

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 Orieux, 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 28, 2013 at 11am (CST)