

QIBA Volumetric CT Group 3B Update

Monday, January 31, 2011; 11 AM CST

Call Summary

In attendance

Lawrence Schwartz, MD (Chair)

Rick Avila, MS

Andrew Buckler, MS

Charles Fenimore, PhD

Hyun Grace Kim, PhD

Michael Mc-Nitt Gray, PhD

P. David Mozley, MD

James Mulshine, MD

Lino Ramirez, PhD

Anthony Reeves, PhD

Yuanxin Rong, MD, MPH

Ying Tang, PhD

Binsheng Zhao, DSc

RSNA

Joe Koudelik

Julie Lisiecki

I. 3B effort

- A new effort – part of the groundwork activities that are developing to inform the Profile
- Analysis on retrospective analysis of data from prior trials (“3B”); Correlation with clinical outcome
- Data request from pharma companies; pre-existing data donated by Merck
- Goal to turn clinical validation into reality; there will be specific projects associated with this effort
- Dr. Schwartz – noted that therapeutic options can dramatically change concordance or discordance; speaks to the heterogeneity of data – concordance not as well known; not able to draw conclusions yet
 - Need to demonstrate *why* controlling acquisition parameters is so important from a clinical perspective
 - Dr. Tang discussed her related literature search and lack of strong supporting articles from the literature
 - There is a need to start educating people about the importance of these topics as related to QIBA efforts

II. Quality Control

- Dr. Mulshine suggested reviewing methods/ quality control; definition of standards and QC processes
- As qualification is concerned, there are gaps in the knowledge; parameters may not be well set
- Variance may be due to methodology; further discussion needed

III. Goal of the 3B group

- Study to characterize clinical utility/efficacy with respect to clinical endpoints
 - Using data to prove their hypotheses
- Clinical acceptance as a biomarker; qualification part of end goal
 - Biomarker could be prognostic or predictive
- Real goal is clinical acceptance and the creation of new algorithms and clinical hypotheses
- Compliance testing to circumvent bias
- Precision in terms of measurements and slope of response
- Retrospective re-analysis of clinical trial data
 - What are acceptable variations
 - What are acceptable tolerance levels in the protocol?
 - Need to identify clinical validity of techniques that drive technical performance metrics.

Next steps:

- Group 3B to determine meeting schedule. Wish to keep the Monday time slot for Vol CT, either alternating meetings, or using a portion of the Vol CT large group meeting to share updates.

Next call: Monday, **February 7, 2011**, 11:00 am CST.