

# QIBA Quantitative CT Committee Update

Monday, March 22, 2010

11 AM CDT

## Call Summary

### In attendance

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

Kevin O'Donnell  
Nicholas Petrick, PhD  
Ganesh Saiprasad, PhD  
Daniel C. Sullivan, MD

### RSNA

Fiona Miller  
Susan Anderson, MLS  
Joe Koudelik

### QIBA Q-CT Ctte Abstract Submission for RSNA 2010 (Dr Petrick)

- Two abstracts proposed; one clinical focus and one medical physics focus
  - Drs Petrick and Kim have drafted concept for physics abstract
- Abstract submission deadline for RSNA is April 15, 2010 (Noon CT)

### Profiles (Mr O'Donnell)

- Merged format integrating UPICT protocol into Lung Nodule Profile developed in mid-2009; posted on QIBA and UPICT wiki  
[http://qibawiki.rsna.org/index.php?title=Profile: CT Lung Nodule Volume Measurement for Primary/Regional Nodes and Metastatic Sites](http://qibawiki.rsna.org/index.php?title=Profile:_CT_Lung_Nodule_Volume_Measurement_for_Primary/Regional_Nodes_and_Metastatic_Sites)
  - UPICT template has flexibility built in to adapt with additional language for clinical trial use, e.g. calendars, linkages
- Next steps for Profile development include:
  - Incorporating results and parameters of groundwork from 1A, e.g. slice thickness, placeholder for Dr McNitt-Gray's specs on noise and resolution
    - FDA and RadPharm may be able to supply wording based on image acquisition and reader instructions for 1A study
    - Mr Fraunberger will locate RadPharm reader instructions used for 1A study
  - Improving overall readability
  - Completing Technique/Parameter tables in Appendix G
  - Input also needed on image interpretation and post-processing sections
- Encourage hands-on participation from ctte members; comments welcome to Mr O'Donnell or Mr Buckler; Wiki access and editing/comments encouraged; QIBA Profile and UPICT protocol/template formats to be linked on Wiki pages
- Profile will supply concrete specs for vendors and practical/usable acquisition specs for clinicians (complete but workable)
- Committee will continue work on Profiles during May 25-26 QIBA meeting

### **FDA Briefing Document update (Mr Buckler)**

- Mr Buckler explained the context for the Briefing Document via diagram of pathway process “Process for Qualification for Clinical Research and Clinical Practice”
  - Focus to be on two qualification paths with endpoints for clinical care and clinical research, respectively.
- The Methods section of the Briefing Document includes Profile information
- The draft Briefing Document is in circulation; discussion on timing of sending Request Letter to FDA to initiate process
  - Suggestion to send letter only when clinical efficacy data available
- Although Nelson trial reporting in NEJM 2009 is strong evidence, group is not aware of clinical trials using volumes with evidence on health outcomes
  - Need an inventory of “F-Like” trials in process
    - Dr Schwartz will report on current trials, e.g. ACRIN 6678, CaLGB,
- Completing Boxes B-E could drive work agenda for the committee
- A briefing document for PET is moving forward with expected completion in summer 2010
  - There has been some SUV evidence published; discussion continues on ‘acceptable’ level of studies for FDA.

### **FDA white papers**

- Considering mid-April date for end of review cycle
- *Radiology* has expressed interest in collaboration paper
- Mr Buckler will update the authors on status of papers

### **Next Steps**

- Mr O'Donnell will sync versions of Lung Nodule Profile on UPICT and QIBA wikis
- Mr Fraunberger will locate RadPharm reader instructions
- Dr Schwartz will report on current trials, e.g. ACRIN 6678, CaLGB, Mr Buckler will update the authors on status of FDA white papers
- Next call scheduled for Monday, Mar 29 at 11 am CDT