

QIBA Quantitative CT Committee Update

Monday, April 19, 2010
11 AM CDT

Call Summary

In attendance

Andrew Buckler, MS (co-chair)
P. David Mozley, MD (co-chair)
Sung Chang, PhD
Charles Fenimore, PhD
John Fraunberger
Grace Kim, PhD
John Lu, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD

Nicholas Petrick, PhD
Ganesh Saiprasad, PhD
Daniel C. Sullivan, MD

RSNA

Fiona Miller
Susan Anderson, MLS
Joe Koudelik

FDA/SNM/RSNA joint workshop, April 13-14, 2010

- Value of the joint workshop was opportunity to meet with FDA officials who will be crafting new guidance and fellow stakeholders with interest in the upcoming guidance
- There appeared to be resonance on issues such as GMP and the scientific process among participants
- Understanding that upcoming guidance will be high-level and concept-oriented
- Workshop presentations will be posted to a website; participants will be notified of URL

Committee activities

- With near completion of Group 1A work, Group 1B activity is scheduled and Group 1C is being finalized
- Future activities include work on briefing document/data package and continued discussion on sufficiency of cases/study size

Finalization of Group 1A data (Dr Petrick)

- Dr Petrick and team submitted RSNA abstracts by April 15 deadline; will begin work on manuscript
- Partial data (spherical data) posted on NBIA; Dr Petrick will send RSNA staff the link to be posted on wiki
 - Dr Petrick will investigate use of Reference Listing function on NBIA to group data
- Task remaining is mapping Profile and data sets
 - Pharma is conducting retrospective analysis of trials exploring volume instead of Longest Diameter
 - Need data set matching bull's eye conditions of Ideal / Target / Acceptable
 - Need images with known "ground truths" beyond spherical shapes
 - Need reference standards to help support Claims
 - Decision to work as Committee to select set of data using Profile and experimental groundwork, e.g. match Profile and set-up of 1A
 - This "QIBA-endorsed dataset for quantifying accuracy of tools" can be posted to allow others to comment
 - Challenge segmenting dataset of 1A into defined group of cases; would be useful to start with clearly defined use case of needs statement
 - Dr Mozley will draft problem statement from pharma perspective that is driving need to create standard reference objects of known volume and will suggest what dataset should look like
 - Use case/needs statement to be discussed when segmenting 1A data sets

Group 1B update (Dr McNitt-Gray)

- Design is like Group 1A but with patient data sets from MSK coffee-break experiment (32 patients, all with non-small cell lung cancer, repeat CT scans over short period of time, all 1.25mm thin slices)

- Multiple readers with randomized intervals
- Inherent variation in time points 1&2
- The cases are identified and prepared
- RadPharm software is installed and running; training to be completed week of April 19
- Reads should start week of April 29
- Dr O'Neal will prospectively identify cases that may be problematic
- Dr McNitt-Gray will revisit study design re including LIDC cases

Group 1C update (Dr Fenimore)

- Groundwork will be interclinical and interplatform comparison of phantom data
 - Looking at accuracy and precision across scanning platforms
- Currently defining the collection protocol with quality defined as level of noise and resolution
- Have engaged with sites: Duke, UCLA, UMd Baltimore, FDA and Johns Hopkins
- Performance protocol will feed the Profile

Next Steps

- Dr Petrick will send RSNA staff the specific NBIA link to data to be posted on wiki
- Dr Petrick will investigate use of Reference Listing function on NBIA to group data
- Dr Mozley to formulate a problem statement on need to create standard reference objects of known volume from pharma perspective
- Dr McNitt-Gray will revisit design of 1B re LIDC cases
- Continue discussion on mapping Profile and data set from 1A
- Next call scheduled for Monday, April 26 at 11 am CDT