

QIBA Quantitative CT Committee

Monday, February 22, 2010

11 AM CST

Call Summary

In attendance

Andrew Buckler, MS (co-chair)
P. David Mozley, MD (co-chair)
Lawrence Schwartz, MD (co-chair)
Maria Athelougou, MD
David A. Clunie, MBBS
Patricia E. Cole, PhD, MD
Charles Fenimore, PhD
John Fraunberger
David Gustafson, PhD
Grace Kim, PhD
John Lu, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD

Kevin O'Donnell
Michael O'Neal, MD
Nicholas Petrick, PhD
Anthony Reeves, PhD
Yuanxin Rong, MD, MPH
Daniel Sullivan, MD
David J. Vining, MD

RSNA

Fiona Miller
Susan Anderson, MLS
Joe Koudelik

Group 1A Data Interpretation and Results (Drs Petrick, Kim and Lu)

- Plan to submit scientific abstract(s) to RSNA by April 15 deadline
 - In conjunction with abstract submission, Dr Petrick can also work with small group to draft paper for publication
- Dr Lu is continuing work on RECIST, WHO and volumetric comparison; technology and methodology to best analyze data needed; how to compare and scale needed. Dr Clunie to look at 1A data for trends that suggest best metrics based on lesion shape
- Interest in interpretation from top-down (describing performance of measure with indication for use) and bottom-up (describing experiments) approach
- Study design looked at reader variation as well as bias and variability between metrics: RECIST (1D), WHO (2D) and volumetric (3D)
 - Measurements not directly comparable; context needed where measurements may be conditional
- Variation exists within RECIST
- Primary hypothesis and sub-hypotheses should be clearly stated
- Distill study conclusions to simple concepts and statements:
 - State at a high level for QIBA consumers, e.g. is variance less using volumetrics?
 - Answer may vary by clinical context; volumetrics may be more precise but may not always be important
 - Need to translate data into meaningful statements to help clinical trials; simple propositions needed, e.g. RECIST works well for simple lesion shapes
- Consider:
 - Installed base of equipment already in place
 - Use of findings in Profile, e.g. acquisition parameters
 - Conclusions can also provide content for FDA Briefing document which is in process
 - How to work with thin slices
 - Use of volumetrics may slow workflow due to multiple thin slice acquisitions, e.g. virtual colonoscopy

- Dual slice presentation number proposed
- Thinner slices at targeted lesion
- Thicker slices for 'general' use
- Transmission, archiving and reconstruction of data are an issue with thin-slice CTs
- Radiation dose also a consideration

Group 1B (Dr McNitt-Gray)

- Group has identified sites and study design; will examine variance, not bias, on patient data
- Study can begin when RadPharm software update complete (possibly week of Feb 22, 2010)
- Will aim to gather data to test hypothesis; avoid collection of data which is not needed

Group 1C (Dr Fenimore)

- Preparing specifications for collection conditions
- Study of ACR phantom underway with results available from some sites
- Next group call to be scheduled

Documents for April 2010 FDA/SNM/RSNA Meeting

- Sections of FDA Briefing Doc for update:
- Implications on reading and equipment – Dr Mozley
- Steps to follow in Profile with thin slice acquisition – Dr McNitt-Gray and Mr O'Donnell
- Interpretation section – Drs Gustafson, Clunie, Cole and Mulshine

Next Steps

- Dr Mozley to provide an update on a project to retrospectively evaluate performance of volumetric imaging analysis to RECIST
- Dr Clunie to look at 1A data for trends that suggest best metrics based lesion shape
- Dr Reeves to provide update on VOLCANO work on next call
- Continue 1A data analysis discussions and data interpretation
- Next call scheduled for Monday, Mar 1 at 11 am CST