QIBA VOL-CT WebEx
August 25, 2008 (11am-12pm CDT)
Call Overview

In attendance:

Andrew Buckler, BSEE, MSCS (Chair)
Martin Barth, PhD
Ekta Dharalya
Charles Fenimore, PhD
Robert Ford, MD
Wendy Hayes, DO
Bruce Hillman, MD
Michael McNitt-Gray, PhD
P. David Mozley, MD
James Mulshine, MD
Kevin O'Donnell
Nicholas Petrick, PhD
Sandra Scheib, RN, MSN
Daniel Sullivan, MD
Binsheng Zhao, PhD
Fiona Miller (RSNA)
Joe Koudelik (RSNA)

The group began discussing the phantom study protocol in development by Dr. Petrick's subcommittee. With a few modifications, such as slice thickness, phantom density, "large object" imaging, this was considered a solid base to build upon. The use of various vendors and multiple sites trials was suggested. A summary of this call will be distributed to determine how the proposal ties in with the overall approach.

Dr. Mozley mentioned pharma (Merck) is interested in supporting QIBA, but a full prospective trail may be costly. Key requirements from Merck's perspective is that of clinical data acquisition for study. Drs. Gottlieb and Mozley to discuss offline.

Dr Mozley provided an overview of his updated validation "master plan"

- Long-term goals - quantification; eventually to meet required Volumetric CT objectives:
  - Establish volumetric change as predictor of patient outcomes
  - Use of biomarker as a surrogate in therapy response
- Multi-stage validation plan proposed

Part I Discussed - Image Acquisition

- FDA data is too comprehensive - Need to narrow scope
  - A sub-set of phantom data needed to begin project
- Build evidence where process will work - to keep industry interested
- Mathematical rigor needed (stats)
  - Laurie Dodd to assist with bio-statistical significance
- Criteria for quality needed
  - Conformance to a minimum standard - control efforts in Part 1 data collection so we can articulate the performance threshold
  - Accuracy vs. Precision
  - What level of precision are we getting now?
  - What level is necessary?
  - Will better precision make a better biomarker? - Needs to be determined
  - Reproducibility
  - How much variability is acceptable?
  - Gold Standard has been changing - what's important?
- Obtain grounding - where we stand now

Retrospective vs. Prospective image acquisition discussed

- Retrospective elements - Phantom data from FDA/CDRH/OSEL and clinical data from NCI-RIDER project
- Prospective elements- Proposed phantom studies, required analysis software tools, etc.
    - Need to get feeling for how software packages work on various phantom designs
    - Need software candidate for phantom study
- Suggested was to begin image analysis with available phantom and clinical data (retrospective) while pursuing proposed phantom trials (prospective) in parallel
- What would proposed phantom trial look like based on Matrix-identified issues?
    - Operator differences/variability
    - Scanner calibration variability
    - Multi-vendor variation (software and hardware)
    - Phantom study required to address issues above - to rule out variance

Moving forward:

Quantification of Test Data Reliability

Part 1-a Quantification of FDA acquired anthropomorphic phantom images (retrospective)
Part 1-b Quantification of NCI-RIDER standard clinical data set (retrospective)
Part 1-c Phantom Study Protocol Development - data to be acquired (prospective)

Part 1-a & 1-b ready to go - require subgroups to take form and pursue
Dr. Petrick's subgroup already addressing Part 1-c

Action Items:

- Kevin O'Donnell to work with Dr. Mozley to incorporate the QIBA Process Plan into the Validation Plan - updated draft.
- Drs. Gottlieb and Mozley to discuss offline how to merge their strategies for integrating phantom and clinical material for volumetric change analysis

Discussion Items for Next Meeting- Sept 8th, 2008

- Establish a subgroup to work on Section 1A
- Identify what additional data is needed