

**QIBA Volumetric CT Tech Committee Update**  
Monday, September 12, 2011 at 11 am CDT

DRAFT Call Summary

**In attendance**

P. David Mozley, MD (Co-chair)  
Maria Athelougou, PhD  
Hubert Beaumont, PhD  
Andrew Buckler, MS  
Alden Dima, MS  
Charles Fenimore, PhD  
Philip F. Judy, PhD  
Hyun Grace Kim, PhD  
Alex J. Megibow, MD, MPH  
James Mulshine, MD  
Kevin O'Donnell

Guillaume Orioux  
Nicholas Petrick, PhD  
Yuanxin Rong, MD, MPH  
Neil Steinmetz, MD, JD  
Daniel C. Sullivan, MD  
Ying Tang, PhD  
Binsheng Zhao, DSc

**RSNA**

Fiona Miller  
Joe Koudelik  
Madeleine McCoy

**Discussion**

- FDA f2f meeting- review proceedings and plans for reactions
  - The FDA was very receptive and sharply focused on regulatory context use.
  - An issue raised during the meeting was a reluctance to accept radiological evidence as a response to treatment
  - The role of QIBA is to improve qualification guidelines, supply more evidence and to internally work on tasks brought up by the FDA.
- Discussion of the FDA *Guidance for Industry Standards for Clinical Trial Imaging Endpoints* - strategy for reacting and roll to be played by QIBA
  - Dr. Steinmetz questioned the use of the regulatory tools in relation to software
    - Computer-assisted interpretational, more comprehensive
    - Calibration of monitors—features not yet included in the profile---to what extent does QIBA want to be involved in guidance?
      - Work with other groups
      - Offer a response
      - Expand the profile according to other issues that QIBA would like to raise as points of dispute
  - Dr. Petrick suggested comments be submitted to the FDA if the Tech Ctte has issues with the language of imaging being pictorial and subjective; the comment period is open through mid-October 2011
- Meeting schedules going forward
  - The VOL-CT TC committee calls will begin a new bi-weekly call schedule; any gaps in between calls will be filled via e-mail
- **Next steps:**
  - The VOL-CT Group will gather comments and submit one document to the FDA
  - Determine whether QIBA should respond to the FDA as a part of RSNA; an “official” RSNA statement would need Board approval

**Next Call**

- There will NOT be a call on Monday, September 19, 2011
- The next VOL-CT Tech Ctte call is scheduled for Monday, September 26, 2011 at 11 am CDT which will follow the new bi-weekly schedule