QIBA Volumetric CT Group 1C Update

Wednesday, January 19, 2011; 3:30 PM CST Draft Call Summary

In attendance RSNA

Charles Fenimore, PhD, (Chair) Hyun Grace Kim, PhD Joe Koudelik

Andrew Buckler, MS John Lu, PhD Julie Lisiecki

David A. Clunie, MBBS Anthony P. Reeves, PhD Bruno DeMan, PhD Ganesh Saiprasad, PhD

Marios Gavrielides, PhD Ying Tang, PhD

I. Imaging Schedule

Image acquisition expected late January through February, with the reading process slated for March

Tentative schedule:

FDA	UMD & NIST	UCLA & Toshiba	DUKE
at the FDA lab in late	UMD & NIST – February 22 +23, most	Tentatively February 9-10,	TBD - Drs. Gavrielides and
January, Dr. Gavrielides	likely. (NIST now has a Philips 16, same	Drs. Gavrielides & McNitt-	Samei
	series as the device at the FDA).	Gray (UCLA/Toshiba)	

II. Discussion of the Reader Study

- Information required to develop and power this study discussed
- First goal is to analyze accuracy and precision by imaging site and device (imaging protocol factors)
 - Strive for image quality measurements to be device-independent
- Does it make a difference to have a quality-based branch of the protocol?
- Not necessary to read all acquired information from all sites wish to be judicious in selections to keep study manageable.
- Study could be algorithmic or semi-algorithmic with assistance from QIBA Group 3A.
- Better to get a reading done (specific site/device/image protocol) rather than have several outstanding
- Dr. Lu had a question about the angle of the phantom with regard to placement, vasculature, etc.
 - Dr. Gavrielides explained that the phantom would be oriented on the axial dimension to minimize the effects of dimensional measurements.

III. Statistical Analysis of the Reader Study

- Dr. Fenimore solicited feedback from Drs. Kim and Lu regarding the statistical design of the reader study.
- Dr. Kim discussed multiple regression, side effects, etc., and inquired about the number of sites (there are a total of 6).
- 80% statistical power to test effectiveness from protocol and the sites can be achieved
 - o Nodule characteristics and reader with addition of 2 other control variables, looking for effects
 - 6 nodules, 2 protocols, 6 sites: 72 new samples (with 2 co-variates of site and protocol) = significant protocol effect and side effect
 - Recommended use of 1A data would reduce the number of reads by a factor of 2-3; (closely related data) not
 a huge difference expected between 1-D and 2-D derived measures
 - 1A tried to get reader variation; 1C aiming to control variables we know already looking for effect
- Can we find any supporting multi-phantom studies to help us with establishing parameters?
- Dr. Gavrielides mentioned a study that compared different scanners (to circulated article from European Radiology).
 - o This study (Netherlands) was not a reader study; however, it could help to determine how to best power 1C
 - M. Das, J. Ley-Zaporozhan, H. A. Gietema, A. Czech, G. Mühlenbruch, A. H. Mahnken, M. Katoh, A. Bakai, M. Salganicoff, S. Diederich, M. Prokop, H. U. Kauczor, R. W. Günther, and J. E. Wildberger, "Accuracy of automated volumetry of pulmonary nodules across different multi-slice CT scanners." (Eur. Radiology, 17 (8), 1979–1984 (2007).)

Next steps:

- 1. Before next call, Group 1C will receive an email with the revised image protocol table, an article detailing another scanner study found by Dr. Gavrielides (European Radiology), and the design of the statistical analysis by Dr. Kim.
- 2. Group to review these documents and be prepared to discuss how to properly size the reader study.

Next call: Thursday, January 27, 2011, 3 pm CST.