

## QIBA CT Volumetry Technical Committee Update Call

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

### Call Summary

#### In attendance:

**James J. Conklin, MS, MD (Co-Chair)**

**Lawrence Schwartz, MD (Co-Chair)**

Samuel G. Armato III, PhD

Maria Athellogou, PhD

Hubert Beaumont, PhD

Andrew Buckler, MS

David A. Clunie, MBBS

Barbara Croft, PhD

Vinay A. Duddalwar, MD, FRCR

Edward A. Eikman, MD

Charles Fenimore, PhD

Gregory V. Goldmacher, MD, PhD

David Gustafson, PhD

Philip F. Judy, PhD

Hyun Grace Kim, PhD

John Lu, PhD

James Mulshine, MD

Reginald Munden, MD

Guillaume Orioux, MSc

Nicholas Petrick, PhD

Sarah Sherlock, PhD

Uri Shreter, PhD

Daniel C. Sullivan, MD

David J. Vining, MD

Binsheng Zhao, DSc

#### RSNA:

Joe Koudelik

Madeleine McCoy

### General Discussion

- Discussion continued how best to respond to FDA Biomarker Qualification Review Team (BQRT) questions regarding CT Volumetry biomarker qualification
  - Further planning and analysis may be required
  - Dr. Grace Kim agreed to review questions and provide formal statistical analysis plan by mid-February 2013
  - FDA expectations for QIBA regarding current tumor type groundwork not yet clear; additional tumor types beyond lung may be required, e.g., liver, lymph nodes, kidney and metastatic disease
  - Additional volume measurements/groundwork needed to gather Phase II outcomes data to assist with developing a general guideline
  - Interest was strong to pursue new organ systems, even though questions were raised whether CT Volumetry qualification was technically achievable
- Dr. Conklin reviewed the 3-year CT Tech Committee deliverables previously outline for NIBIB
  - Modification of current late-stage Profile based on other tumor types discussed
  - Contrast, scan slice thickness and system noise may provide the most challenge
  - Additional Technical Subgroups based on new anatomic sites suggested to pursue these new efforts
  - Tech Ctte has the authority to charter subgroups as needed; Steering Ctte approval not required at this level
  - Retrospective vs. prospective data collection discussed in efforts to support Profile compliance
- QIBA Steering Committee in-person meeting on January 31, 2013
  - Drs. Schwartz, Armato, Judy and Mr. Buckler to develop a few slides for the CT Modality status report

### Next steps

- Drs. Gustafson, Schwartz and Zhao to discuss the need for animal models off-line
- Drs. Schwartz, Armato, Judy and Mr. Buckler to develop a few slides for CT Modality report out
- Next QIBA CT-VOL Tech Ctte t-con is February 11, 2013 at 11am (CST)