Status update for Q-CT projects

- Request letter sent to FDA to begin qualification efforts for Volumetric CT
- Supporting experimental groundwork
  - Group 1A: Almost done
  - Group 1B: Underway
  - Group 1C: Underway with protocol-writing process

Statistical meta-analysis of phantom studies update (Dr Kim)

- Fourteen current studies found on PubMed comparing volume to 1-D change measurements; different phantoms, doses used, detector number and slice thickness used making analysis a challenge
- Dr Kim to summarize conclusions and identify what data could be extracted

Manuscript updates (Mr Buckler)

- “QIBA as a whole” accepted in Radiology
- “Regulatory Pathways” accepted in Radiology
- “Performance Evaluation Manuscript” not accepted in Radiology
  - What performance is appropriate for quantitative imaging biomarkers in general
  - Manuscript may be used as a resource moving forward

Broader knowledge base of input needed; all welcome to join efforts; contact Andrew Buckler at: andrew@bucklerbiomedical.com

- Evaluation of clinical performance-change of disease statistics section needs updating
- Better definition for quantitative imaging terms needed
- One consistent example (manuscript) may unify various efforts such as data reduction, classification, phenotyping, etc providing a “How-To” approach
- RECIST 1.1 already discusses the “How-To”, but without rigorous statistical support
- Education process a large goal as well; caution against claims that may be too difficult to prove
Biomarker Validation Roadmap and Plan

- Statistical methodology to be applied to the QIBA Roadmap; applicable to multiple biomarkers
- Roadmap broken down into tasks, encompassing both QIBA and higher-level program efforts
- NIBIB contract set out a work breakdown structure for project tracking
- Viewer to browse projects without making edits to be identified
- Mr Buckler to post project to QIBA Wiki for short-term reference

Next Steps:

- Extend invitation to Dr Gatsonis to join the Q-CT statistical analysis effort
- Dr Mozley to forward full literature review to Dr Kim for reference
- Dr Kim offered to complete summary of meta-analysis done by mid-August
- Mr Buckler to post project to QIBA Wiki for short-term reference
- Next call scheduled for July 26, 2010 at 11 am CDT