QIBA Q-CT Committee Weekly Update
Monday, August 23, 2010
11 AM CDT

Call Summary

In Attendance
Andrew Buckler, MS (co-chair)
P. David Mozley, MD (co-chair)
Harris Ahmad, PhD
Maria Athelogou, MD
David Clunie, MBBS
Dirk Colditz, PhD
Charles Fenimore, PhD
David Gustafson, PhD
Hyun Grace Kim, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Daniel R. Nicolson
Kevin O'Donnell
Nicholas Petrick, PhD
Anthony P. Reeves, PhD
Robert Schwanke
Ying Tang, PhD
Hiro Yoshida, PhD
Binsheng Zhao, DSc

RSNA
Joe Koudelik
Julie Lisieski
Madeleine McCoy

General Overview of QIBA Process (Mr Buckler)

- The Quantitative CT (Q-CT) Subcommittee focus is on volumetric analysis in CT imaging
- Initial focus was on lung disease, now broadening
- Pursuing analysis and experimental activities to characterize and reduce variance is the methodology for research, drug development and clinical care
- Practicing radiologists, oncologists, device manufacturers, pharmaceutical, government agencies (both regulatory and non-regulatory) and academicians make up the stakeholders in QIBA
- Progress has been made with the validation and qualification of volumetric CT as a response measure
- Consensus protocol development based on standardization is a large part of reducing variance to utilize and qualify as a biomarker
- Current project status
    - **Group 1A**: Completed large scale single-center, single-algorithm studies with acquisition parameters for determination of accuracy
    - **Group 1B**: Inter- and intra-reader study using clinical data collected in "coffee break" studies for determination of minimum detectable limit (MDL)
    - **Group 1C**: Protocol development done and methodology development for multi-center phantom study to characterize multi-site and multi-vendor variability
    - **Group 2**: Determine clinical context for use
    - **Group 3A**: Study to tie meta-analysis of multiple phantom studies together while also expanding to multiple algorithm types
    - **Group 3B**: Parallel study based on outcomes using clinical data

Group 1B Update (Dr McNitt-Gray)

- Coffee break experiment data used from MSK
- 32 cases scanned repeatedly over 15 minute period under a no-change condition
- RadPharm readers performed multiple reads to study inter- and intra-reader variability based on (1) single longest diameter, (2) perpendicular diameter and (3) volume using semi-automated software tool utilizing seed points
- Data analysis is next
- RadPharm readers rated lesions as "readable/not-readable in a clinical setting"; these grouping to be categorized as "Yes/No" values
- Dr McNitt-Gray to send reference link for NBIA data to Mr Schwanke for reference

Quantification in Imaging Applications Presentation

- Dr Dirk Colditz of Definiens presented an engineer's view to aspects of a problem in medicine
- Dr Colditz provided a brief personal background in medical imaging and digital imaging analysis
- Quantification of imaging applications extends well beyond CT to other biomarkers

- Discussion as to whether classification or allocation were the major qualification issues needing attention
- Solution space with control loops developed based on a two hemisphere model, where a machine view (modality environment) interacted with a human expert view (human observer)
- Modality Environment – transformation – Machine View – transformation – Human Expert View – transformation – Therapy Decision Environment comprised the principle control loop structure
- Biological variation exists in all (image) data acquisition methods
- Comparability, Independence, Reproducibility are the three aims to be pursued

- **Machine vs. Ground Truth**
  - Phantom and clinical data all useful
  - Four fiducials needed to help obtain Ground Truth volumes
  - Ground Truth may be beyond the human visual field; need to understand human use of Ground Truth

- **Regulator Proof Points**
  - Demonstrating that a biomarker is useful is the 1st step
  - Demonstrating the biomarker is measurable is 2nd step
  - Classification of biomarkers may not be enough; classification belongs to a category, e.g., with or with out cancer, or patient "got better/worse/no change"
  - Classification vs. estimation needs further discussion
  - Tumor Size vs Percent Change in tumor discussed; both considered important

Next Steps:

- Dr McNitt-Gray to send reference link for NBIA data to Mr Schwanke for reference
- Mr Schwanke to follow-up offline with AVT modeling exercises following caBIG meeting; second half of September
- Next call scheduled for August 30, 2010 at 11 am CDT; Dr Athelogou to propose a design for 3A activities; parallel activities based on clinical data and outcomes will also be discussed