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)
• Biological variation exists in all (image) data acquisition methods
• Comparability, Independence, Reproducibility are the three aims to be pursued

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

• Regulator Proof Points
  o Demonstrating that a biomarker is useful is the 1st step
  o Demonstrating the biomarker is measurable is 2nd step
  o 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”
  o Classification vs. estimation needs further discussion
  o 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