

QIBA Quantitative CT Committee Weekly Update

Monday, November 16, 2009

11 am CDT

Call Summary

In attendance

Andrew Buckler, MS (Co-Chair)

Maria Athelougou, MD

Rick Avila, MS

David A. Clunie, MBBS

Charles Fenimore, PhD

John Fraunberger

Dana Ghiorghiu, MD, PhD

Philip Judy, PhD

John Lu, PhD

Mahadevappa Mahesh, MS, PhD

Michael McNitt-Gray, PhD

James Mulshine, MD

Kevin O'Donnell

Nicholas Petrick, PhD

Yuanxin Rong, MD, MPH

Daniel Sullivan, MD

Matthias Thorn, PhD

Hiro Yoshida, PhD

RSNA staff

Fiona Miller

Susan Anderson, MLS

Joe Koudelik

Group 1A update (Dr Petrick)

- Drs Petrick and Kim are working on data analysis and interpretation
- Dr Petrick discussed raw data which shows expected variability with differences between nodules
- Dr Petrick will add columns for mm and mm(squared); perhaps a dimensionless comparison is needed
- Discussion on best way to show statistical difference between reading sessions
 - Suggestion of using ANOVA model to determine coefficient of variance
- Group 1C (Dr Fenimore) will use experience of 1A&B, particularly related to inter- and intra-reader variation which is critical to design of 1C mark-up
 - Little data available on intra-reader variability ; have 4 reads for each nodule
 - Have 6 reads for inter-reader variability
- Dr Petrick will send raw data with more statistical significance to Dr Lu

Group 1B update (Dr McNitt-Gray)

- Experimental design is complete
- Analysis of Group 1A data will be informative although Group 1B does not have the variables to investigate
- Considering experimental design with LIDC data
- Ovoid nodule orientations (horizontal vs. vertical) may produce additional variability
- Group 1B will ask Drs Kim, Petrick and Lu to look at data
- Final piece of new RadPharm software (workflow mgmt) should be ready by end November, early December

Group 1C update (Dr Fenimore)

- Drs Fenimore and Lu's visit to RadPharm was helpful in planning 1C mark-up at RadPharm
- Working on performance protocol: setting desired levels of performance on CT imaging devices
- Dr McNitt-Gray's experiments on Siemens system will be topic of discussion on 1C call (Nov 18)

Discussion of regulatory pathway

- Effort in PhRMA Imaging Group (PIG) to establish meeting with FDA in spring 2010
 - Would include discussion of QIBA efforts and FDA needs in terms of a regulatory pathway
- Interest in translating QIBA experimental results/data into regulatory filing
- Began development of pathway at November Imaging Biomarkers Roundtable at RSNA that can feed regulatory pathways for drugs and devices
- Will plan for discussion of FDA CDER and CDRH on a subsequent call
 - device/assay validation and
 - drug/surrogate endpoint qualification (Dr Mozley)

Finalization of content for posters for RSNA 2009

- Concept of errors in volume addressed in Group 1A-1C contributions
- Mr Buckler to send two suggested wording changes to Dr Mozley
- Dr Mozley will incorporate changes, print both posters at Merck and ship to RSNA

Next steps:

- Mr Buckler to send two wording changes for poster to Dr Mozley
- Dr Mozley will incorporate final suggestions from team into posters, print both posters at Merck and will ship to RSNA
- Dr Petrick will share 1A data with Drs Fenimore and Lu; Dr Lu will examine 1A data in reference to 1C needs
- Discussion of FDA CDER and CDRH on subsequent call
 - device/assay validation and
 - drug/surrogate endpoint qualification (Dr Mozley)