QIBA-COPD Quantitative Analysis Technical Subcommittee Update Call Tuesday, August 4, 2009 11 AM CDT Call Summary

In attendance:

Daniel C. Sullivan, MD (Moderator) Andrew Buckler, MS David Clunie, MBBS Harvey Coxson, PhD Eric Hoffman, PhD Philip Judy, PhD Zachary Levine, PhD David Lynch, MD Michael McNitt-Gray, PhD Hrudaya Nath, MD Ehsan Samei, PhD Edwin Silverman, MD, PhD

RSNA Fiona Miller Susan Anderson, MLS Joe Koudelik

General Discussion:

Purpose of this call was twofold:

- Broaden the group discussion and include new member orientation
- Begin the work to move subcommittee forward

QIBA - COPD Quantitative Analysis Tech Subcommittee Structure

- New title proposed to broaden this QIBA technical subcommittee's focus: QIBA "COPD Quantitative Analysis" Technical Subcommittee
- COPD to run in parallel with, but report back, to the QIBA Volumetric CT Technical Committee
- Identify issues, identify work already done, define experimental groundwork
- Need to identify a forward process and how much effort is required with a broad vs. narrow scope
 - Narrow scope work moves fast
 - Broad scope need many interested parties slower movement more effort
- CT phenotype and evaluation assessment judged to be within scope
- Ancillary quantitative studies would also be worth pursuing
 - o e.g. cardiovascular, which already contains quantitative data
- Fundamental morphologies and density questions are common interests between QIBA Vol-CT and COPD

Key COPD Issues

- COPDGene phantom development with findings
 - How to utilize the phantom to determine imaging site qualification
- Airway wall measurements and their limits
- Subject size and how to adjust for differences
- Variability between scanners from different manufacturers
- Variability of measurements data for power calculations so that others could properly size their studies
 - o Measurement and observer variability already being addressed by QIBA

- Industry representation is another key component
 - Need major equipment manufacturers and pharma representation

COPD Committee to design Profile and Claims in terms of airway wall thickening

- Much complementary work done between COPD and asthma on airway wall measurements
- Claims to be based on specific pathway process, not disease name, e.g. parenchyma airway quantitation, high/low density, inflammatory lung disease, interstitial lung disease, etc
- QIBA Vol-CT Profiles underway
 - Late stage lung cancer is the primary focus of Vol-CT Tech Committee
 - Early stage lung cancer has profiling has begun
 - COPD (with asthma) will be the third Profile in development

Mr Andrew Buckler's QIBA Slide Presentation – Overview

QIBA goals are pursued via system engineering activities in attempts to determine sources of scanner bias and variability while increase quantitative analysis power per subject

RSNA's interest in quantification:

- RSNA is interested in fostering more emphasis on quantitative imaging in clinical care and facilitating imaging as a biomarker in clinical trials (slide 1)
- Four reasons RSNA is emphasizing quantification (slide 2):
 - The evolution towards molecular medicine (personalized medicine) requires quantitative test results
 - Progression towards evidence-based medicine depends on more quantitative clinical data
 - Decision-support tools (AI) need quantitative input
 - Pay-for-performance plans need to be based on objective metrics
- Endpoints being pursued (slide 8)
 - Long Term Goals
 - Exploit quantitative imaging biomarkers as surrogate end-points for disease progression and characterization
 - Specific Aims
 - Develop methods and processes for accurate and reproducible measurements of biologically relevant processes
 - Stakeholders
 - FDA, NCI, NIST, ACRIN, Imaging Vendors, Software Companies, CROs, extended PhRMA Imaging Group, and leading academic centers
- Three QIBA Technical Committees based on modalities, each co-chaired by representatives from Device Manufacturers, Pharmaceutical Industry and Academia (slide 10)
 - Fluorodeoxyglucose Positron Emission Tomography (FDG-PET/CT)
 - Dynamic Contrast-Enhanced Magnetic Resonance Imaging (DCE-MRI)
 - Volumetric Computed Tomography (Vol-CT)
 - The initial Vol-CT focus is to be broadened to include COPD

Upcoming COPD-related meetings

- Aim to hold committee meetings in conjunction with existing COPD-related meetings
- Need to meet with other established COPD-related committees, e.g. American Thoracic Society meeting and pre-ATS meeting(s)

Moving Forward

- Need to define what the COPD committee will work on
- What needs to happen to clarify existing issues?
 - Identify a number of topics for future discussion e.g.,
 - Airway wall measurement/limits
 - COPD Gene Phantom work
 - Subject size
 - Variability/Power calculations
 - Spyromics
- Need more discussion concerning venue and process
- Conference calls leading up to a future 1.5 day long face-to-face meetings proposed
- Transition from monthly to bimonthly calls, eventually settling on a weekly call schedule
- Need to assemble reference/foundational documents and identify items requiring scientific work/pursuit
- Consider f2f meeting in conjunction with existing COPD-related meeting(s)

Next Steps:

- Follow-up t-con to be scheduled (Sept 1, 2009)
- Start QIBA-COPD Profile, begin with groundwork activities
- Dr David Lynch to develop charge proposal for this new tech subcommittee
- Circulate any reference/foundational documents among group members
- QIBA-COPD Quantitative Analysis mailing/distribution list to be created and forwarded to members
 - Mr Kevin O'Donnell to be added to the roster for Profile development (later date)
 - Sean Fain (WI) to be invited to join subcommittee
 - Solicit additional COPD group members; send names to RSNA staff (<u>ikoudelik@rsna.org</u>)
 - Names suggested by participants: Joyce Schroeder, John Newell, George Wasco