2 | European |
|---|---|---|---|---|
| Solid NCN, largest | ≥ 15.0 mm | ≥ 8 mm | ≥ 15 mm | ≥ 10 mm |
| Part-solid NCN, largest | solid component ≥ 15.0 mm | solid component ≥ 8 mm | solid component ≥ 8 mm | NONE |
| | | | | |
| b. 3-month LDCT | | | | |
| Solid NCN, largest | ≥6.0 mm but <15.0 mm | - | ≥8 mm but < 15 mm | ≥5 mm but <10 mm |
| Part-solid NCN, largest | solid component of NCN ≥6.0 mm but <15.0 mm | entire size of NCN ≥6 mm with solid component ≥6 mm but <8mm | entire size of NCN ≥6 mm with solid component ≥6mm but <8mm | entire size of NCN ≥5mm |
| Nonsolid NCN, largest* | | | | ≥5mm |
| | | | | |
| c. 6-month LDCT | | | | |
| Solid NCN, largest | NONE | ≥6mm to <8mm | ≥6mm to <8mm | NONE |
| Part-solid NCN, largest | NONE | entire size of NCN ≥6 mm with solid component <6 mm | entire size of NCN ≥6 mm with solid component <6 mm | NONE |
| Nonsolid NCN, largest** | | ≥20mm | ≥20mm | |

Henschke CI, Yip R, Ma T, Aguayo SM, Zulueta J, Yankelevitz DF for I-ELCAP Investigators. CT Screening for Lung Cancer:Comparison of three baseline protocols.  European Radiology. 2018

# Comparison of Protocols
ER = number of people requiring dx tests for each diagnosis of lung cancer

| Workup | I-ELCAP | | ACR-S1 | | ACR-S2 | | European | |
|---|---|---|---|---|---|---|---|---|
| | % | ER | % | ER | % | ER | % | ER |
| OVERALL  ER | | 13.9 | | 18.3 | | 18.3 | | 31.9 |
| | | | | | | | | |

Henschke CI, Yip R, Ma T, Aguayo SM, Zulueta J, Yankelevitz DF for I-ELCAP Investigators. CT Screening. for Lung Cancer:Comparison of three baseline protocols.  European Radiology. 2018

# Comparison of Baseline Protocols:
Estimated % participants requiring biopsies and #biopsies per LC dx

| Workup | I-ELCAP | | ACR-S1 | | ACR-S2 | | European | |
|---|---|---|---|---|---|---|---|---|
| | % | ER | % | ER | % | ER | % | ER |
| Biopsies | 1.6% | 2.2 | 6.0% | 8.1 | 2.3% | 3.2 | 3.3% | 4.4 |

Henschke CI, Yip R, Ma T, Aguayo SM, Zulueta J, Yankelevitz DF for I-ELCAP Investigators. CT Screening for Lung Cancer:Comparison of three baseline protocols. European Radiology. 2018

# I-ELCAP, ACR-LungRADS, European

- All protocols recommend
  - 1) immediate workup, %
  - 2) delayed workup, %
  - 3) annual repeat screening %

- All use different thresholds for recommendations
  - 6.0mm for **I**-ELCAP, 6mm for LungRADS, 5mm European

- ACR-LungRADS recommends PET scans for NCNs, 8 mm or larger, although 3 month follow-up CT is an alternative, therefore 2 scenarios:
  - Scenario 1: immediate PET scan
  - Scenario 2: 3 month LDCT

# Conclusion

▶ Differences among modern protocols lead to major changes in efficiencies.

▶ Accumulated knowledge and data should lead to continual updating of protocols

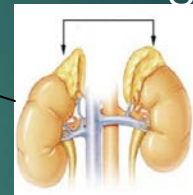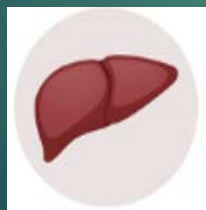▶ Mechanisms should be place to enhance such updating
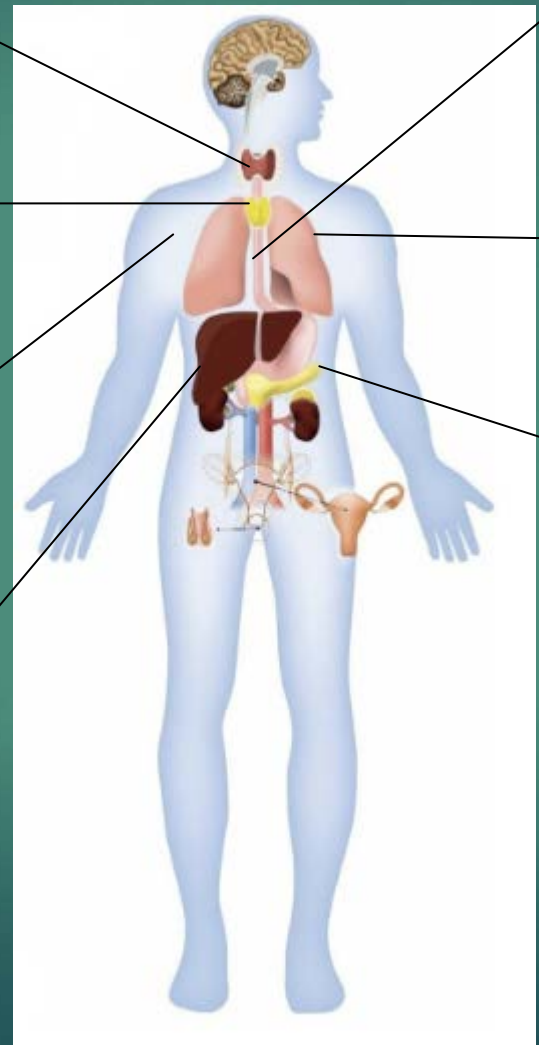
Thyroid
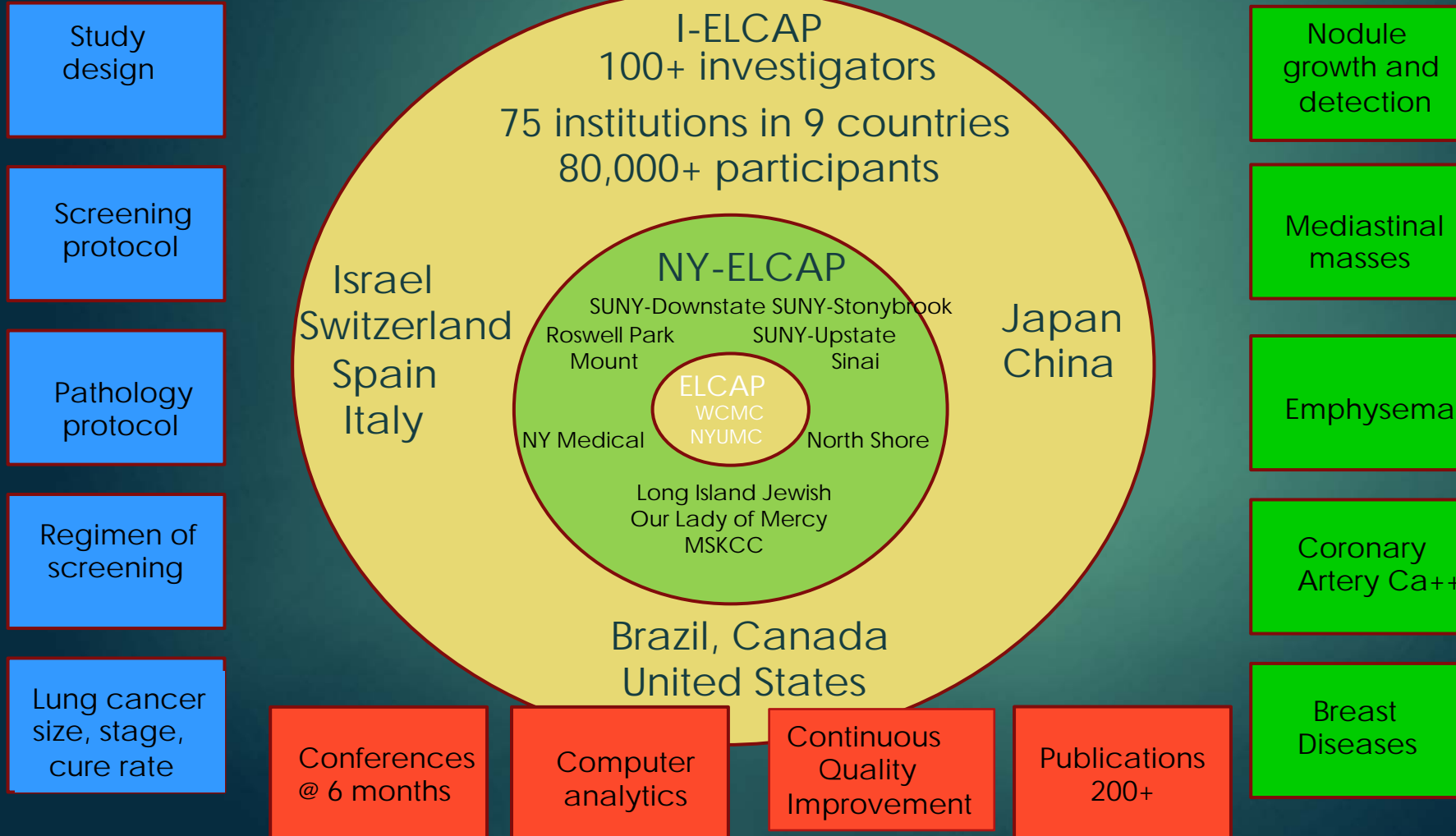
Thymus

Breast

Liver

Heart

Lung

Adrenal glands

Osteoporosis

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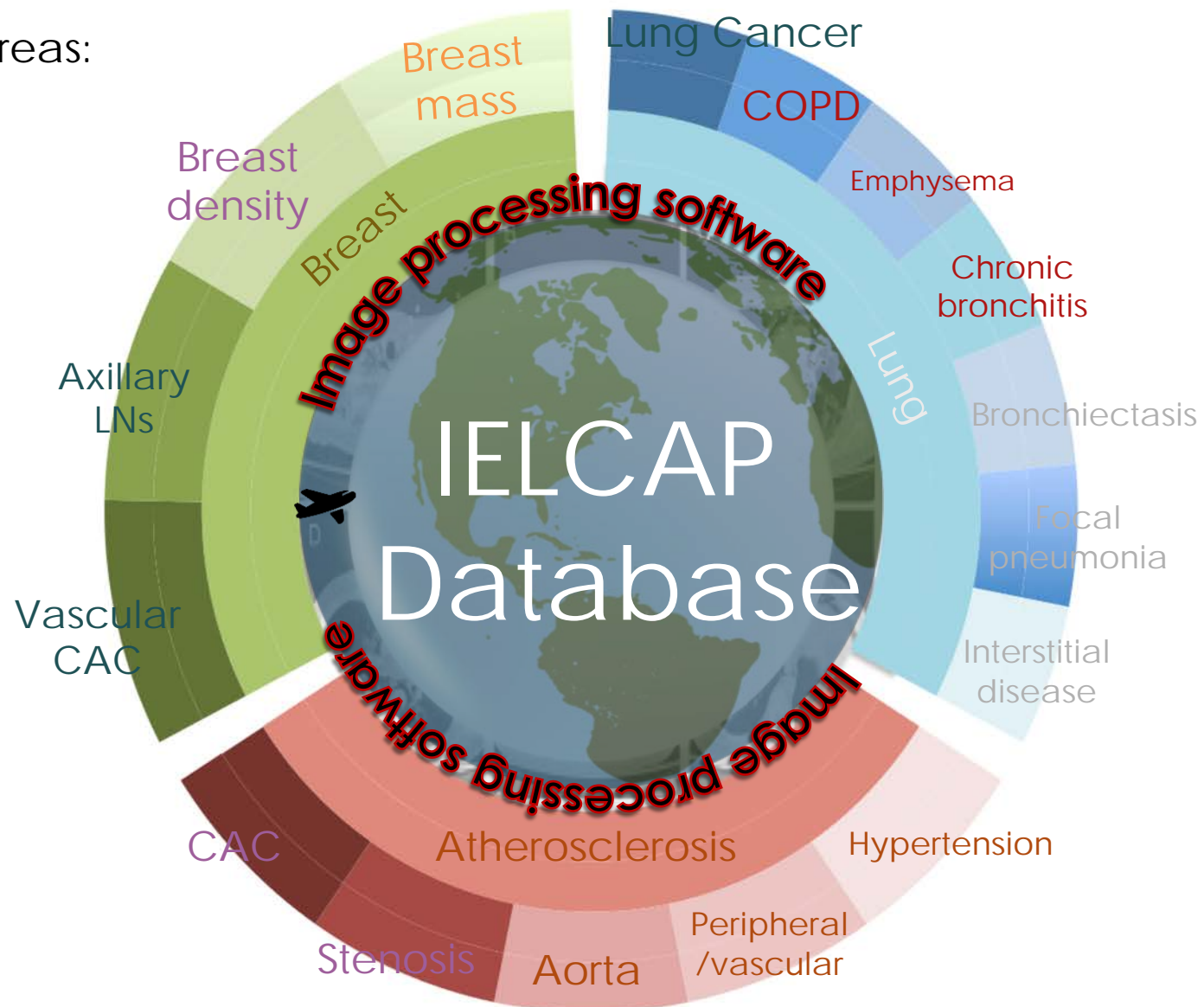e.g., current smokers, former smokers, never smokers

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SUNY-Downstate SUNY-Stonybrook
Roswell Park        SUNY-Upstate
Mount                      Sinai
ELCAP
WCMC
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NY Medical                North Shore

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# MANY UNANTICIPATED FINDINGS



Further areas:
Liver
Adrenals
Thyroid

# Smoking Cessation

Ostroff JS, Buckshee N, Mancuso CA, Yankelevitz DF, Henschke CI.
Smoking cessation following CT screening for early detection of lung cancer.
Preventive Medicine 2001; 33:613-21 PMID:11716658

Anderson CM, Yip R, Henschke CI, Yankelevitz DF, Ostroff JS, Burns DM.
Smoking cessation and relapse during a lung cancer screening program.
Cancer Epidemiol Biomarkers Prev 2009; 18: 3476-83 PMID:19959698

Ostroff JS, Copeland A, Borderud SP, Li Y, Shelley DR, Henschke CI.
Readiness of lung cancer screening sites to deliver smoking cessation treatment:
current practices, organizational priority and perceived barriers.
Nicotine Tob Res 2016; 18:1067-75. PMID: 26346948 PMCID: PMC5903595

# Cardiac Disease on Low-dose CT



▶ ## CAC Score
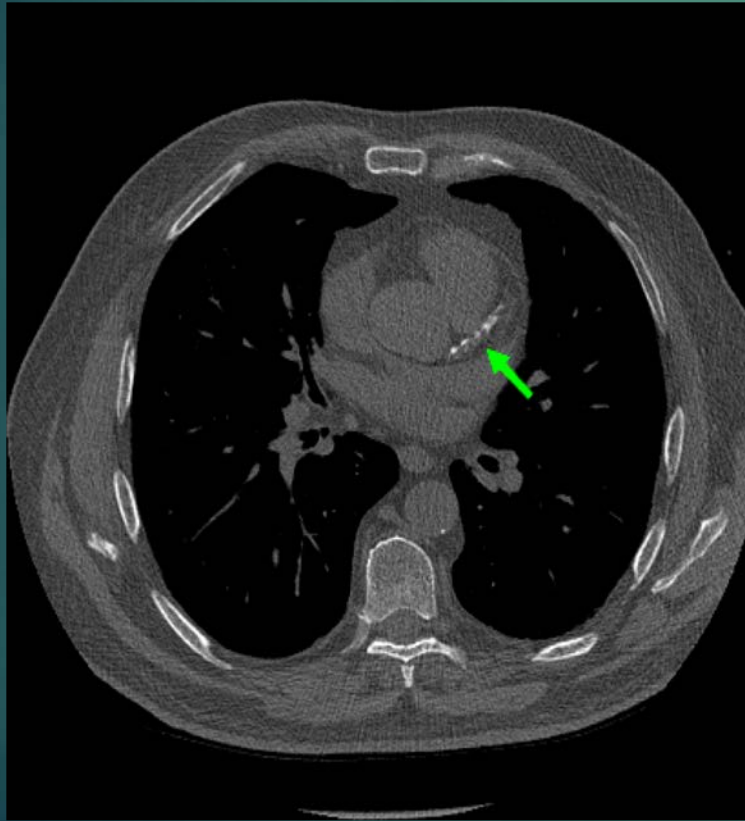
- ▶ Main, LAD, circumflex, right coronary arteries

- ▶ Extent of calcification in each artery: none (0), mild (1), moderate (2), marked (3)

- ▶ CAC score: 0 -12, for any given person

Shemesh et al.  Clinical Imaging 2006; 239: 181-5
Shemesh et al. Radiology 2010; 257: 541- 8

# Survival rates by CAC score (n = 8,872)
adjusted by age, sex, smoking history and diabetes



CAC < 4

CAC > 4

HR = 2.1, 95% CI: 1.4 – 3.1
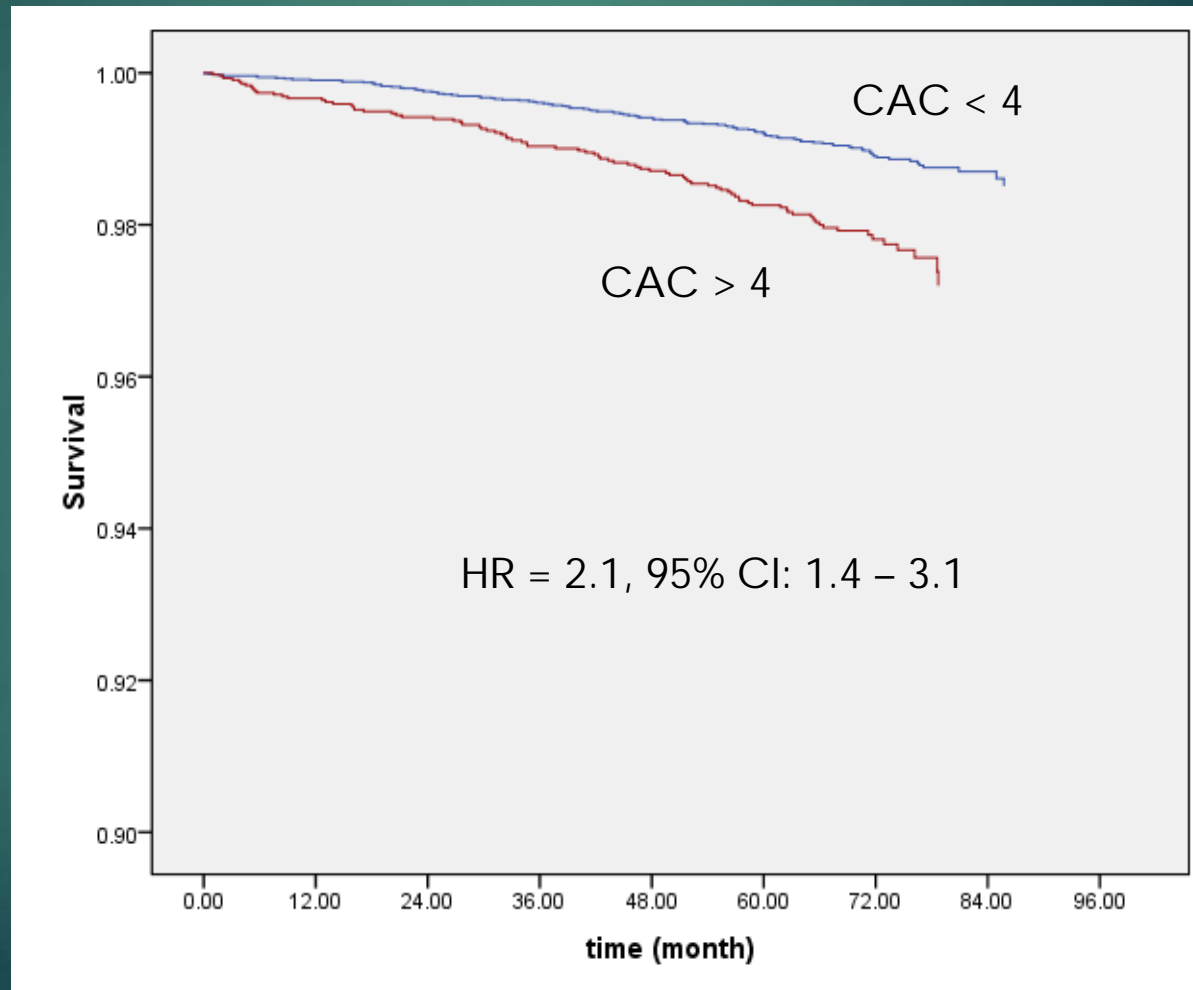
Shemesh et al. Radiology 2010; 257: 541-548

# Cardiac Recommendations
## Endorsed by Cardiology Organizations

| Ordinal CAC Score | Agatston Score | Recommendation |
|---|---|---|
| 0 | 0 | Probability of cardiovascular heart disease (CHD) is low. Reassure and keep healthy lifestyle |
| 1-3 | 1-100 | Probability of CHD is mild to moderately increased; Healthy lifestyle; moderate statin; ASA |
| 4-12 | > 100 | Probability of CHD is moderate to high. Healthy lifestyle; very intensive statin + second drug as needed; ASA; Consider function testing to r/o obstruction; Aggressive BP lowering; Referral to internist or preventive cardiologist |

# Emphysema

- None
- Mild
- Moderate
- Severe

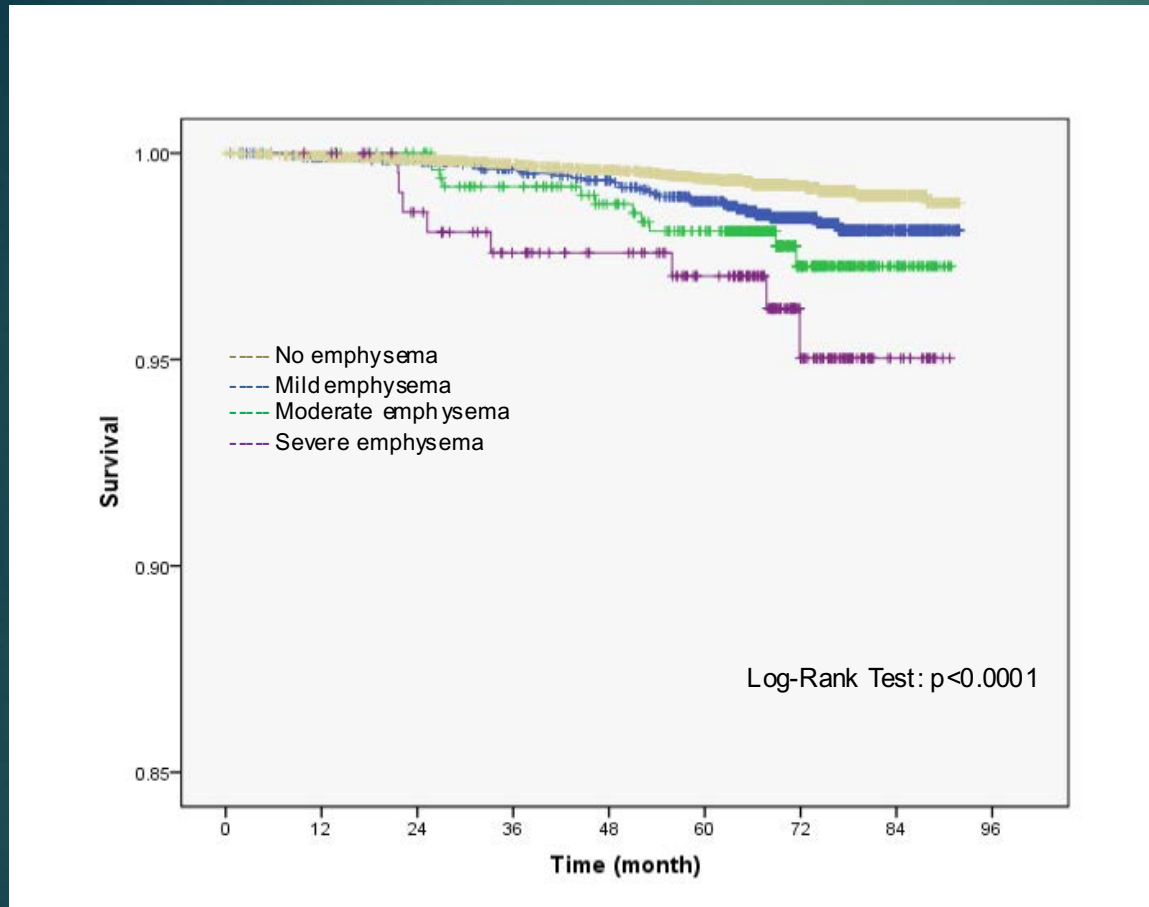

Zulueta JJ et al. Chest 2012; 141:1216-23

# COPD-specific Survival Rates (n = 9,047)
## adjusted by age, sex, smoking history and diabetes
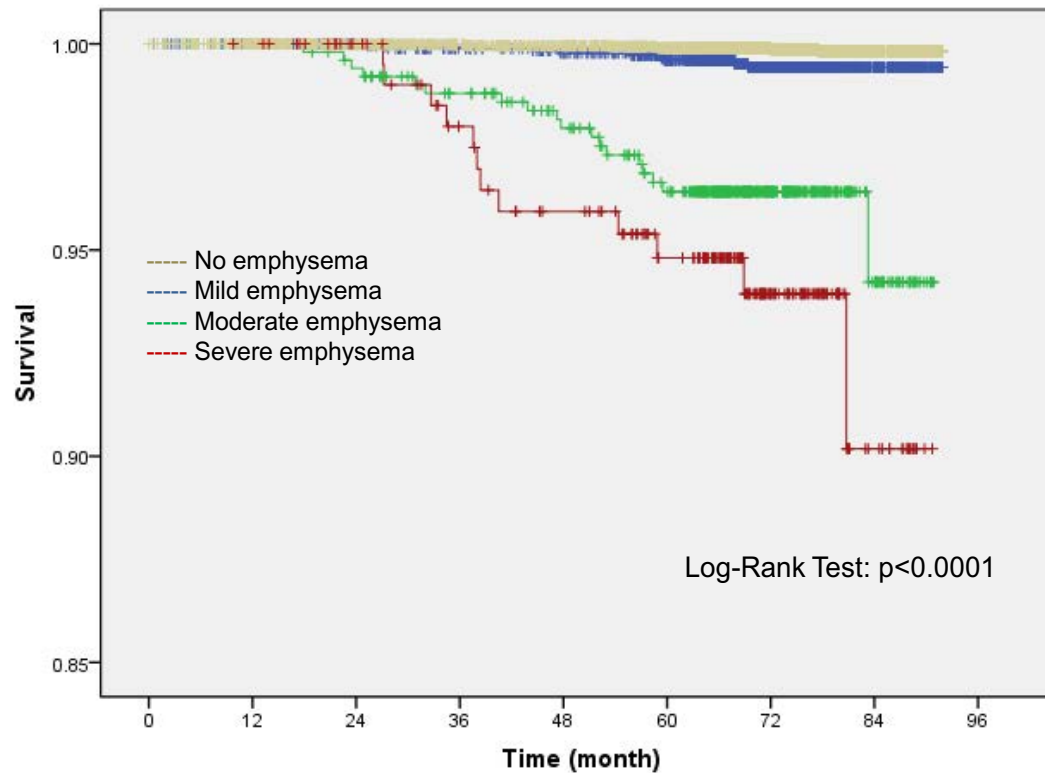


Moderate:
  HR = 17.3 (9.5-52.3)

Marked:
  HR = 43.7 (13.9-86.1)

Zulueta et al. Chest 2012; 141: 1216-23

# Lung Cancer Survival Rates (n = 9,047)
## adjusted by age, sex, smoking history and diabetes



Marked emphysema:
HR = 3.2 (95% CI: 1.5 – 6.7)

Zulueta et al. Chest 2012; 141: 1216-23

# Automated Analysis
## Airway wall thickness and Emphysema on CT

- Thickening of the bronchial walls is associate with many pulmonary diseases such as chronic bronchitis.

- Task: Compare two whole-lung CT scans to evaluate if there has been any change in airway health: (thickening of airways)

- Computer method

1. Identify the bronchial tree in each 3D CT image
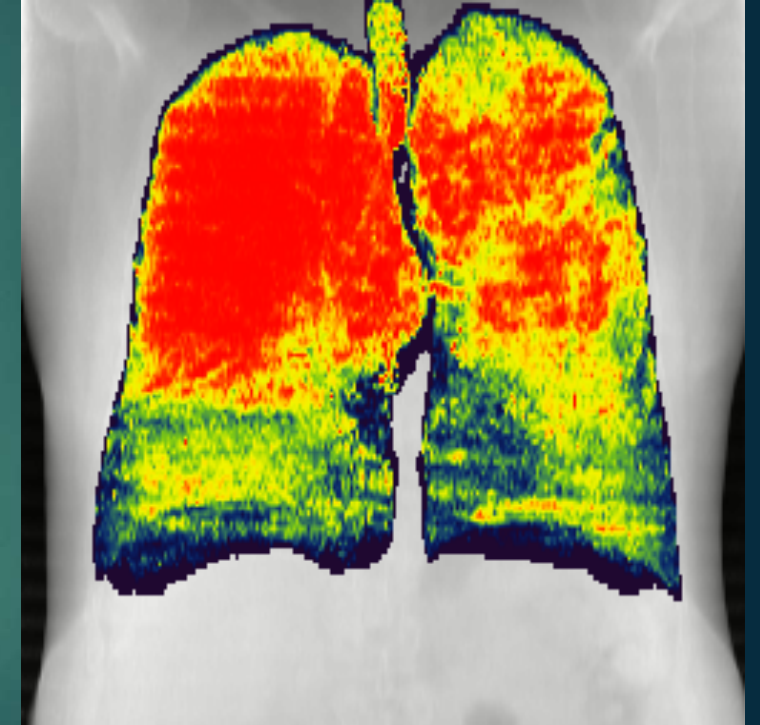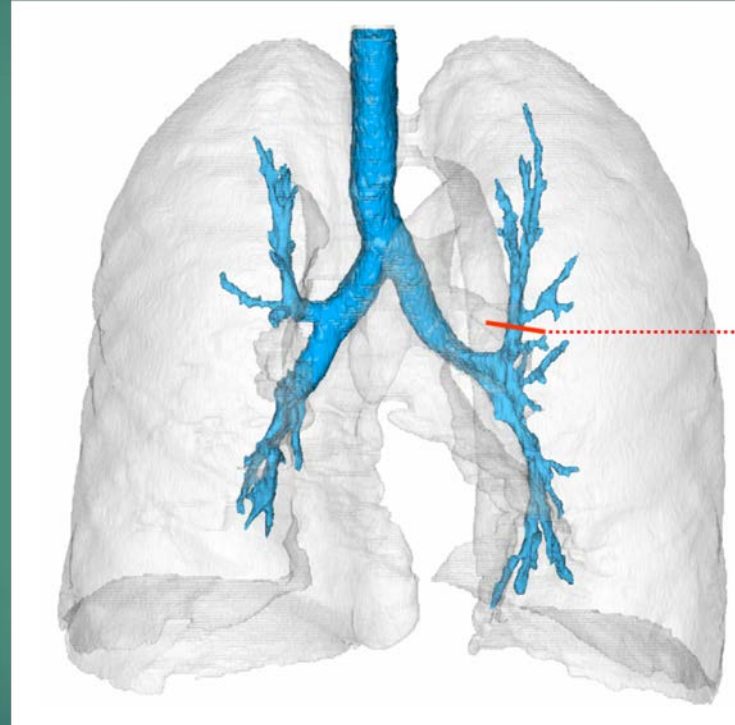
# Ascending Aorta and Aortic Arch Aneurysms

▶ Direct visualization of the aortic root, ascending and descending aorta

▶ Well seen without contrast injection
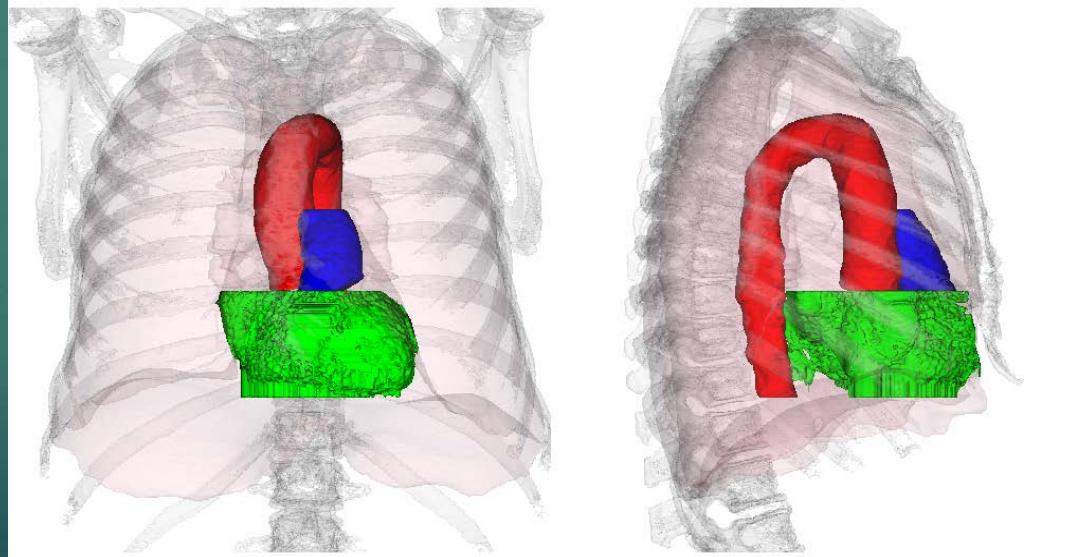
# Aortic Valve Calcifications
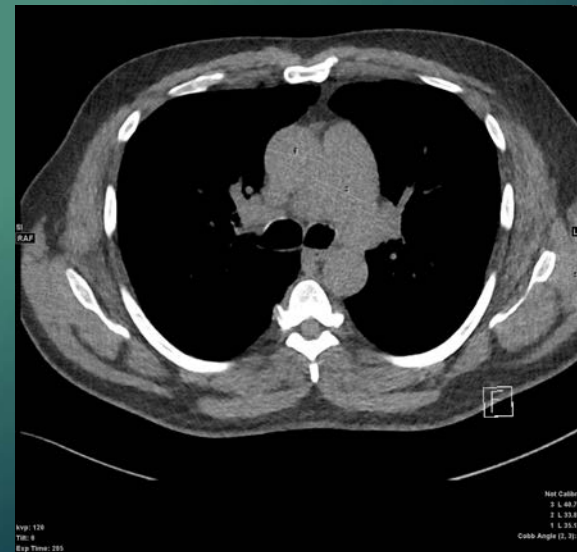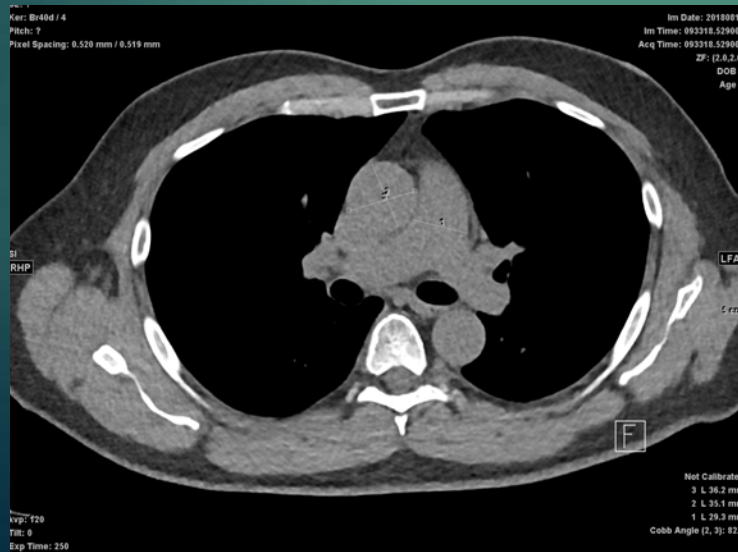
▶ Among 1,225 consecutive screening participants, the prevalence of

    ▶ moderate AV calcifications was 2.1%

    ▶ Severe AV calcifications was 0.2%

▶ Recommend cardiac consultation and echocardiography
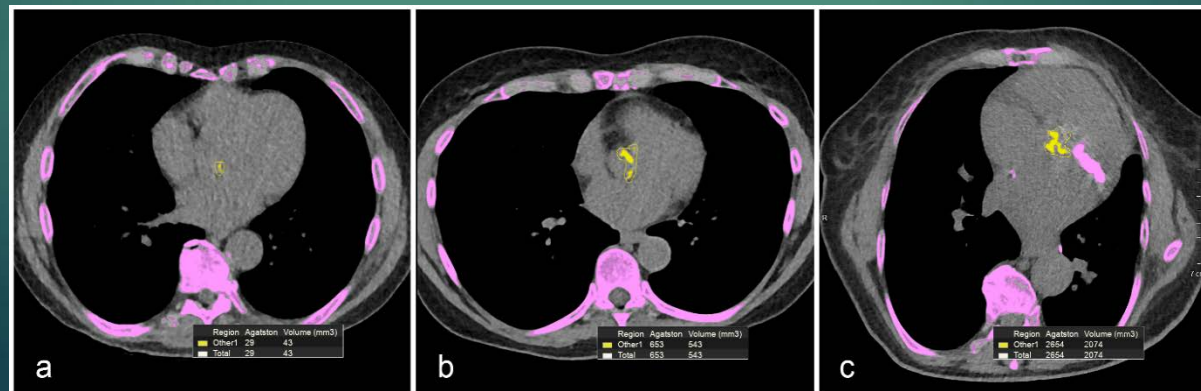
# Pulmonary Hypertension

- If
  - Main pulmonary artery diameter $\geq$ 34 mm or
  - Main pulmonary artery/aorta $\geq$ 1.0
- Recommend pulmonary consultation and possibly echocardiogram

# Pulmonary Hypertension

- Among 1,949 current and former smokers in   I-ELCAP, the prevalence rates were:
    - Main pulmonary artery diameter $\geq$ 34 mm
        - 4.2%
    - Main pulmonary artery/aorta $\geq$ 1.0
        - 6.9%

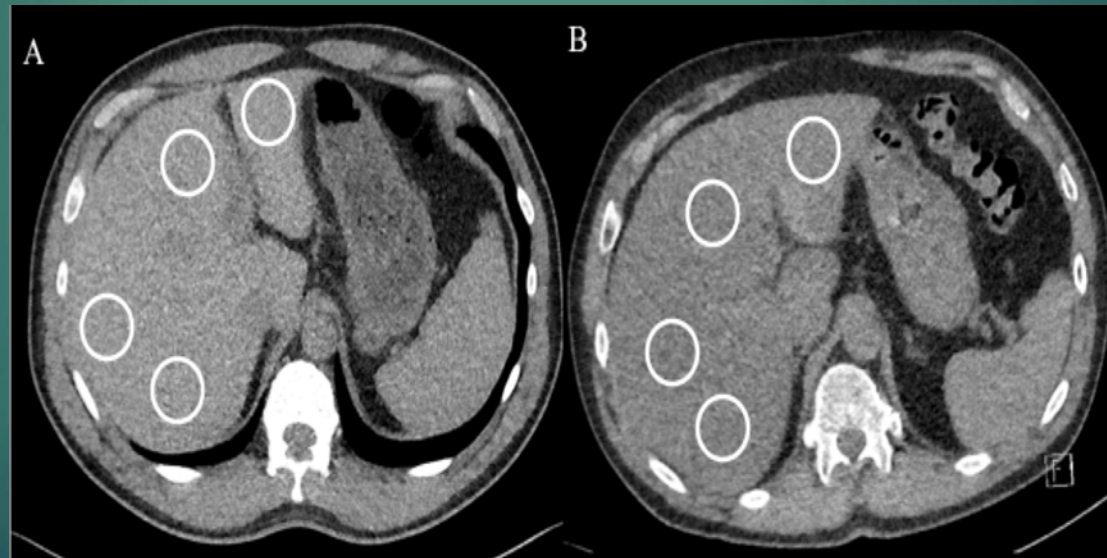- Recommend pulmonary consultation and possibly echocardiogram for further evaluation of pulmonary hypertension

# Interstitial Lung Disease

▶ Can be detected early and there are new treatments

▶ Early findings, typically peripherally located at lung bases

  ▶ Traction bronchiectasis

  ▶ "ground-glass opacities"

  ▶ reticulations

▶ Late findings

  ▶ honeycombing



Salvatore M et al. AJR American J of Roentgenology 2016. 206: 487-94

# Liver Findings: moderate to severe hepatic steatosis

▶ If CT attenuation < 40 HU, recommend seeing hepatologist for further evaluation



Chen X et al. Hepatic steatosis in participants in a program of low-dose CT screening for lung cancer. European Journal of Radiology 2017

# Liver Findings: moderate to severe hepatic steatosis

- Particulate Matter may play an important role in abnormal liver function tests
- In the lung cancer screening, the prevalence was 5.3%
- Higher frequency in World Trade Center responders (16.2%)
- A higher frequency was also reported for the Fire Fighters in NYC

# Liver Findings:
## moderate to severe hepatic steatosis

▶ Moderate to severe hepatic steatosis (< 40 HU) is associated with progressive liver disease that can lead to cirrhosis, liver failure, and hepatocellular carcinoma

▶ On the other hand, liver attenuation can change rapidly due to alcohol intake

▶ Focus is on persistent hepatic steatosis

Chen X et al. Hepatic steatosis in participants in a program of low-dose CT screening for lung cancer.  European Journal of Radiology 2017

# Thymus

- Diameter: > 30 mm or shows growth, recommend further workup

  - Baseline: 0.45% (41/9263) participants, only 5 were larger than 30 mm
    - 1 thymic carcinoma, 4 non-invasive thymomas
  - Annual: No new or growing thymic lesions

Henschke CI, Lee IJ, Wu N, Farooqi A, Khan A, Yankelevitz D, and Altorki NK. CT screening for lung cancer: prevalence and incidence of mediastinal masses. Radiology 2006; 239:586-90.

# Breast Density and Masses

- Grade 3 or 4 according to BI-RADS, report on CT, as masses are obscured on mammography

- Grade 3: heterogeneously dense

- Grade 4: extremely dense

Salvatore M, Margolies L, Kale M, Wisnivesky J, Kotkin S, Henschke CI, and Yankelevitz DF.  Breast density: comparison of chest CT with mammography. Radiology 2014; 270:67-73.

Margolies L, Salvatore M, Eber C, Jacobi A, Lee I, Liang M, Tang W, Xu D, Zhao S, Kale M, Wisnivesky J, Henschke C, and Yankelevitz D. The general radiologist's role in breast cancer  risk assessment: breast density measurement on chest CT. Clin Imaging 2015; 39:979-82.

# Adrenal Glands

- If maximum transverse diameter > 40 mm:  recommend further evaluation

- Baseline:  4% (202/4776) had adrenal enlargement
  - only 2 were > 40 mm
  - remaining 200 were followed on annual repeat to assess change, none showed a change

- Annual: 0.004% (5/11591) were new, all 5 < 40 mm
  - No growing adrenal glands among those being followed

Hu M, Yip R, Yankelevitz D, and Henschke C. CT screening for lung cancer: frequency of enlarged adrenal glands identified in baseline and annual repeat rounds. Eur Radiol 2016;

# Thyroid Gland

▶ Nodules ≥ 15 mm, recommend thyroid sonography

▶ Nodules < 15 mm, annual repeat screening
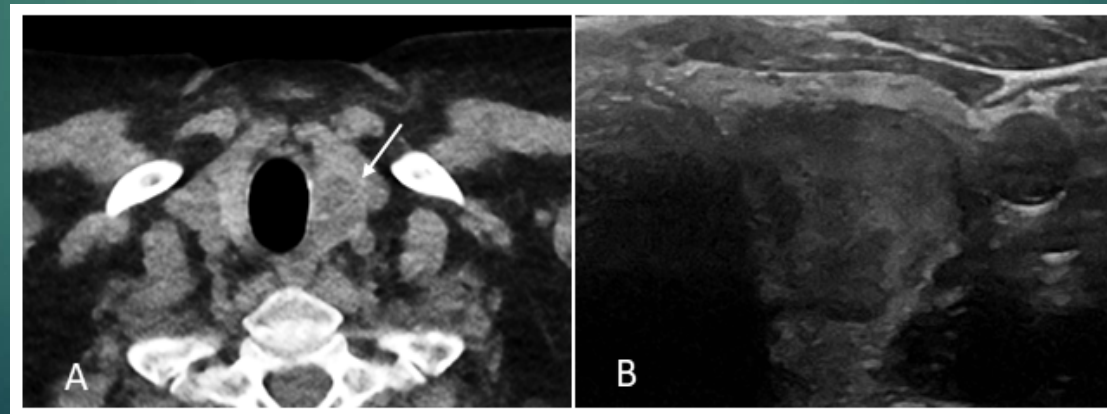
# Osteoporosis

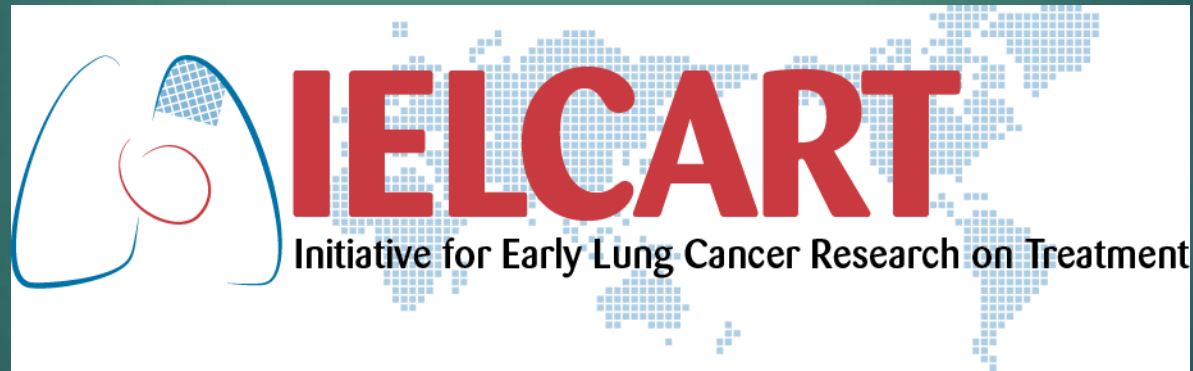► Developing quick visual assessment using specific window settings

► Recommend consultation and further workup
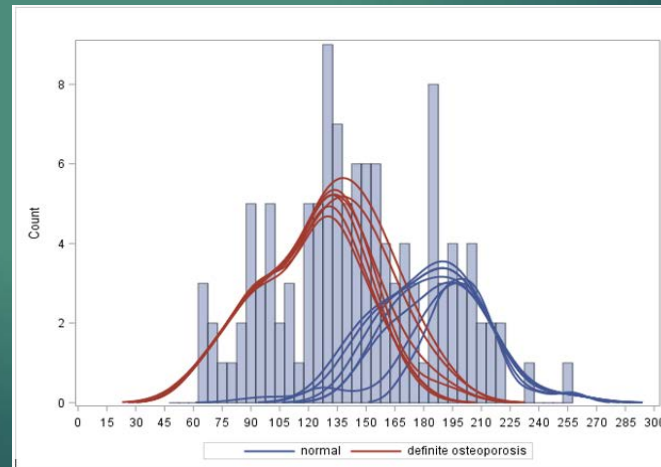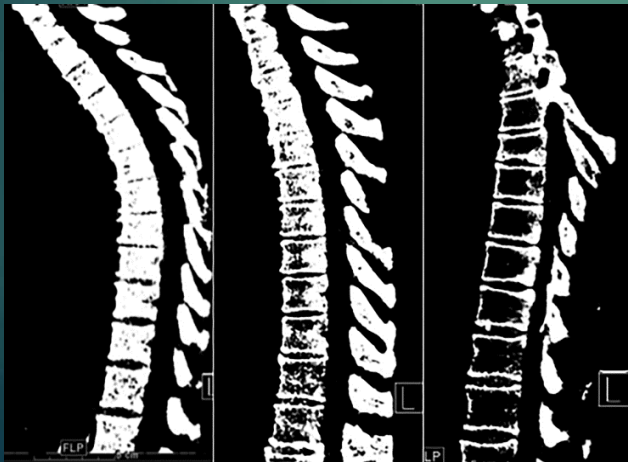
# Protocol: www.IELCAP.org

# Initiative for Early Lung Cancer Research on Treatment

# Prior IELCART Conferences

- January 31, 2015
- February 27-28, 2015
  - History of surgical innovations
    - Evidence needed to change from pneumonectomy to lobectomy
    - Used multiple institutional data
  - Identification of key areas of investigation

# IELCART Workshops and Conferences

Intervention Research in the Era of "Big Data"

► Workshop I:  January 30 and 31, 2015

► Workshop II:  Febr27-28, 2015

► Workshop III:  June 26, 2015

► Workshop IV:  September 18, 2015

► 33rd International Conference and 1st Conference on Research for Lung Cancer Treatment: Dec 4 and 5, 2015

► Workshop V: March 18,2 016

► 34th International Conference and 2nd  Conference on Research for Lung Cancer Treatment:  March 6 and 7, 2016

► Workshop VI: June 24, 2016

► Workshop VII: September 23, 2016

► 35th International Conference and 3st Conference on Research for Lung Cancer Treatment:  Nov 18 and 19, 2016

► Workshop VIII: March 17, 2017

► 36th International Conference and 4st Conference on Research for Lung Cancer Treatment: May 5 and 6, 2017

► Workshop IX: June 23, 2017

► 37th International Conference and 5st Conference on Research for Lung Cancer Treatment: Sep 15 and 16, 2017

► 38th International Conference and 6st Conference on Research for Lung Cancer Treatment: March 16 and 17, 2018

► Workshop X: June 15, 2018

► 39th International Conference and 7st Conference on Research for Lung Cancer Treatment: Oct 16 and 17, 2018

► 40th International Conference and 8st Conference on Research for Lung Cancer Treatment: April 12 and 13, 2018

# IELCART Primary Endpoints: A Prospective Cohort Study

- Long term survival, recurrence rates, and QoL of different treatments and mediastinal lymph node resection
  - Sublobar vs. lobectomy vs. SBRT
- Watchful waiting and Q of L
  - Includes people being watched by CT screening
  - Includes people who decided not to have surgery, either with or without biopsy

# Some Surgical Subtopics

▶ Lobectomy vs. sublobectomy

▶ When to perform mediastinal lymph node resection/sampling

▶ Assessment of resection margin in sublobar resections

▶ Watchful waiting vs. resection for certain subtypes of cancers

# Quality Control Considerations

- Weekly review of complications with surgeons