

QIBA Q-CT Committee Weekly Update
Monday, July 19, 2010
11 AM CDT

Draft Call Summary

In Attendance

Andrew Buckler, MS (co-chair)
P. David Mozley, MD (co-chair)
Lawrence Schwartz, MD (co-chair)
Thomas Baer, PhD
Charles Fenimore, PhD
Gary Fullerton
Grace Kim, PhD
David Miller
James Mulshine, MD
Daniel R. Nicolson
Kevin O'Donnell

Nicholas Petrick, PhD
Anthony P. Reeves, PhD
Ganesh Saiprasad, PhD
Daniel C. Sullivan, MD
David Vining, MD
Hiro Yoshida, PhD

RSNA
Fiona Miller
Joe Koudelik

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