

## QIBA CT Volumetry Technical Committee Update Call

7 January 2013 at 11 AM CST (GMT-5)

### Call Summary

#### In attendance:

James J. Conklin, MS, MD (Co-Chair)  
Maria Athelougou, PhD  
Hubert Beaumont, PhD  
Andrew Buckler, MS  
David A. Clunie, MBBS  
Barbara Croft, PhD  
Jovanna Danagoulian, PhD  
Alden Dima, MS  
Vinay A. Duddalwar, MD, FRCR  
Gregory V. Goldmacher, MD, PhD  
David Gustafson, PhD

Philip F. Judy, PhD  
Friedrich D. Knollmann, MD, PhD  
Michael McNitt-Gray, PhD  
James Mulshine, MD  
Guillaume Orioux, MSc  
Nicholas Petrick, PhD  
Uri Shreter, PhD  
Jenifer Siegelman, MD, MPH  
Daniel C. Sullivan, MD  
Ying Tang, PhD  
Luduan Zhang, PhD

#### RSNA:

Joe Koudelik  
Madeleine McCoy

#### Agenda

- Literature systematic review and meta-analysis for shoring up performance in the lung and extending to the other anatomic regions. Goal of topic is to engage the team in this activity.
- Addressing the first portion of the FDA comments, specifically, those dealing with our completed 1A, 1B, 1C, and the first 3A challenge. Goal of the topic is to engage the team in this thought process and to acquaint them with the proposed approach.

#### General Discussion

- Mr. Buckler outlined concerns of the FDA Biomarker Qualification Review Team (BQRT) regarding CT Volumetry biomarker qualification:
  - QIBA needs to converge on a full development plan during this consultation phase
  - A full data package is still needed
  - Statistical methodology provided by the FDA to be incorporated
- Mr. Buckler displayed the FDA comment document and the best response approach was discussed. Specifically, there were questions on how targeted to be versus having a framework in place and the pros and cons of various approaches.
  - The level of technical rigor and clinical data needed for biomarker qualification was discussed.
  - The question of how to establish qualification most efficiently was raised.
  - Expansion to other organs and what information would be necessary to present to the FDA requires further discussion.

#### Next steps

- Next QIBA CT-VOL Tech Cttee t-con is January 21, 2013 at 11am (CST)