

# **Establishing an International Monitoring Framework to Ensure Quality of Quantitative Images**

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April 12, 2018

**2018 Dialog For Action on Cancer Screening and Prevention**

# Lung Cancer

EVERY DAY  
**427**  
AMERICANS  
DIE OF LUNG  
CANCER.

Lung cancer is the leading cancer killer in men & women in EVERY ETHNIC GROUP.

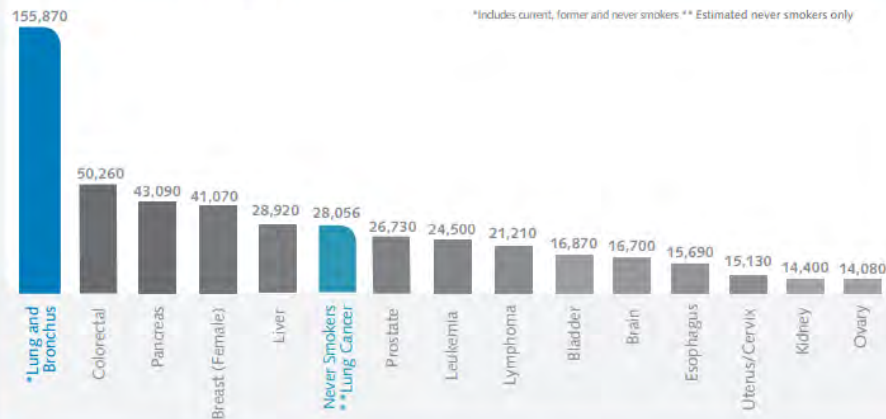
VETERANS have at least a 25% higher incidence rate of lung cancer than civilians.

Lung cancer makes up 26% of all **CANCER DEATHS**.

## 2017 LUNG CANCER FACTS



### LUNG CANCER IS THE LEADING CAUSE OF CANCER DEATH (i)



### SNAPSHOT OF PEOPLE WITH LUNG CANCER (ii)

20.9%  
CURRENT  
SMOKERS

60%  
FORMER  
SMOKERS

17.9%  
NEVER  
SMOKED

(i) National Cancer Institute, Surveillance, Epidemiology, and End Results (SEER), U.S. Cancer Mortality, 1975-2013, published April 15, 2016.  
(ii) Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, "Cigarette Smoking Among Adults -United States, 2006," November 9, 2007/56(44): 1157-1161, Table 2

# Low Dose CT Lung Cancer Screening

Since 2015:  
Annual Low Dose CT Screening is Reimbursed For Those at High Risk



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### Proposed Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N)

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#### Decision Summary

The Centers for Medicare & Medicaid Services (CMS) proposes that the evidence is sufficient to add a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, screening for lung cancer with low dose computed tomography (LDCT), once per year, as an additional preventive service benefit under the Medicare program only if all of the following criteria are met:

**Beneficiary eligibility criteria:**

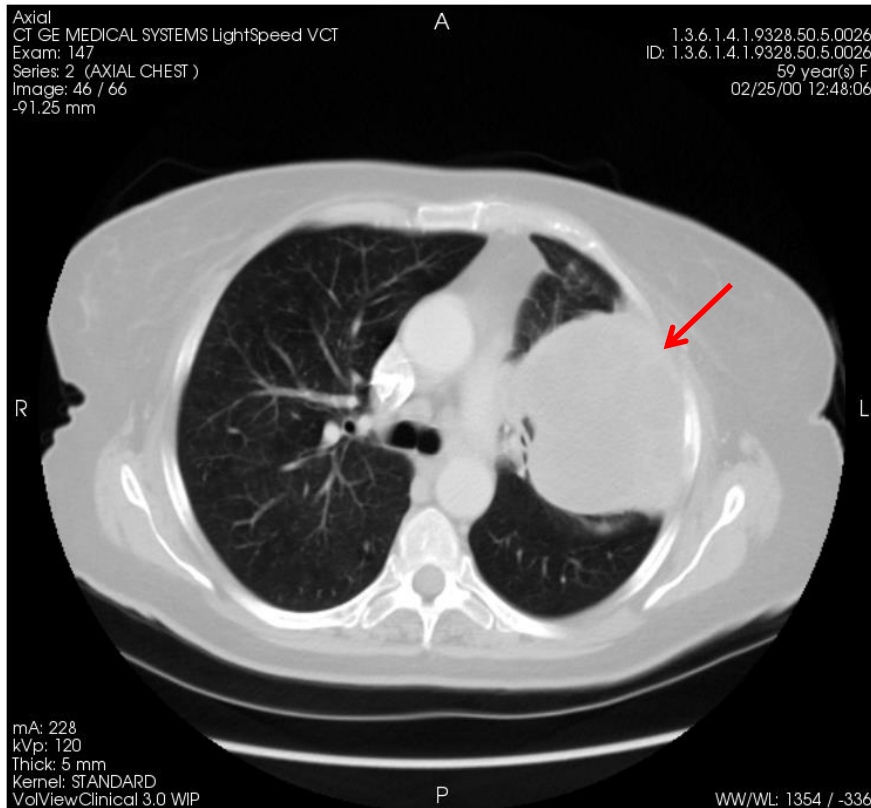
- Age 55-74 years;
- Asymptomatic (no signs or symptoms of lung disease);
- Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Current smoker or one who has quit smoking within the last 15 years; and
- A written order for LDCT lung cancer screening that meets the following criteria:
  - For the initial LDCT lung cancer screening service: the beneficiary must receive a written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision making visit, furnished by a physician (as defined in Section 1801(r)(1) of the Social Security Act (the Act)) or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1801(aa)(5) of the Act).
  - For subsequent LDCT lung cancer screenings: the beneficiary must receive a written order, which may be furnished during any appropriate visit (for example: during the Medicare annual wellness visit, tobacco cessation counseling services, or evaluation and management visit) with a physician (as defined in Section 1801(r)(1) of the Act) or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1801(aa)(5) of the Act).

• A lung cancer screening counseling and shared decision making visit includes the following elements (and is appropriately documented in the beneficiary's medical records):

- Determination of beneficiary eligibility including age, absence of signs or symptoms of lung disease, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting;
- Shared decision making, including the use of one or more decision aids, to include benefits, harms, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure;
- Counseling on the importance of adherence to annual LDCT lung cancer screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment;
- Counseling on the importance of maintaining cigarette smoking abstinence if former smoker, or smoking cessation if current smoker and, if appropriate, offering additional Medicare-covered tobacco cessation counseling services; and
- If appropriate, the furnishing of a written order for lung cancer screening with LDCT. Written orders for both initial and subsequent LDCT lung cancer screenings must contain the following information, which must also be documented in the beneficiaries' medical records:
  - Beneficiary date of birth;
  - Actual pack-year smoking history (number);
  - Current smoking status, and for former smokers, the number of years since quitting smoking;
  - Statement that the beneficiary is asymptomatic; and
  - NPI of the ordering practitioner.

# Lung Cancer Screening Benefit

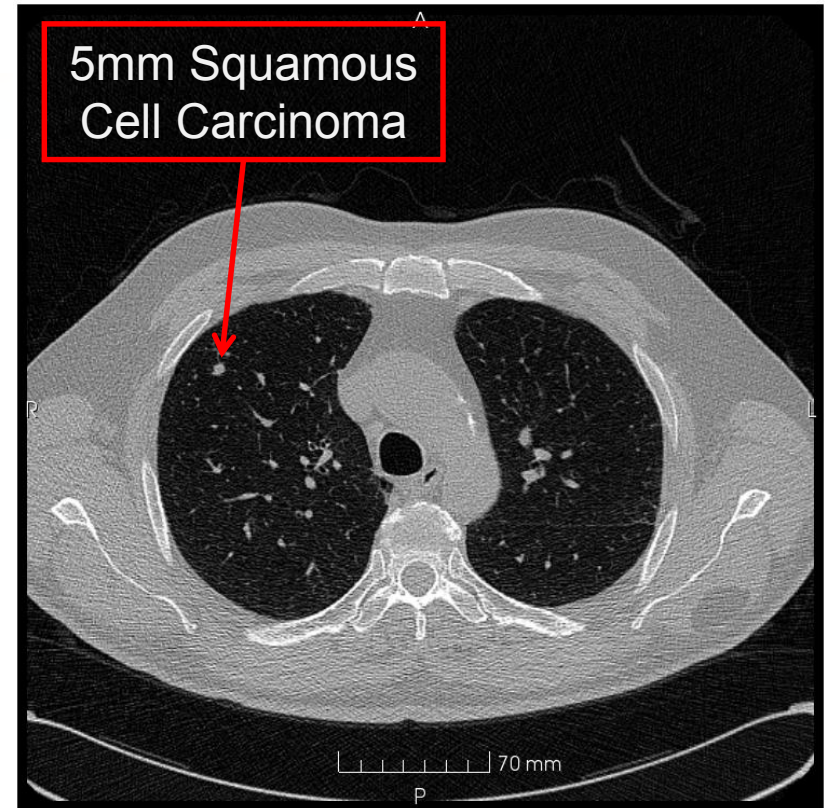
## Late-Stage Lung Cancer



[R. Gottlieb, Roswell Park Cancer Institute]

**~5% five year survival**

## Early Lung Cancer



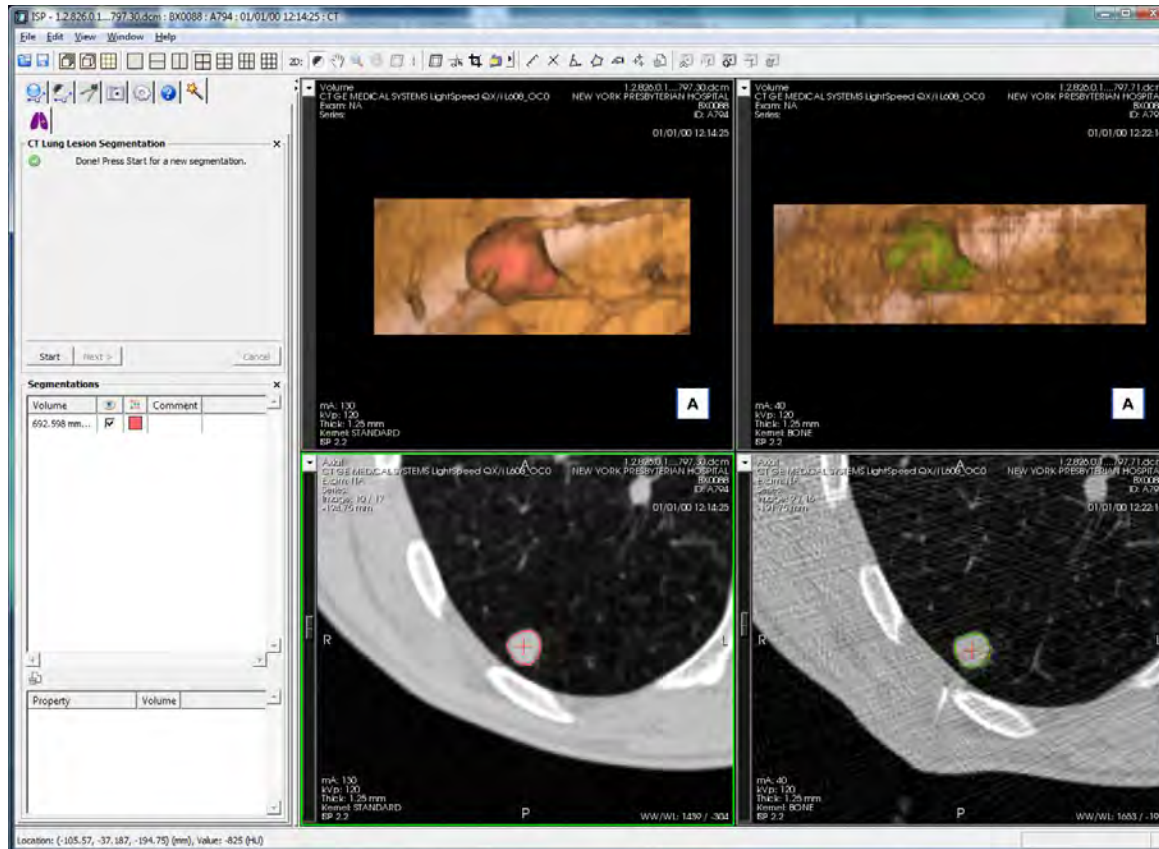
[Dr. Javier Zulueta, University of Navarra]

**~85% five year survival**

# Pulmonary Nodules

Time 1

Time 2



= 668 mm<sup>3</sup>

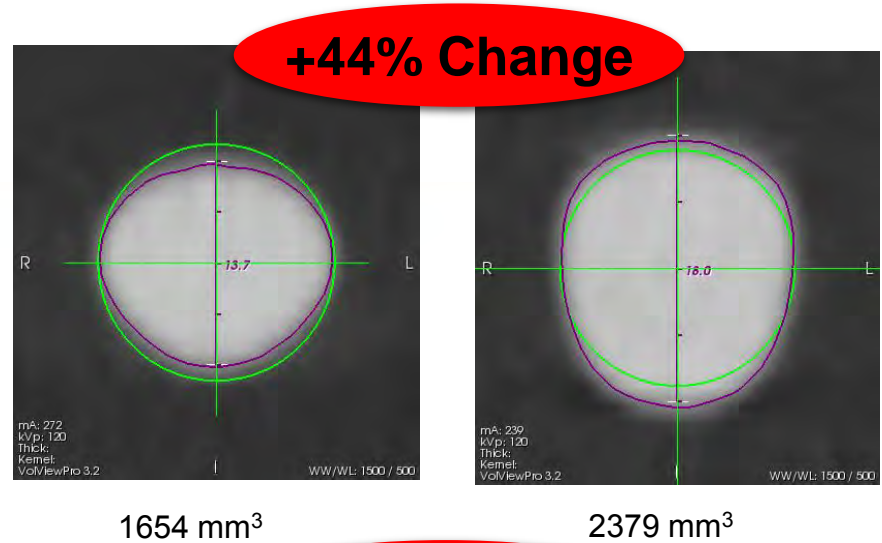
T2 = 661 mm<sup>3</sup>

$\Delta V = \text{No Change}$

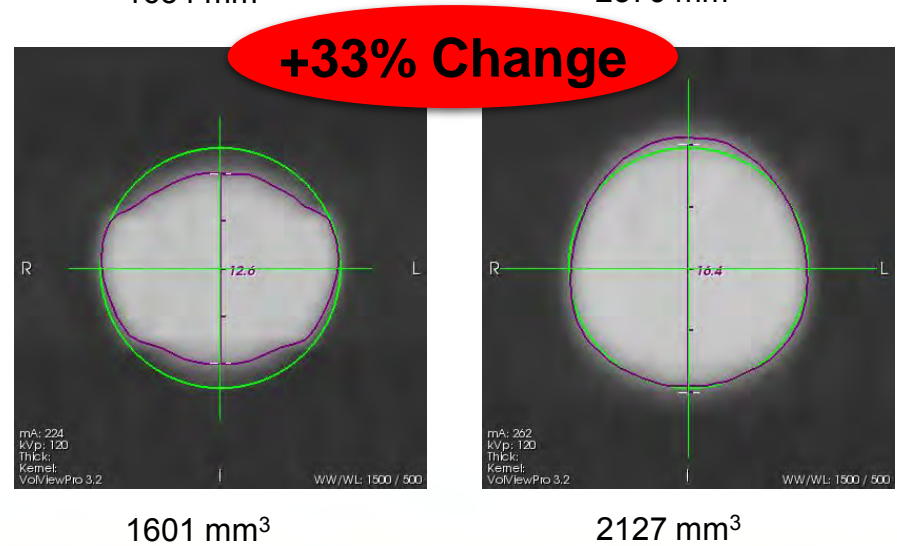
# 2010: Roche ABIGAIL Study



**Model A  
Site 1**



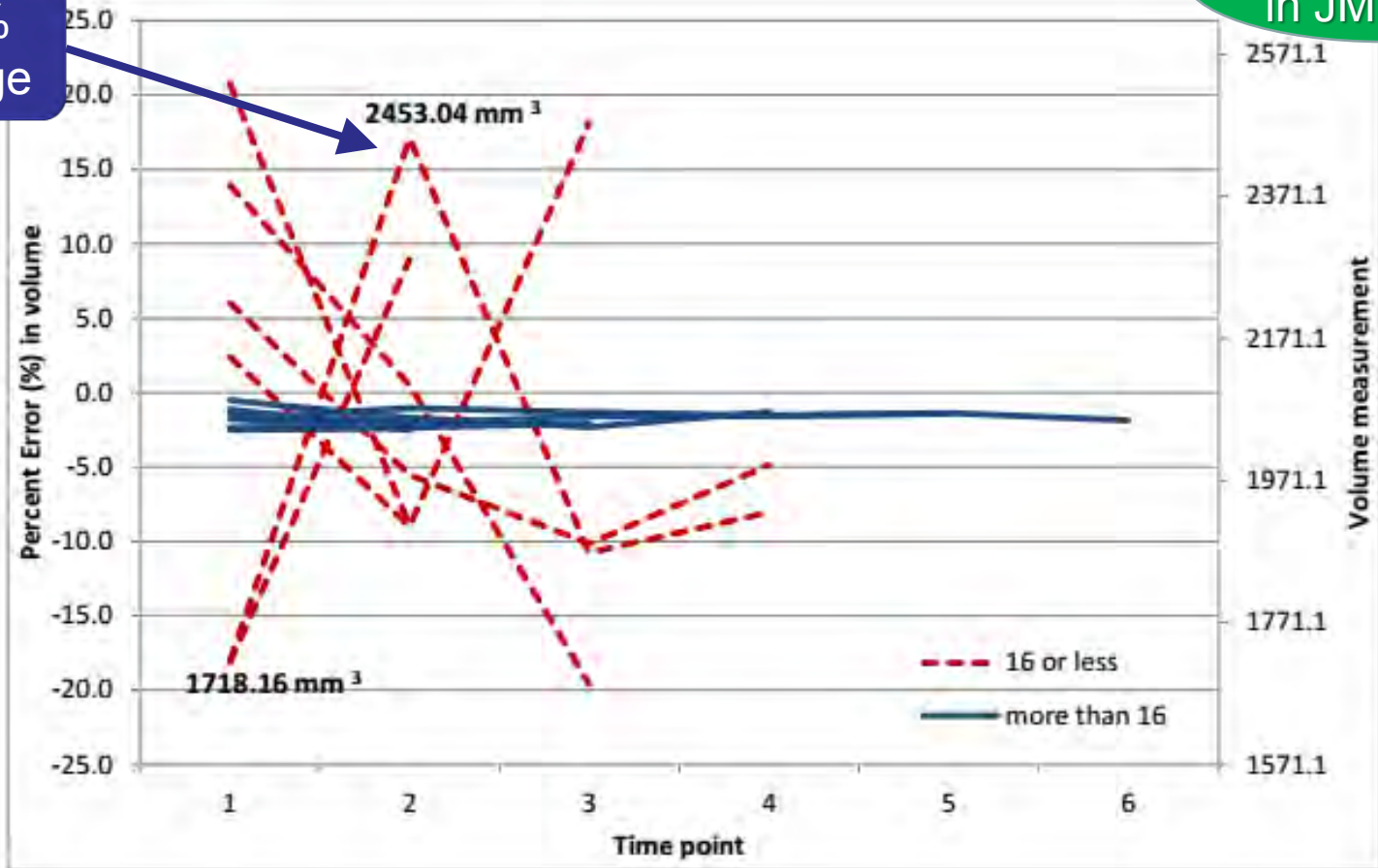
**Model A  
Site 2**



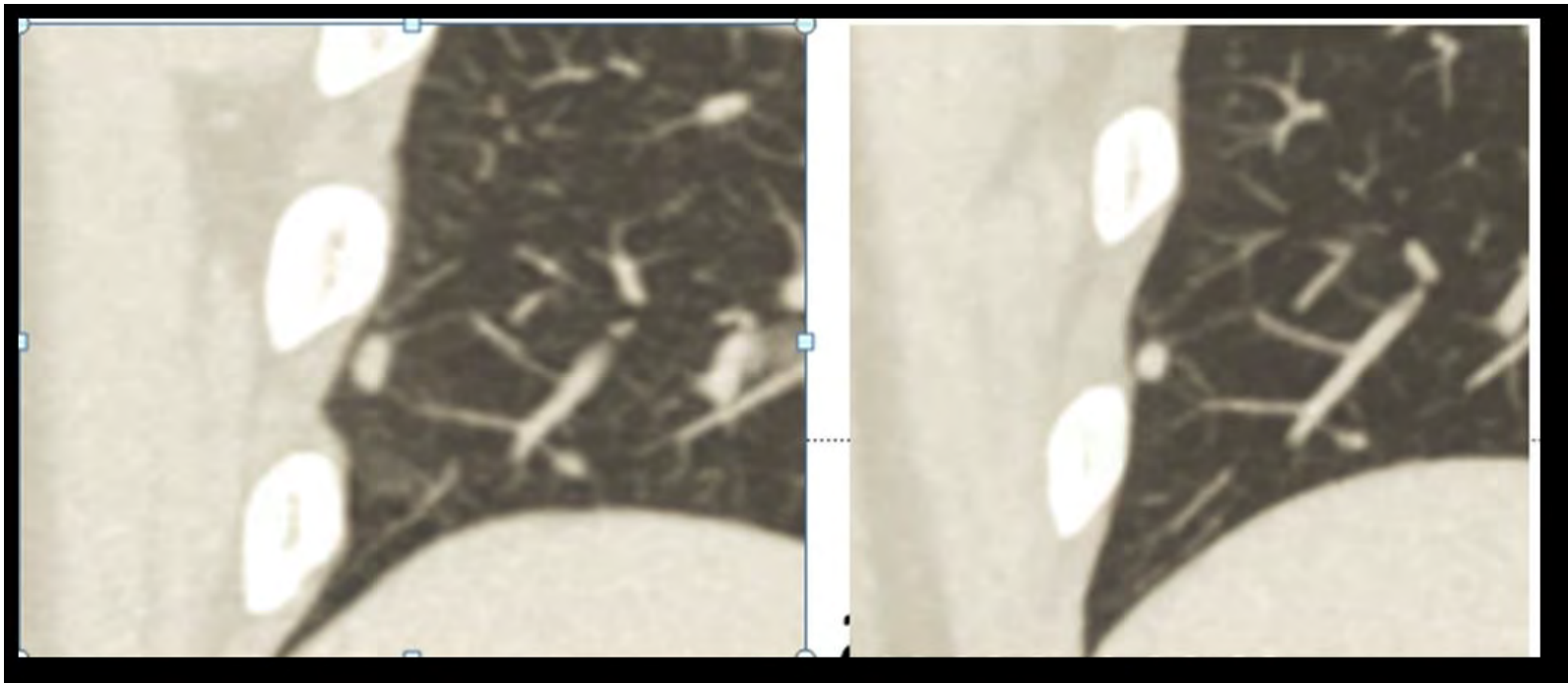
# Volume Measurements Over Time

To Appear  
in JMI 2016

+43%  
Change



# Periodic Z Warping





# 2016 CT Lung Cancer Screening Protocol Challenge

- **Goal**

- To quantitatively determine the most effective lung cancer screening CT scanners and protocols using an ultra-low cost, crowd-sourced approach.
- In addition, to identify the best protocols for combined lung cancer and COPD screening.



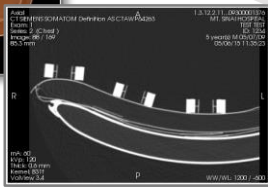
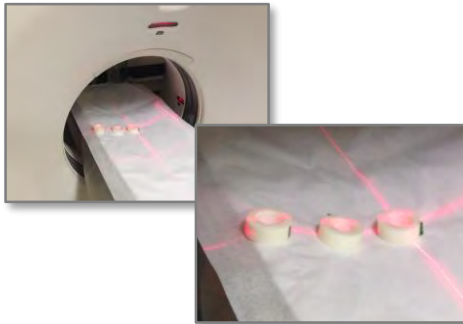
# Team

- Accumetra
  - Challenge Leadership
  - Image Assessment Technology
- Prevent Cancer Foundation
  - National Cancer Patient Advocacy
  - Lung Cancer Workshop XIII
- Lung Cancer Alliance
  - National Cancer Patient Advocacy
  - > 300 Framework Sites
- I-ELCAP
  - Largest Ongoing International Lung Cancer Screening Study
- COPD Foundation
  - National COPD Patient Advocacy



# Free CT Image Quality Report

Can Be Replaced With Calibrated Object

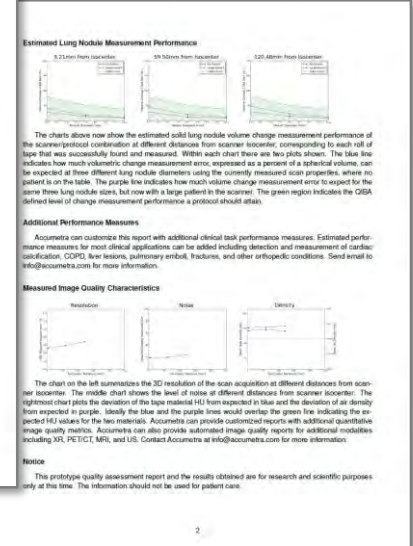
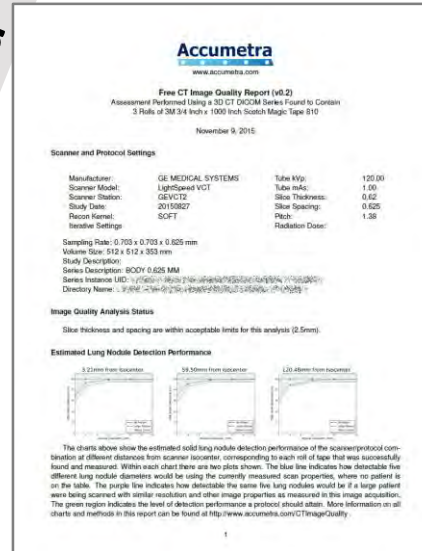


Tech Can Do The Scan In < 5 Minutes

Accumetra.com

Email

Upload



Optimize

# CT Scanning Site Participants



LUNG CANCER ALLIANCE

HelpLine 1-800-298-2436

SCREENING LUNG CANCER BASICS TREATMENT SUPPORT EVENTS GET INVOLVED RESEARCH

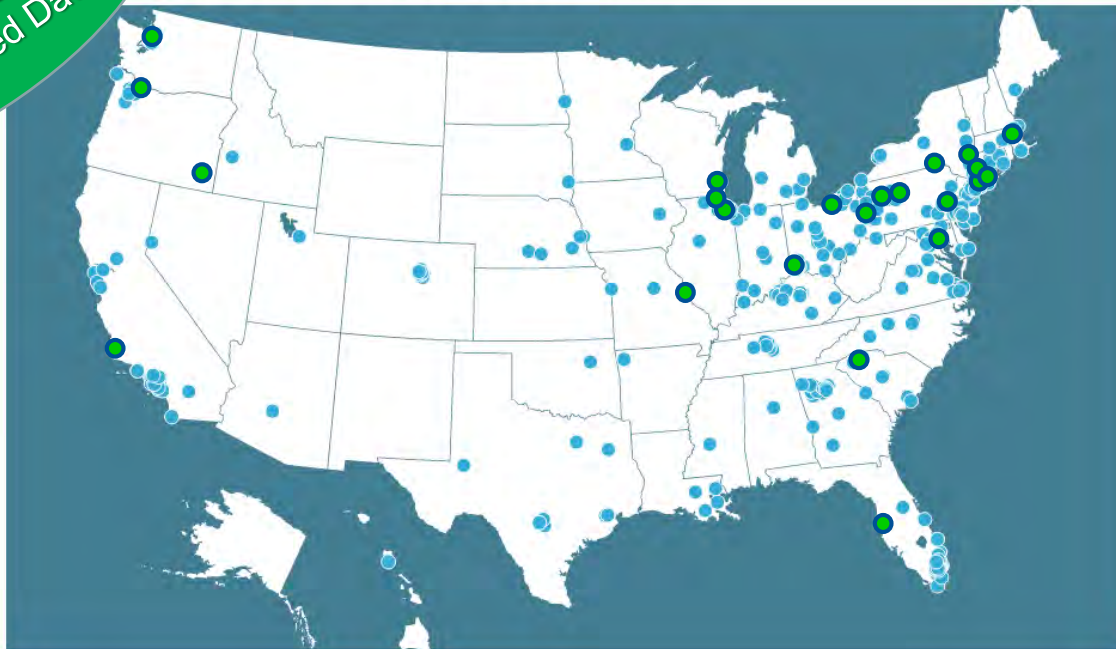
DONATE TODAY!

HOME >> RISK & SCREENING >> LUNG CANCER SCREENING >> SCREENING CENTERS OF EXCELLENCE

## Screening Centers of Excellence

Find Screening Centers of Excellence near you, please click on your state or select from the list below. Use your mouse wheel to zoom in for a closer look at the centers near you. You may also click and hold to drag the map to a new position.

27 Sites  
Submitted Data



- China
- Spain (2)
- Israel
- Switzerland

# CT Scanners (26 sites)

<b>GE (19% = 10/53)</b>	<b>BrightSpeed8</b>	<b>8</b>	<b>1</b>
	<b>LightSpeed VCT</b>	<b>64</b>	<b>5</b>
	<b>Discovery CT750 HD</b>	<b>128</b>	<b>2</b>
	<b>Revolution CT</b>	<b>256</b>	<b>2</b>
<b>Siemens (50% = 27/53)</b>	<b>Sensation 16</b>	<b>16</b>	<b>2</b>
	<b>Biograph40</b>	<b>40</b>	<b>1</b>
	<b>Sensation64</b>	<b>64</b>	<b>4</b>
	<b>SOMATOM Definition</b>	<b>64</b>	<b>4</b>
	<b>SOMATOM Definition AS</b>	<b>40, 64, 128</b>	<b>6</b>
	<b>SOMATOM Definition AS+</b>	<b>128</b>	<b>4</b>
	<b>Definition AS+ 128</b>	<b>128</b>	<b>1</b>
	<b>Definition Edge 128</b>	<b>128</b>	<b>1</b>
	<b>SOMATOM Definition Flash</b>	<b>256</b>	<b>4</b>
<b>Philips (23% = 12/53)</b>	<b>Brilliance64</b>	<b>64</b>	<b>4</b>
	<b>IngenuityCT</b>	<b>128</b>	<b>5</b>
	<b>iCT 256</b>	<b>256</b>	<b>3</b>
<b>Toshiba (8% = 4/53)</b>	<b>Aquilion</b>	<b>64</b>	<b>1</b>
	<b>Aquilon ONE</b>	<b>320</b>	<b>3</b>
<b>4 Manufacturers</b>	<b>18 Models</b>		<b>53 CT Scanners</b>

# CT Lung Screening Protocol Guidelines

## CT Acquisition

	Detectors ≥	Thickness ≤	Spacing ≤	Kernel
2016 RSNA/QIBA Small Nodule Profile (19% to 42%)	16	1.25	1.25	Highest Res.
2016 I-ELCAP Guidelines	64	1.25	1.25	Highest Res.
2015 European Society of Radiology	16	1.0	0.7	No Pref.
2015 American College of Radiology (10 Pillars Publication)	16	2.5, 1.0 pref.	No Pref.	No Pref.
2016 AAPM Lung Cancer Screening Protocols	16	2.5, 1.0 pref.	2.5, 1.0 pref.	Range, Not Easy

Our Specification: ≥ 16 detector rows, ≤1.25 thickness , ≤1.25 spacing

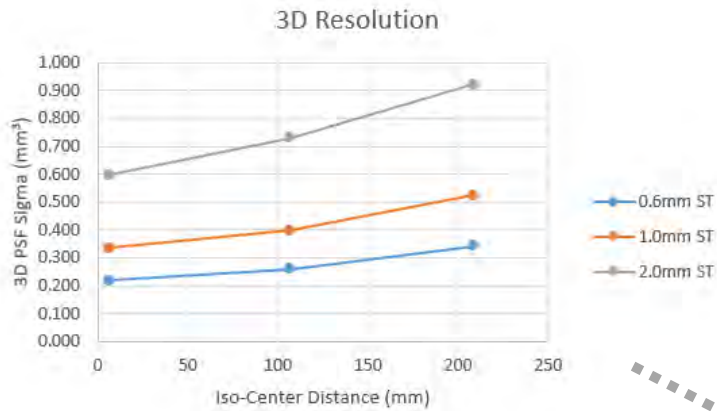
# Detection Slice Thickness & Recon Kernel

Slice Thickness	Sites	Soft Recon	Medium Recon	Edge En. Recon
$\leq 0.625$	4 (15%)	0	3	1
0.8, 1.0, 1.25	12 (46%)	6	2	4
$\geq 1.5$	10 (38%)	6	3	1

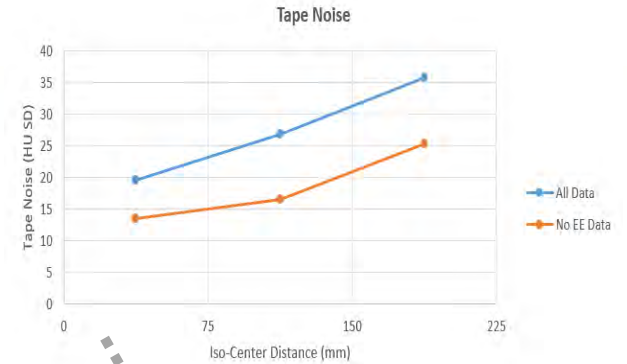
3 used 2mm ST & 1mm spacing

# CT Image Quality Issues

## 3D Resolution

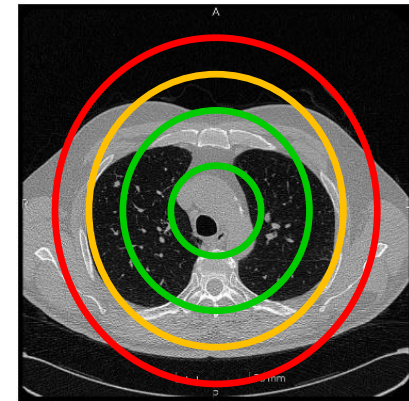
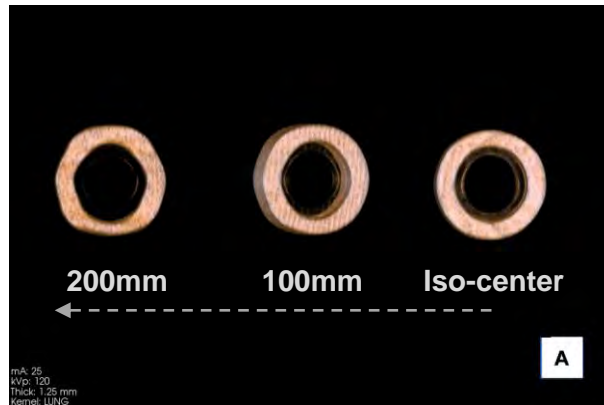


## Noise



## Image Quality Variability

## 3D Spatial Warping





# Mammography Quality Standards Act

W Mammography Quality Standards Act

Secure | [https://en.wikipedia.org/wiki/Mammography\\_Quality\\_Standards\\_Act](https://en.wikipedia.org/wiki/Mammography_Quality_Standards_Act)

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## Mammography Quality Standards Act

From Wikipedia, the free encyclopedia

The **Mammography Quality Standards Act (MQSA)** was enacted by the [United States Congress](#) to regulate the quality of care in [mammography](#). The act was officially effective in 1994, and was extended in 2004 to continue through 2007. The [U.S. Food and Drug Administration \(FDA\)](#) began inspections of mammography facilities to ensure compliance in 1995. In 1997, more comprehensive regulation was added to become effective in 1999.

The FDA explains MQSA:<sup>[1]</sup>

The Mammography Quality Standards Act requires mammography facilities across the nation to meet uniform quality standards. Congress passed this law in 1992 to assure high-quality mammography for early breast cancer detection, which can lead to early treatment, a range of treatment options leading to an increased chance of survival. Under the law, all mammography facilities must: 1) be accredited by an FDA-approved accreditation body, 2) be certified by FDA, or its State, as meeting the standards, 3) undergo an annual MQSA inspection, and 4) prominently display the certificate issued by the agency.

**Contents** [hide]

- History
- Accrediting bodies
- Effects on patients
- References
- External links

### Mammography Quality Standards Act



**Long title** An Act to amend the Public Health Service Act to establish the authority for the regulation of mammography services and radiological equipment, and for other purposes.

**Acronyms (colloquial)** MQSA

**Nicknames** Mammography Quality Standards Act of 1992

**Enacted by** the 102nd United States Congress

**Effective** October 1, 1994

**Citations**

**Public law** 102-539 

**Statutes at Large** 106 Stat. 3547 

**Codification**

**Titles amended** 42 U.S.C.: Public Health and Social Welfare

**U.S.C. sections created** 42 U.S.C. ch. 6A  § 263b

# RSNA/QIBA CT Small Lung Nodule Profile



QIBA Profile: Lung Nodule Assessment in CT Screening Profile - 2017

Quantitative  
Imaging  
Biomarkers  
Alliance



2

3

4

5

6

7

8

## QIBA Profile: Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening

Stage: Publicly Reviewed (draft)

# A QIBA Small Lung Nodule Phantom

200 mm from  
Iso-Center

At Iso-Center

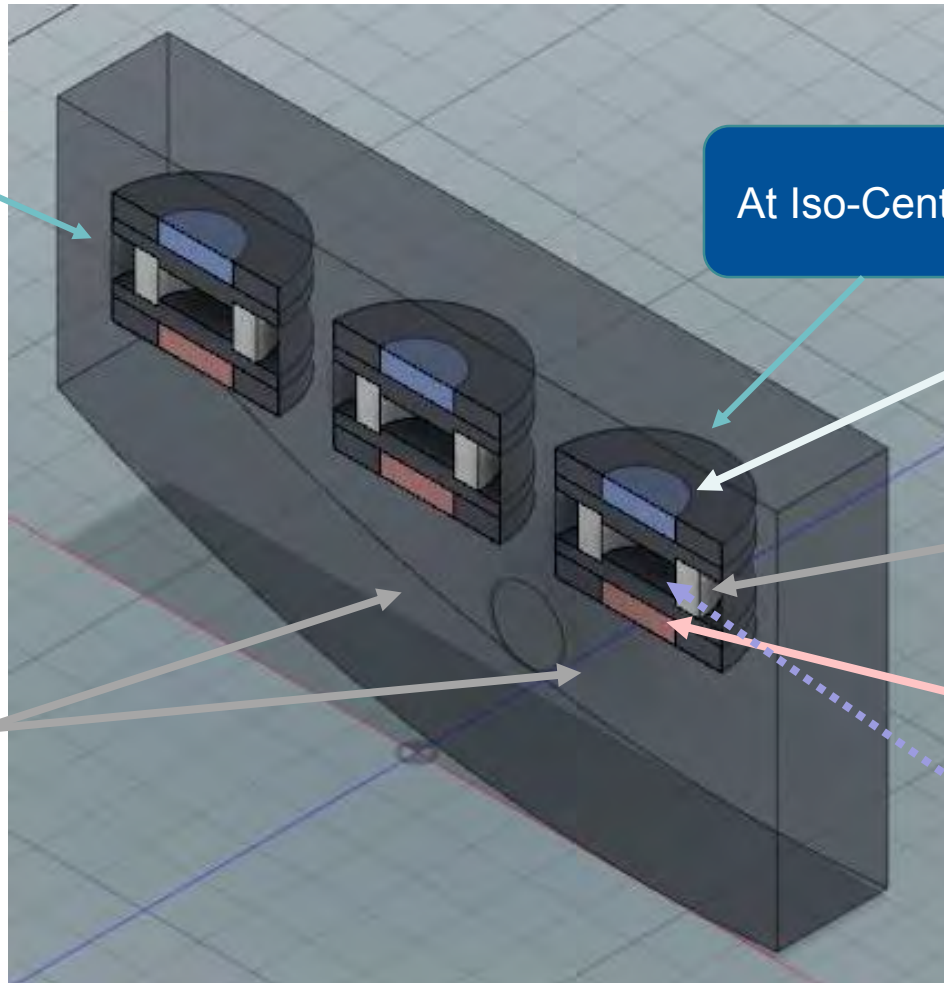
Teflon (~950 HU)  
Cylinder

Delrin (~340 HU)  
Concentric Cyl

Acrylic (~120 HU)  
Cylinder

Air (-1000 HU)

Room For  
Other  
Compartments

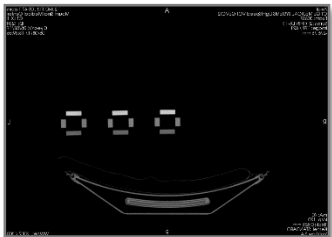
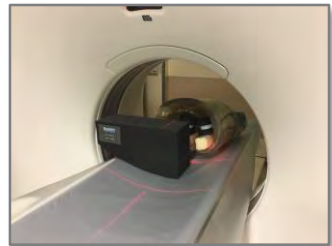
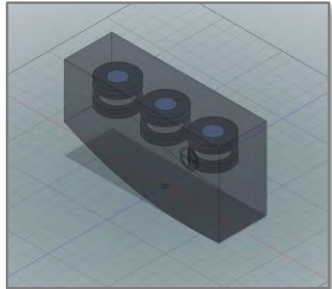


# ~ 100 CTLX1 Phantoms Are Being Globally Distributed

- **Confirms Fundamental CT Image Properties**
  - 3D Resolution:
    - 3D PSF Ellipsoid Volume  $\leq 1.5 \text{ mm}^3$
  - 3D Resolution Aspect:
    - PSF Z/X  $\leq 2.0$
  - Linearity Bias:
    - Air and Acrylic Bias  $< 35 \text{ HU}$
  - Image Noise:
    - Acrylic Noise  $\leq 50 \text{ HU SD}$
  - Kernel Edge Enhancement:
    - Air to Delrin Enhancement  $\leq 5\%$
  - 3D Spatial Warping:
    - Delrin Cylinder RMSE  $\leq 0.3 \text{ mm}$
- **Lung Nodule Volume Change Performance**
  - Verifies That Image Quality Meets or Exceeds The QIBA CT Lung Nodule Profile Volume Change Measurement Claims



# RSNA/QIBA Conformance Certification Pilot Project Using Cloud-Based Computing Services



<http://quality.rsna.org>

Email

Upload

**Accumetra**  
www.accumetra.com

**QIBA CT Small Lung Module (SLM) Profile**  
Automated CT Image Quality Conference Report  
Automated Protocol Using The Accumetra CT SLN Phantom  
And ACCA Prototype Image Quality Assessment Software Platform (v0.7)  
December 10, 2017

**Scanner and Protocol Settings**

Manufacturer:	GE MEDICAL SYSTEMS	Tube kVp:	120.00
Scanner Model:	Revolution CT	Tube mA:	19.00
Scanner Station:	REVCT	Beam Treatment:	0.80
Study Date:	20170503	Shot Strategy:	0.80
Room Name:	STANDARD	Pitch:	0.89

Scanning Mode: QIBA 1.025 x 1.025 mm  
Volume Size: 512 x 512 x 128 voxels  
Beam Orientation: ISOTROPIC  
Serial Instance ID: 1.2.840.1.10163.2.4.16.112803118960286204365007013430249  
Display Name: 1.2.840.1.10163.2.4.16.112803118960286204365007013430249  
Final Image ID: QIBA

**Conformance Assessment Status**

The required number of CT SLN phantom modules were found (2).  
The DICOM file address is within acceptable limits for this analysis (<= 1.25M).  
The DICOM slice spacing is within acceptable limits for this analysis (<= .016).  
The DICOM CT scan pitch is within acceptable limits for this analysis (<= 2.0).

All QIBA CT SLN Profile assessment conformance checks have passed for this CT scanner and image acquisition protocol.

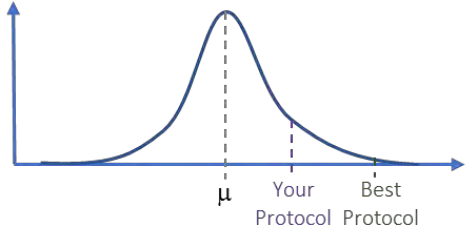
**Measured Image Quality Characteristics**

The QIBA CT Small Lung Module Profile requires that CT image quality performance is verified for six fundamental image quality characteristics. The required CT image data set used for CT scanner conformance evaluation must be used for Small Lung Module volume reconstruction. The center location of each of these characteristic objects from the center of the phantom is different from any other in the phantom geometry (shown in QIBA Small Lung Module Profile image quality performance specifications). Additional information on these image quality characteristics including guidelines on reporting parameters is available at Accumetra's QIBA Conformance Certification Pilot Project Page.

(1) Edge Enhancement

✓	Robust edge enhancement can significantly modify the HU values of objects in CT images and cause problems with quantitative measurement algorithms. We quantitatively tested your levels of edge enhancement at three distances from the center and found the values to be within QIBA CT SLN Profile specifications.	Edge Enhancement
✓	Three-dimensional resolution greatly influences volumetric measurement performance on small objects in CT images. We quantitatively tested your 3D resolution at three distances from the center and found the values to be within QIBA CT SLN Profile specifications.	3D Resolution
✓	System designers can cause significant issues when performing quantitative measurements. We quantitatively tested your levels of spatial frequency response. Results from our analysis showed the values to be within QIBA CT SLN Profile specifications.	Spatial Frequency
✓	Quantitative measurement algorithms work better when uniform acquisition along all three CT imaging dimensions. We quantitated based the Z-axis repeat ratio of your imaging system at three distances from the center and found the values to be within QIBA CT SLN Profile specifications.	Z-axis Repeat Ratio
✓	High-level 170 HU value need to be accurate to perform quantitative measurement of objects in CT images. We quantitatively tested your levels of HU bias for six test objects measured at three distances from the center and found the values to be within QIBA CT SLN Profile specifications.	HU Bias

Check Each  
Time Scanner  
or Protocol  
Changes and  
Once Per Year



Guidance  
Webpages &  
FAQs

Optimize

# International CT Image Quality Monitoring

**54 Phantoms Distributed As Of 4/2/2018**



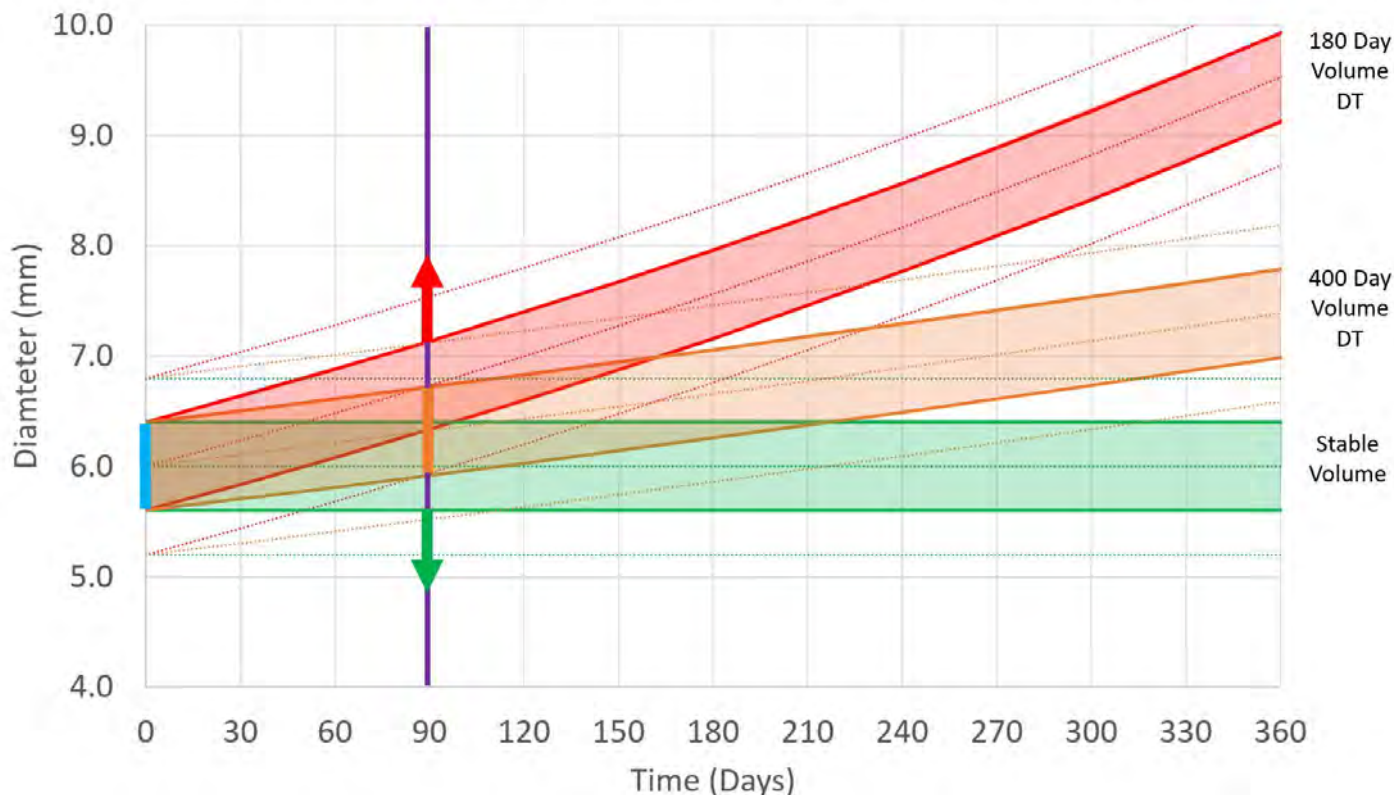
**Data Received & Analyzed From:**

- 25 Sites
- ~40 Unique CT Scanners
- > 200 CT Scans
- 4 Manufacturers
- Siemens, GE, Philips, Toshiba
- > 20 Different Scanner Models

# New Tool: Nodule Diameter/Volume Growth

## Nodule Diameter Growth

What can we say if we use great CT imaging of a ~6mm nodule at baseline and again after 90 days?



# Summary

- As We Ramp Up Low Dose CT Lung Cancer Screening Throughout The World, We Need To Ensure That Screening Services Are Delivered With High Quality
- For the First Time, and With Prevent Cancer Foundation Support, We Are Now Helping International Sites To Monitor and Rapidly Optimize Imaging Protocols For Lung Cancer Screening Using Crowd-Sourcing and Cloud Computing
- We Are Now Working to Establish Minimum Standards and an International Infrastructure For Lung Screening Image Quality
- These New Tools Are Also Enabling New Tools That Will Provide For More Personalized Management and Follow-Up of Lung Nodules



Thank You