

## QIBA Volumetric CT Tech Committee Update

Monday, August 22, 2011 at 11 am CDT

### Call Summary

#### In attendance

P. David Mozley, MD (Co-chair)  
Lawrence Schwartz, MD (Co-chair)  
Hubert Beaumont, PhD  
Andrew Buckler, MS  
Baiyu Chen, PhD  
Alden Dima, MS  
Charles Fenimore, PhD  
Paul Garrett, MD  
David Gustafson, PhD  
Philip Judy, PhD  
Hyun Grace Kim, PhD  
Michael McNitt-Gray, PhD

James Mulshine, MD  
Nicholas Petrick, PhD  
Anthony P. Reeves, PhD  
Ying Tang, PhD  
Binsheng Zhao, DSc

#### RSNA

Fiona Miller  
Julie Lisiecki  
Madeleine McCoy

#### Discussion

- The purpose of the call was to review the comments and questions received in response to the document sent to the FDA, in preparation for the August 31 BQRT meeting in Washington DC.
  - Questions were organized by importance, with a focus on those with the strongest data that will be addressed first.
- FDA comments demonstrated an engaged interest
- The first stage of the process with the FDA is an introductory conversation to include:
  - How volumetrics are used and whether they need to be qualified.
  - The extrapolation of the RECIST responses with outcomes as related to minimal change.
  - The VOL-CT response should make a strong case for measurement and incorporate surrogacy.
- Next steps:
  - RSNA staff to disseminate Dr. Mozley's request to think about a response to FDA issue #11.
  - Agenda topic for next call to be the ***Smallest absolute volume on which to base an assessment of disease progression***
  - Dr. Schwartz and Dr. Mozley to present slides on the next scheduled call in reference to the 8/31 meeting.
  - Dr. Schwartz will look into the possibility of Dr. Bruce Johnson and Dr. Larry Rubinstein participating on future VOL-CT t-cons.
  - Mr. Buckler to confirm the FDA has the latest version of the QIBA Profile.

#### Next Call

- Next VOL-CT Tech Ctte call scheduled for Monday, August 29, 2011 at 11 am CDT.
- There will NOT be a call on Monday, September 5, 2011 - RSNA offices will be closed.