

QIBA Volumetric CT Tech Committee Update

Monday, August 29, 2011 at 11 am CDT

Call Summary

In attendance

P. David Mozley, MD (Co-chair)
Lawrence Schwartz, MD (Co-chair)
Richard Baumgartner, PhD
Hubert Beaumont, PhD
Andrew Buckler, MS
Paul L. Carson, PhD
James Colsher, PhD
Alden Dima, MS
Charles Fenimore, PhD
Michael McNitt-Gray, PhD
Alex J. Megibow, MD, MPH

James Mulshine, MD
Yuanxin Rong, MD, MPH
Daniel C. Sullivan, MD
Ying Tang, PhD
David J. Vining, MD
Binsheng Zhao, DSc

RSNA

Fiona Miller
Joe Koudelik
Madeleine McCoy

Discussion

- The purpose of the call was to continue the review of comments and questions received in response to the Briefing Document sent to the FDA, in preparation for the August 31st BQRT meeting in Washington DC.
 - Drs. Sullivan, Mozley, Schwartz and McNitt-Gray discussed a forward thinking approach for Wednesday's meeting; the FDA wants to know what QIBA is recommending.
 - Confidence to come from strength of QIBA groundwork data in efforts to support future FDA mandates; a single context-of-use to be focused upon.
 - Dr. McNitt-Gray's slides are complete at this point, but he is open to the idea of referencing the **Guidance for Industry** documents, as well.
 - The group confirmed that the full data package will not be presented at this time. After comments are received from the FDA, the next challenge will be identified and the principles to do this will be more specific.
 - The VOL-CT Profile is in the public comment phase. Future work will need to be done to the Profile in regards to quality control, target lesions, and measurement methods
 - The FDA is aware of the process Roadmap and the project planning Gantt Charts; no slides or verbal discussion based on this material deemed necessary. Suggested was that several face-to-face meetings for QIBA, the Imaging Biomarker Roundtable and strategizing meetings be referenced.

- **Next steps:**
 - Participants of the in-person meeting to review the process Roadmap
 - RSNA Staff to circulate the **Guidance for Industry** documents to the VOL-CT Tech Ctte
 - Dr. Zhao to update slides for the August 31st meeting.

Next Call

- There will NOT be a call on Monday, September 5, 2011 - RSNA offices will be closed.
- Next VOL-CT Tech Ctte call scheduled for Monday, September 12, 2011 at 11 am CDT.