QIBA VOL-CT Phantom Study Protocol Update WebEx September 18, 2008 12PM CDT Call Summary

In attendance:

Nicholas Petrick, PhD (Chair) Rick Avila, MS Charles Fenimore, PhD Michael McNitt-Gray, PhD Fiona Miller (RSNA) Joe Koudelik (RSNA)

Dr. Petrick began by discussing current and proposed data collection for the 1A project, identifying areas for collaboration. Aspherical & spherical data is currently available. No need to wait for public-release before moving ahead with QIBA studies (per Dr. Petrick)

Overview of FDA Data Collection Done on both Philips and Siemens Systems

- Data collected shown on attached slides
- Data collection should be done by mid-late October 2008
 - All reconstructions should be done and available
 - Spherical nodules will also be micro-CT'd

Publicly available data and release date overview

- -630, +100 sphere data by 12/08 (RSNA 2008)
- -20 HU sphere data by 2/09
- Aspheric data by $\sim 6/09$

FDA Analysis overview and future plans

- Bias, variance & MSE for 3 semi-automated segmentation packages
 - o OSIRX
 - o Custom NIH software
 - 3D Doctor segmentation package
- Matched filter approach being considered
- Will move on and address aspherical nodules/non-attached nodules
- Plan to expand collection to other hardware
- Possibly expand to heterogeneous nodules
- Plan to have readers provide RECIST/WHO measurements

Overall CT parameters to study:

- CT dose
- Recon slice thickness
- Recon (+100) kernel
- Pitch
- 2 data sets of nodules to study

PHASE I - Potential QIBA trial with readers discussed

- -630, -20, +100 HU spheres
- 5, 10 mm (6 total spheres)
- 100 mAs exposure

- 1.5 and 5.0 mm slices
- 1 recon kernel only
- 5 repeat scans
- 60 segmentations total
- Later to repeat above using aspherical (10mm) ovoid, lob, spiculated lesions
- Movement of phantom (repositioning) not part of original study

PHASE II - Inter/Intra-reader reliability / variability with a single software package

- Single exam/repeat readings
- Multiple exams with same parameters
- 3% intra-reader reliability (previous group discussions) deemed optimistic in clinical trials

Exposure Discussed – Integrity Study of 100 mAs vs. 200 mAs Scans

- Current clinical scans done at 200 mAs exposure
- Worth pursuing 100 mAs data and comparing with 200 mAs
- Determine if image data variation exists between 100 & 200 mAs exposure
 - If no variation, scans may be performed at lower (100 mAs) dose for clinical settings

Potential Recon Kernel Study to Pursue

- Recon kernel seed determines amount of noise
- No bias between dose seen previously
- Variance may be affected, but not bias
- NIST Pocket Phantom could be used with this study
- Dr. Fenimore to forward his recon slides to the group

Software Options Moving Forward

- Ask if in-house software is available (at various testing sites)
- Open source lesion sizing architecture available this fall (KitWare)
 - Reporting methods (capabilities) of software include running image, applying algorithms, and obtaining volumetric data
 - Report-out to "Dr. Fenimore's BIOEXCHANGE" primary format currently

General Agreement on Reasonable Starting Study Design

- Starting study design depends on what type of data will be extracted
- Software to use (needs to be determined)
- # of cases (need to be determined)
- 0.75 & 5.0 mm slices
- Detail and Medium recon kernel
- Philips and GE scanners for now

Inter-reader issues discussed

- Based on reasonable case load, narrow the focus of CT parameters
- What makes sense in the study (Data we have already)
- Pilot study design needed next
- Few readers needed to start
- Plenty of data for pilot study now
- What is considered a "scan"
 - Is segmentation included?
- Non-overlapping CT Slice Study Proposed

Since RIDER access to data is somewhat limited, this group happy to work with QIBA Robert Ford, MD offered 15 readers (RadPharm)

Action Items:

- Dr. Petrick to layout discussed proposal (for larger Vol-CT group) by Monday's call (9/22/2008)
- Dr. Fenimore to forward his reconstruction slides to the group