



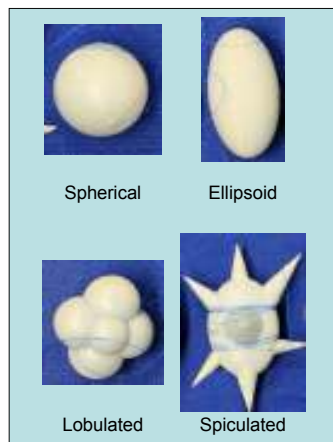
## X-Ray Computed Tomography in Oncology:

The QIBA Technical Committee for  
Quantifying Changes in Whole Tumor  
Volumes as the Basis for Assessing  
Changes in Health Status

### vCT progress report: agenda

- Year 1: status of ground work projects
- update on profiles & proffered protocols
- next steps

## 1A: precision & accuracy, phantoms



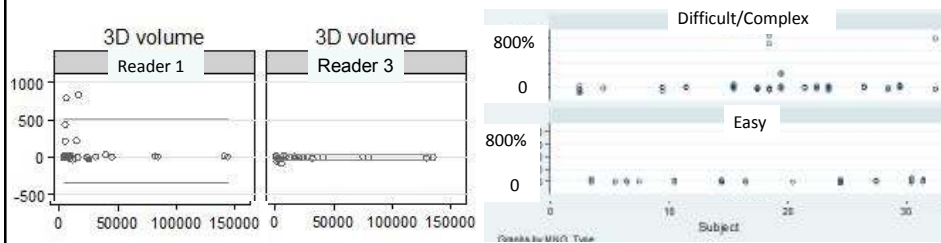
Size Method	Spherical Nodules		Non-spherical Nodules	
	0.8 mm	5.0 mm	0.8 mm	5.0 mm
1D	2% ( $\pm 5$ )	0% ( $\pm 4$ )	-23% ( $\pm 20$ )	-27% ( $\pm 21$ )
2D	4% ( $\pm 10$ )	0% ( $\pm 11$ )	-33% ( $\pm 26$ )	-33% ( $\pm 29$ )
3D	1% ( $\pm 12$ )	5% ( $\pm 23$ )	0% ( $\pm 14$ )	-2% ( $\pm 30$ )

**Conclusion:** Volume has low bias for any shape and was able to achieve low variability for thin slice imaging.

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## 1B: precision, clinical

- Aim: estimate minimum detectable change
- “coffee break” data from MSKCC
  - repeat CT (T0, T1), 32 subjects, 1 lesion per subject
- 5 readers: T0, T1, & repeat (either T0 or T1)
- measure LD, bi-dimensional diameters, volume
- calc % change for each metric, by reader, by lesion



## 1C: synthetic nodules, multiple scanners

**Goals** - Estimate volume uncertainty for imagery from 4 CT scanners using a 2-armed protocol

- ACRIN 6678 arm
- device-independent image quality branch
  - estimate minimum detectable change

### **imaging completed**

noise measured in ACR phantom correlates with that in thorax phantom

### **reading in progress of ramping up**

- reader study design is complete: calls for 7 readers, powered to detect 10% differences in sizing between the 2 protocols and the 4 scanners
- curation of 170 series is underway.
- reading and analysis will be completed by 01 Sep 2011

## 3A: software

- Aim: to estimate *inter- and intra-algorithm variability* by the Volume estimation
  - overall & stratified by method/degree of automation
- data
  - anthropomorphic phantom from 1A
    - overlap ratio from 6 markings
    - bias from actual volume of phantom
  - variability from 1B study in Coffee Break data
  - run batch mode in multiple data sets
    - image analysis of algorithms
    - descriptive statistical analyses

## 3B: quantifying value

### Two-step approach

1. Intra-/inter-reader variability in measuring VOL, UNI and BI / changes  
(50 patients; 3 scans per patient)
2. Volume change vs LD vs WHO in predicting survival  
(451 patients; 4 scans on average)

### Current status

IRB waiver; research agreement; measurement environment;  
two radiologists; statistical design (var); ready to go with the variability

### Timeline

- Step 1: June – September 2011: measurement  
October - December 2011: data analysis
- Step 2: May 2011 – June 2012: measurement  
November – December 2011: preliminary data analysis  
June – August 2012: data analysis

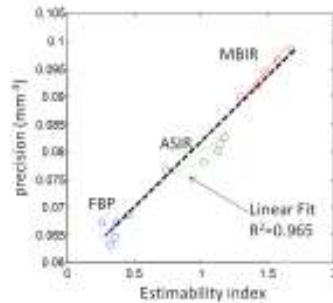
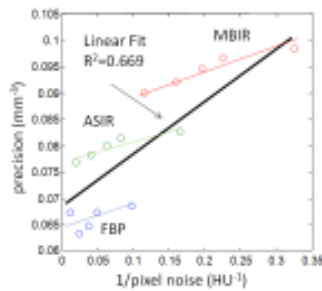
## Part-Solid Lung Nodules: Timeline

- IRB (Months 1)
- phantom Scans (Months 1-3)
- retrospective case gathering and nodule selection (Months 2 –4)
- prospective case gathering and nodule selection (Months 2 –10)
- measurements (Months 3 –11)
- data reporting (Month 12)

## predictive metrics for chest CT

### Aims:

- to develop and validate mathematical framework for assessment metrics
- to identify tolerance thresholds for specification and compliance



Sam Richard and Ehsan Samei, Duke University

## profiles & protocols

- advanced lung cancer
  - Profile v1.1 Word version completed 03 Sep 2009
  - UPICT protocol
    - V1.4 proffered 3Q2010
    - formal field testing started 11 Sep 2010
- whole body solid tumors
  - profile to be distributed to PIG by this Friday
  - UPICT protocol to be proffered by 01 July
- neoadjuvant window of opportunity in lung CA
  - profile draft posted 11 Apr 2011
  - protocol due by 01 July 2011

## next steps

- near term:
  - public comment for whole body profile
  - completion of 1C project
  - profile draft for small lung masses
- mid-term:
  - completion of 1B and 3A
  - field test of whole body profile
  - discussion with FDA BQRT on submitted BD
- by NIBIB contract end:
  - completion of funded studies
  - new versions of extant profiles
  - specific context profiles & protocols