Status of the Quantitative Imaging Profile

Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening

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QIBA

Goal

- Advance the science and implementation of quantitative imaging in clinical trials and practice
  - Use imaging devices as automated, reproducible measurement systems for specific tasks

QIBA

Approach

- Conduct rigorous assessment of the variability inherent in image-based measurements
- Determine performance capabilities of specific imaging biomarkers and requirements for achieving them

QIBA Biomarker Committees

- CT Volumetry
- FDG-PET
- PET Amyloid
- SPECT
- CT Lung Density
- fMRI
- MR Elastography
- Ultrasound Shear Wave Speed
- Ultrasound Volume Blood Flow

QIBA

Collaboration

- Imaging science experts (physicists, engineers, image processing scientists)
- Biostatisticians and metrologists
- Physicians
- Biologists, chemists
- Manufacturers
- Regulators
- Patient advocates

The QIBA Profile

Describes measurement performance achievable and conditions required

- Claims
- Specifications
- Assessment Procedures

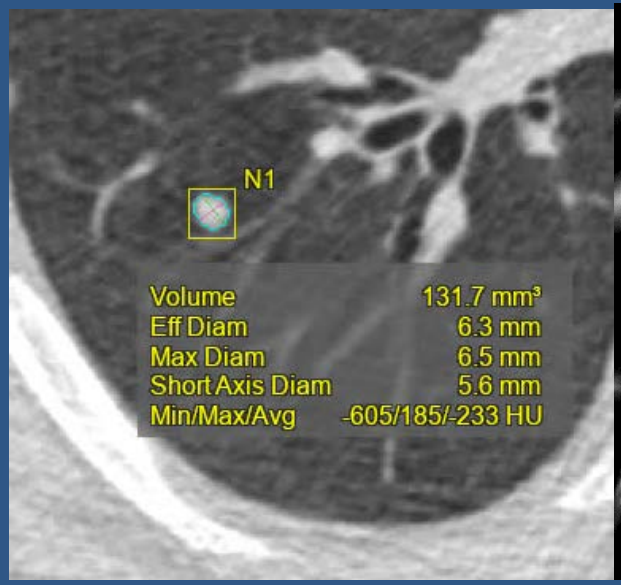
QIBA

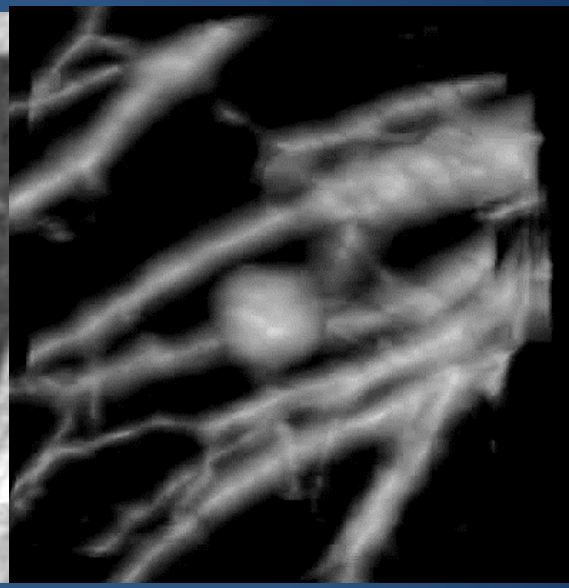
Activities

- Literature review
- Groundwork studies
- Clinical trial data analysis
- Theoretical analysis and simulations
- Discussion and expert consensus

CT Volumetry

vs.





Advantages :

- Independent of lesion and measurement orientation
- Independent of selected slice and orientation
- Sensitive to size change in all directions
- Reproducible

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CT Volumetry Biomarker Committee Profiles

- Change Measurements in Solid Tumors (Lung ≥10 mm)
  - Publicly reviewed 2011 (http://qibawiki.rsna.org/images/e/e3/2011_07_28_Profile_CT_Advanced_Disease_V2_0f.pdf)
  - Updated version in progress, liver lesions being addressed
- **Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening**
  - Released for Public Comment 6/2/16-8/1/16
  - Open at http://qibawiki.rsna.org/index.php/Work_Product_for_Review

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Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening
Claim 1

Nodule Volume

- 95% confidence interval = ±(measured volume x 1.96 x CV)

Nodule Diameter (mm)	Nodule Volume (mm^3)	Coefficient of Variation (CV)	95% Confidence Interval
≥ 6 and < 8 mm	≥ 113 and < 268	0.29	± 57%
≥ 8 and < 10 mm	≥ 268 and < 524	0.19	± 37%
≥ 10 and < 12 mm	≥ 524 and < 905	0.14	± 27%
≥ 12 mm	> 905	0.11	± 22%

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Claim 1 Examples
Nodule Volume

Nodule volume	CV	95% CI	Corresponding diameter	95% CI (diameter)
150 mm^3	0.29	65-235 mm^3	6.6 mm	5.0-7.6 mm
500 mm^3	0.19	314-686 mm^3	9.8 mm	8.4-11.0 mm
800 mm^3	0.14	580-1020 mm^3	11.5 mm	10.4-12.4 mm

Calculator at http://www.accumetra.com/NoduleCalculator.html

- Currently for investigational use only

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Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening
Claim 2

Change in Nodule Volume (95% confidence)

- Real if measured %change>2.77xCV1x100
- Amount of change $\pm 1.96 \times \sqrt{([Y_1 \times CV1]^2 + [Y_2 \times CV2]^2)}$

Nodule Diameter (mm)	Nodule Volume (mm^3)	Coefficient of Variation (CV)	% Change Required
≥ 6 and < 8 mm	≥ 113 and < 268	0.29	80%
≥ 8 and < 10 mm	≥ 268 and < 524	0.19	53%
≥ 10 and < 12 mm	≥ 524 and < 905	0.14	39%
≥ 12 mm	> 905	0.11	30%

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Claim 2 Examples
% Change in Volume

Change	% Change	Min required (2.77xCVx100)	Real change? (95% confidence)
524 - 917 mm^3 (10.0 - 12.0 mm)	75% (20%)	2.77 x 0.14 x 100= 39%	Yes (149-637 mm^3)
180 - 270 mm^3 (7.0-8.0 mm)	50% (14%)	2.77 x 0.29 x 100= 80%	Uncertain

Calculator at http://www.accumetra.com/NoduleCalculator.html

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Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening
Profile Conditions

- Solid nodules close to spherical (shortest dimension is at least 60% of longest dimension)
- Nodule segmented without manual editing
- Subject handling, acquisition, reconstruction, analysis specifications followed
- Volume: Zero measurement bias and covariance
- Change: Measurement system components same at both time points
- CT scanner meets conformance requirements

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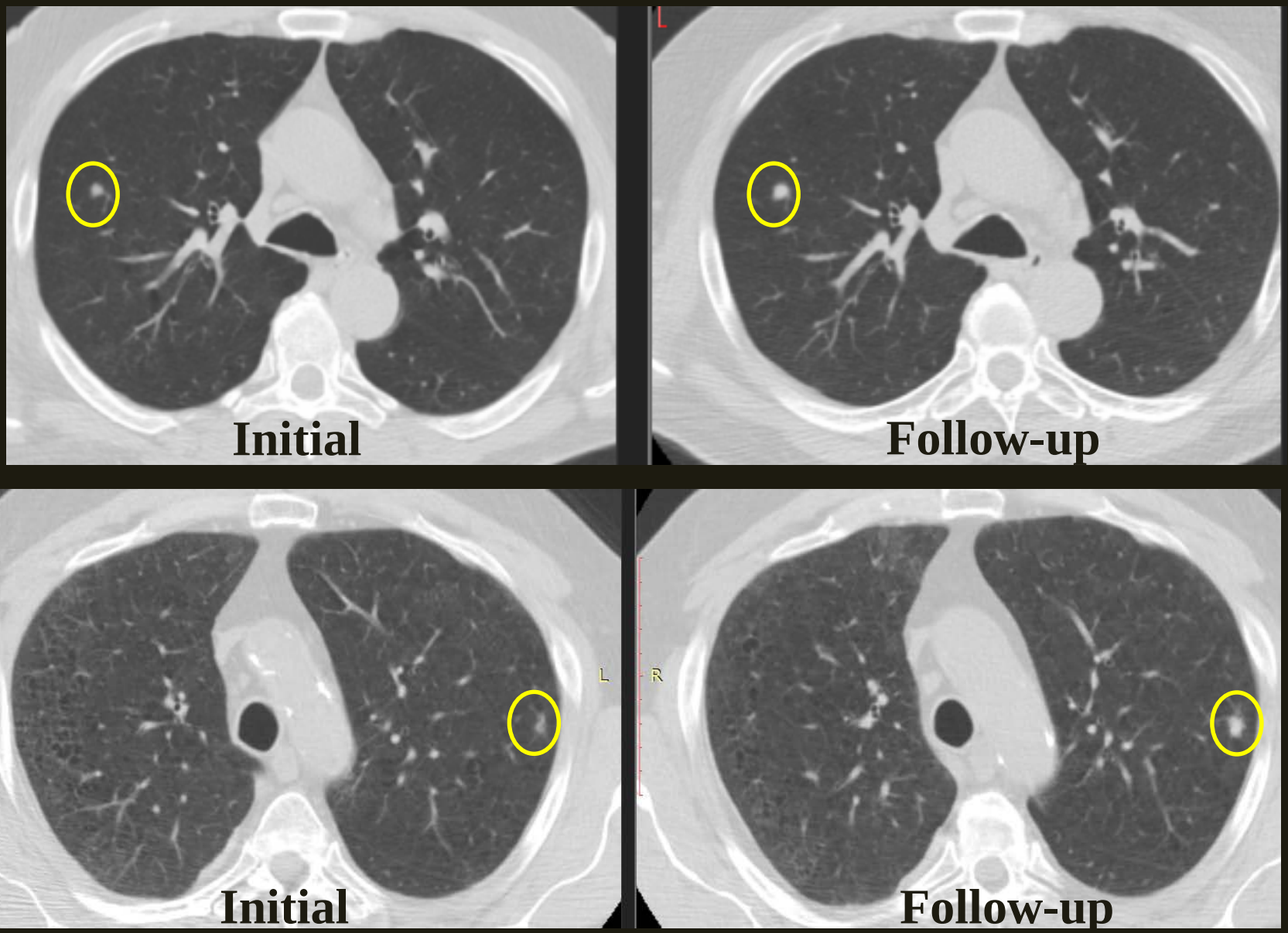
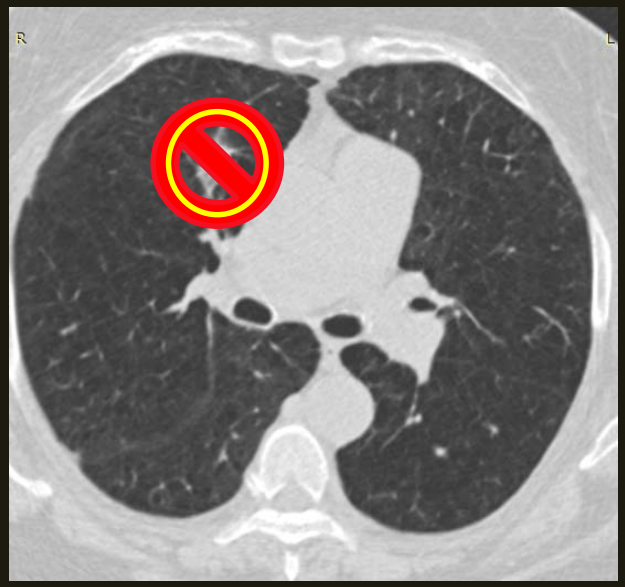
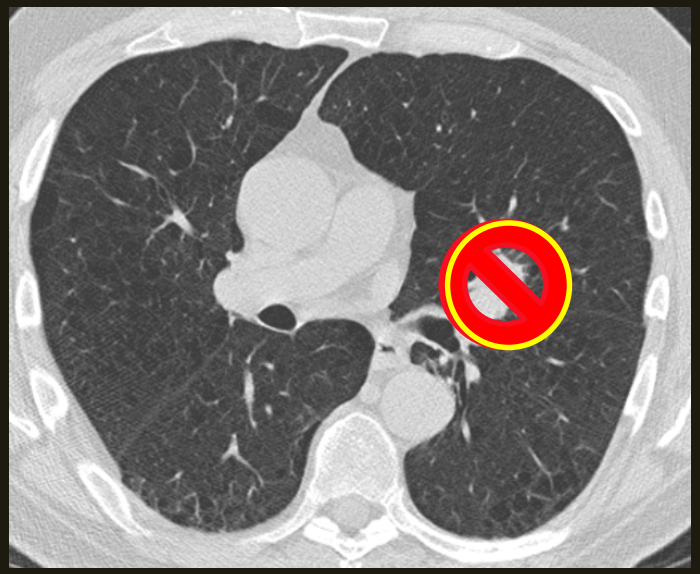
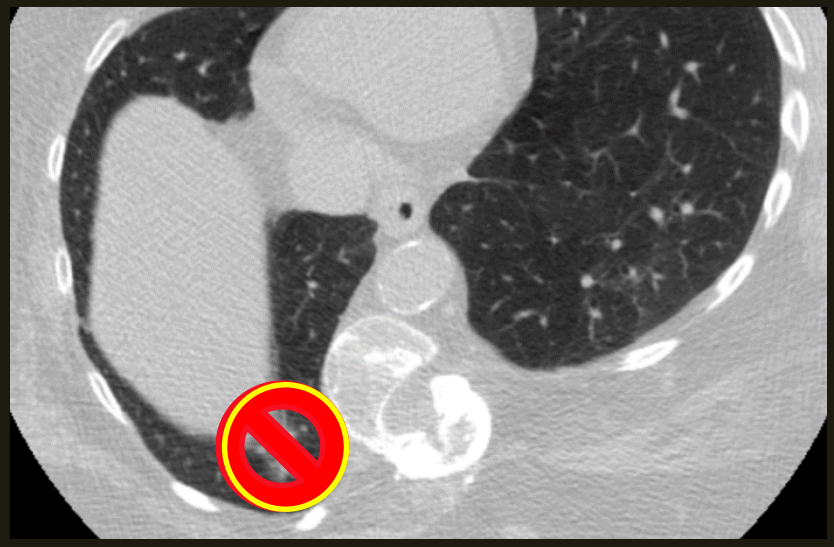
Solid, Spherical, Isolated



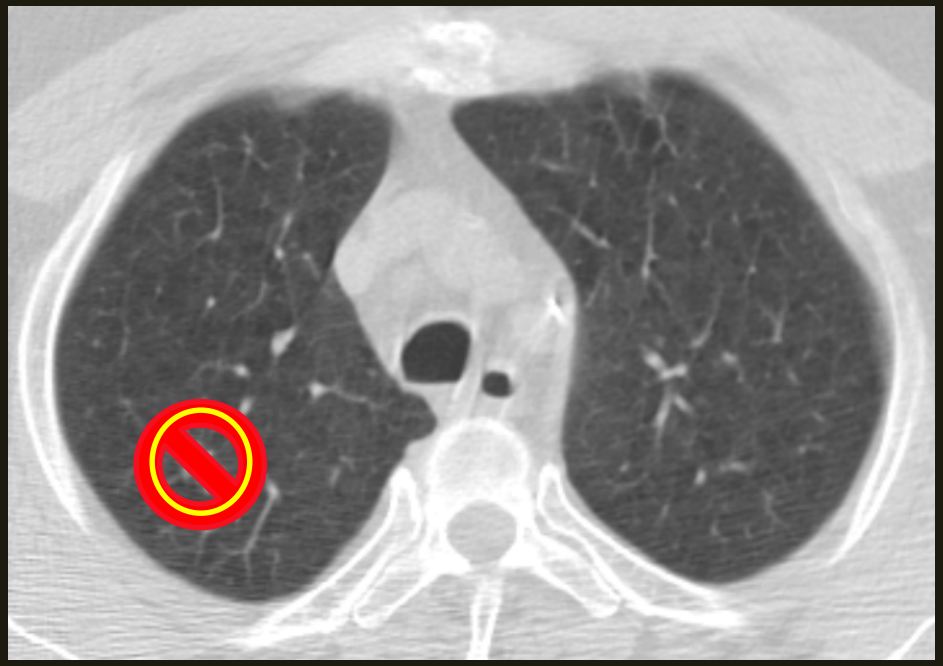
Attached, Non-spherical







Subsolid/Ground Glass
Semisolid/Mixed



Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening
Specifications

- Subject selection and handling
  - Symptoms, positioning, breath holding
- Image Data Acquisition
  - kVp, mAs, collimation, pitch
- Image Data Reconstruction
  - Slice thickness and interval, kernel
- Image analysis
  - Software, reading paradigm

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Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening

Assessment Procedures

- CT Equipment
  - ACR and manufacturer guidelines
- Technologist, Radiologist, Image Analyst
  - ACR guidelines, relevant training
- Image Analysis Software
  - TBD

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

Post-comment period

http://qibawiki.rsna.org/index.php/Work_Product_for_Review

- Address issues raised and finalize
- Verify in practice and modify as needed
- Update with technical improvements
- Assess clinical value

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Acknowledgements

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- RSNA Staff: Fiona Miller, Joe Koudelik, Julie Lisiecki, Susan Weinmann

Thank You!

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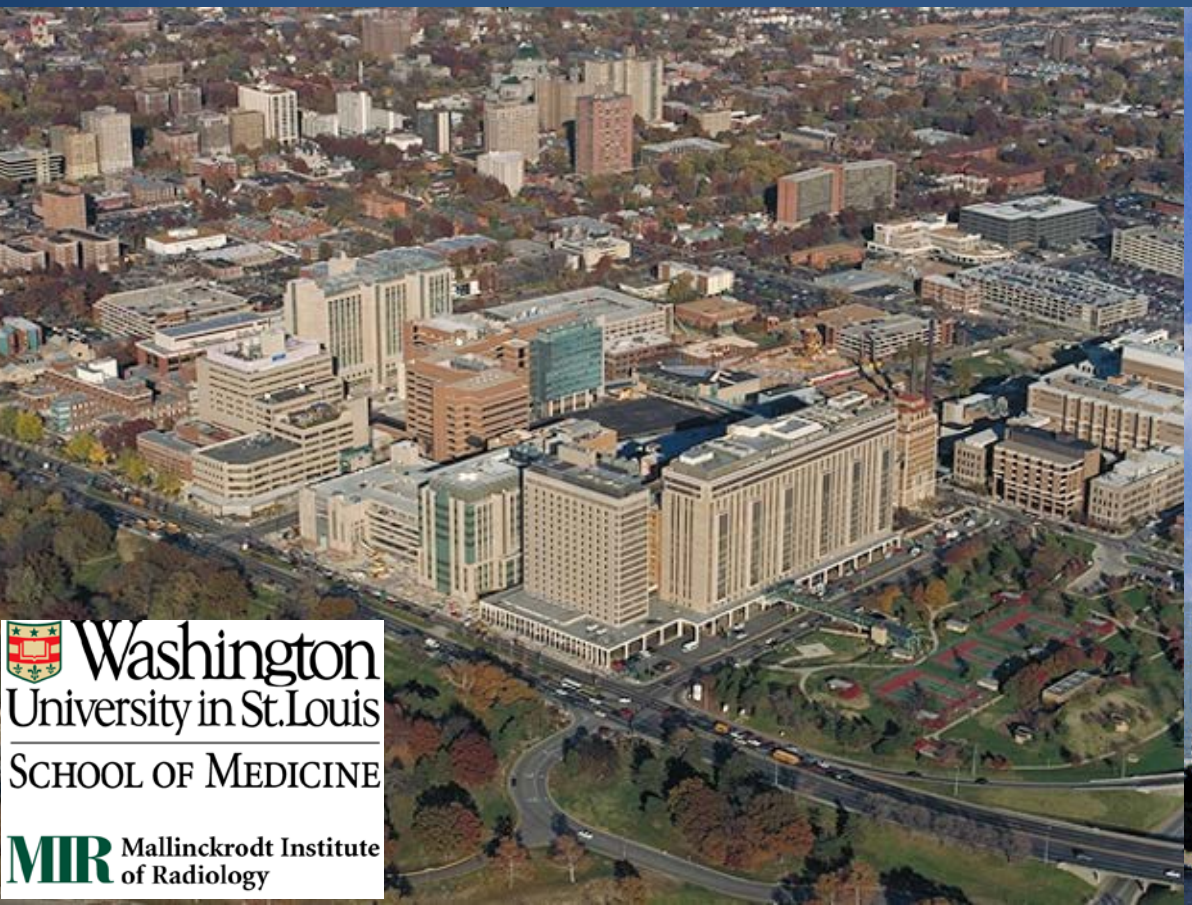

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